

* **HIGH COURT OF DELHI: NEW DELHI**

% Judgment reserved on: 01.06.2012
Judgment pronounced on: 07.09.2012

+ **CS (OS) No.89/2008 and C.C. 52/2008**

1. F. Hoffmann-La Roche Ltd,
Switzerland.
2. OSI Pharmaceuticals, Inc.,
New York.

..... Plaintiffs

Through Dr.C.S.Vaidyanathan, Sr.Advocate with
Mr.Pravin Anand, Ms.Archana Shanker,
Mr.Shrawan Chopra, Mr.Mahabir N.,
Ms.Lakshmi Kruttika Vijay, Ms.Prachi
Agarwal, Advocates

versus

Cipla Ltd., Mumbai Central, Mumbai

..... Defendant

Through Mr.Harish Salve, Sr.Advocate with
Ms.Pratibha M.Singh, Ms.Bitika Sharma,
Ms.Ujjwala Jeremiah and
Ms.Anusuya Mehrotra, Advocates

CORAM:

HON'BLE MR. JUSTICE MANMOHAN SINGH

MANMOHAN SINGH, J.

1. Two plaintiffs, namely, F. Hoffmann-La Roche Ltd. and OSI Pharmaceuticals Inc., have filed the suit for permanent injunction restraining infringement of patent, rendition of accounts, damages and delivery up through their duly constituted attorney, namely, Mr.Shivprasad Laud, against Cipla Ltd. Mumbai, having its office also at Delhi.

2. The plaintiff No.1 Company claims that it is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. It is stated in the plaint that for the purpose of research and development, the said plaintiff engages inter alia into collaborative agreements and alliances with numerous partners and invests approximately 7 billion Swiss Francs in such activities.

3. It is averred in the plaint that the plaintiff No.2 jointly owns a patent with Pfizer Products Inc. in respect of a small drug molecule medically termed as a "Human Epidermal Growth Factor Type-I/Epidermal Growth Factor Receptor" (HER/EGFR) inhibitor which is popularly known as 'Erlotinib' (pronounced as err-lot-i-nib). This drug marked a major breakthrough and innovation in the treatment of cancer and is used to destroy some types of cancer cells while causing little harm to the normal human cells. Various tests conducted on this drug have shown a marked increase in the survival benefit in the patients suffering from advanced or metastatic non small cell lung cancer, the metastatic NSCLC is most prevalent form of NSCLC being the most prevalent form of this cancer.

4. This drug is administered in the form of a tablet. The tablet formulation of Erlotinib is sold by the plaintiffs under the trademark and name of "Tarceva", which is registered in the name of plaintiff No.1. The drug Erlotinib and its formulation "Tarceva" has been approved by the U.S. Food & Drug Administration in the year 2004 and thereafter by the European Union in the year 2005.

5. A specific statement has been made in para-7 of the plaint that plaintiff No.2 along with M/s Pfizer Products Inc. had applied for grant of

patent in respect of drug Erlotinib and its process vide application No.537/DEL/1996 on 13th March, 1996. The Controller General of Patents, Trademarks and Designs, New Delhi, granted a certificate bearing Patent No.196774 (hereinafter referred as IN'774 or suit patent) dated 23rd February, 2007 which has been recorded in the Register of Patents on 6th July, 2007. The molecular name of patent is 'A NOVEL [6, 7-BIS(2-METHOXYETHOXY) QUINAZOLIN-4-YL]- (3-ETHYNYLPHENYL) AMINE HYDROCHLORIDE'. It is averred that the drug as well as the process of its manufacture is patented as per the provisions of the Patent Act, 1970 and entitled to their protection as such. The plaintiffs' product Erlotinib Hydrochloride Tablets (Tarceva), which was registered by the Central Drug Standard Control Organization, Directorate General of Health Services, Government of India vide Registration Certificate dated 23rd December, 2005 is issued in the name of plaintiff No.1. It is also stated in the said paragraph that on 8th January, 2001, the plaintiff No.2 and the plaintiff No.1 had entered into a Development Collaboration and Licensing Agreement (the Licence Agreement) wherein the plaintiff No.1 has a licence to use, sell and offer for sale the licensed products including the drug Erlotinib, which is the subject matter of the present suit. The plaintiff No.1 is further licensed and authorized to cause enforcement of any intellectual property rights for any of their products.

6. Under these circumstances, it is averred by the plaintiffs that the plaintiff No.1 is actively engaged in manufacture, marketing and sale of the innovative drug Tarceva (Erlotinib) in various countries including India. The plaintiff No.1 introduced Tarceva in India sometime in April 2006. The announcement regarding the launch of Tarceva by Roche Scientific

Company (India) Pvt. Ltd., a wholly owned subsidiary of the Roche Group in India, was given wide publicity by the media inter alia in view of its importance in the cancer treatment.

7. The case of the plaintiffs against the defendant is that the defendant is also engaged in manufacture and marketing of pharmaceutical and health care products in India and the plaintiffs had learnt that the defendant is involved in several actions for violation of intellectual property rights including patent rights as the plaintiffs noticed from various news reports appearing in the print as well as electronic media about the plans of the defendant to launch a generic version of the drug Tarceva (Erlotinib) in India and also for exporting the same to various countries. One of such reports appeared on 11th January, 2008 in an English daily “Mint” published by the Hindustan Times Group and from the aforesaid report, for the first time the plaintiffs came to know about the plans of defendant to infringe and violate legal rights of the plaintiffs with regard to patent.

8. The claim of the plaintiffs is that provision of Section 48 of the Patent Act, 1970 provides for exclusive right of the patentee of a product or a process to prevent any third parties from non-consensual usage of the product or the process. Section 68 provides that an assignment inter alia by way of a licence of a patent has to be compulsorily by way of an instrument in writing embodying all the terms and conditions governing their rights and obligations. In the present case, it is stated that the licence agreement which is executed between the plaintiff No.1 and plaintiff No.2 contains all the terms and conditions for grant of licence to the plaintiff No.1 by plaintiff No.2.

9. It is submitted that as the plaintiff No.2 and Pfizer Products Inc. are the registered owner of the patent in question and the drug Tarceva (Erlotinib) has been developed after a long and substantial research. The said invention is liable to be protected and no person other than the authorized person can be allowed to copy the same. The defendant in the present case with the unlawful manner is infringing the legal rights of the plaintiffs. Therefore, the plaintiffs had no other option but to initiate the appropriate remedy against the defendant for permanent restraining from manufacturing, selling, offering for sale, marketing, distributing in any manner the drug Tarceva (Erlotinib) or any other generic version of the said drug. The prayer is also sought by the plaintiffs to direct the defendant to render all accounts in relation to such infringing activities as well as to give damages to the plaintiffs from the defendant inter alia for violation of their legal rights.

10. The suit was filed by the plaintiffs on 15th January, 2008. Along with the suit the plaintiffs also filed an application under Order XXXIX, Rule 1 & 2 CPC. First time when the matter was listed on 16th January, 2008 notice was issued in the interim application. The statement was made by the defendant in Court that the defendant has been marketing the disputed drug for the past three weeks. The matter was adjourned to 18th January, 2008. The arguments in the interim application were heard for some time and the same was adjourned to 22nd January, 2008. The defendant filed its written statement as well as counter claim and documents on 21st January, 2008. Further arguments were addressed in the interim application i.e. I.A. No.642/2008. During the course of the hearing of the arguments, the defendant filed an application, being I.A. No.1272/2008 seeking to bring on

record facts about US application US6900221 of Polymorph B. It is stated in the application that the applicant/ defendant had recently discovered that the suit patent is a mixture of Polymorph A and B and Tarceva is Polymorph B version of the compound namely Erlotinib Hydrochloride. Time was sought by the plaintiffs to file the reply.

11. In the written statement, the following defences are raised by the defendant:

- a) The plaintiffs have not filed the copy of the specification.
- b) The patent of the plaintiffs has been granted under suspicious circumstances,
- c) No documents which vest any right in plaintiff No.1 of ownership or right to sue have been placed on record,
- d) The patent in question is liable to be revoked, It only sought to improve from the existing prior art as Quinazoline compounds are known to inhibit growth have been used as anti cancer treatment and are available in the market for treatment of various cancers, Thus, it is a derivative of a known compound and hence not patentable under Section 3(d) of the Indian Patent Act.
- e) The plaintiffs in a subsequent patent filed in the United States Patent Office have admitted the short comings in the patent in issue. The details of the same are mentioned in the counter claim filed by the defendant.
- f) The plaintiff has engaged in Bio-isosterism process which makes the said patent obvious. One of the well-known text books in an article

entitled “Isosterism and Molecular Modification” in Drug Design by C W Thornber, published in 1979 discusses about the isosterism.

- g) There is no inventive step in the patent.
- h) The alleged patented product is nothing but a derivative from Gefitinib of AstraZeneca for which a patent was refused in India on the ground that the said product was already in prior use and was in the public domain. Under such circumstances, the patent office ought not to have granted a patent for the product Erlotinib.
- i) The manner in which the plaintiff is seeking to protect Erlotinib which is nothing but a derivative of Gefitinib establishes that the plaintiff is indulging in ever-greening.
- j) In the area of life-saving drugs, it is thus in the public interest of the general public and patients suffering from diseases like cancer, no injunction can be granted.
- k) The plaintiffs’ capsule costs ₹4,800/- per tablet and equivalent tablet of defendant costs ₹1,600/-.
- l) No documents have been placed on record to establish the plaintiff No.1’s right to sue. The alleged patent was in the name of Pfizer Inc. No documents to support as to the manner in which the rights were transferred have been placed on record.
- m) No statistical comparisons have been produced.
- n) The plaintiffs have failed to place on record the collaboration or licencing agreement. In order to file a suit for infringement, the title of the plaint has to be clearly established which the plaintiff No.1 has

failed to do so. As far as the plaintiff No.2 is concerned, no documents have been placed on record to show as to how the original patent which has been filed in the name of Pfizer Inc. only and is now claiming to be jointly owned by plaintiff No.2.

- o) The defendant has been granted approval from the Government of Goa from manufacturing the said tablet in various pack sizes of 30, 60, 100, 500, 1000 tablets. The defendant has made sale of the produce since December, 2007. In the written statement the defendant also denied all the averments made in the plaint.

12. The defendant has also filed the counter claim, being C.C. No.52/2008, on various grounds under Section 64 of the Patent Act.

13. The written statement to the counter claim was filed on 18th August, 2008 and on 27th September, 2008 replication to the written statement of the defendant was filed by the plaintiff.

14. The order was reserved in I.A. No.642/2008 under Order XXXIX, Rule 1 & 2 CPC. The injunction application of the plaintiffs was dismissed vide order dated 19th March, 2008. The operative para-87 of the order reads as under:

“87. The result of the above discussion is that the plaintiff is not entitled to claim an ad-interim injunction, in the terms sought. However, this Court is not unmindful of the fact that if no equitable balancing order protecting its interest is made at this stage, there is a likelihood of the plaintiff being prejudiced at the final stage. Therefore, the defendant is hereby directed to:

- i) Furnish an undertaking to this Court, within two weeks, to pay damages in the event of the suit being decreed. A

director or other person, on behalf of the Defendant duly authorized by a specific resolution of its Board of Directors, shall execute the undertaking. The undertaking shall also include a stipulation that it would continue to bind the Defendant, regardless of its change in composition.

ii) Towards effectuating direction (i) above, maintain faithful accounts of its sale of the product Erlocip and file quarterly accounts in. This Court, supported by the affidavit of one of its Directors, affirming about the veracity of the same;

iii) File an annual statement of the sales figures, of Erlocip, duly authenticated by its chartered accountants, on the basis of its records, including the Sales tax and Excise returns.”

15. The plaintiffs filed an appeal before the Division Bench against the dismissal of their interim application, being FAO (OS) No.188/2008. By an order dated 24th April 2009, the said appeal was also dismissed.

16. The plaintiffs also challenged the said order of the Division Bench before the Supreme Court in Special Leave to Appeal (Civil) No.20111/2009. The said Special Leave Petition was dismissed by order dated 28th September, 2009 with the following direction:

“Heard learned counsel for the parties.

This Special Leave Petition is directed against the interim order. The Civil Suit is pending before the original side of the Delhi High Court, therefore, we are not inclined to interfere with the impugned judgment. The Special Leave Petition is accordingly, dismissed.

However, in the facts and circumstances of the case, we request the learned Single Judge dealing with the Civil Suit to conclude the trial as expeditiously as possible without being influenced by any observation made by the Division Bench in the judgment.”

17. When the matter was listed before this Court on 18th September, 2008, the following issues were framed in respect of the suit and the counter claim:

“1. Whether the manufacture, marketing and sale of ERLOCIP by defendant is infringing the plaintiffs’ Indian Patent 196774? OPP

2. Whether the Indian Patent 196774 is liable to be revoked on the grounds raised in written statement and counter-claim of the defendant? OPD

3. Whether the plaintiffs are entitled to permanent injunction as prayed for? OPP

4. Whether defendant/counter-claimant proves that the plaintiff’s subsequent US Patent 6900221, is to the effect that the compound of claim No.1 of the suit patent is a mixture of two Polymorph A and B Compound and need to be separated to perform and get the claimed compound for acceptable efficacy; and its effect on the plaintiff’s patent? OPD/CC.

5. Relief.”

18. In the order dated 19th March, 2008, it was directed by the Court that the parties shall complete their pleadings. The plaintiffs were given four weeks time to file the replication to the written statement in the suit and written statement to the counter claim. The defendant was given two weeks time thereafter to complete its pleadings.

19. In the plaintiffs’ application, being I.A. No.12872/2008, the Court also extended the time to file the documents within eight weeks on behalf of both the parties. The matter was listed before the Joint Registrar on 13th January, 2009 for admission/denial of the documents and before Court on 24th February, 2009. On 13th January, 2009, two documents were admitted by the defendant, being Ex.P-1 and Ex.P-2. The documents of the defendant

were admitted by the plaintiffs which were exhibited as Ex.D-1 to Ex.D-14 at the time of admission/denial of the documents.

20. When the matter was listed before this Court on 24th February, 2009, the order was passed in I.A. No.12762/2008 with the consent of the parties that the evidence be got recorded by a retired Additional District Judge Sh.S.N.Chopra as a Commissioner and the matter was sent to him on 1st April, 2009 for fixing dates for cross-examination of witnesses. Parties were also granted time to file their affidavits by way of evidence.

21. The plaintiffs filed three affidavits, namely, Mr. Shivprasad Laud as PW-1, Prof. Mr. Roger Griffin PW-2 and Prof. Mr. Nick Thatcher as PW-3. The said evidence was filed on 31st March, 2009 vide entry No.57771.

22. It appears from the record that the defendant also filed the replication to the written statement filed by the plaintiffs to the counter claim filed on behalf of the defendant along with copies of few patents i.e. by way of documents on the same date, i.e. 31st March, 2009 vide filing No.58515.

23. The defendant produced its evidence by way of three affidavits, namely, Sh. R. Gopalakrishnan, DW-1, Sh. Shashirekha Kanathala, DW-2, Dr. Ashwini Nangia DW-3 and DW-4 Dr. Rajender Kumar Lohiya, Examiner, Patent Office, New Delhi.

24. Both the parties have exhibited the documents in a following manner:

Ex PW1/1	True copy of excerpt of the Commercial register – Letter of Authority dated 15.01.2008
Ex. PW1/2	POA of Hoffman for land

Ex PW1/3	OSI Pharmaceuticals Secretary's certificate
Ex PW1/4	POA of OSI Pharma nominating Shiv Prasad
Ex PW1/4	18.7.2009 (doc given to Court official to be placed on record) OSI Pharmaceuticals INC, Secretary's certificate (collaborative Research agr b/w the Co. & Pfizer Inc)
Ex PW1/5	True copy of Complete Specification of 196774
Ex PW1/6	True copy of Patent Certificate for 537/DEL/1996 Clinical lung cancer
Ex PW1/7	True copy of Patent office letter dated 6, July 2006 intimating grant of Patent & recordal in register for 537/DEL/96
Ex PW1/8	Permission No.Import5075/05 in Form 45
Ex PW1/9	Copy of permission to import Erlotinib Lpgs
Ex PW1/10	Condition for grant of approval/permission
Ex PW1/11	Registration Certificate issued for import of drugs into India dt. 23 Dec. 2005 dt. 15/4/09 Lpgs
Ex PW1/12	Conds. of the Registration Certificate
Ex PW1/13	Tarceva carton and product insert (dt. 15.4.2009)

Ex PW1/19	Decision on 25 Aug 2008 b/w OSI Pharmaceuticals V. CIPLA
Ex PW1/20	Form-3–Statement & Undertaking under Section 8
Ex PW1/21	Declaration to the effect that the commercial form of Erlotinib hydrochloride sold under the trademark name Tarceva® in India is covered by the claims of Indian Patent No.196774 (537/DEL/96)
Ex PW1/X1	Phase 1 - Pharmacologic Study of USI – 774, an epidermal GFR Tyrosine Kinase Inhibitor, Journal of clinical Oncology Vol 19, No.13 (July 1), 2001 PP 3267-3279
Ex PW1/X2	Pfizer Investigators brochure
Ex PW1/X3	Journal of clinical oncology Vol. 25, No.18, June 20, 2007 “Phase II study of Erlotinib in Adv non small cell lung cancer.....”
Ex PW1/X4	Cancer research 57, 4838 – 4848, Nov 1, 1997 “Induction of Apoptosis & Cell cycle arresttyrosine kinase”
Ex PW1/X5	Article – The current situation : Erlotinib... Cancer, the Oncologist 2005 : 10467 (Ex 2/5 is affidavit)
Ex PW1/X6	The new England journal of medicine July 14, 2005. (12/2) of affidavit) (Pw 1/x6)
Ex PW1/X7	(2/4 of aff) article – Symptom improvement in lung cancer....Journal of clinical oncology Aug 10, 2005 (PW

	1/x8)
Ex PW1/X8	(ex 2/10 in aff) article – Erlotinib plus gemcitabine Journal of clinical oncology May 20, 2007 (PW 1/x8)
Ex PW1/D1	US 5747498
Ex PW1/D2 (Colly)	Permission/approval for manufacture of new drug formulation (2 pgs)
Ex PW1/Y	Agreement between Pfizer and OSI
Ex PW2/D1	WO 995/23141
Ex PW2/D2	Gefitinib plus best supportive care in previously treated ...multicenter study the lancet.com Vol. 366 Oct. 29, 2005 dt. 31.10.09
Ex PW2/DA	Dated 18.9.2009 WO 95/23141
Ex PW3/1	Article potency predict clinical efficacy ? Review article Department of Medicine & Biochemistry & molecular Pharmacology Vol. 89, July 2002. dt. 26/4/09
Ex PW3/2	The Oncologist Journal salvage Therapy for Advanced on small cell lung cancer factors influencing treatment selection The oncologist 2006; 11 : 655 – 665 dt. 26/4/09
Ex PW3/3	Smoking History & Epidermal growth factor receptor expression....group study BR 21
Ex PW3/4	PPT – overall survival analyses (dated 26.11.2009) BR 21 & ISEL
Ex PW3/5	FDA Public Health Advisory, New Labelling & distribution program for

	Gefitinib (Inersa) www.fda.gov/CDR/Drug/advisory/iressa.utw dt. 26.11.2009
Ex P-1	Erlocip Carton
Ex P-2	Erlocip Pdt Insert
Ex DW1/1	Dated 25.3.2010 Power of attorney of Gopalkrishnan
Ex DW1/2	Tax Invoice of Mahaveer Medicare Chennai of 31.12.2007
Ex DW1/3	Invoice Mahaveer of 16.1.2008
Ex DW1/4	Copy of Invoice dated 31.12.2007
Ex DW1/5	Mark X claims filed by Remfry and Sagar dated 13.3.1996
Ex DW1/6	Original letter duly signed by Rachna Nandwai + copies of doc. issued with original letter of prosecution file IN'774
Ex DW1/7	Decision of 18 July, 2006 b/w Astrazeneca V. Natco
Ex DW1/8	Dated 25.3.2010 decision 21.3.2007 b/w Astrazeneca V. G M Pharma
Ex DW1/9	US 6900 221 B1
Ex DW1/10	True copy of decision of Controller in respect of hearing held on 27 June, 2007 for 537/DEL/96 dated 25.3.2010
Ex DW1/11	True copy of written arguments made on 27 th Jne, 2007 filed on 5 July, 2007 for 537/DEL/96 dated 25.3.2010
Ex DW1/12	Certified copy of FAO (OS) 188/2008 in CM 219/2008

Ex DW1/13	Certified copy of reply of CM 219/2008
EX DW1/14	Statement of costs Cipla
Ex DW1/15	Visiting card of Mr. Gopal
Ex DW1/16	Patent application No.841/DEL/96
Ex DW2/A	Evidence of DW2 Sashirekha
Ex DW2/P2	WO 2008/059223 A2
Ex DW2/1	Tarceva Erlotinib Packet containing tablets/medicine
Ex DW2/2	Copy of CS/N/PCT/2002/00507/DEL
Ex DW2/3	XRD of Erlotinib tablet sold under Tarceva brand conducted at Cipla lab
Ex DW 2/4	XRD of Erlotinib tablet sold under Tarceva brand conducted at IIT Mumbai
Ex DW3A	Evidence of DW3 Nanga
Ex DW3/2	EP 0477700 A1 dated 28.9.2010
Ex DW3/3	US 4138590 dated 28.9.2010
Ex DW3/4	US 5427766 dated 28.9.2010
Ex DW 3/5	US 5736534 dated 28.9.2010
Ex DW 3/6	WO 93/04047 dated 28.9.2010
Ex. DA	Evidence of Gopal LC 25.3.2010 Page 1-8
Ex. D-1	Getitinib –wiki article
Ex. D-2	EP0635507 A1
Ex D-3	EP 0566226 B1
Ex D-4	Article Isosterism & molecular ----- by CW Thornber

Ex D-5	Indexes Vol 8, 1979 Radioisotopes in Pharmacy & Medicine. Part 4
Ex D-6	EP 0566226 A1
Ex D-7	EP 0635507 B1
Ex D-8	US 69000221
Ex D-9	EP 0566226 B1
Ex D-10	Tarceva Carton
Ex D-11	Pregrant opp by CIPLA against OSI Pharma
Ex D-12	CS 537/DEL/96
Ex D-13	Pregrant Opp by b/w OSI Vs CIPLA
Ex.D-14	Complete Specification 537/DEL/96 between Pfizer and OSI Pharmaceutical

25. The following are marked documents:

Mark PX1	Financial Profile downloaded from cipla.com
Mark PX2	Copy of patent 2004/026879 A1
Mark PX3	Copy of patent WO 2004/099119 A1
Mark PX4	Copy of patent WO 2005/21541 A2
Mark PX5	Copy of article from the Business World magazine, Feb 2010
Mark PX6	73 rd Annual Report of Cipla (2008-2009)
Mark PX7	Copy of article "Cipla eyeing copies of 20 patented drugs"
Mark PX8	US CBO Study "Research & Development in the Pharmaceutical

	Industry”
Mark PX9	Copy of article from The Economist
Mark PX10	Copy of article “Mukesh, LNM in richest of rich club”, Economic Times, 12 March 2010.
Mark PX11	Copy of Article from moneycontrol.com
Mark PX12	Copy of article from The Mint (March 18, 2010)
Mark PX13	Copy of order Aztrazeneca v. Ranbaxy, 007 WL 5272018 (DNJ)
Mark PX14	Copy of article from aidsmap.com
Mark PX15	Copy of Patent No.IN213706
Mark PX16	Copy of Patent No. IN237286
Mark PX17	Copy of Patent No. IN219022
Mark PX18	Copy of Patent App No.972/BOM /1999
Mark PX19	Copy of Patent App No.402/MUM/2008
Mark PX20	Copy of patent WO 2009/130437 A1
Mark PX21	Copy of patent WO 2009/083739 A1
Mark PX22	IUPAC Name of the Suit Patent
Mark PX23	Chemical/molecular formula of the Suit Patent
Mark PX24	Chemical name of the Suit Patent
Mark PX25	Chemical structure of the Suit Patent
Mark PX26	Copy of Patent App No.1878/MUMNP/2009

Mark PX27	US RE 41065E (reissue patent)
Mark PX27	Chart of chemical compounds showing existence of Polymorphic forms
Mark PX28	Copy of patent US 5607942
Mark PX29	Interview given by DW3 to Nicola Nugent in RSC Publishing
Mark PX30	Extract from book "The Nobel Prize"
Mark PX31	Copy of article "The Cost of Developing a New Drug"
Mark PX32	Copy of WO 2008/102369A1
Mark PX33	Copy of US 7179937 B2
Mark PX34	Copy of US 5770599
Mark DW2/P1	Book on Polymorphism titled "Polymorphism in Pharmaceutical Solids"
Marx DW4/1	Form 1 – application for Patent – PFIZER
Mark DW4/2	Information US 146/27 – Patent 196774 – Statement of working of patent
Mark DW 4/3	Examination Sheet
Mark DW4/4	Patent 537/Del/96 – PFIZER. Application – reply Statement US 25(1)
Mark DW 4/5	Opp. to 537/Del/96 – written arguments of (Majumdar) Opponent
Mark DW4/6	Written arguments held on 27.6.2007 – PFIZER – applicant
Mark DW4/7	Decision (27.6.2007 hearing) dated

	4.7.2007
Mark DW 4/8	Depenning letters – hearing confirmation for 19.3.2008 etc.
Mark DW4/9	US Certificate – App. No.08/413300 filing dated 30.3.1995
Mark DW4/10	Pregrant Opp. – IP for Natco
Mark DW4/11	Withdrawal of the compulsory license at 15.1.2008 patent 196774 Decision 22.7.2008, Hearings etc.
Mark DW4/12	Complete Specification of 537/D/96 A novel [.....] quine Hel & a process for preparing the same
Mark DW4/13	17.5.2010 Decision for Pat Appl. 537/D/96 & compulsory license & interlocutory petition on 22/Jul/2008 by N.R. Meenal
Mark DW4/14	Appl. for CL U/S 92(A) by Natco Pharma (Depenning)
Mark DW4/15	Natco Pharma Ltd. Letterhead Pregrant opp
Mark DW4/16	25.3.2008 letter with written notes of argument on behalf of applicant for compulsory license/petitioner in IP. Documents – Sec.5 TRIPS, Declaration TRIPs – 30.8.2003 decision Page 1-11
Mark DW4/17	Complete Specification Quinzoline Derivatives PFIZER
Mark DW 4/18	Patent 196774 Compulsory license action
Mark DW4/19	App. for C. License U/S 92/A Patent

	196774
Mark DW4/20	App. for C. License field by NATCO PHARMA
Mark DW4/21	Assignment in favour of Pfizer
Mark DW4/22	International search report
Mark DW4/23	Request to Supply copy of reply statement
Mark DW4/24	US PTO – Obviousness of Species when prior art teaches genus
Mark DW4/25	Natco Pharma Ltd. App. for ERLLOTINIB
Mark DW4/26	IP filed for App. for ERLLOTINIB – Power Point & Written arguments
Mark DW4/27	19.10.99 decision
Mark DW4/28	Article Isosterism & Molecular Modification
Mark DW4/29	Details of file 537/DEL/96-20.8.2008
Mark DW4/30	Current situation article
Mark DW4/31	Written submissions (hearing 1.8.2006) for Patent 592/Del 2000
Mark DW4/32	Decision dated 5.7.2000
Mark DW4/33	16.9.2008. Objections from registry to app. for patent – Natco Pharma
Mark DW4/34	PFIZER Assignment 13.3.1996. Patent 537/Del/96
Mark DW4/35	Written arguments – App.
Mark DW4/36	Close structural similarity bw Chem

	compound” art.
Mark DW4/37	Consideration of Applicant’s Rebuttal Arguments Patent ability (R3) – 2100
Mark DW4/38	Patent 196774 – PFIZER filed Chinese evd. for refusal of Natco Pharma’s Patent
Mark DW4/39	Letter to Assistant Controller of Patents and Designs of S. Majumdar
Mark DW4/40	EPO boards of appeal decisions 17.7.1986
Mark DW4/41	EPO boards of appeal decisions 10.2.1984
Mark DW4/42	EPO boards of appeal decisions 28.2.1984
Mark DW4/43	International search report – PCT/EP 2004/0012
Mark XX	Table of comparison of Background of invention
Mark YY	Chart with structures

26. During the trial, objection has been raised on behalf of the learned counsel for the defendant to Mark PX 5, Mark PX 7, Mark PX 8, Mark PX 9 to PX 14, Mark PX 16, Mark PX 27, Mark PX 32.

27. The cross-examination of the witnesses was commenced in April, 2009 and concluded in November, 2010. Final arguments in the present suit effectively commenced in November, 2011. Both parties have also filed written submissions. The arguments on behalf of the defendant were concluded on last working day before summer vacation i.e. 1st June, 2012.

28. I shall first be taking up issue no. 2 relating to challenge set up by the Defendant praying for revocation of the patent as this is the issue which may go into the root of the matter and the decision in the same may have bearing on the other issues, I propose to decide the same first. The said issue reads as under:

“Whether the Indian Patent 196774 is liable to be revoked on the ground raised in written statement and counter-claim of the Defendant? OPD”

29. The onus to prove the present issue is on defendant. The defendant has prayed for revocation of the suit patent by way of counter claim raising mainly the following grounds:

- a) That the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of earlier priority date contained in the complete specification of another patent granted in India.
- b) That the subject of any claim of the complete specification is not an invention within the meaning of this Act.
- c) That the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in Section 64 of the Patents Act.
- d) That the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in

India or what was published in India or elsewhere before the priority date of the claim.

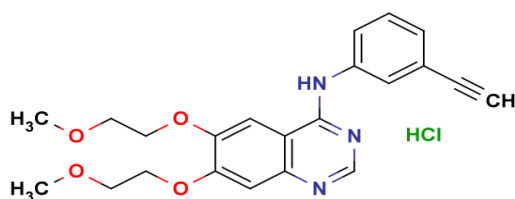
- e) That the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed, that is to say, that the description of the method or the instructions for the working of the invention as contained in the complete specification are not by themselves sufficient to enable a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention, or that it does not disclose the best method of performing it which was known to the patentee for the patent and for which he was entitled to claim protection.
- f) That the scope of any claim of the complete specification is not sufficiently and clearly defined or that any claim of the complete specification is not fairly based on the matter disclosed in the specification.
- g) That the patent was obtained on false suggestion or representation.
- h) That the subject of any claim of the complete specification is not patentable under this Act.
- i) That the patentee for the patent has failed to disclose to the Controller the information required by Section 8 or has furnished information which in any material particular was false to his knowledge.

Re: Obviousness or lack of inventive step

30. The defendant has explained the concept of lack of inventive step in detail by contending that the patent IN'196774 (Ex.PW1/5) (hereinafter

referred to as the ‘Suit Patent) lacks inventive step in as much as arriving at the said patent is obvious to the person skilled in the art. The said concept of obviousness has been explained by the defendant by contending in the counter claim that:

- 1) That the suit patent no. IN’774 is Erlotinib Hydrochloride structurally looks as follows:



The said structure of the patent is based on the teachings of European Patent 566226 (hereinafter referred as EP’226) where under there are number of structures are mentioned as examples and one of the structures depicted therein teaches any person skilled in the art to arrive at the Indian Patent.

- 2) It is contended in the counter claim that **EP’0566226** (Ex.D3) is a patent filed by Zeneca Ltd. on **15.01.1993** in respect of Quinazoline derivatives. It is stated that this patent concerns a Markush formula of a Quinazoline derivative, the pharmaceutically acceptable salts thereof. This patent was published on 08.11.1995. This patent discloses a molecular structure in a quinazoline derivative in which methyl is at third position. This molecular structure (Example 51) is the **closest prior art** to the suit patent.
- 3) The defendant has contended that not merely the said EP’226 patent is prior art but there are structural similarities between

the suit patent compound and the one depicted therein. A comparison of the closest prior art (example 51 of EP'226) and the granted claim of suit patent (example 20 of suit patent) reveal that they are depicted in the same manner. This also shows that the patentee was aware the existing state of art. It is contended that Structural similarities by itself may be sufficient to lead an inference of obviousness.

- 4) It is contended in the counter claim that after knowing the nature of art, the plaintiffs have just replaced the component of alkyl group and by treating the same arrived at the desired result. It is stated that the mere the substitution of **Methyl with Ethynyl** which are members of same alkyl group can be done by any reasonable person skilled in the art. It is also contended that the said substitution is a mere workshop result. Had it not been so, the plaintiffs would have explained the positive steps towards according the treatment with Ethynyl and difficulties faced by them during experimentation. The complete specification is absolutely silent on the ways of arriving at such substitution. In these circumstances, as per the defendant, it would be safe to infer that the suit patent was obvious to the person skilled in the art.
- 5) It is contended that **Example 51 of the EP'226 is the closest prior art**: - From the analysis of the specification it is clear that IN'774 is a patent which relates Quinazoline derivative. It is established in the art and known art that Quinazoline derivative has anti cancer properties. From the perusal of all the relevant

patents EP'534, EP'507, US'498, EP'226 it is clear that they all belong to a family of patents which are related to similar compound having identical/similar characteristics and similar effect. Any person who is working on Quinazoline derivative would obviously look at these patents. The compounds disclosed in EP'226 (patent which is an admitted prior art in the complete specification of suit patent) are compounds which are obvious to try permutations and combinations on. There is sufficient motivation to do further developments in the preferred compound which are disclosed in EP'226. EP'226 explains and shortlists preferred compounds and thereafter specific preferred compounds. EP'226 itself discloses 3 preferred compounds amongst which one is example 51 which is the closest prior art.

- 6) It is also stated by placing reliance on the documents that the aspect of substitution of methyl component with that of ethynyl one which are part of the same alkyl group is not uncommon in the field of experimentation though it may not relate to the same drug. This has been explained by the defendant by way of evidence that the substitution of Methyl with Ethynyl in the light of the five patents which act as a sample (being EP0477700, US4138590, US5427766, US5736534 and WO93/04047 Exhibited by DW3 as Exhibit DW3/2 to Exhibit DW3/6 respectively) is common. The five said patents are sufficient in themselves to establish a motivation.

- 7) The defendant has filed the evidence by way of Affidavit of Prof Nangia DW 3 in support of its averments and grounds raised in the counter claim. The said deponent deposes that as to how EP'226 would act as prior art to the suit patent IN'774. He also deposes as to how the suit patent would have been arrived at by the inventor by starting from EP'226. The EP'226 is taken as a starting point on the basis of limited disclosure made in complete specification of the suit patent. In the suit patent there are five European patent publications including EP'226 which have been disclosed. It is EP'226 which discloses that Quinazoline derivative has anti cancer properties. Prof. Nangia DW 3 picked up EP'226 and on the basis of his knowledge and have tried to explain that how the substitution can be made at the third meta position of example 51 of EP'226. Such substitution can be tried and made following the concept of Bio-isosterism. On the basis of the same one of the possible substituent is Ethynyl.
- 8) The said affidavit of DW 3 deposes after citing the structures of example 51 from EP'226 and alongside the structure of the suit compound that two structures are identical in nature barring the substituents in as much as -CH₃ (methyl) in 3rd Position in EP' 226 is replaced with -C≡C (ethynyl) in IN' 774. It is deposed in the affidavit of DW 3 that after going through EP 0477700 (Ex.DW3/2), US 4138590 (Ex.DW3/3), US 5427766 (Ex.DW3/4), US 5736534 (Ex.DW3/5), WO 193004047 (Ex.DW3/6), it is evident that there is a clear teaching that

methyl and ethynyl may be used interchangeably. It is deposed that there is no fixed pattern can be laid down as to the superiority of one over the other as a matter of rule. In some cases methyl is found to be superior to ethynyl and in some cases vice versa.

- 9) It is deposed in the said affidavit of DW 3 that that when the said EP' 700 is referred, there are three tables namely Table -1 2 and 3. It is stated in the affidavit that in table 2, the properties of compounds having methyl and ethynyl substituents are shown to have identical MIC value, but Table 3 shows that methyl and ethynyl substituents have substantially similar properties with ethynyl showing showing marginal higher value. It is therefore stated in the affidavit that the said patent teaches as how the methyl and ethynyl can be used interchangeably as antiviral agents.
- 10) Likewise, it is stated in the affidavit that US 4138590 (Ex.DW3/3) in column 10 provides that the comparative data in the table indicating that methyl substitution gives a better blood platlet aggregate than the compound having ethynyl substituent. Thus, the US' 590 goes on to teach that one may use methyl, ethynyl or phenyl interchangeably. Similarly, US 766 (Exht.DW3/4), column 3 – H methyl, ethynyl or vinyl are used interchangeably.
- 11) Thereafter DW3 deposes that US 534 Exht.DW3/5 which is owned by Lee. D Arnold, who is incidentally one of the two inventors of IN' 774. It is stated that US' 534 is a continuation

in part (CIP) application of application 200259 dated February 23, 1994 while IN'774 finds basis in a CIP of application no. PCT/IB95/00436 dated June 6, 1995. It is stated that before the priority date of IN'774, Mr. Arnold had himself studied methyl, ethyl, ethynyl, and ethynyl derivatives of 4-Heterocycle substitution quinazolines which are very close analogues of the claimed compound in IN'774. It is deposed that Mr. Arnold was wholly aware of the interchangeability of the methyl and ethynyl heterocycle position of quinazoline and on the basis of such knowledge it would have been obvious for him to try a similar interchangeability approach in N-phenyl quinazolines. If Mr. Arnold in IN'774 patent had included both methyl and ethynyl in the 3rd position, the compound having methyl would have been identical to the aforesaid compound of EP'226. It is deposed that the witness would presume that for such reason reference to methyl as a interchangeably usable substituent in the place of ethynyl was omitted. It is stated that while the patent holder acknowledges the other documents as prior art. However, the patent holder did not mention US 534 which was prior in time containing a vital information as to the interchangeability of methyl with ethynyl. It is deposed that it could be possible that the ethynyl substitution in 3rd position in IN'774 would not have worked but still it was always a reasonable approach on the part of the research scientist to try such alternative which in other applications have proved successful.

12) It is deposed that there could not have been a guarantee to the inventor that the ethynyl substitution would work but due to the successful use of both methyl and ethynyl in an interchangeable manner in several chemical compounds, it was not at all surprising to substitute methyl with ethynyl.

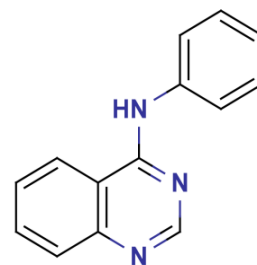
31. By raising the aforementioned grounds supported by the evidence of DW-3 and the contentions afore-recorded, the defendant prays that the suit patent is liable to be revoked on the ground of the lack of inventive step. (There are other affidavits filed of DW-1 and DW-2 which are mainly not relating to aspect of revocation and are discussed later on in another head.

32. Per contra, the plaintiffs have filed the written statement to the counter claim, adduced the evidence of PW-3 and PW-2, Mr. Nick Thatcher and Mr. Robert Griffin, in support of the same thereof and proceeds to answer the grounds of the counter claim by contending the following:

a) It is contended by the plaintiffs that the defendant has not discharged the onus casted on the same by not explaining as to how the said EP'226 will act as a motivation towards arriving at the suit patent invention. The same has been explained by the plaintiffs in the following manner:

(1) It is submitted The Defendant merely relies upon the prior arts stated by the Plaintiffs in their own patent specification of the suit patent, IN'774, namely, EP0520722A1 (EP'722), EP0566226A1 (EP'226), EP0602851A1 (EP'851), EP0635498A1 (EP'498) and EP0635507A1 (EP'507) – all of which disclose '4-anilinoquinazoline' derivative compounds possessing anti-cancer

properties. Each of these prior arts, EP'722, EP'226, EP'851, EP'507, and EP'498 have same core structure i.e. "4-

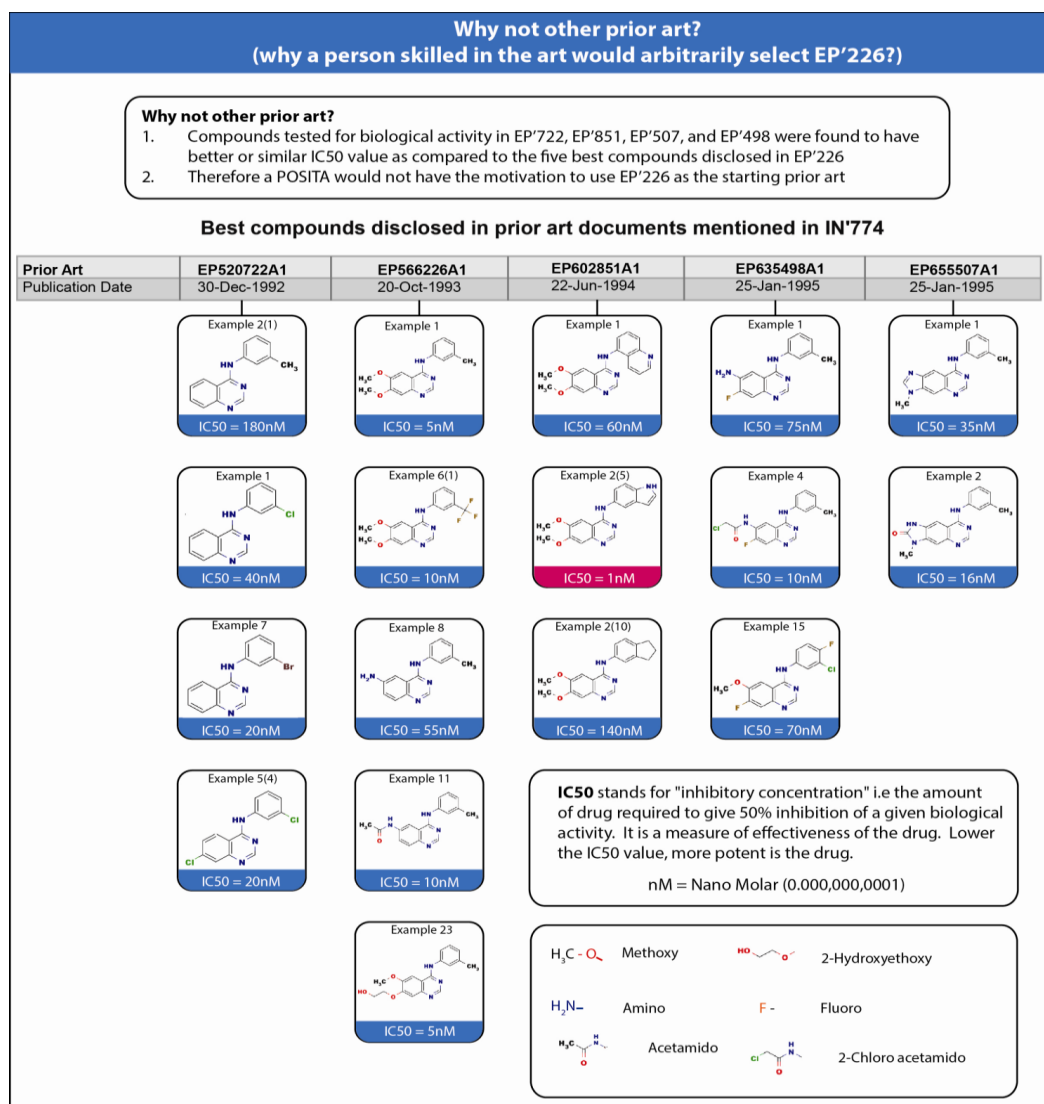


anilinoquinazoline" core structure and are represented by 'Markush Structure' thus encompassing millions of compounds. It is stated that a Markush structure means a General formulae or description to represent various substitutions on core structure used in patent application. (*Q. 112, PW2,*)

- (2) Each of these prior arts discloses specific compounds for which biological activity has been tested (by in vitro and/or in vivo tests) and specific values are provided. It is stated that in vitro testing means testing a pharmaceutical compound outside the cell. For example, in a test tube. In vivo testing means testing a pharmaceutical compound inside a living cell. For example, inside an animal.
- (3) It is stated by the plaintiffs that the compounds tested in prior arts EP'722, EP'851, EP'507, and EP'498 were found to have better or similar IC₅₀ values as compared to compounds in EP'226. In all, there are seventeen specific compounds for which biological activities are reported. {In IC₅₀, IC stands for "inhibitory concentration" i.e. the amount of drug required to give 50% inhibition of a given biological activity. It is a measure of effectiveness of the drug. Lower the IC₅₀ value, more potent is the

drug. Daiichi Sankyo v. Matrix Laboratories & Ors., 2009-1511 (Fed. Cir. 2010) at p. 4 [reported as 670 F. Supp.2d 359]]

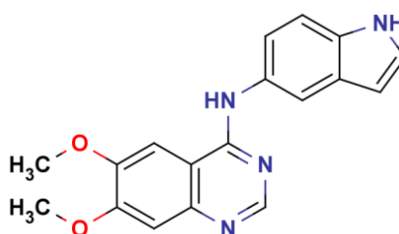
Thereafter a chart is depicted below showing such IC values of the compounds:



(4) It is submitted that a person skilled in the art will, at the first stage of research, look at these seventeen compounds because of the "well-defined IC₅₀" value. As evident from the above chart, a

person skilled in the art will in particular look at Example 2(5) i.e. 6,7-dimethoxy-4-(5-indolylamino)-quinazoline (structure provided below), disclosed in the EP'851 which has the IC₅₀ value of 1nm.

(5) Therefore, amongst all tested compounds in prior art, the compound [6,7-dimethoxy-4-(5-indolylamino)quinazoline] as disclosed in EP'851 has the least IC₅₀ value, therefore representing the most potent compound having anti cancer properties.



6,7-dimethoxy-4-(5-indolylamino)quinazoline

(6) Therefore it is submitted that the defendant has provided absolutely no evidence to show why EP'226 is the starting prior art as opposed to EP '851. This has been shown by the plaintiffs to contend that when it comes to possibilities, then any one compound can be out of many can be a starting point for further development.

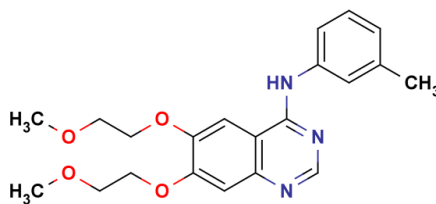
(7) In fact, this is conclusively established by DW3, the defendant's own witness who states in paragraph 4(a) of his Evidence Affidavit that was directed to the specific prior art document, EP'226.

b) It has been orally argued and countered by the plaintiffs that there is no formal proof on record to show as to how the plaintiffs had taken

Example 51 of EP'226 patent as a lead compound and treated the same as base to arrive at the suit patent. It has been stated that EP' 226 patent discloses numerous formulae and several structures of the quinazolines derivatives, it cannot assumed by the Court at the behest of the defendant's saying that the same would act as prior art solely by looking at one of the several depictions cited in the EP'226.

c) The plaintiffs have countered depositions made in the affidavit of Mr. Nangia where under he has deposed about the process of arriving at the suit patent by treating EP'226 as a base is obvious to the person skilled in art. The plaintiffs criticized the said depositions and process explained thereunder by calling the same as "hindsight" as the defendant today is aware of the patent of the plaintiffs and also of that of the EP'226 and thus, it is very easy to state that EP'226 would have taught the suit patent. This has been explained by the plaintiffs in the following manner:

- The defendant has selected Example 51 with full knowledge of the structure of Erlotinib Hydrochloride, i.e. the defendant has selected Example 51 as the lead compound purely on the basis of hindsight. The defendant has stated that the difference between Example 51 and Erlotinib Hydrochloride is that the Example 51 has a 3'-methyl group, whereas Erlotinib Hydrochloride contains 3'-Ethynyl group in the phenyl ring of the '4-Anilinoquinazoline' core structure. The defendant argues that this makes the structure of Erlotinib Hydrochloride obvious to a person skilled in the art.



Example 51 of EP'226

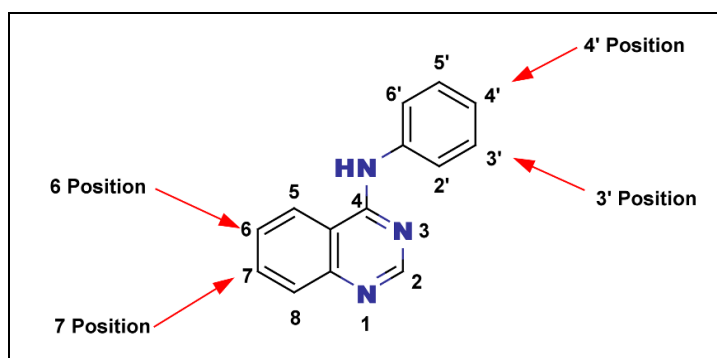
- It is submitted that the above submission is incorrect and erroneous, and that the defendant has failed to provide any motivation for a person skilled in the art to replace the methyl group [-CH₃] of the Example 51 with ethynyl group [-C≡CH].
- EP'226 discloses “4-anilinoquinazoline core compounds” by way of a Markush structure representing millions of compounds. Further, EP'226 discloses 80 examples providing 102 specific exemplified compounds, 32 specifically preferred compounds, 18 claimed compounds and five prominent compounds for which specific IC₅₀ values are given.
- Example 51 is part of the 102 exemplified compounds, 32 specific preferred compounds and of 18 claimed compounds (claim 7, claim 9 and claim 11) of EP'226, however, Example 51 does not feature amongst the five prominent compounds mentioned in EP'226 for which IC₅₀ value have been provided. Therefore, there is no teaching, suggestion or motivation in EP'226, regarding any “useful properties” or “potent and promising activity” to select Example 51 as the lead compound.

d) The plaintiffs have further endeavoured to put shadow on the affidavit of Prof Nangia by contending that no motivation or reason exists to select Example 51 of EP'226 is bolstered by the "expert" witness of the Defendant. DW3, Dr. Nangia, has straight-away arrived at Example 51 of EP'226 as the lead compound on instructions of his lawyer, Mr. S. Majumdar. (Para 4 and 6, Evidence Affidavit of DW3; Question nos. 5, 7, 8, 14, 52, 60, 83, 84, PW2.). He has neither provided any reason for selecting Example 51 as the starting point nor has he independently evaluated whether Example 51 was the best starting point as compared to other compounds of EP'226.

Thus, the Defendant has completely failed to provide any reason/motivation for a person skilled in the art to select Example 51 of EP'226 as the lead compound over the 5 prominent compounds for which defined biological data (IC_{50} values) is provided in EP'226.

e) It is further argued orally as well as contended in writing that even if it is admitted for the sake of argument that Example 51 is the correct lead compound for the obviousness enquiry, it is submitted that the Defendant has failed to prove that there was any motivation for a person skilled in the art **to modify the 3'-prime position in Example 51 of EP'226. This has been explained by the plaintiffs in the following manner:**

- It is submitted that there are ten positions available in the 4-anilinoquinazoline core structure where substitutions can be done i.e. five positions in the phenyl ring and five positions in the quinazoline core.



- In EP'226, Methyl is kept constant in **3'**-position:
 - a. In 73 (72%) out of 102 exemplified compounds,
 - b. In 25 (78%) out of 32 specific preferred compounds,
 - c. In 9 (50%) out of 18 claim compounds, and,
 - d. In 4 (80%) out of the 5 prominent compounds for which specific IC50 values are given.

- Therefore, EP'226 clearly teaches a person skilled in the art to make substitutions at the 6, 7 position on the quinazoline ring while keeping 3'-Methyl on phenyl ring constant or undisturbed. Thus, it is submitted that the Defendant has failed to provide any teaching/suggestion/motivation for a person skilled in the art to make a substitution at the 3'-prime position of the phenyl ring of '4-anilinoquinazoline' core structure and not on any other positions.

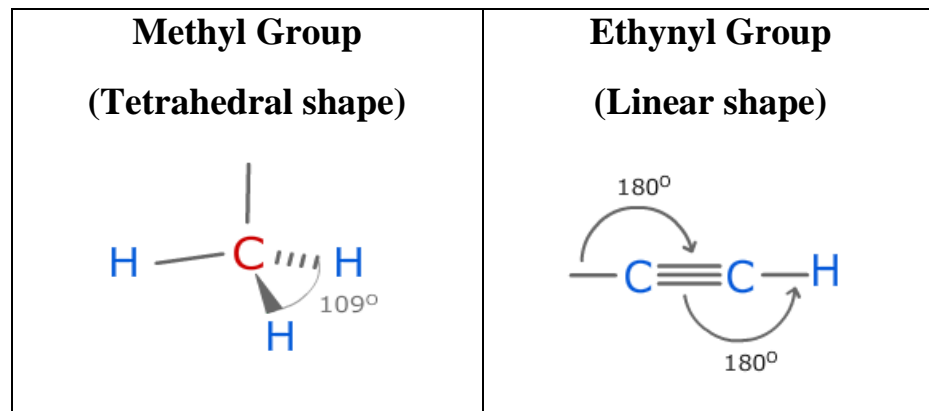
- f) The plaintiffs have further replied the counter claim and the ground of obviousness by arguing orally as well as in writing that the defendant has not explained the motivation which may come to the person

skilled in art to substitute the ethyl with that of methyl component. This has been articulated by the plaintiffs by explaining in the following terms:

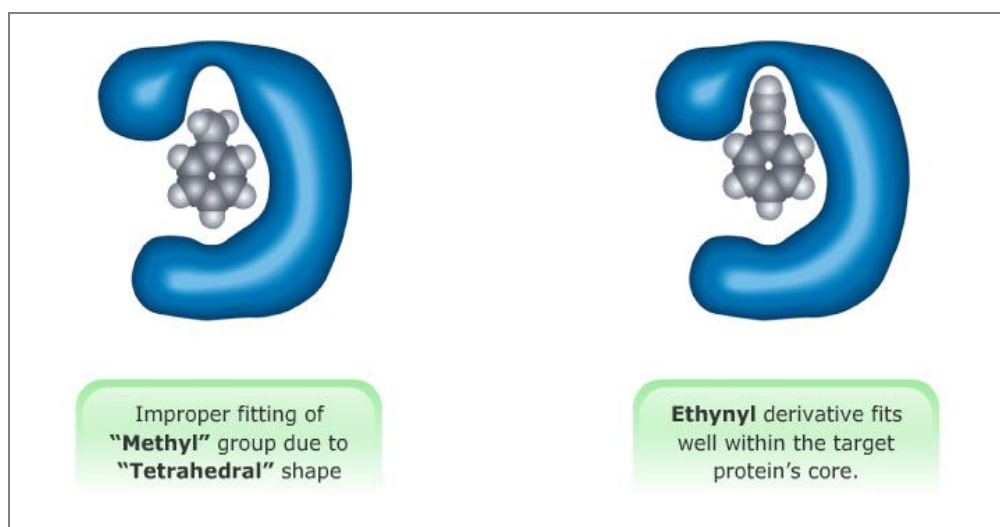
- The defendant has failed to prove that there was any motivation to substitute Methyl with Ethynyl. It is submitted that even though Example 51 and Erlotinib Hydrochloride may look similar when represented in two-dimensional format, however, in actual practice, the Example 51 and Erlotinib Hydrochloride are structurally and functionally different due to presence of the different functional group, methyl group [-CH₃] in Example 51 with ethynyl group [-C≡CH] in Erlotinib Hydrochloride.
- It is pertinent to note that in chemistry, any change may have dramatic and unpredictable effect on the activity of the molecule. This has been conclusively stated by the Plaintiffs' witness, PW2, in his affidavit and cross examination (*paragraphs 21 and 26.10, Evidence Affidavit of PW2,; Q, 52, 59, 60, 88, 94, 119, 139-149, PW2,*)
- More specifically, in the field of pharmaceutical sciences, any change in the structure of a compound can alter its activity and affects the manner in which the compound interacts with the target site, such as EGFR kinase, and thus affecting its biological activity.
- Further, the activity of a compound cannot be predicted in advance without performing empirical studies. As an

illustration, the core of the enzyme, here being EGFR kinase, is considered *a lock* and the claimed compound, here being Erlotinib Hydrochloride, which acts on the enzyme, is considered as *the key*. In pharmaceutical sciences, the researcher in order to make a key for the lock has to perform empirical studies to arrive at a particular conclusion. The researcher cannot make arbitrary choices and do further development without any reasons to do so. One has to apply the reasoned approach for further development of compounds since a small change anywhere in the molecule may alter activity of the compound for a particular target, such as EGFR kinase, and therefore it is not possible to predict activity of the compound in advance without performing the empirical studies.

- In the case of the methyl and ethynyl group, the difference in the physical properties such as bond angle, bond length and bond strength of the methyl group [-CH₃] and ethynyl group [-C≡CH], affect the manner in which Example 51 and Erlotinib Hydrochloride interact with the target protein, EGFR kinase, and the differences in the chemical properties of the methyl group [-CH₃] and ethynyl group [-C≡CH] may affect the reactivity of the Example 51 and Erlotinib Hydrochloride with respect to the EGFR kinase.



The methyl group [-CH₃] has a tetrahedral structure. In contrast, the ethynyl group [-C≡CH], has linear structure. Due to this difference in the shape, the methyl group [-CH₃] and the ethynyl group [-C≡CH] interact very differently with the EGFR kinase. The methyl group [-CH₃] being a tetrahedral structure does not fit well within the core of the EGFR kinase, however, the ethynyl group [-C≡CH] being linear in shape fit perfectly within the core of the EGFR kinase and thus possesses better activity.



Importantly, this has not been disproved by the Defendant in any manner. In fact, the Defendant has presumed that any change will result in

the same or similar activity and has explained obviousness in its Counter Claim and Replication to the Counter Claim on this presumption.

g) The plaintiffs have simultaneously countered the basis of obviousness which has been laid down by the defendant in relation to substitution of ethyl in lieu of methyl component. This has been also elaborately explained by the plaintiffs and argued too during the time of oral arguments, the same can be explained as under:

- It is submitted that the both the road-maps suggested by the Defendant for the substitution of Methyl with Ethynyl at the 3' position are misleading and misconceived:

I. The bio-isosterism route in Counter-Claim, and,

II. The direct interchangeability route in Replication to Counter-Claim.

I. Counter-Claim – Bioisosterism Route:

- The Plaintiffs submit that there is no reason/motivation to modify 3'-position to Ethynyl since as shown hereinabove, the teachings of EP'226 direct a person skilled in the art that 3'-Methyl should be left undisturbed for good biological activity.
- The Plaintiffs submit that there is no reason/motivation to modify 3'-position to Ethynyl since as shown hereinabove, the teachings of EP'226 direct a person skilled in the art that 3'-Methyl should be left undisturbed for good biological activity.
- Nonetheless, the Defendant, without showing any motivation, has arbitrarily selected Example 51 having 3'-Methyl as the lead

compound and applied bio-isosterism principle to arrive at the claimed compound having 3'-Ethynyl group.

- The Defendant proceeds to arbitrarily replaces Methyl group at 3'-position with Cyano group. The Defendant has provided absolutely no teaching/suggestion/motivation for a person skilled in the art to change Methyl to Cyano. EP'226 describes that 'R2' i.e. 3'-position in Markush structure stands for 45 different substituents. Therefore, EP'226 provides for 43 substituents other than Methyl or Cyano for 3' position. The Defendant has not provided *any* teaching/suggestion/ motivation that a person skilled in the art will substitute Methyl with only Cyano group and not the other 43 functional groups disclosed for R2 position.
- It is submitted that none of the 32 specific preferred compounds or the 18 claimed compounds or the 5 prominent compounds in EP'226 include the Cyano substitution at the 3' position. Instead this position is largely dominated by Methyl as stated above. Thus, the Defendant has failed to provide any reason as to why a person skilled in the art would substitute the "Methyl" group with "Cyano" group. The Plaintiffs submit that the same is done only on the basis of 'Hindsight' after knowing the structure of Erlotinib Hydrochloride"

II ***"Methyl to Ethynyl Direct Interchangeability:***

- It is submitted, that the Defendant filed their replication to counter-claim after the Plaintiffs filed the Evidence Affidavits of their witnesses. It is submitted that once the Plaintiffs pointed out the

fallacy of the Defendant's argument on obviousness in its written statement to the counter claim the Defendant dropped the bio-isosterism route, and adopted a completely new route i.e. direct inter-changeability of Methyl to Ethynyl. This new route taken by the Defendant to explain a claim of obviousness is based on 5 completely new patent documents which were not mentioned or disclosed prior to the filing of the Replication to the Counter Claim. The Plaintiffs had no opportunity to provide evidence on the new route taken by the Defendant. Therefore, the Plaintiffs submit that the 5 documents filed with the Replication to the Counter Claim cannot be taken on record. Each document is a material fact by itself. Defendant's act has surprised the plaintiffs and will cause prejudice, if it is read in evidence.

- It is further submitted that replication to counter-claim is not part of the pleadings. Even if the replication is considered to be a part of the pleadings, then the grounds taken cannot be different from what has already been stated in the Counter Claim.
- It was submitted by the plaintiffs that assuming that the 5 prior arts are read in evidence, it is submitted that the Defendant has still failed to explain why a person skilled in the art would have been motivated to replace the Methyl group with the Ethynyl group.
- The defendant's arguments in the Replication to the Counter Claim are totally artificial and can only be the result of hindsight bias. In other words, the defendant starts the discussion by presuming that the structure of claimed compound, Erlotinib Hydrochloride is

known and only then proceeds to discuss the prior art. (*Paragraph 8 of the Evidence Affidavit of DW3*)

- This approach is completely erroneous, since the inventive step must be examined on the priority date of the suit patent i.e. on 30.3.1995. The Plaintiffs submit that on the priority date of the suit patent and without having the knowledge of claimed compound, Erlotinib Hydrochloride, there was no motivation to replace the Methyl group with Ethynyl group.
- It is submitted that 5 patent documents (US4138,590; EP0477700A1; WO1993/04047; US5,427,766; US5,736,534) are cited by the Defendant in the Replication.
- Of these five patent documents, two patent documents US5,427,766 and US5,736,534 are not valid prior arts under Section 64(1)(f) because they were published subsequent to the priority date of the Suit Patent.
- The Plaintiffs submit that out of the 2 cited patent documents, which are not valid prior arts, one document US'534 belongs to the same inventor as the suit patent.
- US'534 was filed prior to the suit patent but was published almost 3 years after the priority date of suit patent.
- Additionally, US'534 does not even disclose “4-**anilino** quinazoline” compounds. Instead US'534 discloses “4-**heterocyclic** substituted quinazoline” compounds. Therefore, no structural similarity exists between the compounds of the US'534 and the suit patent.

- The Defendant has erroneously contended that since the inventor was common and he already had knowledge of including Ethynyl in 3'-position, the claimed compound of suit patent becomes obvious.”
- h)* It has been contended orally as well as in writing that the inference of non obviousness can be drawn by the Court on the basis of the commercial success of the product which is a subject matter of the patent, the same may become weighty consideration for assuming that the invention in question qualifies the tests of obviousness. In this respect, the plaintiffs have mainly relied upon the evidence by way of affidavit of Mr. Thatcher which has been articulated by the plaintiffs and their counsel in the following manner:
- “Evidence with respect to this consideration can include assertions based on cogent evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art or even that the claimed invention was copied by others. In the present case, such evidence has been provided extensively by the Plaintiffs’ witnesses.
 - Specifically, the Plaintiffs’ witness, PW-3 Dr. Nick Thatcher in his capacity as an experienced oncology clinician, has stated that the patented compound Erlotinib Hydrochloride was efficacious in the treatment of non-small cell lung cancer conferring consistent survival benefits across multiple patient sub-groups including smokers (*Paragraphs 25-27, 32 of the Evidence Affidavit of PW3*).
 - In his opinion, the results shown by the patented compound Erlotinib Hydrochloride were even more surprising and

unexpected since they were far superior than the results of the Phase III trial of the compound Gefitinib which was targeted towards the same treatment. (*Paragraphs 29-33 of the Evidence Affidavit of PW3*). This has also been reiterated by the second expert witness produced by the Plaintiffs, Prof. Roger Griffin in response to a question posed to him during cross examination (*Q. 152 and 154*)

- Dr. Thatcher has further stated that Erlotinib Hydrochloride is the only Quinazoline derivative approved for the treatment of patients who have incurable advanced or metastatic pancreatic cancer. (*Paragraphs 34-37 of the Evidence Affidavit of PW3*).

33. In placing this evidence on the Court's record, Dr. Thatcher has relied on several articles including:

- i.** Ex. PW1/X6: "Erlotinib in Previously Treated Non-Small Cell Lung Cancer"
- ii.** Ex. PW1/X7: "Symptom Improvement in Lung Cancer Patients Treated with Erlotinib: Quality of Life Analysis of the National Cancer Institute of Canada Clinical Trials Group Study BR.21"
- iii.** Ex. PW1/X8: "Erlotinib plus gemcitabine compared with gemcitabine alone in patients with advanced pancreatic cancer: a phase III trial of the National Cancer Institute of Canada Clinical Trials Group."
- iv.** Ex. PW2/D2: "Gefitinib plus best supportive care in previously treated patients with refractory advanced non-small-cell lung cancer: results from a randomised, placebo-controlled, multicentre study (Iressa® Survival Evaluation in Lung Cancer)"

- v. Ex. PW3/1: "Does potency predict clinical efficacy? Illustration through an antihistamine model"
- vi. Ex. PW3/2: "Salvage Therapy for advance Non-Small Cell Lung Cancer: Factors Influencing Treatment Selection"
- vii. Ex. PW3/3: "Smoking History and Epidermal Growth Factor Receptor Expression as Predictors of Survival Benefit from Erlotinib for Patents with Non-Small Cell Lung Cancer in the National Cancer Institute of Canada Trials Group Study BR.21"
- viii. Ex. PW3/5: "US FDA Public Health Advisory: New Labelling and Distribution Program for Gefitinib"

34. By placing reliance on the aforementioned reply, submissions, evidence, anomalies in relation to the case of the counter claimant, it has been argued by the learned senior counsel for the plaintiffs that there is no case made out for obviousness for so many reasons stated, explained and articulated above. The defendant has therefore failed to discharge burden of obviousness.

35. Likewise, the plaintiffs have responded to the other grounds of the counter claim and have also discussed the law subject wise.

36. I have gone through the records of the proceedings including plaint, counterclaim, written statement, replication and evidence adduced by the parties and also given the careful consideration to submissions advanced at the bar noted above in detail. Let me now deal with the various aspects involved in the revocation of patent one by one.

Re: Lack of Inventive step in the Suit Patent

37. Firstly, I think it is for me to discuss the challenge which has been laid by the defendant to the plaintiff's suit patent in relation to lack of inventive step. As it is seen above, the ground of lack of inventive step in the plaintiff's Ex PW1/5 IN'774 patent has been set up by urging several points which as per the defendant would demonstrate that the plaintiff's patent was anticipated. Likewise, the plaintiffs have equally taken pains to find out number of anomalies in the grounds raised by the defendant by responding on each and every point seeking to justify as to why the plaintiffs reply should be accepted and not the defendant's ground. I think much labour and exercise has been done by finding out defects on either side's stand which has resulted into several sub categorizations of the competing stands of the parties rather than putting the positive case on either side. This I have noticed at the outset as the same will also come in to aid while weighing the evidence of the competing parties.

38. As there are number of arguments and grounds raised by the parties in relation to the concept of lack of inventive step, persons skilled in the art and thereafter while making the submissions, the terminologies are transposed with the ones laid down in US judgments and English judgments suitably as per the convenience of the parties by contending that the said person is one who is an "unimaginary person" or for that matter what "motivated" the inventor to choose any structure as lead compound and various other facets which are laid down as tests in such judgments are being imported in order to satisfy this Court, I think it is necessary to discuss the patent law as governing in India in form of Patents Act 1970 in order to find out the true

test on basis of which the obviousness or inventive step in the patent is required to be tested.

39. Indian Patents Act 1970 has been amended in the year 2005 where under the concept of the product patent in relation to pharmaceuticals has been introduced. The definition of inventive step is the defined under Section 2 (1) (ja) of the patents Act. The definition of “inventive step” in The Patents (Amendment) Act which is inserted by way of amendment of 2005 u/s 2(ja) reads as under:-

2(1) (ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;"

40. The provisions relating to revocation of Patents which are statutorily engrafted u/s 64(1) (f) provides specifically a ground of lack of inventive step for the purposes of revocation. The said provision reads as under:-

64. Revocation of patents

1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, [be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counterclaim in a suit for infringement of the patent by the High Court] on any of the following grounds, that is to say—

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

- (b) that the patent was granted on the application of a person not entitled under the provisions of this Act to apply therefor;
- (c) that the patent was obtained wrongfully in contravention of the rights of the petitioner or any person under or through whom he claims;
- (d) that the subject of any claim of the complete specification is not an invention within the meaning of this Act;
- (e) that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in Section 13 : 2
- (f) that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in India or what was published in India or elsewhere before the priority date of the claim;
- (g) that the invention, so far as claimed in any claim of the complete specification, is not useful;
- (h) that the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed, that is to say, that the description of the method or the instructions for the working of the invention, as contained in the complete specification are not by themselves sufficient to enable a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention, or that it does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection;

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

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

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

(l) that the invention so far as claimed in any claim of the complete specification was secretly used in India, otherwise than as mentioned in sub-Section (3), before the priority date of the claim;

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

(n) that the applicant contravened any direction for secrecy passed under Section 35 or made or caused to be made an application for the grant of a patent outside India in contravention of Section 39;]

(o) that leave to amend the complete specification under Section 57 or Section 58 was obtained by fraud.

[(p) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;

(q) that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.]'

(2) For the purposes of clauses (e) and (f) of sub-Section (1),—

(a) no account shall be taken of [personal document or secret trial or secret use]; and

(b) where the patent is for a process or for a product as made by a process described or claimed, the importation into India of the product made abroad by that process shall constitute knowledge or use in India of the invention on the date of the importation, except where such importation has been for the purpose of reasonable trial or experiment only.

(3) For the purpose of clause (1) of sub-Section (1), no account shall be taken of any use of the invention—

(a) for the purpose of reasonable trial or experiment only; or

(b) by the government or by any person authorized by the government or by a government undertaking, in consequence of the applicant for the patent or any person from whom he derives title having communicated or disclosed the invention directly or indirectly to the government or person authorized as aforesaid or to the government undertakings; or

(c) by any other person, in consequence of the applicant for the patent or any person from whom he derives title having communicated or disclosed the , invention, and without the consent or acquiescence of the applicant or of any person from whom he derives title.

(4) Without prejudice to the provisions contained in sub-Section (1), a patent may be revoked by the High Court on the petition of the Central Government, if the High Court is satisfied that the patentee has without reasonable cause failed to comply with the request of the Central Government to make, use or exercise the patented invention for the purposes of government within the meaning of Section 99 upon reasonable terms.

(5) A notice of any petition for revocation of a patent under this Section shall be served on all persons appearing from the register to be proprietors of that patent or to have shares or interest therein and it shall not be necessary to serve a notice on any other person.”

41. On the bare reading of the aforementioned Sections, it is clear that the definition of “inventive step” nowhere accords any differential treatment to any particular type of invention. Rather, it lays down the general test which is indicative towards technological advancement and the non obviousness of an invention to a person skilled in art. Besides the same, the said definition of inventive step u/s 2(ja) which has been newly inserted in the Patents Act (Amendment) 2005 once read with grounds of revocation u/s 64 nowhere indicate any special treatment or different tests to be applied for any particular type of invention more specifically medicinal, chemical, industrial, etc.

42. On conjoint reading of the Section 64 read with Section 2(ja), it is clearly discernible that there are certain essential ingredients of Section 2(ja) in order to call any invention to qualify the threshold of inventive step. The said ingredients are:-

- a) That the said invention involves a technical advancement as compared to existing knowledge or economic significance or both; and
- b) That makes the invention non obvious to the persons skilled in art.

43. These are conjunctive requirements u/s 2(ja) which means that not merely there should be a technical advancement in the invention but at the same time, it should not be obvious to the person skilled in art. Therefore, both the requirements are to be satisfied conjunctively. It is noteworthy here again that beyond the said two ingredients, there is no further ingredient

which should be read into in order to enlarge or limit the scope of the Section.

44. Consequently, what follows from the above discussion is that as per the provision of Patents Act there is nothing which is indicative of the fact that any stricter approach is to be followed while testing the patents relating to chemical compounds due to any reason whatsoever including that the patent relates to chemical compounds which are preexisting in the field and therefore some departed approach unlike other kinds of patents may be followed in order to adjudicate upon the obviousness relating to chemical compounds or medicinal patent be it product or process.

45. One has to travel not very far in order to understand the test relating to obviousness which has been minutely discussed by the Supreme Court of India in the case of *Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries* cited as *AIR 1982 SC 1444*, which is a Three Judges Bench decision. In the said judgment, tests of patentability are discussed in extenso and the expressions used under the Patents Act which has been defined and discussed thoroughly including the expression “inventive step”. The said judgment is a landmark judgment followed by the Courts across the country and is still holding the field till date and all the matters relating to Patent infringement are decided on the basis of the tests carved out in said case of *Biswanath Prasad(supra)* till date without any departure.

46. It is further noteworthy that in the said case too, a decision was rendered after trial culminating into the final adjudication. The said case and the observations made therein by Hon’ble Supreme Court of India gains more importance due the said reason also as I am proposing to decide this

case finally. In the said case of *Biswanath Prasad (supra)*, Hon'ble Supreme Court has laid down the test as to what constitutes inventive step. In the words of Hon'ble Supreme Court of India it was observed thus:-

"24. Whether an alleged invention involves novelty and an 'inventive step', is a mixed question of law and fact, depending largely on the circumstances of the case. Although no absolute test uniformly applicable in all circumstances can be devised, certain broad criteria can be indicated. Whether the "manner of manufacture" patented, was publicly known, used and practised in the country before or at the date of the patent ? If the answer to this question is 'yes', it will negative novelty or 'subject matter'. Prior public knowledge of the alleged invention which would disqualify the grant of a patent can be by word of mouth or by publication through books or other media. "If the public once becomes possessed of an invention", says Hindmarch on Patents (quoted with approval by Fry L. J. in *Humpherson v. Syer*, "by any means whatsoever, no subsequent patent for it can be granted either to the true or first inventor himself or any other person; for the public cannot be deprived of the right to use the invention..... the public already possessing everything that he could give."

25. The expression "does not involve any inventive step" used in Section 26(1) (a) of the Act and its equivalent word "obvious", have acquired special significance in the terminology of Patent Law. The 'obviousness' has to be strictly and objectively judged. For this determination several forms of the question have been suggested. The one suggested by Salmond L. J. in *Rado v. John Tye & Son Ltd.* is apposite. It is: "Whether the alleged discovery lies so much out of the Track of what was known before as not naturally to suggest itself to a person thinking on the subject, it must not be the obvious or natural suggestion of what was previously known." (Emphasis Supplied)

26. Another test of whether a document is a publication which would negative existence of novelty or an "inventive step" is suggested, as under:

"Had the document been placed in the hands of a competent craftsman (or engineer as distinguished from a mere artisan), endowed with the common general knowledge at the 'priority date', who was faced with the problem solved by the patentee but without knowledge of the patented invention, would he have said, "this gives me what I want?" (Encyclopaedia Britannica; ibid). To put it in another form: "Was it for practical purposes obvious to a skilled worker, in the field concerned, in the state of knowledge existing at the date of the patent to be found in the literature then available to him, that he would or should make the invention the subject of the claim concerned ?" Halsbury, 3rd Edn, Vol. 29, p. 42 referred to by Vimadalal J. of Bombay High Court in *Farbwrke Hoechst & B. Corporation v. Unichem Laboratories.*" (Emphasis Supplied)

47. From the bare reading of the afore quoted observations of Supreme Court, it is manifest that the Hon'ble Supreme Court has laid down the test for the purposes of ascertaining as to what constitutes an inventive step which to be seen from the standpoint of technological advancement as well as obviousness to a person who is skilled in the art. It is to be emphasized that what is required to be seen is that the invention should not be obvious to the person skilled in art. These are exactly the wordings of New Patents Act, 2005 u/s Section 2(ja) as seen above. Therefore, the same cannot be read to mean that there has to exist other qualities in the said person like unimaginary nature of the person or any other kind of person having distinct qualities.

48. Such observations made in the foreign judgments are not the guiding factor in the true sense of term as to what qualities that person skilled in art should possess. The reading of the said qualities would mean qualifying the said statement and the test laid down by the Supreme Court.

49. The said observations relied upon by the parties are judicially created tests depending upon the nature of the case and the subjective satisfaction of the Judge in the given case. As there is no such requirement which exists at least in Indian Patent Act defining the further qualities of a person skilled in art, therefore, one has to leave the said point there and then which is that what is required to be seen is the obviousness from the standpoint of a person who is skilled in art.

50. Normal and grammatical meaning of the said person who is skilled in art would presuppose that the said person would have the knowledge and the skill in the said field of art and will not be unknown to a particular field of art and it is from that angle one has to see that if the said document which is prior patent if placed in the hands of the said person skilled in art whether he will be able to work upon the same in the workshop and achieve the desired result leading to patent which is under challenge. If the answer comes in affirmative, then certainly the said invention under challenge is anticipated by the prior art or in other words, obvious to the person skilled in art as a mere workshop result and otherwise it is not. The said view propounded by Hon'ble Supreme Court in *Biswanath Prasad (supra)* holds the field till date and has been followed from time to time by this Court till recently without any variance.

51. Therefore, it is proper and legally warranted to apply the same very test for testing the patent; be it any kind of patent. It would be improper to import any further doctrinal approach by making the test modified or qualified what has been laid down by the Hon'ble Supreme Court in of *Biswanath Prasad (supra)*.

52. It is also not disputed that the Courts internationally have laid down certain other criterion while dealing with the patents relating to chemical compounds and the tests are somewhere seem to be different from what has been governing the field in Indian context as per the Indian Patents Act, 1970 as amended in 2005. However, the said test laid down by the Courts either in Europe or in US cannot be as a matter of natural consequence applied in the Indian context on the mere insistence of the parties. This is more so when the observations of Hon'ble Supreme Court earmarking "inventive step" and defining the scope and ambit of the same are governing the field with no caveat or exception to any particular kind of patents.

53. This is also emerging from amendments made in the year 2005 which speaks in the same voice with that of the view of Supreme Court while introducing the product and process patents for medicines. All this is indicative of the legislative intent that the legislature was conscious while providing the definition of inventive step that it is according patent protection to medicines, still no such other treatment either in the form of explanation or proviso to the definition of inventive step or anywhere has been provided.

54. On the other hand, wherever it was necessary, such explanations in the form clarifications relating to medicinal patents are provided like

explanation appended to Section 3(d) which provides that the Polymorphic version of the drug shall be deemed to be the same substance unless backed by the efficacy. In absence of any such intent to provide such different tests of obviousness in pharmaceutical patents, it would be legally impermissible to import any such new tests which may somehow seem or appear to be facets of the tests of obviousness as Indian Act nowhere provides such requirement.

55. Therefore, it would be wise to say that there exists a jurisprudential difference between the countries like India where the patent law is still at the nascent stage vis-à-vis the European countries where the law has developed up to one level and far away in US where the patent law is operating at the advanced stage. The tests shall accordingly vary as per the prevalent conditions of the respective countries.

56. In the country like India where we have followed the Product Patent Regime relating to medicines and pharmaceuticals reluctantly after 10 years since 1995 on a phase by phase basis as against the US where the said regime is preexisting for a healthy passage of time, it is but natural that the tendency of the Courts in such countries to protect the patents and to lay down the tests for measuring the obviousness, novelty shall vary and will certainly be at the advanced stage than that of what has been existing in India.

57. One must also not forget that the tests are carved out by also considering the language of the Statute, coupled with other factors including the avowed object of the Act and constitutional goals to be achieved and not in abstract. Accordingly, the test of obviousness as discussed above in the Indian context holds good so far as Indian Statute is concerned and may

change in the future depending upon the change of definition of “inventive step” in case the legislature deems fit to amend the definition of inventive step or in the alternative provide some safeguards to medicinal patents so as to deal with them differently. Till the time it is not done so, it cannot be said that the test of American Courts and European Courts may be applied when it comes to adjudicate the obviousness of Indian Patents.

58. This clarification became necessary as lots of decisions are cited at the bar where American Courts have first laid down some tests and thereafter year after year changed the approach which goes either in favour of the plaintiffs in one case and in favour of defendant in another. I think it is not prudent to just follow such decisions in favour of either side and would be correct approach to consider only those decisions which go in consonance with our Indian patent law regime and judgments passed by the Supreme Court of India. It does not mean that the English and American decisions are not helpful. The aid is being taken from such decisions where it is necessary, which goes consistent with Indian law.

59. The discussion done above is also evident from the conflicting opinions existing in the English Courts in UK where the similar debate is prevalent too, the reference is invited to the decision of the Court of appeal in the case of *Dr. Reddy's Laboratories (UK) Ltd. vs. Eli Lilly and Co. Ltd.* reported as 2010 RPC Page No.9 where the Court of appeal has observed that the ordinary approach relating to obviousness should be followed even in cases relating to patents involving chemical compounds rather than what has been followed by other European Courts, patent offices and no special approach is warranted in the law. It is however different matter that in the

result, the Court of appeal decided in favour of the patentee but what is important is the observations relating to the tests of obviousness which as per the Court are the same as ordinary approach of obviousness. In the words of Court of Appeal, it was observed thus :-

“ Further, as I have tried to show and as Jacob L.J.’s analysis in paras 44 to 50 demonstrates, the Board’s approach in cases such as these is consistent and clear and it is based on its general approach to patent validity on novelty and obviousness. There is nothing in the 1977 Act (any more than there was in the 1949 Act, it is fair to say) which recognizes, or even implies, a special approach to, or even the existence of, selection patents as a special category of patent, which require a different approach when determining validity from other patents. Indeed, although it involves a slightly different analysis, it seems to me that the point at issue is not dissimilar from the enantiomer/ racemate issue, in relation to which this court and the House of Lords adopted the approach which had been taken by the Board – See Generics (UK) Ltd. V H. Lundbeck A/S [2008] UKHL 12; [2008]EWCA Civ 311 [2008] RPC 19, at para 9 (where Lord Hoffmann specifically referred to and followed the Board’s reasoning in T 0296/87 HOECHST/ Enantiomers). Quite apart from this, as Jacob L.J. points out in para 39, there may be some difficulty in applying Maugham J.’s three stage approach where the prior class of compounds is very large” (Emphasis Supplied)

60. It has also been recognized by the author in the Book titled “Modern Law of Patents” where this decision of Dr. Reddy’s (supra) has been quoted to suggest that the ordinary approach of obviousness should be applied in adjudging the patentability of inventions involving chemical compounds relating to selection inventions. Learned Author observed thus:-

“2.132- The approach of the English courts has purportedly moved towards that of the EPO although in Dr. Reddy’s Laboratories (UK) Ltd. v Eli Lilly and Co Ltd. the Court of Appeal appears to suggest the patentability of selection inventions is a question of inventive step whereas the EPO predominantly looks at it as a question of novelty (and simply applies the normal rules for inventive step)” [Emphasis Supplied]

61. From the abovementioned view taken by the Court of Appeal as well as by the learned author, it is clear that even the European Courts are still thinking as to whether any such departure or special treatment should be given to medicinal patents or not when it comes to deciding the obviousness and in the said case Dr. Reddy’s (supra) it was laid down that the ordinary approach of obviousness would suffice.

62. There is no reason why in the present case, the same observation should not be applied and more so when Hon’ble Supreme Court of India lays down the tests of inventive step in the case of Bishwanath Prasad (Supra) which is in consonance with the observations of Court of appeal that the obviousness has to be tested on the basis of technological advancement and what has been known to the person skilled in art and nothing beyond the same. Therefore, the tests which are further modified and are doctrinal in nature are not relevant for the purposes of seeing the obviousness of a patent or for that matter any other patent.

63. Now, the related question arises as to what can be said to be obvious to the persons skilled in art and how to determine the same. It is seen above that the Supreme Court in Bishwanath Prasad observed that the question of obvious to the person skilled in art is a mixed question of fact and law. Therefore, a person setting up a challenge to the patent must aver so and

establish the facts material to establish obviousness. The said material facts are bundle of facts which can be said to be chain of events making the invention obvious to the person skilled in the art. The said chain of events in the case of Bishwanath Prasad which were established on record in that case are the 6 points mentioned in the judgments which are established on the record in that case.

64. Therefore, one has to immediately advert to the question as to what chain of events is necessary in order to establish obviousness to the person skilled in art in relation to chemical compounds. Is it only the establishment of the fact that there is depiction of the similar looking compound in the examples in the cited prior art and coupled with the further experimentation which may find somehow common place after the priority date of the patent or something more. I think for the same, some guidance from English authorities or the books can be taken only to the limited extent of finding out as to what are the essential facts or material facts necessary to establish the obviousness should be proved by the applicant for revocation.

65. The chain of events which are necessary for the purposes of finding obviousness in relation to selection of chemical compounds from the larger formula or molecule are discussed in the book titled as "The Modern Law of Patents" by Roughton, Johnson, Cook & Fysh, 2011 Edition, (Lexis Nexis), wherein the learned author quotes an authority from European Patent office. The learned author observed thus:

“2.125 In T279/89 Moulded polyurethane elastomers/ Texaco, the Board of Appeal gave some practical requirements which must be satisfied for a selection invention to be novel, in particular:

- (a) The selection invention or range should be narrow.
- (b) The selection invention or range should be sufficiently far removed from the known range illustrated by means of the examples.
- (c) The selected area should not provide an arbitrary specimen from the prior art, is not mere embodiment of the prior description but another invention (purposive selection) (In T279/89 Moulded polyurethane elastomers/ Texaco (unpublished*) 9th July 1991 at (r 4.1); this test was based on the earlier decision T198/84 Thiochloroformiates/ Hoechst, (1985) OJ EPO 209)”

“2.126 the meaning of “narrow” and “sufficiently far removed” in criterion (a) and (b) is decided on case by case basis. Furthermore, in relation to criterion (c), a technical effect which only occurs in the individual selection (or in a range) within a larger range is indicative of this criterion has been satisfied. It is not enough, however to discover that a subrange within a range demonstrates a new characteristic, rather the range itself had to be new.” (Emphasis Supplied)

66. From the reading of the aforementioned observations of the learned author, it is clear that the afore noted chain of events or material facts are to be satisfied at least for the purposes of calling the invention new and non obvious, for the purposes of challenge which has been set up against the patentee, these very chain of events are to be established by the counterclaimant conversely as the onus is upon the defendant to show that the patent is obvious in the revocation proceedings. Therefore, after analyzing the aforenoted events, the following material facts are essentially required to be established by the counterclaimant:

- a. The selection of the impugned invention is taken from the examples of the known prior art.
- b. That the selected invention is not far removed from the known range illustrated in the example. Rather, the same is closer to the known range.
- c. That the selection area is not on the basis of any purpose of the inventor and is merely an arbitrary picking up the compound.

The above noted tests are some broad criterion on the basis of which, it can be tested that the whether the onus of the counterclaimant is discharged so far as it relates to revocation of the patent by establishing the material facts necessary for the same. The existence of the said events is essentially a question of the fact and shall vary from case to case basis as noted by Modern Law of Patents (supra). These factors are also inclusive and not exhaustive as there may exists some more chain of events which may prove helpful in arriving at the finding of obviousness to the person skilled in art as attending circumstances peculiar to the said case.

67. It is also necessary to examine the legal aspect of onus of proof involved in the revocation proceedings. It is well settled principle of law that the onus of proof in the revocation proceedings is akin to the principle of onus of proof involved in the civil cases which is on balance of probabilities.

68. Sh. P. Narayanan in his book titled "Patent Law" Fourth Edition, published by Eastern Law House, has observed in relation to standard of proof required in the revocation proceedings by citing English authorities that the said standard of proof is based upon balance of probabilities and is

not beyond the reasonable doubt which is required in criminal cases. The learned author observes in the following words:-

“15-16 Standard of proof required. The court will not allow grants, which have on the evidence been proved to be invalid to remain on the register. The court is not concerned with proof beyond reasonable doubt which is required in criminal cases, but with the normal standard required in civil cases, namely proof based on the balance of probabilities.”(Emphasis Supplied)

[Languerre’s patent [1970] RPC 587 at 595 (a case of revocation under s. 33 of the U.K. Act of 1949), decision affirmed by CA [1071] RPC 384. See also *Bonninton Castings Ltd v Wardlaw* (1965) ac 613 AND Halsbury’s Laws of England, 3rd Ed. Vol 15, p. 272”]

69. On the reading of the aforementioned excerpts from the book of learned author, it is amply clear that the onus of the proof which is required to be discharged in the cases of the revocation and infringement proceedings are based on the balance of the probabilities. The said onus of the proof cannot be equated with the Burden of the Proof of criminal cases which is that one has to prove the case beyond reasonable doubt.

70. This discussion on onus of proof in revocation proceedings became necessary in order to delimit the scope of the enquiry as to weighting of the evidence. This is due to the reason that the parties in instant case continue to insist on the anomalies done by each other and also stating the lack of evidence on either side one way or the other. Therefore, it has become necessary to point out that the evidence of the parties are to be tested on the balance of the probabilities. Though, the defendant had raised almost all the grounds available in Section 64 of the Act. However, this Court inclines

to discuss only those grounds on which specific pleadings and evidence adduced by the counter claimant.

71. Let me apply the principle of laws enunciated above relating to obviousness and test the present case on the basis of balance of the probabilities in order to see whether the defendant has discharged the burden as to show the obviousness or lack of inventive step in the suit patent. I propose to discuss the same by enumerating the following pointers:

1. The defendant has filed counter claim alleging the ground as to obviousness or lack of inventive step of the suit patent IN'774. In order to support the ground, it is stated and documents to the effect have been filed that the suit patent is anticipated by EP'226. The said document depicts the structure of the compound as example 51 which seems to be similar in structure and look with that suit patent but the same does not coincide with the suit patent as it contains certain further treatments by way of substitution of ethynyl at the third position with that of methyl.
2. The defendant has also filed documents containing the specifications of EP 477700, US 4138590, US 5427766, US 5736534, WO 193004047 though objected to that they are after replication, which showed that in the field of derivative compounds, it is not uncommon or unusual to substitute the treatment of ethyl or ethynyl with that of methyl components. The said documents are filed and marked as Exhibit DW 3/ 2 to 3/6 respectively. I think the said documents have been filed by

the defendant after the replication to the counterclaim has been filed after framing of issues. The admissibility of the said documents have been questioned by the learned counsel for the plaintiffs that they are not to be admitted in evidence as no permission was sought in this respect from the Court and the plaintiffs are taken by surprise. I have answered this in detail in the later part of the discussion.

3. The defendant has filed an affidavit of Mr. Nangia (DW-3) as expert who has explained in his words as to how the suit patent is anticipated by EP' 226. It has been explained in the said affidavit in detail as to the aspect of arriving of the said subject invention on the basis of the teachings of the Zeneca patent which is EP' 226.
4. The learned counsel for the plaintiffs has cross examined Mr. Nangia DW-3 where under DW gave some answers to the question which may mean that the witness has analyzed the said patents on the basis of instructions of Solicitors and has less knowledge of the Patent law, DW also has been cross examined on the aspect of hindsight and the fact that there are number of the compounds revealed by the plaintiffs suit patent IN774.
5. On reading the depositions of Mr. Nangia, the following position emerges:
 - That DW3 has deposed positively that the chemical structure of EP'226 which looks someway similar in the structure to the chemical structure of the suit patent with the reaction of methyl component at the third position

finds mention in the one of the example 51 of the EP'226.

- That DW has deposed that US 534 and other patents cited in the documents somehow indicate the use of methyl and ethyl component.
- On the basis of the aforementioned two facts, the conclusion was deduced by DW 3 that due to the reason that the inventor Mr. Arnold was common in US 734 and US' 498 which corresponds to IN'774, therefore the said Indian patent was obvious to the person skilled in art.

Likewise, Mr. Nick Thatcher PW3 and Mr. Robert Griffin PW2 have filed the affidavits.

6. The defendant has cross examined the plaintiff's witnesses PW3 and PW2 who state that they are the experts. However, the careful reading of the depositions made in the affidavits would reveal that the said experts nowhere inform in the express terms as what was the lead compound for the purposes of arriving at the invention, what steps were taken from time to time in order to work upon the said compound from time to time and thereafter as to when eventually the said compound was arrived at. The expert evidence as well as the evidence by way of affidavit is completely silent about the same.
7. The defendant has been able to cross-examine the plaintiffs' witnesses which reveal that the plaintiffs' witnesses inform that they were not involved in the research of quinazoline derivatives with the owners namely OSI which is answer to

question Nos.15 and 16, the said witness PW2 Roger Griffin informs that he is not into the field of quinazoline derivatives but into quinazolinone. Though he denies the suggestion that he does not have the knowledge about the same. The said witness further states on being asked that the he is not aware the name of the scientists who have invented the suit patent. Accordingly if the said expert witness does not properly know about the derivatives in question, nor himself worked upon the invention, not is even aware of the said scientists who are involved in the invention, not even consulted with the plaintiffs at the relevant time of 1995 when the invention was made and the said witness deposes in the affidavit everything relating to experimentation and working on of the invention on the “might have been” basis or “would have been” basis, it can be safely said that the said witness is not aware of the state of affairs through which the said invention has passed through including the number of experiments, work upon done on the said invention in order to arrive at the desired result.

It can also be concluded in view of statements contained in the affidavit of Roger Griffin that the said deposition on what “might have” happened or “would have” done basis are all speculative in nature. The witness is not aware personally as to whether the said happenings and steps of experimentation narrated in the affidavit have in fact actually taken place. Under these circumstances, it is one of the probabilities which may have happened as per the witness who is

himself not aware of the state of affairs through which the invention passed through.

72. Mr. Thatcher (PW3) has been cross examined at great length by the defendant where also similar answers are coming forth. Mr. Thatcher in his affidavit indeed deposes about some kind of efficacy which may be shown in clinical trial but the same is again not clarifying the aforestated questions, which goes into the root of the matter. The said affidavit again informs about clinical trial about efficacy tests but does not inform and deposes as to what were the steps defining the work upon done on the said patent invention from time to time and how many trials were made in order to arrive at Ernotilib Hydrochloride. Such depositions if could have been filed and made in the affidavit by the scientist or research and department official of the plaintiff company involved in invention could have brought forward the positive case of the plaintiffs in relation to innovativeness and inventive step which is missing in the present case.

73. Mr. Salve, learned senior counsel and Ms. Pratibha Singh both have submitted that the impugned patent is obvious and is based on EP'226 by making comparison of specification of EP'226 vis-à-vis that of IN'774 and its connected US Patent in the following manner:

- It is submitted that the Patent specification (**Exhibit PW1/5**) consists of the following Sections;
 1. Background of the Invention.
 2. Summary of Invention.
 3. Detailed description of the Invention.

4. Examples

5. Claims

The specification was originally titled as "*Quinazoline Derivatives*" OR "*Quinazoline Derivatives Compound and Composition*". Thereafter, finally, the title was changed to the present title which is "*A novel [6,7-bis(2-methoxyethoxy)quinazolin-4-yl]-(3-ethynylphenyl) amine hydrochloride and a process for preparing the same*".

74. It is submitted that it is important to note the fact that this change took place in February, 2007 i.e. 14th February, 2007 when the original 27 claims were replaced with 2 claims i.e. One Product Claim and One Process Claim. The reading of the specification does not disclose any connection whatsoever with the Claims as granted except for one Example i.e. Example 20.

75. Counsel for defendant also submits that after analysis of the specification reveals that this is nothing but cut and paste job done by alleged inventor. He relied upon the following:-

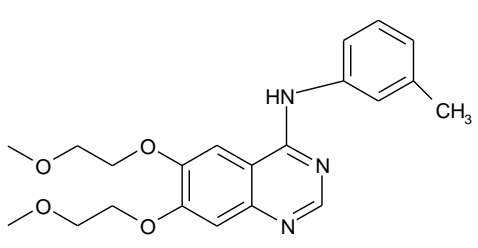
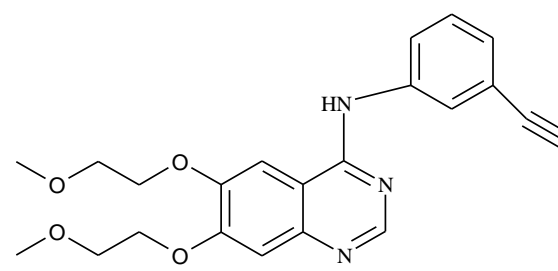
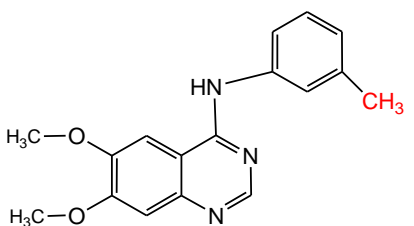
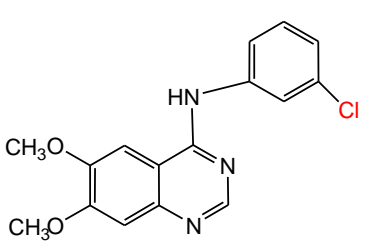
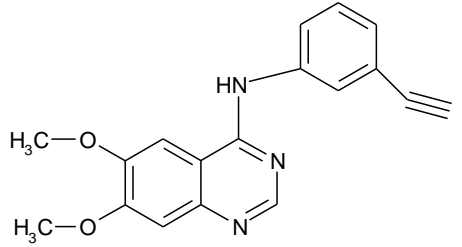
A. Background of Invention: The entire Background of the Invention has been copied word to word from EP566226 (Exhibit D-6) and WO 1995023141 (Exhibit No.PW2/D1 and Exhibit P2/DA).

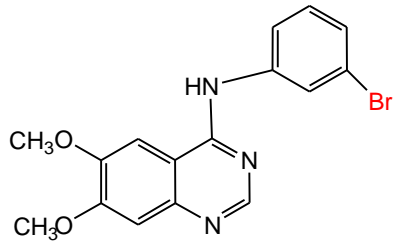
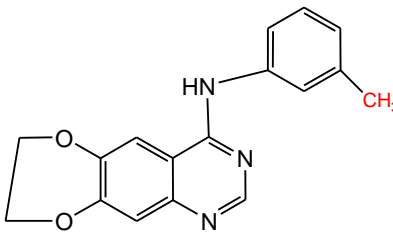
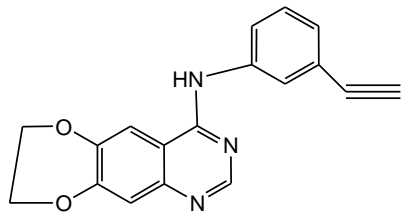
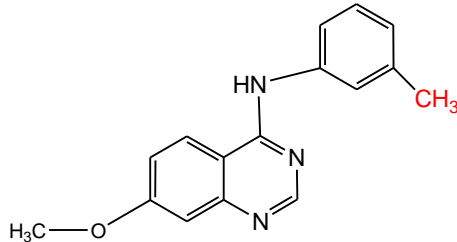
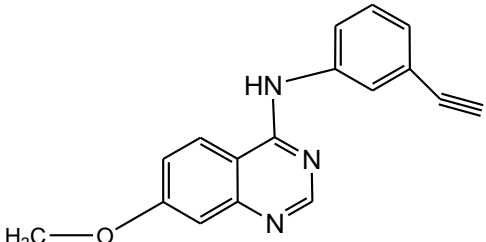
B. Summary of Invention: Coming to the Summary of the Invention, it deals with the Markush Formula consisting of several compounds and the possible substitution thereof. The purpose of the Invention merely mentions the various substitution and does not give any reason whatsoever as to why

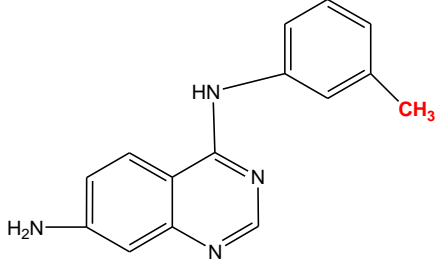
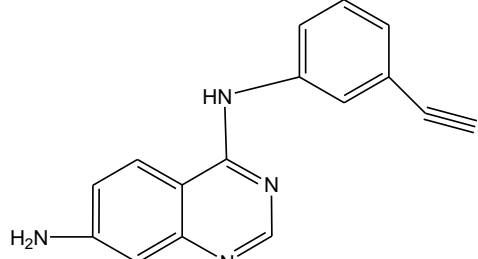
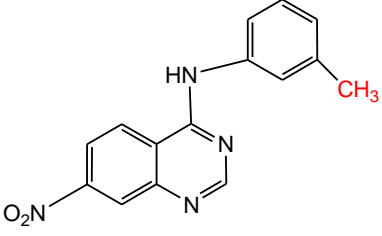
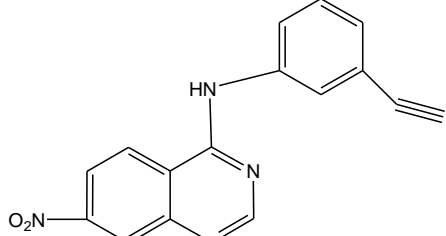
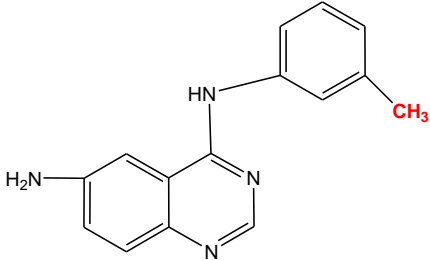
the said substitutions have been made. Out of 100 compounds mentioned in the Summary, only one line at Page-6 line 22 mention the claim compound. None of the remaining compounds contained in that summary has any connection with the Claimed compound. The statement at Page-10 with relation to hyperproliferative disease in mammals is extremely general in nature.

- C. **Detailed description of the Invention:** In the detailed description of the invention, the first line mentions that the compound in Formula 1 and the pharmaceutically acceptable salts may be prepared by any process known to be applicable to the preparation of chemically-related compound. After saying so, different processes are discussed. The entire detailed description relates to processes and has no mention of NSCLC. In fact in the detailed description at several places as per the language of the specification recognizes that these are known procedures. For instance:- Page-14 line 30, Page-15 line 15, Page-15 line 26, Page-16 line 1, Page-18 line 14, Page-18 line 33, Page-19 line 3 to 4, Page-19 line 8 to10, Page-22 line 26, Page-27 line3. Even the detailed description is not sure of the kinds of effect that the compound may have. This is clear from Page-20 line 31, Page-21 line 2, and Page-27 line 7. He also relied upon various compounds disclosed in EP'226 which have been picked up and the Methyl with Ethynyl substitution has been made. Methyl and Cyno are shown as substituent in EP'226. By applying the well known principle of

Bioisosterism, Methyl and Ethynyl substitution is known in the art.

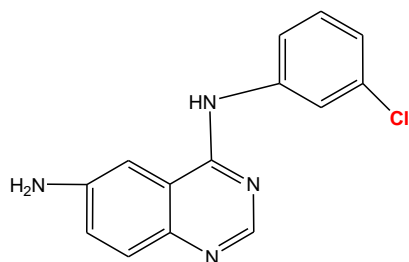
 <p>6,7 di (2-methoxy ethoxy)-4- (3 methyl anilino) quinazoline hydrochloride</p> <p>Example 51</p>	 <p>[6,7 bis (2-methoxy ethoxy)- quinazolin-4-yl]-(3-ethynyl phenyl) amine hydrochloride</p> <p>Example 20</p>
 <p>6,7-dimethoxy -4- (3-methyl anilino) quinazoline hydrochloride</p> <p>Example 1</p>	
 <p>[6,7 dimethoxy- quinazolin-4-yl]-(3-chlorophenyl) amine</p>	 <p>[6,7 dimethoxy- quinazolin-4-yl]-(3-ethynyl phenyl) amine</p>

<p>6,7-dimethoxy -4- (3-chloro anilino) quinazoline</p> <p style="text-align: center;">Example 2 Compound 1</p>	<p>hydrochloride</p> <p style="text-align: center;">Example 2</p>
<div style="text-align: center;">  </div> <p>6,7-dimethoxy -4- (3-bromo anilino) quinazoline</p> <p style="text-align: center;">Example 2 Compound 2^a</p>	
<div style="text-align: center;">  </div> <p>6,7-methylenedioxy -4- (3-methyl anilino) quinazoline</p> <p style="text-align: center;">Example 2 Compound 3^b</p>	<div style="text-align: center;">  </div> <p>(3-ethynyl phenyl)-(6,7-methylenedioxyquinazolin-4-yl)amine hydrochloride</p> <p style="text-align: center;">Example 10</p>
<div style="text-align: center;">  </div>	<div style="text-align: center;">  </div>

<p>7-methoxy -4- (3-methyl anilino) quinazoline</p> <p>Example 2 Compound 4^c</p>	<p>(3-ethynyl phenyl)-(7-methoxyquinazolin-4-yl)amine hydrochloride</p> <p>Example 17</p>
 <p>7-Amino -4- (3-methyl anilino) quinazoline hydrochloride</p> <p>Example 7</p>	 <p>7-Amino-quinazolin-4-yl-(3-ethynyl phenyl) amine</p> <p>Example 16</p>
 <p>4- (3-methyl anilino)-7-nitroquinazoline</p> <p>Example 7</p>	 <p>(3-ethynyl phenyl)-(7-nitroquinazolin-4-yl)amine hydrochloride</p> <p>Example 12</p>
	

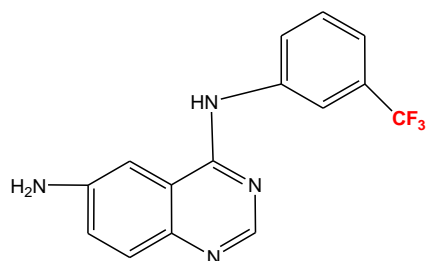
6-Amino -4- (3-methyl anilino) quinazoline hydrochloride

Example 8



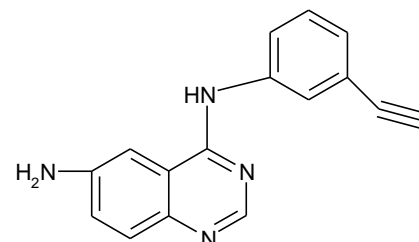
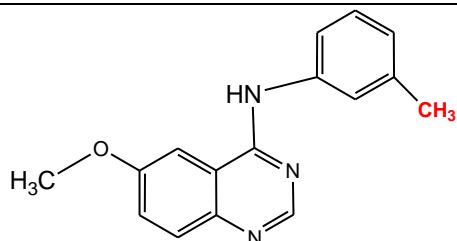
6-Amino -4- (3-chloro anilino) quinazoline hydrochloride

Example 9



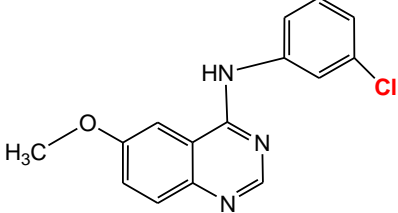
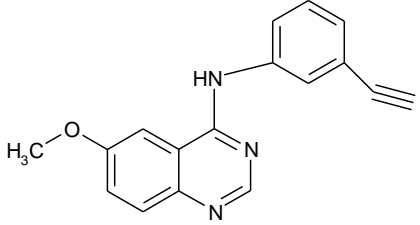
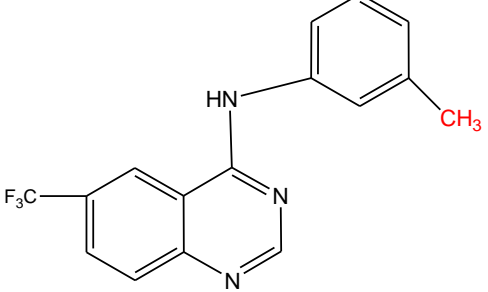
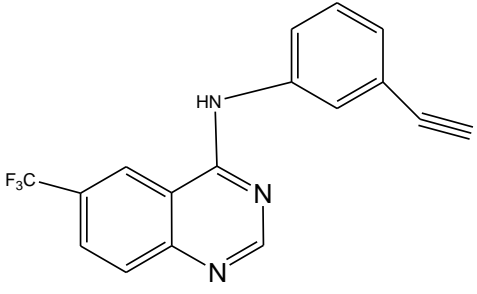
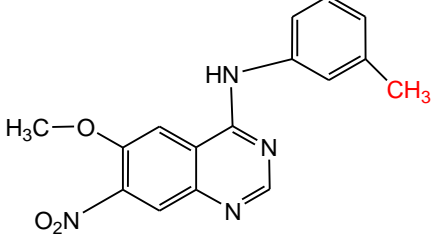
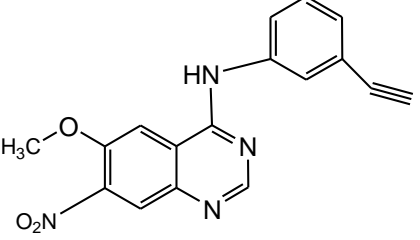
6-Amino -4- (3-trifluoromethyl anilino) quinazoline hydrochloride

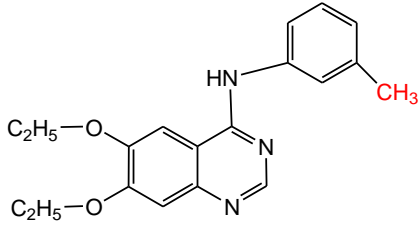
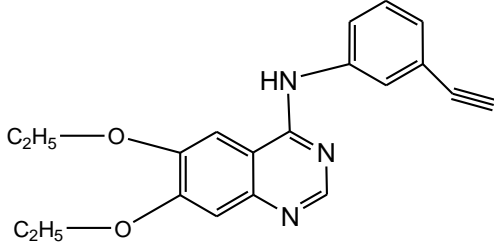
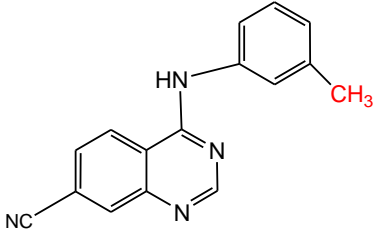
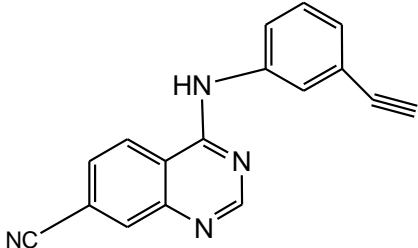
Example 10



6 Amino- quinazolin-4-yl-(3-ethynyl phenyl) amine

Example 8

<p>6-methoxy -4- (3-methyl anilino) quinazoline</p> <p style="text-align: center;">Example 34 Compound 1^a</p>	
 <p>6-methoxy -4- (3-chloro anilino) quinazoline</p> <p style="text-align: center;">Example 34 Compound 2^b</p>	 <p>(3-ethynyl phenyl)-(6-methoxy-quinazolin-4-yl)- amine hydrochloride</p> <p style="text-align: center;">Example 52</p>
 <p>6-trifluoromethyl -4- (3-methyl anilino) quinazoline</p> <p style="text-align: center;">Example 34 Compound 4^d</p>	 <p>(3-ethynyl phenyl)-(6-trifluoromethyl quinazolin-4-yl)- amine</p> <p style="text-align: center;">Example 62</p>
 <p>7-methoxy-4-(3-methyl anilino)-6-nitroquinazoline</p>	 <p>(3-ethynyl phenyl)-(7-methoxy-6-nitro-quinazolin-4-yl)- amine</p>

Example 38	Example 104
 <p data-bbox="469 703 839 730">6,7-diethoxy-4(3-methyl aniline) quinazoline</p> <p data-bbox="671 757 775 784">Example 50</p>	 <p data-bbox="1002 678 1573 705">(6,7-diethoxy-quinazolin-4-yl(3-ethynyl phenyl)-amine hydrochloride</p> <p data-bbox="1235 730 1342 757">Example 42</p>
 <p data-bbox="469 1182 866 1209">6-cyanomethyl-4(3-methyl anilino) quinazoline</p> <p data-bbox="671 1234 775 1261">Example 65</p>	 <p data-bbox="1002 1205 1449 1232">4-(3-ethynyl phenyl amino)-quinazoline-6-carbonitrile</p> <p data-bbox="1235 1256 1342 1283">Example 70</p>

76. It is also argued by the defendant's counsel that the said substitution is in several of the compounds disclosed in EP'226. The examples disclosed in the suit patent are a mere variation of Methyl and Ethynyl compared to EP'226. From this it is clear that when the patent was filed, it contained no inventive step whatsoever and it was merely a trial and error long sought which was being tried by the Applicants. The fact that more than one example is a copy of compound specifically disclosed in EP'226 further establishes that this is nothing but a combination method without any

inventive step. What appears to have happened in the present case is in the compound disclosed in EP'226 or other similar Claim of Quinazoline Derivatives have been altered by substituting Methyl/ Fluoro with Ethynyl in order to arrive at the IN'774. If not for this explanation, there could be no other explanation whatsoever as to how the same very substitution using Ethynyl has been made in so many compounds. There is also no discussion whatsoever in the entire specification as to what are the effects of such substitution & the efficiency of each of the compounds disclosed. There is also no comparative data or any data relating to studies.

77. The closest prior art for this case in comparison with the Claim 1 is Example 51 of EP'226. The said example 51 is one of the preferred compounds in EP'226 and even by applying the test of obviousness the compound preferred in EP'226 is a good starting point. There is no disclosure in the specification as to how claimed compound in Claim 1 is a technical advancement of example 51 of EP'226.

78. EP'226 patent related to “quinazoline derivatives, or pharmaceutically acceptable salts thereof, which possess anti-cancer activity,” as well as their methods of manufacture, pharmaceutical compositions containing them, and the compounds' use in mammals.

The following disclosure was provided for example 51 of Zeneca's European patent application No.0566226:

“Example 51

2-Bromoethyl methyl ether (D.834 g) was added to a stirred mixture of 6,7-dihydroxy-4-(3'-methylanilino)quinazoline (0.534 g), potassium carbonate (0.828g) and DMA (10 ml). The mixture was stirred at

ambient temperature for 16 hours. The mixture was evaporated and the residue was partitioned between ethyl acetate and water. The organic layer was dried (MgSO₄) and evaporated. The residue was purified by column chromatography using increasingly polar mixtures of methylene chloride and methanol as eluent. The gum so obtained was dissolved in ethyl acetate (4 ml) and acidified by the addition of a saturated solution of hydrogen chloride in diethyl ether. The precipitate was isolated. There was thus obtained 6,7-di-(2-methoxyethoxy)-4-(3'-methylanilino)quinazoline hydrochloride (0.292 g). m.p. 218–220°C.”

79. In view of the aforementioned discernible facts and evidences emanating from the records of the present case, I find that the defendant has been able to establish the following:

- That there is an indication of some structurally similar compound present in the form of example 51 of EP'226. (except the position of methyl which in the suit patent has been replaced with ethynyl at the particular position)
- That there is some kind of similarity in the abstracts of specification EP'226 vis-à-vis with that EP566226 (Exhibit D-6) and WO 1995023141 (Exhibit No.PW2/D1 and Exhibit P2/DA and PW 1/5 which has resulted into IN'774.
- That there can be a possibility of treatment of ethynyl instead of methyl as they are related to the same kind of group of alkyl which is done in the other patents relied upon by DW3.

80. If one sees the afore-noted three facts emerging from the evidence of the defendants, it is clear that the defendant has been able to show some selection of the compound or range of compounds from the known range as shown and depicted in EP'226, but still it is not shown on record by positive evidence as to how the said selected range is not far removed from the known range and how the selection was arbitrary in nature. The answers to the said two crucial material facts are essential in order to say that the defendant has been able to successfully discharge and displace the onus of the proof lying upon him. This could have been done by the defendant by showing clinically that the substitution of the compound containing ethynyl component are not far removed from that of the methyl component. There should have been depositions to this effect which are not there in the affidavit of PW3. The said finding of far removed of the range cannot be simply arrived at by mere look of the structure and assuming the state of the affairs that it is so simple to substitute the ethynyl with the methyl at the particular position. Therefore, the defendant has not been able to demonstrate as to how the said suit patent compound or range is not far removed from the one depicted in EP'226.

81. As recorded above in the defendant's submissions, where in comparison is done by defendant relating to compounds of EP'226 with that of the suit patent compound, it is clear that some range of compounds is selected from the earlier range already contained in EP'226 wherein ethynyl position has been replaced at third position with that of the methyl or cyano and others. The said argument has been considered but cannot be said to be solely aiding the defendant towards discharging the onus of the proof casted upon it towards proving the reason behind selection of the range

(whether arbitrary or purposeful). There should have been depositions in the affidavit to the effect that the how the selection of such a range was arbitrary and nor purposeful. I find the affidavit of Mr. Nangia DW3 is equally speculative as he deposes that the substitution of the ethynyl and methyl can lead to efficacy by vice versa basis. He deposes that there is no guarantee of the desired result but the possibility. I think the said deposition does not satisfy the criteria as to how the said selection of range was not purposeful but arbitrary in nature. This should have been explained by the defendant only once the defendant witness is so sure about the obviousness and further deposing positively about the arbitrariness in the selection, which in fact has not been done so in the present case. All this is seen above discussion that there are same material facts which are required to be proved on which the law is applied in order to arrive at the finding of obviousness. The said submissions done orally by comparing the compounds and advanced at the final arguments stage cannot take the form of depositions when none are present in the form of depositions in the affidavits DW 1, 2 and 3 or in the pleadings and therefore the third material fact relating to reason behind the selection is not established.

82. Even if the case of the defendant as per the later submissions made during final arguments is seen to be established, still, the material facts relating to second and third requirements as noticed above still remain to be established are as how the said selected range is not far removed from the earlier range and how the said selection is an arbitrary selection of the compound and why not purposive selection of the same. A submission is canvassed at the bar that there are some similarities in the compounds cited as examples in EP'226 vis-à-vis IN'774. The said example coupled with

later denotes the substitution of ethynyl with that of methyl a third position and that is the reason why the said method is arbitrary and based on trial and error. It is also stated that there are similarities in the abstract of the EP'226 with that of IN'774 with the specification initially filed as marked as Ex D6 which reveal that there is cut and copy job done by the inventor.

83. The said submissions are neither present in the written-statement nor in the counter claim nor same are deposed in the affidavit of DW1, 2 and 3 towards establishment of the fact that the said working on the compounds is arbitrary and based on trial and error. I find that the said submissions cannot be believed in the abstract in the absence of the any positive evidence coming from the defendant's end showing some tenability of the same clinically as to how the said invention could be arrived at on trial and error method or selection is arbitrary. This could have been done by the defendant by going step by step. Firstly to show the example from the known compound, which the defendant has done, secondly to show as to how the said selection is not far removed not merely by relying upon the structural similarity or generally saying that the ethynyl or methyl could reap the similar results but by clinically showing what is the effect of the said working of ethynyl at the several positions and how it is not far removed from EP'226 and lastly by showing that the entire selection is arbitrary. All this could have been done by the defendant in the affidavit by showing positive evidence. Failure on the part of the defendant to establish the bare minimum material facts would thus lead to inference as to non obviousness.

84. In the absence of the positive evidence from defendant to the effect that the selection of the range is arbitrary by non application of mind which

is crucial factor in discerning whether the said impugned patent is obvious or not, It cannot be assumed on a priori basis that the mere fact that there exist some similarities in the structure of ranges, the replacement of the third position with ethynyl may follow and thus the said patent is obvious based on trial and error method.

85. The defendant counsel has argued at length and it has also been deposed that US' 534 along with the other specifications establish the substitution of ethynyl and methyl components are usual.

I find that if the evidence to show the selection is arbitrary is not present on record and even it is established on the record that there is a sort of inspiration taken from EP'226, the existence of the said fact, by itself does not denote obviousness. This is due to the reason that it is seen in the deposition of the PW-3 Nick Thatcher and in the other pleadings also stating that there were certain defects in the medicine GEFTINIB and for the said reason the said medicine was not able to cure the patients properly and consequently was not recommended. Therefore, even if it is shown that the starting point of the invention is EP'226 and there are changes made in the chemical structures cited as example compounds in the said patent by reacting the same with ethynyl later on in relation to selected range, I do not find that such selection can be arbitrary, rather it can be inferred that there may be some further experimentations done in future on the Gefitinib compounds which eventually narrowed down the examples cited by the defendant in its submissions, ultimately resulted into the claim No.1 of the patent. All this rather indicates towards purposeful selection rather than arbitrary one.

86. I am inferring this in view of totality of the circumstances, the plaintiffs are engaging into manufacturing of the drugs, their inventors surely are the persons skilled in the field and are aware of quinazoline derivatives and the compounds therein. Of-course, the inventors cannot change the main compound as the said characteristic of curing the cancer emerges from the said very compound which is a quinazoline derivatives.

The plaintiff's inventor being a conscious person is equally aware of the defects in the pre-existing medicine or compound and its inability to cure the disease properly and therefore would select the range from the point from where the last research ended. Therefore, there is no harm so far as taking the compounds from the previous state of the art is concerned unless it is further backed by the evidence that the said selection and the working thereupon is not far removed from the known range, further that the said selection and the working is arbitrary in nature. On the other hand, it indicates that inventor was conscious about the existing state of art. Accordingly, even if the range from EP'226 is selected by the plaintiffs to conduct the further workings upon the same, unless shown contrary, it cannot be said that the said selection to be an arbitrary one.

87. Another reason which persuades me to infer to the contrary in the absence of the evidence is that there is a commercial success of the medicine worldwide which has been widely recognized and the same is proven to be successful medicine. This is clear from the depositions of PW 3 Nick Thatcher. It is true that the said commercial success per se is not determinative of the fact that there is a non obviousness, but it at least somehow acts as an attending circumstance to show that there could have

existed the purposeful research on the existing state of the art by the person who is skilled in the art, who has made certain experiments and by narrowing down the compounds resulting in a single compound which has been widely successful and efficacious.

88. Such inference of non establishment of the arbitrary selection is due to the reason that lack of the evidence in the form depositions of defendant's witnesses showing the existence of the said material fact which is that the said selection of the range is arbitrary. The only thing which is deposed by Mr. Nangia (DW-3) that the inventor Mr. Arnold was common in US' 534 and US 498 and therefore, he was fully aware of the substitution of capability of methyl with that of the ethynyl component. I find that by itself does not explain as to how the said selection of the range from EP'226 is arbitrary. If the inventor is common to US 534 and US 498, that event itself show that the inventor is skilled in the art and is continuously working towards the making of anti cancer drugs, but the same nowhere indicates that his selection may be random or arbitrary.

89. The defendant has not been able to fully discharge the onus of proof of establishing the obviousness due to non establishment of three material facts. After appreciation of the evidence of the competing parties, I find that the defendant has not been able to show as how the selection of the range of the compound was arbitrary as merely contending vociferously without any deposition will not suffice. On the other hand, plaintiffs though have responded to the defendant's case by pointing out number of mistakes on the part of the defendant. The defendant has not pointed out whether the lead compound was example 51 of EP'226 or not.

90. On balance of probabilities, it can be said that the defendant is not able to discharge the onus lied upon him, though the defendant was able to show that there is a selection of range from the compound which is not far removed at least structurally but has failed to established that the role of the said change in the reaction is bare minimal or the said reactants are known to the person skilled in the art. It is also not established on record clinically to show as to how the suit patent compound is not far removed from the selection or example 51 of EP'226 by positive evidence in the form of depositions and I find the structural similarity on the look and perusal is not the decisive of this establishment of the far removed material fact.

91. The said material fact goes into the root of the matter and affects the case of the defendant, consequently must be given the treatment prescribed in the law as per the stages of the suit. To sum up, the bundle of facts or chain of events leading towards inference as to the obviousness of the patent are not clearly established on record as per the evidence of the defendant. The similar is the case with the plaintiffs but the same remains inconsequential as the initial onus by satisfying the three requirements was on the defendant which the defendant failed.

92. Again, it is reiterated that what has been stated in *Biswanath Prasad* (supra) that the inventive step is a mixed question of fact and law and not a pure question of law which means that both the parties should discharge the onus on facts as well as in law, as to how the innovativeness cannot be ascribed to particular invention and corresponding response to dislodge the case.

93. Even if one sees in law whether this kind of inference was correct then it is again worthy to go back to the *Biswanath Prasad* (supra) where the Hon'ble Supreme Court had drawn the inference as to non obviousness on the basis establishment of six discerning facts which are as under :-

“The learned trial Judge, after a careful appraisal of the evidence produced by the parties, found that the following facts have been established:

“(i) The manufacture of utensils is an old industry at Mirzapur and at other places in U.P. and in other parts of India;

(ii) lathe is a well-known mechanism used for spinning and a number of other processes; (iii) adapters were in use for holding turnably, articles (7) of suitable sizes, for holding plates and dishes, also, were in use before 1951;

(iv) the tailstock was probably used in this industry before 1951;

(v) no bracket or angle, as used in the defendant's machine (Ex. CC) appears to have been used in this industry before 1951;

(vi) work on plates and dishes was suspended at Mirzapur for a few years before 1951.”

94. The learned trial judge in the said case of *Biswanath* (supra) exactly criticized the evidence of inventor by saying that they have not shown as to what was going through the mind of inventor at the time of working upon the invention and also how many experiments were carried out. Para 48 of the said judgment of Hon'ble Supreme Court recording the trial Court findings is reproduced below:-

“48. The learned trial Judge then noted that Purshottam, who was stated to be the inventor, and, as such, was the

best person to describe the invention, did not appear in the witness-box, though, as admitted by Sotam Singh (D.W. 3), Purshottam had attended on some dates of hearing. Sotam Singh tried to explain Purshottam's disappearance from the Court without appearing in the witness-box, by saying that he had gone away due to illness. The learned Judge found this explanation unsatisfactory and rejected it- and in our opinion rightly-with the remark that recording of evidence lasted for several days and it was not difficult to secure Purshottam's attendance. Apart from being the best informed person about the matter in issue, Purshottam was not a stranger. He was a partner of the patentee firm and a brother of Sotam Singh (D.W. 3). He was the best informed person who might have answered the charge of lack of novelty levelled by the opponent side, by explaining what was the novelty of the alleged invention and how and after, what research, if any, he made this alleged 'discovery'. Being a partner of the respondent-firm and personally knowing all the circumstances of the case, it was his duty as well as of the respondent-firm, to examine him as a witness so that the story of the particular invention being a new manufacture or improvement involving novelty, could, in all its aspects, be subjected to cross-examination. By keeping Purshottam away from the witness-box, the respondent-firm, therefore, took the heavy risk of the trial Court accepting the charge of lack of novelty made by the appellant herein.”

95. Thereafter, the Hon'ble Supreme Court affirmed the finding of the learned trial judge by observing that they do not find any piece of evidence as misread and overlooked or omitted from the consideration and view expressed by the trial judge as **reasonable and entitled to be given due weight** and proceeded to set aside the order of Division Bench which interfered at that time the order of trial judge.

96. A careful analysis of *Biswanath (supra)* would reveal that in similar circumstances also the evidence of patentee was criticized as to the reason that no positive evidence was given to dislodge the claim of lack of novelty, inventive step and obviousness. The same has attained judicial stamping of Hon'ble Supreme Court by observing it as weighty and reasonable approach. Applying the same to the instant case which is based on the same facts, it is equally reasonable in law to draw such inference as to the non obviousness when the defendant has not been able to discharge the onus by showing the material facts leading to inference of obviousness.

97. The only difference in the present case with that of *Bishwanath Prasad* case (*supra*) is that on facts in *Bishwanath (supra)*, the defendant therein was able to discharge the onus by proving the material facts leading towards obviousness which has been seen above in six points noted above in the judgment of Supreme Court, and the patentee was not able to dislodge the same. On the contrary, in the present case, the defendant has attempted to move forward towards the direction of proving the said facts, however, not able to establish on record as to how the said substitution of ethynyl with the methyl was obvious on the date of priority of the US' 498 which 30.3.1995, how the selected range is not far removed from the known compound, also that how the said selection of compound range is not purposeful and merely arbitrary. The plaintiffs evidence in response is equally weak and therefore, the same can be criticized on the same count by not establishing the material facts as to how the substitution of ethynyl with methyl is innovative and steps towards the arriving of the invention by providing who conducted such experiment, and how many and during what period.

98. Accordingly, I reject all the submissions of the defendant on this issue including the argument that the defendant has not shown what motivated the plaintiffs to take example 51 as prior art, all other motivation submissions without prejudice ones, the submission relating to replacement of ethyl from methyl component, secondary consideration as to assuming obviousness.

99. I do not agree with submissions of the defendant that the mere fact that there were commonality in the wordings of the specification of EP'226 with that of US 498, there can be any inference which can be drawn as to non obviousness as that the specification is copied from EP'226. It needs to be emphasized that the chemical research requires lots of experimentation on the existing compounds. Therefore, the background of the inventions arising out of the same molecule or compound may be same, may have similar properties which may be expressed in the limited ways, therefore the reading of the same may look similar in grammatically. But that does not testify the fact that chemical compounds are the same nor the structural similarities are decisive factor. The structural similarities may be one of the indicators that the said invention or compound is derived from particular compound or set of the compounds, but may not be sole criteria as per settled law. Unless the other factors like selection of range, arbitrary nature of selection, are established.

100. The defendant has sought to rely upon 5 patent documents namely EP 477700, US 4138590, US 4138590, US 5427766, US 5736734, WO 193004047 (DW 3/2 to 3/6) which are the documents filed along with the replication on 31st March 2009 to show that the use of the ethynyl, methyl or phenyl is as product substituent is not alien to chemical science and

therefore, the said change if any done by the plaintiffs in EP' 226 would make the invention as workshop result. I do not find agreement with the submission of the learned counsel for the defendant and also the depositions made by DW 3 in this respect. My reason of rejecting such submissions can be enumerated as under:

- Firstly the said documents are filed with this Court after framing of issues which were framed on 18th September, 2008. In fact, replication along with documents DW-3/2 to DW3/6 was filed after producing the complete evidence of the plaintiffs. No leave of the Court is sought to bring these documents on record. Order 8 rule 1 A of the code of civil procedure provides as amended in the year 2002 mandates that the documents are to be filed along with the written statement. There is another provision under the code which is order 13 rule 1 which also provides for the production of the original documents. The said provisions read as under:

“Order VIII

[1A. Duty of defendant to produce documents upon which relief is claimed or relied upon by him

(1) Where the defendant bases his defence upon a document or relies upon any document in his possession or power, in support of his defence or claim for set off or counter claim, he shall enter such document in a list, and shall produce it in Court when the written statement is presented by him and shall, at the same time, deliver the document and a copy thereof, to be filed with the written statement.

(2) Where any such document is not in possession or power of the defendant, he shall, wherever possible, state in whose possession or power it is.

(3) A document which ought to be produced in Court by the defendant under this rule, but, is not so produced shall not,

without the leave of the Court, be received in evidence on his behalf at the hearing of the suit.].

(4) Nothing in this rule shall apply to documents—

(a) produced for the cross-examination of the plaintiff's witnesses, or

(b) handed over to a witness merely to refresh his memory.]

Order XIII

[1. Original documents to be produced at or before the settlement of issues

(1) The parties or their pleader shall produce, on or before the settlement of issues, all the documentary evidence of in original where the copies thereof have been filed along with plaint or written statement.

(2) The Court shall receive the documents so produced

Provided that they are accompanied by an accurate list thereof prepared in such form as the High Court directs.

(3) Nothing in sub-rule (1) shall apply to documents,-

(a) produced for the cross-examination of the witnesses of the other party, or

(b) handed over to a witness merely to refresh his memory.]

101. On the plain reading of order 8 rule 1 A (3), it is manifest that there is legislative command engrafted in the said provision which is not to receive the documents in evidence which ought to have been filed and produced by the defendant under this but has not been produced. The Court's discretion to receive such document is conditional of the fact of defendant seeking to leave from the Court to produce the said document on the record. The said leave is thus a jurisdictional fact which enables the Court to exercise such discretion as to the reception of the document in evidence which has not been produced in the manner prescribed under Order 8 Rule 1A. The said

provision has been added after amendment which unequivocally speaks of the said legislative mandate emerging therefrom.

102. The said provision of sub rule added in order 8 rule 1A is in pari materia with the similar amendment effected in the order 7 rule 14 wherein the similar sub rule 3 has been added by way of amendment and therefore can be given the same interpretation as give to the corresponding sub rule 3 of order 7 rule 14. The said provision has come up for interpretation before Courts from time to time. Recently, learned single judge of this Court (Hon'ble Badar Durrez Ahmed, J.) in the case of *Gold Rock World Trade Ltd. vs. Veejay Lakshmi Engineering Works*, (2008) 149 PLR 40, has interpreted the sub-rule 3 of Order 7 Rule 14 and arrived at the same conclusion by observing the following:

“Plain reading of Order 7 Rule 14 (3) makes it clear that a document which ought to be produced in Court by the plaintiff when the plaint is presented, or to be entered in the list to be added or annexed to the plaint but is not produced or entered accordingly, shall not, without the leave of the Court, be received in evidence on his behalf at the hearing of the suit. The learned Counsel for the plaintiff submits that leave of the Court ought to be granted to the plaintiff for producing the additional documents referred to in the application under Order 7 Rule 14 and as also for calling the witness for producing the documents mentioned in the other application. The learned Counsel for the plaintiff referred to the decision of the Supreme Court in the case of Salem Advocate Bar Association, Tamil Nadu v. Union of India . With reference to paragraph 13 thereof, the learned Counsel submitted that the Court may permit leading of such evidence even at a later stage subject to any terms that may be imposed upon by the Court which may be just and proper.

4. I have heard counsel for the parties. The Supreme Court decision in Salem Advocate Bar Association (supra) was in the context of additional evidence. By virtue of the 1976 amendment, Rule 17-A had been introduced in Order 18. The said Rule 17-A granted discretion to the Court to permit production of evidence not previously known or which could not be produced despite due diligence. Rule 17-A of Order 18 was deleted by the Code of Civil Procedure (Amendment) Act, 1999 which took effect on 1.7.2002. While considering the effect of this deletion the Supreme Court observed:

13. In Salem Advocate Bar Assn. v. Union of India , it has been clarified that on deletion of Order 18 Rule 17-A which provided for leading of additional evidence, the law existing before the introduction of the amendment i.e. 1-7-2002, would stand restored. The Rule was deleted by Amendment Act of 2002. Even before insertion of Order 18 Rule 17-A, the court had inbuilt power to permit parties to produce evidence not known to them earlier or which could not be produced in spite of due diligence. Order 18 Rule 17-A did not create any new right but only clarified the position. Therefore, deletion of Order 18 Rule 17-A does not disentitle production of evidence at a later stage. On a party satisfying the court that after exercise of due diligence that evidence was not within his knowledge or could not be produced at the time the party was leading evidence, the court may permit leading of such evidence at a later stage on such terms as may appear to be just.

Thus, the Supreme Court held that the insertion of Rule 17-A was only clarificatory of the in-built power of the Court to permit parties to produce evidence not known to them earlier or which could not be produced in spite of due diligence. The learned Counsel for the plaintiff sought to invoke this in- built power of the court even in respect of Order 7 Rule 14(3) which relates to production of documents at a belated stage. There would be no difficulty in holding that the in-built power referred to in the said

Supreme Court decision could also be invoked when the question of granting leave arises in the context of Rule 14(3) of Order 7. **Consequently, before leave of the Court can be granted for receiving documents in evidence at a belated stage, the party seeking to produce the documents must satisfy the Court that the said documents were earlier not within the party's knowledge or could not be produced at the appropriate time in spite of due diligence.** It has been submitted by the learned Counsel for the defendant that the documents pertain to a settlement between the plaintiff and a foreign party (COGETEX). The settlement was arrived at, as per the statement recorded in the cross-examination of PW1, on 7.10.1996. However, there is not a whisper of this statement even in the replication which was filed on 11.9.1997. In fact, the affidavit by way of evidence was filed by the plaintiff in the year 2003 and even in that affidavit, there is no reference to the documents which are now sought to be introduced. **In my view, these circumstances clearly show that the conditions necessary before leave of the Court can be granted have not been satisfied. It cannot be said that the plaintiff was not aware of the documents earlier, or that the same could not be produced in spite of due diligence on the part of the plaintiff. All the material now sought to be introduced, was well within the knowledge of the plaintiff at least in the year 2003. As the plaintiff was not diligent enough at that point of time, this Court is left with no alternative but to reject its request.”(Emphasis Supplied)**

103. I find that the similar situation has arisen in the present case. Till the final arguments were addressed in this matter, the defendant had never made this attempt to bring the said documents on record. No application for seeking a permission of this Court has been preferred which enables the Court to exercise such discretion vested in the Court. The plaintiffs have strongly objected to taking these documents on record and its admissibility

at the time of recording of the evidence of DW3 Mr. Nangia and the said objection has been categorically recorded by the learned LC Mr. S.M. Chopra leaving it to this Court to decide. In the absence of any leave sought from the Court which leaves no room for the Court to exercise any such discretion, I upheld the objection raised by the learned counsel for the plaintiffs as no steps have been taken by the defendant to cure such objection till date by seeking a permission of this Court. Therefore, the question of taking the documents on record at such belated stage after the commencement of trial does not arise unless the leave of the Court is sought in the prescribed manner providing the sufficient reasons for non-filing at the earlier stage. In fact these documents were filed along with replication in counter-claim filed by the defendant and after production of evidence of plaintiffs. In case, these documents are taken on record, I am of the considered view that a great injustice would be done to the plaintiffs as no chance of rebuttal at present would be available.

104. Even if the said documents in the form of 5 patents are looked into for my satisfaction and conscious, it is seen that EP 700 relates to antiviral agents where there has been use of methyl and ethynyl in relation to reactions. I think the said argument is misconceived and based on lack of understanding in chemistry. Everybody knows this fact that methyl, ethynyl and phenyl also belongs to alkyl group and no one can deny this fact and the same can be reacted interchangeably. The defendant is showing 5 patents to show the same, I would say there may exist numerous of them where there experimentations are done on the basis of the methyl, phenyl, ethynyl from time to time to see the efficacy in relation to different fields of chemical compounds and process. But that by itself does not really answer the

question, the question is that why there would be an arbitrary adoption of example 51 and why the said plaintiff would apply and react the ethynyl only by replacing the methyl at the third position, when the as per the plaintiffs version which is not disputed by the defendant EP'226 teaches to keep the methyl component stable and not variable. The said patents cited relating to different fields of derivative compounds containing reaction with ethynyl or methyl are thus irrelevant for the purposes of adjudging the obviousness of the present suit compound which quinazoline derivative.

- The only patent out of 5 ones is US 534 which relates to Quinazoline derivatives invented by Mr. Arnold who is common inventor of the present patent and the said application was filed as PCT application on January 27, 1995 and thereafter the patent which the defendant is relying upon was filed in US in the year 1996. To this, the response of the plaintiffs is that the said application as PCT was published on August 31, 1995 and prior to the same, the same cannot be treated as prior art to the plaintiffs patent US 498, the priority date of which is March 30, 1995, I agree with the submission of the plaintiffs. The prior art in the form of prior patent can be said to be pre published document only when the said patent gets published prior to the priority date of the application filed before the patent office. Therefore, till the time, the PCT version of US 534 was not published on August 31, 1995, the US 498 filed on March 30, 1995 as a priority date cannot be anticipated by way of the said PCT application.
- Further, the said invention provides again some references to methyl, ethynyl at 6 and 7 position and the said compound was structure wise

is totally different though it has common quinazole core. Accordingly, the mere presence of methyl and ethynyl reactions at the different place would not make the patent obvious. If the defendant's argument is to be believed that the methyl and ethynyl reactions are so common and was present in EP 534, then it is noteworthy to mention that EP'226 is mentioned as prior art even in US 534, If it was so obvious to the person skilled in the art, then why the inventor who is Mr. Arnold and the owner of US 534 which is Pfizer, who was also the stakeholder in US 498 and IN'774 in the instant case earlier with the plaintiff No. 2 herein had to wait to apply for US 498 for months together, then the same very patentee as the defendant states that he was aware of methyl and Ethynyl substitution could have easily arrived this successful compound even prior to arriving at US 534 but in fact it is not so in the instant case. What follows from the same is that it is not so easy to assume that the mere fact that there is ethynyl or methyl reactions are known and therefore the result is the suit patent compound unless it is backed by positive evidence which is missing in the instant case.

- Mr. Nangia DW 3 deposes that US 534 provides a vital information as to substitution capacity of ethynyl and methyl component, I think the same again is not positive evidence to show as to how US 534 teaches where to apply to ethyl and methyl component in to which of structures or range of compounds and at which position, the deposition is therefore as good as saying that the mere fact ethynyl and methyl components are used, the reasonable person skilled in art would arrive at the suit compound, I have already answered above

about the mere existence of ethynyl and methyl as reactant unless their role as reactants are defined is inconsequential to infer obviousness.

- Mr. Nangia (DW3) also deposes that Mr. Arnold as a common inventor was fully aware of the interchangeability of methyl and ethynyl amongst other at the c phenyl ring appended to the 4-hetrocycle position of quinazoline and on the basis of such knowledge, it would have been obvious for him to try a similar interchangeability in N- phenyl quinazolines, I again find that the said deposition is based on speculation and not on cogent medical reasoning, as the US 534 nowhere teaches as to which of the compound of quinazoline derivatives like example 51 in EP'226, the said interchangeability is to be effected nor does the said patent talks about phenyl quinazolines which is relating to the suit patent, further the position or the place of the reaction is also not made obvious. Therefore, the said depositions made are again based on one premise which is that the reactant methyl and ethylene interchangeability which per se is inconsequential.
- The order of controller of the patents dated 27.6.2007 in respect to pre-grant opposition to IN 77 wherein the said opposition was filed by Natco Pharmaceuticals also analyses on similar count the prior arts containing some relevance pertaining the substitution of methyl with that of ethynyl component. Similar are the prior art documents DW 3/2 to 3/6 relied by the defendant now in order to enable this Court to infer such obviousness. I reject the same in view of finding the concurrence with the findings of the Controller that the said

document does not reveal as to how the applicant for the patent learnt about the said reactions, where to react, why not to react with phenyl and at what position. Therefore, the similar prior arts are rejected. So far as the emphasized prior art US 534 is concerned, my answers in specific are recorded above.

In view of the same, I find that the documents which are marked as DW 3/2 to 3/6 are not relevant for the purposes of showing the obviousness of the suit patent compound on the basis of EP'226. And these cannot be considered otherwise an opportunity has to be given to the plaintiffs to rebut the same in evidence and a great injustice and prejudice would be caused if the same are taken on record.

105. There is a related argument raised relating to technique of Bioisosteres which as per the defendant is *groups* or *substituents* having similar chemical or physical properties that impart similar biological properties to a chemical compound. As per the defendant, the suit patent could have been arrived at by using the said technique and therefore the suit patent is obvious. The said argument in other words means the substitution of ethynyl with that of methyl being a component of the same group which can make the suit patent obvious by knowing about the said concept. My answers to this would be the same as recorded in preceding paragraphs relating to the prior arts containing some hint towards the substitution of ethynyl with that of methyl or vice versa. The question is not merely substitution which may be one step towards obviousness but there should something more to indicate as to how the skilled person in the art would be persuaded to apply the said component with the compound and what position. The evidence relating to the same is

still missing from the defendant's end which does not indicate that it is merely an arbitrary selection and not purposefully.

106. So far the decision of District Court of Delaware in the case of *OSI Pharmaceuticals LLC & Ors. v. Mylan Pharmaceuticals* is concerned where there is some finding that the US equivalent of the suit patent is not obvious, I find the same is not relevant as after the due consideration of the entire evidence lead by the parties on record in the present case, the inference as to lack of inventive step has been drawn due to the plaintiffs have not been able to set up a positive case so as to ascribe inventive step to the suit patent. In view of the same, even if the said judgment is considered which is of District Court of foreign jurisdiction having merely persuasive value may not be able to influence the final conclusion reached by this Court on weighting the evidence of parties in the present case, thus the same is not applicable to the present case.

107. Various English decisions were referred to by both parties as discussed earlier in detail the jurisprudential difference existing in the tests adopted by the Courts in India with that of Courts in US. Thus, due to operation of the said doctrinal tests like motivation, suggestion and teaching and others existing in US which gives a kind of presumption of validity to the patent but similar position does not happen to the Indian jurisdiction where the patent is always vulnerable to challenge unless displaced by positive evidence. The details of several decisions referred by the plaintiffs in support of the arguments of motivation, suggestion and teaching tests are given as under:

- a. *Technograph v. Mills & Rockley*, 1972 RPC 346 at Pg. 355 (35)

- b. *Takeda v. Alphapharm*, No. 2006-1329 (*Fed. Cir.* 2007) at pages 10, 11, 17-18, 21 [reported as 492 F.3d 1350]
- c. *Daiichi v. Mylan*, 670 F. Supp.2d 359 at pages 14-15
- d. *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, Nos. 2005-1396, -1429, -1430 (*Fed. Cir.* 2006), at pages 9 [reported as 471 F.3d 1369]
- e. *Star Scientific v. RJ Reynolds*, No. 2010-1183 (*Fed. Cir.* 2011) at Pg 17, 19-20 [reported as 537 F.3d 1357]
- f. *Apotex v. Sanofi*, 2008 SCC 61 at paras 79, 87, 90 and 92. *Eisai Co. v. Dr. Reddy's Laboratories*, 2007-1397, -1398 (*Fed. Cir.* 2008) at pages 8, 9 [reported as 533 F.3d 1353].
- g. *Genetics Institute v. Novartis Vaccines and Diagnostics*, 2010-1264 (*Fed. Cir.* 2011) at pages 22-23, 25-26, 28- 29, 34-35 [reported as 655 F3d 1291]
- h. *Sabaf v. Meneghetti*, 2003 RPC 14 para 43
- i. *Generics UK v. Daiichi*, 2009 RPC 23 at para 22, 23 – Will not pursue every avenue relentlessly if there is only the mildest motive for doing so; must be obvious to try.

108. I may however notice that the said test of motivation, suggestion and teaching seems to be one of the facets of the theory of the person skilled in the art. However, its application of the same by the US Courts and sometimes in EU in the distinct circumstances is such cases somehow leads to the conclusion that challenge to the patents in the pharmaceuticals are tested on the stricter tests and dismissed unless the said tests are qualified by the person setting up challenge. Rather, I am of the view that the tests laid down Supreme Court in *Bishwanath Prasad* (supra) relating ordinary obviousness relating to Patents which have also been applied by the Courts in England in the case of Court of Appeal in *Dr. Reddy* (supra). Therefore,

the decisions referred to by both sides delivered by District Court whatsoever value they hold do not persuade me to change my decision.

109. The defendant has cited several decisions in order to support the arguments of test for obviousness and structural similarities:

Test for Obviousness:

- KSR International Co. v Teleflex Inc., 550 U.S. 398 (2007)
- Altana Pharma AG v Teva Pharmaceuticals USA Ltd., 566 F.3d 999 (2009)
- Application of Gerald McLaughlin, 443 F.2d 1392 (1982)
- Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd. [1985] R.P.C 59
- Actavis v Novartis [2010] FSR 18
- Glaverbel SA vs. Dave Rose & Ors MIPR 2010 (2) 0046

Structural Similarities:

- In re Petering and Fall; 133 USPQ 276
- In re Dilon; 16 USPQ 2d 1897
- In re Merck; 800 F. 2d 1091
- Richard Ruiz v A. B. Chance Co., 69 USPQ.2d 1686

Likewise, the plaintiffs have also relied upon the following decisions relating to success rate or efficacy may be considered to be secondary consideration to the obviousness and other legal aspects:

Case laws on secondary considerations:

- i. *Technograph v. Mills & Rockley*, 1972 RPC 346 at Pg 360 (line 30)
- ii. *General Tire & Rubber Company v. Firestone*, 1972 RPC 457 at p. 506 (line 26-27).
- iii. *Star Scientific v. RJ Reynolds*, 537 F.3d 1357 at p. 18, 20
- iv. *Eli Lilly v. Zenith*, 471 F.3d 1369 at pages 14-15
- v. *Genetics Instt v. Novartis*, 655 F3d 1291 at p. 30

- vi. *Eisai v. Dr. Reddy's*, 533 F.3d 1353 at p. 2
- vii. *Apotex v. Sanofi*,

Inventive Step and Obviousness

- i. *FH&B v. Unichem*, AIR 1969 Bom 255 at para 13
- ii. *Takeda v. Alphapharm*, No. 2006-1329 (*Fed. Cir.* 2007)at p. 6 [reported as 492 F.3d 1350]

Because a patent is presumed to be valid, 35 U.S.C. § 282, the evidentiary burden to show facts supporting a conclusion of invalidity, which rests on the accused infringer, is one of clear and convincing evidence.

- iii. *General Tire & Rubber Company v. Firestone*, 1972 RPC 457 at p. 480 (line 15).

Line 15: “It was common ground that when the validity of a patent is attacked under the relevant provisions of Section 32(1) of the 1949 Act, the onus of proof lies, as regards each allegation, on the party launching attack.

Who is a Person skilled in the Art?

- i. *General Tire & Rubber Company v. Firestone*, 1972 RPC 457 at p. 498 (lines 15-27) – Obviousness adjudged by the person of ordinary skills in the art and not the inventor (or his rival).

Hindsight is impermissible in an obviousness enquiry.

- i. *FH&B v. Unichem*, AIR 1969 Bom 255 at Para 16
- ii. *Technograph v. Mills & Rockley*, 1972 RPC 346 at pages 353 (line 40), 362 (line 35).
- iii. *General Tire & Rubber Company v. Firestone*, 1972 RPC 457 at p. 505 (line 35).

- iv. *Sabaf v. Menenghetti*, 2003 RPC 14 at p. 279-280 (Para 43,44) – Dangers of hindsight are notorious;
- v. *Daiichi Sankyo v. Matrix Laboratories & Ors.*, 2009-1511 (*Fed. Cir. 2010*) at pages 14, 15, 18 [reported as 670 *F. Supp.2d* 359]

Structural Similarity:

- a. *Takeda v. Alphapharm*, No. 2006-1329 (*Fed. Cir. 2007*) at p. 9, 19 [reported as 492 *F.3d* 1350]– Generalization should be avoided insofar as specific chemical structures are alleged to be prima facie obvious one from the other
- b. *Eisai Co. v. Dr. Reddy's Laboratories*, 2007-1397, -1398 (*Fed. Cir. 2008*) at p. 4 [reported as 533 *F.3d* 1353].
- c. *Daiichi Sankyo v. Matrix Laboratories & Ors.*, 2009-1511 (*Fed. Cir. 2010*) a at p. 11 [reported as 670 *F. Supp.2d* 359]
- d. *Genetics Institute v. Novartis Vaccines and Diagnostics*, 2010-1264 (*Fed. Cir. 2011*) at p. 22 [reported as 655 *F3d* 1291]

Mosaicing-

- a. *General Tire & Rubber Company v. Firestone*, 1972 RPC 457 at p. 505 (line 35) – When assessing whether a person of ordinary skills in the art would look at unrelated pieces of prior art to arrive at the patented solution, “(I)t is very dangerous and in law not permissible to assess obviousness in the light of carefully selected pieces of prior knowledge only.”
- b. *Technograph v. Mills & Rockley*, 1972 RPC 346 at Pg 355 (line 5), 356 (line 5)
- c. *Sabaf v. Menenghetti*, 2003 RPC 14 at Pg 279 (43).

110. I may notice lastly that the finding arrived at as to non-establishment of obviousness is due to the lack of evidence and deposition in the present case wherein the defendant is not able to show by way of positive evidence three requirements as to material facts leading up to obviousness in the chemical compounds. If the chemical compounds are held to be obvious on the basis of mere perusal and appearance of the structures and assuming that

the slight change here and there is inconsequential without a positive evidence medically and clinically as to how the said reaction is immaterial, then several novel compounds can be declared obvious by such exercise and the same shall affect the research process adversely. The innovation or invention in the sense of chemical compound is not merely to innovate a new set of the compound per se but also making improvements in the existing state of the art by taking the aid of the already existing compound and working upon the same by way of experimentation by way of the reactants. This is the reason why, the Court cannot simply be satisfied by mere reliance of similar structure in the previous art and thereafter assuming that slight substitutions are inconsequential. Therefore, the establishment of the material facts is essential, which is missing in the present case. Resultantly, no ground of obviousness or lack of inventive step under Section 64 (1) (f) of the Patents Act is made out due to the inability of the defendant to discharge the onus casted upon it.

Re: Patent violating Section 3(d) of Patents Act 1970 (as amended in 2005)

111. Now, I shall be proceeding to discuss the challenge which has been set up the defendant in relation to Section 3(d) of Patents Act.

112. The defendant has raised in the counter claim a ground that the suit patent violates Section 3(d) of the Patents Act by urging that the patent applied by the plaintiffs is another form of the EP' 226 and therefore is an attempt by the inventors like the plaintiffs to renew the patent of the invention which has already pre existing in the art. Learned counsel for the defendant in order to set up the said challenge has explained the concept of

the evergreening as well as the provisions of Section 3(d) by making the submissions in the following manner:

113. It is submitted that prior to the introduction of Product Patents in India, the country could derive and consider the vast experiences of global markets where Product Patents have been granted with respect to medicines/drugs. The experience of other countries revealed that there was a practice in the pharmaceutical industry to increase the term of patents for medicines and pharmaceutical substances by claiming different forms of the same substance as being patentable inventions. This can be illustrated with the following examples:-

- It is submitted that the term of a patent is 20 years. Unlike in other countries, India does not have patent term of extension. [In USA, patent term extensions can be granted under some circumstances].
- In India if a new drug is invented in the year 2000 and applied for a patent, the term of the patent irrespective of whenever it is granted comes to an end in 2020. However, this term of 20 years is sought to be extended by pharmaceutical companies by applying for different “forms” of the same molecule.
- This concept of increasing the term of the patent by claiming different form of known substance as inventions is known as Evergreening.
- For e.g.: EP’226 which was applied for by Astrazeneca UK Limited was the main patent with respect to Quinazoline derivatives. This patent disclosed a large number of molecules encompassed in a Markush formula which could be effective in treating different forms

of cancer. One patent which was filed, originating from EP'226 was for the drug GEFITINIB. When GEFITINIB was applied for in India, the same was rejected by the Patent office with the following observations.

- The EP'226 was published on 20th October, 1993. The Gefitinib patent which is a selection patent from EP'226 had a priority date 27th April, 1995, it was filed in India on 23rd April, 1996. The Defendant has referred to EP226 as GEFITINIB patent only for the purpose of convenience of arguments in pleadings.
- Pre-grant opposition was filed by NATCO and G.M. Pharma Ltd. and the ground of anticipation and obviousness were raised. i.e. **Exhibit DW1/7** (NATCO order) is recorded as below;

“Opponent further argued that the applicant is merely attempting to claim prior art in the guise of selection patent and referred to a cited decision T-0124/87 of European technical board of appeal.”

In the Gefinitib patent the invention was claimed in the 7 metha positions in the Quinazoline molecule and R2 was shown as 3' 4 diholo substituents. The applicant had also provided reference to various foreign patents granted for the Gefinitib for the specific molecule claimed in this patent and even the comparative test data was provided.

The Controller held as follows:

“On the basis of the arguments and evidence given by both parties I am of the opinion that the basic skeleton of the prior art compound and the present invention are same. The prior art also teaches chloro fluoro substituent in the aniline attached to the 4th position of the quinozoline

molecule and a methoxy group at the 7th position of the quinoxaline. But I find that none of the compound disclosed in the prior art is identical to the compound disclosed or claimed in the proposed claim-1 in the present application with respect to the 3, 4 and 7th position of the quinoxaline molecule. The prior art does not teach exclusively the claimed compound. Therefore the said selected compound of the present invention is novel over the prior art.”

“Regarding closest prior art issue I find that in the present application following substitution has been claimed.

- (a) 3' & 4' position; could be chloro or fluoro
- (b) 7th position of quinoxaline ring; Methoxy and
- (c) “...position of the quinoxaline ring; a basic group.”

“Following the above basis, I find that the compound of Table 3 within example 34 comes structurally closure to the claimed compounds than any of the compounds of example 26, 41 and 64 of the prior art in disclosing the same 3' 4' substituent and 7 – methoxy substituent. Therefore compound 5 within example 34 is the closest prior art compound, which would require minimum structural modification in order to reach the compound claimed in the present invention.

The requirement for a comparison with the closest prior art is based on the principle of the structural dependence of the properties of the substance i.e. on the fact that these properties reflect the structure of the substances.

Therefore it is very difficult to accept the applicant's claim of 16 fold potency of the compound of the present invention against the compound disclosed in the prior art because the comparison provided is not against the closest prior art.”

“I do not agree with the contention of the applicant that “the compound 5 of the example 34 of the prior art EP/0566226

was not considered for comparative test data as the same compound did not contain a basic group”. The technical advancement could only be demonstrated by looking forward from the prior art to the claimed invention and not the other way around. The proper approach to demonstrate the inventive step is to move forward from the prior art i.e. the comparative test data should have been provided vis-à-vis the structurally closest compound of the prior art which in my opinion is the compound 5 of example 34 of EP/0566226, because this compound of the prior art differ from the claimed compound only in the presence of the basic group, which the applicant admitted, play an important role in the activity of the claimed compound.”

“I agree with the opponent’s contention that for the demonstration of ‘technical advancement’ must be shown to have been achieved by a claimed invention vis-à-vis the prior art by way of demonstrating the presence of an unexpected effect over the closest prior art. Any comparative test data provided against said compound 5 of example 34 could have highlighted the criticality of the ‘basic group’ in achieving an enhanced activity, which could have formed the basis for the invention. Therefore, I have no doubt that the applicant has failed to provide comparative test data vis-à-vis the structurally closed compound of the prior art.”

The Controller of Patents thereafter further, holds as follows:

“Regarding patent ability under Section 3(d), I find that the test data provided by the applicant does not substantiate the applicant’s claim or significant enhanced potency residing in the selection of a basic group at 6-position of the quinazoline ring. The applicant has attempted to claim enhanced efficacy by demonstrating that the compounds of the claimed invention possess 4 to 16 fold potency compared to the compounds of the prior art. Based on my findings under the ground of obviousness and lack of inventive step wherein I concluded that the claim of the

applicant that the compounds of the present invention are 4 to 16 times more potent than the prior art compounds, are not persuasive, I conclude that all the compounds claimed in the present invention do not significantly differ in efficacy compared to the prior art which is the explicit requirement under Section 3(d) and therefore is not patentable under Section 3(d) of the Patent Act.”

For conclusion the Controller holds as follows:

“In view of my findings in the preceding paragraphs, I conclude that the present invention as claimed in revised claim 1 to 12 of the application number 841/DEL/1996 is;

- (a) Novel over the prior art disclosure of EP 0566226
- (b) Obvious and does not involve an inventive step over the prior art EP 0566226;
- (c) Not an invention within the meaning of Section 2(1)(j) of the Patent Act 1970;
- (d) Is not patentable invention within the meaning of Section 3(d) of the Patents (Amendment) Act.”

The said order was not challenged by the Natco/opponent and ultimately suit patent was granted to the plaintiffs.

114. The defendant, by placing reliance of the decision in the opposition proceedings relating to the IN’507 (which is a fresh application made by the plaintiffs for registration of patent of Polymorph-B version and the same was rejected by the controller of patent) which is an order of controller dated 15.12.2008 where there is a finding as to evergreening or violation of Section 3(d) of the Patents Act; and the structural similarities existing between the plaintiffs suit Patent IN’774 as well as the EP’226 more so when both are derivatives of Quinazoline and all other contentions recorded above, has urged this Court should consider the challenge and proceed to

hold that the suit patent violates the provisions of Section 3(d) of the Patents Act.

115. Per contra, the plaintiffs while defending the counter claim for revocation have given several reasons as to why this Court should not infer any such violation of Section 3(d) by contending the following:

- a) “The defendant has alleged that the Erlotinib compound that has been patented by the Plaintiffs is allegedly a ‘derivative’ of “Quinazoline” which is “known” for its anti-cancer activity and hence, since no new property or enhanced efficacy has been shown by the suit patent over the known substance, the same is not patentable under Section 3(d) of the Indian Patent Act. (*paragraphs 16-18 of the Written Statement; paragraph 3.5-3.10 of the Counter Claim*).
- b) *In this regard, it is pertinent to note that the Defendant has not led any evidence to prove this averment.* However, in any event, the averment of the Defendant is completely fallacious and does not merit any consideration in light of the following:
 - i. It is submitted that "Quinazoline Derivatives" refer to a very wide range/class/family of compounds having a common Quinazoline ring, and the patented Erlotinib compound is just one specific compound of this family. It has further been admitted by the Defendant’s expert witness that the Erlotinib compound was not known as a drug or a compound in the year 1995 from which is the date that the patent claims priority.
 - ii. Furthermore, it is pertinent to note that Quinazoline Derivatives have diverse uses that are not targeted to anti-cancer activity or

even limited to pharmaceutical uses. Quinazoline Derivatives are also used as dyes, etc. Therefore, merely to infer from the term 'Quinazoline Derivatives' that a newly invented compound is a 'derivative' and hence have similar activity, obvious/non-inventive/non-novel, would be illogical.

- iii. Lastly, it is submitted that the Defendant's averment that no efficacy data has been provided is completely erroneous. It is submitted that the suit patent has specifically mentioned IC₅₀ values for the patented compounds."

116. The plaintiffs have also filed the evidence by way of affidavit of Mr. Thatcher PW3 in order to substantiate that there exist some kind of efficacy which has been deposed by the witness in his affidavit in the form of reference to the clinical trial and other aspects of efficacy. The said efficacy is deposed in the form of clinical trials conducted by the plaintiffs. This aspect of efficacy involved in the suit patent is deposed in the affidavit in order to show that even if the said derivative Ertolinib is found to be one of the forms of the EP'226 patent, still the same being an efficacious cannot be presumed to be same substance by virtue of explanation appended to Section 3(d).

117. I have considered the records of the proceedings in the present case in relation to the challenge under Section 3(d) of the Patents Act. The onus was again on the defendant at the first place to show as to how the plaintiff's compound of Ertonolib Hydrochloride is a new form of known substance. The defendant has set up a challenge on the ground of violation of Section 3(d) in paragraph 3.5 and the said challenge runs upto 3.10 of the counter claim. Likewise in paragraph 17 to 19 of the written statement, there

is a reference of Section 3(d) as ground of invalidity of the patent. The said ground is taken by contending the following in particular:

1. The alleged patent for Erlotib is liable to be revoked as being a Quinazoline Derivative. The said derivative of the known compound is thus not patentable. There are at least three patents which date back since 1993 which disclose Quinazoline Derivative.
2. The defendant again provided similar averment in the counter claim that the suit patent is derivatives of the prior arts compounds.
3. There is an aspect of lack of efficacy which is also mentioned in the paragraph 3.5 to 3.7 of the counter claim in order to contend that provisions of Section 3(d) are attracted.

118. In order to discharge the said onus, the defendant has relied upon the documents showing the compounds in EP'226 patent and also read the observations of the Controller of Patents in this respect while finding that IN'507 is hit by Section 3(d). The DWs.1, 2 & 3, Mr. Gopalakrishnan, Ms. Shashirekha and Mr. Ashwin Nangia do not depose anything specific in their affidavits about the challenge as to Section 3(d) and rather the depositions of Mr. Nangia attempted to show that the plaintiffs' product is Polymorphic B version of the compound which is the subject matter of the suit patent and the same is free from the combination of Polymorph A and B of the suit patent. The said affidavit of Mr. Nangia though deposes as to how the IN'774 would be obvious to the person skilled in the art but does not deposes as to how the IN'774 is the new form of same substance based on EP'226.

119. The defendant, however, has set up the challenge as to the clinical trials relating to efficacy as relied by the PW3 Nick Thatcher. Learned counsel for the Defendant did cross examination of Mr. Thatcher where under, there were questions asked as to on whether the clinical trials relied upon by the defendant are conducted on Tarceva or the suit patent, the witness answered that the trials are conducted on both. No clear picture has emerged so as to say with certainty from the cross examination as the said clinical trials are either bad or were never conducted. It is correct that the PW3 states that clinical trials were conducted in the years 2004 and 2005, but that by itself is not conclusive of the fact that the clinical trials were not related to the IN'774 except to presume that by that time Polymorph B version was in existence and therefore the said trials may or may not relate to the suit patent compound. Besides this I find number of questions on Polymorphism but no specific question or suggestion relating to the Section 3(d) or evergreening is put to the plaintiffs' witness PW3 and PW2.

120. I have gone through the said averments in the counter claim, written statement and depositions made in the affidavit and also the submissions of the learned counsel for the defendant in this respect. I have already observed that the depositions made by the Defendant's witnesses do not contain any specific mention as to how the said patent of the plaintiffs in relation Erlotinib Hydrochloride is the new form of what has been mentioned in the EP'226. The affidavit does depose that EP'226 is a closest art. The said affidavit of DW does not indicate except deposing that the same is falling with in quinazoline derivative as to how EP'226 and the suit patent are derivative of each other. There should be some positive deposition towards the same. The deposition of DWs do not contain the comparison as to what

was claimed in EP'226 and what was granted in EP'226, though it does contain a mention that the example 51 of EP'226 corresponds with the structure of suit patent. It is also conceded position that the EP'226 was based on the treatment of Methyl component whereas the plaintiff's patent is based on the treatment of the said compound with Ethynyl component. All these are attending circumstances which would reveal that the defendant is not able discharge the onus on the defendant to show that the suit patent IN'774 is new form of old substance which is EP'226. However, it is not in dispute that EP'226 relates to quinazoline derivatives also contain some compounds, which are structure wise akin to the suit compound excepting the reaction of ethynyl at the third position, would do not axiomatically permit this Court to believe that the suit patent IN'774 is a new form of EP'226 unless shown clinically with some evidence.

121. It is one thing to say that the Patent lacks the inventive step in as much as the same is obvious to the person skilled in art as the same may amount to workshop result which is *per se* not patentable. However, it is another thing to say the patent is a new form of the old substance which is pre-existing. The line may be blurred between the two but there lies a subtle difference. This is the reason why even the legislature thought it appropriate to insert and define both the concepts separately under Section 2 (j) (a) and Section 3(d).

122. There are some more facts which may be required to be proved which include the complete analysis as to what was actually the old substance, how it can be said to be same as that of the subject invention or new use of the same substance. In the present case, though the defendant has stated in the

affidavit that there was a preexisting patent of EP'226, but the defendant at the same time could not provide any positive evidence as to whether the suit patent coincides with the said compound which was the subject matter of EP'226 or new form of what is contained in EP'226. There is an attending circumstance which is that the suit patent specification corresponded with EP'226 which somehow seems to provide a hint that the plaintiffs had worked on the EP'226, but the presence of the same by itself nowhere establish that the said compound is the new form of the same compound as stated in EP'226. I have already noticed and observed that there may be a cases in chemical substances where the research is common and the same is represented in a very limited manner, accordingly it is not safe to assume that mere fact that there is grammatical similarity in the description of the invention in abstract or in the middle may lead to the inference as to the same substance or new form of the old substance. Yet another crucial aspect is that there is no deposition in defendant's affidavit as to how EP'226 and the IN'774 are the same or same substance. EP'226 contains several depictions of compound and out of which one of the example 51 form alleged to be worked upon by the plaintiffs by further reactants in order to arrive at the suit patent, the existence of the said fact itself cannot establish that the suit compound is new form of the old compound, unless proven to be contrary. Rather, the reaction with the new reactant may give birth to new compound or new of the form of the old compound which the defendant is supposed to establish and clarify but the defendant is unable to do in the instant case.

123. Consequently, I find that so far as the challenge as to violation of Section 3(d) is concerned, the defendant has not been able to discharge its

onus of proof. It is noteworthy the plaintiffs on the other hand has been able to provide the evidence of the efficacy in the evidence of PW3 Mr. Thatcher. The PW3 has also suitably deposed in the affidavit as to how the plaintiffs patent Erlotinib is not the same as that of EP'226 namely Gefitinib. The cross examination of the PW3 deals with aspect of the clinical trials and challenge to the same vis-à-vis EP'226 but nothing can be inferred to the contrary while going such cross examination. Accordingly, the plaintiffs have been able to at least justify that the said product Erlotinib is not the same as that of GEFTINIB. This has been done by the plaintiffs by comparing the efficacy. The plaintiffs have not led any positive evidence in the form of deposition before the Court (except comparing the structure as to how they are structurally different), as to how the same shall not be called as new form of the same substance either. However, considering the evidence as to efficacy differences, it can still be inferred that the plaintiffs' patent is not hit by Section 3(d).

124. So far the finding of controller in the opposition proceedings relation IN 507 by way of order dated 15.12.2008 (Ex.DW1/12) is concerned which is on Section 3(d) is concerned, the conclusions deduced by the controller nowhere finds that the said IN'507 is a new form of EP'226 and rather the said order finds that the said IN'507 is Polymorphic form of Erlotinib Hydrochloride which is IN'774 compound. Therefore, the said finding of the controller will not enable this Court to infer that the suit patent is hit by Section 3(d) of the Act. The said order was passed in the application filed by the plaintiffs for registration of Polymorph-B. The defendant's stands in the said opposition and in the counter-claim filed in the present suit are different. In case, the defendant's admissions made in the opposition to

IN'507 are applied here, the prayer made in the counter-claim is liable to be rejected.

125. Accordingly in relation to aspect of Section 3(d), I find that the defendant has not able to discharge the onus casted upon it. Thus, the impugned patent is not hit by Section 3(d) of the Patents Act.

126. I therefore reject the submissions of the learned counsel for the defendant on the count of Section 3(d). I think there is no reason to further advert to case laws and legislative intendment relating to Section 3(d) when I find that the defendant has not discharged the onus of proof on balance of the probabilities on the count of the violation of Section 3(d) of the Act.

Re: Violation of Section 8 of Patents Act.

127. There is a ground which is raised in the counter claim set up by the defendant that the impugned patent IN'774 has been registered in violation of the information which is required to be given to the patent office and the patentee who is the plaintiff is guilty of not disclosing the material facts before the patent office and also before this Court.

128. Before examining the ground of violation of Section 8 of the Patent Act 1970 in the revocation proceedings, it would be wise to consider as to what are the requirements of Section 8 of the Act and what kind of disclosure is required to be given under Section 8 of the Act.

129. Section 8 of the Indian Patents Act, 1970 as amended in 2005 reads as under:-

“8. Information and undertaking regarding foreign applications

(1) Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application-

(a) a statement setting out the name of the country where the application is being prosecuted, the serial number and date of filing of the application and such other particulars as may be prescribed; and

(b) an undertaking that, up to the date of the acceptance of his complete specification filed in India, he would keep the Controller informed in writing, from time to time, of details of the nature referred to in clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause within the prescribed time.

(2) The Controller may also require the applicant to furnish, as far as may be available to the applicant, details relating to the objections, if any, taken to any such application as is referred to in sub- Section (1) on the ground that the invention is lacking in novelty or patentability, the amendments effected in the specifications, the claims allowed in respect thereof and such other particulars as he may require.”

130. As the said Section 8 has been raised as a ground of challenge in the revocation, it would be necessary to also reproduce Section 64 relating to revocation where clause sub clause (m) reads as under:-

“64(1) (m) that the applicant for the patent has failed to disclose to the Controller the information required by

Section 8 or has furnished information which in any material particular was false to his knowledge;”

131. On the conjoint reading of both the above Sections, it is clear that there is a mandatory provision provided u/s 8 where under the applicant for patent is under obligation to disclose the information to the Controller of Patents regarding any patent application which is pending in the country outside India in respect of the same or substantially the same invention or where to his knowledge such application is being prosecuted by some person through whom he claims title, he shall file along with the same or subsequently a statement setting out the detailed particulars of such application and also give an undertaking to that effect.

132. It is also manifest from the collective reading of Section 64(m) with that of Section 8 that the consequences of not disclosing the information as per Section 8 would lead to the revocation of patent as the violation of Section 8 can be raised as a ground for revocation of patent and the same is permissible by way of Section 64(1) (m).

133. The question then arises for consideration is as to what extent the disclosure is required to be made by an applicant for patent in the Patent Office and how the Court has to deal with the same when the violation of the said provision is pressed into service by calling upon the Court to examine as a ground of rectification or revocation proceedings.

134. For doing the same, one has to understand the scope and ambit of Section 8 as to what can be subsumed within purview of Section 8 which may attract Section 64 and as a matter of consequence may lead to revocation of patent.

135. From the closer and minute reading of Section 8, it may be seen that Section 8(1) has the following ingredients:-

- a) That where application for patent either along or jointly is prosecuting the application for patent outside India;
- b) In respect of the same or substantial invention;
- c) Where to his knowledge such application is being prosecuted by some person through whom he claims or by some person deriving the title from him, he shall file along with his application; and/or
- d) Subsequently a statement setting out a detailed particular of such application; and
- e) Undertaking that upto the grant, he shall keep the Controller informed in writing from time to time of the detailed particular as required under clause (a) in respect of every other application relating to the same invention if any filed in any country outside India subsequently to the filing of statement within the prescribed time.

136. If the ingredients of Section 8 are examined closely, it can be discerned that the obligation which is casted upon the applicant for patent relates to any application which he is prosecuting either along or jointly on the date of patent or where the application which is being prosecuted by some person through whom he claims title on the date of application. This is evident from the wordings “...*is prosecuting either along or jointly*” used in the said Section or “*is being prosecuted by someone through whom he claims...*” which means that the said Section talks about the applications which are being prosecuted or is prosecuted by the applicant or his

predecessors in the foreign countries at the time of preferring the patent applications in India.

137. It is also seen from the reading of said Section that Section 8(1) covers within its sweep not merely the applications which are being prosecuted at the time of filing of patent, but also the other applications which are filed subsequently during the time when the prosecution before the Indian Patents Office is underway. This is clear from the undertaking which the applicant for patent has to give under clause 8 (b) relating to the applications preferred in countries outside India subsequently to the filing of statement referred to in clause (a).

138. Careful examination of entire scheme of Section 8(1) of the Act would reveal that the Section-8 is aimed at to provide the Controller true and faithful disclosure of all the information relating to the applications for patents which are same or substantially the same invention and also to provide the information to the Controller in relation to the title of the said Patent owned by the applicant and the other persons in the foreign countries.

139. Thus, the twin requirements of ascertainment of the foreign applications relating to the same or similar patent, the title and details contained in those applications have to be furnished and complied with mandatorily in order to apprise the Controller about the current developments in relation to the inventions in foreign countries which are same or substantially the same. This is due to the reason that when the Controller is abreast with the updated information provided to him as to the development and the prosecution trend going in foreign country, then the same may affect his decision making in adjudging the substantial issues

arising in the patent including the aspect of prior art, title, obviousness or other related issue depending upon the views which the other foreign offices take in relation to the same or substantially the same invention and that is why, it is the bounden duty of the applicant for patent to keep the Controller informed from time to time in relation to prosecution progress and also coupled with the title aspect in relation to patents to the Controller and any violation of the same may attract Section 64(1)(m) of the Patents Act upon the insistence of the adversary party.

140. This is the only way Section 8 and Section 64(1)(m) can be reconciled and interpreted. Otherwise, curtailing the sweep and ambit of Section 8 would mean that it will become highly difficult to examine as to what sort of information was mandatorily required and what was not required.

141. It is, however, to be noted that the necessary ingredients noted above must be satisfied in order to attract Section 8 which include foreign application or the application outside India and not the Indian application. Therefore, the expression ***“any other application”*** should also be read in the context with the accompanying words which are ***“relating to the same or substantially the same invention if any filed in country outside India”*** only in relation to foreign applications which is also clear from the head note as well as from the ingredients of Section, the said provision will attract in relation to Indian application. Therefore, the Court seized of with the revocation u/s 64(1)(m) will examine the question of disclosure or non disclosure as envisaged u/s 8 must confine itself to the enquiry which is permissible u/s 8 and not beyond the same which is relating to information

and undertaking regarding foreign application and the aspects relating to the same.

142. Let us see whether in the instant case provisions of Section 8 gets attracted. It has been said by the defendant that the plaintiffs as Patentee has not disclosed before the Indian Patent Office while prosecuting IN'774 about the patent namely US'221 which was filed subsequently in 2000 in US which relates to the same or substantially the same invention. This ground is raised in the instant case as it is the case of the plaintiffs that the compound which is involved in the suit patent IN'774 and the compound which was filed subsequently in India in the form of IN'507 as well as in US'221 are one and the same and the subsequent ones being the derivative of previous one would not have any impact on the enforceability of the previous one in the instant suit. This has also assailed by the Defendant by stating what has been in actual use in the market is the Polymorphic version B which was filed subsequently and not the one claimed in IN'774 which is the suit patent.

143. Essentially, the challenge of the defendant is that had the full and faithful disclosure relating to the filing of the substantially same patent been made before the learned Controller in relation to applications preferred before foreign country like in the case of US'221, the same would have impacted upon the patentability of the IN'774 which is the suit patent and also influenced the decision making of the Controller in grant or non grant of the patent. It is also the case set up by the defendant that there are agreements which are related documents where under the patent title has been flown in favour of the current patentee has not been properly informed

and filed before the Patent Office in order to apprise the Patent Office about the developments in relation to ownership of the patent and neither any chance has been given to the Defendant or any other opponent to set up a challenge. (The title aspect has been dealt with by me under the head of concealments and false representation).

144. To this challenge, response of the plaintiffs is that there are disclosures made before the Patent Office in the form of filing Form 3 along with Patent application on 13.3.1996 when the statutorily prescribed form was filed making the disclosure as of that date. Thereafter, the disclosure was made on 1.6.2006 when second Form-3 was preferred and also later during the pendency of the opposition proceedings which is stated to be along with the reply statement with the pre grant opposition and the said form filed in 2006 was also re-filed in the opposition proceedings pending between the patentee and the third party. Therefore, the plaintiffs are of the firm belief that the true disclosure has been made. Secondly, it is also stated that Polymorphic version B of the said compound would not come within the meaning of same or substantially the same invention used u/s 8. Thirdly, it is stated that the said Polymorphic version B compound was filed four years after the suit patent IN'774 in the year 1996 in India and the same is different from the suit patent and therefore the same ought not to have been disclosed to the Patent Office on the count of being different in nature.

145. It is also stated that independent of all this, when the derivative compound in Polymorph form B was filed before the Controller of Patents subsequently in India by way of IN'507, There is a complete adjudication done by the Controller in an opposition proceedings on all the aspects

including the kind of similarity between the said compound and its Polymorph form considering the impact of US'221. Therefore, there is no need for this Court to go into the question now as to whether such disclosure is warranted or not. It is urged that the said decision of the Controller otherwise came on 15.12.2008. However, IN'774 was granted in February 2007. Consequently, the plaintiffs who were always under the belief prior to the said order of the controller that the suit patent IN'774 and US'221 are different could not have filed the said description of US'221 prior to the order dated 15.12.2008. The alleged similarity or substantial similarity has been held by the Controller in the opposition proceedings later in point of time and till that time the plaintiffs were under the belief that both the compounds are distinct and therefore the disclosure was not warranted.

146. By submitting all of the aforementioned in response, it has been said that no disclosure was required to be made when it comes to US'221 subsequently relating to Polymorphic version B of the compound. Even otherwise Natco in its pre-grant opposition lost the objection of Section 8. The opposition of Natco was filed by the same patent agent to the suit patent. The said order passed by the controller was never challenged by the Natco. It is also a matter of record. The defendant did not file either pre-grant or post-grant opposition to the suit patent.

147. There are few facts which are discernible in the instant case which are worth noting for the purposes of analyzing the present aspect as to whether the disclosure or non disclosure was warranted:-

- a) That the suit patent contains the compound which comprises of combination Polymorphs A & B;

- b) That it has been brought to the notice of the Court that there is another compound Polymorph B which is at the instance of the defendant that in the patent filed by the plaintiffs in US'221 there are categorical statements made in the specifications exhibited as DW1/9 that earlier patent comprising the combination of Polymorph A & B was unstable.
- c) It is also the admitted position that medicine which is sold in the market relates to the tablet version and it is categorical stand of the Defendant that what has been sold in the market is in consonance with subsequent patent which is US'221 which relates to Polymorph B version and the same is rejected in India as IN'507 to which the plaintiffs have not been able to give any answer except by urging time and again that it is immaterial that there is an existence and filing of Polymorph B vis-à-vis the compound containing the combination thereof A & B as both are same in their properties and efficacies.

148. Considering this backdrop, one has to analyze whether such disclosure was warranted. In the light of afore noted discernible facts, it is seen the application which was filed in US'221 was in the year 2000 and the patent was filed in 1996 and patent was granted in the year 2007. The language of Section 8 is very clear where under it is stated that there is a continuous duty of the inventor or the applicant for patent to inform from time to time the Controller about the developments in the patent including filing of subsequent applications in foreign countries relating to same or substantially the same invention.

149. If in the light of the day, which is today when the plaintiffs once faced with the challenge from the defendant as to validity of the suit patent and as to the fact that drug sold in the market corresponds to the suit patent IN'774, is urging that the existence of Polymorph version B and the usage of the same in the market of the said version is immaterial as suit patent IN'774 and its subsequent Polymorphic versions are the same, then it does not lie in the mouth of same very plaintiffs to urge to the contrary while filing two applications for patents in India as IN'774 and In 507 to contend that they are distinct from each other. If the said patent was relating to the same field which is of the same compound or derivative of the same compound, the same could have been disclosed to the Patent Office that the Polymorph version of the same has been filed in 2000 in US patent office. This is more so, when the specification of subsequently filed patent as US'221 exhibited as DW 1/9 contained the same information relating to efficacy and the stability of the earlier patent whatever inference the Patent Controller could have drawn either in favor of the patentee or against him, that by itself does not absolve the responsibility of the plaintiffs as applicant for patent to disclose such information before the Controller.

150. It is legally untenable to say that the plaintiffs were under the belief that US'221 was a different invention at that point of time and it is only when the Patent Office declared in December 2008 as a deeming fiction that they are substantially the same, this has been learnt by the plaintiffs and by the time IN'774 was granted. The plaintiffs who claim to be one of the leading companies in medicinal research and masters in chemical science cannot be oblivious to the fact that conversion of one compound into another Polymorph version may be either same or similar to the earlier version of the

compound. It is not reasonable to presume that upon the decision of the Controller in the year 2008 only, the said researchers remained in the company of plaintiffs were enlightened of the fact that both the patents are actually the same or substantially the same inventions. Therefore, it cannot be said that it is only later on the patentee was able to understand the similarity between the two inventions.

151. It is also pertinent to mention that what is the requirement of law u/s 8 is the disclosure in respect of same or substantially the same invention which may subsume within its ambit the inventions which are substantially the same but may have slight difference here and there and that is the reason the legislature has used two expressions “same or substantially the same”. The plaintiffs cannot deny the nexus between the previous invention which is IN’774 and the one which is Polymorphic B version of the said compound as it is evident from the specification as Ex.DW1/9 itself. Therefore, the same ought to have been disclosed before the Patent Office in order to comply with the provisions envisaged u/s 8.

152. There are no depositions which are made by the defendants witness DWs.1, 2 and 3 in their affidavit. Likewise, the plaintiffs’ witnesses also did not depose the about the justification as to non disclosure. Therefore, the challenge is restricted to what has been stated in the counter claim and the written statement and thereafter the submissions advanced by the parties at the bar.

153. When the defendant has raised this challenge in the counter claim and also filed the documents to that effect that there is an application which was made in US in 2000 as US’221 containing a nexus between the previous compound and the Polymorphic B version of the same and also has read in

consonance with the stand which is preferred by the plaintiffs now that both the versions are of the same nature and non grant of one in India is inconsequential, The defendant is able to discharge the onus which lied on him to show that there was an obligation to disclose. Thereafter, it was upon the plaintiff to displace the onus and justify as to how the said disclosure was not required or the said disclosure was actually made. The responses which are coming forth from the plaintiffs for filing of Form-3 twice in 1996 and 2006 nowhere relates to foreign application and does not satisfy as to how the disclosure was properly made of the developments which happened in the year 2000. The fact that the Controller incidentally dealt with such application filed in US'221 while testing the opposition with the third party does not absolve the responsibility of the plaintiffs as applicant for patent to disclose the said information before the Controller which could have impacted the decision making of the Controller.

154. Likewise, the stand of the plaintiffs that both the inventions are different also seems unjustifiable in the light of their present stand before this Court and no other response has been made except what has been discussed above in detail by the plaintiffs. In view of the same and also the requirements of Section 8 discussed above, it cannot be said that the plaintiffs have been able to displace the said onus casted upon them as to why the disclosure was not made as per the requirement of Section 8 of the Act. It appears at this stage from the attending circumstances that the disclosure was not made and the said Section was in fact violated by the patentee and therefore the ground contained in Section 64(1)(m) is made out.

155. The submission canvassed by Dr. Vaidyanathan on instructions that the defendant has given up the objection under Section 64(1)(m) by putting some reliance on the pleadings of reply to C.M.No.219 preferred in continuation of the opposition order passed by the controller is rejected. I do not find that there can be estoppel against the statutorily prescribed ground of revocation especially when the said ground has been categorically urged in the counter claim in paragraph-4 and paragraph-21(i) of the written statement.

156. Consequently, the ground of violation of Section 8 read with Section 64(1)(m) is made out. However, still there lies a discretion to revoke or not to revoke which I have discussed later under the head of relief. Under these circumstances, even in case, the said compliance of Section 64(1)(m) of the Act has not been made by the plaintiffs, still there lies a discretion in the Court not to revoke the patent on the peculiar facts and circumstances of the present case. The said discretion exists by use of the word “may” under Section 64 of the Act. Thus, solely on one ground of non-compliance of Section 8 of the Act by the plaintiffs, the suit patent cannot be revoked.

Re: Ground of concealments and false representation under Section 64 (1)(i)

157. The defendant has further raised the ground of concealments by elaborating that the suit patent has been obtained on the basis of the false statements and misrepresentation and therefore the IN'774 is liable to be revoked under Section 64(1) (j) of the Patents Act 1970. Learned counsel for the defendant has pointed out series of the concealments besides

Section 8 requirements, the same can be enumerated in the following manner:

- Concealment of all agreements and status of title of plaintiffs;
- Concealments of patents filed with respect to Erlotinib Hydrochloride abroad and in India;
- No witness was produced who had knowledge of the patent filings in India or abroad;
- Concealment about the true form of TARCEVA;
- TARCEVA was launched after the Polymorph B patent was filed;
- No product was ever launched by the Plaintiffs which was a combination of Polymorph A+B;
- Contradictory stands as to the second patent being an independent or a selection patent before the patent office;
- Creation of backdated agreements and over-reaching this Court without disclosing later agreements and getting recordals done behind the back of the Court;
- No clinical trials record has been filed or produced or pleaded;
- Witnesses were specifically briefed not to answer questions on Polymorphism.

158. By placing reliance upon the aforementioned concealments, learned counsel for the defendant urged that the plaintiffs are guilty of non disclosure of material facts which may have bearing upon the decision of the present case as stated above. It is also argued that the plaintiffs have deliberately withheld the documents of this Court which are title documents and also from the patent office, therefore, the adverse inference may be

drawn against the plaintiffs and on that count too the patent is liable to be revoked being based on the false suggestions and non disclosure.

159. On the bare reading of the said ground under Section 64(1)(j), it is amply clear that the said ground does not raise any qualification as to what aspects can be said to be false representation or for that matter false suggestion.

160. Although there is no doubt that the said ground is speaking for itself as to what it covers within its ambit but for the sake of clarity Sh.P.Narayanan in his book titled as Patent Law, 4th Edition, Eastern Law House, discusses the said ground by noting the ambit and sweep of the said provision by observing that the said ground may include any aspect relating to patent application. Therefore, the said ground as it is worded in the Statute Book has to be read in the widest term and should not be necessarily curtailed. While discussing the said ground u/s 64(1)(j) the learned author has observed thus :-

“16-10 Section 64(1)(j) –“ The patent was obtained on a false suggestion or representation”

There is no similar ground under s. 25 for opposing the grant.

A patent may be revoked on the ground that it was obtained on a false suggestion or representation. There is no limitation as to the nature of the false suggestion or representation. It may thus relate to the specification or relate to any fact or statement required to be made in connection with the application for a patent. Ordinarily, however, false suggestion or representation is alleged in respect of something contained in the specification.

If false suggestion is alleged, it must be established on the basis of the documents in which the alleged false suggestion was made, the onus being of course on the objector. (Emphasis Supplied)

161. From the bare reading of the said observations coupled with the wordings of Section 64(1)(j), it can be said that any other kind of concealment which affect the prosecution of the patent before the office of Controller can certainly be urged as the ground for challenging the patent u/s 64 (1)(j). Therefore, the Court can look into any such concealment if any made before the Controller of Patents affecting materially the prosecution of the patent. Therefore, once the Defendant criticizes the grant of patent on the ground of misrepresentation, then the Court after looking into the facts which are material or non material can draw an inference by analyzing as to which of the concealments would have material bearing while securing the patent.

162. So far as concealments relating to title are concerned, it has been stated that there are deficiencies in the documents relating to title. Number of inconsistencies has been pointed out in order to state that the title of the patent is defeated and does not inure in favor of the plaintiffs. It is stated that the agreements are created as an afterthought and have been recorded later on in the back of the party in order to deprive them the chance of disputing the said documents.

163. The response given by the plaintiffs in this respect is that the plaintiffs are the true owner of the patent in question and even if there are certain documents which have been executed by them subsequently, the same do not affect the passing of the title as the same may amount to feeding the

grant of estoppel. The said principle enunciates that even a person at the time of effecting the grant did not have the title but subsequently attains the title or his title subsequently becomes perfect, then the said perfection of title shall inure in favor of the purchaser who has purchased the said property and therefore the title is fed by the principle of estoppel existing in common law.

164. This has been explained by the plaintiffs by placing the reliance on the judgment passed by Hon'ble Supreme Court in the case of *Renu Devi vs. Mahendra Singh & Ors.*, AIR 2003 SC 1608 at para 12–15, that this feeding the grant by estoppels is a principle of equity is part of the common law and fully applies in India. Section 43 of the Transfer of Property Act is just one facet of the application of this principle but this principle being of common law is not limited to Section 43 alone. This is a principle of equity that if a person who has no title whatever to property grants it by a conveyance which in from would carry the legal estate, and he subsequently acquires an interest sufficient to satisfy the grant, the estate, instantly passed. It is thus argued by the plaintiffs that the subsequent attainment of title does not affect the status of the plaintiffs as a patentee.

165. It is also stated by the plaintiffs that no one besides the plaintiffs has come to dispute the said title and the challenge which is set up by the defendant is also based on some bald allegations and therefore the same should not be seriously considered as affecting the title of the patentee. To this, the defendant responds that the said principle of feeding the grant by estoppel is applicable to immovable properties and not to moveable properties.

Lack of Title/Ownership in respect of plaintiffs

166. During the course of the arguments the learned counsel for the defendant has challenged the ownership of the suit patent as well as title documents. It was argued by the defendant that the entire patent office record shows that there are many discrepancies in order to claim the ownership of the patent in question which also lacks valid title in order to maintain the suit for patent. No doubt, certain averments have also been made in the written statement questioning the rights of the plaintiffs to sue for infringement of patent against the defendant. The defendant has also sought to allege that the plaintiffs have fraudulently obtained the patent which is contrary to Section 64(1)(j). It is a matter of fact that the patent was issued in the names of the plaintiffs. No issue in this regard was framed by the Court. The objection about the title and ownership was not proved by the defendant in its evidence. Since the patent has been granted in favour of the plaintiffs and no issue has been framed by the Court, this Court is not inclined to go into the objection raised by the defendant with regard to the lack of title/ownership. In case any discrepancy with regard to chain of documents/deeds as well as on stamp duty or other objection raised by the defendant is there, I am of the view that the defendant would have pressed for framing of issue in this regard at the appropriate time and ought to have proved the same before Court. The said discrepancies whatsoever are otherwise too trivial and do not material affect the case as to title unless shown otherwise.

167. Therefore, it cannot be said that the titles of patent is defective solely by pointing out certain defects which are intermittent in the chain of title relating to patent. Therefore, the said concealments will not strictly fall

within the purview of Section 64(1) (j) and may not be relevant for the purposes of discussion chapter of revocation.

168. There is another aspect which has been raised by the Defendant that the grant of patent is bad on account of improper examination of the patent by the Controller.

169. This aspect has been explained by the defendant by placing the reliance on all these events between the relevant dates which is 22.2.2006 till 9.2.2007, it is stated that no proper examination was conducted by the Patent Office and there are procedural irregularities committed by the Patent Office while granting the said Patent and therefore the said patent is granted under suspicious circumstances where the practice and procedure have been overlooked considerably.

170. The defendant has cited several documents containing the prosecution history in order to support this challenge that there was a case of improper examination. It is further contended that as per Section 13(3) of the Patent Act whenever the claims are amended in the patent specification then the patent has to be re-examined and advertised again, and the process of registrability falls from there and then. It cannot be the case that after the amendments the patent is not examined and investigated upon by the Controller by overlooking the provisions of Section 13(3). It is therefore argued that there is serious challenge which exists is that the claims were amended on the very last day and taken on record without any examination which is complete irregularity apparent on the face of record.

171. The plaintiffs responded the same by stating:

- That the Defendant has not discharged the burden which is cast upon him to show that the patent was examined improperly.

- That it is not the ground for revocation as envisaged in Section 64 to examine as to whether any improper examination has happened during the time when the patent was examined.
- That the counter claimant has not taken any such ground u/s 64 to urge such improper examination.
- That there are no pleadings to the effect of improper examination and no allegation of improper examination has been pleaded anywhere and patentee has been taken to surprise.
- That the obligations in the examination report have been made by the patentee and the Patent Office has examined the application thrice by two different examiners.
- That the amendments to the claims prior to the grant of patent need not be advertised.
- That that rule 81(2), Section 57(3) and 57 (6) collectively would reveal the said position. It is also stated that the amendments which were made were already falling within the scope of the patent specification which was originally filed and the said amendment was permissible and therefore no useful purpose would have been served by re advertising the said amendments in the patent.

172. So far as the improper examination of the patent as a ground is concerned, there is no need for any specific mention of the said expression is covered in the grounds of revocation when there is a ground of revocation in para-4 which provides that the patent is obtained on false suggestion and representation which can include any aspect relating to prosecution of the patent application which can materially affect the decision making or the grant of the patent.

173. The said improper examination may arise either on the default of the controller or examiner by overreaching the process of the law and not following the provisions of the Act or on the basis of misrepresentation of the applicant for the patent. The complaint of the defendant when it criticizes the examination process is based on two fold grounds which include both the defaults at the controller's end and consequent contravention of the provisions of the Act as well as the misrepresentations made by the plaintiffs. It may also be possible that the misrepresentations made by the plaintiffs might have persuaded the controller to proceed in the manner which has lead to contravention of the provisions of the Act. Therefore, it cannot be said that no such ground is available for revocation under the Patents Act.

174. The Court can surely look into the deeper aspects of the patent including its prosecution history which may reveal that the patent ought not to have been granted due to the representations of the plaintiffs before the patent office by drawing an inference from the plaintiffs conduct if not ascribing any malice to the patent controller. Therefore, the plaintiff's objection that no such ground exists is therefore rejected. It is also clarified that the defendant has raised such ground in the counter claim relating to false suggestions and misrepresentations.

175. The next question which arises for consideration is whether the amendments which are made prior to the grant can be allowed to remain unpublished under the Patents Act and the same can proceed to grant of patent without publication of the said modification / amendment. This is due to the reason that the defendant has raised the said objection as to non

publication of the amended specification. For the purposes of said discussion, following provisions are relevant:-

“13. Search for anticipation by previous publication and by prior claim

(1) The examiner to whom an application for a patent is referred under Section 12 shall make investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification—

(a) has been anticipated by publication before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in India and dated on or after the 1st day of January, 1912;

(b) is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification, being a specification filed in pursuance of an application for a patent made in India and dated before or claiming the priority date earlier than that date.

(2) The examiner shall, in addition, make an investigation [x x x] for the purpose of ascertaining, whether the invention, so far as claimed in any claim of the complete specification, has been anticipated by publication in India or elsewhere in any document other than those mentioned in sub-Section (1) before the date of filing of the applicant's complete specification.

(3) Where a complete specification is amended under the provisions of this Act before [the grant of a patent], the amended specification shall be examined and investigated in like manner as the original specification. (Emphasis Supplied)

57. Amendment of application and specification before Controller

(1) Subject to the provisions of Section 59, the Controller may, upon application made under this Section in the prescribed manner by an applicant for a patent or by a patentee, allow the application for the patent or the complete specification 1[or any document relating thereto] to be amended subject to such conditions, if any, as the Controller thinks fit:

PROVIDED that the Controller shall not pass any order allowing or refusing an application to amend an application for a patent or a specification 1[or any document relating thereto] under this Section while any suit before a court for the infringement of the patent or any proceeding before the High Court for the revocation of the patent is pending, whether the suit or proceeding commenced before or after the filing of the application to amend.

(2) Every application for leave to amend an application for a patent 2[or a complete specification or any document relating thereto] under this Section shall state the nature of the proposed amendment, and shall give full particulars of the reasons for which the application is made.

3[(3) Any application for leave to amend an application for a patent or a complete specification or a document related thereto under this Section made after the grant of patent and the nature of the proposed amendment may be published.]

(4) Where an application is 4[published] under sub-Section (3), any person interested may, within the prescribed period after the 5[publication] thereof, give notice to the Controller of opposition thereto; and where such a notice is given within the period aforesaid, the Controller shall notify the person by whom the application under this Section is made and shall give to the person and to the opponent an opportunity to be heard before he decides the case.

(5) An amendment under this Section of a complete specification may be, or include, an amendment of the priority date of a claim.

3[(6) The provisions of this Section shall be without prejudice to the right of an applicant for a patent to amend his specification or any other document related thereto to comply with the directions of the Controller issued before the grant of a patent.]

59. Supplementary provisions as to amendment of application or specification

1[(1) No amendment of an application for a patent or a complete specification or any document relating thereto shall be made except by way of disclaimer, correction or explanation, and no amendment thereof shall be allowed, except for the purpose of incorporation of actual fact, and no amendment of a complete specification shall be allowed, the effect of which would be that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or that any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment.]

2[(2) Where after the date of grant of patent any amendment of the specification or any other documents related thereto is allowed by the Controller or by the Appellate Board or the High Court, as the case may be,—

(a) the amendment shall for all purposes be deemed to form part of the specification along with other documents related thereto;

(b) the fact that the specification or any other documents related thereto has been amended shall be published as expeditiously as possible; and

(c) the right of the applicant or patentee to make amendment shall not be called in question except on the ground of fraud.]

(3) In construing the specification as amended, reference may be made to the specification as originally accepted.

176. There are Patent rules 2003 (as amended in the year 2006) wherein there is a procedure prescribed for amendment or to carry out the amendment in the specification which reads as under:-

“81. Amendment of application, specification or any document relating thereto – (1) An application under Section 57 for the amendment of an application for a patent or a complete specification or any document related thereto shall be made in the Form 13.

(2) If the application for amendment under sub-rule (1) relates to an application for a patent which has not been [granted] the Controller shall determine whether and subject to what conditions, if any, the amendment shall be allowed.

[3(A) If the application for amendment under sub-rule (1) is made after grant of patent and the nature of the proposed amendment is substantive, the application shall be published.

(b) Any person interested in opposing the application for amendment shall give a notice of opposition in Form 14 within three months from the date of publication of the application.

(c) The procedure specified in rules 57 to 63 relating to the filing of written statement, reply statement, leaving evidence, hearing and costs shall, so far as may be, apply to the hearing of the opposition under Section 57 as they apply to the hearing of an opposition proceedings.]

177. On the conjoint reading of the aforementioned provisions, following position emerges:-

- a) Where the complete specification is amended before the grant of patent, the amended specification shall be examined and investigated in the like manner as the original specification which is clear from Section 13(3) of the Patents Act.
- b) Section 57 provides for the amendment of application and specification or document before the controller and the said provision is subject to Section 59.
- c) The reading of head note of Section 57 and the wordings of the said Section would indicate that the said Section provides for the process of amendments carried either prior to the grant of patent and/ or after the grant of patent.
- d) A reading of Section 57(3) would reveal that any application for leave to amend the complete specification made after the grant of the patent and the nature of proposed amendment may be published.
- e) The said Section 57 though seemingly provides for the process of amendment for both pre grant and post grant proceedings. But, so far as publication is concerned, sub Section 3 only expressly provides for publication in the case where amendments are proposed after the grant which would invite construction of the said provision.
- f) Section 57(6) provides that the provision of this Section shall be without prejudice to the right of applicant for patent to amend his

specification or any document related thereto to comply with the directions issued before the grant of patent.

- g) The conjoint effect of Section 57(6) and Section 57(3) indicates that the amendments which are filed under Section 57 relates to voluntary amendments and not the amendments which are consequent upon the directions of the Controller as the same remains unaffected as per sub Section 6 of Section 57 of the Act.

178. Uptil this stage, there is no confusion. However, the debate begins when one sees Rule 81(3) (a) read with Section 57 (3) which provides that the application for amendment made after the grant shall be published and reads it with Section 13(3) alongside which says that when the complete specification is amended before the grant of patent, the amended application shall be examined and investigated in the like manner.

179. Now the question arises as to whether the expression “examined and investigated” as original specification would include the stage of publication or not in order to come to the finding as to whether publication of the amendment is possible pre grant in the absence of express provision regarding such publication of amendment.

180. For the purposes of the same, one has to consider Section 57(3) and rule 81(3) deeply as both the provisions are inserted by virtue of amendments made and carried out in the year 2005 which came to into effect on 1.1.2005. Section 57(3) as it was prior to the amendment reads as under:-

“57(3) – Any application for leave to amend an application for a patent or a complete specification or a document related thereto under this Section made after the acceptance of the complete specification and the nature of the proposed amendment may be advertised in

the Official Gazette if the amendment, in the opinion of the Controller, is substantive.”

181. Likewise, Rule 81 (3) was also substituted with the corresponding amendment of 2005 and the said Rule as it stood prior to the date of amendment reads as under:-

“81(3)(a) – If the application for amendment under sub-rule (10 is made after the acceptance of the complete specification and the nature of the proposed amendment is substantive, the application shall be advertised in the Official Gazette.

(b) Any person interested in opposing the application for amendment shall give a notice of opposition in Form 14 within three months from the date of advertisement of the application in the Official Gazette.

(c) the procedure specified in rules 57 to 63 relating to the filing of written statement, reply statement, leaving evidence, hearing and costs shall, so far as may be, apply to the hearing of opposition under Section 57 as they apply to the hearing of the opposition to the grant of patents”

182. From the bare reading of the provisions existing prior to the amendment vis-à-vis newly inserted provisions after the amendment of 2005, it is amply clear that the amendments are indicative of the legislative intent which is manifest on the face of it. The said legislative intent emerging from the reading of the provisions can be enumerated as under:

- a) That prior to the amendment of 2005, the said Section 57(3) as well as rule 81(3) provided that any application for amendment of specification after the acceptance shall be advertised and the same holds good both under the Section as well as for rule as they stood prior to the amendment.

- b) After the amendment, the said aspect of publication has been qualified by addition of words “made after grant” in order to provide the aspect of publication only when the amendments are proposed after grant.
- c) This is also clear when the said amendment has been carried out restricting the duty to publish with the corresponding discretion which is conferred upon the controller to issue further directions which will remain unaffected. This has been done by insertion of Section 57(6) wherein the controller in any case may give such directions in spite of what has been contained in Section 57.
- d) The legislative intent of this nature is self-evident from the fact that the amendment of 2005 conferred the right of post grant opposition to the third party in addition to pre grant opposition and thereafter the patent is also vulnerable to challenge in civil court or in IPAB in the form of revocation proceedings and therefore there are ample opportunities conferred upon the third party opponent with the additional right to object post grant which was earlier absent prior to the amendment.
- e) Therefore, the legislative intent which is emerging from the collective reading of the Sections as seen above is that the process for grant of patent has been simplified with less obstructions and opposition right has been classified into two parts so that there should be less obstruction or hurdles at the pre grant stage and the patent should proceed smoothly towards the grant and in the event amendments are carried out after acceptance but prior to grant, the same can be taken care of at the post grant stage where the third

party has got the right to challenge the said patent post grant. Accordingly, consciously the said Section 57(3) and also rule 81(3) have been amended whereas the earlier provisions were giving wider right of opposition to the third party upon publication of each and every amendment with the corresponding duty to the controller to advertise every amendment on the other hand, the newly enacted provisions wherein both rights and duties are curtailed in the pre-grant stage by not insisting the publication prior to the grant but after acceptance and the same are shifted to the post grant stage in order to align the scheme of the Act.

183. This can be the only recapitulation and interpretation which can be done in the light of what existed prior to amendment and what has been conferred after the amendment. It is thus seen that the legislature has consciously amended the said provision and the amendments done cannot be rendered otiose by conferring any additional duty upon the Controller to advertise which was his duty prior to the amendment of the Act and this would be doing injustice to the express words of the Statute and the mandate and command emerging therefrom in the form of amended provisions which will tantamount to reducing the words of the Statute into dead letters. Therefore there exists no such duty on the controller to publish each and every amended if the complete specification is amended after acceptance but before the grant.

184. Now, still, the question remains what is the import of the words “examined and investigated” as stated under Section 13(3). This is important for discussion as the defendant is also setting up a challenge to the effect that the patent application has not been examined properly within the meaning of

Section 13(3). The said words “examined and investigated” have the same meaning what has been stated in the preceding and subsequent Sections relating to the examination process and investigations carried out during such examination and nothing beyond the same. This can be seen by having closer look at the examination process under the Patents Act. For the purposes of the same Section 12, 13 and 14 are reproduced hereinafter:

“12. Examination of application

(1) When a request for examination has been made in respect of an application for a patent in the prescribed manner. [under sub-Section (1) or sub-Section (3) of Section 11B, the application and specification and other documents related thereto shall be referred at the earliest by the Controller] to an examiner for making a report to him in respect of the following matters, namely,—

(a) whether the application and the specification and other documents relating thereto are in accordance with the requirements of this Act and of any rules made thereunder;

(b) whether there is any lawful ground of objection to the grant of the patent under this Act in pursuance of the application;

(c) the result of investigations made under Section 13; and

(d) any other matter which may be prescribed.

(2) The examiner to whom the application and the specification and other documents relating thereto] are referred under sub-Section (1) shall ordinarily make the report to the Controller within [such period as may be prescribed].

13. Search for anticipation by previous publication and by prior claim

(1) The examiner to whom an application for a patent is referred under Section 12 shall make investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification—

(a) has been anticipated by publication before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in India and dated on or after the 1st day of January, 1912;

(b) is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification, being a specification filed in pursuance of an application for a patent made in India and dated before or claiming the priority date earlier than that date.

(2) The examiner shall, in addition, make an investigation [x x x] for the purpose of ascertaining, whether the invention, so far as claimed in any claim of the complete specification, has been anticipated by publication in India or elsewhere in any document other than those mentioned in sub-Section (1) before the date of filing of the applicant's complete specification.

(3) Where a complete specification is amended under the provisions of this Act before [the grant of a patent], the amended specification shall be examined and investigated in like manner as the original specification.

(4) The examination and investigations required under Section 12 and this Section shall not be deemed in any way to warrant the validity of any patent, and no liability shall be incurred by the Central Government or any officer thereof by reason of, or in connection with, any such

examination or investigation or any report or other proceedings consequent thereon.

1[14. Consideration of the report of examiner by Controller

Where, in respect of an application for a patent, the report of the examiner received by the Controller is adverse to the applicant or requires any amendment of the application, the specification or other documents to ensure compliance with the provisions of this Act or of the rules made thereunder, the Controller, before proceeding to dispose of the application in accordance with the provisions hereinafter appearing, shall communicate as expeditiously as possible the gist of the objections to the applicant and shall, if so required by the applicant within the prescribed period, give him an opportunity of being heard.”

185. Upon the conjoint reading of the aforementioned provisions, the following aspects relating to scheme of the examination and investigation of the patent applications can be discerned:

1. Section 12 provides that upon receipt of the request for examination, the controller shall forward the said request for the purposes of examination to the examiner, who shall in turn send his report to the controller within the prescribed time. The said report shall contain the matters provided under Section 12 (1) (a) to (d). This is clear from reading of Section 12 (1) and Section 12 (2).
2. The said examiner so appointed under Section 12 shall thereafter proceed to make the examination and investigation as per the Section 13 and make the investigations in relations to the matters of anticipation and prior claim as contained in the Section 13. This

is clear from the collective reading of Section 12 and 13 (1) and (2).

3. The patent application and the specification so amended shall be examined and investigated in the like manner as that of the original specification. The said Section 11 (3) provides that the criterion for the evaluating the amended specification for the purposes of examination and investigation under Section 12 and 13 would be in the like manner. The said wordings “examined and investigated in like manner” by itself do not indicate either that the clock will set back for the purposes of the procedure or process of registration of the patent but the said provision only provides that the threshold for the enquiry as to the amended specification shall be same or at par with that of the original specification.
4. The said Section 13(3) and the entire process of examination and investigation as per Section 12 and 13 does not talk about any issuance of the examiner report at each successive stages of the examination by the examiner or by the controller. The only place where the examination report is referred and provided under the Patent Rules under the chapter of the examination and investigated is under rule 24B (3) which reads as under:

“24. Publication of application

The period for which an application for patent shall not ordinarily be open to public under sub-Section (1) of Section 11A shall be eighteen months from the date of filing of application or the date of priority of the application, whichever is earlier:

2[PROVIDED that the period within which the Controller shall publish the application in the Journal shall ordinarily be one month from the date of expiry of said period, or one month from the date of request for publication under rule 24A.]

24A. Request for publication

A request for publication under sub-Section (2) of Section 11A shall be made in Form 9.

24B. Examination of application

(1)(i) A request for examination under Section 11B shall be made in Form 18 3[within forty-eight months] from the date of priority of the application or from the date of filing of the application, whichever is earlier;

4[(ii) The period within which the request for examination under sub-sec. (3) of sec.11B to be made shall be forty-eight months from the date of priority, if applicable, or forty-eight months from the date of filing of the application;

(iii) The request for examination under sub-Section (4) of Section 11B shall be made within forty-eight months from the date of priority or from the date of filing of the application, or within six months from the date of revocation of the secrecy direction, whichever is later;

(iv) The request for examination of application as filed according to the 'Explanation' under sub-Section (3) of Section 16 shall be made within forty-eight months from the date of filing of the application or from the date of priority of the first mentioned application or within six months from the date of filing of the further application, whichever is later;]

(v) The period for making request for examination under Section 11B, of the applications filed before the 1st day of January, 2005 shall be 1[the period specified under Section 11B before the commencement of the Patents (Amdt.) Act, 2005 or] the period specified under these rules, whichever expires later.

(2)2[(i) The period within which the Controller shall refer the application and specification and other documents to the examiner in respect of the applications where the request for examination has been received shall ordinarily be one month from the date of its publication or one month from the date of the request for examination whichever is later:

PROVIDED that such reference shall be made in order in which the request is filed under sub-rule (1).]

(ii) The period within which the examiner shall make the report under sub-sec. (2) of sec. 12, shall ordinarily be one month but not exceeding three months from the date of reference of the application to him by the Controller.

3[(iii) The period within which the Controller shall dispose off the report of the examiner shall ordinarily be one month from the date of the receipt of the such report by the Controller.]

(3) A first examination report along with the application and specification shall be sent to the applicant or 4[his authorised agent ordinarily within six months from the date of the request for examination or six months from the date of publication, whichever is later]. In case other interested person files the request for examination, an

intimation of such examination may be sent to such interested person.

2[(4) The time for putting an application in order for grant under Section 21 shall be twelve months from the date on which the first statement of objection is issued to the applicant to comply with the requirements.]”

From the reading of the aforementioned Rule 24B, it is clear that the said rule provides for the process of examination of the patents. The said Rule also provides for the matters like under Section 11B, explanation appended to Section 16 under Rule 24B as purposes for which the request for examination is necessary and the consequent to which the examination report shall be issued. The said Rule 24B nowhere lays down for the purposes of Section 13(3) a similar procedure for filing the request for examination report as done for the other purposes which is again indicative of the view that Section 13(3) only provides a guideline as to the likeness in the manner of examination as a process but does not indicate that the clock relating to prosecution shall be set back and the re-examination in the form examination report can be insisted upon. It is thus still within the discretion of the controller whether to examine and investigate the said patent in the like manner as that of the original specification without issuing a formal examination report or he may proceed to issue the report as per he deems fit. But the same cannot be insisted upon by the third party on the premises that the said examination process should actually result in the examination report when the Rule 24B does not provides for the said purpose a similar examination procedure, though controller may adopt the same approach of examination.

Besides, the said reference of the word “first examination report”, there is no mandate either under the Act or under the rules to issue the examination report at every stage of the objections. However, it is altogether different matter, that the patent office as a matter of the practice issues the examination reports at the subsequent stages also. This is necessary to indicate as to how far under the law and rules framed thereunder, it can be insisted that the authority has to perform the act in a particular manner when no such reference exists either in law and rules made thereunder and even no consequences are prescribed for.

5. There is reference to the words “first examination report” when it comes to the examination of the application, however the legislature as well as the framers of the rules use separate words called “gist of objections” when it comes to the process of investigation under Section 13. This is equally essential to indicate the separate requirements prescribed under the law. This can also mean in practice, which I think is logical that if the examination report has been issued and replied by the applicant, the gist of objections which are residual may follow for further investigation. The same can be cured either by reply or by personal hearing or by both depending upon the satisfaction of the examiner as well as the requirement of the rule if any.

Thus, what follows from the above is that every gist of objections cannot be equated with an examination report and it cannot be said that in the event, the reply of the applicant falls short of the reply to the examination report which might have been a detailed one to

say that the said reply to the gist of the objection should also be in the same manner as that of the reply to the examination report. This is due to the reason that there may be some objections which may require less of an enquiry and investigation.

Thus, there is no set pattern either prescribed under the Act or the rules so far it relates to dealing with the kind of the objections which remain pending satisfaction of the examiner and thus in those circumstances the applicant cannot be accused of not filing a satisfactory response which the third party expects the applicant to respond and even if the said objection is eventually cured during the time of hearing with the examiner. In those circumstances, it can also not to be said equally that there is no such examination and investigation conducted.

6. It is also noteworthy to mention that the cases where the wordings used are “gist of the objections” either under the Act in the form of Section 13, 14, 15 or in the rules (rule 28 and 29) for the purposes of the investigation under Section 13 of the Act, the right to hearing is also given to that of the applicant. It does not provide the mode as to whether the applicant has to file the response to the said gist necessarily or can simply make a request for hearing or proceed to attend the hearing. The said aspect again indicates that the satisfaction and curing of the objections enlisted in the gist of the objections can be taken care of even in the mode of personal hearing with the examiner. This seems logical in practice even due

to the reason that when number of times, there are conversations exchanged between the authorities and the applicant, still there is a room of dissatisfaction or ambiguity in the mind of the examiner, the examiner can inform the gist of the objections and call for hearing and clarify his doubts. There is no irregularity in such cases if the applicant request for hearing to make his submissions rather than to provide a detailed response.

7. The examination and investigation is the matter which is for the satisfaction of the examiner so as to the report to the controller as to whether the said invention submitted in the application satisfies the matters mentioned under Section 12. The same is clear from the Section 13 (4) which expressly provide that the matters of the examination and investigation do not in any way warrant the validity of the patent and no liability can be ascribed to the central government or the officers in relation to the examination or investigation or proceeding thereof. In other words, the said Section is itself making it clear that the said examination and investigation is a matter of the satisfaction of the examiner and does not guarantee the validity of the patent.
8. The said satisfaction is that of the examiner and therefore it is with in the power of the examiner to choose the manner in which he feels fit to get himself completely satisfied that the application is in order for grant. Of course, the said satisfaction cannot be purely subjective and arbitrary but has to be based on reasonable and

justifiable grounds. However, in order to aid the functioning of the authority seized of the complex issues like patent, each and every step taken by the said authority towards the grant of the patent can also not be called into question by calling it irregular without any positive evidence as to what has persuaded the person leveling any such allegation to make the same by urging some factual or legal malice involved in the same. In the absence of the same, no a priori assumption can be drawn of irregularities unless the said manner is prescribed by the Act and the rules and violated by the authority on the face of it.

9. There is a difference between the amendments which are required by the examiner or the controller during the course of the examination and investigation process calling upon the applicant to amend the specification in order to make the application in order as against the amendments which are made voluntarily by the applicant for the patent. This is clear from the collective reading of the Section 13(3), Section 14 and Section 15, rule 28, 29, 30 read with Section 57.

This difference is essential for understanding as to which of the amendments which may be made by the applicant by itself may require further examination and investigation for the purposes of the satisfaction of the examiner and controller as against the amendments which are made during the course of the examination and investigation which are made in order to further the

satisfaction of the controller or examiner who is seized of the application of the applicant. In the later kind of cases, the examination and investigation are being done by the examiner side by side by calling upon the applicant to make appropriate changes in the application and specification so as to make his application in order for grant. This is seen from Section 14 and 15 read with rules 28, 29, 30 which talks about the procedure as to anticipation and amendments which the controller may ask in order to remove the objection as to anticipation.

In those cases, the amendment is consequential to the examination and investigation, the same cannot be said to be re-examined by invoking Section 13(3).

186. The aforementioned discussion relating to process of examination and investigation will enable this Court to consider the challenge as to the improper examination laid by the defendant. Let me now deal with the said objections raised by the defendant.

187. The defendant has raised the challenge relating to examination process by contending the following:

A perusal of the entire Patent office record prior to the grant reveals as follows:

- The Patent had a total of 27 claims – Not clear whether they were 24 claims first and then 3 claims were added;
- It was these 27 claims that were examined by the Patent office; [FER 22.2.06]
- Response dated 2.6.06 – dealt with only these 27 claims. Only claims 19 to 23 were deleted– Response mentions that

corresponding US'498 has been granted. By this time even US'221 and US'613 are granted but this is not mentioned;

- FER dated 12.7.06 – specific objection raised that Claims 1 to 12 and 20 are not allowable under 3(d) and 2(1)(j) as the efficacy over the known compounds not established. Thus the patent office was conscious that efficacy over compounds of EP'226 have to be established. The Patent office refers to EP'226 as the known parent compound.
- Response dated 27.10.2006 – Claims are NOT narrowed down as argued by the Applicant. The claims on file are in fact **REPLACED** with two new claims. Even page 53 which is page on which Claims are typed was **replaced**. The Applicant understood which is the known parent compound and referred to Gefitinib which was derived from EP'226 in its response and tried to show efficacy. The Defendant's submission is that there was no efficacy established qua the compound claimed in suit patent because BR 21 trials were carried out on the Polymorph B form. These trials were already part of the second application IN/507. So the articles relating to Polymorph B could not have been cited when there was a separate patent application for IN/507. The two new publications filed before the Patent office are of the years 2005 and 2006 and they relate to the Polymorph B form.
- FER dated 9.1.2007 – Patent office raises a very serious objection that Erlotinib Hydrochloride is a well known Polymorph. Thus claim 1 is not allowable.
- No response is sent. A personal discussion is held. This is admitted in the Plaintiffs' chart also. All the important objections are given a go-by. Nothing new is said in the Response dated 9.2.2007. Same documents already filed are referred to. **Fresh Form 1, Form 2 and Fresh page 53** [i.e. Claims] are filed. The objection as to Polymorph is not even dealt with or mentioned.
- The fresh claims have not been examined and investigated as per the statutory mandate.

188. Now let me deal with the said objections one by one and test the same on the principles culled out above in relation to examination and investigation:

- On the unclarity of the claims whether they are 24 or 27. I have gone through the complete specification which is **Exhibit PW1/5** as well as the one which has been relied by the defendant as Exhibit DW 1/6 to say that there is unclarity with the said claims. The said specifications under the head of claims runs from 1 to 27. The same holds also good for the initial version of the complete specification relied by the defendant to set up such challenge. If the defendant is unclear about the said claims, this Court is equally unclear unless there is a positive evidence to the said effect that how such allegation can be said to be substantiated. I think at the first place, there does not seem to be any infirmities in the claim and secondly, the defendant has not been able to establish as to how the defendant can state that initially there were 24 claims and 3 claims were added later on where there is no document on record to show the same.
- The examination report dated 22.2.2006 was issued and replied on 2.6.2006. I think firstly, it is essential in order to adjudge the scope of examination and investigation as to what were the objections raised by the examiner, the same objections are reproduced hereinafter:

- 1) Subject matter of claims does not constitute an invention under Section 2 (1) (j) as it lacks novelty and inventive

step in view of citation nos. JP 7138238, JP 6073023 and JP 6336481

- 2) Claims 19 to 24 falls within the scope of sub clause of Section 3 (i)
- 3) Claims 1 to 27 are not clear in respect of the expressions as indicated therein.
- 4) Claims 1 to 27 are not clearly worded.
- 5) Title is inconsistent with description and claims
- 6) Power of attorney should be filed
- 7) Pages of the specification should be renumbered
- 8) Extraneous matter of the specification should be deleted.
- 9) Abstract should be filed with a title and concise summary of the invention within 150 words in accordance with rule 13 (7)(a) of the Patent Rules 2003.
- 10) Details regarding applications for patents which may be outside India from time to time for the same or substantially the same invention should be furnished within three months from the dates of the filing of the said applications under clause (b) of sub Section (1) of Section 8 and rule 12 (1) of Indian Patent Act.
- 11) Details regarding the search and/ or examination report including claims of the applications allowed, as referred to in rule 12 (3) of the Patent Rules 2003 in respect of the same or substantially the same inventions filed in all major Patent offices such as USPTO, EPO and JPO etc, along with the appropriate translation where applicable

should be submitted within a period of 3 months from the date of the receipt of this communication as provided under Section 8 (2) of the Act.

The said objections were responded by the applicant by way of response dated 2.6.2006. The said response includes the response to paragraph 2 which calls upon the applicant to state that claim 19 to 24 are bad due to operation of Section 3 (i) of the Act, the applicant in response deleted claims 19 to 23 and amended claim 24 in order to propose to cure such objection.

- The defendant challenge in this respect is that the plaintiffs at some places state that claim 9 to 23 were amended and in fact 19 to 23 were amended and thus examination is bad. I do not think that the plaintiffs' version in these proceedings or anywhere else except before the patent office is material for the purposes of the examination and investigation. There was an objection relating to claim 19 to 24, which was proposed to be cured by the applicant for the patent by omitting certain claims and suitably proposing to amend certain which is permissible. Thus, no infirmity on this count is found in the said examination process.
- The connected challenge of the defendant is that the information under Section 8 was called upon by the examiner, which was not fully supplied as the applicant talked only about US' 498 but does not inform about US'221 and US 613. I agree with the defendant and has already arrived at the finding that the applicant has not

supplied the complete information relating to foreign application under Section 8 and the same has been dealt with under the separate head of this judgment in detail.

- The defendant has stated that the examination report dated 12.7.2006 refers to the specific objection relating to claim 1 to 12 and 20 are not allowable as the efficacy over the known compound is not established. EP'226 has to be cited as known compound. The response to the same dated 27.10.2006 merely replaced 2 new claims and nowhere satisfied the objection. It is also stated that the applicant could not have relied upon the clinical trials which were carried out on Polymorph B form. The two new publications filed before the patent office related to the new compound.
- I have gone through the record of the examination reports of the 22.2.2006, response thereto on 1.06.2006, thereafter the objections raised on 12th July 2006 and response thereto on 27th October 2006. I think the applicant has attempted to answer the aspect of efficacy by annexing the two publications relating to clinical trials in their response on 27.10.2006. It is equally seen that the applicant has responded to the objection of Section 3(d) and 2 (1) (j) of the Act by dedicating the paragraph relating to the same. Thereafter, the applicant demanded a hearing in the matter. I find the said response whatsoever credibility it holds is sufficient for the purposes of satisfaction of the examiner till the time the examiner himself does not raise the objection to the same.

- I think defendant is missing the point which is that this Court has to test the examination and investigation process and not the fact that the examiner was at fault of being satisfied with the said response. For the same, there are other grounds of lack of novelty and inventive step, which can be independently satisfied by the defendant to challenge the patent. So far as the examination process goes on this count and the response thereto this Court finds the same in the order. The said response dated 27.10.2006 addresses the reply to all the objections however so brief or elaborate it may be. It is a matter of satisfaction of examiner and the applicant and cannot be called into question when there is no apparent illegality on the record in relation to the violation of the rules in the process of the examination and investigation.
- I also do not agree with the defendant that the applicant could not propose to amend the claims or replace the same. If the examiner is reluctant to allow the said claim on the basis of the prior art by way of prior publication or prior claim, it is well within right of the applicant to propose amended claims or replace the claims. The controller or the examiner is equally within its duty to consider those amendments as per the mandate laid down under Section 13, 14, 15 of the Patents Act. Therefore, even if 2 claims were replaced or proposed to be amended, I do not find any such malice or irregularity in such exercise done either by the applicant or for that matter patent office.

- So far as the aspect of clinical trials is concerned, this Court in any case is testing the said trials and its credibility in this suit. The examination process cannot be said to be bad on this count either till the time the process done is fair and reasonable.
- The defendant further stated that examination report dated 9.1.2007 raised some objection that the erlotinib Hydrochloride is a well known Polymorph and the said claim 1 is not allowable. The defendant states that no response thereto is sent and straightaway the personal discussion is held and thus the said examination process is bad. To this my response would be on the basis of the elaborate discussion relating to examination and investigation process done above wherein I have stated that the gist of the objections can be either suitably replied or can be cured on the basis of the personal hearing which sounds reasonable in the practice in the absence of any legislative measure or rules containing set pattern. The said practice cannot be said to be unusual or abnormal to ascribe any malice or arbitrary behavior.
- The defendant is further raising this challenge by asserting that the claims were amended during the last few days between October 2007 to January 2007, the examiner got satisfied within that time and the objections which were serious enough which went un replied still got cured by the examiner and in turn the said case became the perfect case for grant of the patent and therefore there is an infirmity. I think one has to pause here for a moment and then

has to see process of examination and investigation step by step rather than to come immediately to anxious conclusion that the said examination is bad. No doubt that there was a gist of objections raised by the examiner of the patent dated 9.1.2007. But it would be factually wrong to state that no steps were taken in furtherance to the said letter. The noting mad of the examiner contained in the order sheets where under there is an order dated 22.2.2007 clearly records that the agents have re-filed the documents on 14.2.2007 in response to the letter dated 9.1.07. The said document is placed on record. Therefore, it would be factually incorrect to say that no response was ever filed to such gist of objections raised on 9.1.2007.

Thereafter, a personal hearing has been held on 22.2.2007, in which the said examiner records that the case has been discussed and the formal objections have been met with. It is also stated that the submissions have been made by the applicant attorney to meet with the technical objections which have been considered and the necessary amendments have been carried out to meet the objections. It is here noteworthy mention that the amendments which the examiner is mentioning are the ones which were proposed in response to the earlier gist of the objections where under the cover of the letter dated 27.10.2006, 2 claims were replaced and the claim of erlotinib hydrochloride was introduced and the said response also submitted that the said compound is not anticipated by any of the prior art and therefore not hit by Section 3(d) and 2 (1) (j) of the Act. The said response if read with the personal hearing done on 22.2.2007, it is clear that no such amendments were also allowed on the very last day as contended by the

defendant. Rather, the said amendments were carried out as a process of the examination and investigation.

- Now, I again recall my discussion above that the amendments which are consequential to the process of the examination and investigation cannot be equated with the ones which are voluntary ones. The amendments which are forming the part of the process of the examination are examined simultaneously as done in the present case. Thus, once the letter dated 27.10.2006 proposes 2 new claims, thereafter the letter containing the gist of objections is received on 9.1.2007 containing the objections relating to the erlotinib hydrochloride which is a part of the new claim 1, the said examination done by the examiner is as per Section 13(3) of the Act and is in consonance with the provisions of the Act. Thereafter, during the investigations, the personal hearing is carried out when all such amendments were again considered, it cannot be stated that the patent office was at default in not examining and investigating the new claims. Rather, the examination and investigation of the said claims started right from the 9th January 2007 when the gist of objections relating to the same were handed over to the applicant and thereafter the attempt to satisfy the same by the applicant. Consequently, no infirmity can be found on the said count either.
- So far as the republication of the amended claims are concerned, I have already discussed the same that the republication of the amendments during the pre grant stage is not the legislative intent as the patent act has been amended considerably in this respect,

thus, no republication is warranted. Even no issue was framed and no evidence was led by the defendant.

189. Here, I think, at this stage, it is time to examine the submission made by the defendant that the examiner of the patent ought to have passed a speaking order as to how the objections stood removed when there were objections prior to the personal hearing. I find that the said submission though seems to be attractive but the same cannot be acceded to. This is due to the reason that the said order of personal hearing has to be read in the context along side with the previous process of examination and investigation carried out by the patent office and responses thereto given by the applicant herein. The overall collective reading of the same would be determinative of the fact that whether there existed sufficient grounds for the examiner to satisfy himself or herself while arriving at the positive finding that the patent in question is fit for grant or not. I find there is a substantial compliance of the provisions in relation to the same if one reads the entire record of examination process holistically rather than in isolation. No doubt, there was an objection in relation to ertolinib Hydrochloride being a known Polymorph in the letter dated 9.1.2007. However, there is a response on record of 14.2.2007 wherein the applicant has explained as to how Erlotinib Hydrochloride is efficacious than Gefitinib and thus does not attract Section 3(d). Pursuant to the same, if there is a personal hearing held that the examiner records its satisfaction both on technical objections as well as on other objections after considering the records of the patent office, I do not think that the said satisfaction of the examiner is vitiated by the speaking order. Rather, I think that the said satisfaction is based on what has been placed on record and the order is not non speaking, the finding as to the

application is in order for the grant is arrived after meeting all the objections, thus no infirmity can be found on the said examination and investigation process.

190. I wish to again reiterate that the process of examination and investigation is a matter between the examiner and the applicant till the time there is third party opposition is received, therefore, the same has to be adjudged from the same standpoint by ascertaining as to what was passing through the examiner's mind when he or she proceeded to remove the said objections and what was the material placed before him or her. It would be unjust to examine the said examination process from the perspective of third party as the third party would come into the picture at the later stage during pre-grant opposition and no right of the third party would be deprived till the time of conclusion of examination and investigation as per the new scheme of the Act. If the examination and investigation is vitiated by way of contravention of the provisions of the Act and Rules, then certainly illegalities can be ascribed to the said process but if not, then it cannot be said that the examination process is bad on the mere complaint of the third party when the things which went on before the patent office seems to be sequential, just and reasonable.

191. I also do not agree with the defendant's submission that the patent specification does not explain the working of the invention in respect of formulation, dosages etc or the same does not compare with the prior art. All this would cover under the separate ground for revocation of the patent which is misdescription, but the same cannot be used to say that the examination and investigation is bad in process.

192. I find the submission of the defendant meritless that there is no correlation between the originally granted claims with that of the final ones. It is seen that the answer to the same clearly finds mention that in the order of the patent controller dated 4.7.2007 while disposing of the opposition preferred by Natco Pharmaceuticals where under the Controller observed that the claims as finally granted were covered by the scope of Claims 1, 10 and 19 as originally filed. I think that on this basis again, the examination and investigation process cannot be said to be bad as the patent office including the controller was well aware of the fact as to what it was proceeding to do at that time by granting the patent.

193. I have already discussed in detail to what extent the examination and investigation process is to be looked into by this Court and have interpreted the Sections and rules in great detail in order to find out as to how one has to test the said process in the revocation proceedings. In the light of the same, I do not find any aid from the judgment of IPAB in the cases of *Novo Nordisk Healthcare AG vs. Asst Controller of Patents & Designs*, [2009] 41 PTC 577 (IPAB) and *Hindustan Unilever Vs Controller of Patents and Designs and Ors*, 2008 (38)PTC 379 (IPAB) as relied upon by the defendant. I think the plain reading of Sections, rules and analysis done above sufficiently explains as to how to evaluate the examination and investigation process in relation to the patent application by the civil Court seized of the revocation proceedings in the light of the scheme of the act.

194. I wish to further clarify that it may be the case that the patent may attract the objections as to novelty and inventive step and other tests of patentability but the examination as a process cannot be said to be bad on the same count. The said grounds are to be urged in the revocation independent

of the ground false representation. Therefore, I do not find that the plaintiffs have made any such false suggestion or representation before the controller so far as it relates to improper examination.

195. There is no evidence lead on the aspect of the misrepresentation and concealments either by the counter claimant or by the plaintiff. The said aspect of improper examination has been raised in the counterclaim and argued purely on the factual aspects without leading any evidence in relation to the same. This is another reason which persuades this Court to observe that the defendant has not discharged its onus of the proof in relation to the aspect of concealments and misrepresentation.

196. To sum up the findings on the concealments and misrepresentation on facts of the present case, it can be observed as under:

1. The defendant has established that the plaintiffs as patentee has not disclosed the information as required by the controller as per Section 8 of the Act which is evident upon from the examination report dated 22.8.2006 and the responses thereto which do not record the subsequent patent in US'221 which ought to have been disclosed. Thus the ground of revocation under Section 64 (1) (m) is made out.
2. The defendant has failed to discharge the onus of the proof on facts that there were concealments made in relation to the prosecution besides the above before the patent office or there is an improper examination done by the patent office. Therefore, the examination and investigation process cannot be called into question by the defendant in view of the discussion done above.
3. The amended claims stands examined as the same were consequential to the process of the examination and investigation and thereafter the gist of the objections was issued on 9.1.2007 and replied on 14.2.2007 coupled with the personal

hearing on the same, therefore the examination and investigation process cannot be said to be bad in so far as it relates to amended claims. Likewise, the said amendments were not in law entitled to be published in view of the avowed legislative intent emerging from the amendments carried out in the year 2005.

4. The challenge on the ground of ownership title and other concealments have not been established by the defendant by not discharging the onus casted upon it. No issue was framed. No evidence was led by the defendant.

In view of the afore noted conclusions deduced, it can concluded that so far as the grounds of revocation are concerned, the defendant is able to discharge the onus of proof only in relation to ground as per Section 64 (1) (m), and for all other grounds, the defendant has failed to discharge its onus of proof as casted upon the defendant under the law.

It is seen that though the ground under Section 64(1) (m) of the Act has been met, still there lies a discretion in the Court to proceed to revoke or not to revoke the Patent. The said discretion exists by usage of the word “may” under Section 64 of the Act. It is a settled principle of the law that the word “may” shall ordinary be read as in its grammatical meaning and not as shall unless the context otherwise provides so. Applying the said principle of law, it is clear the usage of the word “may” under Section 64 confers a discretion of widest amplitude upon rectification Court which is evident from the language of the Section. The authorities on the subject also indicates towards existence such discretion, Sh. P Narayanan in his renown book titled as Patent law observes on the discretion vested with the revocation Court in the following words:

“15-15 Discretion of the Court- The Court has a discretion to revoke or not to revoke a patent under Section 64(1). This appears to follow from the use of the words “a patent may be revoked”..... “(Emphasis Supplied)

Therefore, I exercise the discretion in this matter by not to revoke the patent. The reasoning for the same shall follow in answer to the issue no. 5 which is a relief in to revocation.

Re: Relief of revocation

197. I have observed in above discussion that the defendant has only made out one ground under Section 64 (1) (m) relating to non disclosure of foreign applications before the controller and the rest of the grounds after evaluation of the evidence and submissions are rejected by me.

198. In the said ground, the objection of the defendant is that the disclosure of US’221 Ex.DW1/8 could have impacted the grant of IN’774 as the said patent relates to substantially the same or the same invention. However, the said position taken by the defendant has to seen by this Court in the light of the stand of the defendant which exists today before this Court. In this Court while resisting the infringement claim, the defendant argued that as the plaintiffs state that both the compounds are different in their Polymorphic forms, therefore the defendant is stating so. In effect, the defendant supports the said position that the combination of Polymorphs A and B as contained in IN’774 is distinct from Polymorphic version B which is contained in US’221.

199. In the light of the said stand taken by the defendant, I find that the discretion tilts in favour of the plaintiffs and against the defendant as no

useful purpose will be served by revocation of the mark on the sole ground of revocation when the defendant is stating otherwise before this Court.

200. It is equally well-settled that the party cannot be allowed to approbate or reprobate at the same time so as to take one position, when the matter is going to his advantage and another when it is operating to his detriment and more so, when there is a same matter either at the same level or the appellate stage.

201. In the case of *Kok Hoong vs. Leong Cheong Kweng Mines Ltd.*, reported in 1964 Appeal Cases 993, the Privy Council held that "a litigant may be shown to have acted positively in the face of the Court, making an election and procuring from it an order affecting others apart from himself, in such circumstances the Court has no option but to hold him to his conduct and refuse to start again on the basis that he has abandoned." (Emphasis Supplied)

202. In the case of *Dwijendra Narain Roy vs. Joges Chandra De*, reported in AIR 1924 Cal 600, the Division Bench of the Calcutta High Court has succinctly held :

"It is an elementary rule that a party litigant cannot be permitted to assume inconsistent positions in Court, to play fast and loose, to blow hot and cold, to approbate and reprobate to the detriment of his opponent. This wholesome doctrine, the learned Judge held, applies not only to successive stages of the same suit, but also to another suit than the one in which the position was taken up, provided the second suit grows out of the judgment in the first." (Emphasis Supplied)

203. Applying the said principle of the law to the present case, I do not find that the discretion to revoke the patent should be exercised when such stand of the defendant is inconsistent and more so when no other ground relating to the revocation of the patent is satisfied under Section 64. Therefore, the defendant is not entitled to relief of cancellation or revocation of the Patent No.196744.

Re: Infringement of Patent

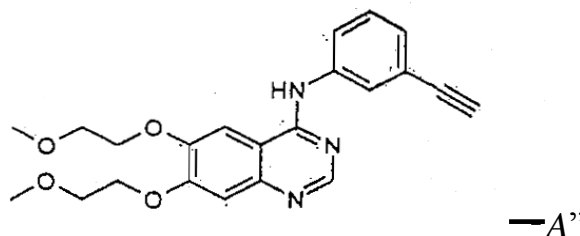
204. Now I shall proceed to discuss the issue no. 1 relating to infringement of the patent. The issue as framed by this Court reads as under:

“Whether the manufacture, marketing and sale of ERLOCIP by Defendant is infringing the Plaintiffs’ Indian Patent 196774?”

205. The onus to prove the said issue lies upon the plaintiffs. The plaintiffs claim to be the owner of the IN’ 774 titled as Erlotinib Hydrochloride comprising the two claims, however the one relevant to the proceedings is reproduced hereunder:

“Claim 1 of the suit patent reads as follows:

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



206. The case of the plaintiffs is that the defendant has infringed the suit patent wherein the rights are granted in claim No.1.

The said suit patent has the same invention and corresponds with US patent No.5747498 (for short, it would be referred to as US' 498) date of application of the suit patent with priority of 30th March, 1995. The date of US'498 is 28th May, 1996, it was granted on 5th May, 1998.

207. The plaintiffs in the paragraph 11 of the plaint have stated that the defendant had been proposing to launch the generic version of the drug namely Tarceva (Erlotinib) which they had learnt from the Newspaper articles published on 11.1.2008 in the English Daily titled as Mint and this led the plaintiffs to file the present suit on the basis of IN'774. In the plaint, the plaintiffs contends that they own a patent no. 196774 dated 23.2.2007 in respect of a compound namely [6,7-bis (2-methoxyethoxy) quinazolin-4-yl]-(3-ethynylphenyl) amine hydrochloride. It is contended that the plaintiff's drug is administered in the form of tablet. The tablet formulation of Erlotinib is sold by the plaintiffs under the trade mark and the name TARCEVA. It is also stated in the plaint that the drug as well as the process of its manufacture is patented under the provisions of the Patents Act, 1970 and this entitled to the protection.

208. The plaintiffs have claimed the following relief on the said basis in the prayer clause:

“a) Pass a decree of permanent injunction restraining the defendant, its directors, officers, servants, agents, and all others acting for and on its behalf from manufacturing, using, selling, offering for sale, distributing, exporting or in any manner infringing the legal rights of the plaintiffs in the drug Tarceva (Erlotinib) and from manufacturing, selling offering for sale, distributing or exporting in any manner any generic version of the drug Tarceva.....”

209. The aforementioned relief is claimed for the purposes of permanent injunction and other reliefs are sought in the prayer clause. As noticed upon careful reading of the prayer clause, what has been prayed in the suit seeking permanent injunction of the infringement of the legal rights in the drug Tarceva (Erlotinib) and also from manufacturing, marketing the generic version of the drug Tarceva. This is necessary to highlight at the threshold as at the time of institution of the suit, it was the understanding of the plaintiffs that the drug Tarceva corresponds with that of the patent and therefore the infringement was sought of the legal rights of the Tarceva (Erlotinib) medicine or drug.

210. The defendant had been served and filed written statement raising several defenses and challenges to the suit patent which has been discussed already and will be discussed under this head so far they relate to resisting the claim of the infringement.

211. An important development took place when the defendant raised a challenge to the plaintiffs' IN'774 by way of the counter claim. In the counter claim in paragraph 3.8 to 4.3, the defendant explained that the impugned patent is an admixture of the Polymorph A and B and the drug Tarceva which has been manufactured in the market is based on the stable version of derived from Indian Patent which has been a subject matter of Patent in US'221 and in India the same patent application bearing No.IN-507/DEL has been refused.

212. To this, the plaintiffs herein in response in the written statement to the counter claim in paragraph 2 did not deny the factum of rejection of plaintiffs' application of Polymorph B version of the compound but has pointed out certain admission which as per the plaintiffs would proceed to

show that the defendant had admitted the aspect of the infringement of the plaintiff's patent. This became relevant as a matter of backdrop of issue relating to infringement so that at the later stage, the arguments and submissions made later on may be evaluated on the pleaded facts of the parties.

213. The plaintiffs have thereafter filed the evidence by way of affidavit of Mr. Shiv Prasad Laud (PW1) who is a constituted attorney of the plaintiffs. He has deposed about the aspect of the infringement on the basis what has been stated in the packaging of the defendant namely Erlotinib Hydrochloride and also some declaration made before the authorities as to what had been contained in the medicine is ERLOTINIB HYDROCHLORIDE. It is noteworthy to mention that no clinical tests have been placed on record either by attorney of the plaintiffs or by the expert of the plaintiffs which would show and analyzes as to what are the exact constituents of the plaintiffs drug Tarceva and the defendant's drug ERLOCIP more specifically the question whether the same corresponds with the Indian Patent in the entirety or whether the same are the Polymorphic version B of the suit patent compound. Rather, the plaintiffs attorney has deposed everything on the basis of what has been shown in the physical form of literature of the drug of the defendant which only demonstrates that it contains Erlotinib Hydrochloride. There are other evidence of Mr. Thatcher PW 3 and Mr. Roger Griffin PW 2 who are experts, they have deposed mostly on the other aspects of efficacy and how the suit patent is not anticipated and not on the question of the exact constituents of the drug TARCEVA and that of the Defendant.

214. The defendant on the other hand has filed the evidence Ms. Shashikala (DW2) who claimed to be an expert and a person competent to make X ray diffraction in order to analyze the compound contained in the plaintiff's drug Tarceva. It is specifically deposed in the affidavit of Ms. Shashikala that she has analyzed the xray diffraction of the said product of the plaintiffs TARCEVA and came to the conclusion that the said drug is based on the Polymorphic version B of the compound namely N- (3-ethynylphenyl)-6-7-bis (2-methoxyethoxy)-4-Quinazolinamine. It is also deposed that the said features of Polymorph B contained in Tarceva corresponds with the US patent 221. (the corresponding Indian patene IN'507 of which has been refused by Indian Patent office). The tests had been conducted in the lab of the Cipla as well as the Independent laboratories namely IIT, Mumbai. The results of the said x ray defraction arising out the tests from Cipla and from IIT have been compared by Ms. Shashikala in her affidavit and thereafter she has come to the conclusion that the plaintiff's drug is Polymorphic B version of the said compound.

215. Learned counsel for the plaintiffs has cross examined DW2 Ms. Shashikala at great length. The cross examination of Ms. Shashikala reveals that though in her affidavit she claimed to be inventor of some patented inventions but once she was confronted with the documents relating to structure of the patents she has not been able to make out as to what are the structures of the compounds at several places like Exhibit PX 25 and PX 26 as cited by the learned counsel for the plaintiff. It has also come out well that Ms. Shashikala may know little about the chemical structure and may not be knowing the subject invention well even as it is apparent from her answers which were mainly that she either does not know or does not recall.

She however maintained all through her cross examination that her role was confined to analyze the x-ray diffraction and compare it with the trends of what has been appended as Figure 3 in the US '221 patent. No questions were asked by the learned counsel for the plaintiffs on the aspect as to when such x-ray reports were taken, where are the originals of the said x-ray diffractions, about the correctness of the trends and no suggestions were put to Ms. Shashikala that the reports submitted by her are not correct or false. It is also not put to her that the reports are false as the plaintiffs are manufacturing the medicine or drug which actually corresponds to suit patent IN'774. Further, it is also not suggested to her that the reports are prepared only as a replica to trends contained in US patent 221 by looking at the diffractions stated therein and actually no such trends ever emerged. The only thing which was put to her was that Indian Patent '774 is broad enough to cover any Polymorphic form prepared by anybody. Besides the same, nothing was to put to her to bring out a positive case that the plaintiff's patent corresponds to the drug manufactured by them in the market.

216. In the absence of the said suggestions, it can be said that the defendant has at least shown on record that the plaintiffs' product which is being manufactured and sold as Tarceva is Polymorphic B version of the compound. It is also clear from the plaintiffs maintaining before the DW2 and asking her that IN'774 compound would cover Polymorphic versions made by anybody and all other questions like diamond and graphite are Polymorphic versions of carbon etc. The plaintiff has thereafter not led any further evidence to dispel such the fact establishment that the plaintiffs' product is actually a Polymorphic B version of the plaintiffs compound. At this stage, it is suffice to observe about the establishment of this fact. It is

altogether different matter as to what bearing this fact will have at the plaintiffs' case of infringement of patent, which shall be seen later.

217. Thereafter, The defendant has also lead the evidence of professor Nangia (DW3) who in paragraph 35, 36 and 37 of his affidavit specifically deposes that the tablet of form of Erlotinib Hydrochloride cannot be made by way of simply following the suit patent No.774. It was deposed that the example 4 and 5 in US'221 patent are relevant for the same purpose and the same shows that the there is further process of reaction of the said compound with that of other constituents like ethanol and water in order to arrive at Polymorphic version. Therefore, it is stated that the suit patent compound may not automatically lead to Polymorphic version.

218. Mr. Nangia was again cross examined where under no questions were put as to factual incorrectness of plaintiffs product being Polymorphic version B of the compound. The questions were asked as to existence of Polymorphs of the compounds in general and that Erlotinib Hydrochloride from Erlotinib base and similarity of the properties, structural formula of the compound with that of the Polymorph. All this indicates that the plaintiffs maintained the position all the time that the said Polymorphic version B may be covered within the suit patent. This at least establishes that the plaintiffs do not seriously dispute that the plaintiffs' drug available in the market is a Polymorph B of the compound which is subject matter of the patent.

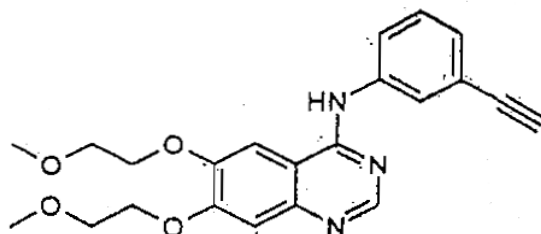
219. The plaintiffs have not led any positive evidence to the effect to establish on record that the Polymorphic versions are always the same as that of the underlying compound. It is also not established on record by way of depositions of the plaintiffs that how many Polymorphic versions are available of the suit compound. If there are, then whether all are the same in

the nature, characteristics, properties in all respects with the parent compound. It is also not established by the plaintiffs' deposition that the chemical structure of the plaintiff's compound may not change when the same is converted into from admixture of Polymorph A & B to Polymorph B. I think all these questions if at all answered in the form of the evidence would have simplified the plaintiff's case so as to establish that the direct case of infringement rather than to say simply that if at all Polymorph B exists in Defendant's tablet, the same is an infringement of the Plaintiffs Indian Patent'774 as it is covered within its ambit.

220. Nevertheless, let me now consider and evaluate what the parties have to say about the case of infringement of the patent at this juncture.

- The plaintiffs contend that the claim defines the scope of the invention and therefore the court while determining the infringement of the patent has to compare what has been contained in the claim of the invention vis-à-vis the constituents of the product of the defendant. The plaintiffs state that in the instant case IN 196774 (IN'774 or the 'suit patent') patent is targeted towards invention of novel "4-anilino quinazoline" compounds having anti-cancer activity. The invented compounds are inhibitors of Epidermal Growth Factor Receptor (EGFR) tyrosine kinase and are used for treating cancer by virtue of their property that destroy some types of cancer cells while causing little harm to the normal human cells (*PW2, para 15 of affidavit; PW3, para 13 of affidavit*). The specification of the suit patent details 105 compound examples, but has restricted the scope of patent protection to only one compound Erlotinib Hydrochloride which is disclosed in example 20 and Claim 1 .
- The claims of suit patent are restricted to only 2 claims. Claim 1 of IN'774 is a claim for the compound Erlotinib Hydrochloride *per se* (DW 3, Q. 22) and Claim 2 is a process claim for the manufacture of Erlotinib Hydrochloride. In the present case, the Plaintiffs have only asserted infringement of Claim 1 of the suit patent –

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

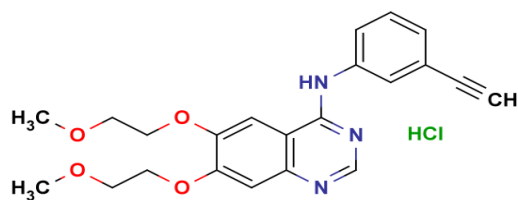


—A”

- It is submitted that the compound claimed in claim 1 of the suit patent is the Active Pharmaceutical Ingredient (API) of the Plaintiff’s drug, TARCEVA®. It is pertinent to note that TARCEVA® has been approved by the DCGI for the treatment of Non-Small Cell Lung Cancer (NSCLC) in the year 2005 and pancreatic cancer in the year 2006.
- It is submitted that Section 48 (a) of the Patents Act, 1970 provides that the patentee can prevent third parties, who do not have his consent, from making, using, offering for sale, selling or importing the said product in India. Therefore, in the present case, the Plaintiffs seek to restrain the Defendant from making, using, offering for sale, selling or importing the claimed compound Erlotinib Hydrochloride.
- The plaintiffs have argued that for the purposes of the infringement of patent, the court has to read the claim and then compare it with the product of the defendant. It is argued by stating that the infringement of a patent constitutes the unauthorized act of making or using or offering for sale, selling or importing the claimed invention. Section 48 provides that infringement analysis has to be assessed upon comparison of the *Claims* of the suit patent with the accused product or process. Therefore, the test to determine infringement is a 2 step process:
 - i. First, the claim needs to be interpreted;
 - ii. Second, the impugned product has to be compared with the claim.

- As per Section 48, it is erroneous to compare the impugned product of the Defendant with the Plaintiff's product. Therefore in the present suit, the infringement should be judged as whether the Defendant's product, i.e., ERLOCIP, falls under the scope of the Claim 1 of IN'774.
- The plaintiffs have cited several authorities wherein the rules of interpretation of the claims in patent are laid down by the courts from time to time. The said authorities relating to several propositions can be discussed in the following manner:
 - i. Interpretation of a patent is a question of law and not fact. (*Markman v. Westview*, 517 US 370 at p. 384).
 - ii. Claims have to be interpreted as on the date of priority of the patent application. (*Philips v. AWH*, 415 F. 3d 1303 at p. 1313)
 - iii. If the words in the claims are clear and unambiguous then no aid of any other document to interpret is admissible. (*Philips v. AWH*, 415 F. 3d 1303 at p. 1314; *F.H.&B. Corporation v. Unichem*, AIR 1969 Bom 255 at para 8)
 - iv. If the words in the Claims are ambiguous, then the case of *Philips v. AWH* (415 F. 3d 1303 at p. 1314-1318) states that the following documents, in this hierarchy, can be looked into to give meaning:
 - a) Patent Specification of the same patent;
 - b) Prosecution History of the same patent;
 - c) Dictionary and other external sources as on the priority date.

221. It is stated that the Claim 1 of suit patent is for the novel compound [6,7-bis (2-methoxyethoxy) quinazolin-4-yl]-(3-ethynylphenyl) amine hydrochloride; which is represented by the below formula:



The scope of a patent for a new compound covers the compound and for whatever purpose it is used.

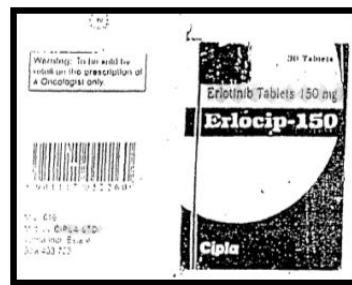
- The claimed compound {[6,7-bis (2-methoxyethoxy) quinazolin-4-yl]-(3-ethynylphenyl) amine hydrochloride i.e. Erlotinib Hydrochloride} of the suit patent is disclosed as Example 20 in the patent specification. Further, Example 20 has characterized the physical state of the claimed compound as solid and is identified as a solid by its melting point.
- Claim 1 of the suit patent is for the Erlotinib Hydrochloride compound per se, and not restricted to any particular Polymorphic form or mixture of any forms, nor claims any particular Polymorphic form. Therefore there is no requirement to provide X-ray diffraction data in the patent specification. It is submitted that X-ray diffraction data is used to characterize and identify the Polymorphic form of a compound since an X-ray diffraction graph is unique for a particular Polymorphic form of a compound.

222. The plaintiffs have submitted that they have discharge the onus of proof upon them to show that the defendant product is infringing the patent of the plaintiffs in the compound which is the subject matter of IN'774. As per plaintiffs, the following narration will indicate the discharge of the onus of the proof:

- a. That the plaintiffs have mentioned in the plaint that the cause of action first arose in January 2008, where, by way of several reports in the media, the Plaintiffs were made aware of the potential infringement of the suit patent by the Defendant. One such report appearing in 'The Mint' stated that the Defendant

was “to sell copycat version of the Roche drug”. This report has not been denied at any point by the Defendant or its representatives. (*Q. 121 read with Q. 205, DW1*)

- b. The packaging of the Defendant’s product ERLOCIP (*Ex. P1*), clearly shows that the Defendant manufactures, offers for sale, and sells Erlotinib Hydrochloride tablets.



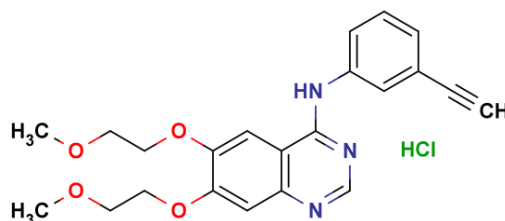
- c. Further, the package insert of the Defendant’s product ERLOCIP (*Ex. P2*) clearly shows the composition of the tablets manufactured by the Defendant have the Active Pharmaceutical Ingredient (API), Erlotinib Hydrochloride.



- d. The license received by the Defendant from the Central Drug Standard Control Organisation on October 19, 2007 (*Ex. PW1/D2*), was for manufacture of Erlotinib Hydrochloride (DW 1, Q 220,).
- e. The approval received by the Defendant from the Department of Food and Drug Administration, Government of Goa in December, 2007 was for manufacture of Erlotinib Hydrochloride tablets.

- f. It is further submitted that the Written Statement in the present suit contains an express admission by the Defendant that it manufactures and markets a generic version of Erlotinib Hydrochloride. Importantly, the Written Statement does not have any denial of infringement of Claim 1 of the suit patent. It is therefore humbly submitted that the Plaintiffs in the present case have discharged the onus of proving infringement of Claim 1 in view of the various admissions made by the Defendant with respect to their product ERLOCIP.
- g. During the course of the trial in the present suit, the Defendant's witnesses have also made specific admissions as to infringement of the Erlotinib Hydrochloride compound claimed in Claim 1 of the suit patent which are stated below.

- Erlotinib Hydrochloride produced anywhere in the world will always have the IUPAC name and chemical formula “[6,7-bis (2-methoxyethoxy) quinazolin-4-yl]-(3-Ethynylphenyl) amine hydrochloride compound” and the chemical structure



(Q. 24 and Q. 35, DW2,; Q. 49, DW3,). This is exactly what has been claimed in Claim 1 of the suit patent IN'774.

- The Active Pharmaceutical Ingredient, i.e. the component of the drug that actually acts on the target, in the Defendant's product ERLOCIP is Erlotinib Hydrochloride (Q. 34, DW2,).
- The International Non-Proprietary Name of their Product is Erlotinib Hydrochloride (Q. 190, DW1,).

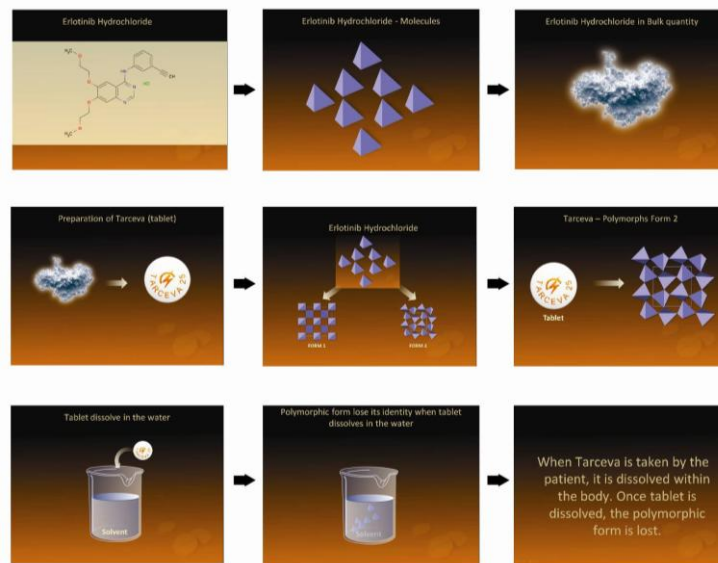
By highlighting the aforementioned statements from the cross examination, it is submitted by the plaintiffs that they have discharged the onus of the proof upon them to establish the infringement of the IN' 774.

- h. Besides, the above stated statements, it is submitted that the defendant has always understood the Erlotinib Hydrochloride as a compound and not in Polymorphic form in any manner.
- i. It is therefore submitted that even prior to January 2008, when the Defendant was “unaware” of the existence of Erlotinib Hydrochloride in Polymorph B form, it had made patent applications, received Government approvals and manufactured Erlotinib Hydrochloride tablets under the trademark ERLOCIP. It is therefore reiterated that the defence taken by the Defendant that it manufactures Erlotinib Hydrochloride in Polymorph B form is an afterthought and a last ditch effort by the Defendant to mislead this Court and deny the claim of infringement by the Plaintiffs.
- j. It is submitted that there is not even a whisper of this defence either in the pleadings or in Defendant’s interim application I.A. No. 1272 of 2008 before this Court. In fact it is submitted that in the Replication to the Counter Claim, the Defendant in fact specifically denies that it is manufacturing Erlotinib Hydrochloride in Polymorph B form. (*Paragraphs 3.8, 4-4.5 of the Reply on merits, Replication to the Counter Claim, Part I(B) of the Court Record*).

- k. It is further submitted the Defendant has not placed on record any X Ray Diffraction data to show that it is manufacturing Erlotinib Hydrochloride in Polymorph B form or that the same differs from Erlotinib Hydrochloride as claimed in Claim 1 of the suit patent IN'774.
- l. Therefore the Defendant's averments in oral arguments that the product manufactured by them is the Erlotinib Hydrochloride in Polymorph B form and therefore, the product does not infringe claimed compound Erlotinib Hydrochloride of suit patent IN'774 is false and contrary to their own admissions.
- m. In the absence of any such pleading or evidence, it is submitted that the Defendant has not rebutted or explained away its admissions that it has the license and governmental approvals to manufacture 'Erlotinib Hydrochloride' and not any Polymorphic form, and that it does so under the brand ERLOCIP.

The plaintiffs submitted that without prejudice whatever alleged difference exists between the combination of Polymorph A and B and Polymorph B, the defendant could not have arrived at Polymorph B form of the molecule which is stated by the defendant without crossing the stage of preparation of combination Polymorph A and B. therefore, the defendant product even if the same is a Polymorphic B version of the molecule would still infringe, the plaintiff's IN' 774. This has been explained by the plaintiffs in the narration below:

n. Assuming for the sake of arguments that the statement of the Defendant is correct, it is submitted once the tablet is consumed, in the body the physical ‘form’ of Erlotinib Hydrochloride is irrelevant. **This has been admitted by Defendant’s own Polymorph expert witness, DW2 in Q.27.**



o. Further, assuming for the sake of arguments that only Erlotinib Hydrochloride in Polymorph B form can be made in tablet form, it is submitted that defendant cannot arrive at Erlotinib Hydrochloride in Polymorph B form without using the claimed compound ‘Erlotinib Hydrochloride’ itself. It is important to note that the Defendant alleges to use the Polymorphic form of the claimed compound and not any other compound or any other salt of the main compound.

p. It is submitted that it is Defendant’s own argument that one person’s finished product can be another’s raw material. More specifically, this implies that Erlotinib Hydrochloride tablets

(the finished product allegedly being Erlotinib Hydrochloride in Polymorph B form) has to be made from Erlotinib Hydrochloride bulk (i.e. the Active Pharmaceutical Ingredient which is undisputedly the same Erlotinib Hydrochloride as claimed in Claim 1 of the suit patent IN'774).

- q. Importantly, even the application for the Erlotinib Hydrochloride in Polymorph B form in the US, US 6900221 (US'221) states that Erlotinib Hydrochloride in Polymorph B form results from re-crystallization of Erlotinib Hydrochloride using different solvents and temperature condition. This has been admitted by DW3 in (Q.82, DW3;), during the course of cross examination.
- r. Simply explained, different Polymorphic forms of a compound are prepared in pharmaceutical sciences by re-crystallisation of the main compound using different solvents under different temperature regimes (Q.22 & Q.24, DW2,). Further, during preparation of Polymorph of a compound there is no chemical changes taking place on the molecule itself, however, during re-crystallization the molecules are re-arranged/re-oriented in a particular manner and it is this arrangement of molecules which is designated as a particular Polymorphic form of a compound.
- s. Importantly, there has been no evidence or process stated by Defendant to show that Erlotinib Hydrochloride in Polymorph B form can be made without using claimed Erlotinib Hydrochloride. (*paragraph 35 of the Evidence Affidavit of DW3*)

- t. It is submitted that it is Defendant's own argument that one person's finished product can be another's raw material. More specifically, this implies that Erlotinib Hydrochloride tablets (the finished product allegedly being Erlotinib Hydrochloride in Polymorph B form) has to be made from Erlotinib Hydrochloride bulk (i.e. the Active Pharmaceutical Ingredient which is undisputedly the same Erlotinib Hydrochloride as claimed in Claim 1 of the suit patent IN'774).
- u. Importantly, even the application for the Erlotinib Hydrochloride in Polymorph B form in the US, US 6900221 (US'221) states that Erlotinib Hydrochloride in Polymorph B form results from re-crystallization of Erlotinib Hydrochloride using different solvents and temperature condition. This has been admitted by DW3 in (Q.82, DW3), during the course of cross examination.
- v. Simply explained, different Polymorphic forms of a compound are prepared in pharmaceutical sciences by re-crystallisation of the main compound using different solvents under different temperature regimes (Q.22 & Q.24, DW2). Further, during preparation of Polymorph of a compound there is no chemical changes taking place on the molecule itself, however, during re-crystallization the molecules are re-arranged/re-oriented in a particular manner and it is this arrangement of molecules which is designated as a particular Polymorphic form of a compound.
- w. Importantly, there has been no evidence or process stated by Defendant to show that Erlotinib Hydrochloride in Polymorph

B form can be made without using claimed Erlotinib Hydrochloride. (*paragraph 35 of the Evidence Affidavit of DW3*)

- x. It is a well settled principle that a Polymorphic form of a compound will infringe the 'basic compound patent' which in this case is the suit patent. It is also a well settled principle that the aforesaid holds true irrespective of the fact that the 'Polymorphic form' in question is covered by a separate 'Polymorph' patent.
- y. In the present suit, since the claims relating to Polymorph form per se were not allowed, the defendant is infringing the basic compound patent i.e. the suit patent IN'774. If claims related to Polymorph form per se would have been granted, the defendant would have infringed two patents, i.e. the suit patent as well as the Polymorph patent.
- z. In such an event, it is submitted that the manufacture of the admittedly separate and distinct invention for Erlotinib Hydrochloride in Polymorph B form will still infringe Claim 1 of IN'774.
 - i. This concept has been statutorily recognized under Sections 19 and 91 of the Patents Act, 1970.
 - ii. Section 19 states that where an application for a patent cannot be performed without substantial risk of infringement of any other patent, the Controller may direct that a reference to such other patent be inserted in

the applicant's complete specification by way of notice to the public.

- iii. Following this, if the patent application is granted by the Controller, then the patentees can under Section 91 license each other's related applications so as to enable they can work the invention efficiently or to the best advantage possible.
- iv. This concept of cross-licensing has been expounded in several leading commentaries including Philip W. Grubb's, PATENTS FOR CHEMICALS, PHARMACEUTICALS AND BIOTECHNOLOGY (at p.4, 1999 edition) stating that,

“Exclusionary Right In a very common situation where A has a patent for the basic invention and B later obtains a patent for an improvement to this invention, then B is not free to use his invention without the permission of A, and A cannot use the improved version without coming to terms with B.”
- v. This passage has been cited with approval in the case of *Hindustan Unilever Limited v. Lalit Wadhwa*, 2007 (35) PTC 377 at paragraphs 14 and 16.
 - a. Therefore, it is well-known as well as statutorily recognized that more than one patent can cover a single product.
- vi. Thus, assuming that Erlotinib Hydrochloride in Polymorph B form or any other Polymorphic form had been granted a separate patent, then such patent could not

be worked without the approval and/or license of the patentees to the suit patent IN'774.

- vii. This situation is also evident upon a reading of the US Judgment, *OSI Pharmaceuticals LLC & Ors. v. Mylan Pharmaceuticals* from the District Court of Delaware in favour of Plaintiff No. 2 since the US Food and Drug Administration's ("FDA's") publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book") lists Nos. 5,747,498 (corresponding to the suit patent), US 6,900,221 (corresponding to the patent for Erlotinib Hydrochloride in Polymorph B form and related methods of treatment) and US 7,087,613 (corresponding to the methods of treatment) for the product Tarceva[®].
 - a. Thus, even if CIPLA re-crystallized Erlotinib Hydrochloride compound to arrive at Erlotinib Hydrochloride in Polymorph B form and sold it under the brand name ERLOCIP, this would amount to use of the compound claimed in Claim 1 of the suit patent IN'774 and therefore is infringement within the meaning of Section 48(a) of the Patents Act.
- viii. The plaintiffs also submitted that in any case while deciding the opposition proceedings relating to subsequent IN'774 which comprised of Polymorph B, the controller had found that the said Polymorph shall be

deemed to be same substance as per Section 3(d) of the Act. Therefore, this Court should also treat the said Polymorph B version to be the same as that of the IN'997 and should proceed to hold the infringement of the patent done by the defendant by giving effect to such fiction provided under the law. This has been narrated by the plaintiffs by contending the following:

- a. In the pre-grant opposition order dated 15.12.2008 (*Annexure to DWI/12*), the Controller accepted the Defendant's contention that Polymorph B was non-patentable subject matter under Section 3(d) and rejected the application for Erlotinib Hydrochloride in Polymorph B holding that:
 - i. The mere discovery of Erlotinib Hydrochloride in Polymorph B form was not patentable;
 - ii. The thermodynamic stability of the Polymorph B form did not meet the requirement of "enhanced efficacy" within the meaning of Section 3(d). Controller of Patents in a well reasoned pre-grant opposition order of IN'507 held that Erlotinib Hydrochloride in Polymorph B is the 'same pure substance' as suit compound Erlotinib Hydrochloride.
 - iii. The above order has attained finality and the plaintiffs have not appealed the same.
- b. A rejection under Section 3(d) of the Patents Act deems Erlotinib Hydrochloride in Polymorph B form to be the same as the known substance i.e. the Erlotinib Hydrochloride compound as claimed in Claim 1 of the suit patent, IN'774. Therefore, once

Erlotinib Hydrochloride in Polymorph B form is deemed to be the same pure substance as Erlotinib Hydrochloride under Section 3(d), it is not permissible to treat Erlotinib Hydrochloride in Polymorph B form as a different substance for the purpose of Section 48 or any other provisions of the Act. The Supreme Court in various cases while applying the principle of 'deeming fiction' has held that if the statute requires a person to treat an imaginary state of affairs as real, then one must, unless prohibited from doing so, also imagine as real the consequences and incidents which, if the putative state of the affairs had in fact, existed must have inevitably flowed from. After one imagines this specified state of the affairs, then one cannot cause or permit one's imagination to boggle when it comes to the inevitable corollaries of that state of affairs.

c. Therefore after the rejection of the application for Erlotinib Hydrochloride in Polymorph B form, the separate invention of Erlotinib Hydrochloride in Polymorph B form has been deemed by legal fiction to be a part of the known substance i.e. Claim 1 for the Erlotinib Hydrochloride compound under Section 3(d) of the Patents Act.

d. The plaintiffs have also provided an instant where the US District Court of Delaware in the case against some third party finds on the admission of the defendant therein that the defendant in that case infringed the US equivalent of the IN'774. This has been explained by the plaintiffs as under:

In the proceedings before the United States District Court of Delaware between Plaintiff No. 2 (amongst others)

against Mylan Pharmaceuticals, Mylan admitted that a generic version of Erlotinib Hydrochloride would infringe Claim 35 of US Reissue Patent 41065E (US RE'065). Claim 35 in US RE'065 corresponds to Claim 1 of IN'774 which is for the Erlotinib Hydrochloride compound per se.

223. The plaintiffs contend that in view of the said position, this Court should consider arriving at the conclusion that the plaintiffs have discharged their onus of proof to show that the defendant's product is an infringement of the plaintiff's patent containing a compound Erlotinib Hydrochloride.

224. Per contra, the defendant through its counsels has argued on the same lines as recorded above prior to the plaintiffs submissions which can be summarized in the following effect:

- That the plaintiffs have not lead any evidence to show that what exactly Tarceva contains whether a Polymorphic version B or combination of A and B.
- The plaintiffs have not asked any questions to the defendant's witness to disprove the fact that the Tarceva actually contained the suit compound.
- In view of the above and absence of the evidence by the plaintiffs, it is established that Tarceva contained Polymorphic version B of the compound.
- If that is so, then the plaintiffs are estopped by their express admissions and conduct from contending to the contrary today that the plaintiffs' drug Tarceva is covered with in the suit

patent compound. As per the defendant, the plaintiffs have made the following admissions:

It is the admitted position on record that a separate patent application was filed in USA for Polymorph B i.e. US'221 and other countries. Separate application for product and process being application no.s IN/507/DEL and IN497/DEL were also filed in India for Polymorph B form of Erlotinib Hydrochloride. In the said subsequent patent in USA and patent applications in India clear admissions have been made that the suit patent is related to Polymorph A+B but the second patent US'221 and corresponding applications in India relates to Polymorph B form of Erlotinib Hydrochloride. The date of application of Polymorph B in USA under US'221 was 9th November, 2000 which was granted on 31st may, 2005 and in India the plaintiffs' application for Polymorph B was IN-507/DEL filed on 14th May, 2002.

- The defendant argued that the Plaintiffs had to explain these admissions which have not been done throughout arguments till conclusion of their arguments. No evidence was led nor was an attempt was made to argue why these admissions cannot be relied upon. The only argument of the Plaintiffs is that the inventors are different of the suit patent and Polymorph B patent or that the subsequent patent cannot be looked into. It is absurd to argue and is not based on any legal proposition that that in a counterclaim, admissions of the plaintiffs cannot be looked into. All these patents being US'221, US'613 and applications IN/497/DEL, IN/507/DEL belong to the same

family. For the Plaintiffs to ask the Court not to look at the subsequent patents for the same product is a dishonest argument. The Court has to see all the arguments, circumstances and then decide.

- It is submitted by the defendant that IN'774 suit patent derives priority from US'498. One patent derives priority from another only if it relates to the "same invention". Thus all statements made qua US'498 automatically apply to IN'774. Hence the same are binding on the Plaintiffs.
- No witness was produced to explain away the admissions by the Plaintiffs. Not a single expert witness appeared from Roche or OSI to explain the various patents on Erlotinib. Third parties cannot explain. Mr.Laud PW1 was not a technical witness, so he had no knowledge on Polymorphism.
- As per the Supreme Court judgment *Bishwanath Prasad vs. Hindustan Metal* [1979] 2 SCC 511 paras 21, 36, 43 to 50, the inventor would have been the best witness. Apart from the witness not being brought, the plaintiffs did not produce any witness from Roche or OSI or Pfizer to establish their case.
- It is argued by the defendant that the plaintiffs have been vehemently trying to define Polymorphism and at the same time attempting to substantiate that the Polymorph B is subsumed in the suit patent. The latter is completely false and factually incorrect. Plaintiffs argue that the product is the same but it is only the packing of the crystals which is different. E.g., of Diamond and Graphite. However, Plaintiffs forget to consider

or point out that Diamond and Graphite have completely different properties. One is soft and one is the hardest substance. Their physical properties are miles apart.

- It is submitted that The Polymorph B patent application IN'507 of Plaintiffs has been rejected in India. The Plaintiffs cannot be better off after Polymorph B patent is rejected. Firstly Plaintiffs consider Polymorph B as a new invention and a new product and thus file an application for getting a patent. Thereafter, when the said application is rejected by the Controller, the Plaintiffs took a complete somersault and are arguing that the second product is covered by the first patent. If that was the case, why was the application made for the second product at first place? The Plaintiffs cannot have it both ways.
- The defendant argued that Section 48 uses the words “that product”. The product has to be identified. A product is a commercially saleable product. This is clear from the following decisions:
 - i. Delhi Cloth and General Mills Co Ltd vs. RR Gupta, Commercial Tax Officer, Jaipur (1976) 3 SCC 443
 - ii. UOI & Ors vs. Tata Iron and Steel Co (1975) 1 SCC 78
 - iii. South Bihar Sugar Mills Ltd vs. UOI & Anr (1968) 3 SCR 21
 - iv. Bhor Industries Ltd Bombay vs. Collector of Central Excise Bombay (1989) 1 SCC 602

Therefore, there is a fallacy in the argument of the plaintiffs that the product in question is irrelevant. If the composition of the said product does

not match with the claims, then the same cannot be covered within the ambit of the patent.

- The defendant argued that by relying on the IN'774 after the rejection of IN 507 relating to Polymorph B, the plaintiffs are indulging into the act of double patenting which is impermissible. It has been argued that the concept of umbrella patent is alien to patent law. It is clear that double patenting is not permissible. The plaintiffs have not chosen to respond to this. It is obvious that there cannot be two patents for the same product. If Polymorph B is an independent invention, it cannot be covered under the suit patent.
- The defendant contended that the plaintiffs have deliberately chosen not to seek the patent of addition as per Section 55 if there was an improvement of the same article. The plaintiffs have rather gone for the fresh patent which means that they themselves believed that the Polymorphic version is distinct from that of the main compound. It is stated that the plaintiffs cannot now therefore state that the working of one patent is dependent upon on the other.
- It is stated that the clinical trials relied upon by the plaintiffs to suggest some efficacy in the compound which find mention in the affidavit of Mr. Nick Thatcher PW 3 are all relating to the Polymorphic version B of the compound in question. The same are all post 2000 documents in the form of articles which was the time when the Polymorphic version was already in the field. The defendant has enlisted such documents as under:
 - ONCOLOGIST Dated 05.02.07

- THE NEW ENGLAND JOURNAL OF MEDICINE dated 14.07.05
- JOURNAL OF CLINICAL ONCOLOGY dated 10.08.05
- JOURNAL OF CLINICAL ONCOLOGY dated 20.05.07

Thus, it is stated that the said efficacy has not been shown by the use of the suit patent but by the use of the Polymorphic version of the compound which was the subject matter of IN 507.

225. By making the aforementioned submissions, learned senior counsel for the defendant has stated that the defendant has been successfully discharge the onus of proof of non infringement of the patent in the present case.

226. I shall now proceed to evaluate the submissions advanced by the parties alongside the discussion of the pleadings and evidence lead by the parties to the same effect in order to determine the question of infringement of patent. In order to facilitate the evaluation of the case of the either side, it is felt expedient to first consider some legal aspects on the basis of which the infringement of patent is determined.

227. It is also argued by the learned counsel for the defendant that the Clinical Efficacy Studies as mentioned in the literature of the products of the plaintiffs are pertaining to the product of Polymorph B and not pertaining to suit patent.

Rule of Construction of Suit Patent Claim

228. The first question for the purposes of the discussion on the aspect of the infringement of patent which arises for the consideration is that how the

Court has to test as to whether the impugned product is infringing the patented subject matter especially when there is a patent claim on the subject and there is a product which may not strictly covered within the patent claim but contains something else as well in form of variant or reactants.

229. As per the plaintiffs, the test is that the Court has to see what has been claimed in the patented invention and the product in question and if the product which is claimed is subsumed within the product which is stated to be infringing, the infringement is established. As per the plaintiffs, the Court has to look only claims and product and if there is exists ambiguity, then the resort must be taken to the specification and nothing else.

230. In effect, the plaintiffs state that the Court has to interpret the claim or specification strictly and compare it with the product which is impugned in order to find out infringement. I find the said tests appears to be correct so far as it relates to simplicitor infringement cases where the impugned product is straightaway subsumed in the claimed portion of the invention without anything else in the said product. However, the question remains whether the said test is determinative one even in cases where there exists a patented claim for a product and another product which may substantially contain the patented product but also contain some other variants or some other parts in addition to the patented article or product. I think this requires some discussion as the answer to this question will enable this Court to determine in the infringement in instant case as well. The enquiry as to answer to this question gains importance in view of the finding arrived by me above that it has been established on record that the plaintiff's product is a Polymorph B version of the compound due to manifold reasons explained above. Therefore, the answer to this question will aid the decision of the

infringement in the instant case too.

231. True, it is that the Court has to strictly follow what is claimed in the invention and compare it with the product which is alleged to be infringing the patent. But the said rule of construction is not without an exception. There may arise certain cases where the product which is alleged to be infringing does not completely correspond to what has been claimed in the patented invention of the product. The product may be deemed to be substantially containing the patented product but also contain some parts or variants other than the same also. The Courts have in those cases developed a different rule of construction of the patent claim and specification which is a slight departure from what has been stated by the plaintiffs in the present case.

232. The Courts in such cases have evolved the rule of the purposive construction of the patent claim so that in the cases wherever the need be, the claim in the invention is not construed too narrowly which was never the intention of the inventor and not the purpose of the said invention so that the maximum benefit should be given to the inventor by not interpreting the patent claim in a pedantic manner and giving the same an effect which was the real purpose for which the product was invented in furtherance of the practical approach.

233. The said rule of purposive construction was used for a long period of time in the Court of appeal in England and time and again the same was approved to accord the benefit wherever possible to the inventor of the patent. However, the Courts have from time to time thereafter also faced a situation where the resort was taken to such construction of the patent claim in order to enlarge the scope of the patent, which was never the intent or the

purpose of the said invention, the Courts also came across the cases where the properties and characteristics of the product significantly varied from what has been claimed in the patented invention. Those were the cases where the alleged infringing product contained some additional variant or the part in addition to the product or process under patent, the Courts in such a case answered the said question by laying down that much shall dependent upon the role of the said variant in the said product. The cases in which the role of the said variant is inconsequential in nature and does not change the nature and characteristics of the article, then in those cases, the product in question is an infringement of the patent, in all other cases, where there is a role of such variant which may alter the characteristics and quality of the said product or process, there is no infringement of the patent. However, what is a role of such variant in each case is essentially a question of the fact and same shall depend upon case to case basis.

234. This rule of purposive construction aimed at following the practical approach by finding out the purpose behind the invention was laid down by Lord Diplock sitting in House of Lords in the famous case of *Catnic Components Ltd & Anr v. Hill & Smith Ltd*, (1982) RPC 183. In the famous speech of Hon'ble Lord Diplock, it was observed thus:

“My Lords, in their closely reasoned written cases in the House and in the oral argument, both parties to this appeal have tended to treat “textual infringement” and infringement of the “pith and marrow” of the invention as if they were separate causes of action, the existence of the former to be determined as a matter of the construction only and of the latter upon some broad principle of the colourable evasion. There is, in my view no such dichotomy, there is but a single cause of action and to treat

it otherwise, particularly in cases like that which is the subject of the instant appeal is liable to lead to confusion”

He then further explained the applicability of the purposive construction in interpreting the patent specification and the claim in the following words:

“My lords, a patent specification is a unilateral statement by the patentee, in words of his own choosing, addressed to those likely to have a practical interest in the subject matter of his invention (i.e. skilled in the art), by which he informs them what he claims to be the essential features of the new product or process for which the letters patent grant him monopoly. It is those novel features only that he claims to be essential that constitute the so called “a pith and marrow” of the claim. **A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge. The question in each case is whether persons with the practical knowledge and experienced of the kind of the work in which the invention was intended to be used, would understand that strict compliance with the particular descriptive word or phrase appearing in a claim is intended by the patentee to be essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.**” (Emphasis Supplied).

The true question to be asked is thus in summary, whether the strict compliance with the particular piece of the claim language would be understood to be an essential requirement of this invention. The necessary understanding is that of those skilled in the art (though ultimately, as explained below, the final determination of the true construction is a matter for the Court, once properly instructed, and not witnesses.”

Lord Diplock then proceeded to lay down the exception to the said principle or true question by discussing as to in which cases the said question framed above will not arise. As per him, the said question of strict construction of the claim and generally understanding of the persons skilled in the art would not arise in cases where the variant which is included in the invention would have material impact or effect on the working of the invention. This is in a way exception to the rule of construction laid down by Lord Diplock which is in applicable where there exists a role of the variant which may have effect on the working of the invention. Lord Diplock propounded this approach by observing in the following manner:

“The question, of course does not arise where the variant would in fact have a material effect upon the way the invention worked. Nor does it arise unless at the date of the publication of the specification, it would be obvious to the informed reader that this was so. Where it is not obvious, in the light of then- existing knowledge, the reader is entitled to assume that the patentee thought at the time of the specification that he had good reason for limiting his monopoly so strictly and had intended to do so, even though subsequent work by him or others in the field of the invention might show the limitation to have been unnecessary. It is to be answered in negative only when it would appear to any reader skilled In the art that a particular descriptive word or phrase used in a claim cannot have been intended by a patentee, who was also skilled in the art, to exclude minor variants which, to the knowledge of both him and the readers to whom the patent was addressed could have no material effect upon the way in which the invention worked.”
(Emphasis Supplied).

235. From the reading of the aforementioned quoted illuminating observations of Lord Diplock in *Catnic* (supra), the following propositions can be deduced:-

- a) That there are exceptions to the rule of purposive construction of patent claim which was aimed at giving the benefit to the inventor even in cases where the product impugned does not strictly fall within the ambit of the patent claim.
- b) That much shall be dependent upon the role of variant attached with the invention which is claimed in the patent in order to arrive at the impugned product.
- c) There is a compartmentalization of variants, viz major variants and minor variants has been done by Lord Diplock in order to define as to the permissible extent of applicability of rule of purposive construction of the patent claim.
- d) In cases where the variant attached to the invented work which is in the form of product or process under challenge would have material bearing upon the working of the invention. In such cases, the rule of purposive construction is not applicable as in those cases the variant attached its role thereof would exclude the product in question from the ambit of the patented claim and thereby there will be no infringement of patent.
- e) The said rule of purposive construction is also not applicable where the invention itself is obvious to the person skilled in art.
- f) There is thereafter an exception to exception which is laid down by Lord Diplock so as to determine in which cases where variant is present, the said rule of purposive construction can still be applicable.

Those are the cases where it is proved on record that from the reading of the patented claim the patentee could not have intended to exclude the minor variants which to the knowledge of him as well as readers of the patent could have no material effect in the way in which the invention worked. The said exception can be sub-categorized into the following fact finding enquiry:-

- i) That one has to show by an evidence as to what is missing in the patented claim and the product in question is a minor variant;
- ii) That there could not have been intention of the patentee to exclude such minor variant from the ambit of invention;
- iii) That the said minor variant could have no material effect on the way in which the invention worked.

236. The presence of these facts collectively on record coupled with the positive evidence to the said effect would be determinative of the fact that the invention and the patented claim would subsume even the product which contains some minor variant and thereby it an infringement. This approach is popularly and widely known as Catnic approach as laid down by Lord Diplock as it was decided in the case of *Catnic Vs Hillsmith* (supra) and the later part of the tests relating to variants is known in UK as improver questions as the same was decided in the leading case of *Improver Corporation and Ors. v. Remington Consumer Products Ltd. and Ors.*, 1990 FSR 181.

237. There was lot of debate thereafter post Catnic decision as to whether the Catnic test and the rule of construction laid down in Catnic is the good

law or not in the House of Lords as well as in the Court of Appeal. However, the recent line of authority emerging from the UK has approved the Catnic approach and recently even the House of Lords again has put its judicial stamping on the test laid down by the Lord Diplock.

- a) *Assidoman Multipack v Mead* [1995] RPC 321 AT 328-337
- b) *Beloit Technologies Inc v Valmet Paper Machinery Inc (No.) 2*, [1995] RPC 705.
- c) The Court of Appeal also approved the same in the case of *Kastner v Rizla* [1995]RPC 585.

238. Thereafter, the House of Lords has more recently authoritatively confirmed in the case of *Kirin-Amgen vs. Hoechst Marion Roussel*, [2005] RPC 9 that Catnic approach is a good law by observing the following:-

“The Catnic principle of construction is therefore in my opinion precisely in accordance with the Protocol. It is intended to give the patentee the full extent, but not more than the full extent, of the monopoly which a reasonable person skilled in the art, reading the claims in context, would think he was intending to claim”
(Emphasis Supplied)

239. In view of the above observations and the line of authorities emerging from UK, it is clear that the test laid down by Lord Diplock in *Catnic* (supra) holds the field and is a good law. The said case of *Catnic* has been followed by the Indian Courts time and again while evaluating the patents in India so far as it relates to obviousness and infringement claims and therefore the approach laid down in *Catnic* is not alien to the Indian context and consequently can be conveniently relied upon by the courts in India. (See case **Bajaj Auto Ltd., State Of vs Tvs Motor Company Ltd, MIPR 2008**)

(1) 217 where Catnic case has been relied upon by the Madras High Court and same has been confirmed by the Division Bench while deciding the appeal on 18.5.2009, although it is another matter in that the case how the said approach was used depends upon the facts of that case)

240. To take the discussion further, the rule of purposive construction laid down by Lord Diplock does not rest here and the Courts have taken this test further in order to analyze the infringement claims in the future patent claims by applying conveniently either the rule or the exception or the exception to exception depending upon the facts and circumstances of the case as to in which case there are major variants added in the product or claim and in which case there are minor variants added to the patented claim.

241. Justice Laddie of Patent Court in UK applied the Catnic approach in the cases relating to chemical compounds in the case of **Merck and Co. Inc. Vs Generic UK Limited**, reported as 2004 RPC page 31. The said case gains its relevance as Justice Laddie laid down further test as to what the patented claim should contain in order to arrive at the finding as to whether the role of variants is sufficiently explained or not and further whether only the patented claim or specification is relevant for the purposes of construction or whether the attending circumstances can also be seen in the light of absence of role of variant which is improperly explained in the patented claim. The Judge answers the question by observing that the Court is not precluded from drawing an inference from the facts which co relate the patented claim with that of role of variants present in the impugned product and in those cases it cannot be said that merely one has to read the

specification and claim and compare it with the product in order to arrive at the infringement as by doing this the court would not be following the Catnic approach by not examining the role of existing variants in the product and its corresponding inclusion of the same in the patented claim depending upon whether it is a major variant or minor variant.

242. This discussion has been done by Justice Laddie in the following words:-

“38. The purpose of a patent is to convey to the public what the patentee considers to his invention and what monopoly he has chosen to obtain. These are not necessarily the same. The former is primarily to be found in the specification and the latter is primarily to be found in the claims. Although he is not deemed to be a patent lawyer, the Patentee should be taken to be aware of the primary and rather different purposes of the specification and the claims when drafting his patent. So the patentee must be taken to know the framework of form and purpose when he drafts his patent. It is his duty to communicate his invention and his assertion of monopoly to the public in language it will understand. He is warned by the Protocol that his exclusive rights will not necessarily extend to everything which from a reading of the specification it can be seen that he contemplated. Furthermore, the drafting of the specification and claims has to be considered against the background that no one is forced to apply for a patent or to seek as wide protection as possible. The patentee can be taken to be aware of the fact that there is always a balance to be achieved between width of protection and validity. It is up to the patentee to choose the level of risk he wishes to run.

42. Notwithstanding the adaptability of scientific language, the patentee is not expected to be omniscient or to exhibit superhuman thoroughness in drafting. He may not be able to foresee future developments which will be useable with

his invention but which make no material difference to the way it works. For example, the invention may relate to a mechanical device in which two parts are connected together. A new method of connection might not be covered by the exact words of the claim, but the notional reader would be reasonably confident that the patentee may choose a form of language which emphasizes which features of an invention are important and which are not. For example it is common to find claims which start with general description followed by “characterized in” followed by a list of features. The addressee would appreciate that the latter features are particularly important but the features before the words “characterized in” are less so. **If there is a variant to the latter which obviously does not affect the way in which the invention works, the notional reader may be reasonable confident that the inventor wanted to cover this variant as well. In these types of cases, the monopoly is likely to extend to the new variant.** (Emphasis Supplied)

43. In my judgment, the same principles underpin the Protocol. The aim is always to determine objectively from the words used particularly, but not necessarily exclusively, in the claim to what the patentee wanted to claim exclusive rights. The Protocol is directed at allowing protection for the discernible intention of the patentee, to be derived from the words used to express that intention.

45. The second sentence in the Protocol emphasizes the primary of the claim. The notional addressee is not expected to find the patentee’s presumed intention from the specification. In particular, as noted already, this sentence makes clear that just because a reading of the specification suggests that the patentee “contemplated” a wider protection than that set out in ‘the claims does not mean that he obtains that wider protection. The patentee is taken to know the rules. If he wants a monopoly which covers all embodiments which he contemplates may make use of his technical contribution to the art, he should use language

which conveys that intention to the notional reader and that language should primarily be found in the claims. It seems to me that this part of the Protocol conveys the same message as is to be found in the speech of Lord Cairns in *Dudgeon v Thomson* (87) 3 App Cas. 34 when he said that there is no such thing as infringing the equity of a patent”

49. Determining whether a skilled reader would conclude with reasonable confidence that a particular embodiment was one the patentee wanted to cover involves assessing all the facts of the case. The wording of the claims is the most important one, but is not necessarily determinative. Matters such as the way the inventor describes his inventive contribution and his explanation, if any, of how the invention achieves its claimed results are matters to be taken into account. The factors, and how they interrelate to each other, will vary from case to case.” (Emphasis Supplied)

243. From the above observations of Justice Laddie, it is clear that the wordings of the claims and specifications are important but are not necessarily determinative one and if the court has to conduct an enquiry in view of Catnic approach as to whether the benefit which was aimed by Lord Diplock by propounding the rule of purposive is to be given, all the attending facts and circumstances are to be given due respect besides the strict reading of the claims in order to objectively arrive at the conclusion as to what actually the patentee intended to include within the ambit of his patented claim. Justice Laddie thereafter compared /tested the said chemical compound on the basis of improver questions which are exception to the rule laid down in Catnic in the following words:-

“55. The first Improver question does not create a factual dispute which needs to be resolved in order to determine whether an embodiment outside the

contextual scope of the claim is within the monopoly created by the patent. It is only question (3) which determines construction. In most cases the answer to the first question will not be in dispute. If the variant does not work in the same way as the invention it cannot be within the scope of the patent. The patentee could not have intended otherwise. Thus a negative answer to this question will inevitably lead to the third and crucial question being answered in a way which excludes the variant from protection. But what if it is unclear to those skilled in the art whether the variant works in the same way as the invention, either because the way the invention works is not clear or the way the variant works is not clear, or both? In such a case it is impossible for it to be apparent to the reader that the limitations in the claim were not intended by the patentee. In other words, adopting the purposive construction set out in *Catnic*, the issue of construction must be answered so as to exclude the variant from protection. Much the same analysis applies to the second Improver question. Where it is not obvious that the variant works in the same way :

“..... the reader is entitled to assume that the patentee thought at the time of the specification that he had good reason for limiting his monopoly so strictly and intended to do so...” (per Lord Diplock in *Catnic* p.243)

56. Neither of these questions justifies the carrying out of experiments. At the most the answer to these questions provide shortcuts to the only important question namely question (3).

57. For the above reasons, if one is adopting the structured approach, it is only Improver question (3) which needs to be answered. However, it appears to me that there is one respect in which that question needs to be approached with caution. In formulating the questions, Hoffmann J. said he was applying the guidance in *Catnic*. There is no doubt that the binding

authority on construction in this jurisdiction is the latter case. That was confirmed by the Court of Appeal I Kastner v Rizla Ltd [1995] RPC 585. Yet there appears to be a potential difference between the way the issue of construction was put in Catnic to the way it is explained in Improver. Imagine the case where the notional skilled reader does not understand why the patentee put a limitation in the claim. According to Catnic, in such a case the limitation is effective because it is not “apparent” that the limitations “cannot have been intended by the patentee”. The variants will be excluded from the monopoly. By contrast the same facts would be answered differently if Improver question (3) is applied rigidly. Where the reason for introducing the limitation is unclear, the skilled reader could not say that he understood “that the patentee intended to confine his claim”. Thus improver question (3) would be answered in the negative and the claim will be construed to include the variants. I think that this difference is more imagined than real. At p.197 of Improver it appears to have been accepted that if the notional skilled addressee would speculate that the patentee had good reason for including the limitation in the claims, the limitation is effective. In other words the Catnic approach was adopted. (Emphasis Supplied)”

244. In view of the above stated observations of Court in Merck (supra) it is clear that the said Catnic approach is good law and can also be applied to the cases relating to chemical compounds. Even in the case of Merck & Co.(supra) Justice Laddie proceeded to apply the said test and came to the conclusion that there was no infringement in the said case as the role of variants outweighed the patented claim. This has been observed by learned Justice Laddie in the following words in para 67 by applying the Catnic approach and coming to the conclusion that further experimentation with the

reactants was never contemplated within the ambit of patented claim. In the words of Justice Laddie:-

“67. As Hoffmann J. said in relation to Improver question (1) whether use of a product or process outside the acontextual scope of a claim has a material effect on the way the invention works depends on the level of generality at which one describes the way the invention works. If in this case, the inventions consists simply of running a process for making alendronate in which the reaction is maintained in a fluid and homogeneous state, it is not disputed that using other sulphoic acids (as long as, when mixed with the other reagents, they are molten at the reaction temperature) will work the same way. Furthermore, it is also accepted that the processing and crystallization features of claim 1 can b modified within fairly wide limits without preventing the production of alendronate, at least in moderate quality and at moderate yield. However, if the invention consists of running a process for making alendronate in which the reaction is maintained in a fluid and homogeneous state so as to secure high purity and a yield of at least 85-90 per cent, it is by no means clear that making the alterations advocated by Mr Kitchin will result in a process which works the same way.”

245. Justice Laddie also came to the conclusion that in the said case of Merck (supra) it was not shown by evidence by the patentee about the role of variants existing in the alleged infringing products. This has been observed the learned Judge in the following words:-

“78. I was unconvinced by this cross-examination. Furthermore, I think it is important to appreciate that the test of obviousness in Improver question (2) cannot be the same test as used to invalidate a patent over published prior art. In the latter case it is enough to demonstrate that the reader of the prior art found the

prospects of achieving the desired result sufficiently encouraging to warrant trying it out, even if there are commercial reasons why going down that route is unattractive (see *Brugger v Medic-Aid*[1996] RPC 635, 661). Where however one is attempting to broaden the patent monopoly to cover variants which are not within the a contextual meaning of the claims, a higher degree of confidence of success must be involved. The reader must have little or no doubt that the variant will, not may, work in the same way to produce the same results. In my view, the distinction between the obviousness test for invalidity and the obviousness required for Improver question (2) is apparent from *American Home Products* paras [28] and [29]. The claimant gets nowhere near demonstrating the relevant level of confidence in this case. For example, for Professor Scott to say that he would be disappointed if he could not improve the yield and purity were another sulphonic acid to be used instead of MSA does not mean that it is obvious that such improvement would be achieved.”

“79. In my view it is not proved that the notional skilled reader would have even thought of substituting another sulphonic acid for MSA. The hesitation of Dr. Cunningham represented more closely the approach of such a reader. Furthermore, it is not proved that any skilled worker would have considered it obvious that replacement of MSA by another sulphonic acid would be so effective that it would achieve the same, or substantially the same, level of purity and yield promised by the patent. He would not have been confident that such substitution would produce such a yield and purity that the production of alendronate could be achieved in a one-pot process as promised by the patentee, rather than with a separate extraction and purification step (as in the CIPLA process) Improver question 2 is answered in the negative.”

246. The afore quoted observations of Justice Laddie make it apparent that

the test of obviousness to revoke a patent is distinct from the test of obviousness to a person to whom the specification is made available to arrive at the product containing variant is concerned. Both do not coincide and if the Court believes that they coincide then the Court will be giving much broader interpretation to claims on the basis of the teachings of the patent. This is due to the reason what can be obvious to a person to further work upon the invention may revoke the future patent but it cannot be said afortiori follow that due to the reason that it is obvious for such person, the said workings or variation done is subsumed within the patent claim itself. That is why, one finds the respectful agreement with the proposition laid down by Justice Laddie which is that obviousness as to revocation or for testing patentability does not coincide with the obviousness which may be required to a person to make a product containing variant after studying the patent.

247. To sum up this discussion on *Catnic (supra)* and *Merck (supra)*, at this stage, it is relevant to note the aforementioned observations of the Courts and also the test which is that in the cases where the product contains further variants or reacted versions of the compounds claimed in the patent, not merely the claim in the specification is relevant but also all the facts correlating the said invention with that of the role of such variant or reactant are also important and necessarily to be looked into by the Court seized of such kind of patent infringement suit while construing the patent specification vis a vis the product or process in question.

248. This persuades me to reject the first submission of learned senior counsel for the plaintiffs that the test is that the Court has to look into the claim and the product and nothing else and no further document can be

imported to draw such inference. As I have found during the course of my discussion above as held in the Merck(supra) that the claims are not always decisive, the factors which correlate the role of the variant and reactant with that of the patented claim are also relevant, therefore the Court can see all such documents and draw inference according after analyzing everything.

249. Let me now apply the tests laid down in Catnic (supra) and Merck (supra) to the facts and circumstances of the present case. As seen above, it is already established fact on the evidence that the plaintiffs are making a product which is a Polymorphic version B of the compound Erlotinib Hydrochloride in view of the plaintiffs inability to provide any positive evidence to dislodge the claim of the defendant that the plaintiffs are doing so and time and again maintaining that the Polymorphic version is subsumed in the underlying patent which is IN'774 and all other reasons discussed above. The stand what the defendant is taking is that the defendant is making what the plaintiffs are making which is the Polymorphic B version of the compound which was never intended to be included in the patent and does not even corresponds with the patent claim. To which, the plaintiffs' response is two-fold, first is that the defendant is making Erlotinib Hydrochloride which is under suit patent and the said position is thus disputed, second is that in any case whatsoever is the case, due to manifold reasons and admissions discussed and enumerated above, the defendant's Polymorphic version B if any shall still fall within the ambit of the suit patent. I shall now discuss both the said positions of the plaintiffs after applying the test of comparison in the present case.

It is the case of the plaintiffs that the plaintiffs are concerned with the claim 1 of the Compound namely Erlotinib Hydrochloride. It is seen that the

onus is on the plaintiffs to show that the said product of the defendant corresponds with the patent claim which is subject matter of IN'774. The said onus is an independent to that of what position defendant's take in the proceedings. As seen above during the discussion of Catnic principle which is that whether the patent claim subsumes the product or the process impugned is a matter to be examined from the standpoint as to whether the patentee could have reasonably included the said product or process in question which is he is impugning on the fair reading of the invention. the said onus is thus operating independent and dehors to the position which the defendant takes in the infringement action. This is due to the reason that it is the plaintiffs who are alleging that there is an infringement of the patent claim and not the defendant.

250. The plaintiffs in the instant case could have discharged the onus by way of establishment of the following facts which are germane to the present controversy:

1. By showing through the positive evidence which include the medical and clinical evaluation of the product of the defendant and all other facts incidental thereto to establish that the position which the defendant is taking that the defendant's product is a Polymorphic version B of the suit patent compound is incorrect and actually the said version is the same which corresponds with that of the plaintiffs patent. The plaintiffs do take the said position but not by way of showing the evidence of the nature stated in this point but rather taking another route of admissions, the impact of which shall be discussed later in this head.

2. If the plaintiffs were unsuccessful in doing above in the instant case, the plaintiffs could have then proceeded to approach the present proposition by establishing that the fact through giving some positive evidence in the form of depositions that how the role of the reactants with which the patented invention is reacted pursuant to the arriving at the product or process in question is bare minimal and the same is sufficiently covered within the ambit of the patented claim. As seen above in the case of Merck (supra) and Catnic (supra), this is essentially a question of fact. The said fact finding is impossible without the aid and assistance of the plaintiffs by showing the positive evidence towards the establishment of such fact. The positive evidence towards establishing the said facts could have been done by deposing on the following facts:

- The fact as to what is exactly claimed in the patent claim as a compound.
- The fact as to what is the actually the Polymorphic version B of the said compound Erlotinib Hydrochloride
- The fact as to how many reactants or variants with which the Erlotinib Hydrochloride as a compound is reacted with in order to arrive at the Polymorphic version B of the same.
- The fact whether the properties and the characteristics of the said compound changes or varies after the said variants or reactants are reacted with or not. The plaintiffs in order to show that there is an infringement should have deposed to the effect that the said properties and characteristics are not changed pursuant to the reaction.

- The fact that whether the change if any to the property or characteristic is based on the role of the reactant in the said process of crystallization or otherwise due to the presence of the main compound itself.
- The fact that the conversion of the Polymorphic version B from the main compound which is combination A and B is not based on the major reactants and the result of minor reactants or variants, the role of which is inconsequential to the products and thus the same is impliedly covered or purposefully covered within the purview of the claim contained in the specification.
- The fact that the defendant is making the Polymorphic version B and consequently on the basis of what has been deposed above is an infringement of the patent.

251. These are some of the facts which should have been deposed by the plaintiffs in order to discharge the onus of proof to show that there is an infringement done by the defendant by manufacturing the Polymorphic version B which is sufficiently covered in the main compound due to the aforesaid reason. The above stated list is not exhaustive but is inclusive in as much as the plaintiffs could have shown some other facts connected to the aforementioned fact finding enquiry.

252. Curiously, the plaintiffs do not adopt either of the route towards establishment of the facts in order to arrive at the infringement. I think there are certain reasons behind it which according to me are relevant for the consideration:

- If the plaintiffs could have followed point 1 approach, then by the establishment of the fact that what is contained in the product of the defendant is sufficiently covered in the suit patent by clinical examination of the product of the defendant, the infringement could have been proved on balance of probabilities. The only basis which is emerging for not following the said approach is due to the reason that the plaintiffs are themselves aware that the tablet version of the compound Erlotinib Hydrochloride cannot exist in the form as contained in the claim of the suit patent. This has been clear if one reads the US'221 wherein it is stated that after much reactions are done with several elements at the relevant temperature, the crystalized version and pure form of the Erlotinib Hydrochloride is arrived at which is sold in tablet form. As the plaintiffs were aware that the tablet form could not have contained the exact version of the claimed compound as they have themselves made the tablet in a stable form after obtaining a subsequent patent in US'221, corresponding to IN'507 which has been refused in India on the ground of Section 3(d) of the Patents Act 1970. Having known all this, the plaintiffs have consciously not followed the said approach 1 as enlisted above and rather followed a middle path on the basis of some existing facts by picking and choosing the versions of the parties from here and there in the collateral litigations. I think the same by itself is not sufficient discharge of the onus which is independently casted upon the plaintiffs to show that the invention of the plaintiffs under IN'774 subsumes the product in question of the defendant. Therefore, the plaintiffs have followed this indirect route by relying on some stands

taken in the case of the defendant from time to time and not by directly adducing any positive evidence to dislodge the defendant position that the drug in question is made on the basis of Polymorphic version B of the compound. The other reasons stated below would further unveil as what compelled the plaintiffs by taking such stand and not adducing the direct positive evidence towards the establishment of the facts essential and material to determine the infringement.

- The plaintiffs have not followed the approach 2 as the plaintiffs do not want to adduce an evidence to the effect that the role of the reactants or the variants attached to the said compound is minimal which though may somewhere include their Polymorphic version B in the suit patent compound but will directly affect their declaration made before the US patent office in US'221, as the same will undermine the novelty, inventive step of the said invention claimed therein. The fact of the claiming patentability in such Polymorphic version B itself is indicative towards drawing an inference to the effect that the role of the reactants or the variants and the experimentation thereof is not minimal to subsume the said version within the claim of Indian Patent. The said reactants and variants have major role as propounded by Lord Diplock as well as Laddie J in Catnic (supra) and Merck (supra) which will materially affect the working of the product as evident from the US'221 specification which reads that the said Polymorphic version B is more stable and consists of several steps of chlorination and then further reactions described in DW1/9, for which reason the said invention as the plaintiffs is new and persuaded them to file a

new patent in US in the year 2002 as well as in India. The question which can be then to be asked is if the role of the reactants was so minimal so as to subsume in the main compound, then how can the same very role of reactants to the compound can persuade the plaintiffs to secure the patent in US. What follows from the same is that the plaintiffs by securing the patent successfully in US, are not in the position to contend before this Court that the said role of reactants is minimal. That is the major reason why, the plaintiffs have not also not followed the approach 2 by way establishment of the fact finding as noticed above.

253. What is left by not following the above stated approaches is the case of the plaintiffs before this Court which is that the plaintiffs attempt to discharge this kind of independent onus by pinpointing the facts from here and there from the stands taken by the parties during the progression of the proceedings and calling upon this Court to draw an inferences as to the establishment of the infringement therefrom.

254. The plaintiffs have filed the affidavit of PW3 namely Mr. Nick Thatcher who stated to be a person who has qualified PHD on tumor immunology. The said PW3 states to be familiar with the Erlotinib and other quinazoline compounds in the treatment of the lung cancer. The said PW discusses what contains in the IN'774 by describing a formulation of the said compound. PW3 discusses about the role of the said compound in preventing human cancer. The said witness deposes that the Erlotinib is sold in tablet form. It is stated that European Medicines Agency and other references no references to the Polymorphic forms. The said witness however does not depose positively as to what is clinically and medically

correct position as to whether the drug Tarceva is a Polymorphic version B of the compound in the suit patent or not. The said PW3 nowhere relies upon any x-ray diffraction reports relating to the said deposition which could have clarified this aspect. Thereafter PW3 immediately proceeds to discuss clinical trials, the success of the medicine by deposing that Erlotinib is the only compound recommended for treatment of the cancer and that Erlotinib and Astrazeneca's Gefitinib are different. There is no whisper in the entire evidence relating to what exactly is the plaintiff's product and the defendant products and the approaches discussed above are completely missing. The said PW3 was cross examined in great detail where in some questions were asked relating to US'221 and about the existence of unstable version Erlotinib Hydrochloride in other form, the answers to which were avoided by stating I do not know, though in one answer the witness states that clinically the stability of the compound is not important factor, but it is unclear as for what purpose it is not important factor, in any case as the said portion also does not find any mention in deposition and thus the role of the said efficacy as stated in US'221 has not been defined by the witness either in evidence or cross examination. This strengthens the conclusion derived above that the plaintiff's inability to follow any of the approaches highlighted above leads to not discharging the onus of the proof.

255. Likewise is the evidence of Mr. Roger Griffin (PW2) who again discusses the summary of IN'774 by describing the chemical formulation as well as the structural depiction of the compound. The in between contents of the affidavit of Mr. Griffin are repetitive with that of Mr. Thatcher's affidavit. Thereafter, PW discussed about the obviousness aspect, prior art test, comparison with the other prior arts and thereafter discusses the

difference in the Erlotinib and Gefitinib. The said affidavit of PW also does not follow any of the approaches.

256. Lastly, PW1 Mr. Laud's affidavit as discussed above only deposes in relation to infringement of patent on the basis of what is depicted on the drug insert of the defendant's drug and what has been applied before the drug controller. The said affidavit nowhere provides any hint towards what exactly is the plaintiffs product or for that matter defendant so far as it relates to the question of Polymorphic version or otherwise. The said affidavit also does not address the role of the reactants in arriving at the Polymorphic version. The witness was cross examined by the learned counsel for the defendant where Mr. Laud says that he is not technical person etc.

The sum total of all this discussion would be that the plaintiffs have not been able to show by way of positive evidence as to what is the exact nature of the plaintiffs and defendant products which are being sold in the market, further, whether the said products corresponds exactly with the claim of the suit patent is also not established. The plaintiffs have not been able to provide any evidence as to whether the Polymorphic version if at all is included with in the same patent claim (except by making legal arguments and arguments on some alleged admission), if so, then what is the role of the reactants with which the claimed compound is reacted in order to arrive at the Polymorphic version and whether the properties and characteristic of the Polymorphic version corresponds with that of the suit patent. Consequently, the plaintiffs have not been able to discharge such onus of proof upon the plaintiffs in relation to establishment of such facts which would aid towards establishment of the infringement of the patent.

257. The answer to all these questions can be found if one reads the document DW1/6 which is the US221, placed on record by the defendant. The said patent was applied in the year 2002 which provides that the US 498 which corresponds with IN'774 relates Erlotinib Hydrochloride in the form of combination of Polymorphs A and B. However, it has been seen that by adopting the steps of chlorination, further steps stated in the said patent in requisite temperature, the Polymorphic version B of the said compound can be arrived at. Some of the excerpts from the said specification documents are worth noting and the same reads as under:

“The present invention relates to Polymorphs and methods for selective production of Polymorph of N- (3-ethynylphenyl)-6,7-bis(2-methoxythoxy)-4-quinazolinamine hydrochloride particularly in stable Polymorph form.

The present invention also relates to novel uses of N- (3-ethynylphenyl)-6,7-bis(2-methoxythoxy)-4-quinazolinamine in either its hydrochloride or mesylate forms, in an anhydrous or hydrous form as well as its various Polymorph forms in the treatment of hyperproliferative disorders, such as cancers in the mammals.

“It is accordingly an object of the present invention to provide a method for the production of Hydrochloride salt of N-(3-ethynylphenyl)-6,7-bis(2-methoxythoxy)-4-quinazolinamine in HCL form (formula 2) making it more stable for tablet and oral administration and consisting essentially of the stable Polymorphic form (Polymorph form B) as well as the compound in such Polymorphic form B and the intermediate Polymorph A in essentially pure form.”

“Stability of the hydrochloride compound is of concern for

its use in the treatment of the 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-methoxythoxy)-4-quinazolinamine exists in two Polymorph form A and B. this contrasts with the mesylate compounds which exist in three Polymorph states (mesylate Polymorph A B and C). Polymorph B of the hydrochloride was found to be thermodynamically more 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 the Polymorph B, particularly in tablet form and a method of selective production of the compound”

“The Hydrochloride compound disclosed in the US Patent no. 5747498 actually comprised a mixture of the Polymorphs A and B, which because of its partially reduced stability (i.e. from the Polymorph A component) was not more preferred for tablet form than the mesylate salt forms.”

“Specifically, the present invention relates to methods of produced the hydrochloride compounds forms of N-(3-ethynylphenyl)-6-7-bis (2-methoxyethxy)-4-Quinazolinamine and for producing the stable form B in high yield. The mesylate salt of N- (3-ethynylphenyl)-6-7-bis (2-methoxyethxy)-4-Quinazolinamine has been discovered to exist in at least three Polymorphic forms which have been designated A, B and C of increasing stability with different x-ray powder patterns.....” (note there are other paragraphs which compare such x-ray diffractions which are not reproduced for the sake of brevity.)”

258. From the reading of the afore noted paragraphs of the specification of US’221, the following facts can be deduced:

- The said compound namely N-(3-ethynylphenyl)-6-7-bis (2-

methoxyethoxy)-4-Quinazolinamine exists in different Polymorphic versions and what contained in US'498 which corresponds to IN'774 is a combination of the Polymorphic A and B version of the said compound.

- The stability of the compound varies with the existence in the different Polymorphic forms and the most stable is the one in form B which forms subject matter of US'221 and the same is rejected in India in the form of IN'507.
- The Polymorphic B version is preferred in tablet form over the combination form due to its reduced stability.
- Stability has been a matter of concerns for the patients.
- There are several steps involved in reactions of the said compound in order to arrive at the pure Polymorphic form B
- Not merely the form changes and the characteristic changes, but the working of the invention also changes as the dosage also gets affected by the change in the Polymorphic form B as stated above.

259. The above facts noted in the specification of US'221 are nowhere clarified by the plaintiffs as incorrect which are relevant to qualify the tests of the construction of their claim in the present suit patent. Upon the entire reading of the said specification of US'221 and the facts contained therein which are facts correlating the product in question with that claim of the suit patent, upon evaluating the current stand of the plaintiffs that IN'774 sufficiently includes Polymorphic version in oral arguments, it is difficult to reconcile as to how both the stands can co-exist and also the case of the plaintiff is believable.

260. Applying the Catnic approach, it is beyond the cavil of any doubt that either the said process of arriving at Polymorphic version B is stated to be innovative enough by the plaintiffs themselves to sustain a new patent or to be called as patent in itself or else the said role of the reactant could have been bare minimum in the said Polymorphic version B which means that the same can be covered in the suit patent. In absence of the explanation of the said role either as a major or minor reactants coupled with the fact that both in India as well as in US, the plaintiffs have applied for the patent for the said process and product separately than the underlying compound, the purposive construction of the claim and the specification of IN'774 clearly indicates that the said plaintiffs did not intend to include the Polymorphic version B in the suit patent IN'774. It can also be said that this will fall in an exception to the rule of applicability of the purposive construction as no benefit can be given to the plaintiff under the existing patent claim. This inference can be easily drawn in the absence of any positive evidence towards disproving the said fact by indicating that the role of the reactants was minimal and rather inconsequential. Resultantly, the plaintiff has not been able to discharge his burden towards proving an infringement of IN'774 committed by the defendant.

261. The plaintiffs can argue that the IN'507 which corresponds with US'221 which has been relied upon by this Court to infer the role of reactants have been rejected in India on the ground of Section 3(d) and obviousness and thus there was in fact no role of the reactants in the Polymorphic version and the said inference is incorrect. I think there is inherent defect in such an argument due to the reason that the mere rejection of the Indian Patent on the ground of new form of the old compound does

not automatically minimize the role of the reactant as inconsequential on basis of which the compound was worked upon. There may arise a case where the reactant role is still substantial in nature but they are mere workshop results and not innovative one which may exclude Polymorph from the suit patent and at the same time leads to rejection of new patent on the ground of being obviousness or lack of novelty.

262. In this context, I find my respectful agreement with to the test laid down by Justice Laddie (supra) in Merck which is that the obviousness in the context of the patentability cannot be equated with the obviousness in relation to person who is given a specification to arrive at the product containing variant is concerned. If in the later case, the said person has to do the further experimentation, then the same would fall outside the scope of the claim in the original patent. I therefore think the rejection of IN 507 does not affect the role of reactants which has been remained unexplained throughout the present proceedings.

263. Now I shall deal with the plaintiffs' attempt to show infringement and how the same does not discharge the onus of proof one by one. The plaintiffs have attempted to establish infringement on the basis of what has been written by the defendant on its packaging of the drug which is Erlotinib Hydrochloride and what has been declared by the defendant before the authority. It has been contended that the defendant has not made any reference any Polymorphic version of the compound anywhere on the product and therefore this Court should find that the onus as to establishment of the infringement to be proved. I think the existence of the said fact by itself does not establish infringement. It must be remembered that the

present claim of the plaintiffs is premised on the right of the plaintiffs in the patent of a chemical compound, therefore the infringement of the same has to be established by corresponding chemical analysis of the defendant's product and not by mere comparison of the labels, strips or what is written thereon to show that there is an infringement. The said description of the defendant's product nowhere indicates as to which form of the compound, the defendant is making. The defendant has categorically stated, it making Polymorph B version which corresponds to the Tarceva product, to which the plaintiff has not lead any direct evidence, therefore the mere comparison of trade description, label, drug approvals are insufficient to arrive at the conclusion as to infringement of what is claimed in the suit patent.

264. If at all there is a material on record which suggests that the defendant is making generic version of Tarceva product, even then the same by itself nowhere establishes infringement. This is due to the reason that the defendant has been able to show by x-ray diffraction as to what contained in Tarceva is the Polymorphic version B of the compound. Thus, again the plaintiffs' argument on this count fails and cannot enable this Court to assume infringement in the manner stated by the plaintiffs due to the reason that in the prayer, the plaintiffs sought injunction against the defendant in any manner infringing the legal rights in the drug Tarceva. In para-11 of the plaint, it is specifically stated that the plaintiffs are manufacturing the drug under the process of patented product. The said statement apparently untrue as it is evident as per material available on record that they are marketing the product under new version of Polymorph B for which the plaintiffs have registration in India.

265. The plaintiffs' argument that the defendant's witness is able to identify the formula of the erlotinib hydrochloride and thus the infringement should be inferred on the basis of admission is equally incorrect because the plaintiffs have knowingly sought to restrain the defendant from infringing the legal rights in the product Tarceva. The prayer as to infringement of Patent IN'774 is not mentioned in the prayer clause. After the discussion done under this head, it has been found that no such legal rights subsist in the product Tarceva which is a Polymorphic version B which was never intended to be included in the claim of the suit patent on the purposive construction of the claim. These attending circumstances clearly establish that on the date of filing the suit, the plaintiffs were aware that they are manufacturing and marketing the product under new/latest version of Polymorph B.

266. The plaintiffs' contention that the defendant's witness is able to admit that the active ingredient in the drug is Erlotinib Hydrochloride and thus the same is admission of the infringement. The said admission in my view is ambiguous and not clear and unequivocal as the admission of active ingredient in the product does not mean ruling out the role of the reactant or variant. On the contrary, there are specific depositions of Mr. Nangia to suggest that the change in characteristic of the product upon change from the one form of the suit compound to another in form of Polymorph B version. There are depositions of Mr. Nangia to the effect that there is no material on record to show that the compound get automatically converted into Polymorphic B version. In these circumstances, the mere admission of active ingredient will not lead to any inference as to infringement by the defendant.

267. The plaintiffs' contention that the defendant has not mentioned about the Polymorphic B version of the compound at anytime earlier by placing reliance upon drug approvals, patent applications and all other places in tabular form to show the alleged admissions. The answer of mine to this contention would be again that the plaintiffs have to first establish infringement on the basis of what is contained in the defendant's product and not what the defendant claims to be doing. The defendant might have been inspired by ongoing drug of the plaintiffs in the market which in fact the defendant is doing as the defendant stand before press and media is clear that the defendant is intending to launch the generic version of Tarceva Drug. In case, the plaintiffs were able to prove before Court that the defendant's products are not Polymorph B version but under the patented product of suit patent, the position would have been different. . However, until the plaintiff explains who is a patentee and is under duty to explain what exactly is contained in the drug and how the patent is being infringed in the said product by taking from what is contained in the drug, the defendant cannot be imposed the responsibility of remaining in non- denial mode. The question of admission and non denial would come when the plaintiffs explain everything as to constituents of the plaintiffs' drug and whether the same corresponds with the suit patent which is clearly missing in the instant case. Therefore, the said alleged admissions are inconsequential for the purposes of discharge of the plaintiffs' onus of the proof.

268. Further, the admissions which the plaintiffs are setting up are not the ones which are clear and unambiguous. There are chains of the facts which are to be established in order to show an infringement. Mere identification of

the chemical structure of the compound by the witness and reading along side with the fact that earlier in the written statement there was no reference of Polymorphic B version made by the defendant and to say that would lead to clear admission on the part of the defendant that what the defendant is actually making is the drug under the suit patent will not actually establish infringement. This more so, when the defendant is disputing such position till date in the arguments as well as there is a reference of the Polymorphic versions in the counter claim. In these circumstances, the admissions which the plaintiffs are setting up are not clear and unambiguous to draw such inference. This reasoning is in addition to the finding above which is more crucial that the plaintiffs being a patentee have to inform fully as to what contained in the drug and whether the same corresponds with the suit patent.

269. The argument of the plaintiffs that one compound has the ability to remain in two or more Polymorphic forms by stating that the compound will remain the same and its form shall change, the said argument again does not explain as what was the role of the reactants while arriving at the Polymorphic version B and how the said properties of the products under both the Polymorph are same. The positive evidence should come from the plaintiffs that the role of such reactants is inconsequential. But that is not so done in the present case, thus, the mere explanation that the compound will remain the same and only the alignment will change by citing the example of the apple is unconvincible in absence of the deposition specific to the instant case. I think chemical science is not so easy to propound a theory like this which is that the substance shall remain a substance but only alignment changes rather the change in alignment of the chemicals make lot of difference in the products, their forms, characteristics. Learned counsel for

the plaintiffs himself asked that the question in cross-examination from defendant's witness that diamond and graphite are two Polymorphic versions of the carbon in the cross examination. If the answer is in affirmative, then even if the plaintiffs have obtained the patent of the carbon and thereafter attempted to obtain the patent diamond separately by showing the working upon the carbon, the infringement has to be measured from by comparing the rights under the diamond patent vis-à-vis the product of the defendant and not by simply placing relying on the fact that the plaintiffs have obtained carbon patent and as the diamond contains carbon, therefore it will infringe carbon patent. This is due to the reason that the diamond is different in form, composition and its features than the mere carbon. Therefore, unless the plaintiffs explain from the purposive construction of the claim that the inventor intended at the time of framing of the patent to include such substance be it diamond in an example or Polymorphic B form of the suit patent in the suit patent, the said onus of the plaintiffs is not discharged. In the present case, the plaintiffs have not adduced any positive evidence to show the role of the major or minor reactant. On the contrary, the US'221 patent specification reveals that there are number of the steps involved in arriving at the Polymorphic version B. therefore, the argument of the plaintiffs that the compound patent will take care of the Polymorphic version in absence of the positive evidence is rejected.

270. The contention of the learned Senior counsel appearing on behalf of the plaintiffs that the Polymorphic form loses its significance when the said medicine is consumed and therefore what is left over is the suit compound, therefore the Court should infer the infringement. Again, the said submission does not addresses the key questions which are that why there is no positive

evidence defining clearly that the role of the reactants stated in US'221 is inconsequential in nature, the question that the tablet containing the Polymorphic version of the compounds contains reactants?, if so what is the role of the said reactants?, Whether the role of the reactants also leads to change in the working of the invention? The said answers are not coming forward rather it is evident for the reason given above that as regards the plaintiffs Polymorphic version B, positive results of invention came after filing of the said application for registration for Polymorph B.

271. Learned counsel for the plaintiffs has placed some reliance on the answers given by DW1 and 3 that the Erlotinib Hydrochloride is an active ingredient in the medicine of the defendant and the product in question arrives different Polymorphic forms of a compound are prepared in pharmaceutical sciences by re-crystallization of the main compound using different solvents under different temperature regimes. During preparation of Polymorph of a compound there is no chemical changes taking place on the molecule itself, however, during re-crystallization the molecules are re-arranged/re-oriented in a particular manner and it is this arrangement of molecules which is designated as a particular Polymorphic form of a compound. I think the same does not also rescue the case of the plaintiffs and that is what exactly, I have arrived at after discussing Catnic approach. The same has not been explained by the plaintiffs by defining the role of the reactants, rather there is contra evidence which shows such steps are material so such an extent which persuaded the plaintiffs to approach the patent office again to secure the patent from US and also an attempt of similar kind was made in India. Further, the said role of reactants stated in the specification would show that the reactants and steps mentioned in

US'221 leads to more stability and change in dosage etc which means that the said role affects the working of the invention. In such a case, the plaintiffs' argument cannot be acceded to.

272. The argument of dependency of working of one invention over the other has been raised by the plaintiffs by contending the defendant is surely infringing the suit patent as the Polymorphic version is a working upon the suit patent. I think the said argument would have been believed only when the plaintiffs would have shown that the role of such solvents and temperature conditions are inconsequential. But, the US'221 suggest that not merely the said solvents and steps mentioned therein are material but also affects the working, characteristics of the invention which takes it to another level. Then in such a case, the Polymorphic version B of the compound falls outside the scope of the patented compound as it was never intended by the plaintiffs to be included at the first place. Therefore, the said principle propounded by the plaintiffs does not aid the case of the plaintiffs for the purposes of discharging the onus of the proof as to infringement.

273. The reliance on the judgment of the US District Court in the case of, *OSI Pharmaceuticals LLC & Ors. v. Mylan Pharmaceuticals* will also not assist the case of the plaintiffs. This is due to the reason that in the present case after examining material evidence on record, I have found that the plaintiffs have not been able to discharge the onus as to establishing the infringement. The said judgment was rendered where the defendant admitted the aspect of infringement of the patent and also in the context of the law where both the patents US 498 and US'221 are valid and here in India the facts and circumstances are different. Moreover, the suit was also filed on

the basis of two registered Patent Nos.US-221 and US-613 of Poly-B. The defendant challenged only validity. In India, admittedly the plaintiffs' application for Poly-B has been rejected. Thus, the said judgment is clearly distinguishable in these circumstances.

274. Learned senior counsel for the plaintiffs has placed much reliance upon the order of the controller of the patent dated 15.12.2008 in pre-grant opposition wherein it was held that the Polymorphic version B is a new form of old substance and therefore, the same Polymorphic version has to be considered as the same substance which is subject matter of the suit patent, there is a deeming fiction in law to treat the suit patent compound and Polymorphic version B as a same substance and accordingly this Court should treat the putative state of affairs as the ones which have been conferred by the law to have been existing. I think there is no doubt that the Court has to treat the affairs as those treated by the law with no further enquiry so far as the fiction of the law is concerned. But let me see whether Section 3(d) talks about any such deeming fiction. For the discussion purposes, Section 3(d) is reproduced hereinafter:

“3. What are not inventions

The following are not inventions within the meaning of this Act,—

(a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;

[(b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;]

(c) the mere discovery of a scientific principle or the formulation of an abstract theory 2[or discovery of any living thing or non-living substance occurring in nature;]

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

Explanation : For the purposes of this clause, salts, esters, ethers, Polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;]”

Upon the mere reading of the provision Section 3(d) of the Act as well as the explanation appended thereto, it cannot be said that the provisions use the words “deeming” or “deemed to be”, rather the provisions states that the Polymorphic versions shall be considered to be same substance unless they differ significantly in properties with regard to efficacy. The said wordings used are “considered” and not “deemed to be considered”.

It is well settled principle of law that the Courts cannot under the premise of interpretation can read into the words in the provisions of the statute when they are not specifically legislated. The Court also cannot enlarge or limit the scope of the provisions by reading into something which is not present in the wordings of the Section.

Applying the same principle of law to the present case, when the legislature used the word considered unless the Polymorphic version differs in the efficacy, then the same shall be only considered unless the contrary is proved. But that does not mean that it shall be deemed to be for all practical purposes the same product or substance. Therefore, there is only a limited scope of consideration which is enacted in the form of explanation till the time the efficacy differences are shown and not the blanket fiction of law which has been enacted.

It is equally well-settled principle of interpretation that the fictions engrafted under the statute are to be given effect to by the Courts but by confining the scope, ambit and purposes for which the said fictions are enacted in the statute and not beyond the same. It is impermissible to extend the scope of the fiction beyond the purpose for which the said fiction has been enacted.

Applying the said principle of law to the present case, even if the fiction is engrafted under Section 3(d) to treat the Polymorphic version as a same substance, the said treatment has been accorded by the law only for the purposes of applicability of Section 3(d). The said limited fiction nowhere states and construed to mean that for all other reasons too including for the purposes of measuring the infringement of the patent, the said Polymorphic version B shall be deemed to the same substance.

Accordingly, I think reading the said explanation in the manner in which the plaintiffs are reading would amount to extending the scope of the fiction beyond the purpose which is impermissible in law. Therefore, this

fiction argument also does not aid the case of the plaintiffs in order to discharge the onus of the proof upon the plaintiffs.

I think the controller of patent had arrived at the finding in the pre-grant opposition order as he was not convinced with the evidence on record as available with him as to how the Polymorphic version B significantly differs from the efficacy and proceed to treat the same as same substance by not treating the plaintiff's case within the later part of the explanation which is an exception to the rule. At that point of time, the onus was on the plaintiffs herein and the applicant therein to discharge the said onus to the satisfaction of the controller to treat the case of the plaintiffs as the one which may fall in the later part of the provision. The plaintiffs were unsuccessful in discharging the said onus and consequently the finding of Section 3(d) was arrived at by the controller.

Turning back to the present case, here the onus of the plaintiffs is completely reversed, which is to establish the role of reactants are inconsequential which means that in the present case, the plaintiffs have to establish that the role of the reactants are such which is so immaterial or minor so as to show that the product in question is subsumed within the claims of the patent. The said onus has to be discharged by the plaintiffs independently by showing the positive evidence.

There is no merit in the submission of the plaintiffs that the plaintiffs failure to discharge onus to the contrary to show efficacy and ultimately a different substance before the controller may lead to automatically the discharge of onus to prove that the Polymorphic version B is the same substance as that of the claimed in the patent. I think both the onus is

different and distinct lied upon on the plaintiffs at different occasions. The failure to discharge the one cannot be equated to successful discharge of other when both are inconsistent to each other.

There may arise a circumstance that the product in question may not be so novel or obvious to the person or may not have industrial use or may be based on same substance (but not identical) and hence not separately patentable being not novel and at the same time, the said product also does not fall within the ambit of the previous patent too. Thus, in order to dislodge the said circumstance or eventuality, the plaintiffs have to establish independently that the product in question and the suit patent is the same by showing the role of the reactants. Therefore, there is no fiction argument which will work here to discharge the said onus.

275. There is an argument raised that the US'221 teaches a conversion from one form to another Polymorphic form B and does not inform about the separation. It has been argued that the defendant witness also admits so in its affidavit by using the term “transform” etc. I think this aspect is also based on some kind of admission. The reasoning of mine is the same as discussed above relating to other admission and the same also does not answer the key questions which should have been addressed by the plaintiffs themselves.

276. It is further submitted by the plaintiffs that the expert witness of the Plaintiffs, Dr. Nick Thatcher (PW3), who has himself administered TARCEVA® to patients and participated in clinical trials, has stated at several places in response to questions posed to him that the Polymorphic form of a compound has absolutely no relevance whatsoever to the

therapeutic efficacy of a product. (*Q. 26, Q. 73, Q. 91-96, Q. 112, Q. 115, Q. 154-157, Q. 168-169, PW3*). It is also stated that there is an evidence to show that the Polymorphic version B has no relevance to the efficacy of the product. It is also stated as under: The conclusions from the questions posed to PW-3 on this issue have been summarized for the convenience of this Court below:

- a. Polymorphism has never been raised as an issue in terms of patient benefits. (*Q.115, PW3*.)
- b. Polymorphism has never been raised as a problem in terms of the clinical benefits of Erlotinib Hydrochloride. Therefore, from the patient activity point of view, the issue of the stability of the compound in the suit patent (invented in 1995) in the tablet form is irrelevant. (*Q. 168, PW3*)
- c. If there was a clinical patient benefit difference based on Polymorphism of the Erlotinib Hydrochloride, it would have been known prior to commercial availability of the drug to expert and experienced clinicians such as PW3. (*Q. 169, PW3*)
- d. Even assuming, the compound was less stable than Polymorph B, if there was a reasonable expectation of anti-tumor activity the differences in stability may not be a big issue during clinical trials. In fact, there are some anti-cancer drugs, which on account of being unstable have to be protected from light during patient administration. (*Q. 155-156, PW3*)
- e. Further as borne out from the Investigators Brochure (*PW1/X2*), Erlotinib Hydrochloride was successfully administered in the

tablet form in trials conducted in 1997 i.e. two years prior to the invention of Polymorph B form of Erlotinib.

277. I think the reliance of the plaintiffs on the defendant's cross examination to this effect is a step towards the correct approach. But, it should have first come from the plaintiffs end as to for what role then the reactants played in order to arrive at the Polymorphic version B. How the same can be termed as inconsequential when the same affects the change in the property or form of the compound by making it solid, re-crystallized and pure, how the said reactants do not affect the working of the product materially when as per the plaintiffs own declaration before US patent office in US'221, the said reactions as steps make the compound the stable in form. If the answers of these questions would have been emanated from the plaintiffs in the form of depositions so as to establish that the Polymorphic version was intended by the inventor to be included in suit patent itself, the said onus could have been properly discharged. The said cross examination done of Mr. Thatcher does not aid the case of the plaintiffs towards establishment of all these material facts which the plaintiffs should have informed the Court in the detail in the evidence.

It is also submitted by the plaintiffs that the defendant's contention that the tablet form could not manufactured without the aid of the Polymorphic B version is factually incorrect due to the following reasons:

- i. Various modes of administration of the compound are mentioned including in tablets in the specification of suit patent of 1995 (*PW1/5*).

- ii. Example 20 of Suit Patent clearly demonstrates that Erlotinib Hydrochloride was in solid form.
- iii. PW2 had repeatedly reiterated that the specification is clear that Erlotinib Hydrochloride was in solid form (*Q. 73-74, PW2*).
- iv. DW 3 has reiterated that IN'774 results in solid form.
- v. Trials conducted on Erlotinib Hydrochloride in 1997, shows that Erlotinib hydrochloride were administered in tablet forms much before Erlotinib Hydrochloride in Polymorph B form was known (*PW1/X2*).

I think the aforementioned evidence is also one of the steps towards discharge of the onus lied on the plaintiffs. It may be the case that the suit patent may mention as example the mode of the administration in solid form, but that by itself may not establish that what contained in the plaintiffs' product is the same compound as claimed in the suit patent and not the Polymorphic version B. The establishment of the fact tablet was known in the year 1997 again nowhere indicates what is the current position in the market. I think that may be indicative of the only fact which is that somewhere down the line, the plaintiffs' suit patent contemplated an administering of the compound in solid form or tablet form, but thereafter this discussion ought to have been furthered by the plaintiffs by showing positive evidence as to what happens till date is the Polymorphic version B, the role of the steps mentioned in US'221 is inconsequential and no where affects the working of the invention, by not doing so, the onus of the plaintiffs even by placing reliance on the aforementioned facts still remains un-discharged.

278. In US'221 specification it is clearly revealed that the said patent IN'774 corresponding to US Patent No.US'498 is a mixture of Polymorph A&B. Therefore, the plaintiffs had knowledge that the hydrochloride compound in the suit patent was in the form of mixture of Polymorph A&B way-back in the year 2000 when the said application US'221 was made for registration. However, the said fact was not revealed by the plaintiffs either in the suit proceedings or in the pending application in the suit patent till the date of grant of suit patent i.e. July, 2007. It is not denied by the plaintiffs that the compound under the suit patent is not preferred form for making tablets. The B-Polymorph form as admitted in US'221 is more stable and also suitable for making tablets. Significantly, in plaint the plaintiffs chose not to provide the XRD graphs and data of the product "Tarceva" although in the said US Patent No.6900221 the plaintiffs have provided XRD data of both A&B Polymorph forms and which were readily available to them at the time of the filing of the suit.

The defendant in its evidence has been able to prove that Tarceva tablets which are sold in India are wholly B Polymorph of the hydrochloride salt of N-(3-ethynylphenyl)-6, 7-bis (2-methoxyethoxy)-4-quinazolinamine. Under these circumstances, it is clear that the plaintiffs are not manufacturing the drug wholly B Polymorph which was invented by the plaintiffs after filing the applications for registration in US'498 in the year 1995 and in India in the year 1996 and they are using the latest version of B Polymorph. In normal case, this Court would have agreed with the argument of the plaintiffs that at the time of deciding the issue of infringement, the claims are to be interpreted with the product of the defendant. However, in the present case, due to peculiar facts and

circumstances of the case, it became necessary to find out as to whether the plaintiffs were marketing the drug covered under the suit patent strictly or Polymorph B version as in the plaint, there was totally non-disclosure of the US Patent 221 as well as pending application No.IN/PCT/2002/00507 for Polymorph B. The plaintiffs were totally silent on these aspects from the day the matter was filed in March, 2008.

279. As seen above, the plaintiffs have taken an indirect route of showing admissions, attempting to establish infringement by the look and the feel of the product as well as calling upon this Court to assume infringement on the basis of the fiction of law, I think the said indirect route does not discharge the burden of the plaintiffs which is independent and upon the plaintiffs. The admissions which the plaintiffs are again and again emphasizing are all ambiguous and disputed by the defendant here and there, the fiction argument I have already dealt with, the claim interpretation also does not reveal that the product in question falls within the ambit of the patent as the rules are different when the product contains certain variants which is apparent from the discussion done above. The sum and the substance of the entire discussion is that the plaintiffs have not indulged into the clinically examining the defendant product by pointing out as to what exactly the defendant is manufacturing a Polymorphic version B or the combination of A and B, on the other hand, the defendant has been able to provide the x-ray diffraction by the evidence of DW1 Ms.Shashikala which gives a hint towards the fact that the trends taken in x-ray are the same which are mentioned in US'221 which is relating to Polymorphic version B and there is no cross examination on this aspect by the plaintiffs' counsel and no attempt has also been made to dislodge the same.

280. The plaintiffs have admittedly no registration of Polymorph B version. In fact, the plaintiffs filed the application for registration of the same under No.IN'507/DEL. The same was opposed by the defendant. The said application was rejected on the ground that it does not qualify the requirement of Section 3(d) of the Patents Act, 1970. In India, Section 3(d) of the Act does not qualify variant of a basic drug Molecule unless such version shows an enhanced therapeutic efficacy. Though the said application was corresponded with the US'226 application patent of which was granted by US Patents Office who has accepted the claim of the plaintiffs for the same enhanced therapeutic efficacy, the detail of which is already referred in paras-257 & 258 of my order.

After rejection of the said application by the Controller of Patents in India, his order was not challenged by the plaintiffs in higher Court. It is pertinent to mention here that the condition similar to Section 3(d) in Indian Patents Act is not the law in US. No suit for infringement of patent is maintainable unless the patent is registered.

281. The contention of the learned counsel for the plaintiffs is that prior to January, 2008, the defendant was unaware of the existence of Erlotinib Hydrochloride in Polymorph B version, nor the defendant has taken the plea of marketing its product in the written statement under the said form. However, the said plea was taken later on. The entire story with regard to the marketing of Polymorph B form is cooked up by the defendant at the later stage. The said defence was taken by the defendant after having come to know about the registered patent of the plaintiffs US'221 and the pending application of the plaintiff in India bearing No.IN'507/DEL. The said plea

raised by the defendant is totally an after-thought. It is further urged by the plaintiff that even otherwise the defendant could not have arrived at Polymorph B form of the Molecule without crossing the stage of preparation of combination of Polymorph A & B. Therefore, Polymorph B version would still be infringement of the suit patent which was not restricted to any particular polymorphic form.

282. As example 20 of the suit patent disclosed and characterized the physical state of the claimed compound as solid by its melting point. From the testimony of the witnesses of the plaintiffs, it is evident that the plaintiffs have not proved in evidence that they are marketing their product Tarceva other than Polymorph B version. Similarly, no evidence has been adduced by the plaintiffs in order to prove that the defendant's product namely ERLOCIP is other than Polymorph B version. The only explanation given by the plaintiffs at the time of arguments in this regard is that the suit patent was not restricted to any particular polymorphic form and the defendant could not have arrived at Polymorph B of Molecule without crossing the stage of preparation of combination of Polymorph A & B.

283. The defendant many times at the time of arguments has not denied the fact that the defendant is marketing its products under Polymorph B version which is similar to US'221. The justification given by the defendant is that since the patent application of the plaintiffs bearing No.IN'507/DEL which corresponds to 221 has been rejected by the Controller of Patents in India, the defendant is entitled to manufacture and market its product under Polymorph B version. Not only that the statement was also made by the learned counsel for the defendant that any injunction passed on such patent

will not effect the business of the defendant, as it is marketing its products in Polymorph B version. According to the defendant, the plaintiffs have intentionally made the prayer in the plaint to restrain the defendant from infringing the Tarceva product of the plaintiff as on the date of filing of the suit the plaintiffs was aware that the Tarceva is marketed under Polymorph B version.

284. This Court is conscious about the fact that a monopoly of the patent is a reward of the inventor and there must be presumption of validity of the patent but at the same time, law mandates that the Court must look at the whole case, the strength of the case of the patentee and the strength of the defence raised in the matter.

285. In these circumstances, in the absence of the discharge of onus of proof by the plaintiffs which was independently lied upon them, the plaintiffs have not been able to establish the infringement of the IN'774 on balance of the probabilities. Therefore, the said issue is answered against the plaintiffs and in favour of defendant.

286. To sum up the findings arrived under this head relating non establishment of the infringement of suit patent IN'774 is based on the following attending circumstances:

- The establishment of the fact on record that the plaintiffs' product Tarceva does not corresponds exactly with the suit patent IN'774 but is a Polymorphic version B of the suit compound.
- On the purposive construction of the claim of the suit patent IN'774 as per Catnic approach, it has been found that the plaintiffs

never intended to cover the Polymorphic version B of the said compound under IN'774 as it is apparent from the facts correlating the product with that of the claim in the suit patent which are that the plaintiffs have separately filed patent for Polymorph B in US and India separately.

- The plaintiffs' inability to show the role of the reactants or variants as major or minor at the time of establishing infringement which could have enabled this Court to persuade that the said Polymorphic version B was intended to covered within the ambit of the suit patent IN'774.
- The plaintiffs' failure to examine the product of the defendant's clinically, file depositions thereto by establishing that the product of the defendant is actually covered within the suit patent IN'774.
- The plaintiffs' non-denial of the fact that the Tarceva is based on the Polymorphic B version and non traversal to the defendant's position that the defendant product is not actually Polymorphic B version but is the one corresponding the suit patent.
- The plaintiffs maintaining the position that the Polymorphic version B was intended to be covered within the purview of the claim of the suit patent without establishing and defining the role of the reactants as major and minor.
- The plaintiffs' inability to justify as to whether the Polymorphic version of the said compound affects the working of the invention materially or not.

- The existence of the attending circumstances like specification of US'221 which clearly provides that there are reactions done to the suit patent compound subsequently which makes the product under the Polymorphic version B more stable which lead to the conclusion that not merely the role of such reactants are major but innovative enough to call it as a patent in itself. The said US'221 also reveals that the working of the product like dosages and form like tablet one also changes than the earlier one.
- The factum of the rejection of the separate patent IN'507 filed in India which was the attempt of the plaintiff's to seek the separate protection to the Polymorphic version B. this is again indicative of the fact that the plaintiffs as a patentee never intended to include the said Polymorphic version B in the suit patent but always intended to treat the same as a separate invention. The plaintiffs' rejection of the patent in IN'507 is due to the reason of failure of the plaintiffs to satisfy the controller as to efficacy part under the explanation appended to Section 3(d) and the said order has attained finality.
- The plaintiffs' inability to show the positive evidence to establish as to how the statements made in US'221 are not relevant especially when the role of the reactants and workings are clearly defined therein. The plaintiffs could have done so by their own defining the role of the reactants and their effect on the working by leading contrary evidence.

- The plaintiffs not following the direct approach of establishing the infringement by clinically examining the product and taking the indirect route of showing the admissions and orders, product packaging in order to call upon this Court to infer such an infringement.
- The plaintiffs' inability to discharge its onus which is independent to that of the stand of the defendants on their own by establishing the infringement.
- The plaintiffs being themselves being aware of the fact that the suit patent does not corresponds with the Tarceva drug and thereby seeking the prayers in the suit relating to legal rights of Tarceva drug and not seeking the prayers as to infringement of the Patent.

All the afore mentioned attending circumstances, coupled with the other reasoning discussed above and the lack of evidence clearly enables this Court to arrive at the finding that the plaintiffs have failed to discharge the onus of the proof as to establishing the infringement of the suit patent IN'774 in the present case. The present issue No. 1 is answered accordingly.

Issue No.3

287. In view of my findings arrived at on issue No.1, the plaintiffs are not entitled for permanent injunction as prayed as in the present case. As discussed earlier that in the plaint reads that the permanent injunction is sought against the defendant calling upon the Court to restrain the defendant from manufacturing the generic version of drug Tarceva and violating the legal rights in the drug Tarceva. It has been established on record on balance

of the probabilities in view of the answer of issue No. 1 which is in negative that the defendant is not infringing the IN'774 as the tablet Tarceva consists of Polymorphic B version of the compound namely N-(3-ethynylphenyl)-6-7-bis (2-methoxyethoxy)-4-Quinazolinamine. Accordingly, no protection in the form of permanent injunction can be granted.

Issue No.5

288. The issue No.5 relates to relief which may include damages or rendition of the accounts. The plaintiffs have sought the exemplary damages on the basis of the violation of its Patent rights in IN'774. I have already come to the finding that the plaintiffs have failed to discharge the onus of the proof as to show the infringement of the IN'774. Accordingly, the discussion as to the aspect of calculation of damages and prayer for damages is not warranted. The prayer of damages to the plaintiffs is accordingly rejected.

Issue No.4

289. Now I shall proceed to answer issue no. 4. The said issue no. 4 reads as under :

“Whether defendant/counter-claimant proves that the plaintiffs’ subsequent US Patent 6900221, is to the effect that the compound of claim No. 1 of the suit patent is a mixture of two Polymorph A and B Compound and need to be separated to perform and get the claimed compound for acceptable efficacy; and its effect on the plaintiffs’ patent? OPD”

290. The afore noted issue can be classified into two parts:

- Whether the defendant has proved that the plaintiffs' subsequent US patent 6900221 is to the effect that the compound of claim no. 1 of the suit patent is a mixture of the two Polymorph A and B Compound
- Whether the defendant has proved that there is need of separation to perform and the get the compound of acceptable efficacy and its effect on the plaintiffs' patent.

291. I will now answer the said issue collectively as both are interlinked to each other and classified only for the purposes of understanding.

292. The onus to prove this issued was on the defendant.

293. Once I have held that the plaintiffs themselves are not able to explain the role of the existing two patents in US'498 and US'221 and in India in IN'774 and IN'507 and also not able to reconcile as to for what purpose the two patents were applied for. The plaintiffs should have shown by way of the positive evidence, what was the role of the reactant as contained in US'221 in arriving at the Polymorphic tablet version of Tarceva drug and how the said version is covered in the suit patent. In the absence of such exercise done by the plaintiffs. I find that there is no need for the defendant to further establish to the contrary by showing the same.

294. I find to limited extent the defendant has been able to discharge the onus by relying the specification of US'221 and comparing it with the plaintiffs product Tarceva in the evidence of Ms. Shashikala PW2 and proved that the plaintiffs product as sold in the market is Polymorphic version B and trends in the x-ray defraction corresponds with what has been contained in US'221.

295. Therefore, it is clear that the defendant has been able to discharge the onus to show that the plaintiffs' suit compound is a combination of A and B and the compound need to be converted or separated in order to arrive at the Polymorphic version B. I find that though there is no need for the defendant to show by way of positive evidence that clinically the said Polymorphic version needs to be separated or converted in strict sense of term in the present case, unless the plaintiffs could have shown at the first place that the said Polymorphic version B is covered within the suit patent, which the plaintiffs are incapable in the instant case. Hence, I find that the existing depositions and the statements made by the plaintiffs in US'221 are sufficient evidence in this case at least to displace such onus especially in the light of the negative answer coming in relation to issue no. 3 relating to infringement.

296. Now I shall deal with the submission of the learned counsel for the plaintiffs in relation to the present issue which are as under:

- Firstly, the learned counsel for the plaintiffs relied upon the rules of construction of the specification as done above for infringement to urge that the Court has to see the specification and not to rely on other documents to draw the inference. I have already answered the said submission under the head of the infringement that the tests vary from case to case basis and where there is a product containing variants, the tests laid down in Catnic (supra) are applicable.
- Secondly, learned counsel stated that the evidence of the defendant is inaccurate and improper to establish the present issue. I tend to

somehow agree with the learned counsel for the plaintiffs that the evidence is not too strong to establish to the certainty about the same but it's not too weak either especially in the light of the facts of the present case. I find that the case in hand is peculiar to its own facts wherein the plaintiffs are not able to explain and show that the suit patent includes the Polymorphic version B of the compound. Once, the plaintiffs themselves are not able to show the same, I think the evidence of this kind may work towards the discharge of the onus of the proof lied on the defendant.

- Learned counsel for the plaintiffs argued that no external aid of construction can be used to draw an inference against the plaintiff. I have already answered this submission under the infringement head wherein I have stated that overall facts and the facts correlating the invention with that of the product containing variants are relevant and material facts and can be looked into by the Courts. Thus, no such impediment exists in law to preclude this Court from looking US'221 while construing IN'774 and claims mentioned therein.
- The judgments relied upon by the plaintiffs like *Glaverbel v. British Coal Corporation*, 1995 RPC 255 at pp. 268-270; *Pfizer Inc. v. Ranbaxy*, 457 F.3d 1284 at p. 1290; *Abbott v. Dey*, 01-1374 at pp. 11-13. [reported as 287 F. 3d 1097 are all distinguishable on facts as in one set of the facts, there may be need to accord literal interpretation and in another *Catnic* approach is required to be looked into and considered. Both are followed by the Courts in UK

including House of Lords. Thus, I do not find that the said judgments are not laying correct law but the same are clearly distinguishable in the present facts in view of Catnic approach (supra) which has been followed consistently and even in relation to chemical compounds in Merck (supra) following catnic in the cases relating to chemical compounds.

- Learned counsel for the plaintiffs argued that the inventors of US'221 believed that Erlotinib Hydrochloride would exist in many other Polymorphic forms, it has been categorically stated in US'221 that the compound of claim 1 of US'498 was found to 'comprise of' Polymorphs A and B which can be distinguished from 'consists of'. I think one cannot read the words used in the specification like that of the statute. The argument that comprise may be construed to mean that the said patent may contain other forms other than combination of A and B is untenable. If that is so, then the next question arises that where was the occasion for the defendant to take a separate patent US'221 calling the process and product arrived at consequent upon reactions as Polymorphic version B as novel compound. Therefore, this kind of interpretation cannot aid the case of the plaintiffs.
- Learned counsel pointed out weaknesses in the defendant's evidence by arguing that the defendant has not carried out any independent study, the defendant witnesses stated that they are not conversant with the patent law, the conduct of the defendant is bad etc. I have already addressed on the weakness of evidence by

observing that the in the light of the emerging position in the present case, the said evidence though weak is sufficient to discharge the onus.

- Learned counsel for the plaintiffs argued that the subsequent statements made by the plaintiffs cannot be construed as admissions to limit the claim of the suit patent. I have already answered this submission that all the attending facts are relevant to draw an inference. This Court is not coming to finding on the basis of the admission but drawing an inference after evaluating the evidence of the parties and looking into the facts preceding and posterior to the filing of the patents in India and US as to what can be the possible interpretation of the suit patent as contained in claim 1.
- Learned counsel for the plaintiffs argued that there are admissions made by the defendant in the opposition proceedings by reading the pleadings of the plaintiffs in opposition proceedings. I would say that the same are not admissions as the defendant while contesting the opposition has merely stated that the IN 507 may not be allowed as the same lacks efficacy and in a way same substance to that of the Erlotinib Hydrochloride. However, that by itself does not mean that the defendant could not show before this Court that the US'221 relates to Polymorphic version B and IN'774 relates only the main compound and both though relates to same compound but there is a need of conversion or separation. I think the argument of admission is totally misconceived as the

same relates to opposition proceedings containing separate onuses vis-à-vis these proceedings.

- Learned counsel for the plaintiffs argued that the interpretation given by the defendant to US'221 is erroneous and the defendant has failed to prove this issue in as much as US'221 teaches that by a process of re-crystallization, Erlotinib Hydrochloride in Polymorph A and B form, is **converted** to Erlotinib Hydrochloride in pure Polymorph B form (*DWI/9*). It is pertinent to note that US'221 teaches **conversion** and not **separation**. I think the plaintiffs are going into the issue of use of the wordings in the issue framed and in the specification. Whether the said compound is covered or separated, the moot question is that there is something which is done besides the compound as contained in the suit patent in order to arrive at Polymorphic B. if the answer is in affirmative, I think, the onus is discharged. I therefore find no force in the present argument as the defendant has to prove the case on balance of probabilities and not beyond reasonable doubt especially when the plaintiffs have failed to discharge any such onus as to show the infringement.
- It is also stated that the defendant ought to have conducted the surveys to show that the efficacy wise, the suit patent and its Polymorphic version are different rather than merely relying upon specification. I think this could have been valid criticism from the plaintiffs' side when the plaintiffs themselves could have been discharge the onus that both the Polymorphic version and the

patented compound are same. As the plaintiffs have not done so at the first place by clinically and medically examining the product, I think it does not lie in the mouth of the plaintiffs to criticize the defendant's evidence on this count.

- It is argued by the learned counsel for the plaintiffs that the stability which has been mentioned in US'221 relates to the stability in storage. It has been canvassed that the statements contain the specification of US'221 are misread and misinterpreted. The plaintiffs have sought to give their own interpretation to the specification during the argument. I still find that the overall reading of the specification of US'221 indeed shows that there are certain steps which are to be taken in the form of further reactions to the compound claimed in suit patent in order to arrive at the Polymorphic version. The factual dispute, which the plaintiffs are canvassing now either should have been shown by adducing an evidence, which is relevant here as well as in the infringement action as what role these reactions, steps played in the working of the invention. The reactions or variants are shown in the specification playing a significant role which changes the form of the compound from one to another as well as also changes the advantages by making it more stable as stated therein. Therefore, these trivial aspects may not lead to any change in the case and the same are irrelevant.
- Learned counsel for the plaintiffs has placed reliance of the order of the Controller in the opposition to IN'507 as well as some

statement made by the defendant where it is contended that there is no therapeutic efficacy increase between the suit compound and the Polymorphic version B. It is correct that there are inconsistent stands are taken by the defendant but the same are to be evaluated in the light of the overall facts and circumstances. The stand taken by the defendant itself does not lead to an inference when there is a material on the record suggesting contrary. The specification to US'221 and thereafter the affidavit of Mr. Nangia and Ms. Shashikala DW3 and DW2 clearly proves otherwise. In these circumstances, drawing an aid from opposition proceedings and treating it as admission by ignoring the evidence of the present proceedings shall be a far-fetched argument.

297. So far the order of the controller of patents holding that the Polymorphic version is violative of Section 3(d) of the Act, I have already observed that the finding is arrived by the controller after being dissatisfied that the plaintiffs case falls within the later part of the explanation appended to Section 3(d). The plaintiffs if were dissatisfied with the findings should have challenged the same before High Court which the plaintiffs have not done so. Under these circumstances, the plaintiffs' inability and suffering an adverse finding upon not satisfaction of the controller cannot lead to straight conclusion that the Polymorph version B and suit patent coincide or they are the same substance. The same has to be proved by the plaintiffs in accordance with law and that is the reason why the plaintiffs are not able to make out a case for infringement of patent. Thus, the said order also does not rescue the plaintiffs automatically to dislodge the evidence lead by the defendant.

298. I have addressed almost all the submissions advanced by the learned counsel for the plaintiffs. I think there are some submissions which are quite repetitive and are common to this issue as well as the infringement issue. Therefore, the cross-reference can also be made between the two issues in order to find out the answers of the same as the necessity of deciding this issue rests on the strength of the evidence which the plaintiffs have lead in order to establish the infringement of the patent.

299. In view of the abovementioned discussion, I hold that the defendant has proved that the plaintiffs' subsequent US'221 patent contains the admission on the part of the plaintiffs that claim No.1 of the suit patent is a mixture of two Polymorph A&B and US'229 patent has an effect on the suit patent of the plaintiffs. The issue is accordingly decided in favour of the defendant and against the plaintiffs.

Re: Objections relating to marking of documents

300. Both the parties have raised certain objection with regard to marking of documents. There are certain documents which are not referred in the pleadings and the same are marked in the affidavits of the witnesses. I have seen the documents during the course of the proceedings which are mainly patent specifications, orders of the controller and the documents filed with the list of the documents filed by the parties. The said documents are, more or less, of the public documents in nature which are relating to litigation, which has happened between the parties and relied upon by the Controllers and Patent offices as well. Therefore, in case, there are pleadings pertaining to the contents of the documents, I am inclined to deal with the said documents which are in the nature of public/Government documents

considering the exposition of the law that the objections as to exhibit numbers does not necessarily mean that the Court will not apply its judicial mind which document to be looked into and which not. (See the judgment passed in the case of *Sudhir Engineering Company vs. Nitco Roadways Ltd*, 1995 (34) DRJ 86).

Public Interest and other submissions

301. There are other submissions advanced by the parties relating to the impact of the public interest on the grant and non grant of the relief of permanent injunction. Likewise, the plaintiffs have advanced the submissions as to the grant of the damages and costs. I find that the said submissions do not warrant discussion in view of the finding arrived by me in relation to issue no. 1 wherein there is no case made out for infringement, therefore, the question of grant of permanent injunction, damages or costs does not arise.

Conclusion:

302. In view of the discussions done above relating to the several issues, the following conclusions can be drawn which are enumerated issue wise:

1. Whether the manufacture, marketing and sale of ERLOCIP by defendant is infringing the plaintiffs' Indian Patent 196774? OPP

Issue No.1 is decided in favour of the defendant and against the plaintiffs.

2. Whether the Indian Patent 196774 is liable to be revoked on the grounds raised in written statement and counter-claim of the defendant? OPD

Issue No.2 is decided in favour of the plaintiffs and against the defendant.

3. Whether the plaintiffs are entitled to permanent injunction as prayed for? OPP

AND

5. Relief.

In view of the findings arrived at on issue No.1, issue Nos.3 and 5 are decided against the plaintiffs.

4. Whether defendant/counter-claimant proves that the plaintiff's subsequent US Patent 6900221, is to the effect that the compound of claim No.1 of the suit patent is a mixture of the two, Polymorph A and B Compound and need to be separated to perform and get the claimed compound for acceptable efficacy; and its effect on the plaintiff's patent? OPD/CC.

Issue No.4 is decided in favour of the defendant and against the plaintiffs.

303. In the result, both, the suit being CS(OS) No.89/2008 and the counter claim being C.C. No.52/2008 are dismissed. No order as to costs.

MANMOHAN SINGH, J.

SEPTEMBER 07, 2012