* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% *Judgment Reserved on : August 12, 2015*
Judgment Delivered on :November 27, 2015

\+ **RFA(OS) 92/2012**

F.HOFFMANN-LA ROCHE LTD & ANR. ..... Petitioners
Represented by: Mr.Pravin Anand, Advocate with Mr.Shrawan Chopra, Ms.Prachi Agarwala, Ms.Archana Shanker, Mr.Mahabir and Mr.Vibhav Mithal, Advocates

versus

CIPLA LTD. ..... Respondent
Represented by: Mr.Arvind Nigam and Ms.Prathiba M.Singh, Sr.Advocates instructed by Ms.Bitika Sharma, Ms.Jaya Mandella and Ms.Anusuya Nigam, Advocates

RFA(OS) 103/2012

CIPLA LTD ..... Petitioner
Represented by: Mr.Arvind Nigam and Ms.Prathiba M.Singh, Sr.Advocates instructed by Ms.Bitika Sharma, Ms.Jaya Mandella and Ms.Anusuya Nigam, Advocates

versus

F.HOFFMANN-LA ROCHE LTD & ANR. ..... Respondents
Represented by: Mr.Pravin Anand, Advocate with Mr.Shrawan Chopra, Ms.Prachi Agarwala, Ms.Archana Shanker, Mr.Mahabir and Mr.Vibhav Mithal, Advocates

CORAM:
HON'BLE MR. JUSTICE PRADEEP NANDRAJOG
HON'BLE MS. JUSTICE MUKTA GUPTA

PRADEEP NANDRAJOG, J. & MUKTA GUPTA, J.

1. Though at first blush the plot and premise of the Roche Vs. Cipla dispute appears to be straightforward – Roche claims that on March 31, 1991, it filed an application for grant of patent in USA pertaining to Erlotinib Hydrochloride, resulting in grant of patent US '498 on August 05, 1998. During pendency of its application in USA, on March 13, 1996 it filed an application in India for grant of patent for the same molecule which was granted to it vide IN '774 on February 23, 2007. The marketable physical form of the molecule comprised polymorph A and B. Further research revealed that polymorph B was more thermodynamic and as per Roche would qualify for enhanced efficacy and thus on November 09, 2000 it applied for grant of patent for polymorph B of Erlotinib Hydrochloride in USA resulting in grant of patent US '221. Similar application filed in India on February 06, 2002 i.e. DEL '507 was rejected. As per Roche, IN '774 granted in February 2007 by the Controller of Patents, per Claim No.1, covered patent rights over Erlotinib Hydrochloride molecule which has demonstrated breakthrough capabilities as an Epidermal Growth Factor Receptor (EGFR) inhibitor which spiked survival benefit in cancer including non-small cell lung cancer (NSLC) patients.

2. The issues which were finally debated before us in the appeal had various hues. The marathon hearings have resulted in both of us having before us several pages of manuscripts, bearing encouraging and tactful notes penned by us, as learned counsel Sh.Pravin Anand who appeared for

Roche and Sh.Arvind Nigam, Sr.Advocate and Ms.Pratibha M.Singh, Sr.Advocate who appeared for Cipla laboured through the case law, the provisions of the Patents Act, 1970 as amended from time to time, the pleadings of the parties, the various documents exhibited at the trial and the deposition of the witnesses of the two parties. We therefore begin by adequately thanking them in rendering valuable assistance. We are especially indebted to them for their uniform generosity and kindness shown to us with the most heroic reserve of patience in answering one simple but endlessly repeatedly question : '*But could you explain that again?*'

3. The endless labour by learned counsel, apart from making us understand the nuances of the law of patent, made us aware of something probably never highlighted about the Carbon atom. In the atomic world it would be the party animal, latching on to any atom it finds around it, including itself, and holding tight, forming molecular change – the very trick of nature necessary to build proteins and DNA.

4. Claiming that it was based on media intelligence declaring Cipla's intention to launch a generic version of Roche's drug based on IN '774, in January 2008, Roche moved this Court on its original side seeking to injunct Cipla from marketing Erlocip.

5. Roche's plea for interim injunction against Cipla was dismissed by a learned Single Judge of this Court on March 19, 2008, reported as (2008) 37 PTC 71 (Del) *F Hoffman-La Roche v. Cipla Ltd*, with a fascinating characterization of the public interest involved in, and the life-saving nature of, the drug in question playing a large part in the evaluation of the imponderables.

6. Roche's appeal to the Division Bench of this Court against the order passed by the learned Single Judge was dismissed on April 24, 2009, on the back of a heavily public interest-centric reading of the Patents Act, 1970 as amended from time to time, and a detailed discussion of the relative affordability of the two drugs to the common man; and the decision is reported as (2009) 40 PTC 125 (Del) *F Hoffman-La Roche v. Cipla Ltd*.

7. On the substantive legal issues, the Division Bench felt that Cipla had done enough to demonstrate a potentially credible challenge to the validity of IN '774, including raising sufficient doubt over whether IN '774 had complied with full disclosure requirements.

8. Roche's subsequent agitation of the matter on special leave before the Supreme Court was also denied. And the case moved to trial.

9. The learned Single Judge has answered two main questions in the impugned decision: first, whether Roche's IN '774 patent stands to be revoked; and second, whether the Cipla's manufacture of Erlocip infringes Roche's IN '774 patent. Other ancillary issues have also been decided to which we would be adverting to as we move along.

10. The decision of the learned Single Judge on the question of the validity of Roche's IN '774 patent has been largely defied by reference to Cipla's counter-claim in the suit, which contended that IN '774 contains no inventive step. This was for two main reasons – first, Cipla contended that the closest prior art to IN '774 was Example 51 of EP '226 (admitted as prior art in the IN '774 specification) and that the two had extremely materially similar, if not identical, structures. Cipla pointed to the fact that not only did the IN '774 specification fail to disclose how it was inventive over Example 51 but also that multiple examples cited in IN '774 were

specifically disclosed in EP '226, which was compelling evidence that IN '774 was more combination and less innovation. Second, Cipla – claimed that only meaningful difference between IN '774 and Example 51 of EP '226 – was the substitution of a methyl group with ethynyl at the third meta (3') position (*This was extended in the technical plane by Cipla to say that EP '226 teaches a methyl/cyano configuration which anticipates the methyl/ethynyl substitution on account of a property called bioisosterism (the cyano and ethynyl groups, in this case, are chemically similar and produce similar biological properties*). – a change so minor and so well anticipated by prior art that it would be obvious to a person skilled in the art on account of – a minimum of five prior art teachings, all of which suggested that the methyl/ethynyl substitution could be affected with no categorical loss of efficacy.

11. Roche's rebuttal to the counter-claim is centered on the comparative efficacy of IN '774 versus Example 51 of EP '226, which had been mapped according to inhibitory concentration, a parameter in reference to which the nearest prior art reference to IN '774 was EP '851 and IN '774 was inventive over it. Consequently, argued Roche, Example 51 of EP '226, which was not even in the top five nearest references to IN '774 in terms of inhibitory concentration value disclosed by EP '226 should not be treated as the point of departure in the inventive step analysis. EP '226 actually teaches a methyl/ethynyl substitution at the 6, 7 – position and not at the 3' position and there are several appreciable differences in bond angle, bond length and bond strength and the type of reaction with EGFR kinase between methyl and ethynyl group that make the methyl/ethynyl substitution ostensibly inventive.

12. The weighing of these rival contentions by the learned Single Judge is preceded by an interesting foreword – he states that no special understanding of inventive step under the Patent Act, 1970 is necessary qua pharmaceutical patents, discarding any reliance on any jurisprudential qualifications of inventive step for pharmaceutical products in other jurisdictions. The learned Single Judge has cast the '*person skilled in the art*' as a competent craftsman and a skilled worker but nothing further; drawing on the decision of the Supreme Court reported as AIR 1982 SC 1444 *Bishwanath Prasad Radhey Shyam Vs. Hindustan Metal Industries*. Beyond this, any further characterization of the 'person skilled in the art' drawn from other jurisdictions is discarded entirely. This, according to the learned Single Judge is because reliance on foreign jurisprudence is useful only where the position expressed in such references is consistent with the Patent Act, 1970. This reasoning has resulted in the learned Single Judge to refer to precedents such as the decision of the England and Wales Court of Appeals reported as 2010 RPC 9 *Dr.Reddy's Laboratories (UK) Ltd. Vs. Eli Lilly & Co. Ltd.* to support the view that the same standard of obviousness is to be applied to non-pharmaceutical patents. The learned Single Judge has quoted an analysis of the judgment from Roughton et al's : The Modern Law of Patents, thus : '…. *(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')*; and perhaps a little onerously, such reliance is only justified if the consistency is a consequence of legislative change in India. On this basis, the learned Single Judge discards virtually all US and European precedent cited before him on this issue, cases reported as 1972 RPC 346 *Technograph Vs. Mill &*

Rockley, (1985) RPC 59 *Windsurfing International Inc. Vs. Tabur Marine (Great Britain) Ltd.*, 1972 RPC 457 *General Tire & Rubber Co. Vs. Firestone*, 670 F.Supp.2d 359 *Daiichi Sankyo Vs. Matrix Laboratories & Ors.*, 550 U.S. 398 (2007) *KSR International Co. Vs. Teleflex Inc.* among others being prominent among them, as well as the TSM test, stating that it raises a semi-presumption of validity whereas no such presumption exists under the Indian law.

13. Interestingly, in creating this India-specific inventive step test which is based on a joint reading of Section 64 and Section 2(ja) of the Patent Act, 1970. the learned Single Judge has identified certain '*essential ingredients'* of Section 2(ja) which are to be satisfied for any invention to qualify the threshold of inventive step. These ingredients listed out by the learned Single Judge 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.

14. The learned Single Judge interprets this test to posit 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' and rules that both the requirements are to be satisfied conjunctively and 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.'*

15. Further, for reasons not entirely clear, the disavowal as to foreign jurisprudence is reinforced by the learned Single Judge by placing reliance on *Roughton et al's* : *The Modern Law of Patents* to create a matrix of

material facts required to be shown by a defendant to prove obviousness in a revocation inquiry :

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.

16. The learned Single Judge has held that the first condition is fulfilled by Cipla but that the other two are not demonstrated by '*positive evidence*'; and although the learned Single Judge finds that Roche also falls short on the evidentiary threshold with regard to this issue, he concludes that there was no onus on them to defend a validity challenge. The learned Single Judge goes on to suggest that Cipla could have 'clinically' demonstrated deviation (even *via* deposition) and that there was no deposition on Cipla's behalf pointed at establishing the arbitrariness of selection. (We note here that *the deposition on Cipla's behalf stated that there was a possibility of the desired result by a methyl/ethynyl substitution but no guarantee***)**. On the latter issue, the learned Single Judge has held that the primary test to be used is whether the selection reflected in the invention was non-arbitrary/purposeful and that where this is established, it overrides any '*inspiration*' taken from EP '226. Roche's case, in his opinion, was further helped by the teething problems they encountered with their NSLC prototype drug Geftinib and consequent improvements thereto incorporated

into Tarceva, which suggested that the relevant improvements had been purposeful, not arbitrary.

17. One last issue urged by Cipla on the validity question was five patent specifications cited by Cipla to show that methyl/ethynyl substitution was well known in prior art. The learned Single Judge disqualifies these references for two reasons – one, because they were filed after settlement of issues in the proceedings and did not meet the requirement that they could not be filed on account of being outside Cipla's knowledge or resources; and two, since four of the five patents cited pertained to non-quinazoline derivatives and the one that did – US '534 – quotes a 6, 7 methyl/ethynyl substitution which is inconsequential *per se*.

18. Apart from this, the learned Single Judge also invokes commercial success of the drug as an attending circumstance in establishing the purposefulness of the selection and defends his positive evidence standard as being necessary to avoid a slippery slope of judging competing products on the basis of superficial structural similarity. On an overall consideration of factors, the learned Single Judge – holds that Cipla are unable to meet even a balance of probabilities to establish revocation.

19. The second limb of Cipla's counter-claim – a Section 3(d) challenge to the validity of In '774 – was born out of the fact that Roche had unsuccessfully applied for a 'Polymorph B' form of Erlotinib Hydrochloride (DEL '507), a claim which was rejected by the Controller of Patents in December 2008 with findings on evergreening, structural similarities between IN '774 and EP 226 and a lack of conclusive comparative clinical data to prove efficacy. Nevertheless, the learned Single Judge invokes a '*positive evidence*' standard yet again to rule that Cipla failed to show

enough evidence to sustain a Section 3(d) challenge, since it required them to prove IN '774 is the '*new form of an old substance*' (the '*old substance*' being EP '226). The learned Single Judge rules against Cipla on the grounds that none of their witnesses deposed to establish that EP '226 and IN '774 are either, in essence, the same substance or that the simple assertion Example 51 of EP '226, through further reaction, can result in IN '774 is sufficient to establish '*new form of an old substance*' unless proven to be contrary. Thus, much against his initial desire to avoid importing presumptions of validity, the learned Single Judge reconciles the rival claims by holding that the reaction with a new reactant could create a new form of an old substance in this case but that it had not been proved by Cipla. Therefore, given that Roche had established sufficient evidence of difference in efficacy, it was sufficient certainly for it to be inferred that IN '774 was not hit by Section 3(d) – even though this was not done through deposition.

20. Several subsidiary challenges to IN '774 were also raised by Cipla, which can all be classified as allegations of suppression and concealments by Roche. All of them barring one under Section 8 have been rejected by the learned Single Judge. Section 8 of the Patents Act, 1970 which lays down disclosure requirements as to all *corresponding foreign patent applications* which appears to have become the single most problematic area of patent practice in India in recent times following the decision of this Court reported as (2009) 41 PTC 260 (Del) *Chemtura Corporation v Union of India*, which laid down a strict threshold of disclosure and also warns that inadequacy of disclosure would be a ground to seek revocation of a patent disclosure. Though the learned Single Judge has not referred to *Chemtura*,

but he has categorically not revoked IN '774, despite holding on facts that : '*… the plaintiffs as patentee has not disclosed the information as required by the controller as per Section 8 of the Act which is evidence 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'.* Despite holding that the ground under Section 64(1)(m) is made out, the learned Single Jude has chosen to exercise positive discretion in Roche's favour not to revoke the patent by inferring the existence of such discretion from the presence of the word '*may*' in the Section.

21. On the infringement question, armed with a fairly obliquitous '*positive evidence*' standard, the learned Single Judge has cast the onus to establish infringement on Roche.

22. The decision of the learned Single Judge is a bit hazy with regard to this issue because of the interchangeable reference by the learned Single Judge – of Erlotinib Hydrochloride and Tarceva as being covered by IN '774. However, this is clarified in reference to the relief claimed, which was for infringement of rights in the drug Tarceva and also claimed an injunction restraining the manufacturing and marketing Erlocip.

23. Cipla's infringement case was based on the claim that IN '774 is for a mix of Polymorphs A and B of Erlotinib Hydrochloride but Tarceva is just Polymorph B, which corresponds to US '221 (and the rejected DEL '507).

24. In the absence of clinical tests on record by Roche to compare the constituents of Roche's and Cipla's drugs and specifically whether Roche's drug corresponded with the Claim 1 of IN '774, it is crucial that Roche merely led evidence to show that Cipla's drug was also Erlotinib

Hydrochloride and claimed that manufacture of Polymorph B by Cipla was sufficient to trigger infringement of Claim 1 of IN '774. (Clearly, it flows in *sequitur* that any process involved in making Polymorph B would first involve the preparation of a combination of Polymorphs A and B; even US '221 states that Erlotinib Hydrochloride in Polymorph B form results from re-crystallization of Erlotinib Hydrochloride using different solvents and temperature conditions).

25. The observations of the learned Single Judge on this aspect are in para 213 of the impugned decision which reads thus:

> *".... 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*."

26. On this issue, the learned Single Judge has placed significant reliance on expert testimony of two kinds – first, on X-ray diffraction tests which establish that Tarceva is Polymorph B alone and second, that the tablet form of Erlotinib Hydrochloride does not follow directly from the claims in IN '774 (on account of the fact that further reactions of the product from IN '774 are required to produce Tarceva).

27. This has lead the learned Single Judge to a construction of Claim 1 of IN '774 to understand whether it subsumes Polymorph B of Erlotinib Hydrochloride, which is admittedly Erlocip.

28. It is here that the initial confusion (attributed to Roche in the judgment) – about whether the comparison of Erlocip is to be with Claim 1 of IN '774 or with Tarceva – re-surfaces again in the judgment. Two short passages from this part of the impugned judgment illustrate this:-

> "*… 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.*" (para 228)

29. Yet, later on the same page, the words used are :-

> "*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*" (para 230).

30. Thus, the learned Single Judge treats a patent claim on the subject matter interchangeably with patent claim for a product which, in the present case, refer to distinct things – Claim 1 of IN '774 and Tarceva respectively.

31. Given this misalignment, it is perhaps not surprising that the learned Single Judge – looks for aids to claim construction outside the claim specifications. The rationale is explained in para 231 thus : '*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 the 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 corresponds to what has been claimed in the patented invention of the product. The product may be seemed 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.' In the impugned judgment, this takes the form of purposive construction and the learned Single Judge goes on to adopt the reasoning in the decision reported as (1982) RPC 153 *Catnic Components Ltd. & Anr. Vs. Hill & Smith Ltd.* approach to purposive claim construction, extended to chemical compounds in the decision reported as 2004 RPC *Merck & Co. Inc. Vs. Generic UK Ltd.* (the learned Single Judge also cites with approval the decisions reported as 1990 FSR 181 *Improver Corporation & Ors. Vs. Remington Consumer Products Ltd. & Ors.* and (2005) RPC 9 *Kirin-Amgen Vs. Hoechst Marion Roussel* on the issue of claim construction), which advocates giving effect to 'the real purpose for which the product was invented' and explicitly involves a substituted judgment as to what the real purpose of the product is.

32. The other major substantive holding by the learned Single Judge on this issue is the adoption of *Merck*'s case (supra) style different thresholds for obviousness in revocation and in claim construction, based on the reason that an *a fortiori* determination of whether a variant can be subsumed within a broad patent claim is bound to be substantively different (and, presumably, lower) when compared with the obviousness standard in assessing the

question of further working on an invention that could revoke it in the future.

33. With these yardsticks laid down, the judgment offers some rather '*constructive feedback*' on what Roche could have done (by way of legal strategy) and some opinions on why they did not do it and while this is certainly out of kilter in a patent infringement judgment, it does offer some priceless insight into the reasoning of the learned Single Judge. According to the learned Single Judge, Roche could have:

(i) Demonstrated that Erlocip is not Polymorph B but the same as corresponds with IN '774 (It is unclear as to whether IN '774 here refers to the claim or product; it is assumed that it refers to the product since if it referred to the claim, it would have been impossible for Roche to prove).

(ii) Demonstrated that the distance between Claim 1 in IN '774 and Tarceva is trivial and therefore Claim 1 should be read purposively to cover Tarceva in its fold (this would include, *inter alia,* a better articulation of what is claimed in the compound, what Polymorph B actually is, the reactants and process involved in getting from Claim 1 to Polymorph B and proof that Erlotinib Hydrochloride does not change properties/characteristics in being converted to Polymorph B).

34. Further, the learned Single Judge has ventured to observe that the reason why Roche did not take route (i) is because they realized that the description in their own US '221 effectively knifes IN '774. The reason they did not take route (ii), the learned Single Judge feels, is because they did not want to lead evidence in an IN '774 infringement suit that effectively knifes their declarations before the USPTO in US '221. From this, the learned Single Judge infers that the distance between Claim 1 in IN '774 and

Tarceva is rather significant and, vide *Catnic*'s case (supra) and *Merck*'s case (supra), would materially affect the working of the product.

35. This raises the question of whether the impugned judgment ends up effectively re-ruling on the reasons behind the Controller's 2008 rejection of DEL '507. The Controller's order categorically held that increased thermodynamic stability of Polymorph B fell below the Section 3(d) standard of enhanced therapeutic efficacy but, *per* the analysis of the learned Single Judge, the steps in getting to DEL '507 from IN '774 are clearly consequential if indeed, the comparison is a direct one between IN '774 and DEL '507. Indeed, the learned Judge is genuinely skeptical over the derivative nature of Tarceva qua IN '774. He notes in para 277: '*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.*'

36. Ironically, the knife in the back for the IN '774 patent is stuck by its own equivalent US '221 specification documents (which clearly attest to Polymorph B as the sole efficacious commercial manifestation of Erlotinib Hydrochloride) and by the fact that the very factum of Roche's application for DEL '507 knifes IN '774. On the later issue, the learned Single Judge has held in para 260 as under:-

> *"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."

37. This last bit makes almost certain that if Roche had applied for either IN '774 or DEL '507 in isolation or, indeed, DEL '507 before IN '774, the learned Single Judge would have found that Erlocip infringed Roche's first patent.

38. At the forefront of the attack of Cipla was the argument that inventions are required to be *product specific*; where products have to have commercial manifestation. Hence, it was argued that since infringement is relatable to *'that product'* which is patented and not to any '*substance'* (as understood in Section 3(d) of the Act); thus it is important to analyse whether *'the product'* that is patented corresponds with '*the product'* that is being sought to be enforced by Roche against CIPLA i.e. *'the product'* that Cipla is manufacturing.

The product vs. substance dichotomy in the Act

39. It is important to reproduce certain key provisions of the Patents Act to understand the argument of learned Senior Counsel of Cipla:

Section 2(1)(j) *– **"invention"** means a new product or process involving an inventive step and capable of industrial application;*

Section 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;*

Section 2(1)(ac) - "capable of industrial application", *in relation to an invention, means that the invention is capable of being made or used in an industry;*

Section 2(1)(l)- "new invention" *means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art;*

Section 2(1)(m) -"patent" *means a patent for any invention granted under this Act;*

Section 2(1)(ta) - "pharmaceutical substance" *means any new entity involving one or more inventive steps;*

Section 3 –What are not inventions *– The following are not inventions within the meaning of this Act -*

(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;

40. In analyzing Section 2(1)(j) and 2(1)(ja), Ms.Prathiba M.Singh learned senior counsel argued that since the threshold for qualifying as an invention comprises the trinity of: (i) novelty, (ii) inventiveness and (iii) industrial application, it is possible for something to be new, but if it does not involve an '*inventive step'* or have *'industrial application'* it would not qualify as an invention. However, learned counsel conceded that if a product or process arrived upon even per chance, is 'novel' and involves an 'inventive step' (i.e. is not obvious) and fulfils the requirement of industrial application then such a product may satisfy the definition of an 'invention'. Learned senior counsel argued that Section 2(1)(ja) is an exhaustive definition comprising the following broad ingredients:

i) a feature of an 'invention' (as defined in Section 2(1)(j))

ii) that involves

- a technical advance as compared to the existing knowledge or
- a technical advance having economic significance or both

iii) that makes the invention <u>not obvious to a person skilled in the art</u>.

41. The condition laid down in Section 2(1)(ja) that any inventive step of an invention must not be '*obvious to a person skilled in the art*', qualifies the entire provision. Therefore, any product or process, even if the same involves an *'inventive step*' may not satisfy the requirements of the provision, if the said inventive step is obvious to a person skilled in the art. Further, even a *feature* of the invention may qualify as an inventive step, so long as the remaining conditions of the provisions are fulfilled.

42. Section 2(1)(ac) stipulates that an invention [as defined in Section 2(1)(j)] is '*capable of being made or used in an industry*'- thereby necessitating that an invention must have commercial use or manifestation. Further, even though an alleged invention may not be a final product, the same will be patentable only if it has some commercial viability. Thus, it is not the product which is the focus of attention but the actual physical substance created which has the potential of a commercial manifestation. Section 2(1)(ac) is clearly connected with Section 48 as it deals with *'made'* or *'used'* as also *'new product'* [through Section 2(1)(j) by using the term *'invention'*] which are all used in Section 48.

43. Section 2(1)(*l*) defines a *'new invention'* in an exhaustive manner, and contains the following ingredients:

a) any invention or technology

b) which has not been anticipated by publication

i) in any document or

ii) used in the country or elsewhere in the world

before the date of filing of patent application with complete specification, so that the subject matter has not fallen in public domain or that it does not form part of the state of the art.

44. While it may be true that the said term has not been used anywhere in the Act, however, the relevance of the provision lies in the fact that it gives a flavour of the intention of the Legislature. Further, Section 2(1)(*l*) when read in conjunction with Section 2(1)(j) also clarifies as to what is considered to be <u>not new</u> in the terms of the Act. Further, the provision lays down that the

invention or technology must not have been previously made or used in India. It specifies two categories viz., in a '*document*' or in *'practice*' wherein an invention may have been anticipated which in turn would result in such invention not being *'new'* and therefore not *'novel'*. It further lays down that the same should not have fallen into the *'public domain'* or form part of the *'state of the art'*.

45. Section 2(1)(m) defines the term *'patent'* and ties within itself various concepts and definitions, and relates to the requirements of Section 2(1)(j) and 2(1)(ja) as discussed earlier. Section 2(1)(ta) defines '*pharmaceutical substance*' as:

a) a new entity

b) that involves one or more inventive steps.

46. The term '*new entity'* would obviously relate to a New Chemical Entity (i.e. new chemical compounds). Once again we note that in the Act the said term has not been used anywhere, however, the relevance of the provision lies in the fact it gives a flavour of the intention of the Legislature. Further, the provision is also relevant owing to the fact that it a specific definition pertaining to pharmaceuticals.

47. Section 3 is an 'exclusionary clause'. The present provision was expanded by way of the Patents (Amendment) Act, 2005. Despite the fact that *'invention'* is exhaustively defined, the need for an exclusionary provision obviously arose from the Legislative intent that as a matter of policy, due to larger considerations, patents would not be granted to those specified in Section 3. Therefore, Section 3 has to be read as an exception to Section 2(1)(j), and consequently Section 2(1)(j) would be subject to Section

3. These provisions could have been drafted in a manner where Section 2(1)(j) could have contained an exception stating 'what are not inventions'. But that is just by way of a comment.

48. It is relevant to note that the heading of the Chapter is **"Inventions not Patentable"** and the marginal heading read **"What are not inventions"**. Therefore, they relate to inventions that may otherwise meet the tests of Sections 2(1)(j) and Section 2(1)(ja) but may still not be granted patents as a matter of policy.

49. The provision relevant to the present case is Section 3(d), which provides that the following *'are not inventions within the meaning of the Act'*:

- 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;

50. The use of the word *'considered'* shows that this is a fiction being created for the purpose of excluding those inventions which DO NOT show enhanced efficacy. Sub section (d) of Section 3 lays down that the '*new form of a known substance'* which does not result in '*enhancement of efficacy*' or '*does not differ significantly in properties with regard to efficacy'* is not an invention for the purposes of the Act. It is pertinent to note that the legislature has '*considered*' salts, esters, ethers, polymorphs, metabolites, pure form, isomers, mixtures of isomers, complexes, combinations and other derivatives, to be the '*same substance'* for the purposes of this provision. Thus, the conclusion that may be drawn from a reading of Section 3(d) would be as under:

a. A new form is not the same substance.

b. A new form is also not the same product.

c. If you show enhancement in efficacy, one will get a patent for the new form.

d. If one does not show enhancement of efficacy, no patent will be granted as it will be considered as the same substance.

e. But, this form is also not that product for the purposes of Section 48.

51. Section 3(d) is a deeming provision in a legal sense, but in a technical sense it cannot be presumed that once the patent/patent application for a new form of a known substance is rejected/abandoned then the said new form is covered under a prior patent relating to that substance.

52. Ms.Pratibha M.Singh learned Senior Counsel laid particular emphasis on what she states is the purpose of Section 3(d) i.e. to exclude a class of

products from being patented. She argued that any interpretation of Section 3(d) which leads to the conclusion that the product being excluded is actually being granted a patent, is contrary to the legislative intent. Learned counsel argued that such an interpretation would run contrary to the very basis for the enactment of Section 3(d) and would result in unfair monopolies which it sought to curb in the first place. Learned counsel laid emphasis that it is necessary to bear in mind that a patent is granted as a *quid pro quo* i.e. monopoly is granted over certain inventions based on the disclosure made therein by the patentee. Learned counsel argued that concededly the basic tests of patentability are: novelty, inventive step and industrial applicability, and these tests are uniform the world over. As per learned counsel the law in India has provided for a '*second tier of qualifying standards'* by way of Section 3(d) and the same has been done keeping in mind larger considerations of public welfare. As per learned counsel Section 3(d) has been enacted with a view to curb the problem of evergreening. Therefore, learned counsel argued that the same should not be utilized as a tool to enhance the ambit of a patent to cover even those forms which have either been abandoned by the patentee itself or rejected in India. The status of the law in different jurisdictions CAN NOT change the facts underlying the said patent documents and the scope thereof was the contention advanced.

53. It has to be noted that the Act uses the words '*substance'* and '*product'* in a number of provisions without clearly defining the two. Thus, while interpreting Section 3(d) of the Act one has to keep in mind the three distinct words: (i) *new form,* (ii) *known substance*; and (iii) *new product*

used in the Section. In the realm of chemistry, a '*new product'* would be any substance resulting from a chemical change. In the realm of chemistry '*substance*' would be: physical matter of which the thing consists or a matter of a particular kind of chemical composition. Since we are dealing with inanimate objects, a product or a substance has to be a veritable being. Philosophically looked, each inanimate object is, by virtue of its particularity and its limited and determinable form, different from and opposite to the genus – the particular contradicting the universal, so that the later does not fulfill itself in the former. When one talks of a substance being a veritable being, it would mean a real being, in the strict sense by which is meant the concrete individual thing. The individual thing is the subject or substance enduring throughout a movement in which it unifies and holds together the various states and phases of its existence. To illustrate this thought with a practical example, a stone is a being seen in a determinate form. But when chiseled into a statue we say that a new being (the statue) has come into existence.

54. A peep into foreign jurisprudence for guidance on understanding the terms may be useful.

55. Under the Australian Patents Act 1990, certain pharmaceutical patents can be granted a patent term extension if specific criteria are met i.e. whether or not the claims defined 'one or more pharmaceutical substances *per se'*. The phrase '*pharmaceutical substance'* is defined in Schedule 1 of the Australian Act as*:*

> *'A substance (including a mixture or compound of substances) for therapeutic use whose application (or one of whose applications) involves:*

(a) a chemical interaction, or physico-chemical interaction, with a human physiological system; or
(b) action on an infection agent, or on a toxin or other poison, in a human body;
(c) but does not include a substance that is solely for use in in vitro diagnosis or in vitro testing".

56. The term *'therapeutic use'* is, in turn, defined in relation to the definition of *'pharmaceutical substance'* as use for the purpose of:

(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or

(b) influencing, inhibiting or modifying a physiological process in persons; or

(c) testing the susceptibility of persons to a disease or ailment'.

57. Europe, too offers patent term extensions to pharmaceutical or *'medicinal products'* which are defined in Article 1(a) of Council Regulation (EEC) No 1768/92 as follows:

'Any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis, or to restoring, correcting or modifying physiological functions in humans or in animals.'

58. Article 1 (b) qualifies that patent term extensions will be granted only to a *'product'* which is defined as:

'the active ingredient or combination of active ingredients of a medicinal product'.

59. A conjoint reading of Articles 1(a) and (b) of the EU Regulation

reveals that a '*product'* represents the genus and '*pharmaceutical substance'* represents the species, i.e. a product may have an active ingredient but it may not therapeutic efficacy. Once it acquires therapeutic efficacy, it qualifies as a pharmaceutical substance.

60. Now, let us consider the scheme of the Indian Patent Act to understand the scope of the various provisions noted above and their interplay.

61. Section 3 of the Act lays down a threshold for patent eligibility and is not an exception to Section 2(1)(j) as urged by learned Senior counsel for Cipla. Section 2(1)(j) provides a theoretical definition of an invention while Section 3 illustratively outlines what are not inventions. In other words, for subject matter that falls outside the scope of Section 3, a qualitative analysis needs to be employed to ascertain whether it satisfies the conditions of Section 2(1)(j), while for subject matter that falls within the scope of Section 3, an analysis under Section 2(1)(j) need not be employed as it will be rejected at the threshold.

62. Now, Section 3(d) assumes that structurally similar derivatives of a known '*substance'* will also be functionally similar and hence ought not to be patentable. What is of crucial importance is that this is not a provision that merely bars certain subject matter from patentability. On the contrary, it provides that if the new form of the known substance is found despite a structural similarity to demonstrate a better functionality i.e. '*enhancement of the known efficacy'*, it would qualify for assessment under Section 2(1)(j) as if it were a new product involving an inventive step and it would thereafter be up to the applicant for the patent to demonstrate the

patentability of this substance in accordance with Sections 2(1)(j) and (ja). This provision is not a patent term extension or an evergreening provision but in fact recognizes incremental innovations in pharmaceutical patents. The use of the words *'product'* and *'substance'* in Section 2(1)(j) and Section 3(d) is therefore telling, in that, the legislative intent appears clearly to demonstrate that all *'substances'* may not qualify as *'products'* under the Act, where the latter are only those substances that are patent-eligible. In fact, Section 2(1)(ta) provides the bridge between Section 3 and Section 2(1)(j), in that, it defines a '*pharmaceutical substance'* as '*any new entity involving one or more inventive steps*'. Thus, the discovery of an entity or substance may not involve an inventive step. Insofar as there is no inventive step involved in its formation it is merely a substance even though its structural form may be hitherto unknown. A new chemical entity (NCE) that is structurally dissimilar but functionally similar to an existing chemical entity is thus merely a substance under Section 3(d). If the substance has an added layer of enhanced efficacy then it would be treated as a '*new product'* and would be eligible for assessment under Section 2(1)(j) to ascertain whether its formation involved an inventive step. If the new product involved one or more inventive steps, then it would qualify as a pharmaceutical substance. Thus, graphically represented, the same would be:-

	Enhanced Efficacy		Inventive Step	
Substance	→	New Product	→	Pharmaceutical substance
S. 3(d)		S. 2(1)(j)		S. 2(1)(ta)

63. In chemistry, active moiety is a group of atoms forming part of a molecule. In the case of a pharmaceutical product, the active moiety is that part of the molecule of an active substance which gives it its therapeutic effect. Active pharmaceutical ingredients (APIs) are the molecular entities that exert the therapeutic effects of medicines and are biologically active. A drug substance invariably refers to the API or component present in the drug product which is solely responsible for producing the effect of the drug on the body.

64. A product essentially comprises a substance (active ingredient) or composition (combination of active ingredients). A product patent protects the product in any form however it is made, or however it is formulated. Many different drug products may be marketed with the same active moiety and the same product can thus have various structural forms. Thus Section 3(d) envisages a variety of derivatives of known substances, some illustrative types could be as under:-

- A compound which is not active in itself but is metabolized in the body to form an active drug known as prodrug. For eg., chloramphenicol succinate ester is used as an intravenous prodrug of chloramphenicol, because pure chloramphenicol does not dissolve in water.
- A composition (combination of two or more active ingredients or combination of a pharmaceutical carrier with a compound not used as a drug before).
- A drug delivery system which is a composition that its constituents enable to be administered in a particular way.

65. The view which we have taken is in conformity with the law declared by the Supreme Court in the decision reported as (2013) 6 SCC 1 *Novartis AG Vs. Union of India*, in para 88 whereof it was opined as under:-

> *"We have so far seen Section 3(d) as representing 'patentability', a concept distinct and separate from 'invention'. But if Clause (d) is isolated from the rest of Section 3, and the legislative history behind the incorporation of Chapter II in the Patents act, 1970, is disregarded, then it is possible to see Section 3(d) as an extension of the definition of "invention" and to link Section 3(d) with Clauses (j) and (ja) of Section 2(1). In that case, on reading Clauses (j) and (ja) of Section 2(1) with Section 3(d) it would appear that the Act sets different standards for qualifying as 'inventions' things belonging to different classes, and for medicines and drugs and other chemical substances, the Act sets the invention threshold further higher, by virtue of the amendments made in Section 3(d) in the year 2005."*

66. Before we apply the aforenoted legal position to the facts of the instant case we need to discuss the legal position concerning construction of claims. In the decision reported as AIR 1969 Bombay 255 *FH & B Vs. Unichem Laboratories* it was held that specifications end with claims, delimiting the monopoly granted by the patent and that the main function of a Court is to construe the claims without reference to the specification; a reference to the specification being as an exception if there was an ambiguity in the claim. Claims must be read as ordinary English sentences without incorporating into them extracts from body of specification or changing their meaning by reference to the language used in the body of the specification. In a recent decision in FAO (OS) No.190/2013 *Merck Vs. Glenmark* the Division Bench held that claim construction to determine the coverage in the suit patent has to be determined objectively on its own terms

with regard to the words used by the inventor and the context of the invention in terms of the knowledge existing in the industry. Abandonment of an application cannot remove what is patented earlier nor can it include something that was excluded earlier and that a patent is construed by the terms used by the inventor and not the inventors subjective intent as to what was meant to be covered. Merely because an inventor applies for a latter patent that is already objectively included in a prior patent, but which inventor subjectively feels needs a separate patent application, doesn't mean it is to be taken at face value and therefore neither Section 3(d) or abandonment of subsequent patent application can be used to read into terms of prior application, which has to be construed on its own terms. In the decision reported as 415 F. 3d 1303 *Edward H.Phillips Vs. AWH Corporation* it was held that claims have to be given their ordinary and general meaning and it would be unjust to the public, as well as would be an evasion of the law, to construe a claim in a manner different from plain import of the terms and thus ordinary and customary meaning of the claim term is the meaning of the term to a Person Of Ordinary Skill in the Art as of effective date of filing of the patent application. In case of any doubt as to what a claim means, resort can be had to the specification which will aid in solving or ascertaining the true intent and meaning of the language employed in the claims and for which the court can consider patent prosecution history in order to understand as to how the inventor or the patent examiner understood the invention. The Court recognized that since prosecution is an ongoing process, it often lacks clarity of the specification and thus is less useful for claim construction. The Court also recognizes that having regard to extrinsic evidence such as inventor testimony, dictionaries

and treaties would be permissible but has to be resorted to with caution because essentially extrinsic evidence is always treated as of lesser significance in comparison with intrinsic evidence. In the decision reported as 457 F.3.1284 (United States) *Pfizer Vs. Ranbaxy* the Court held that the statements made during prosecution of foreign applications are irrelevant as they are in response to unique patentability requirements overseas. The Court also held that the statement made in later unrelated applications cannot be used to interpret claims of prior patent. In the decision reported as 1995 RPC 255 (UK) *Glaverbel SA Vs. British Coal Corp* the Court held that a patent is construed objectively, through the eyes of a skilled addressee. The Court also held that the whole document must be read together, the body of specification with the claims. But if claim is clear then monopoly sought by patentee cannot be extended or cut down by reference to the rest of the specification and the subsequent conduct is not available to aid the interpretation of a written document.

67. For the above conspectus, pithily put, principles of claim construction could be summarized as under:-

(i) Claims define the territory or scope of protection (Section 10(4) (c) of the Patents Act, 1970.

(ii) There is no limit to the number of claims except that after ten claims there is an additional fee per claim (1st Schedule of the Act).

(iii) Claims can be independent or dependent.

(iv) The broad structure of set of claims is an inverted pyramid with the broadest at the top and the narrowest at the bottom (Manual of Patents Office – Practice and procedure).

(v) Patent laws of various countries lay down rules for drafting of claims and these rules are used by Courts while interpreting claims.

(vi) One rule is that claims are a single sentence defining an invention or an inventive concept.

(vii) Different claims define different embodiments of same inventive concept.

(viii) The first claim is a parent or mother claim while remaining claims are referred to as subsidiary claims.

(ix) If subsidiary claims contain an independent inventive concept different from the main claim then the Patent office will insist on the filing of a divisional application.

(x) Subject matter of claims can be product, substances, apparatus or articles; alternatively methods or process for producing said products etc. They may be formulations, mixtures of various substance including recipes. Dosage regimes or in some countries methods of use or treatment may also be claimed.

(xi) Where claims are 'dependent' it incorporates by reference 'everything in the parent claim, and adds some further statement, limitations or restrictions'. (Landis on Mechanics of Patent Claim Drafting).

(xii) Where claims are 'independent' although relating to the same inventive concept this implies that the 'independent claim stands alone, includes all its necessary limitations, and is not dependent upon and does not include limitations from any other claim to make it complete .... An

independent Claim can be the broadest scope claim. It has fewer limitations than any dependent claim which is dependent upon it'. (Landis on Mechanics of Patent Claim Drafting)

(xiii) For someone wishing to invalidate a patent the said person must invalidate each claim separately and independently as it is quite likely that some claims may be valid even while some are invalid.

(xiv) At the beginning of an infringement action the Courts in the United States conduct what is known as a 'Markman hearing' to define the scope of the claims or to throw light on certain ambiguous terms used in the claims. Although this is not technically done in India but functionally most Judges will resort to a similar exercise in trying to understand the scope and meaning of the claims including its terms.

In the case of (52 F.3d 967 also 517 US 370) *Herbert Markman Vs. Westview* the Courts held that an infringement analysis entails two steps:-

(a) First step is to determine the meaning and scope of the patent claims asserted to be infringed.

(b) Second step is to compare the properly construed claim with the device accused of infringing.

(xv) The parts of the claim include its preamble, transition phrase and the body. The 'transition phrase' includes terms like:-

(a) Comprising;

(b) Consisting;

(c) Consisting essentially of;

(d) Having;

(e) Wherein;

(f) Characterised by;

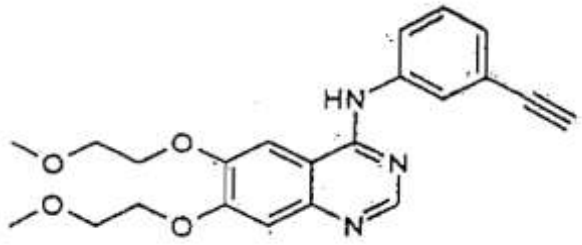
Of these terms some are open ended, such as 'comprising' which means that if the claim contains three elements 'A', 'B' and 'C' it would still be an infringement for someone to add a fourth element 'D'.

Further some terms are close ended such as 'consisting of', i.e. in a claim of three elements, 'A', 'B' and 'C' a defendant would infringe if he has all three elements. In case the defendant adds a fourth element 'D' he would escape infringement.

(xvi) Each claim has a priority date so that in a group of claims in a specification you could have multiple priority dates. This only means that if a patent application with certain priority date and claims was followed by another application with different claims and different priority dates, then if they were consolidated or cognate with another application, each claim would retain the original priority date [Section 11(1)].

68. Applying the aforesaid legal position to the facts of the instant case we find that Claim 1 of the Suit Patent IN '774 *(the basic patent)* which is relevant for the present proceedings is:-

> *"1. A novel [6,7-bis (2-methoxyethoxy) quinazolin-4-y1]-(3-ethynylphenyl) amine hydrochloride compound of the formula A*



—*A"*

69. Ms.Pratibha M.Singh, learned Senior counsel for Cipla argued that the suit patent IN '774 discloses Polymorph A+B of Erlotinib Hydrochloride, whereas Roche has a separate product patent in USA, i.e. US '221 for Polymorph B of Erlotinib Hydrochloride. Furthermore, an application for the grant of Polymorph B of Erlotinib Hydrochloride (IN/507/Del) was also filed by Roche in India, but the same was rejected. Thus, learned counsel argued that the very filing of a separate patent application is indicative of the fact that Polymorph B of Erlotinib Hydrochloride is a separate invention. Whether the same is patentable or not in different jurisdictions does not alter the fact that they are separate inventions was the advanced limb of the argument. It was urged that Polymorph B was neither disclosed, enabled or claimed in the first patent in any jurisdiction and hence something which came into being later cannot be argued as being retrospectively covered in an earlier patent. Learned counsel urged that admittedly Cipla was manufacturing Polymorph B and therefore it was urged that there cannot be an infringement of IN '774.

70. It is not in dispute that Roche's unsuccessful patent application in India (DEL '507) was indeed for a 'Polymorph B' form of Erlotinib Hydrochloride, a claim which was rejected by the Controller of Patents in December 2008 with observations on ever greening, structural similarities

between IN '774 and DEL '507 and a lack of conclusive comparative clinical data to prove efficacy. We also note that the process claims for making Polymorph B in DEL '507 matured into Patent No. 231102 and only the product claims pertaining to Polymorph B were refused.

71. However, we find ourselves unable to agree with the arguments of learned Senior counsel for Cipla on the import of this rejection. As we have discussed earlier, the purpose of Section 3(d) is to encourage incremental innovation in pharmaceuticals. It lays down a threshold for what subject matter would qualify as the '*same'* or '*known'* substance and what would qualify as a '*new'* substance. The purpose of this qualification is that when something is the same/known substance, then the derivatives of such a substance as enumerated in the Explanation to Section 3(d) would be covered under the same protection that exists for the known substance (which could also mean that if the known substance is not covered by a patent then the derivative would not be covered as well).

72. By logical extension, if certain subject matter qualifies as a '*new'* substance on account of the reasons elaborated in the preceding paragraphs, then it would be capable of being considered for the grant of a new patent; separate from the one existing for the known substance. What Section 3(d) certainly does NOT do, is doubly penalize the innovator, which appears to be the argument advanced by learned senior counsel for Cipla. If the argument is to be taken to its logical conclusion, it would mean that a rejection of a polymorphic version of Roche's existing patented molecule (i.e. the '*known substance*' in this case) on the anvil of Section 3(d) would also result in effectively permitting all manufacturers of the said polymorph

from being deemed non-infringers under Section 48. That is in fact not the import of Section 3(d) nor the legislative intent behind the provision.

73. We understand Section 3(d) as a positive provision that in fact recognizes incremental innovation while cautioning that the incremental steps may sometimes be so little that the resultant product is no different from the original. The inherent assumption in this is that an infringement of the resultant product would therefore be an infringement of the original i.e. the known substance and by no stretch of imagination can Section 3(d) be interpreted as constituting a defence to infringement.

74. Hence, while the suit patent covers Erlotinib Hydrochloride (or polymorphs A+B of the same, if Cipla's contention were to be accepted), the rejection of the patent application for Polymorph B (DEL '507) by the Indian Patent Office leads to a direct conclusion that there was a lack of sufficient matter to suggest that Polymorph B qualified as a 'new product' for consideration under Section 2(1)(j) for patentability and should therefore be regarded for all practical purposes as the old product itself i.e. Polymorphs A+B.

75. The matter can be approached from another angle. The suit patent has two claims of which Claim No.1 is a product patent relating to a new molecule Erlotinib Hydrochloride. The ground of anticipation, though pleaded, was not pressed by Cipla for the reason that the molecule Erlotinib Hydrochloride was not found in nature nor published in any publication previous to the priority date. The subject matter of Claim 1 is also not obvious as it involves an inventive step.

76. The complete specification of the suit patent nowhere mentions any polymorphic form of Erlotinib Hydrochloride and neither is the claim restricted to any specific polymorphic form. The chemical structure describes the manner in which each molecule of the compound exists. Thus, how many carbon, hydrogen, oxygen or nitrogen atoms exist and how they are joint to each other is all contained in the chemical structure.

77. It is an 'intra'- molecular concept. As opposed to this, the various molecules may be stacked together in a crystal lattice in a certain configuration and the said 'inter'–relationship between the various molecules results in a certain polymorphic structure. It is possible that a certain molecule has more than one polymorphic forms which may be discovered at some future point of time, as was done in the present case. The present patent does not concern the polymorphic structure or the manner in which the various molecules are stacked in a relationship with each other. It is not an 'inter'-molecular concept but an 'intra'-molecular concept. It is a single molecular structure which is protected in the present patent and therefore, irrespective of which polymorphic form it appears it would have the same chemical structure as contained in Claim-1 of the suit patent.

78. This has come out very well in the evidence of the technical experts, both on the side of the Plaintiff as also the Defendants' expert.

79. When cross-examined, Defendants' witness Shashi Rekha (DW-2) in response to the following questions admitted:

> *"Q.26 Under what circumstance do the polymorphs maintain their crystal structure in the body?*

A. The concept of polymorphic forms is not about how the crystal structure is maintained in the body but how they are made and how it is delivered to the body.

Q.27 In other words within the body they are not different from one another?

A. Yes

Q.35 Erlotinib Hydrochloride has the same 'chemical structure' everywhere in the world and every time it is produced?

A. Yes"

Further the Defendants Expert Witness (DW-3) Dr.Ashwini Nangia has stated the following in response to the cross examination:

"Q.48 Is it correct that polymorphism is the ability of a chemical substance to exist in more than one crystalline form.

A. Yes that is correct I will only add 'in the solid state' to the same definition.

Q.49 Please see PX 25 from the Court record and confirm that all polymorphs of Erlotinib Hydrocholoride have this chemical structure?

A. Yes"

80. Therefore, it logically follows that Cipla's argument that the subsequent polymorph related to patent US'690221, which though granted in USA and its counterpart rejected in India, has relevance is incorrect.

81. The polymorph or the manner in which the Erlotinib Hydrochloride molecules are arranged in a crystal lattice was found several years late (in 1999) than the main invention (in 1995). It was then realized that there were at least two polymorphic forms 'A' and 'B'. A method was found to separate the two and it was also determined that polymorph B has superior properties to Polymorph A. In the polymorph application, an attempt was

made to claim its superiority to the main invention by saying that the main invention related to a combination of polymorph A and polymorph B.

82. What was clearly meant by this statement was that the original compound did not distinguish between polymorphs whereas the improved invention related to a purer form of Polymorph B with far superior properties.

83. However, a closer scrutiny of the polymorph patent also shows that the properties were physical but not biological properties or therapeutic properties. Inside the body the polymorphs have the same chemical structure and behave the same way biologically or therapeutically as admitted by the Defendants witness Ms.Shashi Rekha DW-2 in response to questions:

> *"Q.24 Is it therefore correct that the chemical structure of polymorphic forms is the same but the difference lies in the way the crystals are packed?*
>
> *A. Yes*
>
> *Q.27 In other words in the body they are not different from one another?*
>
> *A. Yes"*

84. It is only that a particular polymorphic form may result in better storage or transportation or manufacture or may have better thermodynamic stability, etc. These properties are certainly improved but the moot question is whether this improvement is covered by Section 3(d) of the Patents Act and if so, has the data been supplied to prove enhanced efficacy in the therapeutic sense.

85. If there are polymorphs, which improve only the non-therapeutic properties, then there may be a difficulty in obtaining a patent for the same in India. Thus, in the decision reported as (2013) 6 SCC 1 *Novartis AG Vs. Union of India & Ors.* it has been held as under:-

> *"157. What is 'efficacy'? Efficacy means 'the ability to produce a desired or intended result'. Hence, the test of efficacy in the context of Section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be 'therapeutic efficacy'. The question then arises, what would be the parameter of therapeutic efficacy and what are the advantages and benefits that may be taken into account for determining the enhancement of therapeutic efficacy? With regard to the genesis of Section 3(d), and more particularly the circumstances in which Section 3(d) was amended to make it even more constrictive than before, we have no doubt that the 'therapeutic efficacy' of a medicine must be judged strictly and narrowly. Our inference that the test of enhanced efficacy in case of chemical substances, especially medicine, should receive a narrow and strict interpretation is based not only on external factors but there are sufficient internal evidence that leads to the same view. It may be noted that the text added to Section 3(d) by the 2005 amendment lays down the condition of 'enhancement of the known efficacy'. Further, the explanation requires the derivative to 'differ significantly in properties with regard to efficacy'. What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy.*
>
> *158. While dealing with the explanation it must also be kept in mind that each of the different forms mentioned in the explanation have some properties inherent to that form, e.g.,*

> *solubility to a salt and hygroscopicity to a polymorph. These forms, unless they differ significantly in property with regard to efficacy, are expressly excluded from the definition of 'invention'. Hence, the mere change of form with properties inherent to that form would not qualify as 'enhancement of efficacy' of a known substance. In other words, the explanation is meant to indicate what is not to be considered as therapeutic efficacy."*

86. It is for this reason that the Indian polymorphic patent application IN/PCT/2002/00507/DEL was partly rejected. While the product claims 1, 2 and 6 were rejected, the process claim 4 was merged with 3 to make it claim 1 and claim 5 was renumbered as claim 2. Section 3(d) came in the way of the product claims as there was no data to support that the polymorphic versions were therapeutically more efficient than the basic compound.

87. The interesting thing is that the Cipla's argument would shoot down the polymorph because of Section 3(d) and also attempts to shoot down the main compound, because of the polymorphs rejection. This cannot be done.

88. Cipla's argument that X-Ray Diffraction Data (XRD) was not specified for the suit patent is also not plausible because XRD shows the manner in which the molecules are arranged in a crystal lattice. This is only important for a polymorphic patent but not for a main molecule where irrespective of the polymorphs, it is the chemical structure which is the sum and substance of the invention.

89. Cipla raised a whole series of arguments on the distinction between product and substance in an attempt to argue that it is the commercial product alone for which a patent can be granted and therefore this was a case

of early patenting as the polymorph version which was invented in the year 1999 was the only deserving candidate for a patent.

90. This argument ignores the fundamental truth about breakthrough inventions, which at the time they are invented may not be commercially the most viable for immediate marketing. They are useful and are industrially applicable as without them there would be no stepping stone to achieve the next lot of improvements. For this reason, the Courts have struck a distinction between commercial utility and patentable utility as set out below:

91. In the decision reported as 1979 (RPC) *American Cynamid Company Vs. Ethicon Ltd.* it has been held as under:-

> *"Whilst it may be true that a commercial articles owes much to later research it seems to me that the amount owed must be a matter of degree depending on the facts, and to succeed under this head a defendant must be able to go as far as establishing that, as a practical matter, the successful commercial article owes nothing to the original invention. As a matter of reality, however, almost every patented article which achieves commercial success embodies the result of improvements and research discovered since the date of publication of the complete specification of the basic patent. That commercial success is not necessary to establish patent utility, and that the improvements made subsequently are immaterial, has long been recognized. Badische Anilin and Soda Fabrik Vs. Levinstein (1887) 4 RPC 449, at 462, where Lord Halsbury, L.C. said:*
>
> > *"The element of commercial pecuniary success has, as it appears to be, no relation to the question of utility in patent law generally, though, of course, where the question is of improvement by reason of cheaper production, such a*

consideration is of the very essence of the patent itself, and the thing claimed has not really been invented unless that condition is fulfilled."

92. In the decision cited in American Cynamide reported as (1889) 6 RPC 243 *Edison & Swan Electric Light Co. Vs. Holland* Lindley, J. held as under:-

"Edison's patent is said to be no use, and the proof of this statement is said to be furnished by the fact that lamps are not made according to the patent, even by Edison himself. The utility of the patent must be judged by reference to the state of things at the date of the patent; if the invention was then useful, the fact that subsequent improvements have replaced the patented invention and rendered it obsolete and commercially of no value does not invalidate the patent"

93. In the decision reported as AIR 1969 255 *E.H. & B. Vs. Unichem Laboratories* it was held as under:-

"20. As stated by Halsbury (3rd Edn.) Vol. 29 p.59 para 123, 'not useful' in patent law means that the invitation will not work, either in the sense that it will not operate at all or more broadly, that it will not do what the specification promises that it will do. If the invention will give the result promised at all, the objection on the ground of want of utility must fail. It is further stated in the said passage that the practical usefulness or commercial utility of the invention does not matter, nor does it matter whether the invention is of any real benefit to the public, or particularly suitable for the purposes suggested, and that it is only failure to produce the results promised that will invalidate the patent, not misstatements as to the purposes to which such results might be applied."

94. Cipla relied very heavily on what was stated to be admissions made in the polymorphic patent US'221. It is a cardinal principle of claim construction that the claim must be interpreted on its own language and if it

is clear then resort cannot be had to subsequent statements or documents either to enlarge its scope or to narrow the same.

95. In FAO (OS) No.190/2013 *Merck Vs. Glenmark* it has been held as under:-

> *"The Court at the same times notes that the claim construction to determine the coverage in the suit patent is to be determined objectively on its own terms with regard to the words used by the inventor and the context of the invention in terms of knowledge existing in the industry. The subsequent abandonment of a patent for SPM cannot remove what is patented earlier (if an objective reading, as indicated above, considers it to be included) nor can it include something that was excluded earlier. The motives for abandonment – since MSD claims that it abandoned the claim due to Section 3(d) of the Act – play no part in the claim construction*
>
> *Section 3(d) does not work backwards, such that two independent patent claims are to be construed in reference to each other. Each claim is regulated by its own terms, subject to the statutory prescriptions of inventive step and industrial applicability. Moreover, such an argument also introduces and undeserved subjectivity in the patent construction process. A patent is construed by reference to the words used by the inventor and not her subjective as to what was meant to be covered… Merely because an inventor applies for later patent – that is already objectively included in a prior patent, but which the inventor subjectively feels needs a separate patent application – does not mean that it is taken to be at face value. The intent to the inventor, through the use of the words that have been employed, must be judged, but the subjective intent cannot replace a detailed analysis of the test of the patent."*

96. In the decision reported as 1995 RPC 255 (United Kingdom) *Glaverbel SA Vs. British Coal Corp* it was held as under:-

> *"6. Subsequent conduct is not available as an aid to interpretation of a written document. This too was established by the Schuler case, re-affirming an earlier decision of the House of Lords.*
>
> *7. A claim must not be construed with an eye on prior material, in order to avoid it effect: Molins Vs. Industrial Machinery Co. Ltd., (1938) 55 RPC 31*."

97. This leads us at the stage to the take of point where we can deal with Cipla's defence to the charge of infringement. The defence is essentially based on the claim that IN '774 is for Polymorphs A+B of Erlotinib Hydrochloride, Tarceva i.e. Roche's product is just Polymorph B, which corresponds to US '221 (and the rejected DEL '507). Hence Cipla urges that while the patent sought to be enforced is for Polymorphs A+B, the product actually under manufacture by both Roche and Cipla is Polymorph B which ought to be assumed to be in the public domain and hence Cipla's activities are non-infringing in nature.

98. In its response to the above argument by learned Senior Counsel for Cipla, Sh.Pravin Anand, learned counsel for Roche argued that while the Learned Single Judge correctly notes that the packaging *(Ex.P1)*,package insert of the Defendant *(EX. P2)* and the declarations/statements made before the Drug Controller *(Ex.PW1/D2)* all demonstrate that the API of Erlocip (Cipla's product) is Erlotinib Hydrochloride, the learned Single Judge erred in disregards this evidence and instead lay emphasis on clinical test not having been conducted by Roche to demonstrate the constituents of Roche's drug Tarceva and Cipla's drug Erlocip and places a positive onus on Roche to establish whether Tarceva corresponds to the suit patent or

whether it is a polymorphic version of the suit patent compound. Learned counsel pointed out that while the Learned Single Judge correctly notes that the physical form of Cipla's drug demonstrates that it contains Erlotinib Hydrochloride, he disregards Roche's submission that manufacturing a Polymorph B version of Erlotinib Hydrochloride infringes Claim 1 of the suit patent. Sh.Pravin Anand, learned counsel for Roche argued that the clinical test of the compound is not relevant for determination of infringement. Learned counsel urged that the basic patent was not confined to any polymorphic form of Erlotinib Hydrochloride and hence as long as Erlotinib Hydrochloride is present in Cipla's product Erlocip, it infringes the suit patent. Learned counsel illustrated this, by stating that if water is discovered for the first time and a claim covers the chemical formula H_2O, then it clearly covers all forms of H_2O whether they will be in liquid, steam, ice or snow. Similarly, Roche's invention as disclosed in Claim 1 of Patent No. IN '774 is a new compound with a specific chemical structure and it is only the research conducted years later which led to further innovation and the finding that Erlotinib Hydrochloride could exist in more than one polymorphic form and that the polymorphic forms differ from each other in physical properties with one version (Polymorph-B) being more suitable than the other version on account of its thermodynamic stability for oral dosage in solid form. According to learned counsel the basic patent discovers a molecule for the first time, which is novel and not found in nature, and consequently anyone who adopts, uses, reproduces or manufactures the said molecule, irrespective of the physical form in which it is done, would be infringing the said Claim.

99. Sh.Pravin Anand, learned counsel for Roche admitted in all fairness that the Learned Single Judge correctly notes that DW-2 analyzed the compound of Roche's drug Tarceva and concluded that the said drug is based on Polymorph B of Erlotinib Hydrochloride which corresponds to US '221 *(the Polymorph B patent)*. However, Sh.Pravin Anand urged that the Learned Single Judge has erred in not appreciating that the X-ray diffraction of Tarceva was wholly irrelevant to the *lis* in the present instance, which was for infringement of Claim 1 of IN '774 by Cipla product Erlocip. It was urged that it was not Roche's case that Tarceva is not Polymorph B of Erlotinib Hydrochloride but in fact it is Roche's case that the compound in Tarceva is Erlotinib Hydrochloride which corresponds to Claim 1 of IN '774. Learned counsel urged that the Learned Single Judge failed to appreciate that new chemical entities (NCE) such as Erlotinib Hydrochloride can be identified and characterized by Chemical Name, International Union of Pure and Applied Chemistry (IUPAC name), Chemical Structure and International Non-Proprietary Names (INN). Having been so described in Claim 1 of the suit patent, it was sufficient for Roche to show that Cipla had admittedly the same Chemical Name, IUPAC name, Chemical Structure and INN for its compound. X-ray diffraction analysis, urged Sh.Pravin Anand, is meant to describe the crystal lattice or the manner in which various molecules are arranged or packed together and this is only relevant when an invention is claimed in a new Polymorphic form. According to learned counsel, the invention does not relate to the physical characteristics of Erlotinib Hydrochloride but to the basic chemical substance itself. Learned counsel urged that if any third party uses, makes, sells etc. a compound or drug and identifies the same by Chemical Name, Chemical Structure or INN

name, it is admitted that infringement has occurred. In fact, in the United States, Tarceva is covered by US '498 *(being the Basic patent)* and US '221 *(being the Polymorph B or improvement patent)* amongst other patents.

100. Any process involved in making Polymorph B of Erlotinib Hydrochloride would first involve the preparation of Erlotinib hydrochloride itself; in fact a perusal of US '221 reveals that it is clearly stated that Erlotinib Hydrochloride in Polymorph B form results from re-crystallization of Erlotinib Hydrochloride using different solvents and temperature conditions. Hence if the suit patent was found to disclose Erlotinib Hydrochloride, any polymorphic version of the same would infringe the suit patent as Erlotinib Hydrochloride itself would be underlying every such polymorphic version.

101. The first error with the impugned judgment which needs to be highlighted before we bring the curtains down on the aspect of the matter concerning issues raised by Cipla on the subject of '*product'* versus '*substance'*. We begin by noting the observations made in this regard by the Learned Single Judge in para 213 of the impugned judgement as under:-

> *"...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".

102. The Learned Single Judge has thereafter relied on expert testimony of two kinds on this issue - first on X-ray diffraction tests which establish that Tarceva is Polymorph B alone and second that the tablet form of Erlotinib Hydrochloride does not follow directly from the claims in IN '774 (on account of the fact that further reactions of the product from IN '774 are required to produce Tarceva). This has lead the Learned Single Judge to a construction of Claim 1 of IN '774 to understand whether it subsumes Polymorph B of Erlotinib Hydrochloride, which is admittedly Erlocip

103. The second error we find is in the casting of the infringement issue, in para 228 of the decision, in the following words:-

> "*...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*." (emphasis ours).

104. Yet, later on the same page, in para 230, the words used by the learned Single Judge are:-

> *"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****"* (emphasis ours).

105. Thus, it is apparent that the Learned Single Judge has referred to two distinct things i.e. Claim 1 of IN '774 and Tarceva, interchangeably, to determine the infringement question and comes to what appears to us to be

an erroneous conclusion.

106. At this stage it is important for us to make some observations on X-ray diffraction as a methodology to ascertain infringement. X-ray diffraction is a method to determine and understand the crystalline structure of a compound. It is primarily used for the following broad purposes:

- In the regulatory field or during drug development, to identify a compound.
- To distinguish between amorphous and crystalline compounds.
- To identify the fingerprints of various polymorphic forms of a compound.

107. X-ray diffraction is certainly not an accurate method to ascertain product patent infringement in the present case as the issue is not and indeed cannot be whether Roche and Cipla's products are identical but whether Cipla's product is covered in the claims of Roche's patent. Although this appears to us to be a fairly elementary issue in appreciation of the nature of evidence in product patent infringement cases, neither counsel have relied on any jurisprudence to demonstrate what ought to be the correct test of infringement of a product patent.

108. While this issue was indeed framed by the Division Bench of the Gujarat High Court in the decision reported as 2008 (37) PTC 128(Guj) *Hind Mosaic and Cement Works & Anr. vs. Shree Shahjanand Trading Corporation & Anr.* in the following words: "*an infringement analysis involves comparison of each and every limitation of the claim with the allegedly infringing device. The analysis cannot be performed by comparing*

the product manufactured by the patentee with the allegedly infringing product," the decision does not expressly address this question. Since no other judgement has been brought to our attention which sets this issue right, we feel it is important for us to underscore it here.

109. It is an incorrect analysis of product patent infringement in a case like the present, to use methodologies like X-Ray diffraction to ascertain whether the competing products are identical in nature. The correct test of infringement in this case is to map Cipla product against the Roche's patent claims, which we find has not been done by the learned Single Judge, and this is the third infirmity on this aspect of the dispute.

110. If Roche's patent was for a polymorphic form of Erlotinib Hydrochloride and not the molecule itself and Cipla had argued that theirs was a '*new substance'*, then alone the Court could have relied on evidence of use of the X-Ray diffraction technique and a consequential analysis of the peaks of both to ascertain whether they are identical or dissimilar compounds. However in that situation too, the comparison would have to be between a product made on the basis of Roche's patent claim and Cipla's product and not between Roche's product as sold in the market and Cipla's product. This subtle distinction is important to be kept in mind because the holder of a patent is by no means limited to only manufacture and sell only those products that are disclosed in the claims of the patent and hence a different polymorph manufactured by the patent holder which is not the subject of the registered patent cannot be used for the purpose of comparison with the infringer product; the very product disclosed in the patent claims must be used.

111. Thus the question at hand is really whether Cipla's Polymorph B (Erlocip) was subsumed in the claims of IN '774. We find the answer in the decision reported as [2008] EWHC Civ 445 *Servier v Apotex.* Servier's attempt to secure a patent for the α-form of the t-butylamine salt of perindopril failed both before the Patents Court and the Court of Appeals which observed that the crystal form could easily be obtained by carrying out the process disclosed in the basic patent. In refusing to 'evergreen' the basic patent it was clear that the Court of Appeals was not denying Servier the right to enforce the basic patent against a third party attempting to manufacture the α-form crystals. In the present case too, the correct analysis that the Learned Single Judge ought to have employed was a construction of the IN '774 claim to understand whether it encompassed the manufacture of Polymorph B of Erlotinib Hydrochloride. By focusing on evidence involving the analysis of X-Ray diffraction data, the Learned Single Judge has erroneously compared the products of Roche and Cipla when he ought to have mapped the claims of the suit patent against Cipla's product. Counsels for both the Appellant and the Respondent have not been able to assist the court with authorities to support their stand on the test of infringement required to be employed and much of the arguments have been on first principles.

112. It is therefore left to the Court to study the specification and claims of the suit patent and note that as they are in relation to Erlotinib Hydrochloride and are not restricted to any specific Polymorph, they would be infringed by any manufacture of Polymorph B by a third party as the same would use the subject matter of IN '774 as its basic starting point. The Learned Single

Judge has correctly applied the principle in the decision reported as AIR 1969 Bom 255 *F.H & B vs. Unichem,* in stating that in case of any ambiguity of the Claim of the suit patent then resort can be taken to the specification of the said suit patent and nothing else. He correctly recognized that a Purposive Construction of the claims is necessary in order to not construe claims too narrowly. Yet we find that neither of these tests have been applied in the present case to construct the claims themselves and hence a conclusion that the IN '774 patent covers Polymorphs A+B itself is erroneous.

113. Once again we go back to Claim 1 of IN '774. It reads : "*A novel [6,7-bis (2-methoxyethoxy) quinazolin-4-yl]- (3-ethynylphenyl) amine hydrochloride compound of the formula A.*"

114. This is a sufficiently broad claim that is clearly not limited to any polymorphic version of Erlotinib Hydrochloride, but to Erlotinib Hydrochloride itself. This compound may exist in several polymorphic forms, but any and all such forms will be subsumed within this patent. Therefore as Cipla's Erlocip is admittedly one particular polymorphic form of the Erlotinib Hydrochloride compound (Polymorph B), it will clearly infringe the IN '774 patent. We thus conclude this issue by noting that the Single Judge's finding that 'Tarceva'and 'Erlocip' were based on the Polymorph B version of Erlotinib Hydrochloride, though correct factually, is irrelevant to the subject matter of the present patent as Cipla has clearly infringed Claim 1 of Roche's IN '774 patent in arriving at the said Polymorph.

Violation of Section 8 of The Patents Act, 1970

115. Cipla seeks revocation of the suit patent for violation of Section 8 of the Patents Act. Learned Senior Counsel for Cipla contends that assuming Roche believed Polymorph B of Erlotinib Hydrochloride to have been covered in the suit patent, thus considered Polymorph B of Erlotinib Hydrochloride to be '*same and substantially the same'* as the suit patent, then it ought to have disclosed before the patent office while prosecuting its application resulting in IN `774 that it had filed an application for grant of patent for Polymorph B of Erlotinib Hydrochloride resulting in US `221 which fact was not disclosed.

116. According to learned senior counsel for Cipla, Section 8 casts an obligation upon the patentee to disclose particulars of application in foreign Country of 'same or substantially the same invention' to the Controller and the same is a continuing obligation coupled with a duty to disclose. It is contended that Section 8 is a mandatory provision, non-compliance whereof results in revocation of the patent under Section 64 of the Patents Act and thus the suit patent is liable to be revoked on this ground as well. It is contended that the word 'may' in Section 64(1) ought to be read as 'shall'. Reference is made to *Maj. (Retd.) Sukesh Behl & Anr. Vs. Koninjlijke Phillips Electronics 2015 (61) PTC 183 (Del)*, *Chief Controlling Revenue Authority & Superintendent of Stamps Vs. Maharashtra Sugar Mills*, *1950 SCR 536*, *Ramji Missar & Anr. Vs. State of Bihar*, *1963 Supp(2) SCR 745*, *State of Uttar Pradesh Vs. Jogendar Singh*, *(1964) 2 SCR 197*, *Sardar Govindrao & Ors. Vs. State of Madhya Pradesh*, *(1965) 1 SCR 678*, *Smt. Bachchan Devi & Anr. Vs. Nagar Nigam, Gorakhpur & Anr.*, *AIR 2008 SC*

1282 and *Anil Soni Vs. UOI & Anr. MANU/DE/4017/2013*.

117. In response, learned counsel for the Roche contends that in the written statement or counter claim there are no pleadings or material particulars to show that the suit patent was violative of the disclosure requirement as mandated by Section 8. Further it is the case of Cipla itself that the claim relating to Polymorph B form was based on entirely independent invention, it not being the same and substantially the same as IN `774, thus the same was not required to be disclosed to the patents office. The stand of Roche that the invention of Polymorph B of Erlotinib Hydrochloride was a separate invention is fortified by a separate patent for Polymorph B of Erlotinib Hydrochloride having been granted in 40 Countries and thus the suit patent cannot be recalled/revoked for non-disclosure of the patent application resulting in grant of patent US `221 for Polymorph B in USA. Further application resulting in grant of the patent US `221 for Polymorph B of Erlotinib Hydrochloride was filed many years after the application for the suit patent. While the claim of IN `774 was for a new chemical entity, the claim of US `221 was for Polymorphic crystalline form of Erlotinib Hydrochloride. Thus, pendency of application resulting in grant of patent US `221 has no bearing on the examination of the suit patent and Roche was not required to disclose the same under Section 8. Further for the reason the Indian patent office rejected the claim of Roche for Polymorph B of Erlotinib Hydrochloride deeming it to be the same substance under Section 3(d) of the Patents Act, the pendency of the application of patent US `221 was not required to be revealed before the Patents Office. The provision under Section 64(1) Patents Act is discretionary in nature and does not mandate

revocation of a patent automatically. Reliance is placed on *Sukesh Behl*(supra).

118. We are in agreement with learned counsel for the Roche that the written statement and the counter claim do not give clear pleadings as to the violation of Section 8. The relevant portions in the counter claim in para 2 relating to grounds of revocation in sub-para (i) states as under:-

> *"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;"*

119. It is trite that a pleading concerning suppression of a fact or failure to disclose a relevant fact has to be specific by highlighting what was required to be disclosed or informed. A general and a bald allegation that the opposite party had failed to disclose information required by law is no pleadings in the eyes of law.

120. Sections 8 and 64(1)(m) of the Patents Act 1970 read as under:-

> *"Section 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 or subsequently within the prescribed period as the Controller may allow-*
>
> *(a) a statement setting out detailed particulars of such application; and;*

(b) an undertaking that upto the date of grant of patent in India, he would keep the Controller informed in writing, from time to time, of detailed particulars as required under 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) At any time after an application for patent is filed in India and till the grant of a patent or refusal to grant of patent made thereon, the Controller may also require the applicant to furnish details, as may be prescribed, relating to the processing of the application in a country outside India, and in that event the applicant shall furnish to the Controller information available to him within such period as may be prescribed.

Section 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 counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds that is to say-

(a) to (l) xx xx xx

(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;"

121. It is evident that when Roche was prosecuting its application for grant of suit patent IN `774 separate application for grant of patent for Polymorph B form of Erlotinib Hydrochloride was filed on February 06, 2002 being DEL '507. We have already held that the suit patent was a product patent relating to the new molecule Erlotinib Hydrochloride whereas US `221 was an improvement patent application which involved intermolecular

relationship between the various molecules of Erlotinib Hydrochloride resulting in a certain polymorphic structure with no enhanced therapeutic values but more thermodynamic and due to the enhanced efficacy of polymorph B not being demonstrated the patent application DEL `507 was declined in India whereas granted in 40 other countries. Thus non filling of the details of the application resulting in grant of patent US '221 by Roche is attributable to the bona-fide belief of Roche that the application resulting in patent US '221 is not same or substantially the same compound. This bona fide belief of Roche is also fortified by the claim of Cipla in para 5 of the reply to CM 219, an application in FAO (OS) 188/2008 Ex.DW-1/13 where it states-

> "*The Respondent states that the doctrine of selection patent is well settled and does not fit into the factual matrix of the invention relating to the polymorph B form which is based on an entirely independent invention, which was made about four years after the main patent and was not known and thus cannot be said to be subsumed in the suit patent."*

122. In the decision reported as (2011) 9 SCC 354 *Delhi Airtech Services (P) Ltd. Vs. State of U.P.* the Supreme Court encapsulated the legal position on determining whether a particular provision of Statute is mandatory or directory. It noted-

> *"116. Let us first examine the general principles that could help the Court in determining whether a particular provision of a statute is mandatory or directory.*
>
> *117. In Principles of Statutory Interpretation, 12th Edn., 2010, Justice G.P. Singh, at pp. 389-92 states as follows:*
>
> *"… As approved by the Supreme Court:*
>
> *'The question as to whether a statute is mandatory or directory depends upon the intent of the legislature and not upon the*

language in which the intent is clothed. The meaning and intention of the legislature must govern, and these are to be ascertained not only from the phraseology of the provision, but also by considering its nature, its design, and the consequences which would follow from construing it the one way or the other.'

'For ascertaining the real intention of the legislature', points out Subbarao, J.,

'the court may consider inter alia, the nature and design of the statute, and the consequences which would follow from construing it the one way or the other; the impact of other provisions whereby the necessity of complying with the provisions in question is avoided; the circumstances, namely, that the statute provides for a contingency of the non-compliance with the provisions; the fact that the non-compliance with the provisions is or is not visited by some penalty; the serious or the trivial consequences, that flow therefrom; and above all, whether the object of the legislation will be defeated or furthered'.

If object of the enactment will be defeated by holding the same directory, it will be construed as mandatory, whereas if by holding it mandatory, serious general inconvenience will be created to innocent persons without very much furthering the object of enactment, the same will be construed as directory. But all this does not mean that the language used is to be ignored but only that the prima facie inference of the intention of the legislature arising from the words used may be displaced by considering the nature of the enactment, its design and the consequences flowing from alternative constructions. Thus, the use of the words 'as nearly as may be' in contrast to the words 'at least' will prima facie indicate a directory requirement, negative words a mandatory requirement, 'may' a directory requirement and 'shall' a mandatory requirement."

118. Maxwell, in Chapter 13 of his 12th Edn. of The Interpretation of Statutes, used the word "imperative" as synonymous with "mandatory" and drew a distinction between imperative and directory enactments, at pp. 314-15, as follows:

"Passing from the interpretation of the language of statutes, it remains to consider what intentions are to be attributed to the legislature on questions necessarily arising out of its enactments and on which it has remained silent.

The first such question is: when a statute requires that something shall be done, or done in a particular manner or form, without expressly declaring what shall be the consequence of non-compliance, is the requirement to be regarded as imperative (or mandatory) or forms prescribed by the statute have been regarded as essential to the act or thing regulated by it, and their omission has been held fatal to its validity. In others, such prescriptions have been considered as merely directory, the neglect of them involving nothing more than liability to a penalty, if any were imposed, for breach of the enactment. 'An absolute enactment must be obeyed or fulfilled exactly, but it is sufficient if a directory enactment be obeyed or fulfilled substantially'.

It is impossible to lay down any general rule for determining whether a provision is imperative or directory. 'No universal rule,' said Lord Campbell, L.C. 'can be laid down for the construction of statutes, as to whether mandatory enactments shall be considered directory only or obligatory with an implied nullification for disobedience. It is the duty of Courts of Justice to try to get at the real intention of the legislature by carefully attending to the whole scope of the statute to be construed.'

And Lord Penzance said:

'I believe, as far as any rule is concerned, you cannot safely go further than that in each case you must look to the subject-matter; consider the importance of the provision that has been disregarded, and the relation of that provision to the general object intended to be secured by the Act; and upon a review of the case in that aspect decide whether the matter is what is called imperative or only directory.' [Ed.: As observed in Howard v.Bodington, (1877) 2 PD 203, p. 211 : 42 JP 6.] "

119. In a recent judgment of this Court, May George v. Tahsildar [(2010) 13 SCC 98 : (2010) 4 SCC (Civ)

774] , the Court stated the precepts, which can be summed up and usefully applied by this Court, as follows:

(a) While determining whether a provision is mandatory or directory, somewhat on similar lines as aforenoticed, the Court has to examine the context in which the provision is used and the purpose it seeks to achieve;

(b) To find out the intent of the legislature, it may also be necessary to examine serious general inconveniences or injustices which may be caused to persons affected by the application of such provision;

(c) Whether the provisions are enabling the State to do some things and/or whether they prescribe the methodology or formalities for doing certain things;

(d) As a factor to determine legislative intent, the court may also consider, inter alia, the nature and design of the statute and the consequences which would flow from construing it, one way or the other;

(e) It is also permissible to examine the impact of other provisions in the same statute and the consequences of non-compliance with such provisions;

(f) Phraseology of the provisions is not by itself a determinative factor. The use of the word "shall" or "may", respectively would ordinarily indicate imperative or directory character, but not always.

(g) The test to be applied is whether non-compliance with the provision would render the entire proceedings invalid or not.

(h) The court has to give due weightage to whether the interpretation intended to be given by the court would further the purpose of law or if this purpose could be defeated by terming it mandatory or otherwise.

120. Reference can be made to the following paragraphs of May George [(2010) 13 SCC 98 : (2010) 4 SCC (Civ) 774] : (SCC pp. 103-05, paras 16-17 & 22-23)

"16. In Dattatraya Moreshwar v. State of Bombay [AIR 1952 SC 181 : 1952 Cri LJ 955] this Court observed that law which

creates public duties is directory but if it confers private rights it is mandatory. Relevant passage from this judgment is quoted below: (AIR p. 185, para 7)

'7. ... It is well settled that generally speaking the provisions of a statute creating public duties are directory and those conferring private rights are imperative. When the provisions of a statute relate to the performance of a public duty and the case is such that to hold null and void acts done in neglect of this duty would work serious general inconvenience or injustice to persons who have no control over those entrusted with the duty and at the same time would not promote the main object of the legislature, it has been the practice of the courts to hold such provisions to be directory only, the neglect of them not affecting the validity of the acts done.'

17. A Constitution Bench of this Court in State of U.P. v. Babu Ram Upadhya [AIR 1961 SC 751 : (1961) 1 Cri LJ 773] decided the issue observing: (AIR p. 765, para 29)

'29. ... For ascertaining the real intention of the legislature the court may consider, inter alia, the nature and the design of the statute, and the consequences which would follow from construing it the one way or the other, the impact of other provisions whereby the necessity of complying with the provisions in question is avoided, the circumstance, namely, that the statute provides for a contingency of the non-compliance with the provisions, the fact that the non-compliance with the provisions is or is not visited by some penalty, the serious or trivial consequences that flow therefrom, and, above all, whether the object of the legislation will be defeated or furthered.'

* * *

22. In B.S. Khurana v. MCD [(2000) 7 SCC 679] this Court considered the provisions of the Delhi Municipal Corporation Act, 1957, particularly those dealing with transfer of immovable property owned by the Municipal Corporation. After considering the scheme of the Act for the purpose of transferring the property belonging to the Corporation, the Court held that the Commissioner could alienate the property

only on obtaining the prior sanction of the Corporation and this condition was held to be mandatory for the reason that the effect of non-observance of the statutory prescription would vitiate the transfer though no specific power had been conferred upon the Corporation to transfer the property.

23. In State of Haryana v. Raghubir Dayal [(1995) 1 SCC 133] this Court has observed as under: (SCC pp. 135-36, para 5)

'5. The use of the word "shall" is ordinarily mandatory but it is sometimes not so interpreted if the scope of the enactment, on consequences to flow from such construction would not so demand. Normally, the word "shall" prima facie ought to be considered mandatory but it is the function of the Court to ascertain the real intention of the legislature by a careful examination of the whole scope of the statute, the purpose it seeks to serve and the consequences that would flow from the construction to be placed thereon. The word "shall", therefore, ought to be construed not according to the language with which it is clothed but in the context in which it is used and the purpose it seeks to serve. The meaning has to be ascribed to the word "shall" as mandatory or as directory, accordingly. Equally, it is settled law that when a statute is passed for the purpose of enabling the doing of something and prescribes the formalities which are to be attended for the purpose, those prescribed formalities which are essential to the validity of such thing, would be mandatory. However, if by holding them to be mandatory, serious general inconvenience is caused to innocent persons or general public, without very much furthering the object of the Act, the same would be construed as directory.'"

121. The legislature in Sections 11-A and 17(3-A) of the Act has used the word "shall" in contradistinction to the word "may" used in some other provisions of the Act. This also is a relevant consideration to bear in mind while interpreting a provision.

122. The distinction between mandatory and directory provisions is a well-accepted norm of interpretation. The general rule of interpretation would require the word to be given its own meaning and the word "shall" would be read as "must" unless it was essential to read it as "may" to achieve

the ends of legislative intent and understand the language of the provisions. It is difficult to lay down any universal rule, but wherever the word "shall" is used in a substantive statute, it normally would indicate mandatory intent of the legislature.

123.Crawford on Statutory Construction has specifically stated that language of the provision is not the sole criterion; but the courts should consider its nature, design and the consequences which could flow from construing it one way or the other.

124. Thus, the word "shall" would normally be mandatory while the word "may" would be directory. Consequences of non-compliance would also be a relevant consideration. The word "shall" raises a presumption that the particular provision is imperative but this prima facie inference may be rebutted by other considerations such as object and scope of the enactment and the consequences flowing from such construction.

125. Where a statute imposes a public duty and proceeds to lay down the manner and time-frame within which the duty shall be performed, the injustice or inconvenience resulting from a rigid adherence to the statutory prescriptions may not be a relevant factor in holding such prescription to be only directory. For example, when dealing with the provisions relating to criminal law, legislative purpose is to be borne in mind for its proper interpretation. It is said that the purpose of criminal law is to permit everyone to go about their daily lives without fear of harm to person or property and it is in the interests of everyone that serious crime be effectively investigated and prosecuted. There must be fairness to all sides. [Attorney General's Reference (No. 3 of 1999) [(2001) 2 AC 91 : (2001) 2 WLR 56 : (2001) 1 All ER 577 (HL)] ; Justice G.P. Singh on Principles of Statutory Interpretation, 11th Edn., 2008]. In a criminal case, the court is required to consider the triangulation of interests taking into consideration the position of the accused, the victim and his or her family and the public.

126. The basic purpose of interpretation of statutes is further to aid in determining either the general object of the legislation or the meaning of the language in any particular provision. It is obvious that the intention which appears to be most in

accordance with convenience, reason, justice and legal principles should, in all cases of doubtful interpretation, be presumed to be the true one. The intention to produce an unreasonable result is not to be imputed to a statute. On the other hand, it is not impermissible, but rather is acceptable, to adopt a more reasonable construction and avoid anomalous or unreasonable construction. A sense of the possible injustice of an interpretation ought not to induce Judges to do violence to the well-settled rules of construction, but it may properly lead to the selection of one, rather than the other, of the two reasonable interpretations. In earlier times, statutes imposing criminal or other penalties were required to be construed narrowly in favour of the person proceeded against and were more rigorously applied. The courts were to see whether there appeared any reasonable doubt or ambiguity in construing the relevant provisions. Right from the case of R.v. Jones, ex p Daunton [(1963) 1 WLR 270 : (1963) 1 All ER 368 (DC)] , the basic principles state that even statutes dealing with jurisdiction and procedural law are, if they relate to infliction of penalties, to be strictly construed; compliance with the procedures will be stringently exacted from those proceedings against the person liable to be penalised and if there is any ambiguity or doubt, it will be resolved in favour of the accused/such person. These principles have been applied with approval by different courts even in India. Enactments relating to procedure in courts are usually construed as imperative. A kind of duty is imposed on court or a public officer when no general inconvenience or injustice is caused from different construction. A provision of a statute may impose an absolute or qualified duty upon a public officer which itself may be a relevant consideration while understanding the provision itself. (See Maxwell on The Interpretation of Statutes, 12th Edn. by P. St. J. Langan and R. v. Bullock [(1964) 1 QB 481 : (1963) 3 WLR 911 : (1963) 3 All ER 506 (CCA)] .)"

123. Thus though as a general rule if a consequence is provided then the rule has to be interpreted as mandatory however in the present case the consequence itself is not mandatory because of use of the word 'may' in

Section 64(1). This issue came up for consideration before Division Bench of this Court in *Maj.(Retd.) Sukesh Behl* (supra) wherein this Court held that though it is mandatory to comply with the requirement under Section 8(1) of the Patents Act and non-compliance of the same is one of the grounds for revocation of the patent under Section 64(1)(m), however the use of the word 'may' in Section 64(1) itself indicates the intention of the legislature that the power conferred thereunder is discretionary and consequently it is necessary for the Court to consider the question as to whether omission on the part of the applicant was intentional or whether it was a mere clerical and bona-fide error.

124. Having held that Section 64(1) is directory in nature and thus non-compliance of Section 8 would not automatically result in revocation of the patent, we need to note the further distinction between a mandatory rule and a directory rule. In the decision reported as 1981 SCC 202 *Sharif-Ud-Din Vs. Abdul Gani Lone* the Supreme Court noting the distinction between a mandatory rule and the directory rule held that while the former must be strictly observed, in the case of the latter substantial compliance may be sufficient to achieve the object regarding which the rule was enacted.

125. The doctrine of substantial compliance is a judicial invention, equitable in nature, designed to avoid hardship in cases where a party does all that can reasonably be expected of it, but failed or faulted in some minor or inconsequent aspects which cannot be described as the "essence" or the "substance" of the requirements. Like the concept of "reasonableness", the acceptance or otherwise of a plea of "substantial compliance" depends on the facts and circumstances of each case and the purpose and object to be achieved and the context of the prerequisites which are essential to achieve

the object and purpose of the rule or the regulation. (See (2011) 1 SCC 236 *Commissioner of Central Excise, New Delhi Vs. Hari Chand Shri Gopal & Ors.*).

126. We have already noted above and repeat that Roche has been granted patent for Polymorph B in 40 Countries and had also applied for the same in India and thus, non-intimation of the patent application for Polymorph B resulting in grant of US '221 was due to the bona-fide belief of Roche that the two patents were separate inventions. Be that as it may, it is a case of substantial compliance inasmuch as even if Roche did not inform about the pending application resulting in grant of US '221, NATCO in its pre-grant opposition application to the suit patent duly informed about the same.

127. The decision of the Assistant Controller of Patents and Designs dated July 04, 2007 clearly shows that in pre-grant opposition, the factum of US '221 was disclosed though the said issue was raised in regard to insufficiency of disclosure regarding the polymorphic version. The contention as noted and dealt by the Assistant Controller of patents and Designs in the order dated July 04, 2007 is as under-

> *"The opponent states that the compound of EX-20 XRD data has not been given. This amount to insufficiency of disclosure in view of the fact that polymorphic version of the same Drug substance have been subsequently disclosed in US 6900221 filed on 11.11.99.*
>
> *Opponent further states that it is also not clear to which polymorphic class the preferred compound viz 6, 7 – Bis (2methoxy ethoxy)-quinanazoline-4yl-(3-ethynyl phenyl) amino hydrochloride III of the current patent application belongs. It is very pertinent and relevant to have the details of the current form for the product claimed in the current application."*

128. It is apparent that even NATCO or for that matter even Cipla was of the opinion that Polymorph B form of Erlotinib Hydrochloride for which the patent US '221 was granted was a different polymorphic version thus not same or substantially the same product and non-disclosure under Section 8 by Roche was due to such bonafide belief, however still substantial compliance thereof has been done as the factum of application resulting in grant of US patent '221 for polymorph B of Erlotinib Hydrochloride were before the patent office, though revealed by NATCO. Thus it cannot be held that non-disclosure of US `221 caused prejudice thereby failing to pass the test of substantial compliance..

129. Thus, we find no reason to revoke the suit patent for non-compliance of Section 8 under Section 64(1) (m) of the Patents Act.

Whether suit patent is obvious

130. On the subject of obviousness, we could illustrate by referring to a passage in the Article: THE RISE OF LIFE: by Bill Bryson in his illuminating book titled '*A Short History of Nearly Everything*', which brings out very succinctly as to how a thing which at first blush may appear to be obvious, but actually is not obvious for the reason looking at a thing from hind sight tends to give an impression that it was obvious. The learned author has written:

> *"The chances of a 1,055-sequence molecule like collagen spontaneously self-assembling are, frankly, nil. It just isn't going to happen. To grasp what a long shot its existence is, visualize a standard Las Vegas slot machine but broadened greatly – to about 27 metres, to be precise – to accommodate 1,055 spinning wheels instead of the usual three or four, with twenty symbols on each wheel (one for each common amino acid). How long would you have to pull the handle before all*

1,055 symbols came up in the right order? Effectively, forever. Even if you reduced the number of spinning wheels to 200, which is actually a more typical number of amino acids for a protein, the odds against all 200 coming up in a prescribed sequence are 1 in 10 (that is a 1 followed by 260 zeros). That in itself is a larger number than all the atoms in the universe.

Proteins, in short, are complex entities. Haemoglobin is only 146 amino acids long, a runt by protein standards, yet even it offers 10 possible amino-acid combinations, which is why it took the Cambridge University chemist Max Perutz twenty-three years – a career, more or less – to unravel it."

131. Down the essay the learned author writes:

"Chemical reactions of the sort associated with life are actually something of a commonplace. It may be beyond us to cook them up in a lab, a la Stanley Miller and Harold Urey, but the universe does it readily enough. Lots of molecules in nature get together to form long chains called polymers. Sugars constantly assemble to form starches. Crystals can do a number of lifelike things – replicate, respond to environmental stimuli, take on a patterned complexity. They have never achieved life itself, of course, but they demonstrate repeatedly that complexity is a natural, spontaneous, entirely reliable event. There may or may not be a great deal of life in the universe at large, but there is no shortage of ordered self-assembly, in everything from the transfixing symmetry of snowflakes to the comely rings of Saturn."

132. For long, chemists were aware of similar characters shown by elements. The chemist had been able to group elements in two ways : (i) either by atomic weight (using AVOGADRO'S principle) or (ii) by common properties (whether they were metals or gases.) That a breakthrough could be achieved by combining the two in a single table had been anticipated. An amateur chemist, named John Newlands had suggested that when elements

were arranged by weights they appear to repeat properties – in a sense to harmonise – at every eighth place along the scale. Newlands called it the Law of OCTAVES, and linked the arrangement to the octaves on a piano keyboard. Perhaps the manner of presentation by Newlands was perceived to be funny and this explains his idea being considered fundamentally preposterous and widely mocked. At gatherings, droller members of the audience would sometimes ask him if he could get his elements to play them a little tune.

133. By 1860, the card game known as solitaire in North America, called patience elsewhere, where cards are arranged by a suit horizontally and by number vertically, had become a rage.

134. Using a broad similar concept, Dmitri Ivanovich Mendeleev arranged the elements in horizontal rows called periods and vertical columns called groups. This instantly showed one set of relationships when read up and down and another when read from side to side. Specifically, the vertical columns put together have similar properties. Thus, copper sits on top of silver and silver sits on top of gold because of their chemical affinities as metals; while helium, neon and argon are in a column made up of gases.

135. The approach used by Mendeleev was slightly different than that of John Newlands, but employed fundamentally the same premise. Suddenly, the idea seemed brilliant and wondrously perceptive because the properties repeated themselves periodically, the invention became known as the periodic table.

136. For the world, the periodic table became a thing of beauty in the abstract, but for the chemist it established an immediately orderliness and clarity that can hardly be overstated.

137. Robort E. Krebs in his book- *'The History and Use Of Our Earth Chemical Elements'* wrote that without a doubt, the Periodic Table of the Chemical Elements is the most elegant organizational chart ever devised. Thus what was anticipated was still a leap in the field of Chemistry.

138. Coming to the case in hand, Cipla claims that the impugned product is invalid under Section 64 (1)(f) of the Patents Act, 1970 for lack of inventive steps and being obvious. It is urged that Example 51 of EP '226 is the closest prior art cited in the suit patent and any person skilled in the art would be motivated to use the same as a starting point. Further EP '226 was the first patent document to disclose the use of Quinazoline derivatives for their anti-cancer properties. The only difference between a large number of compounds exemplified in EP '226 and those exemplified in the suit patent was a mere substitution of Methyl with Ethynyl on the 3 meta position. The motivation to choose Example 51 of EP '226 is also attributed to its relatively effective IC 50 value which has been clearly defined in Example 51 of EP '226. Methyl and Ethynyl are known bioisoteres and a person skilled in the art is aware of the well known basic principles of Grimm's Hydride Displacement Law; applying which example 20 of the suit patent is reached. Cipla claims that having discharged the initial burden of showing that the suit patent was obvious, the onus shifted to Roche to prove that the suit patent was not obvious and was an inventive step from the earlier known example. Further EP '226 itself suggests Cyano as a possible substitute and thus the suit patent lacks inventive steps and is not novel. Reliance is placed on *Terrel on Patents;* 550 U.S. 398 (2007) *KSR International Co. Vs. Teleflex Inc.;* (1985) R.P.C. 59 *Windsurfing International Inc.Vs. Tabur Marine (Great Britain) Ltd.;* (2010) FSR 18

Actavis Vs. Navartis, (2007) EWCA Civ 588 *Pozzoli SPA Vs. BDMO SA;* 566 F.3d 999 (2009) *Altana Pharma AG Vs. Teva Pharmaceuticals USA Ltd.;* decision of Boards of Appeal European Patent Office in case No.T164/83 titled *Eisai Co. Ltd.;* 16 USPQ.2d 1897 *In re Dillon;* 800 F.2d 1091 *In re Merck;* 138 USPQ 22 *In re Zickendraht and Buehler* and 82 U.S.P.Q.2D (BNA) 1321*Pfizer Inc Vs. Apotex Inc.*.

139. Roche rebutting argument of Cipla on lack of inventive steps and obviousness claims that Cipla admitted patent IN 774 being novel, hence anticipation has not been assailed as a ground. It is contended that an invention is obvious or does not involve any inventive steps if the complete specifications are published before the priority date of said claim. Obviousness has to be determined by a person of ordinary skill in the Art (in short 'POSA'). POSA thinks along the lines of conventional wisdom in art and does not undertake risks to go away from the main stream teaching. While conducting an inquiry into obviousness, hindsight is impermissible and the legal conclusion must be reached on the basis of facts gleaned from the prior art and should not include knowledge gleaned from patent disclosure. Teachings in prior art document have to be considered as a whole. Teachings away from the patent claim are treated as non-obvious. To inquire into obviousness, two fold inquiry is required to be conducted i.e. motivation to select and motivation to modify. Mere structural similarity cannot form the basis for selection of a lead compound in a prior art. The legal position is well settled that potent and promising activity in the prior art trumps mere structural similarity. There has to be a teaching, suggestion or motivation in the prior art document in order to modify the lead compound. Besides the primary consideration as noted, the objective indicia

of non-obviousness include secondary considerations such as (i) a long-felt need; (ii) failure of others; (iii) industry acclaim; and (iv) unexpected results. Roche claims that Cipla has not discharged its onus to establish invalidity on the ground of obviousness as no clear and convincing evidence was led to demonstrate that the three distinct approaches canvassed by Cipla that POSA would be motivated to modify the lead compound Example 51 with EP '507 in order to substitute the 3rd meta position of Methyl on Phenyl ring with Ethynyl there being no reference of a teaching to show that Ethynyl would be a suitable alternative; the second being applying the concept of "bioisosteric replacement" to the 3rd position of phenyl ring of Example 51 of EP '226 and thirdly Cipla's relying upon 5 additional documents, two of which are not prior art namely EP 0477700, US 4138590, US 5427766, US 5736534 and WO 193004047 which were exhibited by DW-3 Prof.Ashwini Nangia. The evidence of Prof. Ashwini Nangia DW-3 cannot be relied upon as he was not a person skilled in art neither being a medicinal chemist nor having any experience in drug discovery and development process from inception to animal study and clinical trials, no independent search having been conducted by DW-3 and his search was based on Google and Wikipedia few days prior to cross-examination. Cipla provides no reason to select EP '226 as the closest prior art and as to why Example 51 would have been selected as a lead compound. The teaching of the prior art should be as a whole and various steps cannot be surgically put together. No evidence has been led by Cipla in support of its steps canvassed. Further Prof.Roger Griffin, PW-2 has explained that bioisosteric replacement at best is a rough rule of thumb and provides no motivation to a POSA to develop Erlotinib Hydrochloride. Reliance is placed on the decisions reported as AIR 1969

Bombay 255 *F.H.& B.Corp. Vs.Unichem Laboratories*, (1979) 2 SCC 511 *Bishwanath Prasad Vs.Hindustan Metal Industries*, [2012] EWHC 1848 *Mylan Vs.Yeda*, MANU/USFD/0081/2014 *Pfizer Inc. Vs.Teva Pharmaceuticals*, 520 F.3d. 1358 *OrthoMcNeil Pharmaceutical Inc. Vs. Mylan Laboratories Inc.*, 840 F.2d 902 *Grain Processing Vs. American Maize*, 231 F.3d 1339 *CAFC Yamanouchi Pharmaceutical Co. Ltd. Vs.Danbury Pharmacal Inc.*, MANU/USFD/0845/2012 *Otsuka Pharmaceutical Co. Ltd. Vs. Sandoz Inc. and Apotex Inc.*, 550 U.S. 398 (2007) *KSR International Co. Vs. Teleflex Inc.*, 471 F.3d 1369 *Eli Lilly And Company and Lilly Industries Ltd. Vs. Zenith Goldline Pharmaceuticals, Inc.*, 676 F.3d at 1072 *In re Cyclobenzaprine*, 619 F.3d 1346 (Fed Cir 2010) *Daiichi Sankyo Co. Ltd. Vs. Matrix Labs Ltd.*, decision of United States District Court in Civil Action No.04-2355(JLL titled *Altana Pharma Vs. Kudco*, 858 F. Supp.2d 341 *OSI Pharmaceuticals Vs. Mylan Pharmaceuticals Inc. & Pfizer Inc., Genentech Inc. Vs. Mylan Pharmaceuticals Inc., Teaching of EP `226, Teaching of EP `851, Teaching of EP `498, Teaching of EP `507, 'Isosterism and Molecular medication in drug design' by C.W. Thornber,* decision of Boards of Appeal of the European Patent Office in case No. T 0467/94 titled *Eisai Co. Ltd.*, decision of Boards of Appeal of the European Patent Office in case No. T0156/95 titled *Hoechst Marion Inc.*, decision of Boards of Appeal of the European Patent Office in case No. T 0643/96 titled *Beecham Group PLC.*

140. Before proceeding to test the issue of obviousness and lack of inventive steps on the facts of the present case, it would be appropriate to note the legal position. Sections 2(1)(j) and 2(1)(ja) Indian Patents Act define 'Invention' and 'Inventive step' as under:-

> *"2(1)(j) "invention" means a new product or process involving an inventive step and capable of industrial application;*
>
> *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;*

141. Section 64 of the Patents Act, 1970 empowers the Appellate Board and the High Court to revoke a patent granted subject to other provisions in the Act for being obvious under Section 64(1)(f) which reads as under:-

> *"64(1)(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:"*

142. From a bare reading of Section 64(1)(f) of the Patents Act,1970 it is evident that '*obviousness*' and '*lack of inventive steps*' have to be seen vis-a-vis facts publically known or publically used in India or published in India or elsewhere before the priority date. The priority date of US '498 and IN `774, the suit patent is March 30, 1995, and thus teachings prior thereto can only be seen. Both US '534 and US '766 are admittedly not prior arts and thus could not have been used to test obviousness.

143. Whether an invention involves '*novelty*' and an '*inventive step*' or is '*obvious*' is a mixed question of law and fact, depending on the facts and circumstances of each case. Though no absolute or uniform formula can be laid down to ascertain obviousness however certain broad criteria have been laid down in the various decisions.

144. Obviousness has to be strictly and objectively judged. In the decision

reported as (1979) 2 SCC 511*Bishwanath Prasad Vs. Hindustan Metal Industries* (para 25) the Supreme Court laid down the principles to test '*inventive step*' as under:-

> *25. 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 draftsman (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 Farbwerke Hoechst & B. Corporation v. Unichem Laboratories [AIR 1969 Bom 255 (Bom HC)] .]"*

145. To test obviousness the first test required to be applied is to see who is an ordinary person skilled in art (POSA) and what are its characteristics. The features of a person skilled in the art are that of a person who practices in the field of endeavour, belongs to the same industry as the invention, possesses average knowledge and ability and is aware of what was common general knowledge at the relevant date.

146. The Supreme Court of United States in the decision reported as 383 U.S. 1(1966) *William T. Graham et al. Vs. John Deere Company of Kansas*

City et al. analyzed the factual determination of the level of ordinary skill in the art which analysis was followed with approval in 218 U.S. P.Q. 865 *Environmental Designs Ltd. Vs. Union Oil Company of California*, 702 F.2d 1005*Orthopedic Equipment Co. Inc. Vs. The United States*, 864 F.2d 757*Newell Companies, Inc. Vs. Kenney Manufacturing Company* and 501 F.3d 1254*Daiichi Sankyo Co., Ltd. Vs. Apotax, Inc.* The decisions laid down the following principle factors, though not exhaustive, as under:-

> *"In determining the level of ordinary skill in the art, you should first determine whether there was a number of people who regularly worked to solve the type of problem that the invention solved, and, if so, determine the level of ordinary skill of such people at the time the invention was made. You must consider the level of skill as to the time the invention was made. Among the factors that may be considered in your determination are:*
>
> *(1) The various ways that others sought to solve the problems existing;*
> *(2) The types of problems encountered;*
> *(3) The rapidity with which new inventions are made in this art;*
> *(4) The sophistication of the technology involved; and*
> *(5) The educational background of those actively working in the field."*

147. The triple test of obviousness has been laid down by the U.S. Supreme Court in *KSR International Co* (supra) i.e. 'teaching, suggestion, or motivation'. Noting that the analysis was objective, it was held:-

> *"Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc.,*

might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." Id., at 17-18."

148. In *Windsurfing International Inc* (supra) the Court of Appeals noted the four steps to answer the question of obviousness which were followed in *Pozzoli SPA (supra)* as under:-

"(i) identifying the inventive concept embodied in the patent;

(ii) imputing to a normally skilled but unimaginative addressee what was common general knowledge in the art at the priority date;

(iii) identifying the differences if any between the matter cited and the alleged invention; and

(iv) deciding whether those differences, viewed without any knowledge of the alleged invention, constituted steps which would have been obvious to the skilled man or whether they required any degree of invention."

149. In *Eisai Co., Ltd. (supra)* the Board of Appeals of European Patent Office applying the problem solution approach which consists essentially in (a) identifying the closest prior art, (b) assessing the technical results (or effects) achieved by the claimed invention when compared with the closest state of the art established, (c) defining the technical problem to be solved as the object of the invention to achieve these results, and (d) examining whether or not a skilled person starting from the closest prior art "would" arrive at something falling within claim by following the suggestion made in the prior art held that when deciding upon inventive step in relation to pharmacologically active compounds it is not essential whether a particular substructure of a compound could be replaced by another known isosteric

one, but whether information was available on the impact of such a replacement on the pharmacological activity of the specific group of compounds concerned.

150. Expressing a note of caution, the Bombay High Court in *F.H. & B. Corp.* (supra) guarded the Courts of law against the common human failing of being wise after the event in regarding something that has been discovered by research as obvious. In *Grain Processing* (supra) the Court noted that care must be taken to avoid hindsight reconstruction by using the patent in suit as a guide through the MAZE of prior art references in the right way so as to achieve the result of the claims in suit. In *Pfizer Inc. Vs. Teva Pharmaceuticals* (supra) it was held that a patent challenger however must demonstrate the selection of a lead compound based on its promising useful properties, not a hindsight driven search for structurally similar compounds. Similar caution was advanced in *Yamanouchi Pharmaceutical Co. Ltd.* (supra) and *Otsuka Pharmaceutical Co. Ltd.*(supra).

151. From the decisions noted above to determine obviousness/lack of inventive steps the following inquires are required to be conducted:

Step No.1 To identify an ordinary person skilled in the art,

Step No.2 To identify the inventive concept embodied in the patent,

Step No.3 To impute to a normal skilled but unimaginative ordinary person skilled in the art what was common general knowledge in the art at the priority date.

Step No.4 To identify the differences, if any, between the matter cited and the alleged invention and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical and practical applications,

Step No.5 To decide whether those differences, viewed in the knowledge of alleged invention, constituted steps which would have been obvious to the ordinary person skilled in the art and rule out a hideside approach.

152. On the various tests as noted above, there is no dispute between Cipla and Roche however the dispute arises whether the teaching of prior art document should be considered as a whole, whether there should be no teachings away and whether evidence to try merely on structural similarity can form the basis for selection of lead compound in a prior art.

153. In *Otsuka Pharmaceutical Co. Ltd.* (supra) it was held –

> *"A patent is invalid if an alleged infringer proves, by clear and convincing evidence, that the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the pertinent art."*

154. In re: Dillon relied upon by learned counsel for Cipla, though the majority held that a prima facie case for obviousness of chemical composition is established if there is structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, and if prior art gives reason or motivation to make claimed composition however, the minority judgment noting various authorities held that Courts have expressed dissatisfaction on the earlier rule that 'structural obviousness' alone was deemed to create a presumption of unpatentability. The minority held that the weight of the authorities would show that structural similarity of the prior art compound cannot be the criteria alone and the prior art must prima facie suggest both similar structure and property

before the burden shifts to the applicant to prove the unexpected differences. Even in 444.2d 581 *re: John R. Slemniski* the Court held that similarity of structure alone was insufficient for prima facie unpatentability. Thus to show obviousness besides structural similarity there should be a reason or motivation shown in the prior art to make the particular structural change in order to achieve the properties that the applicant was seeking.

155. In *Pfizer Inc. Vs.Teva Pharmaceuticals*(supra) the Court of Appeals with regard to obviousness inter alia held as under:-

> *The determination of obviousness is a legal conclusion based on underlying facts. Allergan, Inc. v. Sandoz Inc., 726 F.3d 1286, 1290-91 (Fed.Cir. 2013). After a bench trial, we review the district court's factual findings for clear error and its conclusions of law de novo. Honeywell Int'l, Inc. v. United States, 609 F.3d 1292, 1297 (Fed.Cir. 2010). A patent claim is invalid for obviousness if "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. The "underlying factual considerations in an obviousness analysis include the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and any relevant secondary considerations[,]" which include "commercial success, long-felt but unsolved needs, failure of others, and unexpected results." Allergan, 726 F.3d at 1290-91 (citations omitted). Patent invalidity must be established by clear and convincing evidence. Microsoft Corp. v. i4i Ltd. P'ship, 131 S.Ct. 2238, 2242 (2011).*
>
> *Whether a new chemical compound would have been prima facie obvious over particular prior art compounds follows a two-part inquiry under our precedent. First, the court*

determines whether a chemist of ordinary skill in the art would have selected the asserted prior art compound as a lead compound, or starting point, for further development. Eisai Co. v. Dr. Reddy's Labs., Ltd., 533 F.3d 1353, 1359 (Fed.Cir. 2008). A lead compound is a compound in the prior art that would be "most promising to modify in order to improve upon its activity and obtain a compound with better activity." Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1357 (Fed.Cir. 2007). The selection analysis may be guided by evidence of the compound's pertinent properties, such as chemical activity or potency. See Eli Lilly & Co. v. Zenith Goldline Pharm., Inc., 471 F.3d 1369, 1378 (Fed.Cir. 2006). Mere structural similarity between a prior art compound and the claimed compound does not inform the lead compound selection. Otsuka Pharm. Co. v. Sandoz Inc., 678 F.3d 1280, 1292 (Fed.Cir. 2012); see Daichii Sankyo Co. v. Matrix Labs., Ltd., 619 F.3d 1346, 1354 (Fed.Cir. 2010).

Proof of obviousness of a chemical compound "clearly depends on a preliminary finding that one of ordinary skill in the art would have selected [a particular prior art compound] as a lead compound." Takeda, 492 F.3d at 1357. The second step of the obviousness analysis requires a showing that the prior art would have taught a skilled artisan to make "specific molecular modifications" to a lead compound so that the claimed compound may be made with a reasonable expectation of success. Id. at 1356-57.

(emphasis supplied)

156. In *Eli Lilly And Company and Lilly Industries Ltd.* (supra) the Court of Appeals held as under:-

".....As taught by Yamanouchi Pharm. Co. and other precedent, mere identification in the prior art of each component of a composition does not show that the combination as a whole lacks the necessary attributes for patentability, i.e. is obvious. In re Kahn, 441 F.3d 977, 986 (Fed. Cir. 2006) (citing In re Rouffet, 149 F.3d 1350, 1355 (Fed. Cir. 1998)).

Rather, to establish a prima facie case of obviousness based on a combination of elements in the prior art, the law requires a motivation to select the references and to combine them in the particular claimed manner to reach the claimed invention."

"Furthermore, Lilly overcame any prima facie case of obviousness. Among other things, Lilly proved extensive secondary considerations to rebut obviousness. The trial court found the evidence clearly established four of the five proffered secondary considerations. Findings of Fact and Conclusions of Law, 364 F.Supp.2d at 852-74, 905-12. Lilly established (1) a long-felt and unmet need; (2) failure of others; (3) industry acclaim; and (4) unexpected results. Id. The record shows a long-felt need for a safer, less toxic, and more effective clozapine-like drug; a decade (or more) of failure to find a replacement for clozapine; a reasonable amount of commercial success for olanzapine; and a number of awards for olanzapine as indicators of industry acclaim. Id. at 852-53. Specifically, the trial court noted a "long-felt but unsolved need for a safe atypical antipsychotic from 1975 until 1990," as well as extensive evidence supporting the other objective criteria.Id. at 832-34, 906. The trial court also discussed the unexpected differences between the closest analog, Compound `222 and olanzapine, most of which focused on olanzapine not raising cholesterol levels in dogs, and a comparison of some humans tests with other similar drugs that raised CPK. Id. at 853-73. In sum, these objective criteria buttressed the trial court's conclusion of nonobviousness."

157. Thus though initially '*structural obviousness*' alone was deemed to create a presumption of unpatentability however the Courts expressing dissatisfaction with the Rule opined that the properties were also material to show unpatentability of new chemical and must be considered. Thus prior art disclosure should not merely be structurally similar compound but also at least to some degree demonstrate the same desired property which

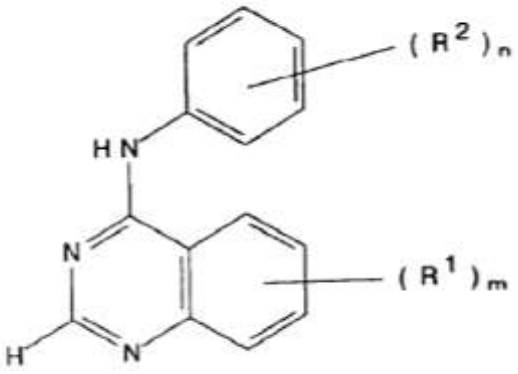
is relied on for the patentability of the new compound. In other words '*idea of new compounds is not separable from the properties that were sought by the inventor when making the compounds and structure and properties are essential compounds of the invention as a whole*'. (See in re: Dillon (supra)).

158. Thus obviousness is a question of law based on facts and the burden to prove is on the party which alleges however after the party which alleges makes out a prima facie case of invalidity on the ground of obviousness, the burden shifts on the inventor to disprove obviousness.

159. In the counter claim Cipla pleads that the closest prior art to the suit patent is Example 51 of EP '226 with a IC 50 value which is as under:-

> *"Example 51*
>
> *2-Bromoethyle methyl either (0.834 g) was added to a stirred mixture of 6, 7-dihydroxy-4-(3'- methylanilino) Quinazoline (0.534 g), potassium carbonate(0.828 g) 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 (mgso$_4$) 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^{o}C. NMR Spectrum: (CD$_3$SOCD$_3$) 2.34 (s, 3H), 3.36 (s, 6H), 3.75-3.8 (m, 4H), 4.1-4.5 (m, 4H), 7.14 (d, 1H), 7.37 (t, 1H), 7.40 (s, 1H), 7.48 (m, 2H) 8.35 (s, 1H), 8.79 (s, 1H);*
> *Elemental Analysis: Found C, 59.8; H,6.4;N, 9.9; $C_{21}H_{25}N_3O_4$. 1HCl requires C, 60.O; H, 6.2; N, 10.0%"*

160. Further Markush Formla of EP '226 is as under:-



161. The claim in EP '226 also notes-

> "*n is 1 or 2 and each R^2 is independently hydrogen, hydroxyl, halogeno, trifluoromethyl, amino, nitro, cyano, (1-4C)alkyl, (1-4C)alkoxy, (1-4C)alkylamino, di-[(1-4C)alkyl]amino, (1-4C)alkylthio, (1-4C)-alkylsulphinyl or (1-4C)alkylsulphonyl;"*

162. After referring to Example 51 of EP '226, Cipla refers to EP 0635507 (i.e. EP '507) and states that POSA would be motivated to modify the said lead compound in order to substitute the 3rd methyl on the phenyl ring with ethynyl. The motivation to Example 51 of EP '226 provided by from EP '507 is as under:-

> *"[0014] According to a further aspect of the present invention there is provided a tricyclic derivative of the formula wherein R^1 and R^2 together form a group of the formula –N=CH-NH-, -N=CH-O-, -N=CH-S-, -N=N-NH-, -NH-N=CH-, -NH-CH=CH-, -NH-CO-NH-, -NH-CO-O-, -NH-CO-S-, -NH-NH-CO-, -N=CH-CH=CH-, -N=N-CH=CH-, -N=CH-N=CH-, -N=CH-CH=N- or –NH-CO-CH=CH- (with in case a nitrogen atom being located at the 6-position of the quinazoline ring) and the 5- or 6-membered ring so formed may optionally bear one or two substituents, any substituent on an available nitrogen atom being selected from (1-4C)alkyl, (3-4C)alkynyl, halogeno-(1-4C)alkyl, hydroxy-(1-4C)alkyl, (2-4C)alkanoyloxy-(1-4C)alkyl, (1-4C)alkoxy-(1-4C)alkyl, cyano-(1-4C)alkyl, amino-(1-4C)alkyl, (1-4C)alkylamino-(1-4C)alkyl and di-[(1-*

4C)alkyl]amino-(1-4C)alkyl, and any substituent on an available carbon atom being selected from halogeno, amino, carbarmoyl, cyano, (1-4C)alkyl, (2-4C) alkenyl, (2-4C)alkynl, (1-4C)alkoxy, (1-4C)alkylthio, (1-4C) alkylsulphinyl, (1-4)alkylsulphonyl, (1-4C)alkylamino, di-[(1-4C)alkyl]amino, (2-4C)alkanoyl, N-(1-4C)alkylcarbamoyl, N, N-di-[(1-4C)alkyl]carbamoyl, halogeno-(1-4C)alkyl, hydroxyl-(1-4C)alkyl, (2-4C)alkanoyloxy-(1-4C)alkyl, (1-4C)alkoxy-(1-4C)alkyl, Cyano-(1-4C)alkyl, amino-(1-4C)alkyl, (1-4C)alkylamino-(1-4C)alkyl and di-[(1-4C)alky]amino-(1-4C)alkyl; and

M is the integer 1, 2 or 3 and each R^3 is independently hydrogen, halageno, trifluoromethyl, hydroxyl, amino, nitro, cyano, (1-4C)alkyl, (1-4C)alkoxy, (1-4C)alkylamino, di-[(1-4C)alkyl]amino or (2-4C)alkanoylamino; or a pharmaceutically-acceptable salt thereof."

(emphasis supplied)

163. Cipla then seeks to apply the concept of 'bioisosteric replacement' to the 3rd position of the phenyl ring of Example 51 of EP '226 using the Grimm's Hydride Displacement theory as under:-

Table 1: Grimm's Hydride Displacement Law

C	N	O	F	Ne	Na
	CH	NH	OH	FH	
		CH_2	NH_2	OH_2	FH_2
			CH_3	NH_3	OH_3
				CH_4	NH_4

164. It is thus claimed that the trivalent "N" and "CH" groups being known bioisosteric equivalents having similar chemical and physical properties that confer similar biological properties to a chemical compound the patent claim

has been reached at.

165. A perusal of the evidence of Mr. Ashwani Nagia DW-3 the expert witness of Cipla would show that he lead no evidence whatsoever either on EP '507 or bio-isosterism. DW-3 a Professor at the School of Chemistry, University of Hyderabad is Ph.D in Chemistry from Yale University and had been a professor of Chemistry for over 20 years. DW-3 was given the suit patent, counter claim of Cipla, written statement of Roche to counter claim, replication of Cipla along with documents relating to EP 0477700, US 4138590, US 5427766, US 5736534 and WO 193004047 Exhibit DW-3/2 to DW-3/6. DW-3 was required to opine on the following issues:-

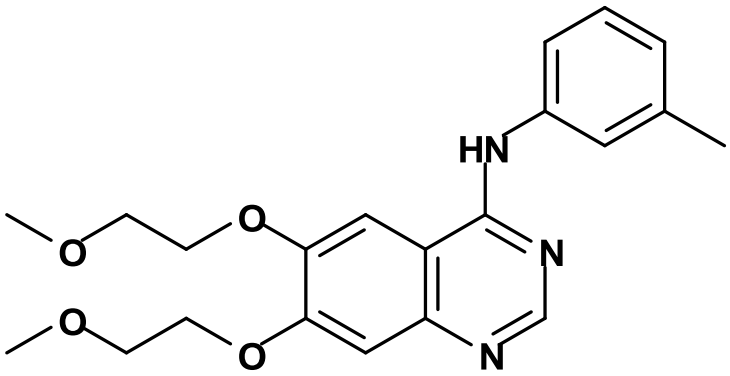
> *"A. Whether the compound Erlotinib hydrochloride is obvious to a person skilled in the art in view of one or more compounds disclosed in EP 0566226 and having regard to the other documents supplied to me and the general state of art?*
>
> *B. Whether the compound Erlotinib hydrochloride as claimed in the suit patent is a combination of polymorphs A and B and whether the suit patent covers polymorph B, free of polymorph A as taught in US 6900221?"*

166. The deposition of DW-3 in his evidence by way of affidavit on issue No.A as noted above i.e. on obviousness is as under:-

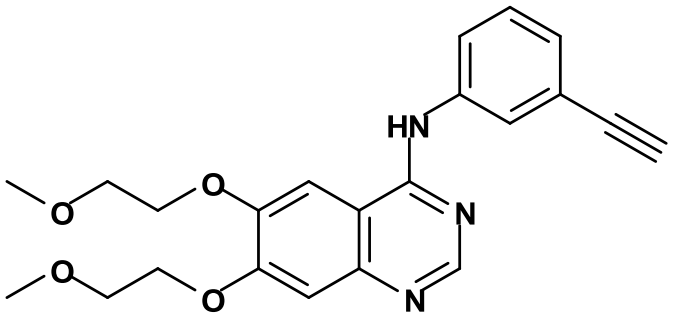
> *"5. For the purpose of the aspect of obviousness, I have in particular read IN `774 and EP `226 as well as EP 0477700, US 4138590, US 5427766, US 5736534 and WO 193004047.*
>
> *6. I was in particular required to consider the teachings and compounds contained in EP `226 and to give my opinion as to the inventive contribution in IN `774 having regard to the compounds disclosed herein including the specific compound taught in EP `226 namely "6,7-di-(2-methoxyethoxy)-4-)3'-methylanilino) quinazoline", referred to at page 18 of EP `226*

lines 16-17, read with EP 0477700, US 4138590, US 5427766, US 5736534 and WO 193004047.

7. EP `226 is an invention of Astra Zeneca relating to quinazoline derivatives possessing anticancer activity. The main finding of EP `226 is that certain quinazoline derivatives possess anticancer activity believed to arise from their receptor tyrosine kinase inhibitory properties. While quinazoline derivatives were known before the EP `226 patent but the anticancer properties of such compounds were not known widely and a major step in this area was claimed to be made by Astra Zeneca as disclosed in its EP `226 patent. Like the disclosure contained in IN `774 patent, EP `226 also covers a large number of compounds covered by the general formula 1 therein (though there is specific disclosure of several compounds by way of example). Each of the disclosed compound in EP '226 is said to have anticancer properties and the several compounds disclosed includes the compound – 6,7-di-(2-methoxyethoxy)-4-)3'-methylanilino) quinazoline, which may be expressed by a formula as set out hereunder.



8. On the other hand, the structure of the compound Erlotinib Hydrochloride as claimed in IN `774 is as under:-



9. I say that if one would make a structural comparison, it can be said without doubt that the two structures are identical in nature barring the substituents inasmuch as –CH_3 (methyl) in 3rd position in EP `226 is replaced with – C≡C(ethynl) in IN `774.

10. In order to appreciate the relevant of the close resemblance of the structure of the said two compounds one has to look into them more closely. It has to be particularly seen whether there was any motivation or otherwise any teaching in the art that could have prompted the patent holder (a person skilled in the art) to substitute methyl with ethynl in 3rd position.

11. Having gone through EP 0477700, US 4138590, US 5427766, US 5736534 and WO 193004047, it is evident that there is a clear teaching that methyl and ethynyl may be used interchangeably. However, it is pertinent to state that while they may be used interchangeably, there is evidence in the aforesaid document to show that there is no fixed pattern or one cannot lay down a hypothesis 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.

12. When I refer to EP `700, I find that there are three tables namely Table -1, 2 and 3. 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 showing a marginally higher value. It is, therefore, suggested in EP `700 that both alkyl and alkynyl can be

interchangeably used in antiviral agents.

13. In US `590 column-10 the comparative data in the table indicates that the methyl substitution gives a better blood platelet aggregator than the compound having ethynyl substituent. Thus, US `590 goes to teach that one may use methyl, ethynyl or phenyl interchangeably. Similar in US `766 column 3 – H, methyl, ethynyl or vinyl are used interchangeably.

14. US `534 is a patent owned by Pfizer, the sole inventor of which is Lee D. Arnold who incidentally is one of the two inventors of IN `774, US `534 is a continuation in part (CIP) of application 200259 dated Feb 23, 1994 while IN `774 finds basis in a CIP of application 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, ethenyl derivatives of 4-heterocycle substituted quinazolines which are very close analogues of the claimed compound in IN `774. In my opinion, Mr. Arnold was wholly aware of the interchangeability of methyl and ethynyl amongst others at the C-phenyl ring appended to the 4-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 3$^{rd}$ position, then compound having methyl would have been identical to the aforesaid compound of EP `226 and I would presume that for such reason reference to methyl as a interchangeably usable substituent in place of ethynyl was omitted. While the patent holder has acknowledged several other documents as prior art, he did not make any reference to the US application number 736534 (which was prior in time) which contained vital information as to the interchangeability of methyl and ethynyl. I say that while developing a new product, a scientist would try all possible options which makes sense in the relevant field of technology and which has been successfully tried by others although it may not produce the desired result in a specific application.

Likewise, it could have been possible that the ethynyl substitution in the 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.

15. I say that strategies of rational drug design are commonplace and in drug designing, molecular modifications are routinely done. A drug designer would as a matter of routine replace substituent, ring, group of atoms etc. for various aspects of the lead component for example pharmacology, pharmacokinetic, toxicology, side effects, half life etc. Bio-isosterism of which I find reference in the counter claim of the Defendant is a mechanism directed to strategies for molecular modification and drug design.

16. In my opinion, there could not have been a guarantee to the inventor that the ethynyl substitution would work but due to 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. Therefore, in my opinion such substitution cannot be said to be an inventive step forward in respect of the compound of formula A of IN `774 when the compound 6,7-di-(2-methoxyethoxy)-4-)3'-methylanilino quinazoline was taught in EP `226 as a quinazoline compound possessing anticancer properties."

167. In cross-examination DW-3 in reply to Question No.51 admitted that he was not aware about the clinical trials of Example 51 of EP '226 and that he read the document EP `226 but with the specific intent of understanding and answering question A in para 4 of his affidavit as noted above and that his understanding of term '*obvious'* to a person skilled in the art describes a situation in which a person carrying out routine experiments for a sufficient period of time is able to make a judgment decision based on the accumulated information and background that he has gained from his experience and

reading of literature and that he was not aware that the concept of hindsight is disregarded, disallowed, rejected and scorned upon in patents law. He admitted that he conducted search on Google and Wikipedia a few days before the cross-examination and found a few hits which gave him the information but most of it was general in nature. He admitted that Google and Wikipedia had in fact started their activities after the priority date of claim and that he had not even worked in drug discovery and development stages.

168. From the evidence of DW-3 the only witness examined on the issue of obviousness the following conclusions can be drawn:-

a) DW-3 was not an ordinary person skilled in the art being a professor of the Chemistry and not a medicinal Chemist. He had not worked in drug discovery and developmental stages himself and had read about the above aspects in the freely available literature;

b) His evidence was based on the documents i.e. the patent claim IN 196774 (IN '774), counter claim of Cipla, written statement of Roche to the counter claim and replication of Cipla, documents relating to patents EP 0477700, US 4138590, US 5427766, US 5736534, WO 193004047, US '498, US `221 and EP `226;

c) The evidence of DW-3 was beyond the pleadings as in the written statement and counter claim Cipla did not base its claim on EP '700, US '590, US `766, US `534 and WO `047 but EP `507;

d) DW-3 based his theory of obviousness only on the basis of structural similarity between Example 51 of EP `226 and IN `774;

e) DW-3 did not depose about bioisosterism or Grimm's Hydride

Displacement theory;

f) DW-3 looked at documents not available on the priority date being Google and Wikipedia;

g) The evidence of DW-3 was a hindsight evidence as he read the document EP `226 but with specific intent of understanding and answering question 'A' posed to him;

h) DW-3 was not aware whether Example 51 of EP `226 went to clinical trials. He admitted that he had no knowledge on this point from his personal reading;

i) DW-3's understanding of the term "person skilled in the art" describes a situation in which a person carrying out routine experiments for a sufficient period of time is able to make a judgment decision based on the accumulated information and background that he has gained from his experience and reading of literature;

j) DW-3's understanding of obviousness in terms of simple example was that if a cleaning liquid could clean refrigerator, television and DVD player, it could be used to wipe away a coffee spill on the dashboard of the car and that is what he could explain in simple language without actually knowing its exact definition;

k) DW-3 had no personal knowledge and the knowledge of EP `700, US `590, US `766, US `534 and WO `047 was based on the documents supplied. He was not aware that the concept of hindsight is disregarded, disallowed, rejected and scorned upon. DW-3 admitted that he had not worked in the drug discovery and development stages himself and he only read about

aspects in freely available literature;

l) Even as per DW-3, the so called five prior arts used are not from analogous arts i.e. they are not drugs on cancer. He admitted EP `700 was an antiviral compound, US '590 a prostaglandin derivative used for dealing with platelet aggregation inhibitor not being an EGFR inhibitor, even US '766 and WO '0047 were not EGFR inhibitors and US '534 was published on August 31, 1995 thus not a prior art.

169. The onus was on Cipla to show prima facie obviousness whereafter the burden would have shifted to Roche. However DW-3 has not been able to satisfy the tests laid down above thus could not establish prima facie that the suit patent was obvious. Consequently, the action of Cipla seeking invalidity of the suit patent on the ground of obviousness fails.

Lack of title

170. In the written statement and counter claim Cipla claims lack of title to the suit patent in favour of Roche. The pleadings in this regard in para 16 of the written statement of Cipla are that the application number 537/DEL/1996 was filed as a convention application in India on March 13, 1996 by one Pfizer Inc. seeking priority from U.S. patent application dated March 30, 1995 under the title "Quinazoline Derivatives". The exact status of Roche's patent and its ownership is neither known nor is fully established and no documents which vest any right in Roche of ownership or '*Right to Sue'* have been placed on record. In counter claim revocation is not sought for lack of title as could not be sought under Section 64 of the Patents Act. During the course of argument, learned counsel for Cipla argued that the plaintiffs in the suit are F. Hoffmann-La Roche Ltd. (in short Roche)

plaintiff No.1 and OSI Pharmaceuticals, Inc. (in short OSI) plaintiff No.2. In the plaint the claim of Roche and OSI is that OSI owned a patent with Pfizer Products but the said company has not been impleaded as a plaintiff. Further in the plaint it is stated that OSI along with M/s Pfizer Products Inc. applied for grant of a patent in respect of drug Erlotinib and its process vide application No.537/DEL/1996 on March 13, 1996 however the copy of the patent application would reveal that OSI along with M/s Pfizer Inc was the applicant and not M/s Pfizer Product Inc. Further it is the case of Roche that it entered into a Development, Collaboration and Licensing Agreement with OSI wherein Roche obtained a license to use, sell and offer for sale, the licensed product including the drug Erlotinib however said document has neither been filed nor produced by the plaintiffs. There being no document to support how the interest was transferred from Pfizer Inc. to Pfizer Product Inc., the claim of OSI that it was a joint owner of the suit patent with Pfizer Product Inc. is not established. Even during patent prosecution after the first assignment dated May 18, 2005 of the patent application of Pfizer Inc. to Pfizer Product Inc. the second assignment took place wherein the patent application had been assigned jointly in favour of Pfizer Product Inc. and OSI. The first assignment document dated May 18, 2005 is given a retrospective effect from May 03, 2004 which is impermissible and not in accordance with law. The second alleged assignment agreement dated May 05, 2004 is on a stamp paper dated August 12, 2005 and could not have been dated May 05, 2004 especially when the first assignment is dated May 18, 2005. No evidence having been led qua ownership of the suit patent, Roche's appeal claiming be a joint owner is liable to be dismissed. Reference is made to Sections 20, 50, 68 and 69 of the Patents Act. It is

further argued that even if accepting OSI to be a joint owner, it became joint owner only on May 05, 2004 , thus prior thereto it had no right in the suit patent. The assignment deeds are neither properly stamped nor registered and having failed to prove so, Roche has failed to prove its title in the suit patent.

171. In response Roche contends that no issue was settled in this regard and as per the counter claim and written statement, the challenge to the validity is to the extent mentioned under Section 64 of the Patents Act and none of the grounds under Section 64 relate to the lack of title in the suit patent. The grant of suit patent IN '774 has not been denied by Cipla and any question regarding title pertains to rectification of the Register of Patents under Section 71 of the Patents Act for which jurisdiction exclusively vests with the Intellectual Property Appellate Board (IPAB). Section 71 read with Sections 117C and 117D of the Patents Act bars the jurisdiction of this Court to try such an issue. Notwithstanding the preliminary objections, Roche claims that the patent application was filed by Pfizer Inc. on March 13, 1996 and by virtue of assignment deed dated May 18, 2005 w.e.f. May 03, 2004 assignment took place from original applicant Pfizer Inc to its wholly owned subsidiary Pfizer Product Inc. assigning its right in the patent application 537/DEL/1996. By way of further assignment deed dated May 05, 2004 Pfizer Product Inc assigned part of their right to OSI, thus OSI became a joint applicant/owner of the rights to accrue pursuant to application No.537/DEL/1996 for which a fresh form was filed seeking change of the names of applicants. Further Pfizer Inc and OSI had also entered into a collaboration research agreement on April 01, 1986 which was renewed on April 01, 1991 and April 01, 1996. The patent

document issued on July 06, 2007 w.e.f. February 23, 2007 is in the name of Pfizer Product Inc. and OSI. Further by way of agreement dated January 08, 2001 OSI granted exclusive license to Roche in relation to suit patent and vide agreement dated September 07, 2008 Roche, Pfizer Product Inc. and OSI confirmed exclusive license agreement dated January 08, 2001 which documents are part of patent office record except Collaborative Research Agreement which was exhibited as Ex.PW1/4. Referring to decision in *AIR 2003 SC 1608* *Renu Devi Vs. Mahinder Singh & Ors.* reliance is placed on the principle of feeding grant by estopple and that a third party cannot question the title.

172. Cipla in the written statement claims invalidity for the reason that the exact status and ownership of Roche in the suit patent is not known. Lack of title not being a ground of revocation under Section 64 of the Patents Act, to press this point CIPLA ought to have insisted on settlement of a issue on lack of title. Be that as it may even treating this issue to be subsumed in issue No.3 i.e. "Whether the plaintiffs are entitled to permanent injunction as prayed for? OPP" CIPLA cannot claim any relief on this count in view of the bar under Section 117C and 117D of the Patents Act.

173. Section 71 provides for adjudication of an application in relation to entries made in the Register. Section 117C provides for a procedure for application for rectification before the Appellate Board under Section 71 and Section 117C bars the jurisdiction of the Civil Court. Sections 117C and 117D read as under:-

> *"71 - Rectification of register by Appellate Board - (1) The Appellate Board may, on the application of any person aggrieved-*

(a) by the absence or omission from the register of any entry; or

(b) by any entry made in the register without sufficient cause; or

(c) by any entry wrongly remaining on the register; or

(d) by any error or defect in any entry in the register,

make such order for the making, variation or deletion, of any entry therein as it may think fit.

(2) In any proceeding under this section the Appellate Board may decide any question that may be necessary or expedient to decide in connection with the rectification of the register.

(3) Notice of any application to the Appellate Board under this section shall be given in the prescribed manner to the Controller who shall be entitled to appear and be heard on the application, and shall appear if so directed by the Board.

(4) Any order of the Appellate Board under this section rectifying the register shall direct that notice of the rectification shall be served upon the Controller in the prescribed manner who shall upon receipt of such notice rectify the register accordingly.

117C. Bar of jurisdiction of courts, etc.- No court or other authority shall have or, be entitled to, exercise any jurisdiction, powers or authority in relation to the matters referred to in sub-section (2) of section 117A or section 117D.

117D. Procedure for application or rectification, etc., before Appellate Board.- (1) An application[1][for revocation of a patent before the Appellate Board under section 64 and an application for rectification of the register] made to the Appellate Board under section 71 shall be in such form as may be prescribed.

(2) A certified copy of every order or judgment of the Appellate Board relating to a patent under this Act shall be communicated to the Controller by the Board and the Controller shall give effect to the order of the Board and shall, when so directed, amend the entries in, or rectify, the register in accordance with such order."

174. Thus, the claim of Cipla qua the invalidity of the suit patent on the ground of lack of title cannot be decided in suit proceedings before this Court.

175. Further though CIPLA pleads that the application for grant of suit patent being application number 537/DEL/1996 was filed by Pfizer Inc. it does not dispute that the suit patent was granted in the joint name of Pfizer Products Inc. and OSI Pharmaceuticals Inc. (OSI). Ex.DW1/10 to Ex.DW4/43 documents from the office of Controller of Patents would evince that the convention application for patent in Form 2A was filed by Pfizer Inc. being the assignee of inventors Rodney Caughren Schnur and Lee Daniel Arnold on March 13, 1996 claiming priority from March 30, 1995 being the date of application in USA. During the pendency of the patent prosecution in India, Pfizer Inc. the original applicant executed an assignment deed dated May 18, 2005 w.e.f. May 03, 2004 assigning its right in the application 537/DEL/1996 to Pfizer Products Inc. exhibited as Ex.DW4/1(colly). By way of further assignment dated May 05, 2004 Pfizer Product Inc. assigned a part of their right to OSI and thus Pfizer Product Inc. and OSI became joint owners of application No.537/DEL/1996 exhibited as Ex.DW4/1 (collectively) and a fresh form in this regard was filed. The letter patent document issued on July 06, 2007 was in the name of Pfizer Product Inc. and OSI.

176. Cipla pleads that two assignment deeds dated May 18, 2005 and May 05, 2004 were back-dated i.e. retrospective operation of the assignment was conferred. In the decision reported as (1998) 7 SCC 348 *Life Insurance Corporation of India Ltd.& Anr. Vs. Dharam Vir Anand* Supreme Court laid

down that while construing the contractual clause the words and term therein must be given effect to and when it uses different expressions, ordinarily those different expressions would convey different meanings.

177. Further it is not the case of Cipla that on the date of retrospective assignment by Pfizer Inc. to Pfizer Products Inc., Pfizer Inc. had no right, title in the property i.e. the patent application. Even assuming no right could be created retrospectively in favour of Pfizer Products Inc., right certainly vested on May 18, 2005 the date of assignment agreement and from which date it vested in OSI. The patent i.e. IN '774 was granted on February 23, 2007 when OSI had been assigned the rights in the patent.

178. The Registration Act does not envisage a deed of assignment of a trademark/copyright or patent to be compulsorily registered not being an immovable property. In the decision reported as (2004) 13 SCC 49 *Collector of Central Excise, Ahmedabad Vs. Vikshara Trading & Investment (P) Ltd. & Anr.* the Supreme Court repelling the contention regarding deed of assignment of trademark to be registered held that the mere fact that the assignment was not registered would not alter the position.

179. In response to the contention of learned Senior counsel for Cipla that as per Section 50 of the Patents Act, no right can be assigned, transferred or licensed without the consent of the co-owner, Roche contends that the exclusive license granted to Roche by OSI in relation to the suit patent vide agreement dated January 08, 2001 was ratified/confirmed by an agreement between Roche, Pfizer Products Inc. and OSI on September 04, 2008. Learned Senior counsel for Cipla referring to the evidence of PW-1 Shiv Prasad Laud canvasses that Development Collaboration and Licensing Agreement dated January 08, 2001 entered into between Roche and OSI was

not produced. No doubt the documents have not been exhibited by the plaintiffs' witnesses during their evidence. Cipla does not deny that the documents were part of patent office record which was duly summoned by Cipla. We agree with the contention of learned counsel for the Roche that since no issue having been settled with regard to the lack of title in the suit patent Roche was not required to prove the same.

180. Even treating as the learned Single Judge has done that the issue of title of Roche was subsumed in the issue of injunction we note that OSI is a co-patentee of the suit patent and it being a co-plaintiff the suit cannot be dismissed on this ground. In the decision reported as (2007) 2 SCC 551 *Prem Lata Nahata & Anr. Vs. Chandi Prasad Sikaria* the Supreme Court laid down that the objection of misjoinder of parties or of causes of action, is only a procedural objection and it is open to the Court to proceed with the suit notwithstanding such defects and if the suit results in a decision, the same cannot be set aside in appeal merely on this ground in view of Section 99 CPC.

181. A Single Judge of the Madras High Court in the decision reported as 2014 SCC OnLine Mad 163 *M.C. Jayasingh Vs. Mishra Dhatu Nigam Ltd.* while dealing with Sections 48, 50 and 51 of the Patents Act, 1970 held that for non-joinder of a co-patentee, the claim of the plaintiff would not fail and we concur. It was held-

> *"29. Keeping the above in mind, let me now examine the question whether the non joinder of the co-patentee is fatal to the claim of the plaintiff or not.*
>
> *30. Sub-Section (1) of Section 50 of the Patents Act, 1970 makes it clear that where a patent is granted to two or more persons, each of those persons shall, unless an agreement to the*

contrary is in force, be entitled to an equal undivided share in the patent. After thus ensuring to all the patentees, an equal and undivided share in the patent under Sub-Section (1), the Act also imposed an embargo under Sub-Section (3) of Section 50 to the effect that a licence under the patent cannot be granted and a share in the patent cannot be assigned by one of those persons except with the consent of the other person or persons. However, this embargo was made subject to the other provisions and subject to Section 51 and to any agreement for the time being in force.

31. But, in so far as the enforcement of the rights conferred by the Act is concerned, Sub-Section (2) of Section 50 enables each of the co-patentees to seek redressal, even without accounting to the other persons. Sub-Section (2) of Section 50 reads as follows:

"Subject to the provisions contained in this section and in Section 51, where two or more persons are registered as grantee or proprietor of a patent, then, unless an agreement to the contrary is in force, each of those persons shall be entitled, by himself or his agents, to the rights conferred by Section 48 for his own benefit without accounting to the other person or persons."

32. The rights conferred by Section 48 of the Act are (i) the exclusive right to prevent third parties from the act of making, using, offering for sale, selling or importing for those purposes that product which is the subject matter of the patent and (ii) the exclusive right to prevent third parties from the act of using that process and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by a process which is the subject matter of the patent.

33. Therefore, it is clear from Sub-Section (2) of Section 50 read with Section 48 that each of the grantees or proprietors of a patent, is entitled by himself or by his agents, to enforce the rights conferred under Section 48, for his own benefit without accounting to the other person or persons. Coupled with the fact that under Section 50(3), a co-patentee cannot even assign

or grant a licence in respect of his share, without the consent of the other persons, the provisions of Section 50(2) makes the suit maintainable at the instance of one of the co-patentees.

182. Each of the co-patentee being entitled by itself or by its agent to enforce rights conferred under Section 48 of the Patents Act, 1970 and there being no challenge to the ownership of OSI, plaintiff No.2 in the suit and a co-patentee, the objection in terms of Section 50 of the Patents Act thus fails. The suit patent cannot be held to be invalid for lack of title, nor is the suit liable to be dismissed on the ground that Roche has not proved its license for the reason title of OSI plaintiff No.2 to the suit patent is established and it being a co-plaintiff, suit was maintainable. We also note that lack of title is not a ground for revocation under Section 64 of the Patents Act. Thus, we find no merit in the contention raised by Cipla seeking dismissal of the suit on the ground of lack of title.

Conclusion

183. To conclude, affirming the impugned judgment and decree dated September 07, 2012 passed by the learned Single Judge in so far counter claim filed by Cipla seeking revocation of IN '577 in favour of Roche has been dismissed, we set aside the impugned decision dismissing suit for injunction filed by Roche. But keeping in view the fact that the life of the patent in favour of Roche in India would expire in March, 2016 we do not grant the injunction as prayed for by Roche against Cipla (because as noted above there was no interim injunction in favour of Roche and due to said reason Cipla continued to manufacture and sell Erlocip). We decree that Cipla would be liable to render accounts concerning manufacture and sale of Erlocip, for which purpose suit filed by Roche against Cipla is restored with

direction that it be listed before the learned Joint Registrar who would record evidence pertaining to the profits made by Cipla concerning the offending product. Thereafter the report of the learned Joint Registrar shall be placed before the learned Single Judge as per roster for appropriate orders. RFA (OS) No.103/2012 is dismissed. RFA (OS) No.92/2012 is partially allowed as above.

184. Costs allowed in favour of Roche and against Cipla in sum of ₹5,00,000/- (Rupees Five Lakhs only).

(PRADEEP NANDRAJOG)
JUDGE

(MUKTA GUPTA)
JUDGE

NOVEMBER 27, 2015
Mamta/ vkm