INTELLECTUAL PROPERTY APPELLATE BOARD

Guna Complex Annexe-I, 2nd Floor, 443, Anna Salai, Teynampet, Chennai-600018

ORA/22/2011/PT/KOL
AND
M.P. NO.140/2012 IN ORA/22/2011/PT/KOL

SATURDAY, THIS THE 27TH DAY OF JULY, 2013

Hon'ble Smt. Justice Prabha Sridevan …Chairman
Hon'ble Shri D.P.S. Parmar …Technical Member (Patents)

FRESENIUS KABI ONCOLOGY LIMITED
B-310, Som Datt Chambers-1
Bhikaji Cama Place
New Delhi – 110 066, India. … Applicant

(Represented by Shri S.Majumdar, Ms. Sanghita Ganguli and Shri Dominic Alwaris)

Vs.

1. GLAXO GROUP LIMITED
Glaxo Wellcome House,
Berkeley Avenue, Greenford,
Middlesex. UB60NN, Great Britain

2. The Controller of Patents,
Patent Office, Government of India,
Intellectual Property Office Building,
CP-2, Sector V, Salt Lake City,
Kolkata – 700 091. …Respondents

(Represented by Ms. Archana Shankar, Ms. Vidish Garg and Mr. Devinder Singh Rawat)

ORDER (No.161 of 2013)

Hon'ble Smt. Justice Prabha Sridevan, Chairman

This revocation application has been filed against Patent No.IN221171 entitled "QUINAZOLINE DITOSYLATE SALT COMPOUNDS".

2. These compounds are protein tyrosine kinase inhibitors (PTKs) of the erbB family. Inappropriate or uncontrolled or aberrant PTK activity has been shown to result in uncontrolled cell growth and has been implicated in a variety of disorders including psoriasis, as well as cancer. Of special interest is the role of erbB family PTKs in hyperproliferative disorders, particularly human malignancies. Consequently, inhibition of this kind of PTKs was expected to provide a treatment for disorders characterised by aberrant erbB activity.

3. The respondent has disclosed its own invention as a prior art in the complete specifications as patent PCT/EP99/00048. This invention is the same as IN221017 (D1 in short) and has been attacked in ORA/17/12/PT/KOL. Both were argued almost at the same time.

4. D1 discloses bicyclic heteroaromatic compounds, including N-[3-Chloro-4-[(3-fluorobenzyl)oxy]penyl}-6-5-({[2-(methanesulphonyl)ethyl]amino}methyl)-2-furyl]-4 - quinazolinamine; (4 - (3-Fluoro-benzyloxy) – 3 - chlorophenyl) - (6 - (2 - ((2-methanesulphonyl-ethylamino) methyl)-thiazol-4-yl) quinazolin-4-yl)-amine; and (4-(3-Fluoro-benzyloxy)-3-bomophenyl)-(6-(5-((2-methanesulphonyl-ethylamino)-methyl)-furan-2-yl)quinazolin-4-yl)-amine as well as hydrochloride salts thereof. But the disadvantage of di-HCl salts is that it sorbs very large amount of water and therefore the stability of the compound as a medicament was compromised. The specifications claim to have identified new ditosylate salts of 4-quinazolineamines, which are suitable

as erbB family PTK inhibitors. These compounds may be prepared in crystal forms and have enhanced physical stability and have superior moisture sorption properties to the di Hcl salts disclosed in the prior art above.

4. The petition is attacked on the grounds of 64(1)(f) relying upon four prior arts;

Exhibit-B – the prior art acknowledged in the complete specification and referred to as D1. This is Patent No.221017 and is the subject matter of ORA/17/2012/PT/KOL

Exhibit-C - which is again a prior patent WO 98/25920. (D2)

Exhibit-D – This is a non patent prior art, titled "Salt selection for basic drugs." International Journal of Pharmaceutics 1986 Gould et al. (D3)

Exhibit-E – Review article "Pharmaceutical Salts." Berge et al., January 1977. (D4)

and on the grounds of Sections 64(1)(k), 64(1)(d), 2(1)(ja), and 64(1)(h) of The Patents Act. But the arguments were focussed on obviousness, S.3(d) and S. 8

5. The learned counsel for both the parties made their oral submissions and also filed written submissions. According to the learned counsel for the appellant Mr. S. Majumdar, Exhibit-B which is an admitted prior art teaches the claimed compound, hereinafter referred to as Lapotinib ditosylate. According to the learned counsel Exhibit B not only describes lapotinib free base but also the salts of the same and in particular the ditosylate salts. He submitted that though a large number of compounds have been mentioned in Exhibit-B, only 19 salts are disclosed in Exhibit B and the two sulphonyl salts include ditosylate salts. It was submitted that when the problem to be solved was hygroscopicity, it was obvious for a person skilled in

the art to try the salts disclosed in Exhibit B which would give the desired result.

6. He submitted that Exhibit C disclosed “A pharmaceutically acceptable salt” and it mentions Exhibit E and says that the preferred salt is ditosylate salt and that the inventors have found that the tosylate salt is less hygroscopic more crystalline and more stable. He submitted that it would be evident from the teachings of Exhibit C that considering the problem to be solved, tosylate salt was a preferred salt. Therefore by a combination of the teachings of Exhibits B and C, one would arrive at this Invention. It is no argument to say that Exhibit C teaches the salt of a different active ingredient which is analgesic. Once there is a suggestion that tosylate salt would solve the problem of hygroscopicity, there is definitely an encouragement to try it.

7. He submitted that Exhibit D is a very basic prior art which indicates how selection is made of suitable salts. The learned counsel submitted that Exhibit D indicates that though HCl salt would be a first move, if there are problems with that salt then a selection issue arises and Exhibit D gives the trends that are available for guidance.

8. The learned counsel extracted certain passages in Exhibit D where the aryl groups are said to minimize hygroscopicity as opposed to the poorly stable hydrochloride and sulphate salts. According to the learned counsel there is a clear direction towards choice of tosylate and that HCl would not answer the problem. A person skilled in the art is provided enough impetus to try tosylate or ditosylate with a reasonable expectation of success.

9. He referred to Exhibit E, which is said to teach that tosylate salt form is used in 0.13% of the total number of anionic and cationic salts. According to the learned counsel though amongst the list of drugs which are Non-FDA approved the tosylate salt is found, after 1977 the date of Ex E the use of

tosylate has increased. He also mentioned that Sorafenib which is marketed as Nexavar is a tosylate salt and is also an anti cancer drug for which a compulsory licence was issued recently.

10. He submitted that the impugned invention was obvious to try with reasonable expectation of success in view of the combined teachings of Exhibit-B read along with Exhibits C, D and E. He submitted that it did not require great skill to expect that the crystalline form would have better stability. According to the learned counsel, the invention was only the result of routine testing. The respondent had filed a miscellaneous petition to prove commercial success and the Form-27 filed in respect of this invention and the invention No.221017 which is same as the Exhibit-B would show that both these patents cover the same product. He submitted that this double patenting shall not be encouraged

11. The learned counsel also raised a Section 3(d) objection to the patent stating that the only improvement that invention had over the di HCl salts was that it provided superior moisture sorbing properties and enhanced stability. Both these qualities were physicochemical and not related to therapeutic efficacy. According to the learned counsel both these qualities would be expected by a person skilled in the art. According to the learned counsel, even if hygroscopicity improved it would not amount to enhanced therapeutic efficacy.

12. The learned counsel submitted that in **T 0200/05** (EP Boards of Appeal), it was held that for assessing inventive step it is not necessary to establish that the success of an envisaged solution of a technical problem was predictable. It is enough to show that the skilled person would have followed the teaching of the prior art with a reasonable expectation of success.

13. He referred to **Pfizer vs. Apotex 2006-1281** and submitted that the suggestion, teaching or motivation to combine the relevant prior art need not be found explictly in the prior art references but may be found in number of sources and that obviousness cannot be avoided, simply by showing of some degree of unpredictability as long as there is a reasonable probability of success.

14. The learned counsel submitted that it was not necessary to produce expert testimony or documentary evidence in this case, since the prior arts along with the common general knowledge show that the impugned patent was obvious to try. He submitted that obviousness is ultimately a question of law, on the basis of the scope and content of the prior art and the differences between the prior arts and the claims in the patent.

15. According to the learned counsel expert testimony is not mandatory in these proceedings. It may be necessary but if even without it the case of obviousness is established then the patent must be revoked.

16. According to the learned counsel, the prior arts in this case did not teach away. Teaching away would mean, there should be a clear disadvantage to follow the prior art. In fact, in the present case all the prior arts alone or in combination relied upon the petitioner teach towards the alleged invention. Therefore there is neither an inventive step nor a technical contribution.

17. Then the counsel raised the ground relating to failure to comply with Section 8. According to the learned counsel, there was no disclosure at any point of the Korean Patent Application filed on 28.09.2007 and published on 12.10.2007. The US Patent Application No.11/558/616 filed on 10.11.2006 which claims the benefit of the parent patent 10.311/678 and which was abandoned during prosecution was not informed and was materially

suppressed. Third, the EP application No.EP06126732.4 which is a divisional clearly shows that the date of grant of patent was 20.12.2006 this was also not disclosed.

18. According to the learned counsel the duty of the respondent to furnish the details u/s 8(1)(b), would not come to an end till the grant of patent which in the present case is 18.06.2008. According to him, the respondent cannot state that it has disclosed the last of the corresponding foreign application, and that the patent shall not revoked for not disclosing a few applications which have been left out by mistake.

19. According to the petitioner, the respondent must give details of the Australian divisional, the Canadian divisional and the New Zealand divisional, the failure to show the EP divisional which is for the preparation of an intermediate and which is therefore integral to the impugned patent. Therefore non disclosure of the said EP Divisional was a breach of section 8(1). Similar would be the case of Korean Divisional.

20. It was submitted that the US child-continuity application is like a patent of addition and therefore non disclosure would be a breach of Section 8(1). As regards breach of section 8(2), it was submitted that the counsel for the respondent had by letter dated 15.12.2005 assured that all the documents relating to processing of corresponding foreign application will be submitted as and when those are available to the applicant.

21. According to the learned counsel, the reports were available even at the time of examination and yet they were not submitted. It is also submitted that a final rejection was made in the US application on 23.09.2005, this was also not submitted.

22. According to the learned counsel, the respondent has failed to submit the details of the US and EP patents which are the counter parts of Ex B.

They are required to be submitted u/s 8(2). These documents are already part and parcel of ORA/17/2012/PT/KOL in which the Ex B which is Patent no 221017 has been challenged.

23. The learned counsel relied on **Chemtura Corporation vs. Union of India & Ors.** *MANU/DE//1880/2009* and the decisions of this Board in **VRC Continental vs. Uniroyal Chemical Company Inc. (USA) and Ors.** *ORA/14/2009/PT/MUM and* in **Tata Chemicals Limited Vs. Hindustan Unilever Limited and Anr.** *ORA/18/2010/PT/MUM* . He submitted that on all these grounds the patent deserved to be revoked.

24. Mr. Praveen Anand, the learned counsel for the respondent submitted that the applicant has not filed any evidence to support his revocation petition, and on this ground alone the revocation application deserved to be dismissed. The entire proceedings are based on mere pleadings without any proof. The onus of proving that the granted patent should be revoked his entirely on the applicant. In **ORA/44/2009/PT/CH – The Travancore Mats & Matting Co. vs. The Controller of Patents and Ors.** – the IPAB had held that without any evidence to support the petition, the patent cannot be revoked. It was also submitted that the revocation petition is time barred having been filed beyond three years from the date of grant of patent. It was submitted that the revocation petition lacked bonafides and it is only with a commercial view that this application has been filed.

25. According to the learned counsel, the prior arts do not teach the invention. The tosylate salts are not approved by FDA. The matter of selection of salts is very unpredictable and the choice cannot be made merely by trial and error. The invention which is marketed as TYKERB or TYVERB was not the result of routine experimentation, there was an inventive step.

26. The learned counsel submitted that a small change can make a huge difference as far as the properties of the compound are concerned. All the compounds in Exhibit B are di HCL salts. The tosylate was never disclosed as a lead compound. When the inventor moved from di Hcl salt to ditosylate he would ensure that the therapeutic efficacy is not compromised and since Ex B related to a different field of endeavour, the person skilled in the art would not even look at it.

27. He submitted that the respondent was bound to identical Form-27 both in relation to this patent and IN221017 which is the subject matter of ORA/17/2012/PT/KOL. The respondent has only done what is correct and accurate since the manufacture and sale of TYKERB will amount to working both the patents, viz, the one impugned herein and the Patent No.221017.

28. He submitted that it is perfectly permissible to have a commercial product that can be covered by more than one patent. As regards the Section 8 disclosure, the learned counsel submitted that he had fully complied with the requirements. Since there are no guidelines in this regard, the respondent bonafide believed that a child continuity application in the US will not be the same or substantially the same invention according to our Act.

29. The learned counsel submitted that the applicant had furnished all information under section 8(1) periodically. He explained the legislative intent of Section 8 as seen from the Ayyangar Report. He submitted that incorporation of Section 8 might have been necessary when there was no infrastructure or technical support to find out what were the applications made abroad, but today with search engines and information from the Internet, the Section 8 requirement must be balanced and read in context.

30. He submitted that this Board should also consider whether the lapse if any in submitting Section 8 requirements had materially affected the examination of the patent herein. He referred to the **Therasense Inc. Vs. Becton, Dickinson and Company (Fed. Cir. 2011, en banc).**

31. As regards the patent itself, the learned counsel submitted that the subject of the invention is a PTK inhibitor that inhibits the activity of both epidermal growth factor receptor (EGFr/ErbB1) and Human Epidermal Receptor (HER2/ErbB2). The patent specification discloses the problem that existed with the dihydrochloride salts of 4-quinazoline amines, since they sorb large amounts of water and stability would be compromised. The ditosylate absorbs lower amount of water.

32. He referred to Fig.3b, 4 and 5 to show the percentage change in weight of dihydrochloride salt, and the comparison between ditosylate and dihydrochloride salt and the before and after stability testing by depiction of the diffraction patterns of Lapotinib anhydrate and monohydrate crystal forms.. He also referred to the documents filed along with the miscellaneous petition to prove commercial success. He submitted that Lapotinib is a small molecule tyrosine kinase inhibitor, TYKERB is the only approved reversible dual PTK inhibitor. It fulfilled a long felt need, and the unexpected result achieved by it has unique potential benefits beyond those of Trastuzumab.(Herceptin).

33. He referred to the EPO judgment in **Simethicone Antacid Case (T2/83)** which said that the question is not whether the skilled man could have provided the solution to the unrecognised problem but whether he would have done so in expectation of arriving at the solution.

34. The learned counsel gave the dictionary meaning of the obviousness as something “clearly perceptible” or” easily seen or understood” and

submitted that if the discovery lies so much out of the track then it cannot be obvious. **(vide Bishwanath Prasad Radhey Shyam vs. Hindustan Metal Industries (1979) 2 SCC 529).**

35. He submitted that one should understand the characteristics of the person of ordinary skill and referred to several cases which describe this person. He also said that one must examine whether the invention was obvious to try and when there is a high degree of unpredictability as in the choice of salts that should be taken into account. He submitted that the Board must consider what kind of prior art documents will be seen by the person skilled in the art and what was the common general knowledge at that time and cited several decisions in this regard.

36. He also submitted that secondary considerations or objective indicia of non obviousness and respondent had provided five such objective guideposts:

a. TYKERB® is the only approved reversible dual protein kinase inhibitor for the treatment of breast cancer.
b. The commercial success of TYKERB® has been provided by the affidavit of Mr. Kaizad Hazari.
c. There has been a long felt need in the world of medicinal chemistry as shown in Respondent No.1 Exhibit 1 of M.P. filed on 15th January 2013.
d. The unexpected result achieved by TYKERB® as an effective treatment for breast cancer has unique potential benefits beyond those of Trastuzumab, a large molecular weight molecule (Herceptin) which is a recombinant humanized monoclonal antibody.
e. Granted patents have been issued in more than 30 countries.

37. The counsel also referred to certain observations that were made in **Pfizer vs. Apotex**:

a. Effects of chemical changes on properties of medicinal products is not predictable
b. Trade-offs in salt properties are a rule and one of skill must usually accept some undesirable properties to achieve other desirable ones.

c. Secondary considerations, when present, must be considered in determining obviousness.
d. Such properties may be biological or physical. A failure to recognize all such properties that may be relevant to the value of such a compound may doom the compound to being poured down the drain rather than becoming an important therapeutic.
e. The properties of new pharmaceutical salt forms are entirely unpredictable. Even the Berge reference on which the panel relied clearly states: “unfortunately there is no reliable way of predicting the influence of a particular salt species on the behaviour of the parent compound.”

38. According to the learned counsel Exhibit B did not teach that tosylate was a preferred salt and there is no exemplification of ditosylate salt, and Ex B being the closest prior art if its disclosure does not make the subject matter obvious, then the obviousness charge must fail.

39. As regards Ex C, the learned counsel submitted that the person with ordinary skill in the art would not even look at it since it was a non-analogous art.

40. According to the learned counsel in Ex C out of the 132 examples only 28 are HCl salt and 28 are tosylate salt. A person of ordinary skill in the art based on the common general knowledge will look at alternatives as seen from Exhibits D and E.

41. The learned counsel referred to Ex D Gould et al and said that this would show that selection of a salt form for a desired combination of properties is a difficult semi-empirical choice and HCl salt is the obvious choice. The selection of salts involves an interplay of a chemical perspective, a formulation and analytical perspective and a drug metabolism perspective.

42. In view of this article, the person skilled in the art would select HCl salt alone as the most preferred salt since it is the frequently successful pharmaceutical salt and after it the most preferred are sulphate, bromide,

phosphate, tartarate, mesylate. Therefore, according to the learned counsel this would not direct a person skilled in the art towards the invention.

43. As regards Ex E he submitted that this is again a screening process that shows there is no reliable way of predicting the influence of a particular salt species:

> "(i) Biological activity of a drug molecule is influenced by two factors: its chemical structure and effect at a specific site and its ability to reach and then be removed from the site of action. Thus, a knowledge of the physicochemical properties of a compound that influence its absorption, distribution, metabolism, and excretion is essential for a complete understanding of the onset and duration of action, the relative toxicity, and the possible routes of administration."

44. Therefore according to him, this prior art also would not help the person skilled in the art. In fact it only shows that this person skilled in the art with a conservative attitude and conventional wisdom will not look at the non FDA approval salts list.

45. As regards Section 3(d) objection, he submitted that to apply 3(d), the invention should be a discovery as opposed to an invention. The prior arts Ex D and E would show that salt selection has an impact on the physiochemical properties of the parent compound which in turn would affect the therapeutic efficacy.

46. The learned counsel submitted that the primary purpose of Section 3(d) is to prevent evergreening and also to encourage incremental inventions. He submitted that the use of the expression 'new form of a known substance' in Section 3(d) presupposes that there exists as on the priority date a 'known substance i.e. a substance which is publicly known and having proven efficacy as opposed to being known to the inventor or to the applicant. The use of the

words ‘enhancement’ and ‘differ significantly’ in Section 3(d) means that the provision requires efficacy to be measured empirically.

47. In view of this, he submitted that the ditosylate salt of Lapatinib being thermodynamically more stable and less hygroscopic is not attracted by Section 3(d). In conclusion, it was submitted that no grounds have been made out for revocation of the patent.

48. This is the invention.

We Claim:

1. A compound of Formula (I).

and anhydrate or hydrate forms thereof, wherein R1 is Cl or Br; X is CH, N, or CF; and Het is thiazole or furan.

2. A compound of Formula (II),

and anhydrate or hydrate forms thereof.

3. The compound as claimed in claim 2, wherein the compound is the anhydrate form.

4. The compound as claimed in claim 2, wherein the compound is characterized by a powder x-ray diffraction pattern, comprising the peaks:

Two theta (deg)	d-spacing (angstroms)
4.8	18
8.7	10
18.0	4.9
19.9	4.7
21.0	4.2
22.3	4.0

5. The compound as claimed in claim 2, wherein the compound is the monohydrate form.

6. The compound as claimed in claim 2, wherein the compound is characterized by a powder x-ray diffraction pattern, comprising the peaks:

Two theta (deg)	d-spacing (angstroms)
6.6	13
8.3	10
11.5	7.7
18.1	4.9
21.1	4.2

7. The compound as claimed in claim 1, wherein the compound is a compound of

Formula (III) (III)
and anhydrate or hydrate forms thereof.

8. The compound as claimed in claim 1, wherein the compound is a compound of Formula (IV)

(IV)
and anhydrate or hydrate forms thereof.

9. A pharmaceutical composition, comprising: a therapeutically effective amount of a compound, or anhydrate or hydrate forms thereof, as claimed in any of claims 1 to 8 and one or more of pharmaceutically acceptable carriers, diluents and excipients.

10. A pharmaceutical composition as claimed in claim 9, capable of being used in the manufacture of a medicament for the treatment of a disorder in a mammal, said disorder being characterized by aberrant activity of atleast one erbB family PTK.

11. A pharmaceutical composition as claimed in claim 10, wherein said erbB family PTK is selected from the group consisting of EGFr, c-erb-B2, and c-erb-B4.

12. A pharmaceutical composition as claimed in claim 10, wherein at least two erbB family PTKs selected from the group consisting of EGFr, c-erb-B2, and c-erb-B4 exhibit aberrant activity.

13. A pharmaceutical composition as claimed in claim 10, wherein at least one erbB family PTK selected from the group consisting of EGFr, c-erb-B2, and c-erb-B4 is inhibited by the compound.

14. A pharmaceutical composition as claimed in claim 10, wherein at least two erbB family PTKs selected from the group consisting of EGFr, c-erb-B2, and c-erb-B4 are inhibited by the pharmaceutical composition.

15. The pharmaceutical composition as claimed in claim 10, wherein the disorder is cancer or psoriasis.

16. The pharmaceutical composition as claimed in claim 10, wherein the disorder is cancer.

49. **First we will take up the S.3(d) objection**. If it fails this test it is not an invention.

a) As regards the S.3(d) bar, the respondent's own statements and the expert's affidavit demonstrate that this invention cannot be held to have enhanced therapeutic efficacy.

b) In the response to the Examination report the respondent had stated that the improved properties over the prior art compounds are that the Invention salts **"sorb much lower amounts of water when exposed to a broad range of humidities and can be prepared in a stable crystal form." And that "Due to the improved moisture sorption properties of these compounds and increase in stability they exhibit enhanced efficacy in their use as a medicament following storage when compared with the di-HCL salts disclosed in the prior art reference**." So admittedly the enhancement as compared to the prior art salts is the moisture absorption property and the increase in stability.

c) According to the respondent Ex D and E show that difference in physio chemical properties would result in greater therapeutic efficacy.

d) According to The respondent's expert witness Dr. S.V. Eswaran "*There was a need to have lapotinib compositions having improved water sorption properties and improved stability*." And this Invention is alleged to have fulfilled this need.

e) But according to our law the improvement in these properties will not amount to greater therapeutic efficacy.

f) In **Novartis Ag vs Union of India (2007 4 MLJ 1153)** the Madras High Court held "*The position therefore is, if the discovery of a new form of a known substance must be treated as an invention, then the Patent applicant should show that the substance so discovered has a better therapeutic effect. Darland's Medical Dictionary defines the expression "efficacy" in the field of Pharmacology as "the ability of a drug to produce the desired therapeutic effect" and "efficacy" is independent of potency of the drug. Dictionary meaning of "Therapeutic", is healing of disease - having a good effect on the body." Going by the meaning for the word "efficacy" and "therapeutic" extracted above, what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease/having a good effect on the body? In other words, the patent applicant is definitely aware as to what is the*

"therapeutic effect" of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for. Therefore it is a simple exercise of, though preceded by research, - we state - for any Patent applicant to place on record what is the therapeutic effect/efficacy of a known substance and what is the enhancement in that known efficacy." *The word "therapeutic" is linked with healing of disease which means healing of that disease. In fact this decision holds that better potency does not mean better therapeutic efficacy.*

g) In the recent Novartis case the Hon'ble Supreme Court held "*We are clearly of the view that the importance of the amendment made in section 3(d), that is, the addition of the opening words in the substantive provision and the insertion of explanation to the substantive provision, cannot be under-estimated. It is seen above that, in course of the Parliamentary debates, the amendment in section 3(d) was the only provision cited by the Government to allay the fears of the Opposition members concerning the abuses to which a product patent in medicines may be vulnerable. We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant especially to deal with chemical substances, and more particularly pharmaceutical products. The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds*. *So S.3(d) is a second tier for patentability which must be cleared by anyone who seeks a grant in India. The underlying text here is that the invention which does not clear this tier is not a genuine and true invention."*

h) The Supreme Court further held "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 advantages 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." *From this it is seen that only those properties that are directly related to efficacy are relevant for S.3(d) and not all advantageous or beneficial properties. More importantly considering the genesis of S.3(d) the words "therapeutic efficacy" must receive a narrow and strict interpretation. The net cannot be widened to bring in other non therapeutic advantages*.

i) It also held that "In whatever way therapeutic efficacy may be interpreted, this much is absolutely clear: that the physico-chemical properties of beta crystalline form of Imatinib Mesylate, namely (i) more beneficial flow properties, (ii) better thermodynamic stability, and (iii) lower hygroscopicity, may be otherwise beneficial but these properties cannot even be taken into account for the purpose of the test of section 3(d) of the Act, since these properties have nothing to do with therapeutic efficacy." *Physico-chemical properties have nothing to do with therapeutic efficacy.*

50. We are bound by the above judgment and our law. Virtually the same properties as mentioned in Para 49(i) supra, are touted to result in significant enhancement of therapeutic efficacy. They may be advantageous in certain ways when compared to the Invention in ORA/17/2012/PT/KOL. But the advantages do not result in therapeutic efficacy as seen from para 49(h) above. Applying S.3(d) and the decision of the Supreme Court in the Novartis case we find that this is not an invention. The patent deserves to be revoked

and we need not examine any further, but we will address the Obviousness and S.8 issue since they are important.

51. **Obviousness:** Next we take up the obviousness ground. The respondent has filed several exhibits and two affidavits one by the expert Dr. S.V. Eswaran to show that the invention is non-obvious and the other by Mr. Kaizad Hazari to prove commercial success. Several foreign decisions were cited to show how obviousness is to be decided, what is hindsight, who is the person Skilled in the Art, what is the Common General Knowledge and so on. In the **F.Hoffman la Roche v Cipla** case the Hon'ble Delhi High Court had observed that the obviousness test is what is laid down in **Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries Ltd (AIR 1982 SC 1444)** and that "*Such observations made in the foreign judgments are not the guiding factors in the true sense of the term as to what qualities that person skilled in the art should possess. The reading of the said qualities would mean qualifying the said statement and the test laid down by the Supreme Court."*

52. In **IPAB Order No.128 of 2013** in **ORA/08/2009/PT/CH AND Miscellaneous Petition Nos. 7/2010, 31/2010, 51/2011, 86/2012, 142/2012 & 143/2012 in ORA/08/2009/PT/CH Enercon (India) Limited vs. Aloys Wobben** we had referred to the CIPLA judgment of the Hon'ble Delhi High Court in the context of obviousness; "*The guide to this is found in the judgment of the Delhi High Court in **F. Hoffman-La Roche Ltd v. Cipla Ltd**, it reads, "Therefore the same cannot be read to mean that there has to exist other qualities in the said person like unimaginary nature of the person or any other kind of person having distinct qualities." "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?" According to the respondent, the applicant should prove that the person skilled in the art knew each and every prior art, read every text book, and the prior art must be widely read, and even if it is in a patent text book it does not mean that it is known, and also that this person skilled in the art is working in India. The Delhi High Court says one need not add further qualities and that one must "presuppose that the said person would have the knowledge and the skill in the said field of art and will not be unknown to a particular field of art and it is from that angle one has to see that if the said document which is prior patent if placed in the hands of the said person skilled in the art whether he will be able to work upon the same in the workshop and achieve the desired result leading to patent under challenge." The Delhi high court asks us not to import any further doctrinal approach by modifying or qualifying the test laid down in Biswanath Prasad.

In view of this judgment, it is definitely not necessary nor proper for us to dumb down the Person Skilled in the Art, nor make him so ignorant of anything that is happening elsewhere or presume he is ignorant of even common text books unless proved otherwise. In fact this hypothetical person is presumed to know all the prior arts as on that date, even non-patent prior art in theory available to public. He has knowledge of the technical advancement as on that date, and the skill to perform experiments with the knowledge of state of the art."

53. In the same decision we had held that according to our law, the obviousness test will be made against the Person Skilled In the Art (Ms.P.Sita) and not a Person with Ordinary Skill In The Art. We had earlier described this person in the **IPAB Order No.250/2012 in OA/8/2009/PT/CH**

42. The non-obviousness and novelty factors are sometimes sitting there cheek–by-jowl, "The Law of Patents" by Nard second Edition says that Novelty "seeks to assure the public domain remains undisturbed" while non–obviousness "demands that the claimed invention be sufficiently removed from the prior art". This text also says that non-obvious enquiry is "a more aggressive sentry" and "a richer policy tool that allows for the combination of prior art references and demands more complex rules." In KSR, the US Supreme Court held that the analysis of obviousness must be made explicit, and the reasoning to support the conclusion of obviousness must be articulated with rational underpinnings, the Court may have to look at the inter-related teachings of the multiple patents, the effect of demands known to the design community and the background knowledge possessed by a person having ordinary skill in the art. So the determination on obviousness is a legal one. The Court has to see a) what is the prior art b) the differences between the prior art and the invention and c) the skill of the imaginary ordinary man. This man has skill but until KSR came along he had no inventive or creative capacity. Such a person is hard to find, but we had to conjure this man in our mind as we do the man on the Clapham omnibus. By way of diversion, it seems he is referred by the acronym Mr. PHOSITA or just PHOSITA, the preferred acronym could be POSIT it sounds better or POSITA if you please. Getting back to the track, as KSR says this man is "A person of ordinary skill is also a person of ordinary creativity not an automaton." So an automaton- like unimaginative but skilled man has now been allowed to have a modicum of creativity and imagination by the grace of the U.S. Supreme Court! We must remember that this ordinary man has skill in this art. He is not ignorant of its basics, nor is he ignorant of the activities in the particular field. He is also not ignorant of the demand on this art. "He is just an average man..... Well... just an ordinary man." But he is no dullard. He has read the prior art and knows how to proceed in the normal course of research with what he knows of the state of the art. He does not need to be guided along step by step. He can work his way through. He reads the prior arts as a whole and allows himself to be taught by what is contained therein. He is neither picking out the" teaching towards passages" like the challenger, nor is he seeking out the "teaching away passages" like the defender. In this case he is a person familiar with or engaged in PEG chemistry. He knew that it was

a time of intense activity in this field of chemistry. The person defending the patent will undoubtedly inform the Court that there was nothing in the prior art to encourage the person skilled in the art to work toward the invention. KSR says "The question is not whether the combination was obvious to the patentee but whether the combination was obvious to the person skilled in the art. Under the correct analysis, any need or problem known in the field of endeavour at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." And one of the easy ways by which "a patent's subject matter can be proved obvious is by noting that there was an obvious solution encompassed by the patent's claims." KSR also says that if pursuit of known options within the technical grasp of the person skilled art leads to the anticipated success " it is likely the product not of innovation but of ordinary skill and common sense".

54. Bastin et al filed by the respondent as Exhibit 1 is around the same time as the priority date of the Invention. It speaks of Salt selection and Optimisation procedures for Pharmaceutical New Chemical Entities. It says that salts are most commonly employed for modifying aqueous solubility but the selected salt may influence a whole range of other properties. This actually shows that the choice of salt could be just routine testing. "A microplate technique has been developed for the screening of salts" and "Once the combination of counterions and solvents are identified studies can be initiated to confirm the suitability and viability of the crystals"

55. S.V. Eswaran the expert says that the prior arts do not teach the invention. According to this expert significant scientific exploration and experimentation have resulted in the discovery that this ditosylate salt has better sorption profile and better stability. He says that an objective reading of D1 (Ex-B) shows that "there is no disclosure of ditosylate salts of 4-quinizoline amine and there is no teaching or direction to prepare the salts in D-1." According to him Ex-B relates principally to the free base forms (although salts in general and dihydrochloride salts in particular are disclosed"

and this invention claims the novel ditosylate salts. And Ex B will not teach (Ms P. Sita) the Person skilled in the art to prepare the salt. He says that one of the key considerations “is whether a skilled person would have been able to predict *a priori* the precise properties of a particular salt, solvate or a crystalline form. “According to him selection of salts is an art and not routine selection. He has referred to Bastin et al filed as Ex-1 along with the counter statement to show that it is necessary to screen a large number of salts to identify the ones which are suitable for preparation of pharmaceutical preparations. According to him this document also demonstrates that the hygroscopicity of a salt varies from compound to compound. He also referred to Ex.2 Handbook of Pharmaceutical Salts to show that salt properties such as solubility, physical form, crystal forms are not predictable. The expert also has said that the objections of obviousness relate only to the discovery of the properties of the ditosylate salts as recited in claims 1and 2, and do not address the inventive contribution in the other claims. According to him, the dependent claims represent a technical advance. As regards Ex C the expert says that “Although D2 does teach the preparation of tosylate salts of such 3-pyridoxyl alkylene azetidine-2-yl compound and that these are less hygroscopic, more crystalline, more stable, have a higher melting point and are readily purifiable as compared to hydrochloride salts, it is not justifiable to extend the disclosure in D2 to other compounds. It is not possible for a person skilled in the art to predict that tosylate and ditosylate salts of another completely unrelated chemical compound will have better water sorption properties than the corresponding hydrochloride salt. It is only after carrying out suitable experimentation that it is possible to determine the most suitable salt.” As regards Ex-D he says that D3 merely teaches that it is technically feasible to prepare tosylate salts and while it provides a few examples of

tosylate salts it will not teach Ms. P. Sita to expect or predict that a particular tosylate salt will have improved properties for use as a medicament for cancer It also speaks of the difficulties in selecting a suitable salt. For all these reasons the expert says that the invention is not obvious.

56. **In re Winslow**, 365 F.2d 1017 (C.C.P.A. 1966) [72 Rich J said, “In performing the obviousness analysis,” courts should “picture the inventor as working in his shop with the prior art references . . . hanging on the walls around him” This is a very evocative scene and does help us in figuring out what the hypothetical person: the Person Skilled In The Art will do.

57. Ex-B is the prior art acknowledged in the Complete Specifications. It is Patent No. ‘017 which has been challenged in ORA./17/2012/PT/KOL.The invention relates to Bicyclic Heteroaromatic Compounds. The PCT application (NP) as filed, relates to quinoline, quinazoline, pyridopyridine and pyridopyrimidine derivatives. The object of the invention is to provide suitable compounds for treatment of disorders mediated by PTK activity. Preferred compounds include the present invention. List 48 mentions the present compound. This prior art says that “Examples of pharmaceutically acceptable acid addition salts include those derived from mineral acids, such as....., and organic acids, such as....and aryl sulphonic for example p-toluenesulphonic acids.” **The last mentioned is the tosylate salt**. It says that “An effective amount of a salt or a solvate of the present invention may be determined as a proportion of the effective amount of the compound *per se*.” **Example 29 in this prior art is the invention herein. It says it was prepared according to Procedure D**. Claims 11 and 12 are for “A compound as claimed in claim 1 selected from {salts which include the invention herein}” and for “A compound as claimed in claim 11 selected from {salts which include the invention herein}” respectively.

58. According to Dr. S.V. Eswaran, this prior art did not deal with the invention but only with hydrochloride salts. Even if we accept this statement of the expert, we find from the Complete Specifications that on the date of the invention problems existed with the HCL salts and the field of art was looking for a compound with better moisture sorption properties and better stability. So all the objections raised on behalf of the respondent that Ex. D and E only spoke of HCl salts and there was no motivation to move to di-tosylate are answered in the Specifications itself. The Persons working in this Field of Science were admittedly looking for an alternative to HCl. There is no point in saying that HCL was the first option, when the field of activity was in search for a compound with better moisture sorption properties and better stability than HCl. Ms P. Sita is a person with skill in the art. She has the prior arts hanging in front of her. She is wondering which salt would answer the bill. She reads of the tosylates in Ex B. It is another matter to say that Ex.B dealt with HCl salts. Example 29 is the tosylate. Then she sees Ex C which undoubtedly is about “3 Pyridyl Enatiomers and their Use as Analgesics”. But it says “The preferred salt is the tosylate salt. The inventors have found that the tosylate salt is less hygroscopic, more crystalline, more stable, has a higher melting point, and is more readily purified than the other salts. In addition, the tosylate salt is better suited for pharmaceutical formulation.” Salt selection especially if there is a wide range is not a matter of routine, according to the respondent. Even if we accept this as correct, it does not help the respondent. Ex D is about salt selection and it shows that aryl groups present a hydrophobic barrier to minimize hygroscopicity. The Person Skilled in the Art would look at Ex.C and find that the tosylate salt of such 3-pyridoxyl alkylene azetidine-2-yl compound shows exactly the same qualities that the persons in this field are looking for in relation to Lapotinib. She knows that tosylate compound is a

preferred compound from Ex B and that it can be prepared by Procedure D. She is not a dullard she can do experiments with skill. She is more likely to think “Let me try a tosylate first. If it demonstrates the same improvements as it has in Ex-C then I need not search further.” She would have tried a tosylate with a reasonable expectation of success. In Pfizer v. Apotex the Court held that the expectation of success need only be reasonable not absolute. It in fact says that if that were not so any new salt would be separately patentable simply because the formation and properties of each salt must be verified by testing.

59. In the present case there is a clear indication in Ex.B of the tosylate compound. There is no doubt that zooming in on a correct salt is not easy, if the choice could only have been made by testing each compound one after the other with no clue available. But Ex.C gives a clue. It was reasonable to hope it might, it would not have been a blindman’s buff choice. So we are of the opinion that to the Person Skilled in The Art taught by Exhibits B and C the invention was obvious. According to our Act, the patent is revoked if the invention is obvious. So the secondary considerations cannot change that. It is true that the applicant has not filed any evidence by way of affidavit, but the prior arts have been filed and on the facts of this case this material is sufficient.

60. **S.8 disclosure and non-compliance**:- This needs some elaborate discussion. S.8 destroys a patent which is otherwise patentable on grounds which have nothing to do with the invention, but only with the Inventor’s lapse during the grant proceedings. So one must carefully apply the provision. The law demands compliance at the same time it must be shown that the Section would apply. S.8 of the Act is not intended to be a bonanza for all those who want an inconvenient patent removed. In The Ayyangar Committee Report it

was said, ”It would be of advantage therefore if the applicant is required to state whether he has made any application for a patent for the same or substantially the same invention as in India in any foreign country or countries, the objections, if any, raised by the Patent offices of such countries on the ground of novelty or unpatentability or otherwise and the amendments directed to be made or actually made to the specification or claims in the foreign country or countries.”

61. In the Hindustan Lever case the FER required the “Foreign filing particulars”. The respondent gave wrong particulars about the GB application, and suppressed the IPER relating to EP 1106578 which was not pursued and the IPER had rejected the claims 1to3 on the grounds of both novelty and inventive step. We held that the ground under S.64 (1) (m) was made out.

62. In Therasense the disclosure obligations were discussed, and the majority ruled that the materiality required to establish inequitable conduct is but-for materiality, and that in assessing the materiality of a withheld reference, the Court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making the patentability determination, the Court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.

63. In India TV Independent News Service Pvt Ltd. vs Yashraj Films Pvt Ltd, the Delhi High Court considered the de minimis doctrine and the factors to be considered in applying them namely size and type of harm, cost of adjudication, purpose of violated legal obligation, effect on legal rights of third parties and intent of wrong doer. In that case the use of the song was held not to cause any harm to the copyright owner. Here the de minimis doctrine is invoked by the patent owner.

64. If the obligation under S.8 has been violated then the harm caused is the continuance of a patent which must be removed. It appears to us then that the harm is not of a minimal nature. The public is affected by the exclusive monopoly to a patent that law makes revocable.

65. The law relating to Interpretation of Statutes was referred to and it was submitted that while construing penal sections and two constructions are possible then the lenient one should be adopted. This provision is not a penal provision. A penal provision is one which enacts an offence or imposes a penalty. Failure to comply with S.8 is not an offence. It is a duty cast on the patentee which results in adverse consequences if flouted. Dishonour of cheque (AIR 2012 SC 2795 Aneeta Hada vs Godfather travels and Tours was cited) fastens a criminal liability. S.8 does not. So the cases arising out of the former will not apply. The State of Tamilnadu vs M.K. Kandaswami (AIR 1975 SC1871) related to a tax statute. Evasion of tax has its consequences. But in this judgment there is a paragraph which is worth extracting. " It may be remembered that Section 7A is at once a charging as well as a remedial provision. Its main object is to plug leakage and prevent evasion of tax. In interpreting such a provision, a construction which would defeat its purpose and in effect, obliterate it from the statute book, should be eschewed. If more than one construction is possible, that which preserves its workability and efficacy is to be preferred to the one which render it otiose or sterile"

66. The Ayyangar Report makes it clear that the purpose for introducing this provision was to ensure that it would be an advantage for our Patent Office to know the objections raised by the patent offices outside India regarding the patentablity of the invention and the amendment if any made or to be made. It also says that it would be of great use for the proper examination to know if the invention was anticipated. In the Hindustan Lever

case we had held that it was in order to secure disclosure of the relevant information regarding the foreign applications that the Ayyangar Report recommended that failure to disclose would be a ground for challenge. In Chemtura Corporation vs Union of India the Delhi High Court said, “45. It is not possible to accept the submission, made by referring to the Halsbury’s Laws of England, that since the omission to furnish particulars is not serious enough to affect the grant of the patent, it did not impinge on its validity. Section 64 (1) (j) and (m) indicate to the contrary. Further under Section 43 (1) (b) a patent can be granted only when the application has been found not to be contrary to any provision of the Act. It cannot be said that the omission to comply with the requirement of Section 8 (2) was not serious enough to affect the decision of the Controller to grant the patent to the Plaintiff. The information, if provided, would have enlightened the Controller of the objections raised by the US patent office and the extent to which the Plaintiff had to limit its claims to the torus shape of the compression spring, which was a key feature of the subject device.”

67. The object of this provision is to ensure disclosure. We will adopt that construction which is to advance the object. When we refer to the object we mean the object of this provision and not the object of the Act. This section has been introduced to make sure that the person who is given an exclusive monopoly is candid and fair in his conduct. So we cannot adopt a construction which relieves the patentee of this duty.

68. In the Sugen vs Cipla case we said, “The respondent had also filed OA 6/2013 against the finding on S.8 violation. Now that the matter is to be heard de novo right from the stage of the Constitution of the Opposition Board, this issue will also be decided by the Controller. The IPAB has in its decisions clearly held that it is the duty of the Patentee to furnish the

particulars under S.8. We are surprised that the Controller should have held to the contrary and observed that such information is available on the internet. This is not the law. This duty under Sect 8 cannot be breached and if violated results in revocation. It deserves to be accorded due respect. What should be furnished by the Patentee shall be furnished by the Patentee. So the Controller shall bear this in mind while considering the ground under S.8 and examine whether the Appellant has fully complied with the S.8 Requirements."

69. We must remember that we are not the law makers. For good reasons S.8 is there. The Controllers cannot ignore it and condone the breach. The patentee cannot tell the Examiners, " We are filing applications nineteen to the dozen, compliance is very difficult, and in any case there is the Super Kamadhenu the Internet which will give you what you want." We cannot wish S.8 a relieved farewell. Tough for Inventors it may be, but S.8 must be complied with. When George Mallory was asked "Why do you want to climb Mount Everest?", he is supposed to have replied, "Because it is there**." To the question "Why should we comply with S.8?" The Answer is "Because it is there.**

70. The IPO must have a consistent stand with regard to S.8. It can not be East West Who is best. We request the Controller General to educate and instruct the officers regarding the requirements of law. We must remember what the Supreme Court said in the Novartis case, "*In order to understand what the law really is, it is essential to know the "why" and "how" of the law. Why the law is what it is and how it came to its present form? The adage is more true in case of the law of patents in India than perhaps any other law."* The why is clear from the Ayyangar report. We must remember it and the IPO must too.

71. Now that S.8 compliance is insisted upon, the applicant seeking revocation may think that it is enough if he just types the password “S.8 not complied with” and the IPAB will do the rest. That will not do. He will have to say that these are the foreign office actions that were not filed with the office. The applicant cannot plead that he is not privy to those applications. These documents are now being downloaded by the reams and placed before us at the time of the hearing, instead the applicant must embark on this exercise at the time of filing of the application and plead how S.8 was violated and why that particular foreign filing ought to have been filed. He must plead how it is the “same or substantially the same invention.” That will be fair to the defender who will know what he has to traverse in his counter statement. Producing a list of foreign applications allegedly covered by S.8(1) on the eve of the hearing is not fair either. At the same time if a document is filed belatedly we will not shut it out on that ground alone, especially if it is a material violation. For after all the IPAB is a guardian of Public Interest. We will however have to think of imposing some costs for filing evidence with delay. This litigation is adversarial in nature with an unmistakeable public interest component, and hence unique. The adversary cannot take advantage of the public interest component and abandon his duty as a litigant to plead and prove his case. It is true that IPAB is not bound by the provisions of the C.P.C but shall be guided by principles of natural justice. Procedural fairness is an aspect of natural justice and it means that the adversaries tell each other what their allegations are clearly, specifically and with the facts to support them. Only then the other will know what the case against him is. We would also urge the counsel to examine each document and consider if it is necessary to be filed. Not every document which is downloaded is worthy of being “uploaded” in to the litigation.

72. The respondent's defence is that it had complied with the S.8 (1) and (2) requirements. The respondent did not think that the child continuity application was for the same or substantially the same invention and a child continuity application filed years after the parent application cannot have any impact on the examination process. The respondent also did not think that the divisional application was the same or substantially the same invention. Further the EP divisional was for a process for preparing an intermediate. According to the respondent it was required to divide the claims into a divisional application which was filed on 3 May 2006. The US continuation application and the EP and the KR divisional applications were all filed after the divisional application had been filed.

73. When we look at the Ayyangar Committee Report it indicates that the object behind introducing S.8 is that the applicant should disclose all foreign applications so that the examiner here may know if it contains obviousness objections or any amendments and so on. The application outside India must be for the same invention or for substantially the same invention. The Ayyangar Committee Report also speaks of anticipation coming to light if the disclosure is made. So the Ayyangar Committee Report is clearly talking of the same invention or almost the same invention. The subject matter of the invention must be the same or almost the same. If there is a divisional, then according to the Indian law there is a plurality of inventions, which means there are more than one invention. The applicant may argue that the divisional application is not"the same or substantially the same invention". There are no guidelines for the office to construe these words. In view of what is stated in the Ayyangar Committee Report, we are of theopinion if in any of the foreign offices the patentee had made a division or was required to make a division, in respect of the same or substantially the same invention or had

amended or was required to amend in respect of the same invention or substantially the same invention such information regarding division or amendment would also be information required to be furnished under Section 8. It is therefore necessary that the person seeking revocation demonstrates that the foreign application the details of which were not furnished, was for the same or the substantially the same application. It is true that the IPAB is not bound by the rules of the CPC, and it is enough if the procedure is guided by the principles of natural justice. If the opponent does not know what the case against him is, then there is a clear violation of natural justice which implies procedural fairness. The strict technical requirements may not be insisted upon at the IPAB e.g. witnesses do not appear before us. But an issue will still have to be pleaded and proved.

74. In this case in the Revocation application, the applicant has merely stated that S.8 has not been complied with and foreign filing particulars have not been given. Nothing more is stated. In the petition filed for receiving additional documents, the affidavit filed by the applicant merely lists the documents were downloaded. We do not think that is sufficient. We understand that the S.8 ground is being raised regularly only after the Delhi High Court's Chemtura judgment and the IPAB orders mentioned above. The Examiners have not given this provision the attention that it deserves. But these proceedings have to be conducted correctly, consistently and fairly. Patentees must comply with S.8(1) provision however inconvenient it is.

75. The records before us show that the respondent has given in their Form 3, details of 3 applications which are for the same/substantially the same invention. In the Annexure to Form 3, the country list of applications has been given. An updated Annexure to Form 3 was also furnished on 15th Dec 2005. On 14/12/05, the FER requires the patentee to give the details

mentioned therein in any one of the major Patent offices as per S.8 (2) of the Patents Act. This request is vague and gives room for manipulation. If out of the three offices mentioned in this request, the examination report issued by EPO is adverse to the Patentee and the report issued by JPO is in favour, the patentee would be justified in giving only the JPO report and not the EPO report. But that would defeat the object of the provisions. The intent of the provision is to make known to the officer in India the objections raised to the same/substantially the same application outside India. Curiously this 14th Dec 2005 letter is followed by a letter dated 15th which states that the Patentee's Counsel had a discussion with the Assistant Controller and "Pursuant thereto, it has been settled that the appellant will be required to submit the 'prosecution' details of **any one** of the major Patent offices." Settled? **We do not understand what "settled" means. It is unfortunate that the office has failed to understand the importance of the S.8 requirement and leaves it to the Patentee to decide what he will give. We earnestly hope that this practice has died a natural death. It is important that the Patentee furnishes details of those search reports where there are objections like obviousness objections and shall not suppress them. If one of the major Patent offices alone has raised an obviousness objection, it is the duty of the Patentee to disclose it, considering the Object of the Act.** On 3rd May 2006 another Annexure to Form 3 was furnished. And in response to the S.8(2) request the respondent submitted the examination reports in the corresponding EP application. It is the Applicant's case which is made in the oral and written submissions that the respondent ought to have given the details regarding those foreign applications which are same or substantially the same invention as IN 221017 which is the subject matter of ORA/17/2012/PT/KOL. The respondent's case is that those

applications are to be given only in the application proceedings in respect of the other invention. According to the respondent, the two inventions are not the same nor substantially the same and that is why two applications were made. It is quite another matter that in the revocation application this Board may decide otherwise. But the respondent cannot be expected to take a stand that is suicidal to its own case**. In the present case we are rejecting the S.8 objection only because the applicant has not made out the grounds of attack by stating the facts**. A bald statement will not suffice. It is not enough to merely reproduce the language of the section. A S.8 violation has severe consequences and the case for it has to be made out. The facts have to be pleaded and the applicant must state how the particular undisclosed application was for the same or substantially the same invention. It is also not enough to just file the documents along with an affidavit. The least that the deponent shall state is how each application mentioned therein is for the same or substantially the same invention. We have indicated the principles behind the S.8 objection, how it should be raised, defended and decided. The Act says failure to disclose the information required by S.8 is a ground for revocation. It does not qualify it by saying that the failure must be deliberate nor are there any words to indicate that the failure must be in regard to material particulars**. In any event, in the absence of pleading and proof of violation, we reject this ground of attack**.

In the result we find that the invention is obvious and is hit by S.3(d) and Patent No 221171 is revoked. The ORA/22/2011/PT/KOL is allowed with costs of Rs.50,000/-.

(D.P.S. Parmar) **(Justice Prabha Sridevan)**

Technical Member (Patents) **Chairman**

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