(2014) 03 IPAB CK 0001

In the Intellectual Property Appellate Board

Case No : OA/15/2009/PT/MUM And Miscellaneous Petition Nos. 29/2009, 30/2009, 139/2012, 65/2013, 78/2013 And 95/2013 In OA/15/2009/PT/MUM

FDC Ltd. Represented By Its Joint Managing Director, Mr. Nandan M. Chandavarkar — APPELLANT

Vs

Sanjeev Khandelwal And Assistant Controller Of Patents And Designs — RESPONDENT

Date of Decision : 21-03-2014

Acts Referred:

Intellectual Property Appellate Board (Procedure) Rules, 2003 — Rule 11, 12(7), 14, 56, 56(4), 58(1), 126(2)
Code Of Civil Procedure, 1908 — Order 11 Rule 5, Order 11 Rule 13, Order 19 Rule 3, Order 41 Rule 27
Patents Act, 1970 — Section 3(d), 3(e), 10(1), 10(4), 10(4)(b), 25(2), 25(2)(a), 25(2)(c), 25(2)(f), 25(2)(g), 25(2)(j), 25(4), 57, 57(1), 59, 59(1), 59(2), 59(2)(c), 78, 107(d), 129

Citation : (2014) 03 IPAB CK 0001

Hon'ble Judges : S. Usha, J;D.P.S. Parmar, Technical Member

Bench : Division Bench

Advocate : Swethashree Majumdar, Maha Dewan

Final Decision : Dismissed/Allowed

Judgement

S. Usha, J

1 . The instant appeal is preferred against the order of the Assistant Controller of Patents dated 12/06/2009 in respect of Patent No. 197'822 (178/MUM/2004) granted on 21/04/2006 under Section 25(4) of the Patents Act, 1970 pursuant to a post-grant opposition dated 21/04/2007. The facts of the case are -

The 1st respondent filed a Patent application No. 178/MUM/2004 on 16/02/2004. The patent was granted on 21/04/2006 as Patent No. IN 197'822. The appellant herein filed a post grant opposition under Section 25(2) of the Act. The appellant also filed expert affidavit of Dr. Nagarsenkar. The 1st respondent filed their reply

statement to the statement of opposition. The 1st respondent had not filed their evidence though sought time to file evidence.

2. The 2nd respondent passed the impugned order rejecting the opposition filed by the appellants.

3 . Being aggrieved by the said order, the appellants preferred the above appeal on various grounds.

(1) that the impugned order is against law, right of evidence and probabilities of the case;

(2) that the impugned order is bad in law as it reduced an opposition under Section 25(2) to a mere review;

(3) that the impugned order is bad in law as the Opposition Board was not constituted properly;

(4) that the learned Controller erred in rejecting the evidence filed by the appellant and passed the impugned order without considering the materials placed on record;

(5) that the order demonstrates non application of mind as the Controller has dealt with grounds of wrongfully obtaining [Section 25(2)(a)] and prior claiming [Section 25(2)(c)] which were not raised by the appellants;

(6) that the Controller erred in rejecting the ground that the invention was obvious and lacked inventive step;

(7) that the Controller failed to differentiate the arguments on anticipation and lack of inventive step;

(8) that the Controller erred in holding that combining two drugs with significantly different half lives and plasma protein binding activity would have been obvious to a person skilled in the art when the half lives of Cefixime and Cloxacillin were known and the common general knowledge had sufficient material on combining drugs with different half lives by devising delayed or sustained release formulations;

(9) that the Controller erred in holding that the problem solved by the invention i.e. the preparation of the antibiotic formulation with piobiotic organism such as lactobacillus sporogenes, was not specifically disclosed in the prior art;

(10) that the Controller erred in holding that if the ground for ancipation failed the ground for obviousness should also fail if it is based on the same document.

(11) that the Controller erred in rejecting every pleaded prior art;

(12) that the Controller appears to have adopted the EPO standard on obviousness where obviousness is considered on the basis of prior art alone;

(13) that the Controller while quoting from Johns -Manville Corporations Patent

1967 RPC 479 failed to consider the ratio of the decision which was squarely applicable to the case;

(14) that the Controller erred in giving importance to secondary aspects of obviousness i.e. technical advancement and economic significance while not considering whether it would have been obvious to a person skilled in the art, which is the primary aspect for considering obviousness;

(15) that the Controller failed to consider the Expert affidavit and as such illustrates non application of mind;

(16) that the Controller failed to uphold the ground of opposition that the impugned patent is not an invention under section 25(2)(f) and that it does not constitute an invention within the meaning of section 3(e) of the Act;

(17) that the Controller failed to reason how, in the absence of the use of a new reactant or the process resulting in a new product, the process could get over the bar in section 3(d) of the Act;

(18) that the Controller erred in rejecting the ground of opposition on insufficiency under section 25(2) of the Act;

(19) that the Controller erred in ordering the respondent to amend the specification during the pendency of the infringement suit filed by the 1st respondent in contravention of section 57 of the Act;

(20) that the Controller exceeded his powers in awarding the costs and

(21) that the Controller failed to consider the pending infringement suit despite the fact being brought to his notice.

4 . The appellant filed the appeal on the above grounds and prayed to remand the matter for denova consideration by the second respondent in accordance with law, to set aside the impugned order dated 12/06/2009, and revoke the Patent 197'822 granted in patent application No. 178/MUM/2004.

5. The 1st respondent herein filed their counter statement on merits. The respondent has relied on the reply statement and has not filed any evidence as per the provisions of Rule 58(1) of Rules.

6. In reply to the appellants averment that the invention as claimed in any claim of the patent is obvious and it does not involve any inventive step the respondent stated that it was envisaged in accordance with this invention that a combination of Cefixime and Cloxacillin would have broad spectrum activity and additional therapeutic effects. In order to enhance the emperic profile of Cefixime which has a narrow spectrum activity, particularly against gram positive organism, such as staphylococci, the addition of cloxacillin provided added impetus to gram positive coverage.

7. Combining Cefixime and Cloxacillin in a single dosage form itself presented a major problem. Therefore no ordinary person skilled in the art could ever have

considered the option of combining Cefixine and Cloxacillin in a single formulation. Thus in one aspect, the inventiveness of the present invention resides.

8 . The respondent further stated that if Cefixime and Cloxacillin are presented in the form of immediate release form, then in that case, cloxacillin will be eliminated quickly out of the body, leading to lowering or absence of cloxacillin in the plasma. If cloxacillin and cefixime are presented in the sustained release form, a low concentration of cefixime will be obtained. When antibiotics are administered in divided dose, there is always a fluctuation in concentration level in between each dose. The level is at a maximum after each dose and falls to a minimum before the next dose is administered. It is necessary to ensure that the plasma level concentration of the antibiotic does not drop below the therapeutic level and also precaution is needed to be taken for avoiding high level because of the possible side effects.

9 . The inventors devised a special formulation to find a solution to the above stated problem. The special formulation comprises of - an immediate release component and a sustained release component. The present invention solves the problem of achieving therapeutically effective amount of cloxacillin and cefixime in the plasma by formulating a modified release drug delivery system which comprises

(a) bulk of cloxacillin, having shorter half life present in a sustained release matrix which is released slowly over an extended period.

(b) a smaller amount Cloxacillin together with the Cefixime is present in the immediate release matrix which is available for therapeutic action. The inventors could anticipate in advance the probable side effects like antibiotic medicated diarrhea, intestinal cramping and sometimes constipation on oral administration of the combination of Cefixime and Cloxacillin in high amount. Lactobacillus sporogenes was used in combination with these two antibiotics in order to prevent diarrhea, which also maintains the normal microbial intestinal flora.

10. The respondent further stated that the appellant's cited documents either alone or in combination teach or enable a person skilled in the art to prepare a specific novel synergistic formulation comprising two antibiotics having different half life periods, dosing frequencies and plasma protein along with lactobacillus sporogenes.

11. The respondent stated that the appellants have misinterpreted the provisions of Section 57 of the Act. The amendments were carried out in accordance with the directions of the Controller and not at the request of the respondent. The amendment is allowed at the request of the applicant (respondent herein), the Controller cannot allow the amendment if the infringement suit is pending before the Court. The amendment therefore falls under section 59(2) and not under section 57 of the Act.

12. The appellant has stated that the Controller who granted the patent ought not to have presided over the post grant opposition. As per Rule 56 of the Rules, the examiner who dealt with the application for patent during the grant of patent shall not be eligible for participating in the post grant opposition proceedings.

13. The appellants have cited number of documents to demonstrate lack of novelty in the present invention, however, it should be noted that in order to demonstrate lack of novelty, the anticipatory disclosure must be entirely contained within a single document. The cumulative effect of the disclosures cannot be taken into consideration nor can the lack of novelty be established by forming a mosaic of elements taken from several documents. The appellant could not produce a single document/evidence that taught a formulation comprising two antibiotics with marked differences in their dosing frequencies on account of their different plasma half lives. Combining Cefixime and Cloxacillin in a single dosage form since both the antibiotics have different half lives, dose and plasma protein binding activity is addressed in the present patent which is not found in any of the cited documents.

14. If there would not have been any problem in combining the two integers then by the time the patentee made an application, they would have been products with the combination of the two integers in the market. There is no product in the market that comprises a combination of the two integers, which indicates that it was not obvious to combine the two integers. Therefore to say combining the integers is obvious is baseless and misleading.

15. There is no primary or secondary aspects associated with the inventive step. Each criteria, be it technical advancement or economic significance either alone or in combination carries equal weightage.

16. A synergistic antibacterial composition comprising Cloxacillin, Cefixime trihydrate and lactobacillus sporogenes was earlier not known. The novel antibacterial composition is not a simple admixture, but a synergistic composition in which two antibiotics having different half life and dosing frequency are mixed together in such a way that Cloxacillin is released in two patterns i.e. immediate release and sustained release which cannot be obtained by simply mixing the components.

1 7 . The formulation prepared in accordance with the present invention maintains therapeutically effective level of drugs in the body of instant release of Cefixime and Cloxacillin so as to maintain the minimum inhibitory concentration initially, show release of the cloxacillin part increases the bioavailability and release of the lactobacillus sporogenes from its spores to supplement the disturbance in the intestinal flora due to antibiotic therapy and so as to prevent the mediated diarrhea.

1 8 . The process disclosed in the present invention results in a new product and therefore it does not fall under the provisions of Section 3(d) of the Act. The patent sufficiently discloses the subject matter and that the disclosure in the

patent would enable any person skilled in the art to perform the invention in the prescribed manner.

19. On completion of the pleadings, the matter was listed for hearing. We heard both the counsel on a number of dates.

20. The learned counsel for the appellant Ms. Swethashree Majumdar submitted that non furnishing of the Opposition Board report does not constitute violation of natural justice. If the report of the Opposition Board is crucial to the final decision, the parties are entitled to know the basis on which the order was passed. In the instant case the appellants are aggrieved if the report is relied on and not the respondent. However, the report have been brought on record. Therefore, this preliminary issue raised by the respondent ought not to be considered.

21. The counsel further submitted that the Controller has held that no insertion of prior art is required while drafting the patent specification, but in the impugned order held that, "But I do not consider the insertion of prior art as a part of specification is mandatory." The Controller cannot force the applicant to do so unless it is extremely necessary. The alleged invention as a whole can be understood from the specification without the aid of the prior art. The counsel relied on the judgment reported in MIPR 2009(2) 345 - Novartis v. Union of India - "Given the nature of incremental improvements in technical areas, it is absolutely necessary for the patentee to disclose the closest relevant prior art references". The effect of non insertion of any prior art with respect to the process claims of the impugned patent appears to point to a conclusion as to their novelty, when in fact the said claims merely list out the steps in the preparation of a formulation.

22. The Controller's observation that the same documents cannot be relied on to show both lack of novelty and non obviousness by applying Miller's Patent (1972 RPC 706) ratio is wrong. Presenting a mosaic of prior art references to demonstrate obviousness is perfectly permissible. Miller's patent ratio was followed in India - 2010 (43) PTC 630 - Glaverbel v. Dave Rose.

23. The Controller was wrong in holding that if the prior art references relied on for establishing anticipation were unsuccessful, the same prior art references could not support a claim of non-obviousness or lack of inventive step. The true legal position is that while obviousness can be proved by combining existing prior art references and anticipation requires that all essential elements of a claim be disclosed by a single reference, there is nothing to suggest that the same prior art reference cannot be relied on to demonstrate both. The counsel relied on the judgment reported in MIPR 2009 (2) 345 -- Novartis v. Union of India -- in this regard.

24. The Controller has given no reasoning in respect of the grounds that were dealt in favour of the respondents. The Controller records the appellants submission that the insertion of the graph in Figure 1 by respondent 10 months

after filing of complete specification but ignores its legal effect by wrongfully recording that the graph was filed on the date of complete specification and not on the date alleged by the appellant. There is no basis for this when the stamp below the graph clearly says 7th October, 2005. It is evident that the paragraph below Table 3 contains a deliberate misstatement about Fig.1 when the same did not exist as on the date of filing of the complete specification. No reasoning given by the Controller in support of his finding that the dates on the documents were all in order.

25. The paragraph titled brief description of drawings, which contain a mention of Fig.1 has been inserted before the paragraphs containing the background of the invention and statement of invention which is contrary to the drafting standards.

26 . Regarding the scope of a provisional versus a complete specification the Controller's order contains incorrect and flawed observations. Claim 1 of the complete specification must be contained in the document from which priority is claimed which is equivalent to the provisional specification according to Chapter 5 of the Draft Manual, Terrell at page 116 and Balmoral at page 5. The provisional cannot form a priority basis for the complete specifications of the impugned patent since the essential elements of the invention as disclosed in the complete specification are missing in the provisional.

27. The title in the provisional specification reads as an antibacterial composition and to a method of making the same whereas the complete specification reads as a synergistic antibacterial formulation and to a method of making the same. In the field of invention in provisional specification the invention relates to an antibacterial composition and to a method of making the same but in the complete specification it relates to a synergistic antibacterial formulation and to a method of making the same. Provisional specification does not include drug delivery system whereas complete specification includes drug delivery system.

28 . Invention envisages composition with ER oral dosage from without specifying presence of Cloxacillin Sodium in ER and IR forms in provisional specification, whereas in the complete specification the invention envisages a composition with Cloxacillin Sodium in ER and IR forms.

29. Role of HPMC as disintegrant or a key recipient is not disclosed as release rate controlling polymer for effecting the SR of the formulation as per the provisional specification. In the complete specification role of HPMC as release rate controlling polymer is disclosed.

30. Use and sale of starch, HPMC and filler in formation of HPMC gel structure as key disintegrant for effecting SR of formulation is not disclosed in the provisional specification. This is disclosed in the complete specification.

3 1 . In the provisional specification the process of making the antibacterial composition does not discloses a multi release matrix (Cloxacillin Sodium in SR and IR forms) whereas in the complete specification, the process for making the

antibacterial composition mentions use of HPMC and distribution of Cloxacillin Sodium in matrix and core. Temperature mentioned in heating of tablet lid is 45-50 degree celsius in provisional specification whereas the temperature range mentioned in subjecting conditioned granules to heated drying in a tray drier or a fluidized bed drier is 45-60 degree celcius. The Controller erred in not post stating the respondents impugned patent application by de-linking it from the provisional and thereby ascribing to it as a new priority date which would form the basis for adjudicating issues like novelty and inventive step. The priority of the impugned patent if postdated to 14th January, 2005 then the prior commercial use of the claimed invention formulation in October would anticipate the impugned patent on this count alone.

32. As per Rules 11 and 14 of the IPAB Rules 2003, the appellant is at liberty to leave evidence in the form of affidavits along with reply to the counter statement. There is no need for a separate permission required to be obtained. It is a well established legal position before this Board that an invalid patent cannot be sustained simply on account of the procedural technicality in filing documents by the party challenging the patent, especially in the case that the said documents constitute prior art which hits at the rest of the patent. The affidavit of Dr. N.K. Jain was filed as early as 2010 and the respondents had not objected to the same till date.

33. As per Rule 11 of IPAB (Procedure) Rules documents may be produced along with the reply to the counter statement Dr. N.K. Jain's affidavit has been dealt with in the reply to the counter statement which is a valid documentary evidence to be taken on record.

34. The additional evidence by way of pleadings and by way of affidavit of a technical expert, after the stage of completion of arguments by the appellant is impermissible in law - MP No. 95/2013 ought to be rejected on grounds of violation of principles of natural justice.

35. The sole basis for the impugned patent passing section 25(2)(f) test is stated to be the synergistic effect of the antibiotic formulation. Table 3 and figure 1 of '822 patent merely present a difference in the levels of plasma concentration of the Cefixime component of the combination which is most likely due to biological variations/experimental errors, according to Dr. Sawarkar's affidavit and Dr. N.K. Jain's affidavit.

3 6 . According to Table 1 A at page 7 of the patent, the rationale for combining Cefixime and Cloxacillin is admitted to be no more than producing an antibiotic with the combined, additive effect of the two antibiotics. The claim of synergy in the '822 patent is evidently an afterthought since the graph of indicated synergy was inserted only on 07/10/2005 more than 10 months after filing of the complete specification. The Controller has erred in tracing both the synergy claim and the filing of complete specification to 14/01/2005.

3 7 . The clinical trials relied on are not helpful in demonstrating the claimed

synergistic effect. The 1st clinical trial is non comparative and therefore unhelpful and the second test claims anti-diarrheal effect on the basis of the lactobacillus sporogenes, a claim which was abandoned during the oral hearing.

38 . The synergistic effect of Cloxacillin and Cefixime, is not found in Table 3 and Figure 1 of '822, even if it exists instead of comparing the individual effects of the integers with the combined effect of formulation the '822 patent compares the individual effect of 500 mg. of immediate release Cloxacillin with the combined effect of 250 mg. immediate release Cloxacillin and 250 mg. delayed release Cloxacillin.

3 9 . Figure 1 demonstrates individual effects of Cloxacillin and Cefixime but no synergistic effect hence the data provided is insufficient. It demonstrates sustained release of Cloxacillin (500 mg. single dose) is better than immediate release of Cloxacillin. The synergy comparison should have been between Cefixime and Cloxacillin as combination over individual prescribed doses of Cloxacillin (dosage is 250-500 mg.QID) and Cefixime (dosage 200 mg. BID).

4 0 . The data presented in the specification is inadequate to calculate statistically significant levels of synergy. Hence patent must fail on the ground of insufficiency. Section 25(2)(g).

41. A combination invention must show a "Combinative effect beyond the sum of their individual effect", which is not demonstrated by the '822 patent. 4.6.6. Draft Manual of Patent Practice and Procedure (2008); Glenmark (Mylan) v. Glaxo Group (2013) EWHC 148 (Pat).

42 . The only conceivable "non obvious" overall effect is that it creates a broader empirical profile for the formulation so as to provide treatment against Gram Positive Organisms. Mere expansion of the overall amplitude of the spectrum in this way does not constitute an invention under either of the subcategories of section 3(d).

43. In the statement of the invention it is the product claim 13, which finds its specific reference and not the process claim. The statement of invention forms the core of the invention and the contents of the same can be covered only under the claims, attributing any novelty or technical ingenuity to the process claims. When the description is silent on the face of it by the explicit absence of any statement of novelty or inventive step in relation to any of the process claims 1-12, which claims are merely a process for product claim, if at all the product claim is proved to be an invention as per the provisions of the Act.

44 . The problem in the prior art, which is stated to be overcome by the claimed formulation is that of combination and administration of two different antibiotics together processing different half lives. The solution as has been prepared by the respondent is the concept of different release matrix for Cloxacillin and Cefixime and is not achieved by the process steps as recited in the process claims 1-12. Whether a person skilled in the art after reading the description of the

specification, would be able to work the invention without any undue experimentation and whether the inventor was in possession of the actual workable invention at the time of filing of the patent application after gleaning the contents of the specification are the parameters that are to be applied to the specification to adjudicate on section 25(2)(g).

45. A reasonable explanation for the selection of claimed percentages of Cloxacillin in sustained and immediate release matrix along with Cefixime in immediate release matrix in addition to various excipients have not been disclosed in the specification, which renders the claimed percentages of aforementioned claim elements as merely arbitrary selection of percentages without any technical ingenuity attached to these values. In this backdrop what is left in the formulation claim is the random distribution of Cloxacillin in sustained and immediate release matrix along with Cefixime in immediate release matrix with lactobacillus sporogenes spores.

46 . The preferred and alternate embodiments in relation to the formulation claims have not been described in the specification. Working examples as have been disclosed in the specification pertain to the process of preparation of the claimed formulation only. No working examples in respect of the claimed formulation are mentioned in the specification.

47. The Controller has observed that he has personally gone through the description and claims and found no difficulty in understanding them, he has quoted the correct test but not applied it and merely deemed it to be satisfied and on the basis of the respondents submissions concluded that the insufficiency ground was not satisfied.

48. The Controller observed that the '822 patent needs more clarity and consistency between the product and process claims which signifies that there has indeed been an insufficiency of disclosure on the part of the respondents since there would be no occasion for him to suggest such amendments at all had the impugned patent specification been complete in all respects.

49. The power to substantively deal with amendments is provided to the Controller under sections 57, 59 and 78 of the Act. The Controller cannot make suo motu amendments to the patent specification and the procedure under sections 57 and 59 must be followed.

50. The Opposition Board Report does not mention any need for amendments to be made nor does the Controller provide any justification for why be ordered amendment.

51. As per section 57(1) no amendment shall be allowed by the Controller while any suit for infringement of that patent is pending in the Court. The amendment to claim

13 along with claim 17 and 18 are not permissible as per section 57(1) in as much as the said claims including claims 1-16 were alleged to be infringed by the

appellant in S. No. 70/2007 before the District Court, Thiruvallur. The Controller was aware of the suit. As per section 59(1) of the Act, only changes that can be made to a patent are by way of disclaimer, correction or explanation and the present amendments clearly do not fall under any of those categories.

52. Without prejudice, insertion of broad percentage ranges for solvent and binder components of the specification are not covered by section 59(1). When the patentability of process claim is disputed by the appellant, such an amendment of product 13 to attempt to render them consistent with process claim is not permissible without first adjudicating on the patentability of the process claim. The addition of solvent and binder limitation changes the scope of claim 13 in its entirety and that such an amendment has to first cross the threshold of conditions enumerated under section 59. In effect, by narrowing the scope of the claims the Controller has created additional claim limitations to safeguard the patent from a novelty assessment.

53 . Combination of Cloxacillin and Cephalosporins such as Cefixime, despite their significantly different half lives to yield synergistic results, is well known in prior art. Increase in relative effect of one of the two antibiotics occurs due to the unbound fraction of the first antibiotic and the knowledge of such increase in efficacy is well known in prior art. Increase in sustained blood plasma concentration levels of multiple antibiotic combination formulations through the method of split/multiple release profiles is well known in prior art.

54 . The non obviousness inquiry has been succinctly expressed in 1985 RPC 59 - Windsurfing v. Tabur Marine and followed in India in: 2011 (1) MIPR 179 - Enercon India v. Alloys Wobben. The test is one of whether the said invention would be obvious to a person skilled in the art, given that such a person is deemed to have carefully read the relevant literature and is supposed to have an unlimited capacity to assimilate the contents of, it may be, scores of specification but to be incapable of a scintilla of invention. The Controller has erroneously demanded that this test be applied by the experts who have submitted affidavits in support of the appellants case, holding that -

In the present case, affidavit from expert does not state how the cited art can be read with additional documents or knowledge in the art to arrive at the results. Under the ground of obviousness, the issue is adjudicated wholly on the basis of the opinion of the expert and in the present case, the opinion is far from justifying technically the obviousness of the claimed invention." This is a complete misapplication of the obviousness inquiry stated in Windsurfing Technograph.

5 5 . By mosaicing the prior art documents in support of the objection of lack of inventive step of the claimed formulation, the result is

(a) Formulations containing a combination of Cloxacillin and Cefixime in order to enhance the empiric profiles of Cefixime are well known and that such a combination along with inclusion of bacillus coagulans sporogenes is evident from

Modi-US '391.

(b) Creation of a multi release profile concept using combination of two antibiotics with different half lives is well known from Storm, Kevin et al, E U 1044680.

(c) Knowledge of "influence of protein binding on biological half life of drugs - Patrick et al."

(d) Knowledge of the fact that "using two drugs at the same time may affect each other's unbound fraction"- Watanabe et al.

5 6 . By application of the knowledge from the above mentioned and the steps undertaken by a person skilled in the art, i.e. drug formulator, the improving formulations, will clearly fall within the scope of obvious or workshop improvements and will not be regarded as inventive.

57. 15-40% of mass of solvent i.e. the mass of Cloxacillin sodium, as claimed in the amended '822 patent specification amounts to 300-800 mg. of solvent (maximum daily dose is 2g) which is far above the maximum permissible daily exposure for least toxic Class III solvents. This implies that the formulation as disclosed in the '822 patent is prima facie therapeutically unremarkable and approving the patent would have the consequence of permitting a highly toxic formulation being released into the market.

58 . After the incorporation of the amendments suggested by the Controller in the impugned order, the therapeutic effect of the patent remains highly questionable since the result is likely to be a highly toxic formulation. The amount of active ingredients or solvents in the formulation claim indicates the final values after all the process steps of claim are completed.

5 9 . The appellant's argument on the source and the geographical origin of the biological material used for the invention has been totally disregarded by the Controller. It can be understood that the biological material is used from the intestinal flora which is not only without basis but also entirely incorrect as the natural occurrence of lactobacillus sporogenes in the intestinal flora has nothing to do with the source and origin of the lactobacillus sporogenes spores as used in the patent. It is therefore observed that human intestines are cut to provide the lactobacillus sporogenes spores which apart from being factually incorrect is also technically unsound as spores are not to be found in the intestinal flora. The external documents such as other patents and various prior arts cannot by any stretch of imagination be relied upon to demonstrate the source of the lactobacillus sporogenes in the patent and hence the non disclosure cannot be cured at this stage, thus resulting in the impugned patent being rendered invalid under section 25(2)(j) of the Act.

60. The learned counsel for the respondent No. 1 Mr. Maha Dewan submitted that the corresponding patent of IN 197822 have been granted in USA and Europe. To substantiate this, the respondents produced the original US and Europe patent

specification along with the certificates.

61. The appellant had given up the affidavits of Dr. Kour Chand Jindal and Dr. Sujatha Pralhad Sawarkan. The appellant's main prayer in the appeal is that "to remand the matter for de nova consideration by the second respondent in accordance with the law, after affording the appellant a fair and reasonable opportunity of being heard". The respondent relied on the judgment of the Supreme Court in the matter of Cipla Ltd. v. Union of India where it was observed, "as the recommendations of the Opposition Board was not shared with either party, the decision of the Controller is vitiated for violation of principle of natural justice and must be set aside and the matter should be disposed afresh."

6 2 . The Supreme Court Judgment is applicable to the case as the report of the Opposition Board was not given to either party.

63 . As per Rule 12(7) of the IPAB (Procedure) Rules, the originals referred in the affidavit should be there at the registry for inspection at any time. The same should be produced at the time of hearing. The respondents requested for the original but the appellants submitted that they do not have the original instead produced in the form of affidavits. The digital source cannot be considered as authentic one. The appellant has violated the procedures. The affidavits are to be rejected.

64. It is mandatory to submit certified copy of the priority patent document, a certified copy of the said patent is desired to be obtained from the patent office and it is required to submit the certified copy of the decision along with the appeal. The appellants have not complied with these and therefore it is prayed that all non-patent documents relied on by the appellants be rejected.

65. The respondents relied on Rule 14(new) and submitted that the appellants cannot go on filing documents. Filing of documents and admission of documents by the registry does not mean the appellant is allowed to rely upon those documents during proceedings.

66. Additional documents and affidavits submitted by the appellant (FDC Ltd.) which were not part of the post grant opposition proceedings should not be considered without the permission of the Board.

67. The affidavits of Dr. Nagarsenkar, Dr. Kaur Chand Jindal and Dr. Sujatha Pralhad Sawarkan were not taken on record by the Controller and therefore were not referred to by the Opposition Board in the report. The Controller did not refer to these affidavits as these were filed after the conclusion of the evidence stage and the intimation of hearing; if the evidence filed the statutory period are taken on record it will prejudice the other party. The affidavits which were not taken on record by the Controller cannot be relied on by the appellants before this Board.

68. The case is an appeal where documents/affidavits filed before the Controller alone can be relied on and no new documents can be filed nor can it be taken on record.

6 9 . The next point raised by the respondent was that the verification clause was fallaciously wrong. Mr. Chandavarkar in his affidavit has stated that the contents are true to his personal knowledge. How can the case related information be to his personal knowledge. The counsel relied on few judgments -

(a) AIR 1952 SC 317 - The State of Bombay v. Purushottam Jog Naik - We wish, however, to observe that the verification of the affidavits produced is defective. The body of the affidavit discloses that certain matters were known to the Secretary who made the affidavit personally. The verification however states that everything was true to the best of his information and belief. We point this out as slipshod verification of this type modeled on the lines of Order XIX rule 3 of the Civil Procedure Code whether the code applies in terms or not. And when the matter deposed to is not based on personal knowledge the sources of information should be clearly disclosed. We draw attention to the remarks of Jekins C.J. and Woodroffe J. in Padmabati Dasi v. Rasik Lal ILR 1910 37 Cal. 259 and endorse the learned Judges observations.

(b) AIR 1988 SC 1987--Savithramma v. Cecil Naronha & Another-- "During the hearing we noticed that the affidavit filed by the complainant as well as the affidavit filed in reply to the contempt petition both were not in accordance with the provisions of the Supreme Court Rules or Order 19 rule 3 CPC. Smt. Savithramma, the complainant, has filed affidavit in support of the contempt petition. In paragraph 2 of her affidavit she stated that the statements contained in the contempt petition were true to the best of her knowledge, belief and information. In paragraph 3 she has further stated that the affidavit had been read over, translated and explained to her and she understood the contents thereof and has further stated that the same were true to her knowledge. The affidavit is clearly vague and general and it does not comply with the requirement of a valid affidavit as laid down in Order XI Rule 5 & 13 of the Supreme Court Rules. The affidavit is defective as it does not indicate as to what facts were true to her personal knowledge, information and belief.

6 . Since the affidavit filed in support of the contempt petition as well as the affidavit in reply to the petition do not comply with Rules, no reliance can be placed on them and both are liable to be rejected. We accordingly reject the same and the contempt petition is liable to be dismissed on this ground alone.

70. As per Rule 126(2) of the Patent Act, affidavits shall be confirmed to such facts as the deponent is able, of his own knowledge, to prove except in interlocutory matters, where statement of belief of the deponent may be admitted, provided that the grounds thereof are given.

7 1 . In reply to appellants contention that the graph was inserted later in the specification, the respondent submitted the facts of the case i.e. the specification and the amendments. There were 4 figures

Figure 1 & 1A represented table 1 (activities of Cefixime and Cloxacillin) and table 1A (parameters of Cefixime and Cloxacillin).

Figure 2 represented table 2A, 2B & 2C (accelerated stability study)

Figure 3 represented table 3(results of clinical studies).

Figure 4 represented comparative graphs of studies concluded on average plasma concentration levels of Cloxacillin and Cefixime.

7 2 . The examiner asked the respondents to absorb the first 3 figures in the specification as there are nothing but tabulated data and thus the figure 4 became figure1 which was submitted on 07/10/2005. The corresponding US patent application was filed much before the date of filing the complete specification in India and that US application also contains the graph. In view of the above it is clear that graph was part of the filed specification and was not inserted later on to support the invention.

73 . The first examination report in respect of the impugned patent was issued on 24/08/2005 and its response was submitted on 07/10/2005 and the examiner who dealt with the application was Mr. Dinesh Patel and not Mr. Bhattacharya, Assistant Controller, as contended by the appellant.

74. The examiner who has dealt with the applicant during the grant of patent shall not be eligible as member of Opposition Board as per Rule 56 of the Rules. In this case, Mr. Bhattacharya was not the examiner during the grant of patent, whereas he was the Asstt. Controller at that time.

75. As regards the report of the Opposition Board, the respondent submitted that the office order to constitute an Opposition Board was issued on 30/04/2007. This office order was recorded by the members of the Board on 08/05/2007 and 08/06/2007 respectively. The report of the Opposition Board was signed on 01/12/2008.

76. Rule 56(4) does not state that the report should be submitted within three months from the date of formation of the Board. From the report of the Opposition Board it is clear that the date on which the documents were forwarded to the Opposition Board is not mentioned.

77. The appellant's argument that the report and the decision should be independent and different is baseless. The Controller's decision as well as the Conclusion of the Opposition Board may be similar. The Opposition Board has provided the reasons on each ground of opposition.

78. The Controller has ordered the respondent to amend the claim under section 25(4) of the Act. In this case, the amendment of the claims does not attract the provision of section 57 of the Act. That apart the amendment has not been made by the patentee and it has been covered out under the directions of the Controller and therefore such amendment should be deemed to form a part of the specification. The amendment requested by the appellant falls under the preview of section 57, it is only in such case the Controller's rights to allow amendment is restricted i.e. the Controller cannot allow any amendment if there

is a case pending at the High Court for revocation or if a suit for infringement is pending.

79. In this case, the amendments to the claims are caused by virtue of Controller's decision and direction under section 25(4) and therefore such amendments fall under the provisions of section 59(2) such amendments cannot be questioned except on the grounds of fraud under the provisions of section 59(2)(c).

80. The respondent requested that the present appeal should be restricted to those grounds which were part of the post opposition and the appeal. The appellants have challenged the impugned order only on three grounds - section 25(2)(e), (f) & (g) of the Act.

81. In reply to the appellants argument that the provisional and complete specification should match, the counsel for respondent brought to our notice the object of provisional specification and the advantages of filing provisional specification.

8 2 . The necessary technical process of applying for a patent, which involves the formulation of precisely expressed claims defining the extent of the monopoly applied for and the equally technical process of investigating the claims made inevitably involves a considerable lapse of time between the date when the inventor first makes his application and the date when his invention is exposed to the public and his patent is granted. Equally it is inevitable, because two or more persons are likely to evolve and develop similar concepts competing application for patents for the same invention will be made, sometime within a short space of time and possibly in different parts of the world, so that provision has to made for regulating priorities between co-pending application both domestically and in different countries. This has for many years been dealt with by international convention which is reflected in domestic legislation, priority being regulated on a "first file" basis, so that the application which is the first in time to be filed for processing by the appropriate scrutinizing authority is accorded precedence even though it may not, at that stage, have complied with all the formalities required by law for a completed specification. Section 10(1) merely requires that the provisional specification should describe the invention and that it should begin with a title sufficiently indicating the subject matter of the invention. On the other, a complete specification should fully and particularly describe the invention and the method by which it is to be performed. It therefore follows that the description of the invention in a provisional specification need not be as full and specific as in a complete specification. Besides it need not enter into minute details as to the manner in which the invention is performed. An applicant is not bound to detail the advantages of his invention in the provisional specification. All that a provisional specification needs to contain is a description of the general nature of the invention, its field of application and the anticipated result. It need not contain the claims.

8 3 . A provisional specification was only required to describe the nature of the invention under the old Act. The omission of the word "nature" in the present provision would appear to suggest that under the new law the description of the invention in the provisional specification should be a little more elaborate than under the previous law.

84. The applicant gets a maximum period of twelve months within which to file the complete specification after filing the application. During this period he may conduct further research on the subject matter of his invention and perfect the method of carrying out the invention or introduce further developments in addition to the invention which he may incorporate in the complete specification and the claims made there under and it has been held - If there is an interval between the provisional specification and complete specification - an interval which is given to the applicant in order that he may perfect his invention, of carrying it into effect, he is bound to disclose it in the complete specification. Section 10(4)(b) however imposes upon the applicant only the duty of disclosing the best method of performing the invention known to him for which he is entitled to claim protection.

85. The respondent has provided sufficient prior art in the specification. The closest prior art of the present invention - US 6306391 (corresponding to IN 183097 - 1998 - Modi - et al - Cadila) is discussed in the specification. The document referred by the appellant (IN 189626 - 2001 - macleod) is in fact based on the similar concept disclosed in US 6306391. This US 6306391 discloses coating of either microorganism or active ingredient, whereas IN 189626 discloses coating of microorganism.

86. The respondent drew our attention to para 3 of the draft manual to show that draft manual cannot impose any line of action. The appellants mainly contested that the impugned patent is wrongfully obtained. There is no ground as to whether complete specification is based on provisional specification or not. The appellant tried to correlate their arguments with wrongful obtainment ground. The appeal is devoid of that ground. The wrongful obtainment as per section 25(2)(a) has altogether a different interpretation.

87. The applicant's invention must have been obtained wrongfully from the opponent. It is sufficient if a person from whom the applicant himself claims the invention had obtained it from the opponent or from the person from whom he claims. Thus the applicants might be ignorant of the obtaining. Even if only a part of the invention has been obtained is a sufficient ground for opposition. Obtaining does not necessarily imply fraud although conscious and deliberate fraud would render an application void.

88 . Where an invention has been obtained from an opponent, the novelty of such invention must be considered in the light of prior specification and patents. The Controller instead of revoking the patent on the ground of obtaining may, on request made by the opponent in the prescribed manner, direct to that the

patent shall stand in the name of the opponent. If, however, only a part of an invention described in the complete specification has been obtained from the opponent, the Controller may allow the specification to be amended by the exclusion of that part. The opponent may file an application under the Act accompanied by a complete specification for the invention so excluded from the applicant's specification. In such an application the opponent will get the same priority date as the earlier application where the opponent has already filed an application for patent for an invention which includes the whole or part of the invention held to have been obtained from him, the obtained portion of the invention will get the same priority date as the opposed application. The opponent will not get a wider claim than that claimed in the application opposed.

89. Obtained the invention means obtained the invention which is purported to be patented meaning thereby to refer to the identity of the invention, not the right of the person from whom it was obtained to be regarded as the first and true inventor.

90. An application for a patent will be refused only if a clear case of obtaining is established. It would appear that when the matter is in doubt, the application will be allowed to proceed on the patent not amended or revoked leaving the question to be decided by the Court in a revocation proceeding.

91 . An opposition upon the ground of obtaining usually involves the credibility of witnesses and will not be decided against the applicant or the patentee unless there is very little doubt on the facts, since the opponent always has an opportunity of having the question tried by the Court or a petition to revoke the patent.

92. The burden of proof is on the opponent if the allegation is that the invention is obtained.

93 . From the specification it is clear that tablet manufacturing process involves a drying step. Drying is carried out at 45 to 60o C. Therefore the organic solvent employed during the manufacturing the tablets get evaporated during drying step. Thus, final tablet will contain residual amount of solvent which will be always below the standard limit.

94. Several drug regulating authorities across the globe have approved the product made in accordance with the present invention (Marbetil as Cefi Xl).

95. The present invention relates to a formulation which contains sustained release core particles containing Cloxacillin, immediate release particles containing Cloxacillin, Cefixime and lactobacillus sporogenes. The main features of the invention are

1. two antibiotics of different classes are combined together,

2. two antibiotics of different half lives are combined together,

3. two antibiotics of different dosing frequency are combined together,

4 . Antibiotics having short half life is provided in both release particles (immediate and sustain) and

5. Synergistic formulation.

96. The related problem and solution provided by the present invention are Conventional tablet -

If Cloxacillin and Cefixime are mixed and formulated in a conventional tablet, Cloxacillin will be eliminated quickly, leading to lowering or absence of Cloxacillin in the plasma, as the half life of Cloxacillin is 30-60 minutes.

Sustained Release tablet --

If Cloxacillin and Cefixime are mixed and formulated in a sustained release tablet, a low concentration of Cefixime will be available in plasma hence the desired effect will not be obtained.

Divided Dose

It is a known fact that when antibiotics are administered in divided dose, there is always a fluctuation in concentration level between each dose. The level is at a maximum after each dose and falls to a minimum before the next dose is administered. It is important to ensure that the plasma level concentration of the antibiotic does not drop below the therapeutic level. At the same time, precaution is also needed to be taken from avoiding high levels because of the possible side effects.

Solutions

A modified release formulation that contains

-- An immediate release component

-- A sustained release component

9 7 . Thus the invention disclosed in the patent solves the problem of achieving therapeutically effective amount of Cloxacillin and Cefixime in the plasma by formulating a modified release drug delivery system which comprise -

(a) bulk of Cloxacillin, having shorter half life present in a sustained release matrix which is released slowly over an extended period.

(b) A smaller amount of Cloxacillin together will the Cefixime is present in the immediate release matrix which is available immediately for therapeutic action.

9 8 . The inventors also considered in advance, the probable side effects of oral administration of the combination of Cefixime and Cloxacillin in high amount and they are antibiotic medicated diarrhea, intestinal cramping and sometimes constipation.

9 9 . In order to overcome this probable limitation and shortcoming, lactobacillus

sporogenes was used in combination with these two antibiotics in order to prevent diarrhea induced by a patent dose of antibiotic. The use of lactobacillus sporogenes maintains the normal microbial intestinal flora.

100. Thus the combined release system maintains therapeutically effective level of drugs in the body by instant release of Cefixime and Cloxacillin so as to maintain minimum inhibitory concentration initially, slow release of the Cloxacillin part increases the bioavailability and pH depended release of the lactobacillus sporogenes from its spores to supplement the disturbance in the intestinal flora due to antibiotic therapy and so as to prevent the antibiotic medicated diarrhea. The invention disclosed in the patent utilized lactobacillus sporogenes which is directly combined with antibiotics in contrast to the teaching of the prior art documents.

101. As per section 25(2)(e) and (f) it is necessary to question the patentability of claims whereas the appellant has not challenged any of the claims. The appellant has failed to show that the claim is not inventive. Thus all the claims stand inventive. The appellant did not deal with the process claim (claim) but only referred to claim 13 (product).

102. The respondent referred to the clinical trials 2 of the invention. Higher plasma concentration levels of both Cloxacillin and Cefixime were observed when these were administered through the formulation of IN 197822 as compared to the plasma concentration levels observed when each of the active agents was administered through separate dosage forms. The patentee conducted comparative study with available marketed formulation.

103. The plasma concentrations of Cloxacillin upon administration of Cloxacillin 500 mg. at one go through the formulation are relatively higher as compared to the Cloxacillin plasma concentration when it is administered in the same dose albeit, in divided dosage form attained at respective time intervals.

104 . The comparative difference between the plasma concentration of Cloxacillin attained over a period of 14 hours when it is administered conventionally in two divided doses of 250 mg. and when it is administered in accordance with invention in one dose of 500 mg. is as follows -

105. In case of administration of Cloxacillin in two doses, the concentration level declined after about 6 hours while the concentration levels in case of the formulation of the patent IN 197'822 were still 27.11% higher. At 12 hours, the concentration levels in case of formulation of IN 197822 is markedly higher (20.4%). At 14 hours the results are remarkable, the concentration levels are still being maintained at 083 in case of the IN 197822 formulation, while concentration levels in case of divided dose administration are completely nil.

106. Just a single dose of the formulation of IN197822 keeps the concentration for a period of 14 hours after ingestion. Even administration of same quantity of Cloxacillin, in two divided doses of 250 mg. given every 6 hourly, cannot match

with the plasma concentration levels, observed over a period of 14 hours, in case of formulation of IN197822.

107. There are no fluctuations in concentration levels of the level seen in case of administration of Cloxacillin in divided dose. In case of divided dose administration, concentration levels drop markedly at 6 hours and then again shoot at 9 & 10 hours followed by a drop again. The synergistic effect upon Cefixime in the IN197822 formulation is even more remarkable and is totally unexpected.

108. The relative improvement in plasma concentration of Cefixime is measured by comparing it with the plasma concentration of Cefixime when it is administered alone in the form of a 200 mg. tablet. It can be understood that the term "Cefixime in combination" means "Cefixime (200 mg.) in combination with Cloxacillin (500 mg) through a formulation of IN 197822". Thus the respective plasma concentration of Cefixime when it is administered through a formulation in IN197822 are significantly better than the plasma concentrations measured at the same time intervals when same quantity of Cefixime was administered in isolation through a tablet.

109. It is true that after the 14th and 16th hour plasma concentration of Cefixime in case of IN197822 formulation is lower than corresponding concentration when Cefixime is administered separately. However, the dose of the formulation of IN197822 will be repeated after 12 hours with the result that the plasma concentration of Cefixime will again follow the repetitive pattern.

110. Since both the active agents are antibiotics then activity is directly proportional to the plasma concentration levels, higher the plasma concentration levels higher will be antibacterial activity. It thus follows that when Cefixime and Cloxacillin are administered together through a single formulation as disclosed in IN197822 their combined activity is greater than the addictive effect attained when they are administered through separate dosage forms. The synergistic effect of the formulation of IN197822 is thus substantiated.

111. The efficacy and safety of the IN197822 product was studied in 500 patients. The results are -

Cure - 61.3%

Improvement - 35.7%

Clinical success - 97.0 %

112. The respondents showed that none of the patients complained of diarrhea or any other symptom. Stool of several patients were tested for the detection of lactobacillus count even after 5 days of administration. The lactobacillus count was found within normal range in all cases. This enhanced efficiency of the formulation of IN197822 is substantiated.

Insufficiency of description

113. The respondent submitted that claim 1 and 13 are not vague and indefinite. The appellants cannot question the format of the claims of IN197822 which is the preference of the patentee with respect of the language of the claims. A person skilled in the art can easily interpret the claims. The specification of IN197822 has provided sufficient illustrative examples based on which a person skilled in the art can practice the invention without any undue experimentation.

114. As per section 10(4) every complete specification shall fully and particularly describe the invention and disclose the best method of performing the invention which is known to the applicant. However, it is not mandatory that the claims should be representative of the best method. The Controller suggested amendment in claim 13 only for clarity purpose i.e. for bringing claim 13 in line with the claim 1. The clarity issue cannot be correlated to insufficiency of description.

115. The detailed analysis of example 1 of Indian Patent No. IN197822 is - Example 1

Step 1

i) 50.00 Kg. of Cloxacillin sodium and 6.00 Kg. of HPMC were passed through a 30-mesh sieve and placed in a planetary mixer. The mixer was run for 25 minutes at 30 r.p.m. so that a homogenous mixture of the particles of Cloxacillin sodium and the HPMC resulted.

ii) 800 gms. of HPMC was mixed with 80 Kg. of Dichloromethane and 12.0 Kg. of isopropyl alcohol in a stainless steel tank under continuous stirring until a clear solution was formed. The solution was then added to the planetary mixer containing the homogenous mixture of the particles of Cloxacillin sodium and the HPMC to obtain sustained release granules of Cloxacillin sodium.

Step 2

Through a vibro sifter of mesh size 40 mesh, 7.6 Kg. of Cloxacillin sodium particles, being the balance remaining quantity of the total mass of Cloxacillin sodium; 11.2 Kg. of Cefixime trihydrate particles 750 gm. of lactobacillus sporogenes spores, 1.0 Kg. sodium starch glycollate, 0.3 Kg. of colloidal silicon dioxide, 1.0 Kg. of sodium lauryl sulfate and 1.0 Kg. of talc were passed.

Step 3

This sifted mass along with the dried sustained release granules of Cloxacillin sodium granules were transferred to a double cone blender. To this 1.0 Kg. of magnesium stearate was then added. Finally this core mass was fed to hopper of a single rotary compression machine.

116. From the example 1 it is understood that total mass of the formulation is 100.65 Kg. and total amount of Cloxacillin is 57.6 Kg. (57%). Sustained release 50 Kg. (86.8% of the total cloxacillin). Immediate release 7.6 Kg. (13.2% of the total cloxacillin) Total amount of Cefixime - 11.2 Kg. (19.64% of the total

cloxacillin).

117. For manufacturing the tablet, a person skilled in the art can easily understand the quantities of each ingredients from the example by following the steps as under -

- accurately weighing the quantity of total cloxacillin (57.6 kg.)

- calculating and weighing the amount of Cefixime (11.2 Kg.) based on mass

of Cloxacillin (19.64% of the total cloxacillin).

- calculating and weighing the amount of excipients based on mass of cloxacillin.

Cloxacillin total 30 to 75% of the mass of the formulation in claim 1 and 57% in example 1.

In claim 1 the cloxacillin in sustained release is 60 to 90% of total cloxacillin and in example 1 86.8%.

Cloxacillin in immediate release is 10-40% of total cloxacillin in claim 1 and 13.2% in example 1.

Cefixime is 15 to 40% of the total mass of Cloxacillin in claim 1 and 19.64% in example.

Obviousness

118. As per Modi's teaching either lactobacillus or antibiotic essentially coated to keep lactobacillus viable throughout shelf life.

119 . Modi et al does not teach/suggest a combination of two antibiotics having different half life and lactobacillus sporogenes spores in a multi release dosage form. It does not teach or suggest how to combine antibiotics with lactobacillus without using a protective barrier in order to achieve the desired results based on the respective function of antibiotic and lactobacillus.

120. IN189626 teaches coating of a microorganism (lactobacillus) with a coating material, preferably dispersion of polymethylmethacrylate. The difference between Modi et al and IN9626 is IN189626 suggest coating of lactobacillus whereas Modi suggests coating of either drug or microorganism. IN189626 does not teach or suggest that Cloxacillin can be combined with Cefixime and lactobacillus.

121. The examples 1-4 out of 54 are restricted to a combination of Cefixime and lactobacillus. None of the examples illustrate a combination of Cloxacillin and lactobacillus and also a combination of Cefixime, Cloxacillin and lactobacillus.

122 . None of the examples provided in IN189626 illustrate a formulation of a combination of two antibiotics having different half lives. The examples provided in the specification of IN189626 essentially involve the coating of the organism.

123. A person of ordinary skilled in the art after referring IN189626 or US6306391 will essentially go for coating of the organism or antibiotic before mixing both in order to keep the organism viable.

124. The document JP64-083025 provided by the appellant is merely an abstract rather than a full text. Prima facie it is difficult to draw any conclusion with respect to teachings or suggestions of the said document. The disclosure provided in the abstract discloses a live bacterium agent for controlling intestinal function showing resistance to antimicrobial agent is blended with an antimicrobial agent. Japanese Patent document only suggest that lactobacillus sporogenes which is resistant to oxacillin, cloxacillin or ampicillin is mixed with an antimicrobial agent. The list of antimicrobial agents is not provided. Further it does not teach or suggest that Cloxacillin can be combined with Cefixime and lactobacillus. It does not teach/suggest a combination of two antibiotics having different half-life and lactobacillus sporogenes spores in a multi release dosage form.

125. EP 1044680 is particularly directed to a method of treatment using a high dosage regimen of amoxycillin and potassium clavulanate.Potassium clavulanate and amoxycillin have similar half lives. Thus EP1044680 does not suggest combining two antibiotics having different half-lives. It does not suggest combining Cefixime, Cloxacillin and lactobacillus sporogenes spores.

126. The object of the invention disclosed in EP1044680 is to provide a high dosage of amoxicillin than the conventionally used in order to achieve the desired results. The crux of the invention disclosed in EP1044680 is use of high dose of amoxicillin. It does not suggest use of conventional dose of amoxicillin, in two release portions in order to achieve the enhanced efficacy.

127 . As per the examples provided in EP1044680, Xanthan gum is preferred as polymer to retard the release. EP1044680 illustrates or teaches a bilayer tablet in which immediate release blend and sustained release blend are compressed in separate layers in a bilayer tablet. In contrast, the invention disclosed in IN197822 is not at all related to a bilayer tablet. EP1044680 suggests use of a release retarding excipient in the tablet.

128. US6544555 discloses a once a day antibiotic product comprising first, second and third antibiotic dosage forms, each of said antibiotic dosage forms comprising at least one antibiotic and a pharmaceutically acceptable carrier, said first antibiotic dosage form being an immediate release dosage form and second and third antibiotic dosage forms being delayed release dosage forms. This also suggests three dosage forms, in contrary the present invention discloses a single dosage form containing two antibiotics and lactobacillus sporogenes spores. It merely provides a list of different antibiotics having half lives ranging from 1 to 12 hours. It does not teach combining two antibiotics having two different half lives.

129. It does not suggest incorporating one antibiotic having shorter half life in

two release portions i.e. in immediate release and sustained release. It does not suggest dividing the total amount of antibiotic having shorter half life in two release portion in a particular proportion in order to achieve the desired effects.

130. US5633012 discloses a method of treating or preventing antibiotic associated or other acute or chronic diarrhea by orally administering a pharmaceutical composition comprising therapeutically effective amount of lactobacilli bacteria sufficient to treat or prevent said diarrhea. It discloses the microencapsulated composition in the form of gelatin capsule containing only viable lactobacillus. It does not teach combining two antibiotics having different half lives and lactobacillus sporogenes spores in one dosage form.

131. US5902578 which is equivalent of WO/1997/035596 discloses a method for reducing the incidence of diarrhea caused by antibiotic therapy in a human. The method comprising the steps of mixing a powder containing viable lactobacillus reuteri, lactobacillus acidophilus and bifidobacterium infantis with a liquid and administering an effective amount of the liquid mixture prior to formation fermentation by products. US5902578 discloses a drink and not tablet. It does not teach combining two antibiotics having different half lives and lactobacillus sporogenes spores in one dosage form.

132. US6645530 discloses a method for the treatment of a chronic gastrointestinal disorder in adult human host. The method comprises substantially completely removing the hosts existing enteric microflora by a method comprising using a lavage and the substitution of an effective amount of fresh or dried or reconstituted feces from a disease screened human donor. Or the administration of an effective amount of a pharmaceutical acceptable composition comprising microorganism selected from group consisting of bacteriosides and E. coli in liquid culture or dried viable form. It suggests administration of an effective amount of antibiotic in separate dosage form prior to the removal of the existing enteric microflora in order to treat chronic gastro intestinal disorder. This also does not teach the combining two antibiotics having different half lives and lactobacillus sporogenes spores in one dosage form.

133. US 4314995 discloses a process for treating a patient having infection which comprises administering locally an effective amount of at least one microorganism strain which is similar to conventional lactobacillus strains in its morphological proportions, but different from known strains of lactobacillus in its nutritional requirements.

134. The antibiotic disclosed here is Tetracycline and the preparation is in the form of a pack dry cells, a solution or an ointment. Even this does not teach combining two antibiotics having different half lives and lactobacillus sporogenes spores in one dosage form.

135. Respondent submitted their arguments on the prior art non-patent documents.

136. Rosario et al

The article of Rosario et al titled "Selection of resistant mutants of citrobacter freundii by second and third generation Cephalosporins and imipenem" describes that using a single step selection procedure resistant mutants could be obtained from three clinical isolates of citrobacter freundii with two second generation and four third generation cephalosporins examined. The study described in the article also investigates the frequency with which citrobacter freundii strains become resistant after in vitro exposure to a number of third generation cephalosporins and imipenem.

137. Rosario et al's teachings are restricted to in vitro study (MIC). As per Rosario et al - Cefamandole and cloxacillin are used in agar plate to check the activity. Both the drugs have same half lives. It does not disclose that two antibiotics are combined in one dosage form and then tested. It is known to a person skilled in pharmaceutical science and pharmacology that Cefamandole is administrated by paranteral route and not by oral route. Rosario et al does not disclose formulating an oral formulation containing a combination of two antibiotics having different half lives.

1 3 8 . Sabath et al, Nature, 1066-1069 - "Synergistic action of penicillins and cephalosporins against pseudomanea pyocyanea"

139. Like Rosario et al, Sabath et al also discloses in vitro study in agar plates. Expert of Sabath et al is

It is possible that the type of synergism found in the laboratory with this strain of Ps. pyocyanea will not be demonstrable in patients even with strains which behave similarly in vitro.

140. The document submitted by the appellant itself support the fact that the in-vivo study not necessarily reproduces the results obtained in the in vitro study. The reason being the pharmacokinetic and pharmacodynamics properties play important role while conducting the in vivo studies. Therefore the studies conducted on microorganism cannot be extrapolated to human.

141. Neither Rosario nor Sabath has suggested that a combination of Cefixime and Cloxacillin exhibits synergy. It is known to a person skilled in the art that each and every drug of same therapeutic class cannot show similar combined effects when combined with a common drug of a different class. Though cefamandole and cefixime belong to cephalosporin class, it is not necessary that Cefixime will also produce a synergistic effect when combined with Cloxacillin as produced by cefamandole. Each drug of same therapeutic class exhibits different pharmacokinetic properties, therefore, it would not be appropriate to make a generalize statement that if one of the drugs of class A shows synergy with a drug of another class B then all the drugs of class A will have synergy when combined with the drug of class B. The route of administration also affects the bioavailability and other pharmacokinetic parameters.

142. Yasuo Watanabe

This was not part of post grant opposition proceedings which was submitted along with the affidavit of Dr. N.K. Jain. Therefore, this is liable to be rejected.

143. The invention disclosed in IN197822 is not at all claiming the fact that protein binding can influence the drug's biological half life. Watanabe particularly studied the effect of cefazolin on the protein binding and pharmacokinetics of cefoperazone. As per Watanabe study both the drugs are administered simultaneously by intravenous route.

144. It is known to a person skilled in pharmaceutical science and pharmacology that cefazolin as well as cefoperazone are given by IV or IM and not orally. Both the drugs are cephalosporin class antibiotics. Yasuo Watanabe does not disclose formulating a formulation containing a combination of two antibiotics of different class having different half lives.

145 . None of the documents either alone or in combination teach the following features of the present invention.

1. Synergy between Cefixime and Cloxacillin either in vitro or in vivo.

2 . A unit dosage formulation containing combination of Cefixime, Cloxacillin and lactobacillus sporogenes spores.

3 . A formulation containing combination of two antibiotics having different half lives and different dosing frequency.

4 . A synergistic formulation containing combination of Cefixime, Cloxacillin and lactobacillus sporogenes spores.

5 . A unit dosage formulation containing distribution of Cloxacillin in two different release portions in a particular proportion.

6 . A process for the preparation of a unit dosage formulation containing combination of Cefixime, Cloxacillin and lactobacillus sporogenes spores.

146. The respondents argued about the IPAB procedure Rules. From the rules it is clear that the pleadings are complete with the reply by the appellant followed by hearing. The respondent does not get an opportunity to file a further response to the reply of the appellant. The Board had not asked the respondent to file any reply to the appellant's reply to the counter statement. Therefore the respondent can respond or object to the appellant's reply only during the hearing.

147. In view of the above, the additional documents along with the affidavit of Dr. Jain which were not part of the post grant proceedings should not be relied upon by the appellant and considered by the Board.

148. The affidavit of Dr. N.K. Jain refers to the present invention, statement of opposition under section 25(2) and order of the Controller whereas does not deal with the appeal as well as the counter statement. Therefore Dr. N. K. Jain is not

aware of the appeal.

149. Dr. Jain has been advised by FDC to state whatever was stated in the affidavit and has not written the same based on his knowledge. Rather he has been advised to do so. The respondent strongly objected to Dr. N.K. Jain's opinion.

150. The respondent relied on section 129 of the Act and submitted that Dr. Jain's opinion should be restricted to technical one and not patentability of the present invention as he is not a registered patent agent. Therefore, Dr. Jain's comments regarding novelty, obviousness, patentability and insufficiency of invention should not be considered. Verification of the said affidavit is also defective. In this regard the respondent relied on these judgments:-

1 . AIR1952SC317 (The State of Bombay v. Purushottam Jog Naik)

2. AIR 1988SC1987 (Savithramma v. Cecil Naronha).

151. Factual errors

Understanding of Dr. Jain about the invention is not correct. The understanding is that all these ingredients of the formulation are processed so as to form a homogenous intimate mixture doing with conventional excipients. The mixture is compressed into cores and coated. The respondent submitted that the formulation of IN197822 is not prepared by forming a homogenous intimate mixture. Instead two separate types of particles are prepared. Particularly, sustained release particles are prepared by wet granulation technique, whereas immediate release particles are prepared by dry mixing.

152. Dr. Jain's understanding is that the process as given in the original patent to obtain the above formulation essentially comprises the following steps -

(1) Cloxacillin sodium which is 20-65% of the mass of the formulation is mixed with hydroxypropylmethylcellulose, 3-15% of the Cloxacillin sodium and granulated with binders 1-6% of the mass of Cloxacillin sodium and solvent 15-45% of the mass of Cloxacillin sodium so as to obtain a sustained release homogeneous mass followed by drying and sizing.

(2) Then Cefixime along with the remaining immediate release Cloxacillin sodium 10-35% of the mass of the total formulation and lactobacillus are mixed along with the disintegrants, surfactants and lubricants and compressed.

(3) The compressed tablets are coated.

153. In response the respondents submitted that as per Dr. N.K. Jain's the above understanding, step 2 ingredients are compressed. There is no mention that step 1 ingredients and step 2 ingredients are mixed together followed by compression.

154. The process as per the granted patent is

1 . mixing together Cloxacillin sodium, hydroxypropylmethyl cellulose, a binder

and a solvent, at speeds of 15 to 50 r.p.m. to produce a sustained release homogenous mass,

2. milling the homogenous mass through mesh sizes ranging from 8 to 18 mm to obtain milled wet sustained release core particles,

3. drying the milled core particles without heating for 10-20 minutes to obtain partially dried sustained release core particles,

4 . drying the partially dried sustained release core particles at temperatures ranging between 45 to 60 degree celsius for 30 to 60 minutes to obtain unsized dried sustained release core particles having moisture not more than 4%.

5. sifting and milling the dried core particles through mesh sizes ranging from

12 to 20 mesh to obtain sized dried sustained release core particles containing Cloxacillin sodium.

6 . vibrating together through a sifter having mesh size ranging from 30-40 mesh Cloxacillin sodium, together with Cefixime trihydrate, lactobacillus sporogenes being, disintegrants, glidants and surfactants to obtain vibrosifted immediate release particles.

7 . mixing together the sized dried sustained release core particles and the vibrosifted immediate release particles at temperatures below 25 ºC, at a relative humidity of less than 60% for 20 to 30 minutes at 20 to 500 r.p.m.

8. adding to the mixture excipients including lubricants and further mixing for 3 to 5 minutes to obtain core particles.

9 . compressing the core particles at temperature below 25 ºC at a relative humidity of less than 60% at compression pressures ranging from 1 Kg./sq.cm. to 12 Kg./sq.cm. to obtain cores of the antibiotic formulation.

10. enveloping the said cores with a coating consisting of a coating polymer, a solvent for dissolving the polymer, a plasticizer and a coloring agent in a coating machine at temperatures ranging from 40-60 ºC to obtain the synergistic antibiotic formulation.

155. Dr. Jain's affidavit provided a list of "available products of antibiotics with probiotics includes

(1) Symbiotik - a combination of amoxicillin, Cloxacillin and LB - launch date - 1997.

(2) LMX - a combination of amoxicillin and LB - launch date - 1998

(3) Clax - a combination of ampicillin, cloxacillin and LB - launch date - 1999.

156. The respondents submitted that it is not substantiated that these were available in the market before the filing of this patent as no proof is filed along with the affidavit.

157. Secondly, the antibiotics of these above products are amoxycillin, Cloxacillin and ampicillin which belong to same class i.e. Penicillin antibiotics and having same half lives (1 hr.). These products are in the form of conventional capsule or tablet and not in the form of modified release tablet. These products are not at all related to a combination of Cefixime, Cloxacillin and lactobacillus sporogenes spores.

1 5 8 . Dr. Jain's affidavit stated that formulations containing a combination of Cloxacillin and Cefixime in order to enhance the empiric profile of Cefixime are well known and there are number of sources that demonstrate such a combination often with the inclusion of bacillus coagulans sporogenes (Modi et at, US 6306391, JP 64-083025 & IN189626).

159. The respondent submitted that none of these documents disclose a formulation containing combination of Cloxacillin, Cefixime and lactobacillus sporogenes spores. None of these documents disclose a combination of two antibiotics having different half lives. Dr. Jain has not provided name of any marketed product which contains a combination of Cloxacillin, Cefixime and lactobacillus sporogenes spores. Therefore, the affidavit is baseless and deserves to be rejected.

160. Dr. Jain's affidavit stated, "knowledge of the methods to create multi release formulations for antibiotics with different half lives has been well known.

161. The respondent submitted that the above statement is grossly incorrect as none of the referred patent documents discloses a combination of two antibiotics having different half lives.

162. The said affidavit mentioned that the formulation described in the patent would have organic solvents many times more than permissible daily exposure by regulatory requirements and therefore toxic. Hence the formulation is not only suitable for practical therapeutic use but also frivolous and contrary to well established ICH guidelines.

163 . The respondent submitted that from the specification it is clear that tablet manufacturing process involves a drying step where drying is carried out at 45 to 60 ºC. The organic solvent employed during the manufacturing of tablets gets evaporated during drying step. Final tablet will thus contain residual amount of solvent and which will be always below the standard limit.

164. Dr. N.K. Jain mentioned that, "I state that the subject matter of the invention lacks novelty as the purported combination of antibiotic and probiotic has been known for last 3-4 decades.

165. The respondent submitted that Dr. Jain has not provided a single document/ a marketed product disclosing a formulation containing a combination of cloxacillin, cefixime and lactobacillus sporogenes spores to question the novelty of the present invention. Novelty is not the ground of appellant which has already been admitted by the appellant.

166. The respondent referred to few judgments

(1) ORA/29/2011/OPT/MUM - La Renon Health Care Pvt. Ltd. v. Kibow Biotech Inc:- Additional grounds raised at this state ought not to be considered. The appellants failed to establish the grounds of opposition.

(2) 2008(

1979 (2) SCC 511 - M/S Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries -Whether an alleged invention involves novelty and an inventive step is a mixed question of law and fact depending largely on the circumstances of the case.

167. In rejoinder the appellants submitted their reply to the respondent's arguments. The appellant relying on Rosario Valencia et al and Watanabe clearly establishes that not only was a stable combination of Cloxacillin and Cefixime with lactobacillus sporogenes known but the synergistic effect of the Cloxacillin/ Cefixime combination was also predicted and explained in prior art.

168. JP '025 -- patent claims a blended preparation of a drug resistant live bacterium agent without administering an unnecessary resistant live bacterium by previously blinding a live bacterium agent for controlling intestinal function showing resistance to a specific anti microbial agent with the anti microbial agent. It specifies the bacterium agent used in the preparation to include Cloxacillin, the reliance or a lack of mention of the anti microbial agent to be used in the preparation is faulty since the impugned patent itself makes no mention of an anti microbial agent and therefore the identity of the anti microbial agent used in this patent is irrelevant to the question of whether this patent renders the impugned patent non-obvious or lacking in inventive step.

169. Claim 1 of US'391 patent combines the lactobacillus and the antibiotic into a single pharmaceutical formulation, the fact that it involves coating at least one of the two ingredients does not affect its relevance to disproving the non-obviousness/lack of inventive step involved in combining the lactobacillus and the antibiotic in the impugned patent. Absence of any specific statement regarding how the presence of the coating agent impacts/alters the effect of the combination, the appellant are open to claim that there is nothing in the claim specification itself that suggests that the coating is anything more than a mere physical feature of the preparation process having no relevant/material chemical impact.

170. IN'626 --Lack of disclosure of the specific combination of all three elements present in the impugned patent does not render it invalid as part of a mosaic to demonstrate non-obviousness. The patent refers to both Cefixime and Cloxacillin as possible parts of the antibiotic element and refers to lactobacillus sporogenes as the probiotic organism. Neither the '822 patent specification nor the Ld. Controller's observation on the synergistic effect disclosed therein to meet the requirement of inventive step through surprising or unexpected effect, which

requires that the measures which lead to this effect should not be near at hand by themselves.

171 . US'012 - Part of appeal grounds under lack of consideration of appellant's arguments on prior art for the purpose of obviousness objection.

172. Claims of US012 is directed to a method for treating or preventing antibiotic associated or other acute or chronic diarrhea in mammal by orally administering to said mammals, a pharmaceutical composition comprising in a unit dose thereof, a therapeutically effective amount of lactobacillus bacteria sufficiently to treat or prevent said diarrhea in a mammal. The claim clearly establishes by use of term "comprising" which according to the laws of patent claim construction is an "open ended phrase" to mean that the composition in addition to lactobacillus includes one or more antibiotics.

173 . US'578 - Part of appeal grounds under lack of consideration of appellants arguments on prior art for the purpose of obviousness objection.

174. A method for reducing the incidence of diarrhea caused by antibiotic therapy in human, comprising mixing of a powder containing viable Lactobacillus reuteri, lactobacillus acidophilus and Bifidobacterium infantis with a liquid and externally administering the liquid mixture to human prior to formation of fermentation by products.

175. WO97/35596 -- discloses intake of ampicillin tablets (500 mg.) together with capsules containing lactic acid producing bacteria (such as lactobacillus acidophilus and Bifidobacterium) to study effect of lactic acid producing bacteria or human intestinal microflora during ampicillin treatment.

1 7 6 . Giving 10 volunteers ampicillin tablets (500 mg.) together with capsules containing lactic acid producing bacteria (lactobacillus acidophilus and Bifidobacterium) and giving other 10 volunteers, ampicillin tablets (500 mg.) together with placebo capsules, to studying effect of lactic acid producing intestinal microflora during ampicillin treatment.

177. Result - The volunteers which received lactic acid producing bacteria group, decolonized slightly faster than volunteers receiving placebo. Also Bacteroides strains were recovered in higher numbers in lactic acid producing bacteria group compared to placebo group.

178. US'530 -- This suggests the use of an effective amount of antibiotic. Antibiotics to be used in composition, discolored eg. Septrin Metronidazole, Vancomycin.

1 7 9 . US'995 -- The said reference is directed to pharmaceutical lactobacillus preparations. Claim 1 and Claim 2 clearly establishes that lactobacillus along with antibiotic may be used for treating a patient having infection or infectious disease.

180. It is desirable to administer to the patients a large amount of present preparation i.e. Lactobacillus preparation, if required in combination with

antibiotics. Antibiotic claimed is tetracycline.

181. Lactobacillus preparation in combination with antibiotics.

182 . Pharmaceutical preparation includes at lease one antibiotic and a protease, wherein lactobacillus strain in resistant to the antibiotic.

183. EP 680 - The said prior art reference discloses formulation comprising First part - immediate release of amoxicillin and potassium clavulanate. Second Part - controlled release of amoxicillin where said composition is further characterized by presence of two types of release matrices, controlled release and immediate release.

1 8 4 . This establishes that knowledge of the methods to create multi-release formulations for antibiotics is well known in the field of antibiotics and pharmacology.

185 . US'555 -- The said prior art discloses an antibiotic pharmaceutical product comprising at least two, preferably at least three antibiotic dosage forms. Each of the dosage forms may contain more than one antibiotic.

186. Antibiotic products may include a first dosage form in the form of tablet that is immediate release tablet and may also include two or more additional tablets, each of which provides for a delayed release of antibiotic, where by the antibiotic released form each of the tablets is reached at different times.

187. Watanabe et al - The two antibiotics disclosed in this article belong to the same genus as that of Cloxacillin and Cefixime. The concept of combination of two different antibiotics with different half lives has already been dealt in detail as above and as such does not constitute an inventive step. In this regard, respondent has filed extracts from Pharmacy text books and Wikipedia extracts to cite the details of half lives of Cefazolin and cefamandole, which are strongly objected to by the appellant on the ground that no additional documents can be relied during hearing.

188. We have heard both the counsel and have carefully considered their arguments and have also gone through the pleadings and documents.

189. The appellants and the respondents had filed several miscellaneous petitions. The main appeal along with the miscellaneous petitions were heard. We heard both the counsel at length and the entire facts and arguments have been given above.

190. The affidavit of Dr. N.K. Jain was not a part of the documents placed before the Controller during the post grant proceedings but the same was filed by the appellant along with the reply to the counter statement. The same was objected to be taken on record by the respondent as given above. The appellants after the first date of hearing had filed a Miscellaneous Petition No. 65/2013 to take on record the affidavit along with the documents. The respondents thereafter filed a Miscellaneous Petition No. 78/2013 to reject the documents.

191. The respondents after the appellants had concluded their argument had filed a Miscellaneous Petition No. 95/13 to take on record the reply to the Miscellaneous Petition No. 65/13 and also to take on record their expert witness affidavit.

192. The instant case being an appeal against the orders of the Controller, principles under Or 41 R 27 CPC - are to be observed.

193. The appellate court should not travel outside the record of the lower court and cannot take evidence on appeal. Section 107(d) is an exception to the general rule and additional evidence can be taken only when the condition and limitation laid down in the rule are found to exist. The parties are not entitled to file additional evidence at the appellate stage as a matter of right whereas it is the discretion of the court to allow/to take on record which could be exercised judicially.

194. We are also aware of the fact that this Board is not bound by the procedures laid down by the Civil Procedure Code but are to apply the principles of natural justice. We will have to mention here that as per the Code of Civil Procedure we cannot accept any additional documents, if additional documents like the one filed here are beyond the records of the lower court. The Board (Procedures) Rules (2007) if followed documents filed could be taken on record. Following Rule 11 of the IPAB Procedure Rules reply to counter statement along with evidence in the form of affidavits may be filed and taken on record.

195. If new documents are filed at the appellate stage without any reason this would definitely give rise to a new cause/case which obviously were not placed before the Controller for his consideration. But here the Procedure Rules prescribe for filing documents/evidence along with the reply to the counter statement.

196. Above all, we also see that the recommendations/report of the Opposition Board was not given to either party. This is clear from the Miscellaneous Petition No. 139/2012 filed by the appellant praying to take on record the documents namely the constitution of the Opposition Board, the recommendations of the Opposition Board. (The documents were procured by filing an application under the Right to Information Act and the same was filed before this Board). In this regard the respondent had placed reliance on the judgment of the Supreme Court in Cipla Ltd. v. Union of India. The Supreme Court has held, "as the recommendations/report of the Opposition Board was not shared with either party, the decision of the Controller is vitiated from violation of principles of natural justice and must be set aside and the matter should be disposed afresh."

197 . It is necessary to mention here that the appellants during the course of arguments insisted that the matter be heard at length and to decide the same on merits though their prayer was for remand. We thought it just to hear the appellants and the respondents to render proper justice. We therefore heard both the parties.

198. Having in mind the observations of the Supreme Court in Cipla case (Supra) and also considering the Miscellaneous Petition filed by the appellant we think it fit to remand the case back to the Controller for deciding the case in accordance with law. It is also made clear that no new/additional evidence/documents shall be filed by either party. The Controller shall decide the matter only on the evidence placed before him as per our directions.

199. As the matter is being sent back to the Controller for fresh consideration, the Controller shall take on record the documents filed before this Board by both the parties i.e. in Miscellaneous Petition No. 65/2013 (appellant's Dr. Jain's affidavit and document) and 95/2013 (respondent's expert witness affidavit) and place the same before the Opposition Board which is to be newly constituted and decide the matter in accordance with law. It is also made clear that taking on record additional documents at the appellate stage will not be a matter of right. In the instant case it is taken on record as it has already been filed before us and also that we have directed for Opposition Board to be newly constituted.

2 0 0 . The Miscellaneous Petition No. 29/2009 for stay of the operation of the impugned order pending disposal of the appeal is closed. Miscellaneous Petition No. 30/2009 for urgent hearing also stands closed. Miscellaneous Petition No. 139/2012 for taking on record the additional documents which are the composition of the Opposition Board and the recommendations of the Opposition Board and they are taken on record and the same is therefore allowed.

201. Miscellaneous Petition No. 78/2013 for rejecting the affidavit of Jain is dismissed as Miscellaneous Petition No. 65/2013 is allowed.

202. Miscellaneous Petition No. 95/2013 to take on record the reply to Miscellaneous Petition No. 65/2013 and also to take on record the respondent's expert affidavit is also allowed as observed in the earlier part of the finding. We therefore direct the Controller to consider the matter in accordance with law within six months from the date of receipt of the order. Accordingly the appeal is ordered. No costs.

