IN THE HIGH COURT OF DELHI AT NEW DELHI

% Judgment delivered on: 16.05.2019

\+ **W.P.(C) 1163/2017 and CM APPL. 38867/2017**

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA ..... Petitioner

versus

UNION OF INDIA & ORS. ..... Respondents

Advocates who appeared in this case:

For the Petitioner :Mr Amit Sibal, Senior Advocate with Ms Archana Shanker, Mr Shrawan Chopra, Ms Prachi Agarwal, Mr Devinder Rawat, Mr Pundreek Dwivedi and Ms Ridhie Bajaj.

For the Respondents :Mr Kirtiman Singh, CGSC with Mr Waize Ali Noor and Ms Shruti Dutt for UOI.
Mr Vishal Sudan and Ms Prachi Tiwari for R-3.
Mr J. Sai Deepak, Mr Guru Narang and Mr Avinash K. Sharma, Advocates for R-5.
Ms Bitika Sharma, Ms Mansee Teotia and Ms Lakshay Kaushik, Advocates for R-7.

CORAM
HON'BLE MR JUSTICE VIBHU BAKHRU

JUDGMENT

VIBHU BAKHRU, J

1. The petitioner has filed the present petition, *inter alia,* impugning an order dated 08.11.2016 passed by the Assistant Controller of Patents and Designs (hereafter 'the Controller'),

whereby the petitioner's application for grant of patent (Application No. 9668/DELNP/2007) was rejected.

2. The petitioner's principal claim was for grant of patent in respect of the compound 'Enzalutamide'. Whilst the Controller, accepted that the said compound is novel and not anticipated in view of cited prior art documents, he rejected the petitioner's application on the ground that the claimed invention lacked inventive steps. He reasoned that a prior art (referred to as "US 981") provided data that disclosed a compound (Example 15) had anti-androgenic activity and is devoid of agnostic activity. The difference between Enzalutamide and the compound (shown as Example 15) of US 981 is the moiety "Fluoro-N-Methylbenzamide at the first Nitrogen of thiohydantoin moiety". He held that the teachings in scientific article – Bohl et al., J. Med. Chem, 47(15)(2004) 3765-3776 (hereafter referred to as "Bohl document") suggested that aryl ring, substituted with a moderately sized group such as acetamido, is required at the first N position to improve the binding affinity of the compounds for androgen receptors. He reasoned that in view of the aforesaid teaching, the selection of Fluoro-N-Methylbenzamide over US 981, was obvious. He also referred to a prior art (referred to as "US 257") and noticed that Fluoro-N-Methylbenzamide was a moiety of the said compound and a person skilled in art would think of or replacing the said moiety with hydrogen attached to N of hydantoin moiety of the compound shown in Example 15 of US 981.

3. The petitioner contends that the impugned order is vitiated, as it has been passed in violation of principles of natural justice. It is stated that the Bohl document, on the basis of which the Controller rejected the petitioner's claim, was filed at the time of oral hearing and the petitioner had no opportunity to effectively deal with the same. It is further contended that the pre-grant oppositions filed by respondent no.3 did not include any pleadings with respect to the teachings of the Bohl document and, therefore, the petitioner had no opportunity to contest the reasoning as articulated in the impugned order. In addition, the petitioner claims that the Controller has completely overlooked evidence of the experts furnished by the petitioner as the impugned order does not refer to any of the affidavits affirmed by the experts.

4. The respondents contested the aforesaid contentions. It is submitted on their behalf that the petitioner had sufficient opportunity to respond to the Bohl document and in fact, the written submissions filed by the petitioner included the submissions in respect of the Bohl document. Insofar as the expert evidence furnished by the petitioner is concerned, it is submitted that even though the impugned order does not specifically refer to the affidavits of the experts furnished by the petitioner, the Controller had considered the same and dealt with the contents thereof.

Factual context

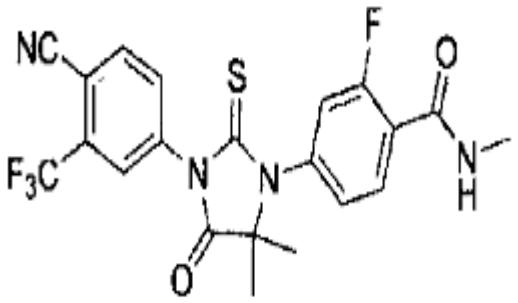
5. The petitioner states that it is a research organization existing under the laws of California and has its principal place of business in California, USA.

6. On 13.12.2007, the petitioner filed an application for grant of patent in respect of its inventions captioned "*Diarylhydantoin Compounds*". The said application (numbered as Application No. 9668/DELNP/2007) was a national phase application of PCT International Application No. PCT/US2006/011417, which was filed on 29.03.2006.

7. The petitioner had made fifty one claims in its International application, however, it entered its application for the National Phase in respect of only forty six claims. On 13.05.2009, the petitioner filed a request for examination. The Controller issued the First Examination Report (FER) under Section 14 of the Indian Patents Act, 1970 (hereafter "the Patents Act") on 24.05.2013.

8. The petitioner responded to the FER further restricting its claims to only fifteen claims. These were further restricted to only three claims at the time of hearing.

9. The principal claim was for a patent in respect of the formula (hereafter referred to as 'Enzalutamide') as set out below:-



10. The second claim related to the pharmaceutical composition, comprising a compound as claimed in claim 1 or a pharmaceutically acceptable salt thereof and pharmaceutically acceptable carriers or diluents. The third claim related to the methods for synthesizing the compound in question.

11. The said application was opposed by respondent no.3 to 7 and each one of them filed their respective pre-grant oppositions, which are referred to as PGO-1 to PGO-5 respectively.

12. On 24.05.2013, a notice was issued to the petitioner in regard to the pre-grant opposition filed by respondent no.3 (hereafter referred to as "PGO-1"). The petitioner filed a reply to the said PGO-1 on 26.08.2013. Thereafter, the petitioner also filed expert evidence of the inventors, Prof. Michael E. Jung and Dr. Charles L. Sawyers, on 03.04.2014. And on 29.08.2014, it also filed the affidavit of evidence of Mr Joshua M. Schafer.

13. Notice with respect to a pre-grant opposition filed by respondent no.4 (hereafter "PGO-2") was issued to the petitioner on 23.10.2013. The petitioner filed its response to PGO-2 on 23.01.2014 alongwith affidavits. The petitioner also filed the affidavits of the inventors, Prof. Michael E. Jung and Dr. Charles L Sawyers, on 03.04.2014. Respondent no.4 filed a rejoinder to the petitioner's reply on 28.04.2014. Thereafter, on 05.09.2014, the petitioner filed the affidavit of Mr Joshua M. Schafer as expert evidence.

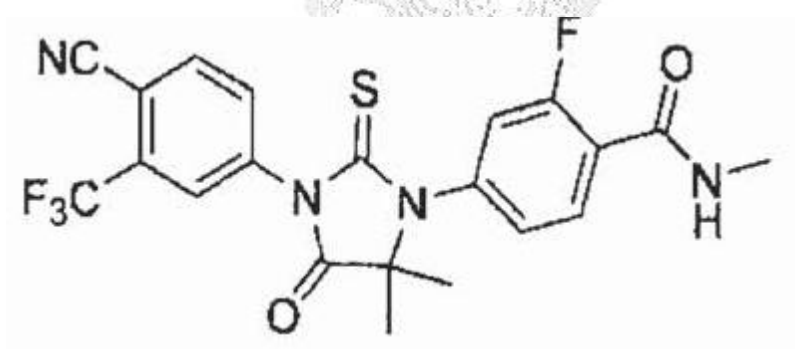
14. Notice in relation to a pre-grant opposition filed by respondent no.5 (hereafter "PGO-3") was issued on 25.03.2015 and the petitioner responded to the same on 19.05.2015.

15. Notice with respect to pre-grant opposition filed by respondent no.7 (hereafter "PGO-5") was issued to the petitioner on 21.04.2016. The petitioner replied to the same on 06.07.2016.

16. On 17.06.2015, respondent no.2 issued a notice for hearing relating to PGO-1, PGO-2 and PGO-3. The hearing was scheduled on 2/3.07.2015.

17. At the hearing held before the Controller on 02.07.2015, the petitioner retained only three claims. The said claims, as set out in the impugned order, are reproduced below:

"1) A compound having the formula

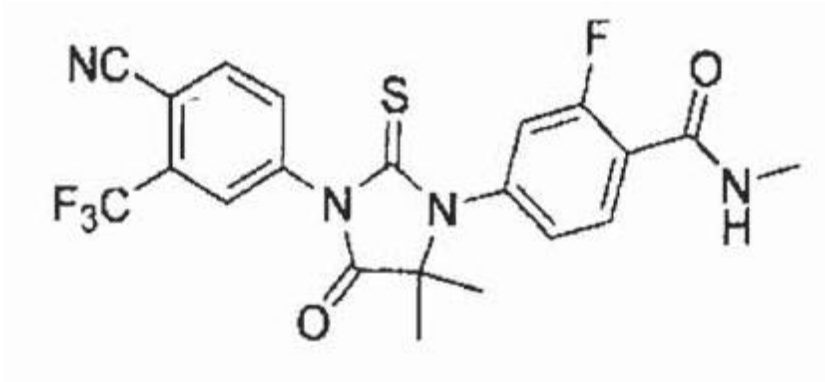


or a Pharmaceutical acceptable salt thereof

2) A pharmaceutical composition comprising a compound as claimed in claim 1 or a

pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier or diluent.

3) A method of synthesizing the compound comprising:



MixingN-Methyl-2-tluoro-4-(1,1-dimetliyl-cyanomethyl)-aminobenzamide and 4-lsothiocyanato-2trifluoromethylbenzonitrile in DMF and heating to form a first mixture;

adding an alcohol and an acid to the first mixture to form a second mixture;

refluxing the second mixture; and

cooling the second mixture, combining the second mixture with water and extracting an organic layer;

isolating the compound from the organic layer."

18. Hearing in respect of PGO-1, PGO-2 and PGO-3 was held on 02.07.2015 and 03.07.2015. Thereafter, on 28.07.2015, respondent no.6 (Ms Sheela Pawar) filed her opposition (PGO-4). Respondent no. 7 (IPA) filed its representation (PGO-5) on 12.01.2016. The petitioner became aware of filing of PGO-4 from the website of the patent office and filed its reply to PGO-4 on 15.03.2016 prior to being served with the notice in respect of PGO-4 (which was served on 21.04.2016). Notice in respect of PGO-5 was served on the petitioner on

21.04.2016, and a reply to the same was filed by the petitioner on 08.07.2016. Hearing in respect of PGO-4 and PGO-5 was held on 25.07.2016.

19. After the hearings in respect of PGO-1, PGO-2 and PGO-3, respondent no.3 filed its written submissions on 27.07.2015. It is not disputed that this was uploaded on the website of the patent office almost immediately. The petitioner also filed post hearing submissions in respect of PGO-1, PGO-2 and PGO-3 on 14.09.2015. The post hearing submissions in respect PGO-4 and PGO-5 were filed on 01.08.2016.

20. The Controller passed the impugned order on 08.11.2016. Aggrieved by the same, the petitioner has filed the present petition.

Submissions

21. Mr Chidambaram and Mr Amit Sibal, learned Senior Counsel advanced arguments on behalf of the petitioner. They contended that the impugned order was passed in violation of principles of natural justice and was vitiated on account of the procedural unfairness. They advanced their contentions, essentially, on three fronts. First, they submitted that the evidence of the inventors filed by the petitioner were not considered by the Controller. It was pointed out that the petitioner had filed the evidence of the inventors and experts, namely, Professor Michael E. Jung, Dr. Charles L. Sawyers and Mr Joshua M. Schaffer, however, the impugned order did not contain any mention of the said affidavits. They submitted that the opening pages of the

impugned order noticed all the documents filed by the parties; however, the Controller had failed to mention the said affidavits and, therefore, it was obvious that the same had not been considered. They contended that the impugned order also did not record any reasons for rejecting the expert evidence.

22. Second, it was submitted that no evidence was filed by respondent nos. 3 to 7 in support of their oppositions. The learned senior counsel referred to Section 77 of the Patents Act and contended that the Controller had powers of a Civil Court, which included power to receive evidence on affidavits. It was further submitted that in terms of Section 79 of the Patents Act, evidence was required to be filed by way of an affidavit and since none of the parties opposing the grant of patent had led any such evidence, the Controller could not have accepted their opposition. The counsel relied on the decisions of the Bombay High Court in ***Glochem Industries Ltd. v. Cadila Healthcare Ltd. and Ors.: 2010 (44) PTC (Bom.) (DB)*** and ***Neon Laboratories Pvt. Ltd. V. Troikaa Pharma Ltd.: 2011 (45) PTC 357 (Bom.) (DB)***.

23. Third, they contended that the petitioner had no effective opportunity to deal with the Bohl document. It was submitted that the said document was referred to by respondent no.3 for the first time during the hearings held on 03.07.2015 and, therefore, the petitioner had no prior notice of the said document. In addition, Mr Sibal earnestly contended that the Bohl document was cited to allege obviousness. He submitted that during the course of hearings before the Controller, respondent no.3 had referred to the Bohl document to

allege that the petitioner's claim was obvious. He submitted that to this end, respondent no.3 had used a hindsight approach to combine the learnings from the Bohl document with the Example 15 in US 981 to form the hypothetical patch. However, in the post hearing submissions filed by respondent no.3, it enlarged its contentions with regard to the inventive steps by also referring to a prior art; US 6518257 (referred to as US-257) alongwith Example 15 of US 981 (D-1) and the Bohl document. He submitted that the petitioner was not granted any opportunity to meet this case, which was set up by respondent no.3 after the hearings were concluded. The petitioner was also denied any opportunity to advance oral submissions in this regard. It was submitted that since the petitioner had objected to taking the Bohl document on record, the Controller should have rejected the same. And, he should have afforded the petitioner full opportunity to deal with the same after deciding the petitioner's objection.

24. Mr Sibal also relied upon the decision of the Supreme Court in ***Automotive Tyre Manufacturers Associate v. The Designated Authority &Ors.: (2011) 2 SCC 258*** and the decision of this Court in ***Krishak Bharat v. Union of India and Ors.: (2015) SccOnline Del. 781*** in support of his contention that written submissions are not a substitute for an oral hearing. He contended that the impugned order is, thus, liable to be set aside and the matter ought to be remanded to the Controller to decide afresh.

25. In addition to the above arguments, it was also contended that the Controller had erred in applying an incorrect test for adjudicating

whether there were inventive steps. It was submitted that the Controller was required to consider the compound as a whole and not apply a hindsight approach for determining whether the compound in question could have been formed by taking patches from various compounds as disclosed in prior art documents. It was further contended that the Enzalutamide was a new chemical entity (NCE).

26. Mr Chidambaram submitted that the Controller had directly copied certain portions of the written submissions filed on behalf of respondent no.3 and incorporated the same as a part of as his order. He referred to certain extracts from the said written submissions and the impugned order to substantiate the same. He submitted that this clearly indicated that the Controller had not applied its mind and had merely extracted the submissions made by respondent no.3.

27. The learned counsel appearing for the respondent nos. 4 to 7 countered the aforesaid submissions. Mr Vishal Sudan, the authorised representative of respondent no.3, made submissions on behalf of respondent no.3.

28. Mr J. Sai Deepak, learned counsel appearing for respondent no.5 submitted that the petitioner had full opportunity to address submissions with regard to the Bohl document. He pointed out that respondent no.3 had filed its written submissions on 27.07.2015, which was uploaded on the website of the patent office and the petitioner had full opportunity to meet with the arguments made therein. The petitioner had in fact addressed submissions with regard

to Bohl document while complaining against the alleged non-compliance of the principles of natural justice. He submitted that the petitioner did not make any request for an opportunity of being heard in respect of the Bohl document. He contended that if the petitioner was aggrieved by the impugned order, it was open for the petitioner to file a review under Section 77(f) of the Patents Act or file an appeal under Section 117A of the said Act. However, the petitioner had failed to take the recourse under the said provisions of the Patents Act and had approached this Court after the time period provided for filing the appeal had elapsed.

29. Next, he submitted that the scope of proceedings and inquiry under Section 25(1) of the Patents Act is materially different from the proceedings in respect of post-grant opposition. He submitted that the pre-grant opposition is an aid of the examination of a patent application and thus, not a quasi-judicial proceeding relating to a *lis* between an applicant and the person who has filed the representation. He submitted that the nature of the said proceedings is to assist the Controller in making the decision under Section 15 of the Patents Act and, therefore, it was open for the Controller to take note of any document or prior art irrespective of whether the same was filed alongwith an affidavit or not. He relied on the decision of this Court in ***M/s UcbFrachim Sa v. M/s Cipla Ltd. and Ors. :2010 2 AD (Del) 713*** in support of his contention. He further submitted that there was a distinction between evidence and documents. He referred to Section 77 of the Patents Act and contended that the said provision also made

a clear distinction between requiring discovery of any document as referred to in Clause (b) and receiving evidence of affidavit to refer to in Clause (c). He further submitted that the petitioner had also filed additional document at the time of the hearing or just prior thereto and, therefore, could not have any grievance with respect to the Controller accepting the documents filed by the opponents.

30. Mr Vishal Sudan, who appeared on behalf of respondent no.3 contended that although the Controller had not specifically referred to the affidavits of the experts filed by the petitioner; he had, however, considered the claims made therein. He submitted that all the three experts were connected with the invention and, therefore, were not strictly independent persons. He submitted that the affidavits submitted by Dr. Charles L. Sawyers and Mr Joshua M. Schaffer did not contain any discussions with regard to the prior art documents which were cited in opposition. The said affidavits were not concerned about the novelty or inventive steps and, therefore, the Controller cannot be faulted for not referring to the said affidavits in the impugned order. He submitted that these affidavits were concerned about clinical trials and marketing approval of the drugs and this was not the subject matter of challenge, which was accepted by the Controller. He submitted that the affidavit submitted by the third expert, Mr Michael E. Jung, was considered. He contended that although the said affidavit has not been expressly referred to in the impugned order, the averments made by Mr Michael E. Jung in his affidavit were dealt with by the Controller in its order.

31. Mr Sudan emphatically contended that the petitioner cannot make any grievance regarding reference to the affidavit of the experts since the petitioner had not referred to the same either during the oral hearings or in the post hearing written submissions. Mr Sudan also countered the contention that a pre-grant opposition was required to be supported by an affidavit. He referred to the provisions of Section 25(1) of the Patents Act and contended that a representation was required to be filed in writing, and there was no requirement that the same be supported by an affidavit. He submitted that in the present case, the lack of inventive steps and obviousness were evident and, therefore, there was no requirement for expert evidence to be led. The prior art documents relied upon by the respondents were available on record and there is no dispute as to the genuineness of those documents.

Reasons and Conclusion

32. As is apparent from the above, the petitioner's challenge to the impugned order is of twofold: the first relates to the decision making process, and the second relates to the merits of the decision.

33. The first and foremost contention to be addressed is whether the principles of natural justice have been violated. Section 25 of the Patents Act enables any person to file an opposition prior to grant of a patent. Sub-section (1) of Section 25 of the Patents Act is set out below:-

"**25 Opposition to the patent.**—(1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground—

(a) that the applicant for the patent or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims;

(b) that the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim—

(i) in any specification filed in pursuance of an application for a patent made in India on or after the 1st day of January, 1912; or

(ii) in India or elsewhere, in any other document:

Provided that the ground specified in sub-clause (ii) shall not be available where such publication does not constitute an anticipation of the invention by virtue of sub-section (2) or subsection (3) of section 29;

(c) that the invention so far as claimed in any claim of the complete specification is claimed in a claim of a complete specification published on or after priority date of the applicant's claim and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than that of the applicant's claim;

(d) that the invention so far as claimed in any claim of the complete specification was publicly known or

publicly used in India before the priority date of that claim.

Explanation.—For the purposes of this clause, an invention relating to a process for which a patent is claimed shall be deemed to have been publicly known or publicly used in India before the priority date of the claim if a product made by that process had already been imported into India before that date except where such importation has been for the purpose of reasonable trial or experiment only;

(e) that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim;

(f) that the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act;

(g) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;

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

(i) that in the case of a convention application, the application was not made within twelve months from the date of the first application for protection for the invention made in a convention country by the applicant or a person from whom he derives title;

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

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

but on no other ground, and the Controller shall, if requested by such person for being heard, hear him and dispose of such representation in such manner and within such period as may be prescribed."

34. It is apparent from the plain reading of Section 25(1) of the Patents Act that a representation to oppose grant of a patent is required to be in writing. There is no requirement that any such opposition is to be supported by an affidavit. The principal object of requiring the opposition to be in writing is, plainly, to enable the Controller to examine the grounds stated therein and to provide an opportunity to the applicant to meet such opposition. It is also not necessary for the Controller to hear the person filing such opposition unless he makes such a request.

35. In terms of Section 25(1) of the Patents Act, the representation is required to be disposed of in the manner as prescribed. Rule 55 of the Patents Rules, 2003 (hereafter 'the Patents Rules') prescribes the procedure to be adopted for considering the representation filed under Section 25(1) of the Patents Act. Rule 55 of the Patents Rules is set out below:-

"**55. Opposition to the patent**—(1) Representation for opposition under sub-section (1) of section 25 shall be filed in Form 7(A) at the appropriate office with a copy to the applicant, and shall include a statement and evidence, if any, in support of the representation and a request for hearing, if so desired.

(1A) Notwithstanding anything contained in sub-rule (1), no patent shall be granted before the expiry of a period of six months from the date of publication of the application under section 11 A.

(2) The Controller shall consider such representation only when a request for examination of the application has been filed.

(3) On consideration of the representation if the Controller is of the opinion that application for patent shall be refused or the complete specification requires amendment, he shall give a notice to the applicant to that effect.

(4) On receiving the notice under sub-rule (3), the applicant shall, if he so desires, file his statement and evidence, if any, in support of his application within three months from the date of the notice, with a copy to the opponent.

(5) On consideration of the statement and evidence filed by the applicant, the representation including the statement and evidence filed by the opponent, submissions made by the parties, and after hearing the parties, if so requested, the Controller may either reject the representation or require the complete specification and other documents to be amended to his satisfaction before the patent is granted or refuse to grant a patent on the application, by passing a speaking order to simultaneously decide on the application and the representation ordinarily within one month from the completion of above proceedings."

36. It is apparent from the above that the Controller is required to consider the representation only when a request for examination is filed. If the Controller is of the opinion that the application is to be refused or complete specification requires amendment, he is required to give a notice of the same to the applicant. The said notice is to enable the applicant to file a statement and evidence in support of his application with a copy to the opponent. The said statement and evidence, as well as the representation filed by the opponent, are required to be appreciated by the Controller. After such examination, the Controller may either reject the opposition or require the complete specifications and other documents to be amended to his satisfaction or refuse to grant the patent by passing a speaking order.

37. It is important to note that the Controller is required to render the decision on the application for patent as well as the opposition simultaneously. A plain reading of Sub-rule (5) of Rule 55 of the Patents Rules also indicates that oral hearing is not an essential part of the procedure and the Controller is required to hear the parties, only if the parties so request.

38. In the instant case, there is no dispute that the respondents had submitted their respective representations. The Controller had issued a notice with regard to the same, thus enabling the petitioner to file a statement and evidence in support of its application. The parties were also heard. Thus, as far as this stage is concerned, there is no dispute that the principles of natural justice were complied with.

39. The only grounds on which the petitioner has raised a grievance regarding non-compliance of principles of natural justice is that respondent no.3 had produced the Bohl document during the course of hearing, and the written submissions filed by respondent no.3 had further expanded the submissions made on its behalf during the course of the oral hearing. It is stated that during the course of hearing, respondent no.3 had relied upon Example 15 of US 981 and the Bohl document to contend that the invention lacked any inventive step. According to its representation, the same was obvious from the said two prior arts. However, in its written submissions, respondent no.3 had expanded the aforesaid argument and contended that FLUORO-N-METHYLBENZAMIDE, which was a moiety of a compound disclosed in US 257, could be combined with hydantoin moiety of the compound shown in Example 15 of US 981.

40. Mr Sibal had contended that this was, essentially, a new argument and the petitioner had no opportunity to deal with the same. It was also contended that since no oral hearing was held after such written submissions were filed by respondent no.3, the petitioner had no opportunity to meet with the same.

41. Insofar as the reference to Bohl document is concerned, admittedly, the said document was produced for the first time during the course of the hearing before the Controller. Although the petitioner had objected to the production of the Bohl document at the belated stage, it cannot be disputed that the petitioner was given full opportunity to make submissions with regard to the said document.

The petitioner had not only made oral submissions with regard to the said document but had also filed written submissions at a later date. The essential requirement of providing the petitioner an opportunity to deal with the said document was, thus, duly met.

42. In view of the above, the contention that the Bohl document was required to be ignored, is unpersuasive. Clearly, the Controller is not expected to ignore any relevant material that is produced before him at a pre-grant stage. It is also essential to bear in mind that the proceeding relating to a pre-grant representation are a part of the process of examination by the Controller. As noticed before, this is also clearly indicated by sub-rule(5) of Rule 55 of the Patents Rules, which expressly requires the Controller to decide the application as well as the representation, simultaneously.

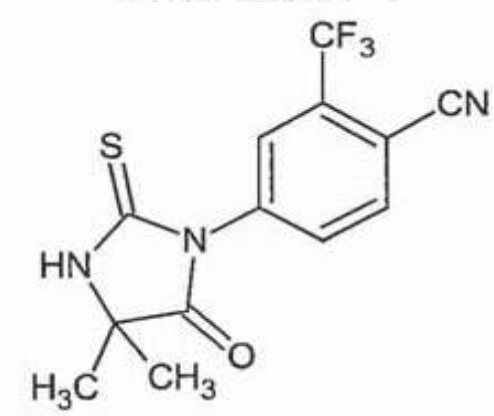
43. The consideration of the representation filed to oppose grant of patent is an intrinsic part of the decision making process whether to accept the claim and, therefore, cannot be viewed as a completely independent proceeding. Thus, the Controller cannot ignore any document or material produced, which may have a bearing on whether the patent ought to be granted.

44. Having stated the above, it is necessary to observe that it is also essential for the Controller to give full opportunity to the applicant to address submissions with regard to any such document/material that is relied upon by it. In the present case, the Controller had provided the

petitioner such an opportunity in so far as the Bohl document is concerned.

45. The next question is whether the petitioner had been afforded sufficient opportunity to respond to the contention that Enzalutamide was obvious in view of the teachings in the Bohl document read in conjunction with US 981 and the prior art document US 257 (US6518257). It was contended that during the course of oral arguments, respondent no.5 had contended that Enzalutamide was obvious in view of the teachings and the Bohl document read with US 981. Admittedly, the said oral submission was expanded in the written submissions filed subsequently. In its written submissions, respondent no.5 had contended that the compound Enzalutamide lacked inventive steps when considered in the context of the teachings in the Bohl document read with US 981 and US 257, as is apparent from the impugned order. The said contention was accepted by the Controller. He concluded that US 981 provides for data which indicates that Example 15 (as indicated therein) "*has Anti-androgenic activity and is devoid of agnostic activity*". He further accepted that the difference between the compound of Example 15 and Enzalutamide (the claim made by the petitioner) is "Fluoro-N-Methylbenzamide at the first Nitrogen of thiohydantoin moiety". He further accepted that the selection of "Fluoro-N-Methylbenzamide at the first Nitrogen of thiohydantoin moiety" was obvious in view of the teaching of the Bohl document. The Controller noticed that the compound of US 257 included the "Fluoro-N-Methylbenzamide at the

first Nitrogen of thiohydantoin moiety" and in view of the teachings of the Bohl document, a person skilled in the Art would think of replacing the said moiety with the hydrogen attached to N of hydantoin moiety of the compound of US 981. The relevant extract of the impugned order is set out below:-

> "12.2) Grounds Of Opposition :- Section 25(1)(e)
>
> a) US' 981 in view of D1:US'981 discloses a compound of example 15 which is represented herein below
>
> 
>
>
> US'981 provides data that shows that the compound of example 15 have anti-androgenic activity and is devoid of agonist activity The difference between the compound of example 15 and Enzalutamide is FLUORO-N-METHYLBENZAMIDE at 1st Nitrogen of thiohydantoin moiety. This moiety is generally disclosed under group R3.
>
> Further D1 suggests that aryl ring substituted with moderately sized groups such as acetamido is required at this position to improve the binding affinity of the compounds for androgen receptors. Therefore, selection of fluoro-N-methylbenzamide is obvious over US'981

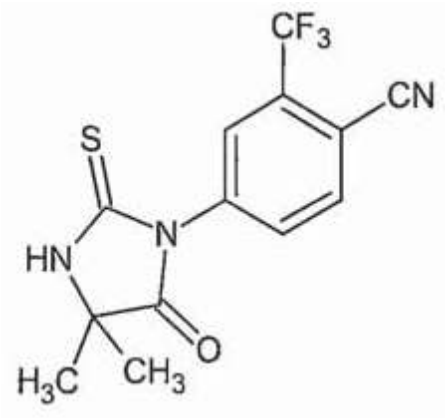
in view of D1. Although D1 does not talk about methylcarbamoyl group instead it suggested acetamido group which is different than the methylcarbamoyl group. But D1 at first place suggests that, only a moderately sized group can be accommodated specifically at para position. Further, D1 suggests that groups such as acetamido (molecular formula C2H4NO) can be favored. Therefore, in view of teachings of D1 the applicant has selected aryl ring substituted with methylcarbamoyl specifically at para-position.

With regard to fluoro substitution at or tho position to the methylcarbamoyl group, it is to be specified that US'98 clearly suggests that aryl is further substituted by halogen (see column 03, lines 05-09 of US'981).

Further D1 suggests that "Bulky para substituents and moderately sized meta and ortho substituents, however, would result in unfavorable steric interaction according to the model" (see page 3772, right hand column, third par, last four lines).

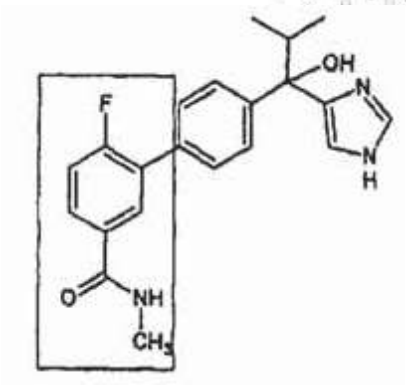
Therefore, D1 clearly mentions that even moderately sized groups are not favoured at ortho and meta position of the aryl ring. Therefore, the only option is halogens out of the disclosure given in D1 at this position. Further the applicant is failed to show in the instant application that fluoro substitution has any effect on the activity as there is no difference in activity of RD153 and compound which has doesn't have fluoro substitution at this position and Enzalutamide.

b) US'981 in view of US'257 in combination with D1 :The documents D1 discloses a compound of the structure in example 15 as shown below



If we look at the above mentioned structure it is obvious that "FLUORO-N-METHYLBENZAMIDE" moiety is required at 1st N of thiohydantoin moiety to arrive at the structure of Enzalutamide.

As mentioned above, D1 teaches that, aryl ring substituted with moderately sized groups such as acetamido is required to improve the binding affinity of the compounds for androgen receptors (see page 3773, left hand column, first para). Now if we look at the US'257 in column 49 line 30-6, it describes a compound of the formula as shown below.



> The FLUORO-N-METHYLBENZAMIDE moiety as shown in the rectangle is clearly taught in US'257. As discussed earlier taking in view of teachings ofD1 a person skilled in the art will think of replacing the moiety sown in rectangle ofUS'257 compound with hydrogen attached to N of hydantoin moiety of the compound 15of US'981.
>
> In view of above it is stated that claimed invention is lacking inventive step with reference to Document US'981 in combination with D1 AND US'981, US'257 in combination with D1."

46. Concededly, this was not the argument that was advanced by respondent no.5 at the oral hearing; it was raised for the first time in the written submissions filed by respondent no.3 after the hearing was concluded on 27.07.2015. It is contended on behalf of the respondents that since the petitioner had filed its written submissions on 14.09.2015 – that is, much after respondent no.3 had filed its written submissions – the petitioner had full opportunity to controvert the aforesaid contention.

47. The aforesaid contention is unpersuasive. Clearly, post hearing written submissions cannot expand the scope of submissions made in the oral hearing. Such submissions are clearly meant to record only the oral submissions made at the hearing in order to assist the decision maker. More importantly, in terms of Rule 55(1) of the Patents Rules, any representation for opposition under Section 25(1) of the Patents Act is required to be filed in Form 7A of the said Rules and is required to include a statement and evidence in support of the representation,

and a request for a hearing if so desired. Rule 55(1) of the Patents Rules does not contemplate submissions of a further statement after the hearing is completed. In terms of Rule 55(3) of the Patents Rules, a Controller is required to give a notice to the applicant if on consideration of a representation, he is of the opinion that the application for patent shall be refused or the specifications require amendment. Such notice is required to be issued on the basis of the FER or on the representation received by the Controller. There is no scope for entertaining additional arguments after the oral hearing is concluded. If the Controller intends to take into account any additional arguments raised after oral hearing is concluded, he is, obviously, required to put the applicant to notice regarding the same. In the aforesaid view, the impugned order inasmuch as it accepts the arguments raised by respondent no.3 after conclusion of the hearing, cannot be sustained.

48. It was contended on behalf of the petitioner that since the Post-Grant Oppositions and the documents produced alongwith oppositions, subsequently, were not supported by an affidavit, the representation could not be accepted. This contention is, plainly, unmerited. The representations made at the pre-grant stage are an integral part of the examination of the claim. In terms of Rule 55(1A) of the Patents Rules, no patent can be granted before expiry of six months from the date of publication of the application. This is to enable third parties to submit objections to grant of the patent. In terms of Rule 55(3) of the Patents Rules, the representation can be

considered only when a request for examination has been filed and in terms of Rule 55(5) of the Patents Rules, the application of the oppositions are to be decided simultaneously.

49. There is no requirement that a pre-grant opposition be supported by an affidavit. Section 25(1) of the Patents Act merely requires the said opposition to be in writing. Form 7A (the Form in which the pre-grant opposition is required to be filed in terms of Rule 55 of the Patents Rules) also does not require any verification or affirmation.

50. In terms of Rule 55(1) of the Patents Rules, the pre-grant opposition is required to be accompanied by a statement of evidence. It is not necessary that such evidence be accompanied by an affidavit. No affidavit would be required to produce documents or material which are otherwise available in the public domain. The reliance placed by the petitioner on Section 79 of the Patents Act is misplaced. Section 79 of the Patents Act mandates that evidence before a Controller can be submitted by way of an affidavit but the Controller also has the right to accept oral evidence. It is not the import of Section 79 of the Patents Act that documents, which are available in public domain, be ignored by the Controller unless supported by an affidavit. It merely enables the Controller to accept evidence on affidavit instead of by oral testimony. In view of the above, the contention that the Controller was required to ignore the Bohl document or the pre-grant representations made by the respondents because they were not supported by affidavits, is erroneous and,

accordingly, rejected as such (See: ***M/s UCB Farchim SA v. M/s Cipla Ltd. & Ors.: (2010) II AD Del. 713***).

51. The next contention to be considered is whether the impugned order is vitiated as the Controller had failed to consider the affidavit affirmed by Prof. Michael E. Jung and Mr Schafer and Dr. Charles L. Sawyers. Admittedly, there is no reference or discussion regarding the affidavits of the aforesaid experts submitted by the petitioner. Nonetheless, the respondents contend that the evidence of Prof. Michael E. Jung and Mr Schafer and Dr. Charles L. Sawyers had been considered and dealt with by the Controller in the impugned order.

52. In support of its contention, respondent no.3 had, in its written submissions, set out a tabular statement referring to the extracts of the affidavit and the impugned order.

53. It was pointed out that Mr Jung had affirmed that Example 15 of US 981 did not have "*a phenyl directly attached to be nitrogen at the 3 position of the imidazolidine ring…*". It was contended that Controller had considered the same and held that "*The difference between the compound of example and Enzalutamide FLUORO-N-METHYLBENZAMIDE at 1st Nitrogen of thiohydantoin moiety. This moiety is generally disclosed under group R3[R3 described in D1]…*". It was further pointed out that Mr Jung had, in its affidavit, affirmed that "*…The methylcarbamoyl on the phenyl ring of the hypothetical compound is meta with respect to the point of attachment of the phenyl to the nitrogen not para as in the RD162'compound, enzalutamide,…*"

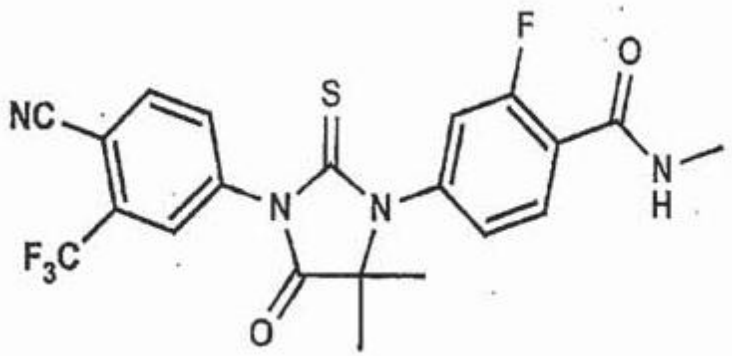
54. The Controller had examined the same and held as under:-

> "…Although Dl does not talk about methylcarbamoyl group instead it suggested acetamido group which is different than the methylcarbamoyl group. But D1 at first place suggests that, only a moderately sized group can be accommodated specifically at para position. Further, Dl suggests that groups such as acetamido (molecular formula C2H4NO) can be favored. Therefore, in view of teachings of Dl the applicant has selected aryl ring substituted with methylcarbamoyl specifically at para-position."

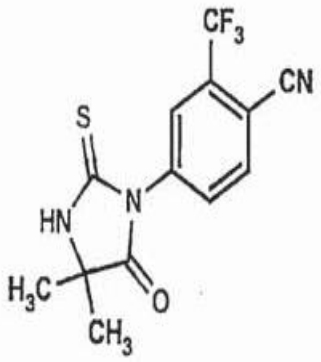
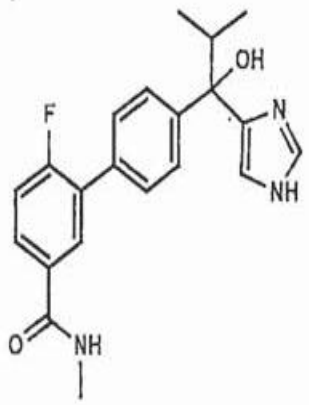
55. Whilst it is correct that the conclusions drawn by the Controller dealt with the issues referred in the impugned order, however, a careful reading of the affidavits and the conclusions drawn by the Controller clearly indicate that observations made in the impugned order are not directly relatable to the issues raised by Mr Jung in his affidavit. The Controller has selectively culled out certain sentences from paragraphs 41, 42 and 44 of the affidavit filed by Mr Jung to indicate that the said issues had been considered in the impugned order. However, a plain reading of Mr Jung's affidavit indicates that the conclusions drawn are not directly in reference to the said affidavit. This is, at once, apparent from the contents of paragraphs 41 to 44 of the affidavit of Mr Jung, when read in entirety. The said paragraphs are set out below:-

> "41. The Opponent has alleged that the compound RD162', enzalutamide, which is the active ingredient of the drug, XTANDI®, can be arrived by combined moieties of example 15 and

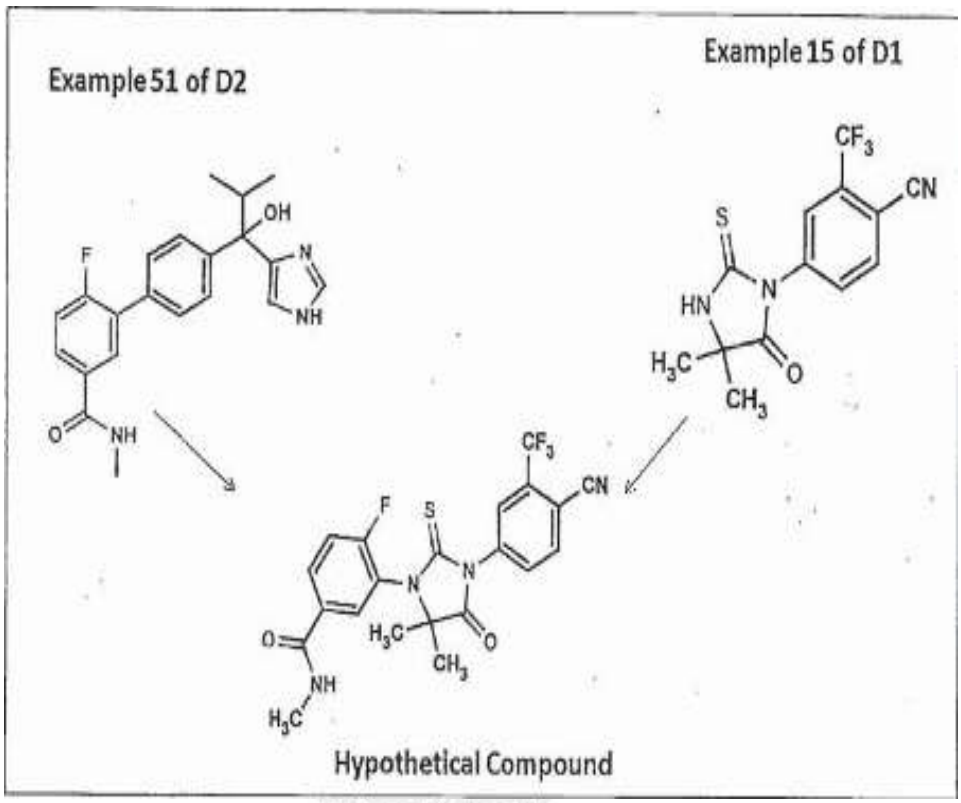
example 51 of Dl and D2, respectively. The molecular structure of the compound RD162' of instant application, enzalutamide, is represented below.



The example 15 differs from the claimed compounds of the instant application in that Example 15 does not have a phenyl directly attached to the nitrogen at the 3 position of the imidazolidine ring. Also, the chemical name of Example 15 [*4-(4,4-dimethyl-5-oxo-3-thioxo-l-imidazolidinyl)-trifluoromethyl-benzonitrile*], set forth in lines 20-21 of column 18 of Dl, appears to contain errors. That is, it appears that a thioxo group cannot be at the 3 position of imidazolidinyl and a trifluoromethyl group cannot beat the 1 position of benzonitrile.

Example 15 of D1	Example 51 of D2
	

42. The Opponent having knowledge of the enzalutamide structure has combined moieties of example 15 of Dl and example 51 of D2, based on a hindsight approach. Moreover, the hypothetical compound thus obtained by combining Dl and D2 is structurally different from the RD162' compound, enzalutamide. That is, the fluorine on the phenyl ring of the hypothetical compound is ortho with respect to the point of attachment of the phenyl to the nitrogen, not meta as in the RD162' compound, enzalutamide. The methylcarbamoyl on the phenyl ring of the hypothetical compound is meta with respect to the point of attachment of the phenyl to the nitrogen, not para as in the RD162' compound, enzalutamide, claimed in the present application.



43. I say that the RD162' compound is structurally different with respect to the example 51 of D2 in the following manner.

    i. Firstly, the methylcarbamoylphenyl group of' the RD162' compound has a fluorine bound at the position ortho to the methylcarbamoyl, instead of at the position para to the methylcarbamoyl as in Example 51 of D2. The Opponent provides no basis for the statement that "*it is evident that the point of attachment of the amide bond on the phenyl ring may not affect the said activity.*"

ii. Secondly, the methylcarbamoylphenyl group of the RD162' compound is bound to the rest of the molecule at the position para to the methylcarbamoyl, instead of at the position meta to the methylcarbamoyl as in Example 51 of D2.

iii. Thirdly, the methylcarbamoylphenyl group of the RD162' compound is bound directly to a nitrogen at the 3 position of a central imidazolidine ring of the compound, instead of to a carbon of a phenylene as in Example 51 of D2.

iv. Fourthly, the RD162' compound includes a central saturated imidazolidine ring, whereas the Example 51 of D2 includes an unsaturated imidazole ring,

v. Fifthly, whereas the imidazolidine ring of the RD162' compound is bound to the additional portions of the molecule at nitrogens at the 1 and 3 positions, the imidazole ring of Example 51 of D2 is bound to the rest of the compound at a carbon at the 4 position.

vi. Sixthly, the RD162' compound includes a 4-cyano-3-trifluoromethyl-phenyl group bound to a nitrogen of the imidazolidine ring, which is lacking in Example 51 of D2.

44. The Opponent did not provide any reasoning as to why a person of skill in the art would combine Dl, which allegedly functions as an androgen

> receptor antagonist, with D2, which has the completely different function of suppressing the formation of androgen and does not have a methylcarbamoylphenyl attached to a nitrogen of an imidazolidine ring. Furthermore, as set forth above, a combination of Dl with D2 would not result in the RD162' compound, which has a fluorine at the or the position and is attached to imidazolidine at the para position with respect to the methylcarbamoylphenyl, rather than having the fluorine at the para position and being attached to the rest of the molecule at the meta position, as does the D2 compound."

56. The decision of the Controller, as recorded in the impugned order, has been set out hereinbefore. A plain reading of the said conclusion indicates that some of the issues raised by Mr Jung had not been addressed. In addition, there is no reference to the affidavits affirmed by Mr Schafer and Dr. Charles L. Sawyers in the impugned order. It was contended that the said affidavits were regarding clinical trials and marketing approvals of the drug and, therefore, were not relevant. This Court finds the aforesaid contention to be unpersuasive. Admittedly, even a minor change in a compound used as a drug can bring in about significant changes in its therapeutic value. In this view, the affidavits affirmed by Mr Schafer and Dr. Charles L. Sawyers could not be considered as irrelevant. However, even if it is accepted that the same were to be rejected as being irrelevant, the Controller was required to indicate the same. However, the impugned order is completely silent on the affidavits submitted by them. In view of the

above, the impugned order is liable to be set aside also for the reason that the Controller had failed to consider the affidavits of the experts placed by the petitioner.

57. It was contended by Mr Sudan that the petitioner had not referred to the affidavits of the experts at the hearing or in the written submissions and, therefore, it was not open for the petitioner to assert that the affidavits had been ignored. This contention is also unmerited. The petitioner had, in the initial paragraphs of its written submissions, clearly stated as under:-

> "As the pre-grant opposition procedure is a continuation of the prosecution of the application, it is submitted that our response to the First Examination Report, reply statements to the representation made by Fresenius Kabi Oncology Limited, and all the declarations of Dr. Sawyers, Dr. Jung and Mr. Schafer be taken as part and parcel of the present submissions and the same are not being reproduced herein for the sake of brevity."

58. In view of the above, the contention that the petitioner had not relied upon affidavits is, plainly, unmerited.

59. For the reasons mentioned hereinabove, the impugned order is set aside and the matter is remanded to the Controller to decide afresh.

60. The pending application is also disposed of.

VIBHU BAKHRU, J

MAY 16, 2019
RK