Akebia Therapeutics Inc. vs Controller General Of Patents, Design, ... on 9 August, 2023

Author: C.Hari Shankar

Bench: C.Hari Shankar

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* IN THE HIGH COURT OF DELHI AT NEW DELHI
+ W.P.(C)-IPD 32/2023, CM 92/2023 & CM 93/2023
AKEBIA THERAPEUTICS INC. ..... Petitioner
Through: Mr. Pravin Anand, Adv.

versus

CONTROLLER GENERAL OF PATENTS, DESIGN, TRADEMARK AND GEOGRAPHICAL INDICATIONS, & ORS. ..... Respondents
Through: Ms. Bitika Sharma, Ms. Vrinda Pathak, Mr. George and Mr. Manjunathan, Advs.

CORAM:
HON'BLE MR. JUSTICE C.HARI SHANKAR
JUDGMENT (ORAL)

% 09.08.2023

1. On 26 September 2017, the petitioner's Patent IN 287720 (IN'720 hereinafter) was granted by the Indian Patent Office in respect of an invention titled "HIF-1□prolyl hydroxylase inhibitor compounds".

Procedure for post grant oppositions

2. Before proceeding further, a brief glance at the statutory scheme, governing pre-grant oppositions and post-grant oppositions to a patent, as contained in the Patents Act, 1970 and the Patents Rules, 2003, may be noticed.

3. Section 25 of the Patents Act permits any person to object to a patent, either before, or after, it is granted. The substantive provisions in that regard are contained in Section 25 of the Patents Act, and the corresponding procedure to be followed is to be found in Rule 25 of the Patents Rules.

4. Section 25(1) envisages an opposition to a patent "where an application for a patent has been published but a patent has not been granted"1. It, therefore, deals with a pre-grant opposition to a patent; in other words, an opposition to the application itself, objecting to the request for grant of a patent.

5. The corresponding procedure, governing pre-grant oppositions, is contained in Rule 57(1) of the Patent Rules.

6. We need not concern ourselves either with Section 25(1) of the Patents Act or with Rule 57(1) of the Patents Rules, as, in the present case, Respondent 3 objected to IN'720 after, not before, it was granted. We, therefore, are concerned with a post-grant opposition, not a pre-grant opposition.

7. Section 57(2)2 permits the filing of a post grant opposition. The procedural stipulations in that regard are to be found in Rules 55- The opening words of Section 25(1) (2) At any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may give notice of opposition to the Controller in the prescribed manner on any of the following grounds, namely:-

> ***** but on no other ground.
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> (Clauses (a) to (k) have been omitted for brevity, as they are not relevant to the discussion in the present case.) A to 62 of the Patents Rules.

8. Rule 563 envisages the constitution of an Opposition Board to undertake a preliminary examination of post grant oppositions. The Opposition Board is required to take into consideration all the material filed before the Controller from Rules 57 to 604.

9. Rule 57 deals with the filing of a post-grant opposition. It permits the filing of a post-grant opposition "and evidence".

10. Section 795 of the Patents Act stipulates how evidence is to be

56. Constitution of Opposition Board and its proceeding. -

(1) On receipt of notice of opposition under Rule 55-A, the Controller shall, by order, constitute an Opposition Board consisting of three members and nominate one of the members as the Chairman of the Board.

(2) An examiner appointed under sub-section (2) of Section 73 shall be eligible to be a member of the Opposition Board.

(3) The examiner, who has dealt with the application for patent during the proceeding for grant of patent thereon shall not be eligible as member of Opposition Board as specified in sub-rule (2) for that application.

(4) The Opposition Board shall conduct the examination of the notice of opposition along with documents filed under Rules, 57 to 60 referred to under sub-section (3) of Section 25, submit a report with reasons on each ground taken in the notice of opposition with its joint recommendation within three months from the date on which the documents were forwarded to them.

57. Filing of written statement of opposition and evidence. - The opponent shall send a written statement in duplicate setting out the nature of the opponent's interest, the facts upon which he bases his case and relief which he seeks and evidence, if any, along with notice of opposition and shall deliver to the patentee a copy of the statement and the evidence, if any.

58. Filing of reply statement and evidence. -

(1) If the patentee desires to contest the opposition, he shall leave at the appropriate office a reply statement setting out fully the grounds upon which the opposition is contested and evidence if any, in support of his case within a period of two months from the date of receipt of the copy of the written statement and opponent's evidence, if any by him under Rule 57 and deliver to the opponent a copy thereof.

(2) If the patentee does not desire to contest or leave his reply and evidence within the period as specified in sub-rule (1), the patent shall be deemed to have been revoked.

59. Filing of reply evidence by opponent. - The opponent may, within one month from the date of delivery to him of a copy of the patentee's reply statement and evidence under Rule 58, leave at the appropriate office evidence in reply strictly confined to matters in the patentee's evidence and shall deliver to the patentee a copy of such evidence.

60. Further evidence to be left with the leave of the Controller. - No further evidence shall be delivered by either party except with the leave or directions of the Controller:

> 79. Evidence how to be given and powers of Controller in respect thereof. - Subject to any rules made in this behalf, in any proceeding under this Act before the Controller, evidence shall be given by affidavit in the absence of directions by the Controller to the contrary, but in any case in which the Controller thinks it right so to do, he may take oral evidence in lieu of, or in addition to evidence by affidavit, or may given thereunder, and the powers of the Controller in respect thereof.

The Section is categorical in requiring evidence to be given by affidavit, subject to the power of the Controller to, in an appropriate case, permit oral evidence in lieu thereof. In any event, mere documents, filed with the post grant opposition, cannot constitute "evidence" under the Patents Act or the Patents Rules.

11. It is settled, from the times of Taylor v. Taylor6, to the pronouncement of the Privy Council in Nazir Ahmed v. King Emperor7, through a veritable plethora of decisions of the Supreme Court which have followed these dicta, that, where the law requires an act to be done in a particular manner, the act has to be done in that manner alone, or not done at all. All other methods of doing the act are necessarily forbidden. State of U.P. v. Singhara Singh8, the most often cited of the decisions of the Supreme Court, expostulates the principle thus:

> "7. In Nazir Ahmed case7, the Judicial Committee observed that the principle applied in Taylor6 to a court, namely, that where a power is given to do a certain thing in a certain way, the thing must be done in that way or not at all and that other methods of performance are necessarily forbidden, applied to judicial officers making a record Under Section 164 and, therefore, held that the Magistrate could not give oral evidence of the confession made to him which he had purported to record Under Section 164 of the Code. It was said that otherwise all the precautions and safeguards laid down in Sections 164 and 364, both of which had to be read together, would become of such trifling value as to be almost idle and that "it would be an unnatural construction to hold that any other procedure was permitted than that which is laid down with such minute particularity in the Sections themselves".

allow any party to be cross-examined on the contents of his affidavit.

(1875) 1 Ch D 426 AIR 1936 PC 253 AIR 1964 SC 358

8. The Rule adopted in Taylor6 is well recognised and is founded on sound principle. Its result is that if a statute has conferred a power to do an act and has laid down the method in which that power has to be exercised, it necessarily prohibits the doing of the act in any other manner than that which has been prescribed. The principle behind the Rule is that if this were not so, the statutory provision might as well not have been enacted. A Magistrate, therefore, cannot in the course of investigation record a confession except in the manner laid down in Section 164. The power to record the confession had obviously been given so that the confession might be proved by the record of it made in the manner laid down. If proof of the confession by other means was permissible, the whole provision of Section 164 including the safeguards contained in it for the protection of Accused persons would be rendered nugatory. The section, therefore, by conferring on Magistrates the power to record statements or confessions, by necessary implication, prohibited a Magistrate from giving oral evidence of the statements or confessions made to him."

(Emphasis supplied)

12. Rule 619 also makes the distinction between the evidence, filed under Rules 57 to 60, and the documents referred to in the evidence, clear.

13. To her credit, Ms. Bitika Sharma, learned Counsel for Respondent 3, candidly and fairly acknowledges that mere documents, sans any accompanying affidavit, would not constitute "evidence" within the meaning of Rule 57 of the Patents Rules.

14. Once the post grant opposition and evidence thus stands filed by

61. Copies of documents to be supplied. -

(1) Copies of all documents referred to in the notice of opposition or in any statement or evidence filed in connection with the opposition and authenticated to the satisfaction of the Controller, shall

be simultaneously furnished in duplicate unless the Controller otherwise directs. (2) Where a specification or other document in a language other than English is referred to in the notice, statement or evidence, an attested translation thereof, in duplicate, in English shall be furnished along with such notice, statement or evidence, as the case may be.

the post grant opponent under Rule 57, the patentee is permitted, under Rule 58, to file a "reply statement", again accompanied with "evidence, if any, in support of his case".

15. Rule 59, thereafter, grants a second chance, to the post grant opponent, to file further evidence, by envisaging that the post grant opponent may file "evidence strictly confined to matters in the patentee's evidence". As is correctly contended by Mr. Pravin Anand, learned Counsel for the petitioner, however, Rule 59 does not envisage, or permit, filing of any "rejoinder" by the post grant opponent. It permits the post grant opponent to file evidence, and nothing more.

16. Rule 60, by way of a residuary legacy, permits, albeit by way of a negative covenant, either party to file "further evidence", with the leave, or on the directions, of the Controller.

17. What the Opposition Board is required to consider, under Rule 56(4) is, therefore

(i) the post grant opposition along the evidence filed therewith, by the post grant opponent, under Rule 57,

(ii) the reply statement, along with the evidence filed therewith, by the patentee, under Rule 58,

(iii) the evidence filed by the post grant opponent under Rule 59, to meet the evidence filed by the patentee under Rule 58, and

(iv) further evidence, if any, filed by either party under Rule

18. This procedure, statutorily prescribed and salutary in its endeavour to ensure complete representation by, and opportunity to, the patentee and the post grant opponent has, unfortunately, in the present case, been observed only in its breach, which has resulted in this, otherwise wholly avoidable, writ petition.

19. Post grant opposition under Section 25(2) of the Patents Act, 1970 read with Rule 57 of the Patents Rules, 2003 was filed by Respondent 3, in the present case, on 24 September 2018. Respondent 3 filed, with the post grant opposition, certain documents, without any accompanying affidavit. What was filed by Respondent 3 on 24 September 2018, therefore, was a post grant opposition with certain documents but without any evidence.

20. Thus, no evidence was filed by Respondent 3 with its post grant opposition.

21. Mr. Anand submits that, as Respondent 3 had not filed any evidence with its post grant opposition, the petitioner, with its reply statement filed under Rule 58 of the Patents Rules on 15

January 2019, also did not file any evidence in reply.

22. Thereafter, on 14 February 2019, Respondent 3 filed a rejoinder to the reply statement filed by the petitioner on 15 January 2019, along with an affidavit of Poonam Raghuvanshi, to support the documents which were earlier filed on 15 January 2019.

23. This provoked the petitioner into moving a Miscellaneous Petition ("MP-1" hereinafter) before the learned Controller on 23 April 2019, objecting to the filing of the rejoinder by Respondent 3 as well as the filing of the affidavit of Ms. Poonam Raghuvanshi. Inter alia, it was contended that any evidence filed under Rule 59 of the Patents Rules could not travel beyond the evidence which was filed by the patentee with its reply statement under Rule 58. The patentee not having filed any evidence under Rule 58 - as, admittedly, no evidence had been filed by Respondent 3 with its post grant opposition under Rule 57 - Respondent 3 could not have filed the affidavit of Poonam Raghuvanshi under Rule 59.

24. Admittedly, the PGO, along with the documents filed by Respondent 3 on 24 September 2018, and the reply statement filed by the petitioner on 15 January 2019, were forwarded to the Opposition Board for consideration.

25. The Opposition Board appears to have forwarded its recommendations to the Controller of Patents on 10 October 2019. No copy of the recommendations of the Opposition Board was, at that time, provided to the petitioner.

26. On 7 February 2020, the petitioner filed a second Miscellaneous (hereinafter "MP-2"), seeking to place further evidence on record under Rule 60 of the Patents Rules. Mr. Anand's contention is that the affidavit of Poonam Raghuvanshi, filed on 14 February 2019, as well as the documents filed by Respondent 3 on 24 September 2018, could not have been taken into account. He submits that, had they been filed simultaneously on 24 September 2018, they would have constituted "evidence" in view of Section 79, and the petitioner would have filed evidence in reply under Rule 58. As they were not filed as "evidence" under Rule 57, the petitioner, too, did not file any evidence under Rule

58. The petitioner having thus been illegally deprived of its opportunity to file evidence under Rule 58, the documents filed by Respondent 3 on 24 September 2018 could also not be taken into consideration by the Opposition Board.

27. In the alternative, if they were to be taken into account, the petitioner would also have to be granted permission to file its evidence by way of response thereto, as it would have done under Rule 58, had the documents been initially filed by Respondent 2 by way of evidence under Rule 57. That opportunity having been denied to the petitioner, Mr. Anand's contention was that, at least, at that stage, the petitioner ought to have been permitted to place evidence on record, to meet the evidence in the form of the documents filed by Respondent 3 on 24 September 2018 read with the affidavit of Poonam Raghuvanshi filed on 14 February 2019.

28. MP-2 continues to languish, undecided, till date.

29. In the interregnum, on 18 April 2023, orders were passed by the Controller, rejecting MP-1. The order also communicated, to the petitioner, the recommendations of the Opposition Board and fixed hearing in the post grant opposition on 30 May 2023 at 10.00AM.

30. By orders passed by this Court, the next date of hearing stands fixed to 11 August 2023.

31. While accepting that the scheme of Rule 57 to 60 may not have been strictly followed in the present case, Ms. Sharma and Mr. Harish Vaidyanathan Shankar submit that no prejudice could be said to have, thereby, resulted to the petitioner. Ms. Sharma further emphasized, and repeatedly, that the petitioner had every opportunity, was it so inclined, to move an application for leading additional evidence under Rule 60, but did not do so till

32. Having considered the statutory provisions and examined the rival contentions advanced at the Bar, the position that emerges is as under:

> (i) Rule 57 envisages the filing only of a written statement/post grant opposition and evidence. Documents, unaccompanied by any supporting affidavit, do not constitute "evidence". On that aspect, Ms. Sharma, too, does not join the issue. The documents which were filed by Respondent 2 with its post grant opposition on 24 September 2018 were, therefore, filed in excess of the right to file documents conferred by Rule
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> (ii) Rule 56(4) requires the opposition board to examine the post grant opposition along with documents filed under Rules 57 to 60. Inasmuch as the documents filed by Respondent 2 with the post grant opposition on 24 September 2018 cannot be regarded as documents allowed to be filed under Rule 57, i.e. as "evidence", the Opposition Board could not have taken the said documents into consideration.

(iii) Had Respondent 3 actually filed the said documents as evidence under Rule 57, in accordance with Section 79 of the Patents Act - which is what the rule permitted Respondent 3 to do - the petitioner would have had an opportunity, under Rule 58, to file evidence by way of reply, to meet the evidence filed by Respondent 3. Respondent 3 having not filed any evidence under Rule 57, the petitioner was also denied the opportunity of filing reply evidence under Rule 58.

(iv) It was only after the reply statement, unaccompanied by reply evidence, was filed by the petitioner under Rule 58 that, in a manner completely foreign to the Patents Rules, the Respondent 3 proceeded to file the affidavit of Ms. Poonam Raghuvanshi along with a rejoinder affidavit. Ms. Sharma candidly acknowledges that the said affidavit was essentially intended to support the documents which were filed by Respondent 3 on 24 September 2018. In other words, what ought to have been done by Respondent 3 on 24 September 2018 came to be done by Respondent 3 only on 14 February 2019.

(v) The rejoinder affidavit would be required to be struck off the record, as Rule 59 does not permit the filing of any such affidavit.

(vi) Had the procedure been correctly followed, Respondent 3 ought to have filed the documents with its post grant opposition, accompanied by the affidavit of Poonam Raghuvanshi so that the said documents could constitute "evidence". In that event, the petitioner would also have had an opportunity to file reply evidence under Rule 58. The Opposition Board would, then, under Rule 56(4), would have considered the notice of opposition along with the evidence filed with it, and the reply statement along with the evidence filed with the reply statement.

(vii) The failure, on the part of Respondent 3, to file any affidavit in support of the documents filed with the post grant opposition resulted in a situation in which the Opposition Board had with it only the documents irregularly filed by Respondent 3 on 24 September 2018, with no evidence in response from the side of the petitioner.

33. Learned Counsel are ad idem that the recommendations of the opposition board have great persuasive value. This aspect stands underscored by the following passages from the judgment of the Supreme Court in Cipla Ltd v. U.O.I.10:

> "11. Provisions of the Act and the Rules, therefore, clearly indicate that the Opposition Board has to make its recommendations after considering the written statement of opposition, reply statement and evidence adduced by the parties with reasons on each ground taken by the parties. Rule 62 also empowers the Controller to take into consideration the reasons stated by the Opposition Board in its report. In other words, the report of the Opposition Board has got considerable relevance while taking a decision by the Controller under Section 25(4) of the Act read with Rule 62(5) of the Rules.
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> 12. The Opposition Board in a given case may make a recommendation that the patent suffers from serious defects like lack of novelty, lack of inventive steps, etc., so also it can recommend that the patent shall be granted since the invention has novelty, inventive steps, etc. Such recommendations are made after examining the evidence adduced by the parties before it. Unless the parties are informed of the reasons, for making such recommendations they would not be able to effectively advance their respective contentions before the Controller. Section 25(3)(b) read with Rule 56(4) cast no obligation on the Opposition Board to give a copy of the report to either of the parties. So also no obligation is cast under Section 25(4) or under Rule 62 on the Controller to make available the report of the recommendation of the Opposition Board. But considering the fact that the report of the Opposition Board can be crucial in the decision-making process, while passing order by the Controller under Section 25(4), principles of natural justice must be read into those provisions. Copy of the report/recommendation of the Opposition Board, therefore, should be made available to the parties before the Controller passes orders under Section 25(4) of the Act."

(Emphasis supplied)

34. The Supreme Court, in Cipla10, therefore, characterized the report of the Opposition Board as "crucial". Ms. Sharma, using another expression, states that the recommendations of the opposition board have "great persuasive value". Recommendations which are crucial or which have great persuasive value and which, therefore, tilt (2012) 13 SCC 429 the scales in favour of one party or the other, have to be returned only after strict compliance with the procedural rules stipulated in that regard. Any failure to ensure such compliance has, in built in it, prejudice, and no separate prejudice needs to be shown by the party against whose interest the failure to observe the statutorily prescribed procedure has operated.

Conclusion

35. For the aforesaid reasons, the present petition is disposed of thus:

> (i) The recommendations of the Opposition Board, in the manner in which they came to be returned, cannot sustain. They are, therefore, quashed and set aside.
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> (ii) The documents filed by Respondent 3 on 24 September 2018 are permitted to be treated as evidence led by Respondent 3 under Rule 57 on the basis of the affidavit of Poonam Raghuvanshi, which came to be filed on 14 February 2019.

(iii) MP-2, filed by the petitioner on 7 February 2020, under Rule 60 for leading additional evidence is allowed. Additional evidence, in terms of the prayer contained in MP-2 may be filed by the petitioner within a period of four weeks from today.

(iv) The additional evidence led by the petitioner shall be treated as evidence led in terms of Rule 58 of the Patents Rules.

(v) The rejoinder affidavit filed by Respondent 3 on 22 May 2019 shall stand struck off the record.

(vi) The matter would be placed before the Opposition Board, to take a fresh decision, de novo, after considering all the documents including the documents filed by Respondent 3 along with its post grant opposition on 24 September 2018, the affidavit of Poonam Raghuvanshi in support thereof, the reply statement filed by the petitioner on 14 February 2019 and the evidence, if any, which the petitioner would lead in accordance with the permission granted by this Court today.

(vii) In case either of the parties desires to lead any further evidence, that would have to abide by Rule 60 of the Patent Rules. A separate application would have to be moved in that regard and it would be for the Controller General to take a decision in that respect.

36. In the circumstances, the date of 11 August 2023 presently fixed stands cancelled. The Controller General, or the competent officer, would proceed in the matter further in accordance with the directions contained hereinabove.

37. The petition stands allowed in the aforesaid terms.

38. The learned Controller General is requested to ensure that, hereafter, there is strict compliance with the provisions of the Patents Rules, particularly Rule 57, read with the judgment of the Supreme Court in Cipla10, while dealing with and processing pre- or post-grant oppositions.

C.HARI SHANKAR, J AUGUST 9, 2023 ar