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

Date of Decision: 12th July, 2022

+ **W.P.(C)-IPD 91/2021 & CM 28/2022, CM 33-34/2021**

NATCO PHARMA LIMITED

..... Petitioner

Through: Mr. Adarsh Ramanujan, Ms. Mitul Dasgupta, Mr. Samik Mukherjee, Mr. S. Shekher & Mr. Afzal B. Khan, Advocates (M-9881880037)

versus

UNION OF INDIA & ORS.

..... Respondents

Through: Mr. Hemant Singh, Ms. Mamta Rani Jha, Mr. Siddhant Sharma & Mr. Abhay Tandon, Advocates for R-4 (M-9557629905).

CORAM:

JUSTICE PRATHIBA M. SINGH

Prathiba M. Singh, J. (Oral)

1. The present petition has been filed by the Petitioner/Opponent- Natco Pharma Ltd. (*hereinafter 'Opponent'*) in respect of pre grant opposition proceedings against the patent application of Respondent No.4/Applicant- Novartis A.G. (*hereinafter 'Applicant'*). The prayer in the petition is to set aside the order dated 16th September, 2021 passed by the Asst. Controller refusing the Opponent's application seeking cross-examination of the Applicant's witnesses. The reliefs sought are:

“a. A writ in the nature of certiorari quashing/setting aside the Impugned Order dated 16.09.2021, and a writ in the nature of mandamus and/or any other appropriate writ, order or direction, directing the Respondent Authorities to pass appropriate directions to enable the Petitioner an opportunity to cross examine Dr. Michael Motto, Dr. Allan S. Myerson and

Dr. Gauri Billa in an expeditious and time bound manner in pre grant opposition proceedings preferred by the Petitioner in Application No. 4412/DELNP/2007; and

b. A writ in the nature of mandamus and/or any other appropriate writ, order or direction, directing the Respondent Authorities to pass appropriate directions to first disposing of the pending Interlocutory Applications I and III, particularly the petition under 137 dated 27.01.2020 preferred by the Respondent No. 4 and the Form-13 with amended claims dated 06.06.2020, respectively; in an expeditious and time bound manner preferred by the Respondent No. 4 in Application No. 4412/DELNP/2007 followed by a final hearing under Section 25(1);

c. For an appropriate writ order or direction restraining the Respondent Authorities from proceeding with the determination/ disposal/ decision on the Patent Application No. 4412/DELNP/2007 during the pendency of the instant Writ Petition;

d. Pass such further order or issue any other appropriate writ(s)/ order(s) further to the Prayers, as to this Hon'ble Court may deem fit and proper;"

2. The background of the present petition is that the Applicant filed PCT application being PCT/US2006/043710 on 8th November, 2006 which had 85 claims (**Claim Set 1**). Thereafter, Indian application bearing no. 4412/DELNP/2007 titled "PHARMACEUTICAL COMBINATIONS OF AN ANGIOTENSIN RECEPTOR ANTAGONIST AND AN NEP INIBITOR" was filed on 8th June, 2007 with the Indian Patent Office. The Indian application was filed along with an amendment vide a Form-13 with only 29 claims (**Claim Set 2**). The application was published under Section

11A of the Patents Act, 1970 (*hereinafter* 'Act') on 24th August, 2007. A request for examination was made on 06th November, 2009 and the First Examination Report (*hereinafter* 'FER') was issued on 30th January, 2015. In the FER, Form-13 filed on 8th June, 2007 and 16th January, 2008 were not allowed by the Patent Office for not being filed in the prescribed manner. The Applicant is stated to have made a representation in respect of this decision of the Patent Office.

3. Another amendment (***Claim Set 3***) with 17 claims was filed by the Applicant on 27th November, 2015 in response to a FER. A hearing was held on 27th May, 2016 and on 30th May, 2016 a fourth amendment (***claim Set 4***) was filed along with the written submissions whereby claims 1 to 17 were reduced to claims 1 to 8. The amendment *inter alia* was for the deletion of crystalline, amorphous form which were objected to by the Controller under section 3(d) of the Act in the hearing notice.

4. The Opponent- NATCO filed a pre-grant opposition under section 25(1) of the Act read with Rule 55 of the Patent Rules, 2003 (*hereinafter* 'Rules') against the grant of the patent on 6th September, 2016 on the basis of Claim Set 3 i.e., which contained claims 1 to 17. In the said pre-grant opposition, various grounds were raised by the Opponent including lack of inventive step, insufficiency and non-compliance of Section 8 and non-patentability [under Sections 3(d) and 3(e) of the Act].

5. In response to the pre-grant Representation, the Applicant filed its reply statement dated 3rd March, 2017 but no evidence was attached with the same. The claim set attached with the reply of the Applicant was Claim Set 4.

6. In the meantime, a suit for infringement was filed by the Applicant-against the Opponent being **CS(COMM) 62/2019** titled **Novartis AG v. Natco Pharma Ltd.** wherein an ad-interim injunction order dated 27th March, 2019 was granted protecting right in IN 229051 in the following terms:

“8. In my opinion, the objections filed by the plaintiff would require a little more detailed consideration. Accordingly, I direct that till further orders, the defendant is restrained from using the impugned product / pharmaceutical composition or any other drug which has pharmaceutical composition comprising combination of Sacubitril + Valsartan as sodium salt complex or in any other form as may amount to infringement of Indian Patent No.229051 of the Plaintiff No.1.”

7. A Hearing was fixed in the pre-grant opposition on 9th January, 2020. However, adjournment was sought by the Applicant. In the meantime, further pre-grant oppositions against Applicant's patent applications have also been filed by -

- Indian Pharmaceutical Alliance (IPA),
- Mr. Kumar Sushobhan,
- Dr. Reddy's Laboratories Ltd.,
- G. Srinivasa Rao.

Pleadings in these oppositions and the examination of the application proceeded parallelly.

8. The Opponent filed a letter to bring on record certain documents on 6th January, 2020 including pleadings from **CS(COMM) 62/2019**. An interlocutory application under Rule 137 of the Rules was moved by the

Applicant on 27th January, 2020 seeking to correct some errors in earlier reply/ correspondence. On 6th June, 2020 a new set of claims (**Claim Set 5**) was filed by the Applicant along with the affidavits of Dr. Micahel Motto, Dr. Allan S Myerson and Dr. Gauri Billa. These three affidavits along with the Form-13 were filed before the Controller and a fresh hearing in the pre-grant opposition was fixed.

9. In the meantime, repeated adjournments in the pre-grant oppositions were also objected to by the Applicant before the IPAB. The IPAB vide order dated 3rd February, 2021 directed the Patent Office to hear the pre-grant oppositions expeditiously. The operative portion of the order is extracted below:

“16. Keeping in view the above mentioned directions, we, vacate the decision of Resondent no. 2 to defer the pre-grant hearings till physical hearing starts. We direct the Resondent No. 2 to offer hearing through Video Conferencing to all the parties in seriatim as clarified in earlier paragraphs, strictly following the directives noted above and decide the matter on merit, strictly within 3 months from the issuance of this order.”

10. At that stage an application dated 7th May, 2021 was filed by the Opponent seeking cross examination of the expert witnesses whose affidavit was sought to be relied by the Applicant. Without deciding the Opponent's request for cross-examination, the hearing in the pre-grant opposition proceedings were held pursuant to the order of the IPAB, over a period of four to five days. Ld. Counsels for the parties inform the Court that all opponents and the applicants have been heard extensively between 13th to 18th May, 2021.

11. Though, the arguments are stated to have been heard in the pre-grant oppositions, orders are yet to be passed by the Patent Office. A writ petition being *W.P.(C) 5558/2021* titled *Natco Pharma Limited v. Union of India* was filed by the Opponent seeking directions for cross-examination of the Applicant's expert witnesses. The same was disposed of by a ld. Single Judge of this Court on 27th May, 2021 directing the Patent Office to dispose of the application by NATCO seeking cross-examination and directing a decision on merits at least 10 days after the order of cross-examination. The said directions are captured hereinbelow:

“8. The writ petition is therefore disposed of with the following directions, with the consent of learned counsel:

a) The Controller is directed to dispose of the application dated 07.05.2021 filed by Natco for cross-examination of the expert witnesses cited by Novartis, expeditiously and preferably within two weeks from today. In the event the Controller considers it necessary, further hearing may be granted to the parties for this purpose.

b) In the event the aforesaid application is decided against Natco, the final decision of Novartis' patent application not be pronounced for a period of 10 days after communication of the order to Natco.

c) In the event the application is decided in favour of Natco, the matter be fixed for cross-examination after hearing learned counsel for the parties with regard to the schedule and modalities for the cross-examination. The Controller will take the submissions into account and pass appropriate orders, in accordance with law.

d) With regard to other pending interlocutory applications referred to by Mr. Grover, I find that

the present petition does not concern any other application. However, in order to expedite the final disposal of the patent application, the parties are at liberty to make their submissions before the Controller in this regard, who will pass appropriate orders.

e) After the consideration of the aforesaid application and disposal thereof, the Controller will also endeavour to dispose of the patent application filed by Novartis, as expeditiously as possible and practicable.

f) Learned counsel for the parties assure the Court that their clients will cooperate in the expeditious implementation of the aforesaid directions, and disposal of the proceedings before the Controller.”

12. Vide order dated 16th September, 2021, i.e., the ld. Asst. Controller has rejected the request of the Opponent for cross-examination of the expert witnesses of the Applicant. The ground on which the said request has been rejected is that under the extant Act and Rules governing pre-grant oppositions, the enquiry contemplated at the stage of pre-grant opposition is summary in nature in the form of a representation which should be decided expeditiously. The Controller further held that cross-examination under section 79 of the Act is discretionary in nature and the same cannot be claimed as a matter of right. In arriving at the above conclusion, the ld. Asst. Controller has relied up the judgment of Bombay High Court in ***Glochem Industries v. Cadila Healthcare 2010 (44) PTC 362 (Bom)***; ***Guest Keen Williams Ltd. v. Controller of Patents 1985 Cal 334***; ***Onyx Therapeutics v. Union of India, 2019(78)PTC189(Del)***.

13. The Asst. Controller was further of the opinion that the Opponent could have asked for cross examination if there was any technical error in

the Affidavit filed. However, the Opponent had failed to prove any such technical error in the affidavit. The Opponent cannot also object to filing of the affidavit, as the Opponent itself filed additional documents in January, 2020 and the affidavits were filed in response to those additional documents. The objective of the pre-grant oppositions is to aid in examination of the application; therefore, cross examination of experts is not routine in proceedings of such nature. The Asst. Controller emphasized the need to avoid multiplicity of proceedings and preventing the abuse of Section 25(1) of the Act. Thus, the application for cross examination filed by the Opponent was refused. This order is under challenge in this writ petition.

Submissions by parties:

14. Various grounds have been raised by both Id. counsels for the parties. Mr. Adarsh Ramanujan, Id. Counsel appearing for the Opponent challenges the order and the procedure being followed by the Patent Office on several grounds -

- i. That the Patent Office ought to have first given a ruling as to whether the amendments filed by the Applicant were allowed and if allowed, which is the final set of claims being considered for grant.
- ii. Upon this decision being made, the pre-grant opponent ought to be awarded a proper hearing in respect of the claims which are finally being considered by the Patent Office.
- iii. Cross examination ought to have been permitted as the affidavits were filed by the Applicant several years after pleadings were completed by the parties and no leave was taken

for the same. There are grounds which need to be confronted to the witness.

- iv. One of the decisions ***Onyx Therapeutics Inc. & Ors. v. Union of India & Ors. MANU/DE/4664/2019*** referred to in the impugned order is an overruled decision.
- v. No proper procedure is being followed by the Patent Office in pre-grant oppositions. Amendments are being entertained parallelly and pre-grant opponents are not given adequate opportunity to challenge the amended claims.
- vi. The amendments sought to be made by the Applicant are beyond what is permissible under Section 57 and 59 of the Act. The final set of amended claims seek to add crystalline and amorphous forms of the compound which were withdrawn in Claim Set 3 filed on 30th May, 2016.

15. On the other hand, Mr. Hemant Singh, Id. Counsel for the Applicant submits that:

- i. The patent application of the Applicant, which was filed way back in 2007, is not being allowed to proceed further due to the repeated hinderances and obstacles being caused by pre-grant oppositions.
- ii. Pre-grant oppositions are being filed and entertained by the Patent Office in an indiscriminate manner even several years after the publication under Section 11A of the Act.
- iii. Due to the delays on part of the Patent Office in adjudicating of the pre-grant oppositions, more pre grant oppositions are being

filed by various parties without any proper system being followed.

- iv. The final set of amended claims which are on record are all claims which are included in Claim Set 3 consisting of claim 1 to 17 which has been supplied to the Opponent. Thus, the Opponent has had the opportunity to oppose all the claims as they currently stand with the final amendment.
- v. Cross-examination cannot be claimed as a matter of right by the Opponent as it would unduly delay the examination and decision on the Applicant's patent application.
- vi. Even if the patent is granted today, the term of the patent expires in 2026 and only four years of the life of the patent is remaining.

Analysis and Findings:

16. Heard ld. counsels for the parties. The chronology of events, in the present writ, clearly shows that the proceedings in the patent application and the pre-grant opposition have been delayed substantially. Blame for the delay cannot be attributed to any one factor or reason, but in the opinion of this Court both parties are to blame. On the one hand, the applicant continues to amend its claims from time to time over a period of five years between 2016 to 2021. On the other hand, the patent application has been exposed to multiple oppositions by several parties due to delay in the examination process. In the opinion of this Court, there ought to be a systematic manner in which proceedings in pre-grant oppositions are conducted. Repeated filing of pre-grant oppositions due to non-existence of any time limits for filing a pre grant opposition and delay in adjudication of

one pre-grant opposition, usually results in further pre-grant oppositions being filed leading to further delays in grant of patent. The patent application has the chance of being caught up in the swirl of pre-grant oppositions by Opponents. Amendments by the Applicant who gets wiser with each objection being taken, leads to further delays.

17. It is the settled position in law, as held in ***M/s UCB Farchim SA v. M/s Cipla Ltd. [W.P.(C) No. 332/2010 order dated 08th February, 2010]*** that a pre-grant opposition proceeding is in aid of the examination of the patent application. The relevant part of this judgment is set out below:

“Distinction between pre-grant and post-grant opposition

13. In the first instance a distinction has to be drawn between a pre-grant opposition and a post-grant opposition. While a pre-grant opposition can be filed under Section 25 (1) of the Patents Act at any time after the publication of the patent application but before the grant of a patent, a post-grant opposition under Section 25(2) of the Patents Act has to be filed before the expiry of one year from the date of the publication of the grant of patent. A second significant difference, after the amendment of 2005, is that a pre-grant opposition can be filed by ‘any person’ whereas a post-grant opposition under Section 25(2) can be filed only by ‘any person interested’. It may be noticed that the application for revocation of a patent in terms of Section 64 of the Patents Act can also to be filed only by ‘any person interested’. In other words, the post-grant opposition and the application for revocation cannot be filed by just about any person who is not shown to be a person who is ‘interested’. A third significant difference is that the representation at the stage of pre-grant is considered by the Controller himself. Rule 55 of the Patents Rules requires the Controller to consider the ‘statement and evidence

filed by the applicant' and thereafter either refuse to grant the patent or require the complete specification to be amended to his satisfaction. Of course, in that event notice will be given to the applicant for grant of patent who can file his reply and evidence. **This Court finds merit in the contention that the pre-grant opposition is in fact 'in aid of the examination' of the patent application by the Controller.** The procedure is however different aspect as far as the post-grant opposition is concerned. There in terms of Section 25 (3), the Controller has to constitute an Opposition Board consisting of such officers as he may determine and refer to such Opposition Board the notice of opposition along with other documents for its examination and recommendations. After receiving the recommendations of the Opposition Board, the Controller gives the patentee and the opponent an opportunity of being heard. The Controller then takes a decision to maintain, amend or revoke the patent. The fourth major difference between the pre-grant and the post-grant opposition is that while in terms of Section 117 A an appeal to the IPAB is maintainable against the order of the Controller in a post-grant opposition under Section 25(4) of the Patents Act, an appeal has not been expressly been made available against an order made under Section 25(1) of the Patents Act.”

18. The language used in Section 25(1) of the Act is in contrast with the language used in Section 25(2) of the Act. A pre-grant opposition is a 'representation by way of opposition' in writing by "any person". Whereas, Section 25(2) of the Act is a 'notice of opposition' by "any person interested". A Representation under Section 25(1) of the Act does not strictly follow the norms laid down under the Code of Civil Procedure. However, since Rule 55(4) of the Rules contemplates filing a reply

statement and evidence, if the applicant wishes to, it can be said that the proceedings is adjudicatory as the same is adversarial in nature.

19. The proceeding in a pre-grant opposition and simultaneous examination of a patent application, however, cannot also result in a situation where the pre grant opponent is kept in dark about the developments taking place in the examination process. For example, when amendments are filed by the Applicant, an immediate decision ought to be taken on allowing or disallowing the amendment so that there is transparency and clarity as to what are the claims being considered by the Controller. A short and brief order should be passed in respect of the amendments which should be uploaded on the website of the Patent Office so that everyone concerned would know the decision on the amendment. In any event, if an amendment is being carried out during the pendency of a pre-grant opposition, the ruling on the amendment ought to be sent to the pre-grant opponent as well. Sometime amendments are carried out during the course of hearings across the table as well, when the patent agent of the Applicant attends the hearing before the Controller. In such a scenario, the Controller ought to examine the said amendments and convey the decision to the Applicant, and if the Opponent is present, even to the Opponent.

20. In the present writ it is noticed by the Court that there are four amendments on record filed by the Applicant and hence five sets of claims have been filed as late as on June, 2021 much after the completion of the pleadings in the pre-grant opposition.

21. The Applicant justifies filing of the expert's affidavit on the ground that the Opponent had filed certain additional documents. Be that as it may, the fact is that three substantive affidavits have been filed by the Applicant

along with an amended set of claims on 6th June, 2021. Rulings on the amendment are yet to be issued by the Patent Office. Thus, in the opinion of the Court, an opportunity ought to be granted to the Opponent to rebut the evidence of the Applicant. The Opponent- Natco has agreed to not insist on its prayer seeking cross examination of Applicant's witnesses- Dr. Michael Motto, Dr. Allan S. Myerson and Dr. Gauri Billa, if it is given an opportunity to file affidavits of its own experts in rebuttal. The said arrangement is not objected to by the Applicant. In the above background, and in order to expedite the decision on the application and the pre-grant opposition, the following directions are issued:

- i) the Opponent is permitted to file affidavits of its own experts in rebuttal to the three expert affidavits filed by the Applicant, within a period of four weeks.
- ii) If any documents are filed by the Opponent along with the said expert affidavits, the same shall be dealt with by the Applicant by way of additional written submissions within one week thereafter, without any further documents being filed by the Applicant.
- iii) The Opponent is also permitted to file its additional written submissions within two weeks after filing of additional written submissions by the Applicant. The written submissions filed by both the parties shall be considered by the Controller for final decision in the pre-grant opposition;
- iv) Parties shall appear before the Patent Office on 12th September, 2022 at 2:30 p.m. Both the Applicant and the Opponent shall be given one hour each to make their submissions.

- v) The situation as it exists today is that there has been no ruling on any of the amendments which have been filed by the Applicant. Thus, before the commencement of oral hearing in the pre-grant opposition, the Controller shall communicate orally to both the parties as to which of the amendments are being allowed and which would be the final set of claims which is being considered for grant.
- vi) On the said date, after hearing the parties for one hour each, the final decision on the application/pre-grant opposition shall be given by the Patent Office on or before 15th November, 2022. The final decision rendered shall be communicated to all the parties and shall also be uploaded on the website of the Patent Office;
- vii) It is clarified that the hearing of any other opposition proceeding which has already concluded is not being re-opened by this Court;
22. The observations made in respect of amendments in the present order shall not be applicable to amendments directed by the Controller under Section 15 of the Act.
23. All contentions of parties are left open. This order shall not be treated as an opinion on the merits of the application or the pre-grant opposition.
24. The Petition is disposed of with no orders as to costs. All pending applications are also disposed of.

PRATHIBA M. SINGH
JUDGE

JULY 12, 2022/dj/sk
(corrected & released on 16th July, 2022)