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

+ LPA 229/2019

Date of Decision: 26th September, 2019

ONYX THERAPEUTICS INC Appellant
Through: Mr.Anil Dutt, Adv. with Ms.Sutapa
Jana, Adv.

Versus

UNION OF INDIA & ORS Respondents
Through: Mr.Manish Mohan, CGSC for UOI.
Mr.Jayant Mehta, Adv. with Mr.Afzal B.Khan,
Ms.Smiti Verma, Adv. for R-3

+ LPA 249/2019

FRESENIUS KABI ONCOLOGY LTD Appellant
Through: Mr.Jayant Mehta, Adv. with Mr.Afzal
B.Khan, Ms.Smiti Verma, Adv.

Versus

UNION OF INDIA & ORS Respondents
Through: Mr.Manish Mohan, CGSC for UOI.
Mr.Anil Dutt, Adv. with Ms.Sutapa Jana, Adv. for
R-3.

CORAM:

HON'BLE THE CHIEF JUSTICE

HON'BLE MR. JUSTICE C.HARI SHANKAR

J U D G M E N T

: **D. N. PATEL, Chief Justice (Oral)**

1. This LPA 229/2019 has been preferred by the original petitioner whose writ petition, W.P.(C) No.5022/2017 was decided by the impugned judgement and order dated 22nd February, 2019 (Annexure - A to the memo of LPA 229/2019). LPA 249/2019 has been preferred by respondent No.3 in the aforesaid writ petition. Thus, both these LPAs arise out of the impugned

judgment and order dated 22nd February, 2019 passed by the learned Single Judge in W.P.(C) No.5022/2017.

2. M/s Onyx Therapeutics Inc. (hereinafter referred to as “**Onyx**”) sought, by W.P.(C) No.5022/2017, quashing of orders/communications dated 11th April, 2017 and 12th May, 2017, and for restoration of the earlier order, dated 10th April, 2017, passed by respondent No.2 (the Deputy Controller of Patents and Designs).

3. **Onyx** had applied for a patent bearing application No.5644/DELNP/2006 with the title “Compounds for Enzyme Inhibition”, which was granted on 9th April, 2013 bearing Patent No.255964. Onyx had also preferred an application in United States of America and thereafter in India. The medicine is meant for compounds and methods for enzyme inhibition. In USA, the application was preferred under the Patent Cooperation Treaty (‘PCT’) being PCT No.US/05/012740 dated 14th April, 2005. **Onyx** preferred an application under Section 7(1A) of the **Patents Act, 1970** (hereinafter referred to as ‘**the Act, 1970**’) in India vide application No.5644/DELNP/2006 dated 27th September, 2006. Publication in PCT was made on 10th November, 2005 and in India, it was published under Section 11A of the Act, 1970 on 31st August, 2007 whereby respondent No.2 issued First Examination Report (‘FER’) on 13th October, 2011 under Section 14 of the Act. Thereafter, post the response to FER and patent was granted by respondent No.2 to Onyx on 9th April, 2013.

4. After publication of this patent in the patent’s journal, Respondent No.3 in W.P.(C) 5022/2017, i.e. the appellant in LPA No.249/2019 (hereinafter referred to as ‘**Fresenius**’) filed a ‘post-grant opposition’ on 7th April, 2014 under Section 25(2) of the Act, 1970 read with Rule 55-A of the

Patent Rules, 2003 (hereinafter referred to as '**the Rules, 2003**'). Along with the aforesaid post-grant opposition, Fresenius filed the affidavit of an expert, namely Dr.Surajit Sinha.

5. Onyx filed a reply to the post-grant opposition under Rule 58 of the Rules, 2003 with a request to cross-examine the expert whose affidavit was filed by Fresenius along with its post-grant opposition.

6. On 1st September, 2014, Fresenius filed additional evidence under Rule 59 of the Rules, in the form of the affidavit of one more expert, namely, Dr.Prachi Tiwari.

7. To all these additional affidavits and the post-grant opposition, Onyx has also filed its reply initially on 3rd July, 2014 and, later, on 5th June, 2015.

8. The reply, dated 5th June, 2015, of Onyx was sent by Respondent No.2 to the Opposition Board on 26th March, 2017 and hearing was fixed on 21st April, 2017.

9. In the meanwhile, on 7th April, 2017, Onyx requested for cross-examination of the aforesaid two experts, whose affidavits were filed by Fresenius namely Dr.Surjit Sinha and Dr.Prachi Tiwari. For the same, Respondent No.2 sent by e-mails on 8th April, 2017, and also on 10th April, 2017 to Fresenius. Vide order dated 10th April, 2017, Respondent No.2 allowed cross-examination of the aforesaid two experts, as sought by Onyx. Fresenius objected to the request to cross-examine the two expert witnesses produced by it, whereupon, vide order dated 11th April, 2017 Respondent No.2 withdrew the earlier permission granted by him, and directed Onyx to submit a proper application. This was one of the orders under challenge in W.P.(C) No.5022/2017.

10. Onyx submitted a formal application reiterating its request to cross-

examine Dr.Surajit Sinha and Dr.Prachi Tiwari, providing detailed reasons for its request. The request of Onyx was, however, declined by Respondent No.2 vide communication dated 12th May, 2017 (Annexure P-1 to the memo of LPA 229/2019), which reads thus:

“I think that I have clarified the same in advance of your such petition. *Prima facie* I do not find any reason with me as to invoke Section 77(a) or Section 79 for cross-examination in addition to affidavit. I also don't see any provision as to allow cross examination through such petition u/r 137 by either party in opposition proceedings u/s 25(2). Provision u/r 137 is meant for amendment to any document or any irregularity in procedures and not to such request for cross examination.

As such is hereby clarified once again that cross examination of Dr.Surajit Sinha and Dr.Prachi Tiwari may not be allowed during procedures in this opposition proceedings.”

11. Thus, the issue involved in the writ petition was whether Onyx should be allowed to cross-examine the experts, namely, Dr.Surjit Sinha and Dr.Prachi Tiwari, whose affidavits were filed by Fresenius.

12. Vide the impugned judgment dated 22nd February, 2019, the learned Single Judge has quashed and set aside the orders/communications of respondent No.2 dated 11th April, 2017 and 12th May, 2017 and allowed cross-examination, of Dr.Surajit Sinha and Dr.Prachi Tiwari, subject, however, to the condition that Onyx would file its affidavit of evidence prior thereto. Onyx and Fresenius are equally aggrieved by the impugned judgment of the learned Single Judge. Onyx is aggrieved by the subjection, of its right to cross-examine Dr.Surajit Sinha and Dr.Prachi Tiwari, on the precondition of producing its own evidence, whereas Fresenius objects to the very grant of permission, to Onyx, to cross-examine its experts.

13. Arguing on behalf of Onyx, Mr. Anil Dutt, learned counsel, contends that, once Fresenius has filed a post-grant opposition, and filed affidavits of experts for consideration by Respondent No.2, and Onyx had filed its reply, thereto, under Rule 58 of the Rules, cross-examination of the witnesses led by Fresenius had necessarily to be allowed to Onyx, irrespective of whether any evidence was tendered by Onyx, before Respondent No.2 or not. Moreover, Mr. Dutt submits that the Patentee is not required to cite any grounds or reasons, to justify its request to cross-examine the two experts whose affidavits have been filed by Fresenius. In fact, the reply filed by the Patentee, to the post-grant opposition, under Rule 58 of the Rules, itself constitutes the reasons as well as the justification, for seeking cross-examination of the experts. It is also submitted, by learned counsel for Onyx, that the veracity of the statement made in the affidavit by the experts can be checked only through cross-examination; therefore, allowing the cross-examination should be treated as a rule, and not as an exception. Grant of cross-examination facilitates Respondent No.2 in evaluating the evidentiary value of the affidavits filed by the experts in support of the post grant opposition.

14. It is also contended that the cross-examination ought to have been allowed by Respondent No.2 in the interest of justice. There is no need to give any evidence or reasons by the Patentee for cross-examination. The reasons are already in-built in the objections raised by the Patentee under Rule 58 of the Rules which are being filed by the Patentee. Moreover, separate application for cross-examination has also been given by the Patentee which is at Annexure -14 to the memo of LPA 249/2019. Furthermore, it is contended that these aspects of the matter have not been

properly appreciated by the learned Single Judge while allowing conditional cross-examination vide the impugned judgment and order dated 22nd February, 2019 and, therefore, to that extent, the judgment and order delivered by the learned Single Judge deserves to be modified to the extent that unconditional cross-examination of the experts may be allowed to Onyx.

15. It is submitted by learned counsel for Fresenius that no error has been committed by the learned Single Judge in requiring Onyx to lead its own evidence as a condition for being allowed to cross-examine the respondent's witnesses vide impugned order dated 22nd February, 2019. He asserts that no right to cross-examination vests with the Patentee.

16. Learned counsel for both the sides have taken this Court through various sections of the Patents Act and Rules made thereunder including Section 79 which is for cross-examination and the Rules, especially, Rule 55A, 56, 57, 58, 59 etc. It is further submitted by the learned counsel for Fresenius that the proceedings before Respondent No.2 are not judicial, but inquisitorial in nature and hence, cross-examination cannot be allowed without there being any disclosure of the reasons for cross-examination by the Patentee. Moreover, no evidence has been adduced by the Patentee. It is, therefore, submitted that Fresenius may also be granted an opportunity of cross-examination, if as a matter of rule, the cross-examination is to be allowed by this Court.

17. The learned counsel further submits that by virtue of grant of patent, a monopoly is created in favour of the Patentee. He submits that it is this monopoly, against which objection is filed by the Respondent, along with expert opinion, and that, therefore, Respondent No.2 was entitled to evaluate

the objections of Fresenius without the Appellant (Onyx) being permitted to cross-examine its experts. Nonetheless, if cogent reasons are given by the Patentee, the cross-examination can be allowed, otherwise not. According to learned counsel for Fresenius, these aspects of the matter have not been properly appreciated by the learned Single Judge while deciding W.P.(C) No.5022/2017 vide the impugned order dated 22nd February, 2019.

18. It is further submitted, by learned counsel for Fresenius, that no error was committed by Respondent No.2 in modifying the order, dated 10th April, 2017 vide order dated 11th April, 2017. Similarly, no error is committed by respondent No.2 while passing order/communication dated 12th May, 2017 whereby demand of cross-examination was denied. He submits that this aspect of the matter has also not been properly appreciated by the learned Single Judge while deciding W.P.(C) No.5022/2017 and, hence, the judgment and order passed by the learned Single Judge deserves to be quashed and set aside.

REASONS

19. Having heard learned counsel for both the parties and looking to the facts and circumstances of the case, it appears that the petitioner (Onyx) in W.P.(C) No.5022/2017 had applied under the Patent Cooperation Treaty vide application No.PCT/US/05/012740 and thereafter preferred an application for patent under Section 7(1A) of the Act on 27th September, 2006 vide application No. 5644/DELNP/2006. It further appears from the facts of the case that there was PCT publication on 10th November, 2005 and similarly, in India it was published under Section 11A of the Act on 13th August, 2007. First Examination Report was given on 13th October, 2011 under Section 14 of the Act. Onyx was then called upon to explain or to file

a response to the FER and, later, the patent was granted to Onyx by respondent No.2 on 9th April, 2013.

20. Thereafter, it was published in patent journals and later on Fresenius filed a post grant opposition on 7th April, 2014 under Section 25(2) of the Act read with Rule 55-A of the Rules along with the affidavit of expert, Dr.Surjit Sinha. Thereafter, additional objections were also filed by Fresenius, enclosing, therewith, an additional affidavit of Dr.Surjit Singh, along with the affidavit of Dr.Prachi Tiwari. Onyx then filed reply under Rule 58 of the Rules, 2003 with request to cross-examine the experts whose affidavits were filed by Fresenius.

21. It appears that the reply of Onyx and the request for cross-examination was sent to Fresenius by e-mail and a reminder was also sent by Respondent No.2 to Fresenius about the request of cross-examination by the Patentee and ultimately on 10th April, 2017, the cross-examination was granted by respondent No.2 to Patentee, however, on Fresenius raising objections regarding cross-examination, the respondent No.2 immediately on 11th April, 2017 withdrew the permission granted for cross-examination vide communication dated 11th April, 2017. The Patentee had once again requested for cross-examination which was further denied by communication dated 12th May, 2017 by respondent No.2.

22. Much has been argued under Section 79 of the Act about the cross-examination. For ready reference, Section 79 of the Patents Act, 1970 reads as under:-

“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 an affidavit, or may allow any party to be cross-examined on the contents of his affidavit.”

23. In view of the aforesaid provision, it has been argued by counsel for Fresenius that it is a discretionary power of Respondent No.2 to allow the cross-examination otherwise there is no right vested in the Patentee to cross-examine the experts whose affidavits have been tendered along with post grant opposition. We are not in agreement with this contention by the counsel for FRESENIUS, mainly for the following reasons:-

- (a) The cross-examination of experts is required looking to the objections filed by the Patentee under Rule 58 of the Patent Rules. For ready reference, Rule 58 of the Patent Rules is extracted hereunder:-

“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.” *(emphasis supplied)*

- (b) There is no need of any separate reasons to be given for cross-examination by the Patentee. The objections filed under Rule

58 of the Rules are the reasons for the cross-examination of the experts.

- (c) It is too much to expect to give reasons for the cross-examination by the Patentee. The cross-examination is an art to demolish what a witness is saying in the examination-in-chief. The defence may not be disclosed by the person who wants the cross-examination of a witness whose affidavit of evidence has been tendered.
- (d) Looking to the peculiar facts of the present case that patent has already been granted to the original petitioner and, thereafter, objections have been filed as post grant opposition by Fresenius along with evidence of two experts, thus cross-examination of these two experts will facilitate respondent No.2/Deputy Controller of Patents and Designs.
- (e) Looking to the power of the Deputy Controller under the Patents Act especially under Section 77 therein, the Deputy Controller exercises the powers of a Civil Court. For ready reference, Section 77 of the Patents Act is reproduced hereunder:-

“77. Controller to have certain powers of a civil court.

- (1) Subject to any rules made in this behalf, the Controller in any proceedings before him under this Act shall have the powers of a civil court while trying a suit under the Code of Civil Procedure, 1908 (5 of 1908), in respect of the following matters, namely:-

- (a) summoning and enforcing the attendance of any person and examining him on oath;

- (b) requiring the discovery and production of any document;
 - (c) receiving evidence on affidavits;
 - (d) issuing commissions for the examination of witnesses or documents;
 - (e) awarding costs;
 - (f) reviewing his own decision on application made within the prescribed time and in the prescribed manner;
 - (g) setting aside an order passed ex parte on application made within the prescribed time and in the prescribed manner;
 - (h) any other matter which may be prescribed.
- (2) Any order for costs awarded by the Controller in exercise of the powers conferred upon him under sub-section (1) shall be executable as a decree of a civil court.”

- (f) Thus, upon conjoint reading of Section 77 read with Section 78 of the Patents Act and Rule 55A, 56, 57, 58 and 59, it appears that there is no need to give separate reasons for cross-examination by the Patentee (Onyx) for cross-examination of the experts whose affidavits have been tendered by respondent No.3.
- (g) The learned Single Judge is, therefore, right in affirming the right, of Onyx, to cross-examine Dr.Surajit Sinha and Dr.Prachi Tiwari. It, however, appears from the order passed by the learned Single Judge dated 22nd February, 2019 that Onyx can cross-examine the experts only after giving evidence before respondent No.2. This is not required, looking to the objections filed by the Patentee under Rule 58 of the Patent Rules.

- (h) If the Patentee is not bringing other evidences before respondent No.2/Deputy Controller, they are doing it at their own risk and peril. The matter is already pending before the Deputy Controller.
- (i) We are not required to examine, in these proceedings, the outcome, on the ultimate merits of its case on the Appellant's (Onyx) decision not to lead its own evidence.
- (j) In these LPAs, we are only concerned with the cross-examination of the experts whose affidavits have been tendered by Fresenius along with post-grant opposition. Cross-examination has rightly been allowed by the learned Single Judge, however, there was no need to make it conditional.
- (k) Suffice it will be for the Patentee to file objections under Rule 58 of the Rules and the reasons given in the objections by the Patentee under Rule 58 are sufficient to allow cross-examination of the experts.

24. Learned counsel for Fresenius has placed reliance upon the decisions reported in ***Biotech Pharma Vs. Pharma Syant***, **2000 PTC 361** as well as decision reported in ***Finance Times Ltd. Vs. Times Publishing House Ltd.***, **2016 (234) DLT 305**. None of these judgments are helpful to the learned counsel looking to the peculiar facts of the present case that:-

- (a) The patent has already been granted to Onyx on 9th April, 2013.
- (b) Fresenius has filed post grant opposition under Section 25(2) of the Patents Act along with affidavits of the experts and heavy reliance is placed upon the affidavits of these two experts.
- (c) Objections have also been filed by the Patentee under Rule 58

of the Rules, 2003.

- (d) Moreover, both these judgments are under the Trademarks Act, 1999 and looking to Section 129 of the Trademarks Act, 1999, there is no provision for cross-examination whereas under Section 77 of the Patents Act, there is a provision for cross-examination of the witnesses. The word 'may' has been used in Section 77 of the Patents Act, it ought to be kept in mind that whenever heavy reliance is placed upon the experts' evidence which are being filed after the patent is granted to the applicant and when objections are filed under Rule 58 by the Patentee, the cross-examination should be allowed for the reasons stated in the objections filed by the Patentee.
- (e) Moreover, cross-examination is a touchstone for the examination-in-chief which is in the form of an affidavit. The cross-examination facilitates in arriving at truth by respondent No.2. Such cross-examination will not be prejudicial to Fresenius. If cross-examination is demanded without filing any objections under Rule 58 of the Rules, there could have been a valid decision for disallowing the cross-examination but looking to the peculiar facts of the present case, the original petitioner – Onyx has already filed objections under Rule 58, hence the cross-examination ought to be granted and that too without any condition of filing evidence by the Patentee.

25. For the aforesaid reasons, we hereby modify the order dated 22nd February, 2017 passed by the learned Single Judge in W.P.(C) No.5022/2017 to the extent that orders/communications dated 11th April,

2017 and 12th May, 2017 passed by respondent No.2/Deputy Controller of Patents and Designs are being quashed and set aside. Cross-examination of the experts, whose affidavits have been tendered by Fresenius is allowed without any condition. It is left at the discretion of the Patentee – Onyx to adduce evidence or not before Respondent No.2.

C.M.No.15502/2019 in LPA 229/2019

C.M.No.16609/2019 in LPA 249/2019

In view of the final orders passed in the LPAs, these applications also stand disposed of.

CHIEF JUSTICE

C.HARI SHANKAR, J

SEPTEMBER 26, 2019/‘anb’