\$~S.B.-1.

* IN THE HIGH COURT OF DELHI AT NEW DELHI

% <u>Date of Decision:12.08.2015</u>

+ LPA 804/2014 & C.M.No.21003 /2014 (stay)

BAYER CORPORATION

..... Appellant.

Through: Mr.Sudhir Chandra, Sr.Adv. with Mr.Sanjay Kumar, Ms.Arpita Sawhney, Mr.Arun Kumar Jena, Advs.

Versus

UNION OF INDIA & ORS.

..... Respondents

Through: Mr.Ripu Daman Bhardwaj, Adv. with

Mr.T.P.Singh, Adv. for R-1/UOI.

Ms.Sonia Sharma, Adv. for R-2 to 4.

Mr.Anand Grover, Sr.Adv. with Ms.Rajeshwari,

Mr. Tahir A.J., Advs. for R-5.

CORAM:

HON'BLE THE CHIEF JUSTICE

HON'BLE MR. JUSTICE RAJIV SAHAI ENDLAW

JUDGMENT

:Ms.G.ROHINI, Chief Justice (Oral)

- 1. This appeal is preferred against the order of the learned Single Judge dated 05.11.2014 in CM No.9687/2014 in W.P.(C) No.1971/2014.
- 2. The appellant before us is the writ petitioner (Bayer Corporation) which was granted Indian Patent No.215758 for a period of 20 years from 12.01.2000 for a pharmaceutical product titled "Carboxyarly Substituted Diphenyl Ureas". It is also not in dispute that the respondent No.5 (Nacto Pharma Ltd.) was granted a compulsory licence on 09.03.2012 under

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Section 84 of the Patents Act, 1970 for manufacturing the pharmaceutical product covered under the patent held by the Bayer Corporation, subject to certain terms and conditions, including that the said licence be used solely for the purpose of making, using, offering for sale and selling the drug covered by the Patent for the purpose of treating HCC and RCC in human beings within the territory of India.

3. W.P.(C) No.1971/2014 was filed by Bayer Corporation (for short 'Bayer') alleging that respondent No.5/Nacto Pharma Ltd. (for short 'NPL') was exporting its product "Sorafenat" outside India in violation of the terms of the compulsory licence. Thus, a Mandamus was sought directing the respondent Nos.1 to 4 to confiscate and seize the consignments for export containing product covered by compulsory licence including "Sorafenat" manufactured by NPL under the compulsory licence. This court while directing the pleadings to be completed, passed the following interim order on 26.03.2014 -

"Keeping in view the categorical conditions on which compulsory licence under Section 84 of the Patents Act, 1970 has been granted, respondents No.1 to 4 are directed to ensure that no consignment from India containing 'Sorafenat' covered by compulsory licence is exported.

The respondent No.5 is given liberty to apply to this Court for permission to export the drug 'Sorafenat' as and when it obtains permission from the Drug Controlling Authority for clinical purposes." (emphasis supplied)

4. On 23.03.2014, NPL filed CM No.6198/2014 seeking permission in terms of the interim order dated 26.03.2014 to export a small quantity not exceeding 15 gms. of "Sorafenat" and the prayer was allowed by this court

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by order dated 29.05.2014. Thereafter, NPL filed another application being CM No.9687/2014 seeking permission to export 1 kg. of "Sorafenat" to one of its partners in China for the purposes of conducting development/clinical studies and trials. Though the said application was opposed by Bayer on various grounds, this court allowed the application by the order under appeal dated 05.11.2014. Aggrieved by the same, Bayer (writ petitioner) filed the present appeal.

5. On 22.12.2014, we passed the following interim order:

"Having heard the learned counsel for both the parties, it appears to us that the question whether the respondent No.5 company can be permitted to export the goods in question to a country outside India even under Section 107-A of the Patents Act in spite of the fact that the compulsory licence granted to it by the Controller of Patents is restricted for the purpose of selling the drug within the territory of India, is an issue of importance and requires consideration.

Post on 16.01.2015.

Till such time, no further steps shall be taken pursuant to the order under appeal."

- 6. The said interim order has been extended from time to time and thus continued to be forced all through from 22.12.2014.
- 7. It may at the outset be mentioned that the question that requires consideration in the present appeal is whether the respondent No.5 NPL, who is holding a compulsory licence subject to the condition that it shall be used for the purpose mentioned therein within the territory of India, can claim the benefit of Section 107-A of the Patents Act for exporting its product to a country outside India. Since the very same issue is involved in

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the writ petition, it appears to us that instead of deciding this appeal on merits, it would be appropriate to direct the disposal of the writ petition itself within a time frame. The learned counsel for both the parties consented for the same. It is further represented by them that the writ petition now stands posted to 18.09.2015 before the learned Single Judge and that the same may be advanced.

- 8. The learned counsel for the parties also submitted that the Drug Controller General of India, who is the competent authority to issue NOC for export of drugs and pharmaceuticals and the Director, Drugs Control Administration, Government of Andhra Pradesh, Hyderabad, the authority who issued the drug license to NPL, are the necessary parties for deciding the issue involved in the writ petition effectively and conclusively. We agree with the learned counsel and accordingly, we implead the said authorities suo moto as respondents No.6 and 7 respectively to the writ petition.
- 9. Sh.T.P.Singh, the learned standing counsel for Union of India has accepted notice for the Drug Controller General of India and he undertakes to file the necessary counter affidavit within two weeks from today. So far as the Director, Drugs Control Administration, Government of Andhra Pradesh is concerned, notice returnable in one week be issued. The learned counsel for the appellant/writ petitioner is also permitted to serve the notice by electronic mail service. The appellant shall file the amended memo of parties in the writ petition within one week from today.
- 10. Since the writ petition is directed to be disposed of within a time frame, it is represented by Sh.Anand Grover, the learned Senior Counsel appearing for respondent No.5 NPL, on instructions, that NPL will not

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export its product 'Sorafenate' to China for any purpose whatsoever till the disposal of the writ petition. The statement of the learned senior counsel is placed on record.

- 11. Accordingly, without expressing any opinion on merits of the case, we dispose of the appeal as under:-
 - (i) The hearing of W.P.(C) No.1971/2014 shall stand advanced to 07.09.2015 from the date already fixed, i.e., 18.09.2015. Accordingly, the date fixed as 18.09.2015 shall stand cancelled and the writ petition be listed before the learned Single Judge on 07.09.2015.
 - (ii) The pleadings in the writ petition shall be completed by all the parties, including the impleaded respondents, by 07.09.2015.
 - (iii) W.P.(C) No.1971/2014 be disposed of within six weeks from today and all the parties shall co-operate for disposal of the writ petition within the time fixed.
 - (iv) Sh.Sudhir Chandra, the learned Senior Counsel for the appellant/writ petitioner and Sh.Anand Grover, the learned Senior Counsel for the respondent No.5 NPL undertake that no adjournment would be sought and that the fullest co-operation would be extended for expeditious disposal of the writ petition. The statement is placed on record.
 - (v) The writ petition shall be decided uninfluenced by any of the findings/observations/reasons assigned by the learned Single Judge in the order under appeal.
 - (vi) The statement of Shri Anand Grover, the learned Senior Counsel appearing for the respondent No.5 that NPL will not export its product 'Sorafenate' to China for any purpose whatsoever till the

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disposal of the writ petition is hereby placed on record.

12. A copy of order be given under the signature of the Court Master.

CHIEF JUSTICE

RAJIV SAHAI ENDLAW, J

AUGUST 12, 2015 kks

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