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

+ LPA 359/2017, CAV No.474/2017 & CM Nos.17922-924/2017

BAYER CORPORATION Appellant
Through: Mr.Amit Sibal, Sr. Advocate
With Mr.Sanjay Kumar, Ms.Arпита
Sawhney and Mr.Arun Kumar Jana,
Advocates
versus
UNION OF INDIA & ORS Respondents
Through: Mr.Ripu Daman Bhardwaj and
Mr.Sahaj Garg, Advocates for R-1
and 6/UOI
Mr.Sanjeev Narula, Sr.Standing
Counsel for R-2 to 4
Ms.Rajeshwari, Advocate for R-5

CORAM:
HON'BLE THE ACTING CHIEF JUSTICE
HON'BLE MS. JUSTICE ANU MALHOTRA

ORDER

% **12.05.2017**

CAV 474/2017

The caveator is represented and has been heard. The caveat is discharged.

CM No.17923-17924/2017 (Exemptions)

Exemptions allowed, subject to just exceptions.

LPA No.359/2017 and CM No.17922/2017 (Stay)

1. Issue notice to show cause as to why the appeal be not admitted.
2. Mr.Ripu Daman Bhardwaj, learned counsel, accepts notice on behalf of respondent No.1 and 6/Union of India, Mr.Sanjeev Narula, learned

counsel, accepts notice on behalf of respondents No.2 to 4 and Ms.Rajeshwari, learned counsel, accepts notice on behalf of respondent No.5/Natco Pharma Limited. Subject to the appellant taking steps, notice shall issue for the service of unserved private respondents.

3. Let the record of W.P.(C) No. 1971/2014 be called for the next date.

C.M. No. 17922/2017

4. Notice.

5. Mr.Ripu Daman Bhardwaj, learned counsel, accepts notice on behalf of respondent No.1 and 6/Union of India, Mr.Sanjeev Narula, learned counsel, accepts notice on behalf of respondents No.2 to 4 and Ms.Rajeshwari, learned counsel, accepts notice on behalf of respondent No.5/Natco Pharma Limited.

6. It is not disputed that the appellant before us is the patentee in respect of pharmaceutical product “SORAFENIB TOSYLATE”. Compulsory licence No.1 of 2011 with regard to the same was granted to the respondent No.5/ Natco Pharma Limited by the Controller of Patents (Mumbai) on 9th March, 2012. It is not disputed that this compulsory licence *inter alia* contained the following prohibition:

“g. The license is granted solely for the purpose of making, using, offering to sell and selling the drug covered by the patent for the purpose of treating HCC and RCC in humans within the Territory of India.”

(Emphasis)

5. It appears that issues arose *inter alia* with regard to respondent No.5/Natco Pharma Limited exporting the finished patented product to other countries resulting in filing of W.P.(C) No. 1971/2014 alongwith an application seeking interim protection against respondent No.5. In this writ

petition, on the application, an interim order dated 26th March, 2014 (page 205) was passed by the learned Single Judge in the following terms:

“ 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.”

7. Mr.Amit Sibal, learned senior counsel, appearing for the appellant has contended that so far as the patented product is concerned, rights in favour of the patentee have been statutorily recognized under Section 48 of the Patents Act, 1970. It is further pointed out that with regard to a suit complaining of rights, statutory recognition is given to the permissible infringement of the patents, defences to such legal action in Section 107 and 107A of the Patents Act, 1970. Learned senior counsel for the appellant would contend that Section 107A(a) has been stanchly pressed on behalf of the appellant for expediency, we extract the statutory provision hereunder:

*“ 107A. Certain acts not to be considered as infringement.—For the purposes of this Act.—
(a)Any act of making, constructing, [using, selling or importing] a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, [use, sale or import] of any product;”*

7. The submission on behalf of the appellants is that the bare reading of the statutory provisions shows that there is a prohibition on selling of a finished patented product which could include sale by exports; that even if it

could be held, the defendant is permitted to export patented invention, the same has to be confined to *“uses reasonably related to the development and submission of information required under any law by the foreign country.”* It is submitted that the appellant was aggrieved by the acts of respondent No.5/Natco Pharma Limited in exporting the finished patented product of the appellants which is not even a recognized defence under Section 107 and 107A of the Patents Act, 1970. It is further submitted that such exports are in undisclosed & unlimited quantities to the prejudice of the appellants rights.

8. Learned senior counsel for the appellant has vehemently contended that so far as dealing with the patented product is concerned, respondent No.5 has to be confined to the terms of the compulsory licence and that the action of respondent No.5/Natco Pharma Limited in exporting the finished product is not only violative of the terms of the compulsory licence but is **rank** dishonesty.

9. It is further submitted that despite the above position, the learned Single Judge has passed the impugned judgment dated 8th March, 2017 permitting respondent No.5 to export the patented invention subject to their furnishing an undertaking in terms of Section 107A, granting liberty to the appellant to bring appropriate proceedings at a subsequent stage. It is submitted that the learned Single Judge has erred in having been so permitted respondent No.5/Natco Pharma Limited, especially after giving a clear finding in paragraph No.42 that the export of patented product is an exclusive right of the patentee which is covered by Section 48 of the Act.

10. Our attention is drawn also to the observation in paragraph 59 of the order contending that the same is erroneous wherein the learned Single

Judge has held that a presumption stands drawn that further export of patented product by a non-patentee is “deemed to be” for which purpose permitted under Section 107A of the Patents Act, 1970.

11. We have heard Ms.Rajeshwari, learned counsel for respondent No.5/Natco Pharma Limited, who has submitted that respondent No.5 ought not to be interdicted from effecting the exports of the patented invention inasmuch as the same is essential to enable respondent No.5 for ensuring conduct of experiments for developing the patented product for sale after expiry of patented product in foreign countries and for processing the licence applications, in terms of the legal requirements of the country to which the product is being exported.

12. This submission cannot be accepted inasmuch as Condition (g) of the Compulsory Licence granted to respondent No.5 restricted it to manufacture and sale of the patented product only in India.

13. The appellants have pointed out the distinction between the export of a finished product and its active pharmaceutical ingredients. It is submitted that if respondent No.5 was really *bona fide* exporting for the purpose of experimentation alone, it is the active pharmaceutical ingredient only which would have been exported, that too in restricted quantities. But this is admittedly not so. We may note that there is nothing on record which informs this Court as to what is the quantity of the patented invention which the respondent No.5 is exporting or expects to export.

14. It is made clear that this order has been passed on a consideration of the appellant’s case against respondent No.5/Natco Pharma Limited only.

15. Notice has been issued in the main appeal. There was an interim order dated 26th March, 2014 interdicting export of the patented invention in force

during the pendency of the appeal. The appellant has made out a case which requires consideration. Prima facie it appears that the appellant would suffer irreparable loss and damage, if the interim protection was not granted.

16. It is, therefore, directed that till the next date of hearing, the respondent No.5 shall stand prohibited from exporting the patented invention which is the subject matter of the compulsory licence No.1 of 2011.

15. List on 21st September, 2017.

ACTING CHIEF JUSTICE

ANU MALHOTRA, J

MAY 12, 2017

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