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

Date of decision: 26th May, 2022.

+ **CS(COMM) 305/2022 & I.As. 7317-18/2022**

NOVARTIS AG & ANR.

..... Plaintiffs

Through: Mr. Hemant Singh, Ms. Mamta Rani
Jha, Mr. Saif Rahman Ansari and Mr.
Siddhant Sharma, Advocates.
(M:7409531351)

versus

MSN LABORATORIES PRIVATE LIMITED Defendant

Through: Ms. Rajeshwari H., Ms. Swapnil Gaur
and Mr. Deepanshu Nagar, Advocates
for D-1. (M:8826968200)
Mr. Harish Vaidyanathan Shankar,
CGSC with Ms. S. Bushra Kazim,
Mr. Srish Kumar Mishra and Mr.
Sagar Mehlawat, Advocates for D-2.

CORAM:

JUSTICE PRATHIBA M. SINGH

Prathiba M. Singh, J. (Oral)

1. This hearing has been done through hybrid mode.
2. The present suit has been filed seeking permanent injunction restraining infringement of Indian Patent No.237430, damages, rendition of accounts, delivery up etc. The details of the said patent are as under:

Patent No.	:	IN 237430
Title	:	Inhibitors of Tyrosine Kinases
Date of filing	:	04th July, 2003
Date of Expiry	:	04th July, 2023

3. Pursuant to the directions issued vide previous orders dated 20th May, 2022 and 11th May, 2022, the Department of Pharmaceuticals, Ministry of



Chemicals and Fertilizers (*hereinafter as 'DOP'*) has filed an affidavit clarifying its position. As per the said affidavit, for various reasons including for enhancing supply of local manufactured products and for self-sufficiency purposes in the case of medicines, drug and medical devices, certain guidelines were issued by the Government classifying Local Suppliers based on local value addition or local content as Class I Local Supplier having local content of more than 80%, Class II Local Supplier having local content of 50-80%, and Non-Local Supplier having local content less than 50%. Thereafter, it is stated that the Ministry of Railways and other procuring agencies had requested for relaxation of the same due to non-availability of local producers. At that stage, a need was felt for ascertaining local manufacturers in respect of various drugs. In this background, a list of 209 drugs was published on the website of the DOP, vide public notice dated 28th February, 2022, seeking details of the local manufacturers available for these drugs. In response to the said notice, the Defendant addressed an email dated 15th March, 2022 to the DOP giving details of its manufacturing capabilities in respect of 44 drugs.

4. The DOP, thereafter, states that a representation was received from Shri Amitabh Baxi, Head, Country Public Affairs, Novartis India, vide email dated 13th April, 2022 informing the DOP of the patent which was granted in their favour.

5. The DOP has now clarified that the effort and intention behind issuing the Public Notice dated 28th February, 2022 was merely to collate the details of the local manufacturers of the drugs, as requested by Central Procurement Agencies. However, the said effort is not, in any manner, to be treated as directions by the Government under Section 100 of the Patents Act, 1970, or



any other provision of the Patents Act, 1970.

6. The relevant portion of the affidavit dated 23rd May, 2022 deposed by Dr. N Yuvaraj, Joint Secretary (Policy), DOP is set out below:

“15. It is kindly submitted that the defendant always knew the intention of the Department's Public Notice dated 28.2.2022 to collate the details of local manufacturers of the drugs, as requested by the Central Procurement Agencies, but, un-necessarily brought in the issue of use of Govt. authorization under the Indian Patent Act which is in no way related to the guidelines issued under Public Procurement Order. The defendant has misinterpreted the Public Notice as if DoP is going to procure the drugs by issuing any authorization which is altogether a different power vested with the DPIIT and issued sparingly under any public health emergency.

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17. That, as to the issue of patent here, it is clarified that the Department's Public Notice dated 28.02.2022 nowhere directs or compels anyone to infringe upon the rights of the patent holders. The Public Notice seems to have been wrongly interpreted by the Defendant as a form of Government Authorization to manufacture the patented drug.

18. Further, it is also clarified that the authorization under section 100 of the Patents Act, referred by the Plaintiff as well as the Defendant in the order has no relationship with the Public Notice issued by the Department since the said provision under the Patents Act, 1970 has altogether a separate mandate and process under the administrative powers of the Department of Industry and Internal Trade (DPIIT) under the Ministry of Commerce and Industry and the Department has no authority over the same.”

7. In view of this stand of the DOP that the Government has not invoked



any provisions of the Patents Act, 1970 for the procurement of the drugs in which patent rights are claimed by the Plaintiff, no further orders are required to be passed *qua* the Government, in respect of the drugs which are the subject matter of this suit. Accordingly, Defendant No.2 – Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, is deleted from the array of parties.

8. Defendant No.1 - MSN Laboratories Private Limited has handed over the original affidavit deposed by Mr. Srinivasan Thirumalai Rajan, Head - Intellectual Property & Technical of the Defendant No.1. Let the same be taken on record. The relevant extract of the said affidavit reads as under:

“I say that the Defendant has been granted manufacturing Licence in respect of product Nilotinib and the copy thereof is submitted as Document 1.

The Defendant submits that Government of India was collecting information with respect to the capability of various manufacturers. The Defendant has responded to the same.”

9. As per the above affidavit, the Defendant No.1 has been given a manufacturing licence on 26th August, 2019 for commercial manufacture and sale of *Nilotinib*. The suit patent is due to expire on 4th July, 2023.

10. Ms. Rajeshwari, Id. Counsel for the Defendant No.1 submits that the Defendant No.1 has no intention to undertake manufacture and sale of *Nilotinib*, at this stage. However, since the Defendant No.1 has a manufacturing licence, as and when the Defendant No.1 decides to manufacture the said product on a commercial scale, she submits that it shall give notice to the Plaintiff of at least four weeks.

11. The above statement made on behalf of the Defendant No.1 is taken



on record and accepted by the Court. It is accordingly directed that if the Defendant No.1 takes a decision to undertake commercial production or sale of pharmaceutical preparations of *Nilotinib*, it shall give advance intimation to the Plaintiff of at least four weeks. At that stage, the Plaintiff is permitted to avail of his remedies in accordance with law. This would, however, not prejudice the rights of the Defendant No.1 to undertake permissible activities, in terms of Section 107A of the Act.

12. The present suit is decreed in the above terms.

13. It is made clear that the Court has not considered the merits of the case, either in respect of infringement or validity of the suit patent.

14. Decree sheet be drawn accordingly. The next date of hearing stands cancelled. All pending applications are disposed of.

PRATHIBA M. SINGH
JUDGE

MAY 26, 2022
dj/ad

