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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**
Date of decision: 26th May, 2022
 + **CS(COMM) 306/2022 & I.A. 7321-22/2022**
NOVARTIS AG & ANR. Plaintiffs

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

versus

CENTURION REMEDIES PRIVATE LIMITED Defendant

Through: Mr. Bhavik B. Patel, Advocate for D-
 1. (M:8238043022)
 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.229051, damages, rendition of accounts, delivery up etc. The details of the said patent are as under:

Patent No.	:	IN 229051
Title	:	Pharmaceutical Compositions Comprising Valsartan and NEP Inhibitors
Date of Filing	:	16th January, 2003
Date of Expiry	:	16th January, 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. On merits of the present suit, the Defendant No.1- Centurion Remedies Private Limited has filed an affidavit of Mr. Ambalal V. Patel, the Managing Director which states as under:

“4) I say that the defendant No.1 has not manufactured or imported or traded or has not caused to manufacture or caused to import or caused to trade the pharmaceutical preparation namely SACUBITRIL + VALSARTAN, in any manner, either directly or indirectly.

5) I say that the defendant No.1 is in knowledge of the fact that the plaintiff is the exclusive proprietor/owner of the Indian Patent No. 229051 titled 'Pharmaceutical Compositions Comprising Valsartan and NEP' (hereinafter referred to as the 'Said Patent').

6) I say that the defendant No.1 has obtained the Export License/Approval numbered G/25/1325 from FDA, India to export the pharmaceutical preparation namely 'SACUBITRIL + VALSARTAN'.

7) It is stated that the defendant No. 1 has not exported or caused to export the pharmaceutical preparation namely 'SACUBITRIL + VALSARTAN', either directly or indirectly, or in any other manner. (A Copy of the Export License obtained from FDA, India is annexed hereto and marked as Annexure-R3.)

8) I say that the defendant No. 1, with regards to export or any other activity, has not conducted any activity of laboratory testing and analysis or caused to conduct any activity of laboratory testing and analysis in relation to pharmaceutical preparation namely SACUBITRIL + VALSARTAN', either directly or indirectly, or in any other manner.

9) I say that the defendant No. 1, either directly or



indirectly, in any manner has not started to use or sell or import or manufacture or cause to use or sell or import or manufacture the pharmaceutical preparation namely 'SACUBITRIL + VALSARTAN'.

10) I say that the defendant No.1, either directly or indirectly, in any manner, does not intend to use or sell or import or manufacture or cause to use or sell or import or manufacture the pharmaceutical preparation namely SACUBITRIL+ VALSARTAN' till the expiration of said patent.

9. A perusal of the above affidavit shows that the Defendant No.1 has taken a stand that it has an export licence for exporting of the pharmaceutical preparation namely Sacubitril + Valsartan. However, the Defendant has undertaken not to use or sell or import or manufacture or cause to use or sell or import or manufacture the pharmaceutical preparation *SACUBITRIL+ VALSARTAN*, till the expiration of the suit patent.

10. In view of the above categorical stand of the Defendant No.1 it is directed that the Defendant No.1 shall not undertake or cause commercial manufacture, sale, use, export or import of any pharmaceutical preparations consisting of *SACUBITRIL+ VALSARTAN*, covered by the suit patent **IN 229051**, till the expiration of the term of the suit patent i.e., 16th January, 2023.

11. The present suit is decreed in the above terms. All pending applications are also disposed of.

12. Decree sheet be drawn accordingly. The next date of hearing stands cancelled.

PRATHIBA M. SINGH
JUDGE

MAY 26, 2022
dj/ad