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

Date of decision: 31st October, 2022

+ **CS(COMM) 481/2021 and I.A. 12882/2021**

CHUGAI SEIYAKU KABUSHIKI KAISHA & ANR. Plaintiff
Through: Mr. Shrawan Chopra, Ms. Prachi
Agarwal and Ms. Ridhi Bajaj,
Advocates (M: 9958045858).

versus

FRESENIUS KABI ONCOLOGY LIMITED & ANR. Defendants
Through: Mr. Afzal B. Khan, Suhvita
Majumdar & Mr. Samik Mukherjee,
Advocates (M. 9881880037).

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. 294424 (*hereinafter*, “*suit patent*”) which is titled “TETRACYCLIC COMPOUND”, along with damages, rendition of accounts, delivery up, and other reliefs, against the Defendants. According to the suit patent, the claimed tetracyclic compound, salts or solvates thereof are useful, *inter alia*, in the treatment of diseases including cancer. The suit patent discloses and covers a compound having the International Non-Proprietary Name (INN) – ‘*Alectinib*’, being commercially sold by the Plaintiffs under the brand name Alecensa®. The term of the suit patent expires on 9th June, 2030.

3. Plaintiff No.1 – Chugai Seiyaku Kabushiki Kaisha (also known as “Chugai Pharmaceutical Co. Ltd.”) is a company headquartered in Japan and is a leading innovator in the healthcare industry. Plaintiff No.2 – F. Hoffmann-La Roche AG is a company headquartered in Switzerland and is also one of the world’s largest pharmaceutical companies. As per the Plaint, Plaintiff No.1 is the patentee of the suit patent and Plaintiff No.2 is the exclusive licensee of the suit patent by virtue of an exclusive license agreement dated 31st October, 2012 entered into between the Plaintiffs.

4. Defendant No.1 Fresenius Kabi Oncology Limited and its Indian subsidiary Company, Defendant No.2 Fresenius Kabi India Private Limited are engaged in the manufacture and sale of various pharmaceutical products in India.

5. It is the case of the Plaintiff that in May, 2021 an investigation was conducted which revealed that Defendant No.1 has engaged in import of Alecensa/ Alectinib and export of Alectinib / Alectinib Hydrochloride on multiple occasions in the past. The said investigation was again confirmed in June 2021 and it was further revealed that various online listings of the product were also being made by Defendant No.1 on www.pharmacompass.com and www.chemicalbook.com. The Plaintiff also discovered that Defendant No. 1 had filed Indian Patent Application No. 201711023632 in respect of “*A process for preparing Alectinib or a pharmaceutically acceptable salt thereof*” on 5th July, 2017. Thus, the present suit was filed by the Plaintiffs seeking injunction against the Defendants as the Plaintiffs apprehend that the Defendants are in the process of launching generic Alectinib which infringed the suit patent.

6. Vide order dated 1st October, 2021, after recording the statement of

the Id. Counsel for the Defendants, this Court had directed that the Defendants shall not launch the product commercially without prior permission. The relevant portion of the said order is set out below:-

2. Learned counsel appearing for the defendant, on instructions, states that without prejudice to the rights and contentions of the defendant, for the time being, the defendant is only using the drug in question, namely, Alectinib or its salt etc. which is the subject matter of IN 294424 for research purpose under Section 107A of the Patents Act. In case the defendant decides to commercially manufacture and launch the said product, the defendant will give four weeks' advance notice to the plaintiffs/learned counsel for the plaintiffs. The above statement is taken on record and the defendant shall be bound by the same.

3. However, it is clarified that the defendant shall not launch the product commercially in the market without prior permission of the court.

7. The Defendants have filed an affidavit dated 10th October, 2022 on 28th October, 2022. The said affidavit is deposed by Dr. Prachi Tiwari, Senior Director Intellectual Property Management at Fresenius Kabi Oncology Limited- Defendant No. 1 company. She has given an affidavit to the following effect:-

I, Dr. Prachi Tiwari, D/O Mr. Krishna Kumar Pandey, aged about 46 years, working for gain as Sr. Director, Intellectual Property Management at Fresenius Kabi Oncology Limited of the address Plot No 11, Echleon Institutional Area. Sector 32, Gurugram, Haryana 12018, currently in New-Delhi, solemnly affirm and declare as under:

1. That I am the authorized signatory of the both the Defendants and under instructions from my company, undertakes as follows:

a) That the Defendants will not commercially

launch the drug in question i.e., Alectinib during the validity of IN294424;

b) That present undertaking is without prejudice to the permissible rights and liberties available to the Defendants under statute including without limitation, rights under the provision of Section 107A of the Patents Act, 1970 to carry out such activity in relation to development and submission of information in India or elsewhere the laws provide for or mandate the submission of such information;

8. In view of the above affidavit, Id. Counsel for the Plaintiffs submits that the suit can be decreed in terms thereof. Accordingly, the suit is decreed in terms of paragraphs 1 (a) and 1 (b) extracted above. Decree sheet be drawn accordingly.

9. Since the matter has been amicably resolved, full court fees is directed to be refunded to the Plaintiffs through counsel in terms of the judgment in *Nutan Batra v. M/s. Buniyaad Associates [2018 (255) DLT 696]*.

10. The suit along with pending applications, if any, is disposed of.

**PRATHIBA M. SINGH,
JUDGE**

**OCTOBER 31, 2022
MR/SK**