



\$~18

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

Date of decision: 3rd June, 2022.

+

CS (COMM) 427/2021

CHUGAI SEIYAKU KABUSHIKI KAISHA & ANR. Plaintiffs

Through: Mr. Sharwan Chopra, Ms. Prachi Aggarwal and Ms. Misthi Dubey, Advocates. (M:8800972785)

versus

NATCO PHARMA LIMITED Defendant

Through: Mr. J. Sai Deepak and Mr. Ankur Vyas, Advocates.

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 Defendant. 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 of expires on 9th June, 2030.
3. The 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 company. As per the Plaint, Plaintiff No.1 is the patentee of the suit patent and the 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. The Defendant – Natco Pharma Limited is a pharmaceutical company engaged, inter alia, in the manufacture, sale, and offering for sale various generic pharmaceutical products in India.

5. It is the case of the Plaintiffs that in the last week of May, 2021, an investigation was conducted by an independent investigator at the behest of the Plaintiffs which shed light on the fact that the Defendant had indulged in the export of *Alectinib* API in May 2019, which amounts to infringement of the suit patent as per Section 48 of The Patents Act, 1970. Thereafter, in June 2021, the Plaintiffs discovered that the Defendant has filed a patent application, namely IN 201941022366 in respect of *Pharmaceutical compositions comprising Alectinib* on June 06, 2019 before the Indian Patent Office. The Plaintiffs also acquired knowledge that another Patent Application was filed by the Defendant pertaining to *Alectinib*, before the Indian Patent Office bearing application no. 201741029461 in respect of *A novel process for the preparation of an intermediate of Alectinib*. Thus, the Plaintiffs filed the present suit apprehending that the Defendant intends to launch generic *Alectinib* or its salt or solvates or intermediate(s) thereof or any other product that infringes the suit patent.

6. The suit was listed on 13th September 2021, on which date, the Id. Counsel for the Defendant had made a statement that the product is being



used only for research purposes. The said order records as under:

“1. This application is filed under Order 39 Rules 1 and 2 CPC seeking the following relief:

"a) An order for ad interim injunction restraining the Defendant, its directors, employees, officers, servants, agents, stockists retailers, semi stockists, wholesalers, marketers, distributors, any other entity/person in the chain of supply and all others acting for and on its behalf from using, making, manufacturing, selling, distributing, advertising, exporting, offering for sale, importing or in any other maimer, directly or indirectly, dealing in any product including but not limited to generic Alectinib or its salt or solvates or intermediate (s) thereof that infringes the subject matter of Indian Patent No.IN 294424."

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. He further states that presently, the defendant does not have any license to commercially manufacture the drug. 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. An affidavit dated 6th April, 2022 has now been filed by Dr. Pratima Jain on behalf of the Defendant stating inter alia, as under:

“4. That I am under instructions by my Company to state, submit and stipulate as follows:

- a. That the Defendant will not be launching any Alectinib product till expiry of IN 294424 on 09.06.2030 or until there is any finding of invalidity in respect of such patent;*
- b. That this is without prejudice to the submissions in the Written Statement of non-infringement and invalidity defences raised in such Written Statement;*
- c. That there has been no commercial use of any kind whatsoever in relation to Alectinib till date and there will be no commercial launch of Alectinib products as aforesaid in paragraph 4(a);*
- d. That the Defendant reserves its rights available under statute including the provisions of Section 107A to carry out such activity in relation to development and submission of information in India or elsewhere where the laws provide for or mandate the submission of such information;.....”*

8. The remaining contents of the affidavit is not pressed by the Id. Counsel for the Defendant. The same shall accordingly stand deleted. In view thereof, the present suit is decreed in terms of paragraphs 4(a) to 4(d) as extracted above. Decree sheet be drawn accordingly. Parties to bear their own costs.

9. Since the matter has been amicably resolved, full court fee is directed to be refunded to the Plaintiff in terms of the judgement in **Nutan Batra v.**



M/s. Buniyaad Associates [2018 (255) DLT 696].

10. Next date of hearing stands cancelled. All pending applications are also disposed of.

**PRATHIBA M. SINGH
JUDGE**

JUNE 3, 2022/dk/ad

