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

Date of Decision: 13th July, 2022

+ **CS (COMM) 515/2021 & I.As. 13467/2021, 13468/2021, 13469/2021, 13470/2021**

CHUGAI SEIYAKU KABUSHIKI KAISHA & ANR. Plaintiffs

Through: Mr. Pravin Anand, Mr. Shrawan Chopra, Ms. Prachi Agarwal, Ms. Ridhie Bajaj & Mr. N. Mahabir, Advocates (M-9958045858)

versus

HETERO LABS LIMITED & ANR. Defendants

Through: Ms. Rajeshwari H., Advocate (M-9910206718)

**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 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 Defendants – Hetero Labs Limited and Hetero Drugs Limited – are part of a pharmaceutical group of companies engaged, *inter alia*, in the manufacture, sale, and offering for sale various generic pharmaceutical products all over India and in many foreign countries.

5. As per the plaint in May, 2021, an investigation was conducted by an independent investigator which revealed that Defendant No.1 had imported Alecensa/Alectinib Hydrochloride from Germany on 3rd August, 2018. Further investigation in June, 2021 revealed that an application had been made by Defendant No.1 for enhancement and expansion of the Defendant’s plant facilities for manufacturing Alectinib Hydrochloride, as per the Pre-feasibility Report dated June, 2020 filed by Defendant No.1 before the State Level Environmental Impact Assessment Authority. The environmental clearance was obtained from the Telangana Government. In one of the online business directories i.e., www.pharmacompass.com, Defendant No.2 was also listed as a supplier of Alectinib Hydrochloride. This led to the filing of the present suit, prior to the launch of the product by the Defendants. Vide order dated 29th October, 2021, the Court had recorded the statement of the Id. Counsel for the Defendants and had passed the



following order:

“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 Defendants, their directors, employees, officers, servants, agents, stockists, retailers, semi stockists, wholesalers, marketers, distributors, affiliates, any other entity/person in the chain of supply and all others acting for and on their behalf from using, making, manufacturing, selling, distributing, advertising, exporting, offering for sale, importing or in any other manner, 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 defendants, on instructions, states that for the time being, the defendants are 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 defendants do not have any license to commercially manufacture the drug. In case the defendants decide to commercially manufacture and launch the said product, the defendants will give four weeks' advance notice to the plaintiffs/learned counsel for the plaintiffs. The above statement is taken on record and the defendants shall be bound by the same.

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

6. As per the above order, the Defendants had made a submission that they were only using the drug in question i.e., Alectinib/Alectinib



Hydrochloride for purposes of research under Section 107A of the Patents Act, 1970 (*hereinafter* “Act”). The written statement wherein the Defendants have taken a categorical stand that the import of Alectinib 150 mg i.e., Alectinib Hydrochloride was purely for purposes permitted under the law, namely, for conducting research and developmental studies and for submissions to various regulatory authorities as permitted under the “Bolar provision” under Section 107A of the Act. The said paragraph is set out below:

“2. WITHOUT PREJUDICE, it is submitted that the Defendants, however, solely imported ALECENSA 150mg for purposes as explicitly permitted under the law, namely for conducting research and developmental studies and also for submission to various regulatory authorities and in order to obtain necessary regulatory approvals, also known as activity permitted under the "Bolar" provision as set out in Section 107A of the Patents Act, 1970. The import of the product from any country for uses reasonably related to the development and submission of information required under any law in India, or in a country other than India that regulates the manufacture, construction, use sale of import of any product is not an act of infringement accordingly to Section 107A of the Patents Act, 1970. The Defendants submit that the imports are solely for development and submission purposes and not for any other commercial purpose. No other activity is or was performed by the Defendants, and as admitted by the Plaintiff themselves, the Defendant has not commercialised/ commercially launched Alectinib Hydrochloride. The Defendants intend to continue with activities under Bolar Provisions for now, if ever a need arises for commercial use.”

7. Ms. Rajeshwari, Id. Counsel appearing for the Defendants, submits



that the Defendants intend to use Alectinib Hydrochloride only for the purposes permitted under the law under Section 107A of the Patent Act.

8. In view of the above stand taken by the Defendants above, binding the Defendants to the statements given, the suit is decreed in terms of paragraph 76(a) and (b) of the plaint. Since the Defendants have not made any commercial manufacture or launch, the prayers for damages or rendition of accounts are not pressed. None of the other reliefs is pressed by the Id. Counsel for the Plaintiff.

9. It is, however, made clear that the Defendants would be entitled to use the product or import/manufacture only for the purposes of research and development or regulatory purposes. There shall be no commercial manufacture or launch during the validity of the suit patent.

10. Considering the facts and circumstances of this case, 50% of the Court fee is directed to be refunded to the Plaintiff, through counsel.

11. The present suit is disposed of in the above terms. All pending applications are also disposed of. Decree sheet be drawn accordingly.

PRATHIBA M. SINGH
JUDGE

JULY 13, 2022
Rahul/MS