$~30

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

\+ **CS (COMM) 229/2019 with CAV 471/2019 and IA Nos. 6384-6386/2019**

NOVARTIS AG & ANR. ..... Plaintiffs

Through Mr. Gopal Subramanium, Sr. Advocate with Mr. Hemant Singh, Ms. Mamta Jha, Dr. Shilpa Arora, Mr. Ankit Arvind and Mr. Pavan Bhushan, Adv.s (M. 9873603089)

Versus

NATCO PHARMA LIMITED. ..... Defendant

Through Mr. Sanjeev Sindhwani, Sr. Advocate with Ms. Rajeshwari H. Ms. Swapnil Gaur, Mr. Saif Rahman Ansari, Mr. Kumar Chitranshu, Mr. Tahir, Ms. Nupur Goswami, Mr. Vikramjeet, Advocates (M. No. 7409531351)

CORAM:
JUSTICE PRATHIBA M. SINGH

O R D E R

% 02.05.2019

1. Both counsels do not have any objection in this Bench hearing this matter.

IA NO. 6386/2019

2. This is an application seeking exemption from filing clearer copies, certified copies/documents with appropriate font and documents with correct margin and seeking thirty days' time to file additional documents/clearer copies of the documents. Exemption is allowed, subject to just exceptions. I.A. is disposed of.

3. Caveat is discharged. Let the plaint be registered as a suit.

4. Issue summons to the Defendant. Ms. Rajeshwari H., Advocate accepts summons. Written statement shall be positively filed within 30 days. Along with the written statement, the Defendant shall also file an affidavit of admission/denial of the documents of the Plaintiff, without which the written statement shall not be taken on record.

5. The Plaintiff Novartis AG has filed the present suit seeking permanent injunction, damages, rendition of accounts and delivery up in respect of its granted patent, Indian Patent No. 276026 titled '*Novel Pyrimidine Compounds and Compositions as Protein Kinase Inhibitors.*' ('*suit patent*'). The case of the Plaintiff is that it has been granted the suit patent for a novel and inventive compound *Ceritinib* which is a drug meant for treatment of non small cell lung cancer (NSCLC). The case of the Plaintiff is that the said molecule, which forms part of the broader group of 2, 4-di aminopyrimidines, is novel and inventive. The plaint discloses that there was a patent granted to AstraZeneca, which covered a broad Markush formula of the same class of compounds, and there were two other patents granted to one M/s. Rigel Pharmaceuticals which also broadly related to the same class of compounds. Paragraph 13.2 of the plaint reads as under:-

> *"13.2 The compounds pertaining to the class of substituted 2, 4 diaminopyrimidines was also subject matter of research by several other companies prior in time and patents were procured for such compounds. One of such companies was Astrazeneca, which filed patent application in 2001 and obtained US Patent No. 7153964 in 2006. Astrazeneca's US Patent No. 7153964 contained a Markush claim thereby claiming*

compounds having inhibitory activity on CDK kinase. However, the said patent did not disclose either the compound of formula 2 or the new chemical entity-Ceritinib, subject matter of the suit patent. Subsequently in 2002, Rigel Pharmaceuticals Inc. also applied for patent and was granted US Patent No. 8188276 for a Markush claim of compounds comprising substituted 2, 4 di-aminopyrimidines having Syk Kinase inhibiting property. Rigel Pharmaceuticals also obtained other patents covering the class of substituted 2, 4 di-aminopyrimidines. The family of such patents owned by Rigel include US8,835,430, US9,018,204, US9,416,112. None of the Rigel patents mentioned herein disclosed the compound of formula 2 of suit patent or the new chemical entity-Ceritinib. However, on September 23, 2015, Rigel filed a patent infringement action in the United States District Court for the Northern District of California against Novartis Pharmaceuticals Corp. (a U.S. affiliate of Plaintiffs) asserting that Ceritinib infringed the broad Markush claims of Rigel's U.S. Patent Nos. 8,188,276, 8,835,430, and 9,018,204. Shortly thereafter, on November 4, 2015, Rigel voluntarily dismissed its patent infringement action after the parties reached an amicable resolution, which resolution included the later issuing U.S. Patent No. 9,416,112. The terms of the settlement are confidential and are therefore not placed on record. In addition, a license was obtained by the Plaintiff No.l from Astrazeneca under the previously referenced AstraZeneca patents. The purpose of taking a license under the AstraZeneca patents and resolving the litigation with Rigel was to obtain 'freedom to operate" under the broad genus claims of the Astra Zeneca and Rigel patents even though none of those patents disclosed formula 2 of the suit patent or the compound Ceritinib within the scope of formula 2. Moreover, because AstraZeneca and Rigel patents did not

> *disclose formula 2 of the suit patent or the compound Ceritinib within the scope of formula 2, Plaintiff No.l was able to obtain its own patent rights claiming the compounds of formula 2 and Ceritinib, including the suit patent in India, and in the U.S. and throughout the world."*

6. The further case of the Plaintiff is that it has two further Indian patents i.e. IN 240560 and IN 232653 which cover the broad class of 2,4-di-aminopyrimidines.

7. It is submitted that the suit patent was filed as a Patent Convention Treaty ('PCT') application claiming priority since 2007, and was granted on 28th September, 2015. The defendant Natco Pharma Ltd. filed a post grant opposition within the statutory period under Section 25 (2) of the Patents Act, 1970. The said opposition was initially referred for the consideration of the Opposition Board, which gave a report in favour of the Plaintiff. However, Natco Pharma thereafter, filed additional material and now the hearing in the post grant opposition itself stands concluded, and the order has been reserved on 10th April, 2019.

8. Mr. Gopal Subramanium, ld. Senior Counsel appearing for the Plaintiff submits that recently i.e. on 29th March, 2019, the Plaintiff came across the Defendant's product under the mark *NOXALK* at a pharmaceutical conference at Kolkata. The packaging of the said product has been extracted at page 59 of the plaint, which shows that the Defendant has launched *`Ceritinib capsules'*.

9. It his submission that the Defendant, having already opposed the Plaintiff's patent by post grant opposition ought to have waited for the

decision in the said proceedings rather than launch the product while the post grant opposition is yet to be decided.

10. Ld. Senior Counsel has taken the Court through the various averments in the plaint, as also the recommendations of the Opposition Board, which has held that the suit patent is novel and inventive, and is also not hit by Section 3(d) of the Patent Act.

11. It is thus prayed that an interim injunction deserves to be granted in the present case, as the Defendant has chosen to launch the product despite the patent having been granted, the opposition having been filed and the decision in the same being pending.

12. On the other hand, Mr. Sanjeev Sindhwani, ld. Senior Counsel assisted by Ms. Rajeshwari H., Advocate submits that the molecule Ceritinib is neither novel nor inventive. It is covered under the broad Markush formula which is disclosed in the AstraZeneca and Rigel patents, and two earlier Novartis patents.

13. It is submitted that the Plaintiff itself, while applying for a patent-term-extension in the U.S. has made statements before the U.S. Patent Office that the product Ceritinib, which is manufactured and marketed under the name ZYKADIA (Ceritinib) in the US, is in fact covered by the US'592 patent which is equivalent to IN'560 in India. It is his submission that this is a classic case of extending the term of the patent and the monopoly as the life of IN'560 ends in 2024 whereas the suit patent is valid till 2027. Ld. Senior Counsel relies upon the documents filed in the patent term extension application and submissions made by Novartis therein.

14. It is further submitted by means of a chart that the broad Markush, even of the AstraZeneca patent, covers the molecule Ceritinib. Reliance is

also placed by the Defendant on the decision of the Supreme Court in ***Aloys Wobben and Anr. vs. Yogesh Mehra and Ors***. ***AIR 2014 SC 2210*** to argue that once a post grant opposition is filed, the rights therein are yet to be crystallized, since the post grant opposition is pending.

15. The Court has heard both sides on the grant of *ad-interim* relief. It is the admitted position that the post grant opposition is now pending decision with the Patent Office and the question as to whether the patent is to be maintained or not will be decided therein. Thus, in so far as the validity of the patent itself is concerned, this court would not like to make any observation at this stage, so as to ensure that the post grant opposition is decided without being affected by any observation which may be made by this court.

16. The drug license for Natco Pharma's product, which is marketed under the mark NOXALK (Ceritinib) was granted to the Defendant in January, 2019, i.e. after the post grant opposition was filed and the Opposition Board had made its recommendations.

17. The actual commercial launch has also admittedly been done only on 20th March, 2019. Thus, during the period when the post-grant opposition decision was yet to come, the Defendant has chosen to commercially launch the product. While the Supreme Court in ***Aloys Wobben (supra)*** held that the rights would be crystallized once the post grant opposition is decided, launch of an allegedly infringing product, prior to the said decision in the opposition by the entity opposing the Patent, did not arise in the facts of the said case. Section 48 of the Patents Act grants rights in favour of a patentee, which are not affected during the pendency of a post-grant opposition. Section 48 provides as under:

> "48. ***Rights of patentees –*** *Subject to other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee-*
> *(a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India*
> (b) *where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India* "

During the pendency of the post-grant opposition, the rights of a patentee subsist – though they may be crystallized once the opposition is actually decided. The Defendant ought to have awaited the decision in the post grant opposition before launching its product. However, since it chose to launch earlier, the Plaintiff has filed the present suit.

18. The molecule Ceritinib with the formula 5-chloro-N^2-(2-isopropoxy-5-methyl-4-piperidin-4-yl-phenyl)N^4[2-(propane-2-sulfonyl)-phenyl]-pyrimidine-2,4-diamine is covered by claim 5 of the suit patent which reads as under:

> "*5. The novel pyrimidine compound as claimed in claim 1, wherein said compound is 5-chloro-N2-(2-isopropoxy-5-methyl-4-piperidin-4-yl)phenyl)-N4-[2-(propane-2-sulfonyl)-phenyl]-pyrimidine-2,4-diamine, or a pharmaceutically acceptable salt thereof*."

The Defendant's product NOXALK is described as 'Ceritinib capsules.'

19. Considering that this is a drug for treating non small cell lung cancer

(NSCLC), stopping the sale of the Defendant's products which are already manufactured would not benefit the patient community in any manner. Thus, the drugs already manufactured by the Defendant under the mark NOXALK (Ceritinib) are allowed to be sold during the pendency of the hearing in the application under Order 39 Rule 1 and 2 CPC and till further orders of this Court. However, Natco Pharma, having been well aware of the fact that the patent stood granted and the fact that the post grant opposition was pending adjudication, ought not to have launched the product while the decision was pending in the Patent Office. Accordingly, the Defendant is restrained from carrying out any fresh manufacturing of pharmaceutical preparations comprising of the active pharmaceutical ingredient (API) 'Ceritinib' till the next date.

20. Let the reply to the injunction application be filed within two weeks. Rejoinder, if any, may be filed within two weeks thereafter.

21. The Plaintiff has filed an application being IA No. 6385/2019 seeking appointment of a Local Commissioner. However, the counsel for the Defendant undertakes to file an affidavit with a complete statement of stock, including the batch numbers of the products which have been manufactured. The affidavit disclosing the entire stock of Ceritinib pharmaceutical preparations in all dosages, be filed within two weeks.

22. It is further directed that a copy of this order be sent to Controller General of Patents, Designs and Trade Marks with a request that the order on the post grant opposition, which is now stated to be reserved may be passed by the Patent Office before the next date of hearing before this Court so that this Court may have the benefit of the decision of the Patent Office.

23. Needless to add, any observations made herein would not have any bearing on the validity of the patent or the merits of the post grant opposition.

24. List on 11th July, 2019 for hearing on the injunction application.

25. *Dasti*.

PRATHIBA M. SINGH, J.

MAY 02, 2019/*b*