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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**
Date of decision: 20th August, 2019

+ **CS (COMM) 229/2019 and I.As. 11304/2019, 11305/2019**

NOVARTIS AG & ANR. Plaintiffs
Through: Mr. Hemant Singh, Ms. Mamta Jha,
Mr. Ankit Arvind, Mr. Rohan
Krishnan & Dr. Shilpa Arora,
Advocates (M: 9873603089)

Versus

NATCO PHARMA LIMITED Defendant
Through: Mr. Sanjeev Sindhwani, Sr. Advocate
with Ms. Rajeshwari H., Mr. Swapnil
Gaur and Mr. Kumar Chitranshu,
Advocates (M: 9897905254).

CORAM:
JUSTICE PRATHIBA M. SINGH

Prathiba M. Singh, J. (Oral)

1. The Defendant has filed two applications – one under Order VII, Rule 11 CPC and the second one under Order XXXIX, Rule 4 CPC seeking dismissal of the present suit and vacation/suspension of the interim injunction operating in the present case on the ground that the patent granted in favour of the Plaintiffs has been revoked in the post grant opposition proceedings. The Defendant relies on the order passed by the Deputy Controller of Patents and Designs (*hereinafter*, 'Controller') on 16th August, 2019. Ld. senior counsel for the Defendant has taken the Court through the findings and shown that the Controller has arrived at a finding that the compounds disclosed in the suit patent lack novelty in view of the

disclosures made in IN 240560 and IN 232653. The submission is that in view of Section 62(2) of The Patents Act, 1970 the interim injunction cannot be continued.

2. 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*'. 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-diaminopyrimidines, is novel and inventive.

3. The suit patent was filed as a Patent Convention Treaty (*hereinafter, '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 was reserved on 10th April, 2019.

4. The suit was first listed on 2nd May 2019. While granting an interim order on 2nd May, 2019, the Court had directed that the post grant opposition wherein orders were reserved, be decided by the Patent Office prior to the next date of hearing. Relevant portions of the said order are set out below:

“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 "*

...

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.*

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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."*

5. However, on the next date, the Court was informed that no orders had been passed in the post grant opposition proceedings. Thus, on the next date, i.e., 11th July 2019, directions were issued as under:

“3. Though arguments were heard on 10th April, 2019 by the Controller General in the post-grant opposition, even on 11th July, 2019, there are no orders passed by the Controller General. This is detrimental to the timely adjudication of opposition matters which is not permissible. Accordingly, the Controller General shall now go ahead and proceed to pass orders in the post-grant opposition within a period of one month from today. No further filing shall be done by either party.”

6. By way of the present applications, the Defendants have informed the Court that the order in the post-grant opposition proceeding has since been passed on 16th August 2019 and the patent has been revoked. A perusal of the said order dated 16th August 2019 passed by the Controller shows that, after examining the matter, it has been held that the suit patent lacks Novelty and the patent has thereafter been revoked. Once a patent is revoked, a suit for infringement of the patent itself would not be maintainable. However, Mr. Hemant Singh, Id. counsel, submits that the order passed in the post grant opposition proceedings has been appealed against by the Plaintiffs and the same was listed before the Intellectual Property Appellate Board (*hereinafter, 'IPAB'*) on 19th August, 2019. On the said date, the IPAB has directed that the matter be listed on 21st August, 2019 at 2:30 PM. He accordingly requests that no order be passed till 22nd August, 2019, which is the next date before Court in this matter.

7. Though the appeal is stated to have been filed by the Plaintiffs immediately after the passing of the order dated 16th August 2019, rights in a

patent are only for the life of a patent which remains granted and has not been revoked. The manner in which patent rights operate is that they are merely statutory rights and there are no common law rights in patents. Patent infringement actions are maintainable only in respect of granted and live patents.

8. The fact that no infringement action is maintainable in respect of an unregistered or revoked patent is further clear from a reading of Section 62(2) and Section 11A (7) of The Patents Act, 1970. Even if a patent is not renewed, no infringement action would lie. Similarly, once the patent is published, no infringement action can be filed till the patent is granted, though damages can be sought with effect from the date of publication. Thus, the continuation of an injunction, even for a day, would not be permissible once the patent is revoked. Considering the development, i.e., the passing of the order dated 16th August, 2019, revoking the patent, the interim order restraining the Defendant from carrying out any fresh manufacturing of pharmaceutical preparations comprising of the API 'Ceritinib', as directed vide order dated 2nd May 2019, stands suspended.

9. The Plaintiffs are, however, granted liberty to seek appropriate orders if any orders are passed in favour of the Plaintiffs by the IPAB, in the appeal preferred by them. Accordingly, I.A under Order XXXIX Rule 4 CPC is disposed of. I.A under Order VII Rule 11 CPC be listed on the next date.

10. List on 22nd August, 2019, i.e., the date already fixed.

11. *Dasti* under signature of the Court Master.

PRATHIBA M. SINGH
JUDGE

AUGUST 20, 2019/MR