(2022) 04 DEL CK 0059

In the Delhi High Court

Case No : Civil Suit (COMM) No. 501 Of 2021, I.A. No. 13256 Of 2021

Novar TIS AG & Anr. — APPELLANT

Vs

Medipol Pharmaceuticals India Pvt. Ltd.& Anr. — RESPONDENT

Date of Decision : 07-04-2022

Acts Referred:
Patent Act, 1970 — Section 107A

Citation : (2022) 04 DEL CK 0059

Hon'ble Judges : Prathiba M. Singh, J

Bench : Single Bench

Advocate : Hemant Singh, Mamta Jha, Saif Rahman Ansari, Anita Sahani, Praveen Singh

Final Decision : Disposed Of

Judgement

Prathiba M. Singh, J

1. This hearing has been done through hybrid mode.

2. The present suit has been filed by Plaintiff No.1-Novartis AG. and Plaintiff No.2-Novartis Healthcare Pvt. Limited seeking permanent injunction restraining infringement in respect of their granted patent, being Patent No.233161 (hereinafter "suit patent") which relates to the invention 'bis-monoethanolamine salt of eltrombopag'. As per the Plaintiff, the same was granted protection as a New Chemical Entity (NCE). The said invention is referred to by the name 'Eltrombopag Olamine' which is the Active Pharmaceutical Ingredient (API) in the Plaintiffs' commercially manufactured and sold drug under the brand name 'Revolade' in India.

3. The suit patent was granted on 27th March, 2009 and the date of priority for the suit patent is 21st May, 2003. Thus, the term of the patent is set to expire on 21st May, 2023. Revolade, containing 'Eltrombopag Olamine', is stated to be approved in more than 90 countries and regions for the treatment of chronic immune (idiopathic) thrombocytopenic purpura (ITP). 'Eltrombopag Olamine' is

stated to raise the platelet count in patients with ITP aplastic anemia and cirrhosis due to chronic hepatitis C during interferon therapy. Promacta, the brand under which 'Eltrombopag Olamine' is sold in the US, is stated to have been approved in 2008 by US FDA and has been approved in India by the Central Drug Standard Control Organisation (CDSCO) in 2010 for the treatment of ITP. Further, the Plaintiffs' product is claimed to be the first orally-used small molecular, thrombopoietin receptor agonist and is also sold in India as a prescription drug in different dosage strength. The product sold under the mark Revolade is shown to have large sales in India to the tune of Rs.700-800 million annually with the global sales figures to the tune of $ 1,700 million in 2020.

4. The Defendants in the present case are Medipol Pharmaceuticals India Pvt Ltd and Metrochem Api Private Limited. In September, 2021, while participating in a tender process floated by Odisha State Medical Corporation Limited (OSMCL) for the procurement of various drugs, including 'Eltrombopag Olamine', the Plaintiffs came to know that the Defendants had submitted a proposal for the supply of tablets containing the patented product.

5. It is the case of the Plaintiffs that in the said tender process, the Defendant No.1 had filed a document stating that it had obtained manufacturing and marketing approval for tablets containing 'Eltrombopag Olamine'. The Defendant no.1 had further declared that it had manufacturing capacity for manufacturing 225 million tablets of drug containing 'Eltrombopag Olamine' monthly. An independent investigating agency was engaged by the Plaintiffs in order to verify the said information. In report that was submitted, it was averred that both Defendant No.1 & 2 have license to manufacture 'Eltrombopag Olamine'. Thereafter, the present suit was filed by the Plaintiffs against the Defendants.

6. Vide order dated 11th January, 2022, owing to the judgment passed by the ld. Single Judge in CS (COMM) 256/2021 titled Novartis AG v. NATCO Pharma Limited, an ad interim injunction was granted. The relevant part of order is set out below:

"11. The issue on merit stands covered by my recent decision in Novartis AG v. Natco Pharma Ltd. as the plaintiff's rights to suit patent IN 161 have been confirmed and it has been held that manufacture or marketing by any entity of Eltrombopag Olamine would infringe the suit patent.

12. In view thereof, a clear prima facie case exists in favour of the plaintiff.

13. Till the next date of hearing, therefore, the defendants, their agents or all other persons acting on their behalf, including their dealers and distributors, shall stand restrained from manufacturing, marketing, selling, importing or exporting or otherwise dealing in Eltrombopag Olamine, being the subject matter of suit patent IN 161 held by the plaintiff, which continues to remain alive till date.

14. Issue fresh notice to Defendant 1 at the aforesaid Baddi address, returnable on 5th April, 2022.

15. Reply to this application may be filed by defendants within four weeks, with advance copy to learned Counsel for the plaintiff, who may file rejoinder thereto, if any, before the next date of hearing."

7. Vide the same order, the Defendants were directed to place on record affidavit relating to the stock of patented product manufactured by them and the stock presently lying with them. The relevant observation of the Court is as under-

"16. The defendants are also directed to place on record, by an affidavit, the figures relating to the stock of Eltrombopag Olamine that have been manufactured by them in the past as well as the stock which is presently lying with the defendants."

8. In terms of the above order, a compliance affidavit/undertaking dated 9th February, 2022 has been filed on behalf of the Defendant No.2 by one Sh. P.M. Dayakar, the Corporate Technical Manager of the said Defendant. The deponent has stated in the said affidavit that the Defendant No.2 has not supplied the patented product to Defendant No.1. It is further deposed that the Defendant No.2 also does not have a commercial manufacturing licence but only had a test licence on Form-29. Relevant paragraphs of the said affidavit are set out below:

"5) That the Plaintiffs have alleged that Analysis India Pvt. Ltd. (SAI) investigator's report confirms that the Defendant No.2 has the manufacturing license for Eltrombopag Olamine API and has made supplies of Eltrombopag Olamine API to Defendant No.1 commercial purposes, which is denied. That there is nothing on record to establish that Defendant No.2 has commercial manufacturing license. The present suit has been filed in absence of evidence in support of actual infringement of the suit patent.

6) That the Defendant No.2 is a law abiding company and is conducting business under prevailing laws. It is submitted that Defendant No.2 has a TEST Licence only on Form 29 (Licence to Manufacture Drugs for Purpose of Examination Test or Analysis) and does not possess a commercial licence for both R&D Centre and Manufacturing Unit in Visakhapatnam. Copy of the Test Licence No's: TS/ MDL/2019-50992 and L.D is .No. 4592/P&B/ 2019 on Form 29 is annexed hereto this Compliance Affidavit."

9. It is also stated by the said Defendant that it has no relationship whatsoever with the Defendant No.1 and that it accepts the rights of the Plaintiffs in suit patent. The relevant paragraphs of the affidavit are as under:

"7) That Defendant No.2, Metrochem has no relationship/concern whatsoever with Defendant No.1. Defendant No.2 has never supplied not even R&D quantity, let alone commercial quantity of the Patented Drug (Eltrombopag Olamine API) to Defendant No.1 (Medipol Pharmaceuticals) or any other customer.

8) That the Defendant admits and accepts the rights of the Plaintiff's in Patent being IN213176 (the "Patent") for Eltrombopag Olamine and acknowledges the validity thereof.

9) That the Defendant No 2 hereby undertakes to this Hon'ble Court and to the Plaintiffs that it will not, either by itself or through its partners, directors, employees, officers, servants, agents and all others acting for and on its behalf from making, using, selling, distributing, advertising, exporting, offering for sale, and in any other manner, directly or indirectly, dealing in any product, that infringes the claimed subject matter of the Plaintiff's Indian Patent No. IN233161 or any of the claims thereof."

10. Thus, as per the above undertaking, the Defendant No.2 acknowledges Plaintiffs' rights in the patent product and has also given an undertaking that it would not manufacture or sell any product which may amount to infringement of the said patent during the term of the suit patent.

11. Insofar as Defendant No.1 is concerned, Sh. Hemant Negi, the authorized signatory of the said Defendant has filed an affidavit dated 1st April, 2022 stating therein that the Defendant No.1 has not been awarded the tender by the Government of Odisha and no supply has also been made by Defendant No.2 to Defendant No.1 of the patented product. The deponent further states that the Defendant No.2 also does not have a commercial manufacturing licence in terms of their own affidavit and no purchase has been made by Defendant No.1. Defendant No.1 also has stated in paragraph 5 of the undertaking that it has never manufactured the said drug nor has dealt with the same in India. In the affidavit, Defendant No.1 has also acknowledged the patent rights of the Plaintiffs in the suit patent being IN'233161 and has given an undertaking not to manufacture or sell any product infringing the patented product. The relevant portions of the said affidavit are set out below:

"5. That the defendant no.l Company was not aware about the patent of the Drug Eltrombopag Olamine vested with the Plaintiff. As admitted by the plaintiff in Para … of the plaint the defendant no.l Company has not manufactured the said Drug nor has dealt with the same in India or abroad. In view of the said averment and other wise it is impossible for the Company to have any stock or supply to any other buyer or Govt.

6. That the defendant no.l Company has not been granted any tender by the Orissa Govt. or any other Government or Non-Government, agency or organisation for supply of Drug namely Eltrombopag Olamine. The defendant no.l company did not manufacture the said patented Drug namely Eltrombopag Olamine at any point in time to supply to any Government or Non Government, agency or organisation.

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9. That the defendant No.1 admits and accepts the rights of the plaintiff in Patent being IN 213766 (in patent) for Eltrombopag Olamine and acknowledges the validity thereof.

10. That the Defendant no.2 hereby undertakes to this Hon'ble Court and to the

plaintiffs that it will not either by itself or through its partners, directors,. Employees, officers, servants, agents and all others acting for and on behalf from making using, selling, distributing, advertising, exporting, offering for sale and in any other manner directly or indirectly dealing in any product that infringes the claimed subject matter of the plaintiff's Indian Patent No. IN 233161 or any of the claims thereof.

11. That in view of the above undertaking the defendant No.1 has no objection if the present suit is disposed of in terms of the present affidavit for the validity term of the Plaintiff's Indian Patent no. IN 233161 and appropriate order may be passed in the facts and circumstances of the case and render justice.

Xxx

13 It is further stated that defendant no.1 did not have any intention to violate or infringe the Patent rights of the plaintiff in the drug Eltrombopag Olamine. The defendant no.1 will not be using the Patent in the suit till the Patent rights of the plaintiffs is valid as shown in the Plaint.

14. That the defendant is not and will not manufacture, sell or offer to sell the suit Patent of the plaintiffs. That there is no cause of action to file the present suit before this Hon'ble Court against the defendant no.1"

12. A perusal of the said affidavit clearly shows that the Defendants do not intend to challenge the rights of the Plaintiffs and in fact positively acknowledge the Plaintiffs' patent rights in patent being IN'233161. Both the Defendants admit to not having manufactured or commercially sold the patented product in India.

13. In view of this stand of the Defendants, it is submitted by the ld. Counsel for the Plaintiffs that the Plaintiffs do not press for damages or costs in this proceeding. It is the submission of ld. counsel that permanent injunction may be granted in favour of the Plaintiffs in terms of prayer clause 41(a) of the plaint. In view of the aforesaid, permanent injunction would be liable to be granted in terms of paragraph 41(a) of the plaint.

14. Accordingly, the suit is decreed in terms of paragraph 41(a) during the term of patent, i.e., till 21st May, 2023. However, it is made clear that any use of the product, by the Defendants, for the purposes of research or development strictly in terms of Section 107-A of the Patent Act, 1970 would be permissible.

15. The decree sheet be drawn in the above terms. There shall be no orders as to costs.

16. The suit, along with all the pending applications, is disposed of in the above terms.

