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

Reserved on: 10th October, 2019
Pronounced on: 18th November, 2019

\+ **CS(COMM) 823/2018**

MERCK SHARP & DOHME CORP & ANR ..... Plaintiffs
Through: Mr.Pravin Anand, Ms.Udita M.Patro & Ms.Pankhuri Malik, Advocates

versus

SANJEEV GUPTA & ORS ..... Defendants
Through: Mr.M.P.Srivignesh, Advocate for D-1 & 2.
Mr. A. Selvin Raja, Advocate for D-3 & 4.

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CORAM:
HON'BLE MR. JUSTICE PRATEEK JALAN

J U D G M E N T

I.A. 5675/2018 *(Application under Order XXXIX Rules 1 and 2 of CPC)* **& I.A. 12403/2018** *(Application under Order XXXIX Rule 4 of CPC)* in **CS(COMM) 823/2018**

1. The present suit is in respect of a patent of the plaintiffs, being Indian Patent No. 209816, for the drug known as Sitagliptin, used for treatment of Type 2 Diabetes. The contention of the plaintiffs is that the manufacture and sale of a drug under the name of "Swizglipt" by the defendants infringes the suit patent, and particularly claims 17 and 19 thereof, which covers the chemical Sitagliptin and its pharmaceutically acceptable salts.

2. I.A. No. 5675/2018, filed by the plaintiffs under Order XXXIX Rules 1 & 2 of the Code of Civil Procedure, 1908 [hereinafter referred to as "the CPC"], is for an order of injunction restraining the defendants from manufacturing, using, selling, distributing, advertising, exporting, offering for sale, or for directly or indirectly dealing in any product that infringes the subject matter of the suit patent, and any claim thereof. This Court, by an order dated 26.04.2018, granted an *ex parte* order of injunction on the said application. I.A. No. 12403/2018 is the application of the defendant Nos. 3 and 4 for vacation of the *ex parte* interim order. Both the applications were heard together and will be disposed of by this order.

3. Plaintiff No. 1 is a company incorporated in New Jersey, USA, which manufactures and markets several pharmaceutical products. Plaintiff No. 1 is the owner of the suit patent, which, according to it, covers the chemical Sitagliptin and its pharmaceutically acceptable salts. Plaintiff No. 2 is the licensee of plaintiff No. 1 for marketing, distributing and selling Sitagliptin and the combination of Sitagliptin and Metformin, sold under the names Istavel and Istamet. Plaintiff No.1 claims to have patents for this product in 102 countries. Defendant No. 2 is a company incorporated in Cambodia, which markets and supplies pharmaceutical products in Cambodia and Myanmar. Defendant No. 1 is the executive director of defendant No.2. Defendant No. 4 is a partnership firm involved in the manufacture of pharmaceutical products, and defendant No. 3 is a partner of defendant No. 4.

4. The case of the plaintiffs is that defendant No. 4 manufactures the impugned product "Swizglipt" for defendant No. 2, at its factory in Himachal Pradesh, and defendant No.2 exports it to Cambodia and Myanmar. According to the plaintiffs, the products of the defendants are either Sitagliptin tablets or contain a salt of Sitagliptin, viz. Sitagliptin Phosphate Monohydrate [hereinafter referred to as "SPM"]. It is averred in the plaint that the plaintiffs conducted a market survey through an independent investigator, which did not reveal any sale of the infringing product in Delhi. However, the plaintiffs claim that the manufacture of the product, even for the purposes of export, is in violation of the rights of the plaintiffs, as protected by Section 48 of the Patents Act, 1970 [hereinafter referred to as "the Act"].

5. The written statement filed by the defendants Nos. 3 and 4 (as also the replies to the plaintiffs' application for injunction and the defendants' application for vacation thereof) dispute the jurisdiction of this Court to entertain the suit. Additionally, it is pointed out that the impugned products are manufactured by defendants Nos. 3 and 4 under licenses granted by the Drug Controller, and only for the purposes of export.

6. Mr. Pravin Anand, learned counsel for the plaintiffs, relied upon several orders and judgments passed by this Court, by which various defendants have been restrained from manufacturing and selling Sitagliptin products. In fact, pursuant to an order dated 07.09.2016 in CS(OS) 586/2013 [*Merck Sharp And Dohme Corporation & Anr.* vs. *Glenmark Pharmaceuticals Ltd.*], this Court issued a certificate of validity in respect of the suit patent. Learned counsel for the plaintiffs

submits that the patent has been protected by thirty-five orders of injunction and twenty-two decrees. Several of the judgments and orders in those cases have been placed before the Court. With regard to the question of jurisdiction, Mr. Anand argued that Section 20(c) of the CPC attracts the jurisdiction of this Court to a case where part of the cause of action has arisen within jurisdiction. He drew my attention to export data of Swizglipt, which shows that the export of the product has taken place *inter alia* from Delhi. He further submitted that the product is listed on interactive websites like www.indiamart.com, by which the defendants invite inquiries in respect of the product from customers, and the said website is accessible to customers located within the jurisdiction of this Court.

7. Mr. Selvin Raja, learned counsel for defendant Nos. 3 and 4, submitted that Section 48 of the Act does not cover manufacture which is undertaken solely for the purposes of export. He also argued that the grant of licenses by the Drug Controller for manufacture of the impugned products indicates the weakness of the plaintiffs' case and disentitles them to an interim order. Mr. Selvin Raja further pointed out that the plaintiffs had in fact made applications for patent in respect of a combination of Sitagliptin and Metformin, which was later abandoned.

8. In rejoinder, Mr. Anand disputed the construction of Section 48 of the Act advanced by Mr.Selvin Raja, and cited the Division Bench judgment of this Court in *Bayer Corporation* vs. *Union of India & Ors.*, 2019 (78) PTC 521 (Del) [Paragraphs 78 and 84] in this connection. In reference to the abandonment of the plaintiff No.1's

applications for patent in respect of Sitagliptin and Metformin combinations, Mr. Anand submitted that this was in view of Section 3(d) of the Act, which provides *inter alia* that mere discovery of a new form of a known substance, not resulting in the enhancement of the known efficacy of that substance, does not qualify as an invention within the meaning of the Act. In any event, he cited the Division Bench judgment in *Merck Sharp and Dohme Corporation & Anr.* vs. *Glenmark Pharmaceuticals* 2015 (63) PTC 257 [Del] [DB], affirmed by the order of the Supreme Court in *Glenmark Pharmaceuticals* vs. *Merck Sharp and Dohme Corporation & Anr.*, (2015) 6 SCC 807, to argue that the abandonment of a patent application is of no relevance to claim construction in respect of a patent granted.

9. Having heard learned counsel for the parties, I am of the view that the plaintiffs have made out a good *prima facie* case for the confirmation of the injunction granted in their favour. The suit patent, in claim 19 specifically, refers to Sitagliptin and its pharmaceutically acceptable salts. The impugned product of the defendants admittedly contains SPM, which is a salt of Sitagliptin.

10. The dispute in the present case, therefore, turns on the question of jurisdiction, the interpretation of Section 48 of the Act, the effect of the licenses granted to the defendants, and the effect of abandonment of the other applications by the plaintiff.

11. Turning first to Mr. Selvin Raja's contention regarding the jurisdiction of this Court, reference to the documents placed by Mr. Anand clearly demonstrates that the impugned product has been exported from Delhi. It is also listed on an interactive website in

Delhi, which constitutes an offer for sale, within the jurisdiction of this Court, in terms of judgment of this Court in *Banyan Tree Holding (P) Limited vs. A. Murali Krishna Reddy & Anr*, 2010 (42) PTC 361 [Del]. Section 20(c) of the CPC, therefore, confers jurisdiction upon this Court, and the defendants' objection to the contrary is rejected.

12. The construction of Section 48 of the Act, urged by Mr. Selvin Raja, also does not commend to me. Section 48 reads as follows :-

> *"**48. Rights of patentees:***
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> *Subject to the 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."*

13. Mr. Selvin Raja's argument that manufacture for the purposes of export is not covered by this provision is contrary to a plain textual reading of the provision. On a reasonable reading, "making", "using", "offering for sale", and "selling" of the patented product in India are *each* covered by Section 48(a) of the Act. The phrase "importing for those purposes" refers to import of the patented product for the enumerated purposes, e.g. using, offering for sale, or selling in India.

The construction advanced by Mr. Selvin Raja requires the words "for those purposes" to qualify the words "making", "using", "offering for sale", "selling", or "importing". I am *prima facie* of the view that this construction is untenable. In the written submissions, Mr. Selvin Raja has also submitted that the enumerated activities must all occur within the territory of India to attract Section 48(a). This is *ex facie* contrary to the use of the disjunctive "or" in the provision. I am therefore *prima facie* of the view that the protection enjoyed as a result of grant of a patent cannot be reduced to cover only domestic manufacture and sale.

14. Mr. Selvin Raja submitted that the absence of the word "export" or "for the purposes of export" in Section 48(a) of the Act is significant and these words should not be read into the statute. In my view, the argument is wholly misconceived, as the alleged infringement in this case is based upon the *"manufacture"* of the product in India and "*making*" is expressly protected by Section 48(a). The judgments cited by Mr.Selvin Raja on the impermissibility of adding words in a statute are, therefore, inapplicable to this case. Similar is the fate of the submission that the application of Section 48(a) to manufacture for exports would render the statute extraterritorial in application. The manufacture of the product has, admittedly, occurred within the territory of India, and the question of extraterritorial application does not arise in this case.

15. The reliance by the defendants upon the licenses granted to them does not carry the case much further. The Division Bench judgment of this Court in *Bayer Corporation & Ors.* Vs. *Union of*

India & Ors., 2010 (43) PTC 12 (Del) clearly holds that the licenses under the Drugs and Cosmetics Act, 1940 are not linked to patent protection, and both statutes operate independently of each other. The purpose of the license in the present case is to permit manufacture under the Drugs and Cosmetics Act, 1940, and Rules framed thereunder. The defendants have not cited any material to establish that the Drug Controller conducts any inquiry into the question of whether the product is protected by a rival patent.

16. Further, the argument that in view of the plaintiff's patent, the defendants have obtained a license only for export, is not supported by a reading of the document itself. The licenses dated 13.09.2017 and 30.03.2015, placed on record by the defendants, contain *inter alia* columns identifying the exporting and importing countries, the name and dosage of the product, a statement as to whether the product is licensed to be placed on the market for use in the exporting country, and as to whether the product is actually on the market in the exporting country. The relevant extracts of a sample license disclosed by the defendants is to the following effect:-

" *GOVERNMENT OF HIMACHAL PRADESH*
DRUGS CONTROL ADMINISTRATION
Certificate of a Pharmaceutical Product[1]
This certificate conforms to the format recommended by the World Health Organisation
(General instructions and explanatory notes attached)

No. of the certificate: DCA/DML/SGL/2017/111	
Exporting (certifying) country	***INDIA***

Importing (certifying) country	*MYANMAR*
1. Name and dosage form of product	*SWIZGLIPT-50* *Sitagliptin Tablets 50 mg*
1.1 Active ingredient(s)[2] and amount(s) per unit Dose[3] For complete qualitative composition including Excipients[4]	*Each film coated tablet contains:* *Sitagliptin Phosphate Monohydrate* *Equivalent to Sitagliptin .... 50mg* *Excipients……q.s.* *Colour: Approved colours used.*
1.2 Is this product licensed to be placed on the market for use in exporting country?[5]: ***Yes/No (Key in as appropriate)***	***:YES***
1.3 Is this product actually on the market in the exporting country? ***Yes/No/Unknown*** ***(Key in as appropriate)*** *If the answer to 1.2 is yes, continue with section 2A and omit section 2B. If the answer ro 1.2 is no, omit section 2A and continue with section 2B[6]*	***: YES***
xxxx	*xxxx* *xxxx*

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(Emphasis supplied)

The identification of India as the country of export and the contents of columns 1.2 and 1.3, *prima facie* do not demonstrate that, as far as the drug license is concerned, the product is not permitted to be sold in

India. The grant of the drug license in this case, therefore, is not in any event dispositive of the plaintiffs' claim for an injunction.

17. Mr.Selvin Raja's argument regarding abandonment of the plaintiffs' application for patent in respect of the combination of Sitagliptin and Metformin also does not bear scrutiny. The Division Bench of this Court in *Merck Sharp and Dohme Corporation* (supra), which concerns the very same patent of the plaintiffs, in paragraphs 55 and 56, expressly rejects the argument sought to be advanced by Mr.Selvin Raja. Although the said judgment was carried to the Supreme Court in *Glenmark Pharmaceuticals* (supra), the reasoning on this aspect has not been disturbed.

18. The certificate of validity of the patent granted by this Court, coupled with several decrees and injunctions protecting the suit patent, lead to a conclusion that the questions of balance of convenience and irreparable injury must also be decided in favour of the plaintiffs.

19. In view of the aforesaid, I.A. 5675/2018 is allowed, and I.A.12403/2018 is dismissed. The *ad interim* injunction dated 26.04.2018 will bind the defendants until the disposal of the suit. The observations contained in this order are only for the purposes of disposing of these applications. The rights and contentions of the parties at the stage of final hearing are expressly reserved.

20. The applications are disposed of.

PRATEEK JALAN, J.

NOVEMBER 18, 2019
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