

Merck Sharp And Dohme Corp & Anr vs Chiral Biosciences Limited on 10 February, 2021

Author: C.Hari Shankar

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IN THE HIGH COURT OF DELHI AT NEW DELHI

CS(COMM) 23/2021

MERCK SHARP AND DOHME CORP & ANR. ... Plaintiffs

Through: Mr. Pravin Anand, Ms. Tusha
Malhotra and Ms. Pankhuri
Malik, Advs.

Versus

CHIRAL BIOSCIENCES LIMITED Defendant

Through: None

CORAM:

HON'BLE MR. JUSTICE C.HARI SHANKAR

ORDER

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10.02.2021

(Video-Conferencing)

CS(COMM) 23/2021

1. Issue summons in the suit to the defendant, returnable on 27th April, 2021 before the Joint Registrar for completion of pleadings, admission and denial of documents and marking of exhibits.

2. Written statement, if any, be filed within a period of four weeks accompanied by an affidavit of admission and denial of the documents filed by the plaintiffs with advance copy to learned counsel for the plaintiffs, who may file replication thereto, if any, within a period of two weeks thereof accompanied by an affidavit of admission and denial of the documents filed by the defendant. Written statement and replication would not be taken up, unless accompanied by an affidavit.

IA 750/2021 (Section 151 CPC for exemption)

1. Subject to plaintiffs filing legible copies of dim documents on which they seek to place reliance within a period of four weeks from today, exemption is granted for the present.

2. The application stands disposed of.

LA 748/2021 (Order XI Rule 1(4) CPC)

1. This application seeks permission to file additional documents. The plaintiffs are permitted to file additional documents within a period of four weeks from today with advance copy to the defendant, subject to right of the defendant to admit or deny the same.

2. The application stands disposed of.

LA 749/2021 (Order XXXIX Rules 1 and 2 CPC)

1. Issue notice to the defendant.

2. Response to this application, if any, be filed within a period of four weeks from today with advance copy to learned counsel for the plaintiffs, who may file rejoinder thereto, if any, within a period of two weeks thereof.

3. Mr. Pravin Anand, learned counsel for the plaintiffs, submits that this case is completely covered in favour of the plaintiffs by the judgment dated 20th March, 2015 of this Court in Merck Sharp and Dohme Corporation v. Glenmark Pharmaceuticals 1 read with the judgment of the Supreme Court on the appeal, preferred there against as Glenmark Pharmaceuticals Ltd. v. Merck Sharp and Dohme Corporation².

4. Prima facie, Mr. Pravin Anand is right.

5. The claim pertains to alleged infringement of Indian Patent No. 209816 (hereinafter referred to as "IN 816" and "the suit patent"), having been issued by the plaintiffs in respect of a molecule name Sitagliptin, the IUPAC name whereof is 7 - [(3 R) - 3 - Amino - 4 - (2 , 4 , 5 - trifluorophenyl) - butanoyl] - (3 - trifluoromethyl) - 5,6,7,8-tetrahydro- 1,2,4-triazolo[4,3- \square]pyrazine, and which, by itself or in combination with Metformin, is used to treat Diabetes Mellitus Type II. Sitagliptin, as set out in the plaint, is a DPP-4 (di-peptidyl peptidase - 4) inhibitor which, by inhibiting the DPP-4 enzyme, helps the pancreas to produce more insulin, as insulin resistance is one the predisposing factors for diabetes mellitus. Thus, Sitagliptin helps lower blood sugar when it is too high. The details of the invention have been tabulated by the plaintiffs, thus:

Indian Patent No.	209816
Title	"Beta-Amino Hetero Dipeptidyl Peptidase Inhibitor The Treatment Or Prevention Diabetes"
Drug covered	Sitagliptin
Number of Claims	20

2015 SCC OnLine Del 8227

(2015) 6 SCC 807

Claims covering	1, 2, 3, 5, 6, 7, 8, 9, 10, and 17
Sitagliptin Claim specifically covering Sitagliptin and its salts	19
Patentee	Merck Sharp & Dohme Corp. (formerly known as Merck & Co. Inc.)
Indian Application No.	26/CHENP/2004
Date of filing in India	January 6, 2004

Date of publication u/s December 2, 2005 11A Date of filing of July 5, 2002 international application Priority date July 6, 2001 Date of grant September 6, 2007

6. It is further averred in the plaint thus:

(i) There was no opposition, either in pre-grant or in post-

grant stage, to the grant of the aforesaid suit patent in favour of the plaintiffs.

(ii) The molecule is sold in India under the brand names "JANUVIA" and (in conjunction with Metformin) "JANUMET".

(iii) Vide order dated 7th September, 2016, in CS(OS) 586/2013, this Court issued a Certificate of validity to the suit patent.

(iv) Sitagliptin, and the salts thereof are covered by claims 1, 2, 3, 5, 6, 7, 8, 9, 10, 14, 15, 16 and 17, and specifically claimed by claim 19 of IN 209816. Claim 19 may be depicted thus:

(v) Scheme 6, in the complete specifications of the suit patent, specifically explains how the molecule Sitagliptin could be prepared, and may be depicted thus:

(vi) Accordingly, the plaintiffs aver that IN 209816 covers Sitagliptin with all pharmaceutically acceptable salts thereof.

(vii) Sitagliptin has been launched in as many as 107 countries, and approved by all regulatory authorities.

(viii) The achievement of the plaintiffs, qua Sitagliptin products have been set out in paras 25 and 26 of the plaint, thus:

"25. Worldwide success of the SITAGLIPTIN products: The Plaintiff No. 1's product JANUVIA is the winner of two Prix Galien Awards. It won the Prix Galien USA Award in 2007 and the Prix Galien UK Award in 2008. The Prix Galien is awarded annually on a national basis in recognition of significant contribution to pharmaceutical research. It is often considered as the pharmaceutical industry's equivalent of the Nobel Prize. Copies of certain articles and publications mentioning the awards won by the Plaintiff No. 1 are annexed with the list of documents filed with the present plaint.

26. Also, according to IMS Health, NPA TM Monthly, TRx's, October 2006-September 2012, JANUVIA is world's No. 1 inhibitor with more than 49.8 million prescriptions dispensed worldwide. The JANUVIA family enjoys a market share of 73% (by value) in the global DPP-4 inhibitor market. Copies of some of the promotional materials of the Plaintiff No.1 are annexed with the list of documents filed with the present plaint."

(ix) The plaintiffs work the suit patent, in India, itself as well as through its licensee M/s. Sun Pharmaceuticals Industries Ltd., which manufactures and sells the products under the trade named "ISTAVEL®" and "ISTAMETTM".

(x) Yearly sales figures of the plaintiffs and of M/s. Sun Pharmaceuticals Industries Ltd., in respect of the Sitagliptin products and the Sitagliptin-Metformin combination drug, have been provided thus:

In respect of plaintiffs:

Year	Volume (strips)	Value (INR)
2013	64,19,628	1,29,76,10,068
	70,13,736	1,71,92,97,981
2014	62,91,664	1,23,73,65,179
	86,07,690	1,97,32,64,652
2015	78,73,387	1,56,53,53,613
	60,91,573	2,57,31,21,557
2016	95,93,650	1,98,88,17,906
	71,31,877	2,72,84,46,955
2017	1,09,06,185	2,24,34,52,887
	86,65,726	3,38,81,96,537
2018	1,28,66,590	2,65,33,03,414
	1,05,52,790	4,13,65,55,718

In respect of M/s. Sun Pharmaceuticals Industries Ltd.

Year	Volume (strips)	Value(INR)
2013	13,05,908	16,24,76,830
	34,16,167	53,46,90,199
2014	24,08,769	29,38,68,351
	40,49,827	52,73,02,877

2015	29,69,048	35,77,67,939
	34,13,885	96,58,82,171
2016	29,05,513	34,34,01,662
	32,61,519	90,38,33,809
2017	27,18,160	31,73,93,967
	39,30,825	1,07,22,42,915
2018	39,42,167	46,64,82,554
	43,10,652	1,26,65,59,185

(xi) The uniqueness and advantage, possessed by Sitagliptin, vis-a-vis other anti diabetics, has been provided thus:

"(ii) First of its kind: The Plaintiffs' drug Sitagliptin was the first in the world, in its class of DPP-4 inhibitor compounds, to get regulatory approval.

(iii) The Plaintiffs' drug Sitagliptin filled a long felt need:

Current opinion regarding origin of type- II diabetes, associates it with insulin resistance. This results in high blood glucose levels, observed in many such patients. Most common drugs function by enhancing insulin production in the body, thereby controlling glucose levels. Popular drugs include Glipizide and Metformin, which are well established in the market for the oral treatment of diabetes. The major problem associated with these drugs is the unwanted side-effect of dramatically lowering blood glucose levels, leading to hypoglycemia. In spite of much effort on the part of the drug industry, many patients have suffered immensely due to such side effects. These are most unwelcome, especially as diabetics suffer from many other complications due to uncontrolled blood glucose levels.

The new drugs discussed here function by a very different mechanism. These competitively inhibit the enzyme, DPP- 4 (di peptidyl peptidase-4). DPP-4 is the enzyme which binds to and blocks two peptides called GIP and GLP-1 (incretins), which are released in the human body only on consuming food. The competitive inhibition of DPP-4 by Sitagliptin results in increased concentration of incretins which in turn results in increased production of insulin, on the consumption of food. There is thus no possibility of hypoglycemia, as the new drugs control only the glucose produced after eating. When used in combination with Glipizide etc., it is tolerated very well by most patients and the results achieved are comparable."

7. Having thus set out the characteristics of Sitagliptin and its uniqueness as anti diabetic therapy, the plaintiffs aver that it came to be known from the webpage of the defendant www.chiralbiosciences.com that the defendant was advertising and offering for sale the infringing Sitagliptin as well as intermediates. It is averred that the defendant was found to be advertising three different compositions of Sitagliptin, and the screenshot thereof has been provided in the plaint thus:

8. It is further alleged that the defendant was found to be advertising and offering for sale the aforesaid three infringing variations of Sitagliptin at various e-marketing websites including indiamart, and the screenshot thereof has also been provided in the plaint.

9. Following the investigations conducted in the matter by the plaintiffs, the plaint alleges that the defendant is, without any authorization or permission from the plaintiffs and without obtaining any licence from the plaintiffs, manufacturing and producing infringing Sitagliptin and its intermediates in India including Sitagliptin Phosphate Monohydrate.

10. It is also alleged that the defendant is advertising, offering for sale and exporting allegedly infringing products. If the defendant's activities are allowed to continue unchecked, the plaint expresses an apprehension that the defendant would flood the market with the infringing products.

11. Mr. Pravin Anand has also invited my attention to the fact that in an identical challenge, interim injunction was granted in favour of the Sitagliptin products of the plaintiffs by this Court in Merck Sharp and Dohme Corporation¹ and the matter was carried to the Supreme Court, which did not choose to interfere with the order of restraint, passed by this Court against the defendant in the said case, restraining the defendant from further manufacturing Sitagliptin Phosphate Monohydrate. Though in the peculiar facts of that case, the Supreme Court, even while maintaining the injunction against further manufacturing of the infringing products, permitted M/s. Glenmark Pharmaceuticals limited to sell existing stocks, Mr. Pravin Anand points out that the said case was the first instance of such a challenge and that thereafter, as many as 47 injunctions have been granted, in all of which there has been an injunction not only of manufacture of the infringing products but also of sale of infringing products in the market. A list of such orders has been provided with the plaint. He also points out that Merck Sharp and Dohme Corporation¹ proceeded to trial and it was finally decreed vide judgment and decree dated 7th October, 2015³.

12. The prayer clause in this application reads thus:

"In light of the foregoing, it is most humbly prayed that the following interim reliefs may be granted by this Hon'ble Court:

(i) An order of ex parte ad interim injunction restraining the Defendant, its directors, employees, officers, servants, agents and all others acting for and on its behalf from manufacturing, using, selling, distributing, advertising, exporting, offering for sale, and in any other manner, directly or indirectly, dealing in either API or intermediates or any product, that infringes the claimed subject matter of the Plaintiffs' Indian Patent No 209816 or any of the claims thereof, including Sitagliptin or any of its pharmaceutically acceptable salts, including Sitagliptin Phosphate Monohydrate;

(ii) An order granting ex parte ad interim injunction during the pendency of the present application;

(iii) An order directing the Defendant to disclose before this Hon'ble Court all details, including its books of account and statements of profit to elucidate details of all transactions made by the Defendant concerning Sitagliptin API till date;

and

(iv) Any other Order(s) as this Hon'ble Court may deem fit and proper in the facts and circumstances of the case."

13. In view of the above, till the next date of hearing, there shall be an ex parte ad interim injunction in terms of prayer (i) (supra) as contained in the application.

14. Inasmuch as this order has been passed in the absence of the Merck Sharp & Dohme Corp v. Glenmark Pharmaceuticals Ltd, 223 (2015) DLT 454 defendant, the plaintiffs are directed to comply with the provisions of Order XXXIX Rule 3 of the CPC within the time provided therefor.

15. Needless to say, the defendant would be at liberty to apply for variation or modification of this order at any appropriate stage.

16. List this application on 10th May, 2021 before the Court.

C.HARI SHANKAR, J.

FEBRUARY 10, 2021 r.bararia