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

% **Date of decision: 5th April, 2013.**

\+ **CS(OS) 586/2013**

**MERCK SHARP AND DOHME CORPORATION & ANR** **.....Plaintiffs**

Through: Mr. Parag P. Tripathi, Sr. Advocate with Mr. Praveen Anand, Mr. Dhruv Anand, Ms. Udita & Mr. D. Sreekumar, Advocate.

Versus

**GLENMARK PHARMACEUTICALS LTD** **..... Defendant**

Through: Mr. A.M. Singhvi, Mr. Rajeev Nayar and Mr. Rajeev Virmani, Sr. Advocates with Ms. Prathiba M. Singh, Ms. Saya Choudhry, Mr. Varun Tikmani, Ms. Anusuya Mehrotra and Mr. Ashutosh Kumar, Advocates.

**CORAM:**
**HON'BLE MR. JUSTICE RAJIV SAHAI ENDLAW**

**O R D E R**

**% 02.04.2013**

**I.A. No.5167/2013 (of plaintiffs u/O 39 R-1 & 2 CPC)**

1. The plaintiffs in this suit for injunction restraining infringement of patent and for other ancillary reliefs, seek interim relief restraining the defendant from making, use, selling, distributing, advertising, offering for sale and in any other manner dealing in any product infringing the plaintiffs'

patent.

2. It is the case of the plaintiffs in the plaint:

(i) that the plaintiff No.1 Merck Sharp and Dohme Corporation (Merck) formerly known as Merck & Company, Inc. manufactures a range of medicines and is also a global research driven company dedicated *inter alia* to development of medicine for addressing unmet medical needs;

(ii) that the molecule having International Non-Proprietary name of "SITAGLIPTIN" was invented by the plaintiff Merck who has patents for the same in 102 countries of the world including India; that the international application for patent was filed on 5th July, 2002 with the priority date of 6th July, 2001 and the application in India was filed on 6th January, 2004 and the patent in India was granted on 6th September, 2007 and is valid for 20 years from 6th July, 2001;

(iii) that the aforesaid patent was neither opposed in the pre-grant opposition nor in post-grant opposition by any member of the public or interested party in India despite extensive publicity given to the plaintiffs' commercial product sold in India under the brand name "JANUVIA" and "JANUMET";

(iv) SITAGLIPTIN was approved for sale in United States of America (USA) in October, 2006 and in the Indian market on 28th March, 2008 and the plaintiffs since then are selling the

product extensively in India. The plaintiff Merck has also granted a license in India to the plaintiff No.2 Sun Pharmaceutical Industries Limited which sells SITAGLIPTIN under the brand name "ISTAVEL" and Sitagliptin-Metformin combination under the brand name "ISTAMET";

(v) that the plaintiffs in public interest have priced JANUVIA as a daily pill at about Rs.43/- a pill, it is roughly 1/5$^{th}$ of its price in the USA - this is probably the first case of differential pricing in India and which price was arrived at after surveys, of the same being within the reach of the people in need of the said medicine. The plaintiffs also have a patient access programme for patient understanding of the diseases of Type-2 Diabetes Mellitus which the said drug controls, for the management of the diseases and has spent approximately Rs.10 crores in the said programme. The plaintiffs have spent another Rs.30 crores in launching and expansion of Certificate Course in Evidence Based Diabetes Management, focused on the management of Type-2 diabetes;

(vi) that the defendant is a large pharmaceutical company and well aware of the plaintiffs' product JANUVIA as well as the patent granted to cover the same and knows of the active ingredient SITAGLIPTIN in JANUVIA. The defendant itself obtained US patent dated 18$^{th}$ December, 2012 for its process for preparation of SITAGLIPTIN and in the said patent has acknowledged the plaintiffs' corresponding US patent for SITAGLIPTIN and its

proprietary rights by making admissions thereof;

(vii) that the product Sitagliptin Phosphate Monohydrate of the defendant infringes the plaintiffs' patent aforesaid;

(viii) SITAGLIPTIN and any of its salts including its various stereo isomeric forms are covered by the claims of the patent of the plaintiffs and by virtue of Section 48 of the Patents Act, 1970, the plaintiffs have the exclusive right to prevent any third party making, using, offering for sale into India products that fall within the scope of the claims of the plaintiffs;

(ix) that the defendant had started distributing SITAGLIPTIN and SITAGLIPTIN PLUS METFORMIN under the brand names ZITA and ZITA-MET in the form of sample packs for the last seven days prior to the institution of the suit and has hurriedly dumped the product in the market to gain mileage in any law-suit instituted against the defendant; with the same intent caveats were also filed.

3. The suit along with this application was filed on 1st April, 2013 and came up first for hearing on 2nd April, 2013, when the defendant through counsels, being on caveat, appeared. The senior counsels for the plaintiffs and the defendant addressed arguments on the grant of interim relief for about two hours. After the hearing, they were informed that after such a detailed hearing, notwithstanding the written statement/reply being not on

record, orders on the application for interim relief will be pronounced and were reserved. I clarify that need is not felt for the written statement/reply of the defendant for final disposal of the application for interim relief, inasmuch as the defendant being on caveats were fully prepared and have during the course of hearing handed over the documents/other materials relied upon by them and which are taken on record and the plaintiffs did not seek any opportunity to meet the same. I may however record that the senior counsel for the defendant has argued that the application for interim relief should not be disposed of and the Court at this stage should consider only the aspect of grant of *ex-parte* relief, saving the disposal of the application to after the reply thereto has been filed but the said request was declined as the defendant had come well prepared with the case which it was required to meet and has chosen to make lengthy arguments in opposition and the Court cannot repeatedly grant opportunities to the parties.

4. Not finding any averments in the plaint demonstrating infringement by the defendant of the patent of the plaintiff, it was at the outset enquired as to on what basis infringement is averred.

5. The senior counsel for the plaintiffs has invited attention to the packaging of the plaintiff No. 1's product JANUMET which describes its pharmaceutical composition as "Sitagliptin Phosphate & Metformin Hydrochloride", to the plaintiff No. 2's product ISTAVEL which describes its pharmaceutical composition as "Sitagliptin Phosphate Tablets" and to the packaging of the defendant's product which describes its pharmaceutical composition as "Sitagliptin Phosphate Monohydrate Tablets". On the basis thereof it is argued that infringement is obvious.

6. Attention is next invited to the package-insert of the defendant's product ZITA and it is contended that the composition of the defendant's product shown therein is the same as the composition of the plaintiffs' product as shown in the patent granted to the plaintiff Merck.

7. The senior counsel for the plaintiffs, to allay any influence of the judgment of the Supreme Court in Civil Appeal Nos. 2706 to 2716 of 2013 titled ***Novartis AG Vs. Union of India*** pronounced on 1st April, 2013 contended that there is no price difference in the product of the plaintiffs and defendant and thus it cannot be said that the product of the defendant is considerably cheaper than that of the plaintiffs.

8. The senior counsel for the plaintiffs has then invited attention to the documents evidencing the process patent obtained by the defendant in US for preparation of R-Sitagliptin and its pharmaceutically acceptable salts to contend that the defendant therein has admitted the plaintiff No.1 Merck's US patent in SITAGLIPTIN.

9. The senior counsel for the plaintiffs has relied on:

(a) ***Hindustan Lever Limited Vs. Lalit Wadhwa*** (2007) 35 PTC 377 (Delhi) laying down that the rights given by the patent do not include the right to practice the invention, but only to exclude others from doing so and that where one person has a patent for a basic invention and another person later obtains a patent for an improvement to this invention, then the latter is not free to use his invention without the permission of the former and the former cannot use the improved version without coming to terms with the latter.

It is argued that patent is an exclusionary right;

(b) ***M/s. National Research Development Corporation of India, New Delhi Vs. M/s. The Delhi Cloth & General Mills Co. Ltd.*** AIR 1980 Delhi 132 laying down the principles applicable to the grant of temporary injunction in suits for infringement of patent including, that if a patent is a new one, a mere challenge at the Bar would be quite sufficient for refusal of

temporary injunction but if it is sufficiently old and has been worked, the Court for the purpose of temporary injunction, would presume the patent to be a valid one.

It is argued that though the said judgment has referred to the age of six years for the patent being an old one but the said rule of six years is not an inflexible one and has in subsequent judgments been reduced;

(c) ***Telemecanique & Controls (I) Limited Vs. Schneider Electric Industries SA*** 94 (2001) DLT 865 where a Division Bench of this Court held that a monopoly of the patent is the reward for the inventor.

10. Per contra the senior counsel for the defendant has argued:

(i) that the plaintiffs are guilty of suppression and are not entitled to the grant of discretionary relief of interim injunction on this ground alone - they have not disclosed that the plaintiff No.1 Merck, in India had applied for grant of patent of the product qua which injunction is claimed but which was not only declined but the plaintiff No.1 Merck affirmatively abandoned the same;

(ii) it is elaborated that the product of the defendant qua which injunction is claimed comprises of three parts namely 'S', 'PD' and 'DC' - the plaintiff No.1 Merck in USA has separate patents, for each of the aforesaid three parts; the plaintiff Merck in India is holding the patent for the part 'S' i.e.

SITAGLIPTIN only and though had applied for separate patents for the parts 'PD' and 'DC' but which were declined and subsequently affirmatively abandoned as aforesaid. From the compilation of documents handed over during the hearing, it is shown that the plaintiffs' patent is for Sitagliptin Hydrochloride only and not for Sitagliptin Phosphate;

(iii) attention, in the compilation handed over, is invited to the application No. 5948 filed by the plaintiff Merck for the invention 'PD' i.e. "Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor" and in which the plaintiff had described the same as a "novel salt" and a new discovery in comparison to its patent Sitagliptin seeking injunction against infringement of which this suit is filed. It is thus argued that the plaintiff in their patent application No.5948 having described the combination of 'S' and 'PD' as a new discovery and not covered by the existing patent 'S' of the plaintiff, cannot now be heard to allege the combination of 'S' & 'PD' of the defendant as an infringement of the patent 'S' i.e. SITAGLIPTIN of the plaintiff. Attention is also invited to the download from the website of Controller General of Patens showing the status of the patent application No.5948 of the plaintiff Merck as "abandoned under Section 21(1)" of the Act;

(iv) it is stated that at least 9 to 10 other persons are also marketing the product SITAGLIPTIN Phosphate Monohydrate, to prevent

the defendant from marketing which this application has been filed. A list of the said persons, also indicating the dates from which they are marketing the same has been handed over and it is argued that since others are also selling the same product which the plaintiffs are seeking to restrain the defendant from selling, the ingredients of irreparable injury and balance of convenience are not in favour of the plaintiffs;

(v) attention is invited to paras 139 & 156 of the judgment in ***Novartis*** supra to contend that coverage in a patent cannot be permitted to go much beyond the disclosure made by the patentee and that the scope of patent cannot be permitted to be determined by the artful drafting of its claim by skilful lawyers instead of intrinsic worth of the invention;

(vi) it is highlighted that had the Sitagliptin Phosphate been not a distinct product from SITAGLIPTIN, the plaintiff Merck would not have obtained separate patent for Phosphate in US and would not have applied for separate patent for Sitagliptin Phosphate in India and which was ultimately abandoned;

(vii) attention in this regard is also invited to the recent dicta of this Court in ***F. Hoffmann-La Roche Ltd. Vs. Cipla Ltd.*** (2012) 52 PTC 1 (Delhi) particularly to paras 147, 211, 212 to 220, 222 to 224, 246, 247 and 249 thereof to contend that the plaintiff in that case also was seeking to injunct the product version application for patent of which had been rejected in

India and in light thereof, the suit was dismissed. On the basis of the said judgment, it is further contended that where the role of variant outweighs the patented claim, there can be no infringement;

(viii) attention is also invited to Sections 10 and 13(4) of the Patents Act, to contend that grant of a patent does not raise any presumption of validity of the patent. It is further contended that since others are also using the same pharmaceutical formulation which the plaintiffs are seeking to injunct the defendant from using, there can be no new invention.

11. The senior counsel for the plaintiffs has in rejoinder contended that a distinction has to be carved out between a basic and an improved patent. Attention is invited to Section 3(d) of the Act particularly to the explanation thereof to contend that there can be no patent in a derivative of a known substance. It is argued that SITAGLIPTIN is the invention and in which the plaintiff No.1 Merck has a patent and Sitagliptin Phosphate is merely a derivative thereof and in which under Section 3(d), no patent could have been granted. It is contended that the application filed by the plaintiff Merck for grant of patent in Sitagliptin Phosphate was misconceived and had been rightly rejected and for this reason only the plaintiff Merck abandoned the same. It is further contended that no weightage ought to be

given to the contents of the said application to the effect that Sitagliptin Phosphate was a new discovery inasmuch as it was essential to write so while applying for a patent, though under Section 3(d) no patent could have been granted therein. It is explained that the need for applying for a separate patent for Sitagliptin Phosphate in USA arose since under the laws of USA, there is no equivalent of Section 3(d) of the Indian Act. Attention is invited to the defendant's application for process patent in USA to re-emphasize that the defendant therein had admitted Sitagliptin Phosphate to be a pharmaceutically acceptable salt of SITAGLIPTIN. Attention is also invited to Section 48 dealing with the rights of the patentees. It is contended that the Supreme Court in ***Novartis*** (supra) was not concerned with the issue as has arisen here but was concerned with the concept of 'evergreening' which is an attempt to keep the patent alive beyond its life/term. Attention in this regard is invited to paras 3, 5, 8 and 9 of ***Novartis***. Attention is also invited to the fifth edition of Philip W. Grubb's book on Patents for Chemicals, Pharmaceuticals and Biotechnology carving out a distinction between a basic patent and an improvement patent.

12. The senior counsel for the defendant has in sur-rejoinder contended that the plaintiff Merck having in its own application which was abandoned

claimed Sitagliptin Phosphate to be a new invention and having suppressed abandonment from the plaint/application in this suit, cannot be heard to orally argue that it was merely an improvement patent. It is also contended that there is no concept of a basic patent in India. Attention is invited to Section 54 of the Act which permits addition to patents and it is contended that the plaintiffs have not come to the Court with a case of Sitagliptin Phosphate being an improvement patent within the meaning of Section 3(d) and as per the documents suppressed by it was making out the same to be a case under Section 54 of the Act. It is contended that the reliance by the plaintiffs on Grubb's Treatise is misconceived since the author is an employee of Novartis and the Supreme Court also did not refer to his Treatise though cited, for the said reason only. Copy of the application dated 19th February, 2007 of the plaintiff Merck to European Patent Office for Sitagliptin Phosphate is handed over to contend that the plaintiff Merck therein also had pleaded Sitagliptin Phosphate to be a different product from SITAGLIPTIN but is arguing to the contrary before this Court. In response to the argument of the counsel for the plaintiffs of the other 9 or 10 persons whose list was handed over having also commenced exports recently only, copy of the letter dated 26/29th September, 2011 of the Central Drugs

Standard Control Organisation (North Zone), Government of India to M/s. Teva API India Limited is handed over to show that Sitagliptin Phosphate is being exported to a large number of countries of the world much prior to February, 2013. Reliance is also placed on ***M/s. Bishwanath Prasad Radhey Shyam Vs. Hindustan Metal Industries*** (1979) 2 SCC 511 in support of the argument that grant of patent does not guarantee the validity of the patent. It is again highlighted that the defendant is challenging the validity of the patent of the plaintiffs and till the said validity is decided in this suit, the question of grant of any interim relief to the plaintiff, does not arise. It is further argued that the rights under Section 48 of the Act are qua the product in which the patent is granted and not in a different product.

13. The senior counsel for the plaintiffs though in further arguments sought to urge that the defendant has not denied to having commenced marketing its product in the last seven days only, was informed that the arguments cannot take the place of pleadings and when the counsel for the plaintiffs has chosen to argue in detail on the very first date of hearing, in the absence of pleadings of the defendant, he cannot be permitted to take advantage of a plea in the plaint having not been denied in the course of oral arguments.

14. I have weighed the aforesaid rival contentions, only for the purposes of grant or non-grant of the interim injunction.

15. The detailed narrative of the arguments and the hearing would disclose that though the plaintiff has approached this Court with a case simpliciter of product of the defendant infringing the patent SITAGLIPTIN of the plaintiff Merck and the senior counsel for the plaintiff also confined the opening argument to pharmaceutical description of the two products being identical but the real controversy for adjudication in the present suit is and the controversy veers around to, whether the combination by the defendant in its product, of SITAGLIPTIN in which the plaintiff Merck undoubtedly has a patent, with phosphate, have a material effect upon the way SITAGLIPTIN works. If the answer to the said question is to be in the affirmative, the product of the defendant would be outside the patent and if not, in infringement of the patent.

16. It is for this reason only that the senior counsel for the plaintiff, arguing in rejoinder, brought in the argument of 'basic' and 'improvement' patent to contend that the combination in the product of the defendant of SITAGLIPTIN with Phosphate is merely an improvement falling within the meaning of Section 3(d) and is not an invention in which patent can be

granted and notwithstanding such improvement, there would be infringement.

17. There indeed is merit in the aforesaid contention. The patent granted to the plaintiff Merck takes within the ambit, "a pharmaceutically acceptable salt" of SITAGLIPTIN and which 'may' include Sitagliptin phosphate i.e. the product of the defendant. The defendant of course denies. The test which is to be applied is, whether the combination embodies the inventive advance of the patent.

18. The plaintiffs in the plaint have described SITAGLIPTIN as a DPP-IV Inhibitor which helps the Pancreas to produce more insulin thereby lowering the blood sugar. The senior counsel for the plaintiffs has in his argument explained that the Type-2 Diabetes is caused not by the failure of the Pancreas to produce insulin but owing to the release in the human body of other substances which suppress production / release of insulin by Pancreas and that SITAGLIPTIN inhibits the release of those substances which come in the way of release of insulin by Pancreas.

19. The package-insert of the defendant's product also describes the same as a combination product which inhibits Dipeptidyl Peptidase-IV.

20. I had for this reason asked the senior counsel for the defendant to explain as to how the combination by the defendant in its product of Phosphate with SITAGLIPTIN amounted to a different treatment of Type-II Diabetes than treatment by SITAGLIPTIN.

21. No satisfactory response was forthcoming.

22. To my mind, if the infringing product are made with the same object in view which is attained by the patented article, then a minor variation does not mean that there is no infringement. Trifling and unessential variations are to be ignored. Conversely, a miniscule advancement could be recognized as an invention.

23. Interestingly in the present case, the plaintiff Merck as patentee of SITAGLIPTIN is also not marketing SITAGLIPTIN alone as a product and is marketing Sitagliptin in combination with Phosphate just as the defendant is doing. The senior counsel for the plaintiff in his opening argument, on being asked to demonstrate infringement, had done so on the basis of identical pharmaceutical composition of the product of the defendant as of the plaintiff.

24. However the defendant pointed out that the patent of the plaintiff Merck was not in the pharmaceutical composition as described on plaintiff's product but only in a part thereof and which fact was not denied by the plaintiff. Thus, similarity of pharmaceutical composition of the products cannot be a ground for infringement.

25. Strangely, the plaintiff, neither in the plaint nor in the opening arguments has pleaded/made out a case on which ultimately interim relief is claimed, i.e., of Sitagliptin Phosphate being made by the defendant being made with the same object as the patent of the plaintiff and the addition of Phosphate to the patented SITAGLIPTIN not embodying any inventive advancement and the treatment of Type-II diabetes by Sitagliptin Phosphate being no different from treatment by SITAGLIPTIN.

26. The plaintiff in a suit restraining infringement of patent ought to have known the defence which the defendant has put forth and ought to have met the same in the plaint, as has been done in the arguments in rejoinder by arguing on 'basic' and 'improvement' patents. There is not an iota of pleading on the said aspect. The plaintiff, to show that the defendants product, inspite of combining Phosphate with patented SITAGLIPTIN, medically remained equivalent to SITAGLIPTIN, was expected to plead in

detail on the aspects of efficacy of SITAGLIPTIN, reason for itself combining the same with Phosphate and the role of Phosphate being inconsequential in the disease which SITAGLIPTIN cures. It was for the plaintiffs to have made a case of Sitagliptin Phosphate being merely a new form of SITAGLIPTIN which does not result in the enhancement of the efficacy of SITAGLIPTIN or being a mere combination of other derivatives of SITAGLIPTIN. I am unable to find any pleading of the plaintiffs to the said effect. Rather, the plaint proceeds on the premise that Sitagliptin Phosphate is the same as SITAGLIPTIN but which is not found to be the case of the plaintiffs in its own application for grant of Sitagliptin Phosphate and which was abandoned.

27. On the contrary it has emerged that the plaintiff Merck itself has in USA taken an independent patent for Sitagliptin Phosphate and similarly applied in India and which has been rejected and while applying for independent patent in Sitagliptin Phosphate in USA, India and Europe having claimed it to be a new invention and a different product than SITAGLIPTIN.

28. The position which thus prevails today is that we have the argument of the defendant of Sitagliptin Phosphate being a different product than

patented SITAGLIPTIN together with the plaintiff Merck's admission to the same effect in its patent applications aforesaid for Sitagliptin Phosphate. Though the plaintiff when faced therewith has urged such patent applications to be a mis-adventure, under wrong advise at least in India, but the plaintiff in the plaint has not pleaded so.

29. I have wondered whether in the absence of the plaintiff having pleaded so, can interim relief be granted on the basis of such explanation. The answer has to be an emphatic no. It was for the plaintiff to plead the circumstances in which its application for a separate patent in Sitagliptin Phosphate was made and to explain away the admission made therein. The plaintiff has not done so. Though it may be open for the plaintiff to at the trial explain so, but the plaintiff certainly cannot be granted interim relief on a case not pleaded and in the face of its admission of Sitagliptin Phosphate being a new invention worthy of patent.

30. The Division Bench of this Court at the stage of grant of interim relief in ***Cipla Ltd.*** (supra), reported as 2009 (40) PTC 125 held that non disclosure of an unsuccessful application for patent for the same product qua which injunction was claimed constituted a reason enough for denial of interim relief. I find the final judgment of the Single Judge in the said

proceeding also, in para 297 holding that mere rejection of the second patent applied for by the plaintiff cannot lead to a straight conclusion of the patented article and the product subject matter of the 2nd application (which is rejected) being the same substance and that it has to be proved so by the plaintiff. In fact in the said case final relief also was denied to the plaintiff for the reason of an unsuccessful application for patent having been filed by the plaintiff in that case also.

31. No only so, the only response of the plaintiff to the plea of the defendant of at least 9 to 10 other persons also marketing Sitagliptin Phosphate, duly supported by documents handed over, was that instructions on that aspect will have to be taken. However, the said plea also belies the existence in favour of the plaintiffs of the ingredients of irreparable injury and balance of convenience. Though, ordinarily infringement by others does not constitute a ground for denial of the relief of injunction against an infringer but it can be a consideration in the grant of interim injunction.

32. I therefore do not find the plaintiffs to have made out a case for grant of interim relief. The application is accordingly dismissed but with a direction to the defendant to diligently maintain accounts of the manufacture/production and sales of the infringing products and to file the

same every quarter before this Court with advance copy to the counsel for the plaintiffs. Needless to state that any observation contained herein shall not have any bearing on the final decision of the matter.

The application is disposed of on the very first date, no costs.

**RAJIV SAHAI ENDLAW, J**

**APRIL 5th , 2013**
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