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

\+ CS(OS) 586/2013 & CC No. 46/2013 & I.A. Nos. 9827/2013, 8048/2014 & 13626/2015

Judgment reserved on 27th August, 2015
Judgment delivered on 7th October, 2015

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

Through: Mr. Pravin Anand, Ms. Archana Shankar, Ms. Tusha Malhotra, Ms. Udita M Patro, Ms. Nupur Maithani and Mr. Devender Rawat, Advs.

Versus

GLENMARK PHARMACEUTICALS LTD. ..... Defendant

Through Mrs. Pratibha M Singh, Sr. Adv. with Ms. Saya Choudhary, Ms. Manika Arora, Ms. Archana Singh, Mr. Aditya Jayaraj, Ms. Mitali Agarwal and Mr. Shobhit Choudhary, Advs.

CORAM:
HON'BLE MR. JUSTICE A.K. PATHAK

A.K. PATHAK, J.

1. Plaintiffs have filed this suit against the defendant for permanent injunction praying therein that defendants, its directors, employees, officers

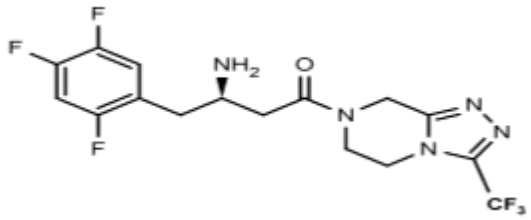
etc. be restrained from making, using, selling, distributing, advertising, exporting, offering for sale or dealing in Sitagliptin Phosphate Monohydrate or any other salt of Sitagliptin in any form, alone or in combination with one or more other drugs or from doing any other thing that infringes the claimed subject matter of the plaintiffs' Indian Patent No. 209816. Damages, rendition of accounts and delivery up of the infringing materials has also been prayed.

2. Briefly stated, plaintiffs have alleged in the plaint that plaintiff no. 1 was formally known as Merck & Company, Inc. Plaintiff no. 1 has been incorporated under the laws of New Jersey, USA, having its principal place of business at Whitehouse Station, USA. Plaint has been signed and verified by its constituted Attorney- Mr. K.G. Ananthakrishnan. Plaintiff no.2 is a licensee of plaintiff no.1 for marketing, distributing and selling Sitagliptin as also Sitagliptin & Metformin combination in India, under the trade marks ISTAVEL and ISTAMET respectively. Mr. Chetan Gupta is the constituted attorney of plaintiff no.2 and is duly authorized to sign, verify and institute the plaint on behalf of plaintiff no.2.

3. Plaintiff no.1 manufactures and markets a range of medicines for treatment of various ailments including diabetes. Plaintiff no.1 invented a

molecule, namely, 'Sitagliptin' and got it patented in various countries, including India vide Indian Patent No. 209816. Application no. 26/CHENP/2004 was filed in India on 6th January, 2004; whereas international application no. PCT/US2002/021349 was filed in USA with priority date 6th July, 2001. Patent in India was granted on 6th September, 2007 under the title BETA-AMINO TETRAHYDROIMIDAZO (1,2-A) PYRAZINES and TETRAHYDROTRIOAZOLO (4, 3-A) PYRAZINES as DIPEPTIDYL PEPTIDASE INHIBITORS for the treatment of diabetes. Grant of patent was not opposed by any member of the public or interested party in India at any stage, despite extensive publicity given by the plaintiffs to its commercial products sold under the brand name 'JANUVIA' and 'JANUMET'. The drug is used for treatment of Type II diabetes. Sitagliptin was approved for sale in USA in October, 2006 and in Indian market on 28th March, 2008. Patent no. 209816 has 20 claims and Sitagliptin is covered by claims 1 to 3, 5 to 10, 14 to 17, inasmuch as, it has been specifically claimed by claim 19 of the suit patent. Example 7 discloses the method for preparation of Sitagliptin hydrochloride salt.

4. Chemical structure of Sitagliptin is as under :-



5. JANUVIA is a once daily pill with Sitagliptin as its active ingredient which helps lower blood sugar levels in people with Type II diabetes. Given below are some additional technical details pertaining to Sitagliptin :-

(i) IUPAC name of Sitagliptin – 7-[(3R)-3-amino-4-(2,4,5 trifluorophenyl) butanoyl]-3-(trifluoromethyl)-5,6,7,8-tetrahydro-1,2,4 triazolol [4,3 a] pyrazine;

(ii) Mechanism of action – it is DPP-4 inhibitor which helps the pancreas to produce more insulin. Thus, Sitagliptin helps lower blood sugar when it is too high;

(iii) The commercial product comprises the R stereoisomer of Sitagliptin. The suit patent claims both R and S forms of Sitagliptin in genus claim1, as well as the specific R- Sitagliptin molecule in claim 19.

6. Keeping in mind public interest JANUVIA was launched in India with price tag of ₹43 a pill which was roughly one-fifth of its price in the USA. The price of ₹43 was fixed after consulting nearly 350 doctors before launching the product in Indian market. Bulk packs of JANUVIA are imported from Italy and are sold by MSD Pharmaceuticals Pvt. Ltd. (licensee of the patentee), after packaging into consumer packs by Shasun

Pharmaceuticals Ltd. at Puducherry Unit. Sales of JANUVIA during the year 2012 was ₹96,24,48,996/- and that of JANUMET was ₹95,64,87,772/-. As regards ISTAVEL and ISTAMET sales were ₹21,91,60,117/- and ₹24,88,69,558/- respectively. Plaintiffs have also launched patient access program under the name 'MSD Sparsh Helpline' which is the first of its kind in India. Objectives of this program is to facilitate optimal and comprehensive management of patients with Type II diabetes mellitus by improving patient's understanding of the disease and its management; patient's adherence and compliance to prescribed therapy and patient's self involvement in the disease management process. Plaintiffs have spent about ₹10 crores from the start of the said programme till filing of the suit.

7. Defendant is a large pharmaceuticals company and was well aware of the plaintiffs' product JANUVIA as also the patent which had been granted to cover the same. They were also aware that active ingredient, R-Sitagliptin is in JANUVIA and that suit patent no. 209816 claims R-Sitagliptin as also S-Sitagliptin, inasmuch as, defendant had obtained US patent no. 8334385 dated 18th December, 2012 for its process for the preparation of R-Sitagliptin and its pharmaceutical salts. Defendant has acknowledged the plaintiffs' corresponding US patent for Sitagliptin and its

proprietary rights in their patent application. Plaintiffs have alleged that defendant infringes the plaintiff no. 1's suit patent no. 209816 since its product Sitagliptin Phosphate Monohydrate is covered by claim 19 as well as several other claims of the plaintiffs, as contained in the suit patent. By virtue of Section 48 of The Indian Patents Act,1970 ('The Act', for short) plaintiffs have exclusive rights to prevent any third party from the acts of making, using, offering for sale, selling or importing into India, products that fall within the scope of the claims of plaintiff no.1 in suit patent as also from the acts of using, selling, importing, offering for sale in any manner, directly or indirectly, commercializing or dealing in any product obtained directly from the process that forms the claimed subject matter of the plaintiff no.1's suit patent. The defendant's act of manufacturing, selling, offering for sale and advertising the pharmaceutical compositions, Sitagliptin Phosphate Monohydrate under the brand 'ZITA' and 'Sitagliptin Phosphate Monohydrate and Metformin Hydrochloride' under the brand name 'ZITA -MET' amounts to infringement of the plaintiff's suit patent.

8. Defendant has filed written statement-cum-counter claim wherein, has prayed for revocation of the suit patent. Defendant has alleged that it does not infringe the suit patent since the products that are marketed and sold by

the defendant are not covered by the suit patent. Suit patent disclosed the products Sitagliptin/Sitagliptin Hydrochloride; whereas Sitagliptin Phosphate Monohydrate is a different chemical entity having different physical and chemical properties. In the suit patent, only disclosure made is in respect of Sitagliptin Hydrochloride, inasmuch as, there is no enabling disclosure qua any other Sitagliptin product. Plaintiffs itself had filed patent application (5948/DELNP/2005) in respect of Sitagliptin Phosphate Monohydrate wherein it claimed that the product under the said patent was novel, inventive and has industrial applicability over the product disclosed in the suit patent. Such admissions were made by the plaintiffs in European Patent Office (EP 1654263) as well. In the said application, plaintiffs have admitted that suit patent disclosed only hydrochloride salt of Sitagliptin and does not contain any disclosure of the dihydrogenphosphate salt. Further, that product disclosed in the suit patent is not capable of being administered as a medicine as the same were chemically and physically unstable in nature. Various objections were raised by the European Patent Office to the grant of European Patent (EP 1654263) to Merck and Co. Inc for Sitagliptin Phosphate Monohydrate. M/s Teva Pharmaceutical Industries Ltd. also opposed grant of patent on the ground that it lacked novelty and inventive

steps, inter alia, in the light of the first patent (WO 03/004498). The said opposition was rejected and validity of EP 1654263 was upheld. Thus, Sitagliptin Phosphate Monohydrate cannot be said to be subsumed or covered by the impugned suit patent. Plaintiffs did not pursue the application in respect of Sitagliptin Phosphate Monohydrate in India and voluntarily abandoned the same, resultantly Sitagliptin Phosphate Monohydrate is currently in public domain, thus, no infringement action was made out qua Sitagliptin Phosphate Monohydrate. As regards combination of Sitagliptin Phosphate and Metformin Hydrochloride, defendant alleges that plaintiffs' patent application (2710/CHENP/2008) was still pending, plaintiffs' two after applications in respect of different combinations of Sitagliptin Phosphate and Metformin Hydrochloride were also pending. Thus, no infringement action was maintainable regarding this combination.

9. Defendant has also denied the title of plaintiff in the suit patent. It is alleged that suit patent was originally filed by Merck and Co. Inc. and was also granted in its name; No documents were filed by the plaintiffs on record to establish the relationship between itself and Merck and Co. Inc. No document regarding assignment or license granted by Merck and Co. Inc., either in favour of plaintiff no. 1 or in favour of plaintiff no.2 was filed on

record. Plaintiff no.2 was not having any right in the suit patent and was not entitled to institute or continue the suit. Plaintiff no. 2 is the licensee of plaintiff no.1, as per the own contentions of plaintiffs, for marketing, distributing and selling Sitagliptin as well as Sitagliptin and Metformin combination under the trademarks 'ISTAVEL' and 'ISTAMET'. However, license agreement between the plaintiff no.1 and plaintiff no. 2 does not indicate that plaintiff no.2 was a registered licensee or assignee qua the suit patent as the agreement related only to the trade marks 'ISTAVEL' and 'ISTAMET' and not in respect of the suit patent. Defendant denies that suit was instituted, signed and verified by the duly authorized person(s) on behalf of the plaintiffs.

10. Plaintiffs have not approached this Court with clean hands and have suppressed material facts. They did not disclose, either to the patent office or to this Court, the factum of filing of various subsequent patent applications, that is, patent application no. 5948/DELNP/2005 abandoned on 23rd August, 2010, patent application no. 1130/DELNP/2006 abandoned on 31st March, 2011, patent application bearing no. 2710/CHENP/2008, patent application no. 4922/DELNP/2010, though all these applications related to Sitagliptin Phosphate Monohydrate salt and combination of Metformin with

Sitagliptin Phosphate Monohydrate. Under the patent law plaintiffs were obliged to disclose all such corresponding applications relating to the same inventions. This fact is sufficient enough to dismiss the suit. Plaintiffs have failed to file any technical analysis either in the form of DSC (Differential Scanning Calorimetry), TGA (Thermogravimetric Analysis) or XRD (X-Ray Diffraction) of the defendant's products 'ZITA' or 'ZITA -MET' as the same would have clearly indicated that the Active Pharmaceutical Ingredient used in 'ZITA' and 'ZITA -MET' is Sitagliptin Phosphate Monohydrate and combination of Sitagliptin Phosphate Monohydrate & Metformin Hydrochloride respectively. XRD data of its products 'ZITA' and 'ZITA-MET' corresponds to peak values as disclosed in Indian patent application being 5948/DELNP/2005 of the plaintiff for Sitagliptin Phosphate Monohydrate, in respect whereof there exists no patent protection in India. XRD analysis of the plaintiff no. 1's products 'JANUVIA' and 'JANUMET' reveal that plaintiff no.1's products do not contain Sitagliptin free base.

11. Defendant has claimed itself to be a company incorporated in the year 1977 under The Companies Act, 1956, having a full-fledged Research & Development Department as well. It is alleged that defendant is having significant presence in branded generics markets across emerging economies

including India. Defendant's business is focused on brand building, low cost manufacturing, and efficient distribution without violating IP rights of others. Defendant's product 'ZITA' and 'ZITA -MET' were different from the plaintiffs' product, as disclosed in the suit patent, which only exemplified salt being Sitagliptin Hydrochloride. It is alleged that Sitagliptin Phosphate Monohydrate as also the combination of Sitagliptin Phosphate Monohydrate and Metformin Hydrochloride are totally different than the Sitagliptin Hydrochloride salt as disclosed in the suit patent. Further, that suit patent is incapable of industrial application and has not worked anywhere in the world. Sitagliptin per se was Sitagliptin Hydrochloride as disclosed in suit patent, is an unstable compound incapable of commercial production and industrial use. It is further alleged that process followed by the defendant in respect of 'ZITA' and 'ZITA -MET' is completely different than the process of manufacturing followed by the plaintiff, inasmuch as, in the process of defendant neither Sitagliptin Free Base nor Sitagliptin Hydrochloride are used either as a raw material or are generated as an intermediate at any stage of the process. The process being devised by the defendant for manufacturing 'ZITA' and 'ZITA-MET' is novel and inventive in nature. Defendant further alleged that price of

'ZITA' and 'ZITA-MET' are lower than the price of 'JANUVIA', 'JANUMET', 'ISTAVEL' and 'ISTAMET'. Not only this, in order to benefit the patients who require a dosage of 50 mg of Sitagliptin Phosphate Monohydrate, defendant has provided a score line in its product 'ZITA' 100 mg to enable a patient to consume half the tablet and obtain a dosage of 50 mg at a price of ₹14/- per tablet as against plaintiffs' product 'JANUVIA' and 'ISTAVEL' priced at ₹43/- per tablet. Accordingly, defendant's product 'ZITA' and 'ZITA-MET' are beneficial to the public at large, inasmuch as, plaintiffs have been overcharging the Indian customers by charging the same price for 'JANUMET' and 'ISTAMET' regardless of potential and strength of the tablet.

12. In the counter claim, defendant has prayed for revocation of the suit patent on the grounds : (a) it lacks inventive step within the meaning of section 64(1)(f) of The Patents Act 1970. The suit patent is obvious to a person skilled in the art in the light of various earlier filed patents of the plaintiff no.1 as also of third parties relating to DPP IV (DIPEPTIDYL PEPTIDASE) inhibiters, that is, EP 1406622 and WO 01/34594; (b) invention claimed lacks industrial applicability within the meaning of section 64(1)(g) of the Act. Invention disclosed was physically and

chemically unstable in nature and was incapable of being used in solid dose formulations; (c) Disclosure was insufficient within the meaning of Section 64(1)(h) as complete specification was not disclosed regarding the preparation of Sitagliptin base so as to enable a person in India, possessing average skill and knowledge to work the invention, inasmuch as, as example 7 of the suit patent describes only hydrochloride salt of Sitagliptin; (d) Any claim of the complete specification is not fairly based on the matter disclosed in the specification, thus, violated section 64(1)(i) of the Act. It is alleged that disclosures in the suit patent were extremely broad. A patentee is granted monopoly only for the subject matter which has been claimed by it and has been adequately and sufficiently described, so that the concerned invention can be worked by a person skilled in the art in favour of general public. However, by way of the claim 19 of the suit patent the plaintiff no.1 is claiming a monopoly qua Sitagliptin and its pharmaceutically acceptable salts thereof without any supporting information and details except that of Hydrochloride salt, thus, no monopoly can be claimed by the plaintiffs qua any other salt of Sitagliptin; (e) Patent was obtained on a false suggestion or representation and was liable to be revoked under Section 64(1) (j) of the Act. It is alleged that Merck & Co. Inc. deliberately did not disclose the

subsequent application filed by it for the dihydrogenphosphate salt of Sitagliptin along with its crystalline forms (both hydrate and anhydrate) before the patent office. It was also not disclosed that Sitagliptin base and its hydrochloride salt (both crystalline and amorphous forms) were not suitable for developing the solid pharmaceutical composition, thus, was incapable of industrial application. Several applications filed by Merck & Co Inc. claiming pharmaceutical compositions pertaining to combination of Sitagliptin Phosphate Monohydrate and Metformin hydrochloride were not disclosed. Had there been a disclosure of the subsequent applications to the controller then the suit patent would not have been granted due to lack of industrial applicability; and (f) Applicant failed to comply with Section 8 of the Act resultantly patent is liable to be revoked under Section 64 (1) (m) of the Act. It is alleged that plaintiffs were required to provide all the information under Section 8 of the Act about the prosecution of corresponding or similar application to that of the suit patent, but it failed to provide updated status of such applications as well as details regarding their prosecution.

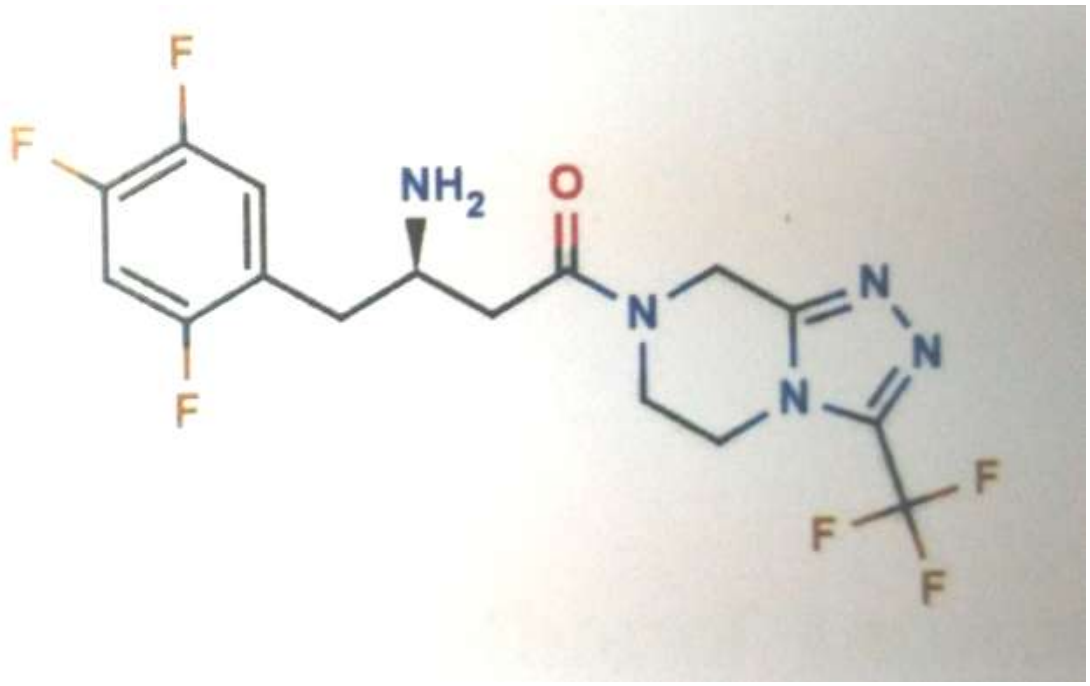
13. Plaintiffs have denied the averments made in the written statement and counter claim and have reiterated the averments made in the plaint.

Plaintiffs have alleged that JANUVIA and JANUMET as also ZITA and ZITA-MET contain Sitagliptin phosphate which is covered by the claims of the suit patent. Sitagliptin is the active moiety in Sitagliptin phosphate as it is Sitagliptin which inhibits the DPP-IV enzyme. Sitagliptin Phosphate has no material effect upon the way Sitagliptin works in the body. The product inserts of the ZITA and ZITA-MET are blatant copy of the product inserts of the plaintiffs' products JANUVIA and JANUMET, which indicate that efficacy in the treatment of diabetes is as a result of Sitagliptin and not the phosphate. Plaintiffs products are fully covered by the suit patent. Plaintiffs' patent in US and EP (corresponding to Indian patent application no. 5948/DELNP/2005) for Sitagliptin Phosphate is a 'selection' patent. Filing of separate patent applications in India and in foreign jurisdictions were for different inventions and not for different products and the filing of subsequent patent applications for improved inventions does not impair the plaintiffs' rights to enforce their rights on the basic patent. The filing of subsequent applications or patents neither amount to an admission that the invention covered by the subsequent application is an altogether different product nor is it an admission that the product of the subsequent application is not covered in the scope of the claims of the basic patent. The concept of

multiple patents, covering one commercial product, has been recognized in the Act by Sections 3(d), 88(3), 91 and 141, therefore, an infringing product can violate more than one patent. Defendant's products ZITA and ZITA-MET comprise Sitagliptin Phosphate and have Sitagliptin as the active moiety. Sitagliptin in all its forms and salts (including Sitagliptin phosphate) are covered by claims 1, 15, 17 and 19 of the suit patent. Sitagliptin Phosphate has no material difference in the way Sitagliptin works in the body, as it is Sitagliptin that is responsible for the treatment of type II diabetes. The therapeutic moiety in JANUVIA/ISTAVEL and JANUMET/ISTAMET, is Sitagliptin. Defendant, in order to disguise its products as being 'non-infringing' of the suit patent, has deliberately deleted the words '100 mg of Sitagliptin free base not only from the product inserts but from the packagings as well. Defendant has misrepresented the public by using the words 100 mg of Sitagliptin Phosphate Monohydrate. In its product inserts plaintiffs have clearly stated that 128.5 mg of Sitagliptin Phosphate Monohydrate is equivalent to 100 mg of Sitagliptin free base. It is the Sitagliptin free base of 100 mg which is the active moiety. Defendant, while removing the part 'equivalent to 100 mg of Sitagliptin' from its product inserts, has retained the expression '100 mg tablet'.

14. Grant of patent for Sitagliptin Phosphate Monohydrate on Indian Patent application no. 5948/DELNP/2005 was not possible under the Indian laws because of Section 3(d) of the Act. Suit patent is the basic patent for Sitagliptin and its pharmaceutically acceptable salts, in all its forms be it chemical or physical. Phosphoric acid is disclosed as an acid that can form a salt with the Sitagliptin free base; and hydrates are also disclosed in the specification. Example 7 shows how to make Sitagliptin and the Hydrochloride salt thereof. One skilled in the art would know how to make the dihydrogen phosphate salt from the Hydrochloride salt. Further, Example 7 prepares the Sitagliptin free base as an intermediate. The patent specification clearly and sufficiently discloses the best method for performing the invention including the process for preparing Sitagliptin free base. Claim 19 specifies Sitagliptin by its structure and includes any of its salt within its scope. Sitagliptin dihydrogen phosphate includes in it the Sitagliptin structure and Sitagliptin dihydrogen phosphate is itself a salt of Sitagliptin. Products of the defendant, thus, clearly infringe the suit patent. It is reiterated that irrespective of the salt form, it is the Sitagliptin free base which treats diabetes by acting as an inhibitor of the enzyme dipeptidyl peptidase IV (DPP-V) that leads to decreased inactivation of incretins

thereby enhancing the effectiveness of incretins in stimulating insulin production. Under Section 48 every use of the patented invention amounts to an infringement of a patent. Therefore, the acts of the defendant constitute an infringement of the suit patent. XRD data or DSC of Thermogravymetric analysis of the defendant's products ZITA and ZITA-MET is not necessary as the plaintiffs have alleged infringement of the suit patent which claims Sitagliptin and its pharmaceutically acceptable salts which is a new chemical entity that can be easily characterized by its chemical formula and structure as being:-



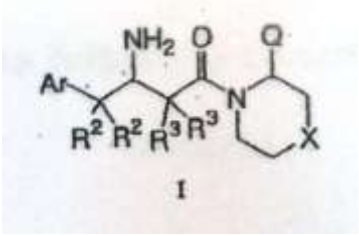
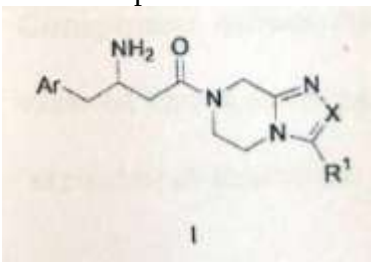
15. The chemical or empirical formula of Sitagliptin in whatever form it exits will always remain $C_{16}H_{15}F_6N_5O$. It is further submitted that XRD data or DSC analysis is required in pharmaceutical or chemical patent cases (essentially in improvement inventions of the NCE itself) such as polymorphs, etc. where the invention cannot be defined and characterized by its chemical formula or when the chemical formula remains unchanged from what has been known. In such cases, the claims must recite the XRD, the physical properties and the chemical properties such as melting point, boiling point etc. Plaintiffs' case is that Sitagliptin phosphate in the defendant's products ZITA and ZITA -MET are claimed and covered by claims 1, 15, 17 and 19 of suit patent, thus, the manufacture and sale of these products by the defendant is violative of Section 48 of the Act.

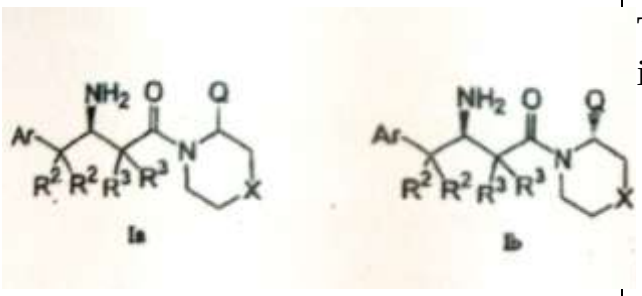
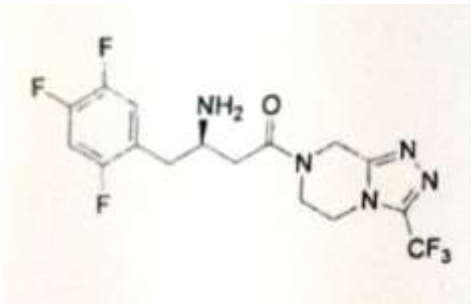
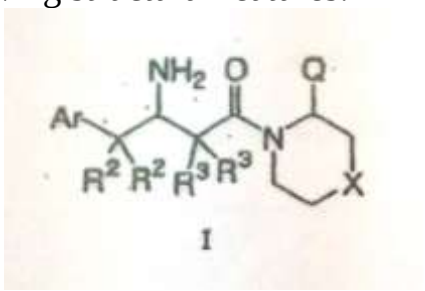
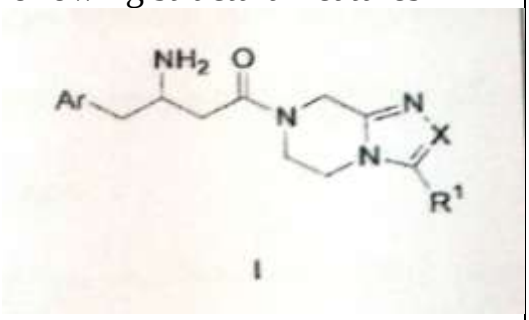
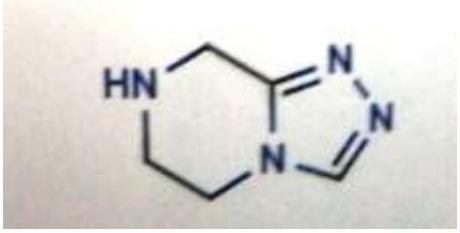
16. It is alleged that the product inserts of the defendant's product clearly show that the chemical formula of Sitagliptin is identical to that provided in claim 19, as contained in the suit patent. Plaintiffs have denied that they have acquiesced to the manufacture or sale of Sitagliptin Phosphate Monohydrate by third parties. Plaintiff no.1 has nowhere admitted that invention of the suit patent was not capable of industrial application. Plaintiffs have denied that suit patent was granted on the basis of

misrepresentation because of non disclosure of subsequent patent applications. It is further alleged that subsequent patent applications are for different inventions and cannot form the basis for the rejection of an earlier filed patent application on the grounds of patentability. Plaintiff no.1 had only demonstrated the technical advancement of Sitagliptin hydrochloride disclosed in the suit patent in order to be able to establish inventive steps of the subsequent application. It was found that dihydrogenphosphate salt of Sitagliptin was selected over the other salts based on a combination of factors, more particularly in view of the fact that said salt was the most stable in aqueous solution and was having advantages in the preparation of pharmaceutical compositions such as ease of processing, handling and dosing. In particular, they exhibit improved physical and chemical stability, inasmuch as, advantages of the phosphate salt over the hydrochloride salt or Sitagliptin free base were restricted to physical and chemical stability which facilitated ease of processing, handling and dosing rendering them particularly useful in the manufacture of various dosage forms. These advantages would make a good case for the grant of a patent in jurisdiction other than India. In India efficacy is restricted to therapeutic efficacy, therefore, such technical advantages are not sufficient to protect the

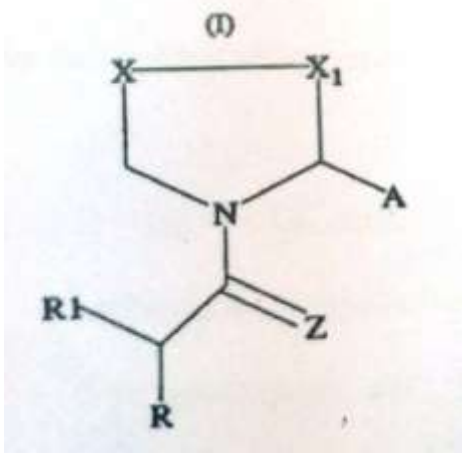
invention claimed in 5948/DELNP/2005 from the prohibitory ambit of Section 3(d) of the Act.

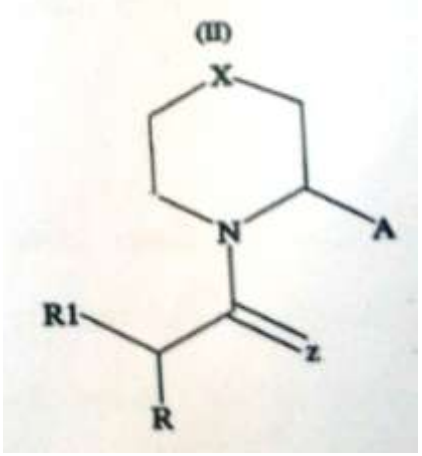
17. In reply to the counter claim, plaintiffs have denied that invention was obvious from the prior art documents referred to by the defendant, inasmuch as, EP1406622 was not even prior art. The international application corresponding to the application, that is, PCT/US2002/019441 was first published on 3rd January, 2003 (WO 2003/000181) which was much after the priority date of suit patent (being 6th July, 2001). Thus, inventors of the suit patent cannot be imputed with an effective notice of this application. That apart, structures of the compounds claimed in the suit patent were distinct than the claim 1 of EP 1406622, inasmuch as, there was no structural similarity between the two compounds for the following reasons:-

EP 1406622A2 or EP 1406622B1	**IN 209816 (26/CHENP/2004)**
No process claims in the granted patent and no process claims were filed in the patent application, i.e. invention is directed to novel compounds.	There is no process claim
Claim 1: A compound having Formula I  I including pharmaceutically acceptable salts and prodrugs thereof, wherein: X is	Claim 1: A compound of Formula I  I Wherein X is selected from the

selected from the group consisting of CH2,O and NR7 Claim 6: A compound having Formula Ia or Ib:  including pharmaceutically acceptable salts and prodrugs thereof, wherein R1, R2, R3, R4, R5, R6, R7, Q, X and Ar are as previously defined in Claim 1-5; with the proviso that X is not N-Me.	group consisting of: N and CR2 and pharmaceutically acceptable salt thereof and individual diastereomers thereof. Claim 19(Specific to Sitagliptin): The compound of claim 17 which is  Or a pharmaceutically acceptable salts thereof.
Compound differs in view of the following structural features:  1. Piperazine or Piperidine ring  2. The Piperazine or piperidine ring is further substituted with Q 3. R3 substitution, (Scheme 2, disclosed compounds with R# substitution.	Compound differs in view of the following structural features:  1. Fused, trizolo[4,3-a] pyrazine ring structure  2. No Q substitution 3. No R3 Substitution.

18. As regards second prior art document cited by the defendant, that is, WO 01/034594. Plaintiff has alleged that only similarity between the WO 01/034594 and suit patent is that both are related to compounds that have the same mode of action, that is, both are compounds which act as Dipeptidyl Peptidase-IV inhibitors. It is alleged that core-structures of the compounds of WO 01/034594 are as under :-



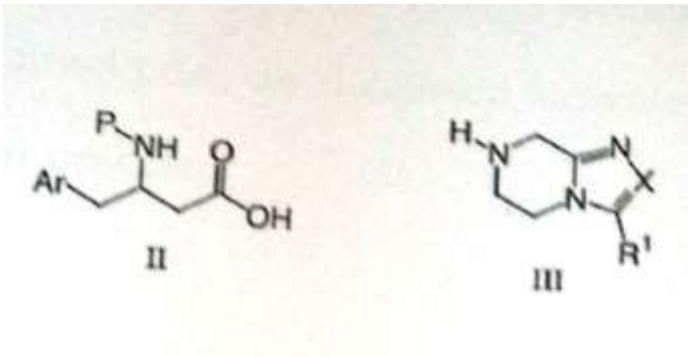


19. Plaintiffs have alleged that the two prior art documents cited by the defendant to establish that the suit patent is obvious, one does not even qualify as prior art and the other discloses just another DPP-IV inhibitor with no similarity or connection with the compound of the suit patent. It is alleged that suit patent was not obvious in the light of the documents cited by the defendant. It is also denied that suit patent lacks industrial

application. It is alleged that Sitagliptin and its pharmaceutically acceptable salts are capable of industrial application in particular for the treatment of type II diabetes. Patent specification document clearly provides the utility of the compounds in accordance with the present invention as inhibitors of the DPP IV enzyme. In the prosecution of the EP application corresponding to 5948/DELN/2005, the plaintiff no.1 had only demonstrated the technical advancement of Sitagliptin phosphate over Sitagliptin hydrochloride disclosed in the suit patent in order to be able to establish inventive step of the subsequent application. Such advancement was restricted to physical and chemical stability, which facilitated ease of processing, handling and dosing rendering them particularly useful in the manufacture of various dosage forms. These advantages make a good case for the grant of a patent in jurisdictions other than India. In India 'efficacy' within the meaning of Section 3(d) of the Act is restricted to 'therapeutic efficacy', which was not sufficient to protect the invention claimed in 5948/DELNP/2005.

20. Plaintiffs have denied that disclosures in suit patent are insufficient. It is alleged that suit patent adequately and sufficiently describes the invention and the manner in which it has to be performed, to a person skilled in the art. Example 7 provides in the patent specification only an illustration, thus,

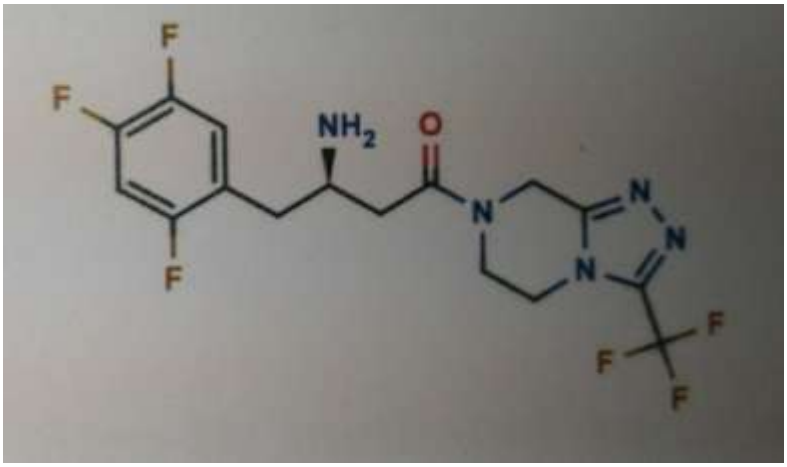
infringement action is based on the claims, inasmuch as, the scope of the claims is not limited by the examples. Sitagliptin and pharmaceutically acceptable salts thereof have been claimed and covered by the claims in the suit patent, which is the "basic patent for Sitagliptin and its pharmaceutically acceptable salts, in all its forms chemical or physical. Phosphoric acid is disclosed as an acid that can form a salt with the Sitagliptin free base; and hydrates are also disclosed in the specifications. Example 7 shows how to make Sitagliptin and the HCL salt thereof. One skilled in the art would know how to make dihydrogen phosphate salt from the Hydrochloride salt. Further example 7 prepares the Sitagliptin free base as an intermediate. The specification sufficiently discloses the general synthesis scheme (scheme 6) for preparation of compounds of the invention (Sitagliptin). It can be prepared by reacting compounds of Formula II and III, using standard peptide coupling conditions followed by deprotection.



Where P in compound of Formula II is a suitable nitrogen protecting group such as tert-butoxycarbonyl (BOC), benzyloxycarbonyl, or 9-fluorenylmethoxycarbonyl.

Synthesis of Sitagliptin free base as disclosed in the complete specification of IN'816

The synthesis of Sitagliptin, as disclosed in example 7, is a two steps process.



SITAGLIPTIN

Step- A

Synthesis of 7-[(3R)-3-[(1,1-dimethylethoxycarbonyl) amino]-4-(2,4,5-trifluorophenyl) Butanoil]-3(trifluoromethyl)-5,6,7,8-tetrahydroimidazo[1,2-a]pyrazine

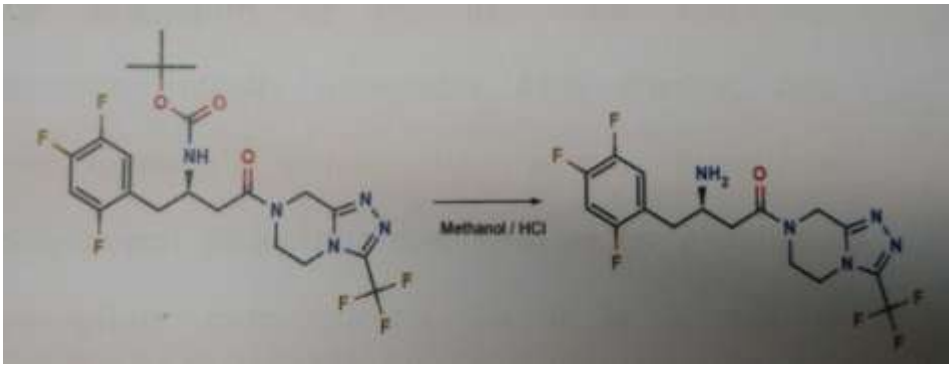
Step-A discloses the process for preparation of general compound **13** referred in scheme 6. (Markush type structure and example 7(Sitagliptin molecule). Further, the general compound **13** is protected at the amino group by the use of an amine protection group like BOC (di-tert-butyl-dicarbonate).

The title compound of formulae **13** is prepared by reacting the **intermediate 3 compound** -[(3R)-3-[(1,1-dimethylethoxycarbonyl) amino]-4-(2,4,5-

trifluorophenyl) butanoic acid] and [3-(trifluoromethyl)-5,6,7,8-tetrahydro-1,2,4-triazolo[4,3-a] pyrazine.

Step-B

Methanol saturated with hydrogen chloride was added to compound of step A to obtain the Sitagliptin free base. The Sitagliptin free base reacted in *situ* with the excess hydrogen chloride (hydrochloric acid) to form the Sitagliptin hydrochloric acid salt.



21. It is further alleged that defendant, in the US patent 8334385, has acknowledged that method of production of Sitagliptin Free Base is taught in US 6699871 (equivalent to suit patent). The scheme disclosed in the US 8334385 shows compound XII to be a BOC protected sitagliptin free base. The scheme further shows that removing the BOC group from the primary amine of Sitagliptin, gives the free amine group. Thus, the Defendant's claim that the method of preparation of the sitagliptin free base is not disclosed is incorrect and contrary to its own assertions made in the US patent. Suit patent claims Sitagliptin as the free base and any

pharmaceutically acceptable salts thereof and encompasses within its scope Sitagliptin Dihydrogen Phosphate monohydrate (SPM), as it is a salt of Sitagliptin. Plaintiffs have denied the averments of the Defendant in relation to false suggestions and misrepresentation/suppression. It is alleged that subsequent patent applications were for different inventions and cannot form the basis for the rejection of an earlier filed patent application on the grounds of patentability. It is denied that patent is liable to be revoked for non-compliance of Section 8(1) of the Act. Plaintiffs allege that in compliance with Section 8(1) of the Act, statement and undertaking in Form 3 were filed on 6th January, 2004, 14th September, 2006 and 31st January, 2007 respectively. In compliance with Section 8(2) of the Act, plaintiff no.1 filed copies of the granted US and EP patents. Under the PCT regulations, if a designated office requires copies of ISR/IPER, they can make a direct request to the international Bureau that is responsible for administrating international applications. Thus, plaintiffs have claimed that suit patent is valid and cannot be revoked.

22. On the pleadings of the parties, following issues were framed on 21st February, 2014:-

1. Whether the plaint has been signed, verified and filed by a duly authorized person? OPP

2. Whether the plaintiff is the proprietor of Indian Patent No. 209816? OPP

3. Whether the plaintiff is not the owner of the patent no. 209816? OPD

4. Whether the defendants have been infringing patent No. 209816 of the plaintiff? OPP

5. Whether the defendant has misrepresentations on the product packaging and package insert? OPP

6. Whether the license agreement between plaintiff No.1 and plaintiff no. 2 has not been executed in accordance with law? OPD

7. Whether the registration/recordal of the license agreement between the plaintiffs qua the suit patent has not been done in accordance with Indian law? OPD

8. Whether the plaintiffs have suppressed material facts and documents, if so, its effect? OPD

9. Whether the defendant's product ZITA and ZITA-MET infringe the patent of the plaintiff? OPP

10. Whether the patent No. 209816 is invalid? OPD

11. Whether the Dihydrogen Phosphate Salt of Sitagliptin is covered, enabled and disclosed in the suit patent? If so, its effect? OPP

12. Relief.

23. Plaintiffs have examined five witnesses. Mr. K.G. Ananthakrishnan, Managing Director of plaintiff no.1, has been examined as PW1. Prof. David Earl Nichols, an Adjunct Professor of Chemical Biology and Medicinal Chemistry at the University of North Carolina, Chapel Hill, Eshelman School of Pharmacy has been examined as PW2. Mr. John C. Todaro, Executive Director has been examined as PW3. Dr. Ann E. Webber, Vice President of Merck has been examined as PW4 and Mr. Shailesh Joshi, Vice President (Marketing & Sales) of plaintiff no.2 has been examined as PW5. As against this, defendant has examined two witnesses. Ms. Meera Vanjari, Senior Vice President (General Counsel) has been examined as DW-1; whereas Dr. Ashwini Nangia, Professor of Chemistry, University of Hyderabad, has been examined as DW-2.

24. I have heard learned senior counsel/counsel for the parties and perused the entire material placed on record and my issue wise findings are as under :-

Issue No. 1

25. Plaint has been signed and verified by PW1-K.G. Ananthakrishnan, Managing Director of MSD Pharmaceuticals Pvt. Ltd, who has proved Power of Attorney in his favour, executed by Charles Caruso, as Ex. PW1/1.

Board resolution dated 1st December, 2012 of Merck & Co. Inc. (the parent company of the Merck group of which the plaintiff no. 1 is a member) has been proved as Ex. PW1/2. A perusal of Power of Attorney Ex. PW1/1 makes it clear that it has been executed by Mr. Charles Caruso before a notary public, New Jersey on 28th March, 2013. Notary public has put his stamp to the effect 'subscribed and sworn before me this 28th day of March, 2013. He has also appended his signatures below his stamp. Thus, it is clear that Power of Attorney has been executed by Mr. Charles Caruso in favour of PW1 K.G. Ananthkrishnan before a notary public. Section 85 of the Evidence Act, 1872 reads as under :-

> "Presumption as to powers of attorney—The Court shall presume that every document purporting to be a power of attorney, and to have been executed before, and authenticated by, a notary public, or any Court, Judge, Magistrate, Indian Consul or Vice-Consul, or representative of the Central Government, was so executed and authenticated."

26. A perusal of Section 85 of the Evidence Act makes it clear that in case Power of Attorney has been executed and authenticated by a public notary, the Court has to presume that it was so executed, authenticated and attested. The provisions are mandatory and it is open to the Court to presume that all the necessary requirements for the proper execution of the Power of

Attorney had been followed. In **National and Grindlays Bank Ltd. vs. World Science News and Ors. AIR 1976 Delhi 263**, it has been held thus :-

> "(10) The document in the present case is a power of attorney and again on the face of it shows to have been executed before, and authenticated by, a notary public. In view of Section 85 of the Evidence Act, the Court has to presume that it was so executed and authenticated. Once the original document is produced purporting to be a power of attorney so executed and attested, as stated in S. 85 of the Evidence Act, the Court has to presume that it was so executed and authenticated. The provision is mandatory, and it is open to the Court to presume that all the necessary requirements for the proper execution of the power of attorney have been duly fulfilled. There is no doubt that the section is not exhaustive and there are different legal modes of executing a power of attorney, but, once the power of attorney on its face shows to have been executed before, and authenticated by, a notary public, the Court has to so presume that it was so executed and authenticated. The authentication by a Notary Public of a document, purporting to be a power of attorney and to have been executed before him is to be treated as the equivalent of an affidavit of identity. The object of the section is to avoid the necessity of such affidavit of identity. Under Section 57 sub-section (6) of the Evidence Act, the Courts have to taken judicial notice of the seals of Notaries Public and when the seal is there, of which judicial notice is taken, there is no reason why judicial notice should not be taken of the signatures as well". What is argued by Shri Rameshwar Dial, learned counsel for defendants I to 3, is that the Notary Public in Section 85 or Section 57 of the Evidence Act merely means notaries appointed under the Notaries Act

1952. The argument is that where a document purports to be a power of attorney, before the Court can presume it to be so executed and authenticated as is contemplated by S. 85, it should have been authenticated by Indian Consul or Vice-Consul or the representative of the Central Government and not by a notary public of a foreign country. For one thing Notaries Act 1952 was not there when Evidence Act which was the first Act of 1872 was enacted. Secondly, the purpose of Sections 57 and 85 is to cut down recording of evidence. For such matters, like the due execution of a power of attorney in the present day of international commerce, there is no reason to limit the word "Notary Public" in S. 85 or Section 57 to Notaries appointed in India. The fact that notaries public of foreign countries have been recognised as proper authorities for due execution and authentication for purpose of section 85 of the Evidence Act is illustrated by the Supreme Court in case Jugraj Singh and anr. vs. Jaswant Singh and or s. MANU/SC/0413/1970 : [1971]1SCR38 . In this case the Supreme Court held that a power of attorney executed and authenticated before a notary public of California satisfied the test of S. 85 of the Evidence Act and S. 33 of the Indian Registration Act. If the interpretation of notary public is limited to notaries public appointed in this country only, it will become impossible to carry on commerce with foreign countries. Surely, S. 57 of the Indian Evidence Act which enjoins upon the Courts to take judicial notice of seals of Notary Public, such judicial notice cannot be limited to Notaries appointed in India only It seems clear if the entire sub-section is read. Once, this conclusion is reached, there is no reason to limit the meaning of the expression "Notaries Public" in S. 85 of the Indian Evidence Act to Notaries appointed in India only.”

27. In **National and Grindlay Bank vs. Radio Electronics Corporation P. Ltd. MANU/DE/0077/1977**, in the context of Section 85 of the Evidence Act, it has been held thus :-

> "4. The section prescribes in clear and unequivocal terms that a power of attorney duly authenticated by a Notary Public shall raise the presumption about its execution and authentication. Authentication is not merely attestation but something more. It means that the person authenticating has assured himself of the identity of the person who has signed the instrument as well as the act of execution. It is for this reason that the presumption under section 85, unless rebutted, stands and the document can be admitted in evidence as a document executed by the person alleged to have executed it without any further proof."

28. In **Baker Oil Tools (India) Pvt. Ltd. vs. Baker Hughes Ltd. and Anr. 2011 (47) PTC 296 (Del),** it has been held as under :-

> "31. It would be thus seen from all the aforesaid judicial pronouncements that the Courts have been consistently taking a view that once the execution and authentication of the Power of Attorney by a Notary Public is proved on record, then Section 85 mandates the Court to draw a presumption in favour of due and valid execution of such a Power of Attorney. The Courts have also taken a view that the use of expression "authentication" in Section 85 of the Evidence Act must be accorded its due meaning, not merely comparing the same with the expression "attestation". The authentication of a Power of Attorney or any document by the Notary Public necessarily would mean that Notary Public has duly satisfied himself about the competence of the Officer and his authority to execute such a Power of Attorney or other document. The purpose of

> Section 85 has thus been rightly held to eliminate the cumbersome evidence which in the absence of the said provision on the statute book would be required to prove the minutes book and Board Resolution etc. for proving the due and valid execution of the Power of Attorney. Looking into the growing international trade and the world economy, any other interpretation of Section 85 of the Evidence Act would unnecessarily burden the parties to bring the witnesses from abroad just to prove the Board Resolutions and minute books etc. However, having said that, one cannot lose sight of the fact that such presumption is not a conclusive presumption as the same being rebuttable. Once a party who seeks to take advantage of Section 85 of the Evidence Act proves the Power of Attorney, its due execution and authentication by the Notary Public with due affixation of necessary seals on such a document then the onus would shift on the other party to disprove or rebut such a presumption arising in favour of the first party."

29. In **Rajeshwarhwa vs. Sushma Govil AIR 1989 Delhi 144**, it has been held thus :-

> "Counsel for the appellant has, then, contended that till It is proved that the person who signed the said power of attorney was the duly appointed attorney, the court cannot draw any presumption under Sections 57 & 85 of the Evidence Act. I am afraid that the very purpose of drawing presumption under Sections 57 & 85 of the Evidence Act would be nullified if proof is to be had from the foreign country whether a particular person who had attested the document as a Notary Public of that country is in fact a duly appointed Notary or not. When a seal of the Notary is put on the document, Section 57 of the Evidence Act comes into play and a presumption can be raised regarding the genuineness of the seal of the said Notary, meaning thereby that the said document is presumed to have been attested by a competent Notary of that country."

30. Accordingly, in my view, PW1 K.G. Ananthkrishnan, being constituted Attorney of the plaintiff no.1, is duly authorized to sign and institute the plaint, on behalf of plaintiff no.1.

31. As regards plaintiff no.2, Mr. Chetan Gupta has signed the plaint, whose signatures have been identified on the plaint by PW5-Shailesh Joshi, who has deposed that he had seen the signatures of Mr. Chetan Gupta on many occasions during the day-to-day affairs of the company, being one of its employees. As per PW5, Mr. Chetan Gupta was authorized by the plaintiff no.2 vide Power of Attorney dated March, 30, 2013(Ex. PW5/2) executed by Mr. Sudhir V. Valia, whole time Director of plaintiff no.2. Further that Mr.Sudhir V.Valia was empowered to sign a letter of authority vide Board Resolution dated 28th May, 2011 of plaintiff no.2. Certified copy of extract of Board Resolution has been placed on record as Ex. PW5/3. Defendant objected to its proof on the ground that original minutes book was not brought, therefore, extract has been only marked as Ex.PW5/3 for identification purposes. In absence of the original minutes books, in my view, extracts of Board Resolution have remained unproved. As regards Ex. PW5/2 is concerned, the same is not a Power of Attorney. A perusal of this document shows that it is a Letter of Authority dated 30th March, 2013

signed by Mr. Sudhir V. Valia, the whole time director of plaintiff no.2-company, thereby authorizing Mr. Chetan Gupta to file the present proceedings. Letter of Authority Ex. PW5/2 has been issued by the whole time Director of plaintiff no.2, who is 'officer' of plaintiff no. 2 within the meaning of Section 2(13) of the Companies Act, 1956, according to which, an 'officer' includes any director, manager or key managerial personnel or any person in accordance with whose directions or instructions the Board of Directors or any one or more of the directors is or are accustomed to act. According to Order 29 Rule 1 CPC any principal officer of a corporation can sign and verify the plaint. In **United Bank of India vs. Naresh Kumar and Others AIR (1996) 6 SCC 660**, Supreme Court has held that dehors Order 29 Rule 1 CPC, as a company is a juristic entity, it can duly authorize any person to sign the plaint or the written statement on its behalf and this would be regarded as sufficient compliance with the provisions of Order 6 Rule 14 CPC. A person may be expressly authorized to sign the pleadings on behalf of the company, for example by the Board of Directors passing a resolution to that effect or by a power of attorney being executed in favour of any individual. In absence thereof and in cases where pleadings have been signed by one of its officers a Corporation can ratify the said action of its

officer in signing the pleadings. Such ratification can be express or implied. The Court can, on the basis of the evidence on record and after taking all the circumstances of the case specially with regard to the conduct of the trial, come to the conclusion that the corporation had ratified the act of signing of the pleadings by its officer. It has been further held that procedural defects which do not go to the root of the matter should not be permitted to defeat a just cause. There is sufficient power in the Courts, under the CPC, to ensure that injustice is not done to any party who has a just case, as far as possible a substantive right should not be allowed to be defeated on account of a procedural irregularity which is curable.

32. In this case, trial has continued almost for two years. Thus, it is difficult in these circumstances to presume that suit has not been filed and pursued without the authorization of plaintiff no.2. Ex.PW5/2 is the letter of authority duly signed by the whole time Director of the plaintiff no.2 authorizing Mr.Chetan Gupta to sign and verify the plaint. This shows that plaintiff no.2 has ratified the action of Mr. Chetan Gupta of signing the plaint and, thereafter, continuing with the same.

33. For the foregoing reasons, this issue is decided in favour of the plaintiffs and against the defendant.

Issue Nos. 2, 3, 6 & 7

34. These issues require common discussion, hence, are disposed of together. Ex. P-10 is a certified copy of extract of patent register which indicates that patent application no. 209816 (suit patent) was filed on 5th July, 2002. It was granted on 6th September, 2007 in the name of Merck & Co. Inc. (USA). Name of the patentee was changed from Merck & Co. Inc. to Merck Sharp & Dohme Corporation vide entry dated 19th January, 2011. There is an entry dated 24th January, 2013 to the effect that name of M/s Schering Corporation was entered in pursuance to an application received on 22nd January, 2013 in the patent office made by M/s Schering Corporation, 2000, Galloping Hill Road, Kenilworth, New Jersey by virtue of Agreement of Merger dated 1st May, 2012 executed between Merck Sharp & Dohme Corporation and M/s Schering Corporation. Entry dated 25th February, 2013 shows that name of the patentee was changed to Merck Sharp & Dohme Corporation in pursuance to the request dated 19th February, 2013 in the patent office. Entry dated 22nd May, 2013 further shows that M/s Sun Pharmaceutical Industries Ltd. was recorded as a licensee pursuant to the application made by M/s Sun Pharmaceutical Industries Ltd. based on the License Agreement dated 16th May, 2013 executed between Merck Sharp &

Dohme Corporation and M/s Sun Pharmaceutical Industries Ltd. From the Ex. P-10 plaintiffs have succeeded in proving that Merck Sharp & Dohme Corporation (plaintiff no.1) is the patentee in respect of the suit patent. After 25th February, 2013 there has not been any subsequent change. As regards plaintiff no. 2 is concerned, it has been recorded as a licensee with effect from 22nd May, 2013.

35. Learned senior counsel for the defendant has contended that from the averments made in the plaint, replication, documents and the evidence of PW-1, it emerges that plaintiff no.1 is not the owner of the suit patent nor plaintiff no.2 is a licensee. Accordingly, plaintiffs have no right to institute the suit in the capacity of patentee. Reliance has been placed on **Dwarkadas DhanjiSha vs. Chhotelal Ravicarandas & Co. AIR 1941 Bom 188** wherein it has been held as under :-

> "……..Section 64 of the general portion of the Act also provides for any person making an application for rectification of the register of patents or designs on the ground that any entry was wrongly made in the register. Counsel further argued that in the absence of any such cancellation the register of designs which contains the name of the proprietor of the registered design was conclusive on the point that the person registered as proprietor was the proprietor of a new or original design.
>
> The words of Section 46(5), however, are that the entry with regard to the name and address of the proprietor or proprietors

> of the registered design is prima facie evidence to that effect. That means in my opinion that there is a prima facie presumption that the person whose name is registered as the proprietor is the proprietor of a new or original design, but the entry in the register is not conclusive proof thereof, and the presumption can be rebutted. It is true that under Section 43 no registration can be effective unless the design sought to be protected is new or original and not of a pre-existing common type. But the certificate is not conclusive, and there is nothing in the Act which prevents the defendant in a suit for damages for infringement of a registered design under Section 53 from raising in defence the plea that the design was previously published and was neither new or original: see Muhammad Abdul Karim vs. Muhammad Yasin (1934) I.L.R. 56 All. 1032. It was pointed out that unless it was final and conclusive there was no advantage in having a certificate of registration. The advantage is that if no evidence is led by the defendants to the contrary, the certificate is sufficient evidence that the plaintiffs are the proprietors, that is, proprietors of a new or original design. If evidence is led, it is for the Court to come to its finding on the question……"

36. Learned senior counsel for the defendant has further contended that PW1 K.G. Ananthkrishnan has deposed that suit patent was first filed in India by Merck & Co. Inc. on 6th January, 2004. Thereafter, name of Merck & Co. Inc. was changed to Merck Sharp & Dohme Corporation on 3rd November, 2009. Merck Sharp & Dohme Corporation became a wholly owned subsidiary of Schering Plough Corporation on 3rd November, 2009, by way of the reverse merger. Subsequently, Schering Plough Corporation changed its name to Merck & Co. Inc. on 3rd November, 2009. It is, thus,

contended that as per plaintiff no.1 itself Merck & Co. Inc. ceased to have any right in patent from 3rd November, 2009 onwards. On 1st May, 2012 Schering Plough Corporation merged with Merck Sharp & Dohme Corporation (patentee) as a result of which all the assets of Merck Sharp & Dohme Corporation were transferred to Schering Corporation. Only copy of the merger certificate was filed before the patent office. Plaintiffs did not place on record any other document before the Court or the patent office to establish the actual transfer of rights from Merck Sharp & Dohme Corporation to Schering Corporation, which is not sufficient to establish transfer of rights in the suit patent. It is further contended that even no document was summoned from the patent office to show that Schering Corporation has changed its name to Merck Sharp & Dohme Corporation on 25th February, 2013. As per learned senior counsel, plaintiffs have failed to produce and prove on record necessary documents to establish the complete chain of documents to authenticate the transfer of patent from Merck & Co. Inc. to another so as to conclude, that plaintiff no. 1 became the proprietor of the suit patent. It is further contended that license agreements Ex. PW1/D-3 and Ex. CW2/A/D-1 are suspicious, inasmuch as, the license agreements have not been registered in accordance with law. A letter requesting to take

the license agreement on record was filed before the patent office on 20th May, 2013 and pursuant thereof plaintiff no.2 appears to have been recorded as a licensee in the e-Register on 22nd May, 2013. The patent office raised objections vide letter dated 20th June, 2013 stating therein that address of the patentee Merck Sharp & Dohme Corporation in the license agreement was inconsistent with the e-Register as well as copy of the license agreement was not filed. Plaintiff no.2 replied to the said objections on 18th June, 2013, that is, even prior to patent office raising the objections. The subsequent copy of license filed on record by the plaintiff no.2 also suffers from various defects. The patent license was signed on behalf of Merck Sharp & Dohme Corporation and Merck & Co. Inc. on 17th May, 2013; whereas by MSD International GMBH and Sun Pharmaceutical Industries Ltd. on 24th May, 2013 and 31st May, 2013 respectively, however, as per e-Register date of the license is 22nd May, 2013. License was executed between four parties, as opposed to two parties, as per the information detailed in the e-Register. No clarity on the 'beneficial owner' viz Merck International GMBH has been substantiated with adequate documents. Two copies of license agreement bearing different dates of execution, that is, 16th May, 2013 and 31st May, 2013 were placed on the patent office record. The patent license is on a

stamp paper of ₹100/-; whereas value of the assignment for the purpose of stamp has been set out therein as US$1. All this creates a serious doubt about the authenticity of license.

37. Learned counsel for the plaintiffs has contended that validity of the patent can be challenged in a counter claim before the High Court only on the grounds as envisaged under Section 64 of the Act and no other ground. None of the grounds as stipulated in Section 64 of the Act pertain to the tile of a patent. Any question with regard to title of a patent, pertains to rectification of the register of patents under Section 71 of the Act for which the exclusive jurisdiction vests with the Intellectual Property Appellate Board (IPAB). Jurisdiction of the High Court to deal with question of title under Section 71 is barred by virtue of Section 117D read with Section 117C of the Act. It is further contended that plaintiffs have explained the chain of title in its various pleadings and also in the evidence of PW1. Plaintiff no.1 had furnished documents to the satisfaction of the patent office and only thereafter its name was recorded as a proprietor of the suit patent. All the records of plaintiff no.1 as well as of patent office establish beyond doubt that plaintiff no.1 is the proprietor of the suit patent. PW5, in answer to question 75, has categorically stated that MSD International GMBH is a

licensee of the suit patent which has been licensed to it by the proprietor of the suit patent, that is, Merck Sharp & Dohme Corporation (plaintiff no.1). It has been further contended that there exists a co-marketing and license agreement dated March 2, 2011 in favour of plaintiff no.2 (Ex. PW1/D2 Collectively). The said agreement grants the plaintiff no.2, vide clause 2.1, an exclusive license for the trade marks ISTAVEL and ISTAMET and a non-exclusive license to use the know-how for the term of the agreement. Clause 4.1 further stipulated that the know-how for the development of products, as defined by clause 1.16 referring to clause 1.10, shall be provided to plaintiff no.2. Clause 1.10 with Schedule B clearly states that products are pharmaceutical products formulated with active ingredients, namely, Sitagliptin and Sitagliptin & Metformin. The agreement dated 16th May, 2013 (Ex. PW-1/D-3) was only clarificatory . It is further contended that when the license was filed at the patent office on 20th May, 2013 an objection as to lack of notarization was raised by the patent office which was cleared by filing a notarized copy of the agreement (Ex. CW-2/A/D-1). On the evidence adduced, plaintiff no.2 was duly recorded as the licensee of plaintiff no.1 by the patent office, which is a conclusive proof in this regard.

38. Section 67 (1) of the Act provides that there shall be kept at the patent office a register of patents, wherein shall be entered – (a) the names and addresses of grantees of patents; (b) notifications of assignments and of transmissions of patents, of licenses under patents, and of amendments, extension and revocations of patents; and (c) particulars of such other matter affecting the validity or proprietorship of patents as may be prescribed. Section 67(5) envisages that notwithstanding anything contained in the Indian Evidence Act, 1872, a copy of, or extracts from, the register of patents, certified to be a true copy under the hand of the Controller or any officer duly authorized by the Controller in this behalf shall, in all legal proceedings, be admissible in evidence.

39. A conjoint reading of Sub-sections 1 and 5 of Section 67 makes it clear that names and address of the grantees of patent, as contained in the register, would be sufficient proof of title of the patentee and the same is admissible in evidence in all the legal proceedings. Section 69 of the Act deals with registration of assignment, transmission etc. Such registration will also be proved by the assignments etc. Section 71 of the Act reads as under :-

71 Rectification of register by [Appellate Board]. -

> (1) The [Appellate Board] may, on the application of any person aggrieved-
>
> (a) by the absence or omission from the register of any entry; or
>
> (b) by any entry made in the register without sufficient cause; or
>
> (c) by any entry wrongly remaining on the register; or
>
> (d) by any error or defect in any entry in the register, make such order for the making, variation or deletion, of any entry therein as it may think fit.
>
> (2) In any proceeding under this section the [Appellate Board] may decide any question that may be necessary or expedient to decide in connection with the rectification of the register.
>
> (3) Notice of any application to the [Appellate Board] under this section shall be given in the prescribed manner to the Controller who shall be entitled to appear and be heard on the application, and shall appear if so directed by the [Board].
>
> (4) Any order of the [Appellate Board] under this section rectifying the register shall direct that notice of the rectification shall be served upon the Controller in the prescribed manner who shall upon receipt of such notice rectify the register accordingly.

40. A perusal of aforesaid provision makes it clear that Appellate Board has power to rectify the register on an application filed by any aggrieved person, if any entry is made without any sufficient cause or there is any error or defect in any entry in the register. Section 117C of the Act stipulates that no court or other authority shall have or, be entitled to, exercise any jurisdiction, powers or authority in relation to the matters referred to in sub-

section (2) of section 117A or section 117D. Section 117D envisages that an application for revocation of a patent before the Appellate Board under section 64 and an application for rectification of the register made to the Appellate Board under section 71 shall be in such form as may be prescribed.

41. A conjoint reading of Section 117C and 117D makes it clear that no court or authority shall have jurisdiction in relation to the matters regarding rectification of the register as envisaged under Section 71 of the Act. Accordingly, I am of the view that plaintiff no.1 is proprietor of the suit patent and plaintiff no.2 is a licensee of plaintiff no.1. Dwarkadas (supra) is in the context of different facts and is of no help to the defendant, inasmuch as, above-referred provisions have not been considered and discussed therein. As regards plea that authenticity of license is doubtful since value of assignment is US $ 1 also has no force. In Wonderweld Electrodes (Pvt.) Ltd. & Ors. Vs. Ahura Welding Electrodues Manufacturing Limited & Ors. 2003 (26) PTC 37 (DB) (Mad), it has been observed thus: "According to them, trade mark can be assigned even for a nominal consideration of ₹1 or US $ 1. In such a circumstance, we are unable to appreciate the argument that deed of assignment is a sham transaction and was entered into only to

bye-pass the agreement dated 27th January, 1996". Accordingly, in my view, inadequacy of consideration will not be sufficient to doubt the license agreement.

42. The above issues are answered accordingly.

Issue Nos. 4, 5, 9 and 11.

43. Learned senior counsel has contended that in the suit patent (Ex. P-9) disclosure made by the plaintiff is 'insufficient'. Patent is granted as a *quid pro quo* for a complete disclosure of the invention along with the manner of its operation. A mere mention or general disclosure is not sufficient as there has to be an enabling disclosure, which means that after the patent term expires, a person skilled in the art should be able to make the product taught and enabled by the patent without further undue experimentation. Section 10(4) of the Act stipulates that complete specification shall be described fully in respect of the invention, operation and use with a claim or claims defining the scope of the invention for which protection is claimed, inasmuch as, technical information on the invention is also to be provided. Reliance has been placed on Terrell on Law of Patents; Chapter 13-08 to 13-09 regarding need for an enabling disclosure which states as follows :-

"……An enabling disclosure is, as the name suggests, a disclosure of a product or process which is sufficient to enable a skilled reader to obtain or perform it. It may be distinguished from a mere disclosure of the existence of something: for example the identification of a chemical structure which the reader would not be able to synthesis without further direction……

The Act therefore requires that the claims shall be supported by an enabling disclosure, and the absence of an enabling disclosure can lead to revocation for insufficiency…….

How extensive must the disclosure be for a patent to be sufficient?

……More recently, the Courts have frequently had to consider the position where the patent adequately enables a limited subset of embodiments, but its claims are broader. This aspect of insufficiency is sometimes referred to as "Biogen" insufficiency, though of course it is important to remember that there is only a single test under the Act. The patentee is not entitled to protection wider than the contribution which he has made to the art, and so may not obtain a monopoly for matter which he has not told the public about and enabled them to do for themselves on the basis of what he has disclosed in the specification. An insufficiency attack along the "Biogen" lines is therefore concerned with the breadth of claim……."

44. It is further contended that in **Novartis AG Vs. UOI & Ors AIR 2013 SC 1311,** Supreme Court has also recognized the said principle in the following manner :-

"Para 139: The dichotomy that is sought to be drawn between coverage or claim on the one hand and disclosure or enablement or teaching in a patent on the other hand, seems to strike at the

> very root of the rationale of the law of patent. Under the scheme of patent, a monopoly is granted to a private individual in exchange of the invention being made public so that, at the end of the patent term, the invention may belong to the people at large who may be benefited by it. To say that the coverage in a patent might go much beyond the disclosure thus seem to negate the fundamental rule underlying the grant of patents.
>
> 156. …… We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skillful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent…….”

45. It is further contended that in the suit patent plaintiffs have merely claimed the chemical structure of Sitagliptin Free Base, without providing any details pertaining to the manner of preparation of the Sitagliptin Free Base or the conditions under which the same may be prepared. In effect, the suit patent only teaches Sitagliptin Hydrochloride and thus the coverage of the suit patent ought to be restricted to the same. Sitagliptin Free Base does not fall within the purview of the suit patent. The suit patent contains a total of 20 claims wherein it is alleged that claims 1, 15, 17 and 19 are Sitagliptin Free Base. By way of claim 19 plaintiffs have specifically sought to cover Sitagliptin Free Base along with all its pharmaceutically acceptable salts. Scheme 6 does not disclose preparation of Free Base as the same results in

preparation of a salt as opposed to a Free Base. PW2 has admitted this fact during his cross-examination in answer to question no. 136 and 140. DW-2 Prof. Nangia has deposed that Sitagliptin Free Base is not disclosed in the suit patent. Suit patent is a 'Markush patent' and covers billions of compounds, it has only 33 examples, all of which will result only in hydrochloride salts. Coverage cannot be broader than disclosure, hence all claims have to be restricted to hydrochloride salts only including claim 15, 17 and 19. Sitagliptin Phosphate Monohydrate does not fall within the purview of the suit patent. Plaintiffs had filed a separate patent application being 5948/DELNP/2005 in India but the same was subsequently abandoned; meaning thereby that plaintiffs cannot claim any patent right in respect of Sitagliptin Phosphate Monohydrate, in view of the Section 21 of the Act. In the said patent plaintiffs have admitted that Sitagliptin Phosphate Monohydrate is a novel salt. Pharmaceutically acceptable salts of Sitagliptin Free Base are generically encompassed within the scope of WO 03/004498, however, there is no specific disclosure in the said reference about Sitagliptin Phosphate Monohydrate, which, in fact, is used as a drug substance, that is, Active Pharmaceutical Ingredient. Sitagliptin Phosphate Monohydrate exhibits pharmaceutical advantages over the Free Base and

previously disclosed Sitagliptin Hydrochloride salt. Sitagliptin Phosphate Monohydrate has enhanced chemical and physical stability. Sitagliptin Phosphate Monohydrate exhibits potent DPP-IV inhibitory properties and is particularly useful for prevention of Type-2 Diabetes. Process of preparation of Sitagliptin Phosphate Monohydrate is disclosed for the first time in the subsequent application. Process of preparation of Sitagliptin has not been disclosed in the suit patent. Characteristics of Sitagliptin Free Base such as NMR data, melting point etc. is not disclosed in the suit patent and has been disclosed for the first time in subsequent application for Sitagliptin Phosphate Monohydrate. Reliance has been placed on **Ferid Allani v Union of India and Others 2008 Indlaw DEL 813**, wherein it has been held as under :-

> "18……..Having heard learned counsel for the parties at length, I find that the first issue which requires to be considered is the impact of the deemed abandonment of an application for grant of patent. The impact is prescribed inasmuch as the applicant is deprived of the valuable rights which flow in favour of any invention as are guaranteed under Section 48 of the Patents Act, 1970…"

46. It is further submitted plaintiffs had filed patent application before the European Patent Office (EPO) qua Sitagliptin Phosphate Monohydrate wherein also similar admissions which were made in the abandoned Indian

patent application, have been made. Objections were raised by EPO and WIPO in the European Patent Application (PCT Publication corresponding of the suit patent) on the grounds that (a) claimed invention cannot be considered novel and (b) cannot be considered to involve any inventive step. However, in response to the said objections Merck & Co. Inc. (original applicant) reiterated that suit patent teaches Sitagliptin Hydrochloride Salt; whereas the subject application discloses Sitagliptin Phosphate Monohydrate which had remarkable advantages over Sitagliptin Hydrochloride Salt with regard to chemical stability. Further, Sitagliptin Free Base and its other salts were evaluated as possible candidates for clinical development, however, Sitagliptin Phosphate Monohydrate was selected over others as it was thermodynamically and chemically stable. Ultimately, European Patent was granted in respect of Sitagliptin Phosphate Monohydrate. A third party, Teva Pharmaceutical Industries Limited opposed the EP patent corresponding to the Sitagliptin Phosphate Monohydrate patent on the grounds that the same lacks novelty and inventive step over the suit patent. Merck & Co. Inc opposed this plea and reiterated that Sitagliptin Phosphate Monohydrate was inventive over the suit patent and clearly represented enormous advantages over the disclosures made in the suit patent, inasmuch

as, Sitagliptin Hydrochloride Salt was disclosed in the suit patent which was not having physio-chemical properties that are compatible with drug use. It is contended that the admissions made before the European Patent Office makes it clear that Sitagliptin Phosphate Monohydrate is novel, inventive, capable of industrial application and is a new and distinct product which is neither covered nor subsumed in the suit patent. It is vehemently contended that plaintiffs cannot wriggle out from their own admissions and, in fact, admissions made are the best form of evidence. Reliance has been placed on Narayan vs. Gopal AIR 1960 SC 100.

47. It has been further contended that no enabling disclosure or teaching related to Sitagliptin Phosphate Monohydrate is disclosed in the suit patent as it required extensive experimentation for making Sitagliptin Phosphate Monohydrate, which fact has been admitted by PW2 Prof. Nichols in his cross-examination. It is further contended that combination of Sitagliptin Phosphate Monohydrate and Metformin Hydrochloride does not fall within the purview of the suit patent, inasmuch as, patent application bearing no. 2710/CHENP/2008 of plaintiff no.2 was still pending, thus, defendant cannot be said to have infringed the suit patent in respect of its product ZITA-MET.

48. Next contention of defendant is that for identifying the chemical compound various analytical methods such as XRD, Differential Screening Calorimetery, Proton NMR, Carbon-13 NMR, Fluorine NMR etc. are required for identifying and characterizing such compounds. None of the aforesaid methods were utilized by the plaintiffs to indicate presence of Sitagliptin Free Base or Sitagliptin Hydrochloride. It is further contended that XRD analysis of Active Pharmaceutical Ingredient used by the defendant to manufacture ZITA and ZITA-MET reveals that it contains Sitagliptin Phosphate Monohydrate and not Sitagliptin Free Base. It is also the case of the defendant that Sitagliptin Phosphate Monohydrate converts into Sitagliptin Free Base inside the human body due to natural process and does not amount to infringing the suit patent. Reliance has been placed on **Feed Service Corporation v Kent Feeds, Inc (528 F.2d 756)** and **Novartis Pharmaceuticals Corporation v Eon Labs Manufacturing, Inc., (363 F.3d 1306).**

49. Learned counsel for the plaintiff has contended that Section 48(A) of the Act vests exclusive rights in the Patentee, in relation to the product patent, to prevent third parties who do not have their consent, from making, using, offering for sale or selling the said product in India. Thus, patent

rights are negative rights. It is contended that suit patent claims Sitagliptin and its pharmaceutically acceptable salts in compound no. 7 of claim 15, compound no. 4 of claim 17 and claim 19 in particular. Pharmaceutically acceptable salts, as stated in the patent specification of the suit patent, includes phosphoric acid as the preferred acid. Sitagliptin is the biologically active ingredient that binds to the DPP-IV enzyme and is responsible for bringing about the biological/therapeutic effect. In fact, Sitagliptin is a DPP-IV inhibitor. Sitagliptin is contained in both the plaintiffs' as well as defendant's product. In ZITA 100 mg Sitagliptin Phosphate Monohydrate is 128.5 mg and, in fact, it contains 100 mg of Sitagliptin Free Base and is the active moiety. Defendant has intentionally not mentioned this fact in its product insert. It is further contended that DW2 in response to question 104, 116 and 187 has admitted that Sitaglitpin in Sitagliptin Phosphate Monohydrate exists as Sitagliptin –H + and the anion will be phosphate – along with a molecule of water. In response to question 105 DW2 has admitted that calculation of the amount of Sitaglitpin free base in one tablet of 128.5 mg of Sitagliptin Phosphate Monohydrate would work out to 100 mg. Sitagliptin is the biologically active moiety in Sitagliptin Phosphate

Monohydrate. The use of Sitagliptin at the site of activity to bring out the desired therapeutic effect also amounts to "infringement of the suit patent".

50. It is further contended that expression *"use"* mentioned in Section 48 of the Act includes use of Sitagliptin by the defendant as the therapeutic/ biologically active moiety for bringing out the desired biological/therapeutic effect, that is, treatment of Diabetes Mellitus–Type II through DPP-IV inhibition. Reliance has been placed on the judgment rendered by the Supreme Court of Canada in **Monsanto Canada Inc. v. Schmeiser, 2004 SCC 34** wherein it has been held :- "whether the inventor has been deprived in whole or in part, directly or indirectly, of the full enjoyment of the monopoly conferred by the patent.". It has been further held that "if there is a commercial benefit to be derived from the invention, it belongs to the patent holder". It is contended that DW2 has categorically deposed that the active molecule is the Sitagliptin base in the Sitagliptin Phosphate Monohydrate tablet. The amount of Sitagliptin Free Base is 100 mg in the Sitagliptin Phosphate Monohydrate tablet of 128.5 mg. Sitagliptin molecule is the active substance independent of the salt and Sitagliptin base is converted to a di-hydrogen phosphate salt to provide superior formulation or pharmacokinetic properties.

51. Learned counsel has next contended that after Sitagliptin tablet is consumed it disintegrates in human body. Sitagliptin molecule binds to the DPP-IV enzyme. It is, thus, contended that use of Sitagliptin Free Base by the defendant in its products ZITA and ZITAMET amounts to infringement of the suit patent. It is further contended that Sitagliptin Phosphate Monohydrate is covered by the suit patent. Reliance has been placed on **Farbewerke Hoechst Vs Unichem Laboratories AIR1969Bom255** wherein, it has been held that: "the specification is to be read as a whole, and that the body of the specification, or changing their meaning by reference to the language used in the body of the specification, though the body of the specification should be referred to for the purpose of resolving difficulties of construction occasioned by the claims when read by themselves. It is, therefore, clear that, in an infringement action, the main function of the court is to construe the claims which are alleged to have been infringed, without reference to the body of the specification, and to refer to the body of the specification only if there is any ambiguity or difficulty in the construction of claims in question". Learned counsel submits that it is established that pharmaceutically acceptable salts have been defined in the body of the patent specification of the suit patent as including phosphoric acid or the

phosphate salt of Sitagliptin, which has been listed as being one of the 8 preferred salts. The patent specification also describes the compounds of the suit patent, including Sitagliptin, which can exist in the form of hydrates such as a monohydrate. The above disclosures are sufficient to conclude that defendant, by using Sitagliptin Phosphate Monohydrate in ZITA and ZITA-MET, clearly infringes the claims of the suit patent. The disclosures made in the suit patent can be well understood by a person of ordinary skill in the art to select Sitagliptin Free Base, as pointed out in claim 19, and prepare all the salts of Sitagliptin from the 8 preferred acids. It is further contended that there is nothing in the European Patent prosecution of the Sitagliptin Phosphate Monohydrate patent that disregards the coverage of all the salts of Sitagliptin by the suit patent. In fact, it has been repeatedly asserted during the prosecution of the European Patent that all the pharmaceutically acceptable salts of Sitagliptin are covered by the suit patent. Every document before the European Patent Office indicates that there was a generic disclosure of all salts of Sitagliptin including the phosphate salt in the suit patent and that a patent on Sitagliptin Phosphate Monohydrate was being sought only as a "selection invention" for Sitagliptin Phosphate Monohydrate's surprising and unexpected

physiochemical properties, over the free base and the hydrochloride salt. European Patent Office, in their interlocutory decision in the opposition proceedings dated 15th March 2010 in para 5, held that "In agreement with the opponent, the division is of the opinion that the presently claimed dihydrogen phosphate is obvious to the skilled person if the technical problem is merely the provision of an alternative form of Sitagliptin, However, the selection of the dihydrogen phosphate can be regarded as inventive, if this salt exhibits certain effects and if the objective technical problem to be solved is therefore more ambitious".

52. It is further contended that defendant has admitted in its various documents that Sitagliptin Phosphate Monohydrate contains Sitagliptin as base and Sitagliptin is the active moiety in Sitagliptin Phosphate Monohydrate. Ex. P6 is a patent granted in the United States wherein Glenmark Generics Ltd., that is, one of the sister concerns of the defendant, has admitted as under :-

> "R-Sitagliptin is commonly available as sitagliptin phosphate, 7-[(3R)-3-amino-1-oxo-4-(2,4,5-trifluorophenyl)butyl]-5,6,7,8-tetrahydro-3-(trifluoromethyl)-1,2,4-triazolo[4,3-a]pyrazine phosphate (1:1) monohydrate,
>
> "Sitagliptin phosphate is an orally administered dipeptidyl peptidase-4 (DPP-4) inhibitor. Sitagliptin has been developed for the treatment of Type-2-diabetes and is available in the

market under the brand name JANUVIA® as tablets in the dosage strengths of **25, 50, or 100 mg equivalent base**."

"U.S. Pat. No. 6,699,871 (equivalent to suit patent) describes various DPP-4 inhibitors including sitagliptin and their pharmaceutically acceptable salts,.."

53. In another patent application of Glenmark Generics Ltd., relating to process of preparation of R-Sitagliptin and intermediates thereof, it has been admitted as under :-

"[0003]R-sitagliptin is commonly available as sitagliptin phosphate, 7-[(37?)-3-amino-l-oxo-4-(2,4,5-trifluorophenyl)butyl]-5,6,7,8-tetrahydro-3-(trifluoromethyl)- 1 ,2,4-triazolo[4,3-o]pyrazine phosphate (1 : 1) monohydrate,

[0004] Sitagliptin phosphate is a glucagon-like peptide 1 (sic) metabolism modulator, hypoglycemic agent, and dipeptidyl peptidase-4 (DPP-4) inhibitor. R-Sitagliptin is currently marketed in its phosphate salt in the United States under the trade name JANUVIA® in its monohydrate form as tablets in the **dosage strengths of 25, 50, or 100 mg equivalent base**."

"[0006] United States Patent No. 6,699,871 describes various DPP-4 inhibitors including sitagliptin and their pharmaceutically acceptable salts, a pharmaceutical composition and method of treatment and a process for the preparation of sitagliptin hydrochloride."

54. In pre-grant opposition against Indian Patent Application no. 2710/CHENP/2008 filed by Glenmark Pharmaceuticals Ltd. similar admissions have been made which read as under :-

"WO 03/004498 teaches DPP-4 inhibitors, which are useful in the treatment or prevention of diabetes and particularly type2

diabetes. This document discloses and claims sitagliptin and its pharmaceutically acceptable salts in claim 15.....”

55. It is contended by the learned counsel that WO 03/004498 is equivalent to the suit patent.

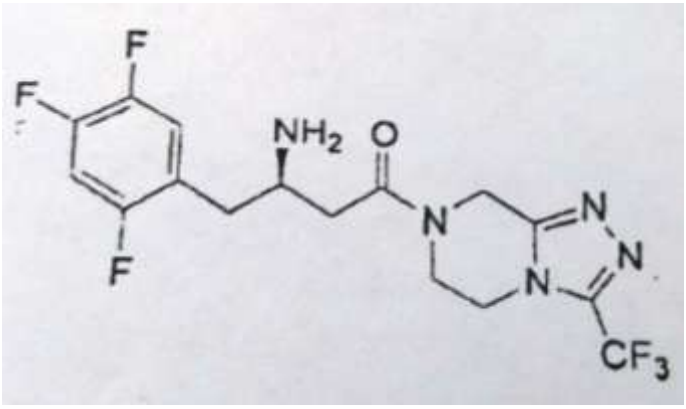
56. Defendant’s own publication Ex. DW1/P22 refers to abstracts from 5 scientific publications all of which define Sitagliptin as DPP-IV inhibitor. In the said publication defendant admits as under :-

> “Sitagliptin is an orally-active dipeptidyl peptidase-4 (DPP-IV) enzyme inhibitor that improves glycemic control in patients with Type 2 diabetes mellitus by slowing the inactivation of incretin hormones……Sitagliptin is currently marketed in its phosphate salt in the United States under the trade name JANUVIA™ in its monohydrate form JANUVIA™ is indicated to improve glycemic control in patients with type 2 diabetes mellitus.”
>
> “U.S. Patent No. 6,699,871 ("the '871 patent") discloses a class of beta-amino-tetrahydrotriazolo [4,3-a]pyrazines such as Sitagliptin and its hydrochloride salt form, a potent inhibitor of DPP-IV enzyme. Other pharmaceutically acceptable salts of this compound are generically encompassed within the scope of the '871 patent. It also discloses a process for the preparation of sitagliptin and related compounds.”

57. From the facts narrated hereinabove it is clear that matter involves invention of a chemical molecule/compound in the medicinal field and is of highly technical nature. In such like matter court has to go by the opinion of the experts in the field, whose testimony is found trustworthy and reliable,

inasmuch as, is supported by the documents. The court has not to super impose its view over and above the technical experts, more so when Judges are not experts in chemical and medicinal filed. In Martin F. D'Souza vs. Mohd. Ishfaq (2009) 3 SCC 1, Supreme Court held thus : "the Courts and Consumer Fora are not experts in medical science, and must not substitute their own views over that of specialists".

58. PW2 is an independent technical expert. He is not the employee of plaintiff. He is chemical and medicinal expert. He has deposed that suit patent provides compounds that inhibit the activity of DPP-IV along with compositions, articles of manufacture and processes for making the compounds. The pharmaceutical compound, Sitagliptin, is covered by claims 1, 15, 17 and in particular by claim 19 and also at example 7 in the suit patent. Sitagliptin is the active pharmaceutical ingredient of the drug JANUVIA. Its chemical name is 4-oxo-4-[3-(trifluoromethyl)-5, 6-dihydro[1,2,4] triazolo [4,3,a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl) butan-z-amine. The structure reads thus:-



59. He has further deposed that a person of ordinary skill in the art would have been readily able to produce the phosphate salt of Sitagliptin, and in particular the dihydrogenphosphate of Sitagliptin. It is a trivial matter for one skilled in the art to convert one salt of an amine into another different salt. For example, the hydrochloride salt can readily be converted to the free base by treatment with a base such as sodium hydroxide. After isolation, the free base can be treated with a stolchlometric (one molecule of base + one molecule of phosphoric acid) to produce the dihydrogenphosphate salt. Same operation can be carried out to prepare any pharmaceutically acceptable salt simply by treating the free base with a different acid (e.g. sulphuric acid, maleic acid, and the like). He has further deposed that one skilled in the art could readily read and apprehend the teachings of the suit patent. The methods of synthesis are competently illustrated with accompanying discussions and references. Analytical

properties of intermediates are provided (i.e. ^{1}H-NMR and mass spectra), as well as specific reaction conditions and compound isolation procedures. Seven specific examples are provided, as well as Table 1, which lists 26 additional compounds that were prepared by the methods described in examples 1 – 7. Example 7 in particular illustrates the synthesis of Sitagliptin. Any person skilled in the art could follow the directions in the examples to prepare Sitagliptin.

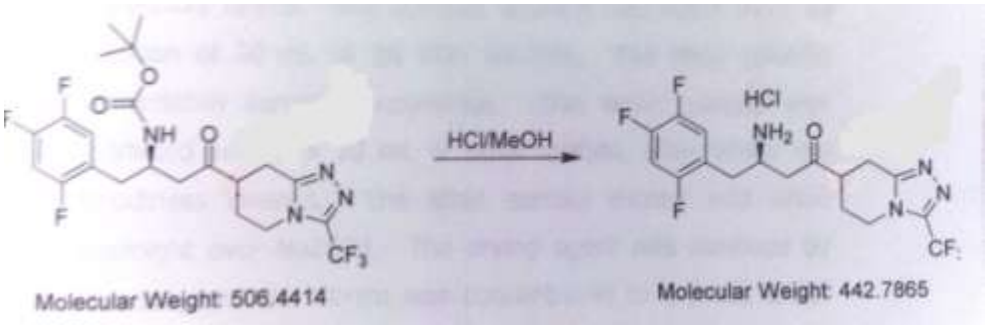
60. He has further deposed that he himself conducted the experiments in his laboratory in order to demonstrate that the teachings of IN 816 (suit patent), including the examples and the general process scheme described therein, provide a person skilled in the art along with his common general knowledge, sufficient information to prepare Sitagliptin Free Base and its pharmaceutically acceptable salts:

> Experiment No. 1: Converting Boc-protected Sitagliptin to Sitagliptin Hydrochloride;
>
> Experiment No. 2: Converting Sitagliptin Hydrochloride to the Free Base;
>
> Experiment No. 3: Converting Sitagliptin Free Base to the dihydrogen phosphate salt; and
>
> Experiment No. 4: Converting Sitagliptin free base to the sulphate salt.

In the experiment 4, above, while crystals of Sitagliptin sulphate were obtained by suction filtration, with mp 187-188 ^{o}C.

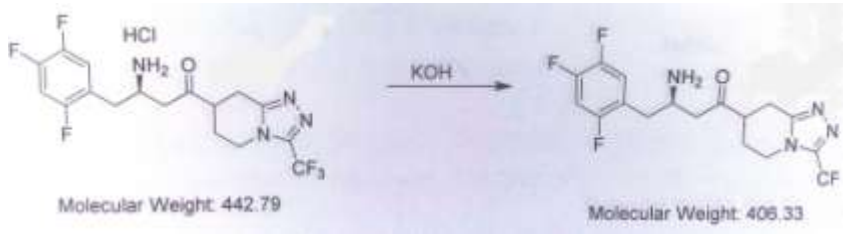
Experiment No. 1: Converting Boc-protected Sitagliptin to Sitagliptin Hydrochloride:

As described in Example 7 of the suit patent 7-[(3R)-3-amino-4-(2,4,5-trifluorophenyl) butanoyl]-3- (trifluoromethyl)-5,6,7,8-tetrahydro-1,2,4-triazolo[4,3-a]pyrazine hydrochloride was prepared from 7-[(3R)-3-[1,1-dimethylethoxycarbonyl) amino]-4(2,4,5-trifluorophenyl)-butanoyl]-3-(trifluoromethyl)-5,6,7,8-tetrahydro-1,2,4-triazolo[4,3-a]pyrazine (obtained from Merck), as shown below:-



A solution of 16: ml of freshly prepared 4N HCI/MeOH was added to a 50 ml round bottom flask containing 1.012 g (2 mmol) of N-Boc-protected Sitagliptin. The Boc-sitagliptin, obtained from Merck, was a light white solid, which dissolved readily in the HCI/MeOH after a few seconds to provide a clear water-white solution. The reaction was stirred at room temperature for 1 hour and was then concentrated under reduced pressure to afford the hydrochloride salt of Sitagliptin as white foam.

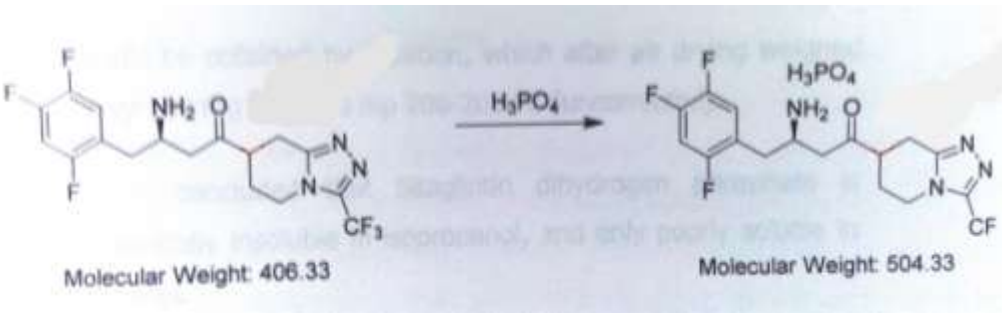
Experiment No. 2 Conversion of Sitagliptin hydrochloride to the free base:-



The crude hydrochloride salt obtained above was dissolved in 40 ml of water and this solution was transferred to a separatory funnel. The aqueous solution was made basic by addition of 20 ml of 2N KOH solution. The clear solution immediately turned cloudy-white. This basic solution was extracted with 3 x 20 ml of ethyl acetate, after which the cloudliness cleared. They ethyl acetate extract was dried overnight over Na2SO4. The drying agent was removed by filtration, and the fitrate was concentrated to dryness under reduced pressure. The free base was obtained in quantitative yield as a thick viscous water-white syrup. After storage overnight in the cold room, the free base solldified to a white, somewhat waxy solid with mp 116-118 ^{o}C.

Experiment No. 3 Conversion of Sitagliptin freebase to the dhydrogen phosphate salt:

In this preparation, we remained mindful of the reagents that might likely be used in a manufacturing process. Thus, we avoided chlorinated or toxic solvents. In particular, although in a research laboratory methanol might be used to prepare an amine salt, it is toxic and it was considered that ethanol and isopropanol would be relatively nontoxic solvents of commerce, and with a higher flash point than methanol.



Ethanol as a solvent

A solution of 203 mg (0.5 mmol) of Sitagliptin freebase prepared aboe in experiment No. 2 was dissolved in 10 ml of abs EtOH, heating with a heat gun to near boiling to ensure all the base was in solution. A solution of 0.34 ml of 1.47 M phosphoric acid in ethanol was then added all at once. On standing at room temperature, very fine white crystals began to form. The solution was allowed to stand at room temperature for 30 min, then placed into the cold room overnight. The next morning the white precipitated salt was collected by vacuum filtration. The particles were very fine and filtering was extremely slow. After air drying, the dihydrogenphosphate salt weighed 215 mg (85% recovery), with mp 208-210 $^{\circ}$ C (uncorrecgted).

Isopropanol as a solvent

A solution of 203 mg (0.5 mmol) of Sitagliptin freebase was dissolved in 10 ml of IPrOH, heating with the heat gun to ensure all the base was in solution. As solution of 0.34 ml of 1.47 M phosphoric acid in ethanol was added all at once. There was an immediate white cloudiness that did not settle. After standing at room temperature for 30 min, this solution was placed in the cold room overnight. The next morning an attempt was made to filter the product. However, it was more like a colloidal suspension and only a small amount of product could be obtained by filtration, which after air drying weighed only 100 mg and had mp 206-208 $^{\circ}$C (uncorrected).

It is concluded that Sitagliptin dihydrogen phosphate is essentially insoluble in isopropanol, and only poorly soluble in ehanol.

Experiment No. 4 Conversion of Sitagliptin freebase to the Sulfate salt:

The sulphate salts of amines are often prepared as "pharmaceutically acceptable" salts. Thus, 203 mg (0.5 mmol) of Sitagliptin freebase was dissolved in 10 ml of abs EtOH by

> warming with the heat gun. A solution of 0.28 ml of 1.8 M sulphuric acid in ethanol was then added. After 30 min, no evidence of crystallization had occurred. The solution was therefore reduced to dryness to afford Sitagliptin sulphate as a fine white powder. They dry powder was dissolved in a minimum amount of boiling absolute ethanol and then allowed to cool. After storage overnight in the cold room, fine white crystals of Sitagliptin sulphate were obtained by suction filtration, with mp 187-188 ^{o} C (uncorrected).

61. He has further deposed that it would be completely obvious to one skilled in the art that the biologically active molecule is Sitagliptin, illustrated earlier as formula I. It is the chemical structure of Sitagliptin that specifically binds to the DPP-IV enzyme and produces inhibition. This fact has been beautifully illustrated in the publication by Kim et al. (2005). He has further deposed that one skilled in the art would readily appreciate that the particular anion that was associated with the molecule in its salt form (e.g. chloride, dihydrogenphosphate) would play no role whatsoever in the biological activity of the molecule once it was within the body.

62. In his cross-examination he has reiterated that Sitagliptin Phosphate Monohydrate is generically disclosed in the suit patent though not specifically. He has reiterated that because the suit patent claims Sitagliptin and all its pharmaceuticals acceptable salts, Sitagliptin Phosphate Monohydrate would be covered by the suit patent. He has further deposed

that novelty of Sitagliptin Phosphate Monohydrate would be that it is deserving of a 'selection' patent. He has further deposed, in his cross-examination, that suit patent indicates that any number of pharmaceutically acceptable salts of Sitagliptin could be prepared and the skilled person would understand how to make those salts. So in his opinion, Sitagliptin Phosphate Monohydrate and any other pharmaceutically acceptable salt are enabled by the patent. He has further deposed that active molecule is Sitagliptin base that has been converted to a dihydrogen phosphate hydrate salt to provide superior formulation, stability and pharmacokinetic properties. He has also reiterated that Sitagliptin molecule itself is the active substance, independent of any particular salt, it should still provide DPP-IV inhibition.

63. In question 91 it was put to PW2 that DPP-IV inhibition of such free base dosage forms in comparison to Sitagliptin Phosphate Monohydrate is different. He responded by saying that degree of DPP-IV inhibition is dependent on the plasma concentration of Sitagliptin. If such a formulation achieved the same plasma concentration as following Sitagliptin Phosphate Monohydrate, then the degree of inhibition would be comparable. One must appreciate that after Sitagliptin or Sitagliptin Phosphate Monohydrate is

administered to a patient it must become soluble and ionized in the lumen of the small intestine. In the lumen of the small intestine all drugs that are amines exist largely in the protonated form, that is, the ionized form as defined by the Henderson Hasselbalch equation. In general only a small percentage of amine containing drugs are unionized in the small intestine. This is critical because only the unionized form of the drug is absorbed into the system. Thus, the nature of the salt associated with the amine is essentially irrelevant because the salt is not absorbed along with the amine. Once the free base of an amine (e.g. Sitagliptin Phosphate Monohydrate) has been absorbed into the system it equilibrates with all the biological anions present in the plasma, which would typically include chloride, bicarbonate, carbonate, phosphate and other salts typically present in the plasma. Importantly, as noted in the affidavit, Sitagliptin binds to the DPP-IV enzyme without any associated anion. In answer to question 95, he has deposed that Sitagliptin Phosphate Monohydrate is a potent inhibitor of DPP-IV because it delivers Sitagliptin to the system. The dihydrogen phosphate salt hydrate does not add to the potency of Sitagliptin, rather, it creates a pharmaceutical composition that has superior properties in creating a dosage form.

64. It was put to him, in his cross-examination, that neither scheme 6 nor example 7 discloses the isolation of the free base of any compound arising from the Markush. He responded by saying that in any text book illustrating the deprotection of a N-BOC group, it would be typical not to show the anion as that is irrelevant to the actual chemical transformation. To suggest that the skilled person would not recognize that the N-BOC deprotection would lead to the ability to obtain a free base, would rob a skilled person of one of the most fundamental chemical transformations in organic chemistry. It was also put to him that isolation both in scheme 6 and in example 7 is of the salt, inasmuch as, the H-NMR at the end of example 7 relates to the hydrochloride salt. He responded by saying that in scheme 6, there is no indication that structure "1" is a salt. With respect to example 7, it may be correct that proton NMR is of the salt. He volunteered by saying that anyone with basic skill in the art would know how to carry out readily, inasmuch as, he himself converted the hydrochloride of Sitagliptin to the free base. It was further put to him that in scheme 6 due to the reaction with TFA, formula 1 encircled at portion M would be in a salt form. He responded by saying that reaction named above the arrow converting 13 to 1 indicates "deprotection". One skilled in the art would

expect during the work up of this reaction that some base could be added to neutralize the TFA salt. Nevertheless, it would be common in discussing the tBOC deprotection to omit presentation of the anion. In answer to question 138 he reiterated that the compounds illustrated in claim 15 are all shown as free bases. So, if they were isolated as the hydrochloride salts, they are all presented in the claims as free bases.

65. In answer to question 155 he deposed that if he gave one of his students any salt of any of the compounds exemplified in the suit patent and instructed them to convert it to the free base, they could do so without any further instructions. If he then gave them a list of the 8 most preferred acids and instructed them to use the free base to prepare salts with each of the acids they could do so without further instructions. This overall chemistry is very fundamental in organic chemistry and is taught in all sophomore organic chemistry classes in the United States. As regards non-disclosure of XRD, NMR, DSC curve, etc. is concerned, in answer to question 85 he has deposed that these refer to solid state analysis that would be appropriate for characterizing a specific polymorphic form of Sitagliptin Phosphate Monohydrate. Further that such methods would be necessary to claim a

specific polymorphic form of the drug. There is no reason not to accept this explanation of the PW2.

66. In question 162 it was put to him that free base of Sitagliptin is not specifically exemplified in the suit patent. He respondent by saying "suit patent clearly identifies the Markush structure as well as Sitagliptin free base in claim 19, as well as of the pharmaceutically acceptable salts. I do not understand the basis for your assertion that the free base is not claimed. If you intend to mean that no process is disclosed for actually isolating and characterizing the free base of Sitagliptin within the suit patent, that may be true. A skilled person would recognize that the active molecule is Sitagliptin, per se, and not a specific salt." PW2 has further deposed that it is the Sitagliptin molecule itself that binds to and inhibits the DPP-IV enzyme. It was put to PW2 in question no. 175 that inhibition by Sitagliptin is after conversion of Sitagliptin Phosphate Monohydrate to the free base within the intestine by a natural process in the human body, though the administered product contains only Sitagliptin Phosphate Monohydrate. He responded that question was not technically correct. He explained that when Sitagliptin Phosphate Monohydrate is taken into the stomach, due to the high concentration of Hydrochloride within the gastric fluid it will exist

primarily as a Hydrochloride salt. When it passes into the lumen of the small intestine where the pH is higher, an equilibrium will be established between Sitagliptin free base and an ionised form of Sitagliptin, based on the content of anions in the small intestine. The percentage of Sitagliptin free base present in the small intestine can be estimated to be on the order of about 1%. This small fraction of Sitagliptin free base is what is actually absorbed across the intestinal wall into the systemic circulation. Once in the blood, an equilibrium is re-established between Sitagliptin free base and protonated Sitagliptin. This protonated Sitagliptin will be associated with a variety of anions that will include chloride, phosphate, bi-carbonate and carbonate. The protonated or ionised form of Sitagliptin is the form that actually binds to and inhibits the enzyme. That much is evident from the publication of Kim et. Al., 2005, where the X-ray crystal structure of Sitagliptin is illustrated binding to DPP-IV. The amino group of Sitagliptin is coordinated with two glutamate anions and a tyrosine residue within the enzyme active site. He went on saying, in answer to question 176, that equilibration between Sitagliptin free base and various protonated forms of Sitagliptin occur within the human body by natural processes.

67. PW4 Dr. Ann E. Weber also reiterated, in her cross-examination, that phosphate salt and hydrate are generally disclosed in the suit patent. They are novel and specifically disclosed in the EP 263 patent. It was put to her in question 39 that process for isolation of the Sitagliptin free base as disclosed in the Sitagliptin Phosphate Monohydrate patent was also not known to her on the date of filing of the suit patent. She responded by saying that the process of isolation of the Sitagliptin free base would be well known to any chemist. In question 72 it was put to her that 33 examples as mentioned in the suit patent were of hydrochloride salt. She responded that examples 1 to 7 describe hydrochloride salts of compounds 1 to 7 including Sitagliptin and compounds 8 to 33 describe free base compounds as shown in table 1. In response to question 77 she reiterated that conversion of a hydrochloride salt to a free base or another pharmaceutically acceptable salt is a process well known to sophomore level organic chemistry students. In response to question 102 she stated that to one skilled in the art of medicinal chemistry the suit patent clearly points to Sitagliptin as it is the sole compound claimed in claim 19.

68. As against this, DW2 Dr. Ashwini Nangia, technical expert of defendant has deposed that no details or descriptions in respect of

preparation of a phosphate salt of Sitagliptin along with its different hydrates are provided anywhere in the suit patent. The same have been provided in the abandoned patent. He further stated that on the basis of reports provided by the defendant regarding testing qua the polymorphic forms of the Active Pharmaceutical Ingredient, ZITA and ZITA-MET contain nothing but Sitagliptin Phosphate Monohydrate which is the subject matter of the abandoned patent. Claim 19 of the suit patent discloses only Sitagliptin Hydrochloride and its process of preparation. All the 7 examples specifically teach preparation of Hydrochloride salts only. The end-product in Scheme 6 is a salt and not a free base. There are no details or guidance in the suit patent which will motivate and educate a person skilled in the art about i) Sitagliptin Free Base, its preparation and its use as a potent DPP-IV inhibitor for treatment of type II diabetes mellitus; and ii) about Sitagliptan Phosphate Monohydrate, its preparation and its use as a potent DPP-IV inhibitor for treatment of type II diabetes mellitus – out of the billions of compounds. However, stand taken by him is contrary to the stand taken in Ex. DW2/P1, which is a patent application filed by Laurus Labs Private Limited in respect of Sitagliptin Pterostilbene Phosphate Salt of which DW2 is one of the inventors. It has been stated therein as under :-

I. (Pg-3 of application) "Ü.S. Patent No. 6,699,871 ("the '871' patent") discloses a class of beta-amino-tertahydrotriazolo [4,3-a] pyrazines such as Sitagliptin and its hydrochloride salt form, a potent inhibitor of DPP-IV enzyme. Other pharmaceutically acceptable salts of this compound are generically encompassed within the scope of the '817 patent. It also discloses a process for the preparation of Sitagliptin and related compounds".

II. (Pg-8 of application) "The Sitagliptin free base, used in the present invention, can be prepared by any known method for example Sitagliptin free base may be synthesized as disclosed in U.S. Patent No. 6,699,871".

69. Similar is the stand taken by Glenmark Generics Limited, Mumbai a sister concern of the defendant. Glenmark Generics Limited, Mumbai had filed U.S. Patent (Ex. P-6) in respect of R-sitagliptin and its pharmaceutically acceptable salts wherein in column 2 it has been stated as under :-

I. "Sitagliptin phosphate is an orally administered dipeptidyl peptidase-4 (DPP-4) inhibitor. Sitagliptin has been developed for the treatment of Type -2- diabetes and is available in the market under the brand name JANUVIA as tablets in the dosage strengths of 25, 50 or 100 mg equivalent base".

II. AND "U.S. Patent No. 6,699,871 describes various DPP-4 inhibitors including sitagliptin and their pharmaceutically acceptable salts, a pharmaceutical composition and method of treatment and a process for the preparation of sitagliptin hydrochloride".

70. The stand taken by DW2 in his affidavit is in conflict with what has been stated in Ex. DW2/P-1 of which DW2 is one of the inventor. That apart, I find that DW2 has taken shifting stand. He has not been able to specify as regards to what happens in the human body when Sitagliptin Phosphate Monohydrate is consumed. He asserts that he was only aware that Sitagliptin Phosphate Monohydrate is Sitagliptin-H+ Phosphate (-) H2O. He further stated that what happens to Sitagliptin Phosphate Monohydrate after it is consumed in the human body is a series of biological processes and transformation which are governed by the natural processes in the human body. It was put to him that when the positively charged Sitagliptin passes into the small intestine it is only the free base which is absorbed across the wall of the small intestine, it then passes into the blood stream and reaches the site of action as a protonated form without the phosphate anion. He responded by saying that once Sitagliptin Phosphate Monohydrate enters the stomach and is sprayed by gastric juices, it belongs to the patient. It is neither JANUVIA nor ZITA. He stated that "I really don't know, and I mean really, what happens as it continues its journey in the patient's stomach and beyond." At the same time, in answer to question 104 he has deposed that Sitagliptin in Sitagliptin Phosphate Monohydrate

will exist in the salt form as Sitagliptin-H+ and the anion will be phosphate(-) along with a molecule of water. According to him, tablet of Sitagliptin Phosphate Monohydrate will not contain Sitagliptin Free Base but in ionized and protonated form as Sitagliptin-H+. A question was put to him that amount of Sitagliptin Free Base in one tablet of 128.5 mg will be 100 mg. He answered this by saying that calculation is correct for Sitagliptin Free Base but Sitagliptin will be present in the ionized and protonated form as Sitagliptin H+ in Sitagliptin Phosphate Monohydrate. Strangely enough, on the one hand he has claimed that suit patent was obvious from the prior arts, as disclosed in four other patents, but at the same time has claimed that Sitagliptin Free Base or its phosphate salt will not be obvious to a person of ordinary skilled in art. He is one of the co-inventor in the patent of Laurus Labs in respect of Sitagliptin Pterostilbene Phosphate Salt, but in his deposition, he claimed that he had not worked in any drug discovery himself. He also avoided to answer as to whether Sitagliptin was actually the DPP-IV inhibitor. It is also evident that Prof. Nangia has personal interest in Sitagliptin, being one of the inventors of Ex. DW2/P1, inasmuch as, he has given evasive replies to the questions which were inconvenient to

the defendant. Accordingly, I find PW2 to be more trustworthy and reliable witness in the chemical, biological and medicinal field.

71. PW1-Shri K.G. Ananthakrishnan has deposed that defendant's products ZITA and ZITA-MET (Ex. P1 to P4) contain Sitagliptin Phosphate Monohydrate and combination of Sitagliptin Phosphate Monohydrate plus Metformin Hydrochloride respectively and are used for the treatment of type II diabetes. A perusal of record shows that Ex. P1 and Ex. P3 are packagings of ZITA 100 mg and ZITA-MET 50 mg/500 mg; whereas Ex. P2 and Ex. P4 are product inserts of ZITA 100 mg and ZITA-MET. Packaging and product inserts of the defendant clearly mentions that ZITA 100 mg is Sitagliptin Phosphate Monohydrate Tablets and ZITA-MET is combination of Sitagliptin Phosphate Monohydrate plus Metformin Hydrochloride tablets. Packagings and product inserts of JANUVIA/ISTAVEL 100 mg. JANUMET/ISTAMET have also been proved on record as Ex. PW1/6 to PW1/9 and PW5/4 to PW5/7. JANUVIA 100 mg and ISTAVEL 100 mg are Sitagliptin Phosphate tablets; whereas JANUMET 50/500 mg and ISTAMET 50/500 mg are combination of Sitagliptin Phosphate Monohydrate plus Metformin Hydrochloride tablets. A perusal of the product inserts clearly shows that product inserts of ZITA

and ZITA-MET are replica of product inserts of plaintiffs' products with minor and insignificant variations, inasmuch as, molecule structure of both the products, as reflected in the product inserts are similar.

72. Learned senior counsel has contended that in a patent infringement suit, infringement cannot be established by mere comparison of labels and molecule structures etc. Reliance has been placed on **F Hoffman La Roche Vs. Cipla Limited (2012(52) PTC 1(DEL)) and 263** wherein it has been held thus : "It must be remembered that the present claim of the plaintiffs is premised on the right of the plaintiffs in the patent of a chemical compound, therefore the infringement of the same has to be established by corresponding chemical analysis of the defendant's product and not by mere comparison of the labels, strips or what is written thereon to show that there is an infringement". I find the said judgment to be in the context of different facts, inasmuch as, in this case plaintiff has not sought to establish infringement of the suit patent only on the basis of these packaging and product inserts but by other ocular as well as documentary evidence on record. In my view, defendant cannot conveniently disown what has been written on the packagings and the product inserts, which is a disclosure to the public at large including the doctors and consumers of the drug about the

contents used and utility of the drug. In case a manufacturer is permitted to disown the declarations made in the packaging and the product insert it will have disastrous consequences. Be that as it may, it emerges from the comparison of the product inserts of the plaintiffs' product and that of defendant that they are same and contain same compound, that is, Sitagliptin Phosphate Monohydrate, inasmuch as, the drug is DPP-IV inhibitor and used for treatment of type II diabetes.

73. Defendant has claimed that process used by it is different than the process used by the plaintiffs for manufacturing Sitagliptin Phosphate Monohydrate as contained in ZITA and ZITA-MET. First of all, no such process has been disclosed in the written statement and counter claim, inasmuch as, no employee of the defendant has stepped in the witness box to prove such process. Certain documents were introduced in evidence through DW2, which cannot be taken as duly proved, as he is neither the author of said documents nor had an occasion to verify the said process having not monitored the manufacturing at any stage or having involved himself in such manufacturing process. DW2 has not even personally analyzed the products of the defendant so as to verify the said processes. I do not find any force in the contention of defendant that plaintiffs ought to have proved that

defendant had been deploying same process, as was being practiced by the plaintiffs. Defendant has taken this plea in the written Statement and should have proved the same, more so when products of the plaintiffs and defendant contain same chemical compounds.

74. Use of Sitaglpitin in ZITA and ZITA-MET, by itself, amounts to infringement of suit patent within the meaning of section 48 of the Act. In Novartis AG & Ors. Vs. Union of India & Ors. 2013 (54) PTC 1 (SC), it has been held that "in whatever way therapeutic efficacy may be interpreted, this much is absolutely clear; that the physic-chemical properties of beta crystalline form of Imatinib Mesylate, namely (i) more beneficial flow properties (ii) better thermodynamic stability and (iii) lower hygroscopicity, may be otherwise beneficial but these properties cannot even be taken into account for the purpose of the test of section 3(d) of the Act, since these properties have nothing to do with therapeutic efficacy". PW3 John Todaro has deposed that Merck decided to abandon the sitagliptin salt patent because they did not have data to support enhanced efficacy, as required by section 3(d) of the Act and in view of the existing patent protection for sitagliptin and its pharmaceutically acceptable salts afforded by Indian Patent No. 209816 (suit patent). He has further deposed that as per the first

examination report issued by the Indian Patent Office on January, 15, 2009, claims were objected to under section 3(d). In addition, the claims were found to be anticipated by WO2003/004498, the international application (equivalent to Indian Patent No. 209816) covering the sitagliptin compound. The claims were also said to lack inventive step in view of a) WO 2003/004498 b) Edmondson, S.D. PROUS Science. Drug Data Report, vol. 25, No. 3, 2003, pp. 24-246 and c) Database PROUSDR (online) 2003. XPOO2295584.

75. Judgments Feed Service Corporation and Novartis Pharmaceuticals Corporation (supra) are in the context of different facts and are of no help to the defendant. In the said cases, infringing products were found to be forming inside the body by natural process. In the present case, Sitagliptin is not formed by natural process but, in facts, is administered in the human body. It has come on record that Sitagliptin forms the major portion of Sitagliptin Phosphate Monohydrate. In fact, 100mg Sitagliptin freebase is present in a 128.5 mg Sitagliptin Phosphate Monohydrate tablet. Dosage of Sitagliptin as prescribed are 100mg, 50mg and 25 mg, as the case may be, for inhibition of DPP IV, for treating type II diabetes. Thus, use of

Sitagliptin Free base alone in Sitagliptin Phosphate Monohydrate tablet by the defendant itself amounts to infringement of the suit patent.

76. From the above discussions, I am of the view that plaintiffs have succeeded in proving that suit patent discloses Sitagliptin Phosphate Monohydrate generically. Sitagliptin Free Base is also disclosed. It is the Sitagliptin Free Base which is the DPP-IV inhibitor and phosphate salt is used for delivery of Sitagliptin in the body. Sitagliptin Phosphate Monohydrate has enhanced properties in the sense that it has improved chemical and physical characteristics, but the active moiety is Sitagliptin. Therapeutic efficacy is not enhanced by Sitagliptin Phosphate Monohydrate since it is the Sitagliptin itself which is the active moiety and is effective for inhibiting DPP-IV enzyme and is useful for treatment of type II diabetes. Sitagliptin is not produced in the human body by a natural process but, in fact, Sitagliptin is delivered in the human body which is the bulk compound in the Sitagliptin Phosphate Monohydrate. All the literature placed on record including the Indian Pharmacopoeia (Ex. DW1/P-21), indicates Sitagliptin is a DPP-IV inhibitor.

77. All the above issues are decided accordingly in terms of the findings returned herein above.

Issue Nos. 8 and 10

78. Defendant has claimed revocation of the suit patent on the following grounds :-

a) Subject matter of the patent is obvious in nature and does not involve any inventive step having regard to what was publicly known or used or published in India or elsewhere – **Section 64(1)(f)**;

b) The invention as claimed in any claim of the complete specification is not useful – **Section 64(1)(g)**;

c) The complete specification of the patent does not sufficiently and fairly describe the invention and the method by which it is to be performed, that is to say, that the description of the method or the instructions for the working of the invention as contained in the complete specification are not by themselves sufficient to enable a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention, or that it does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection -**Section 64 (1)(h);**

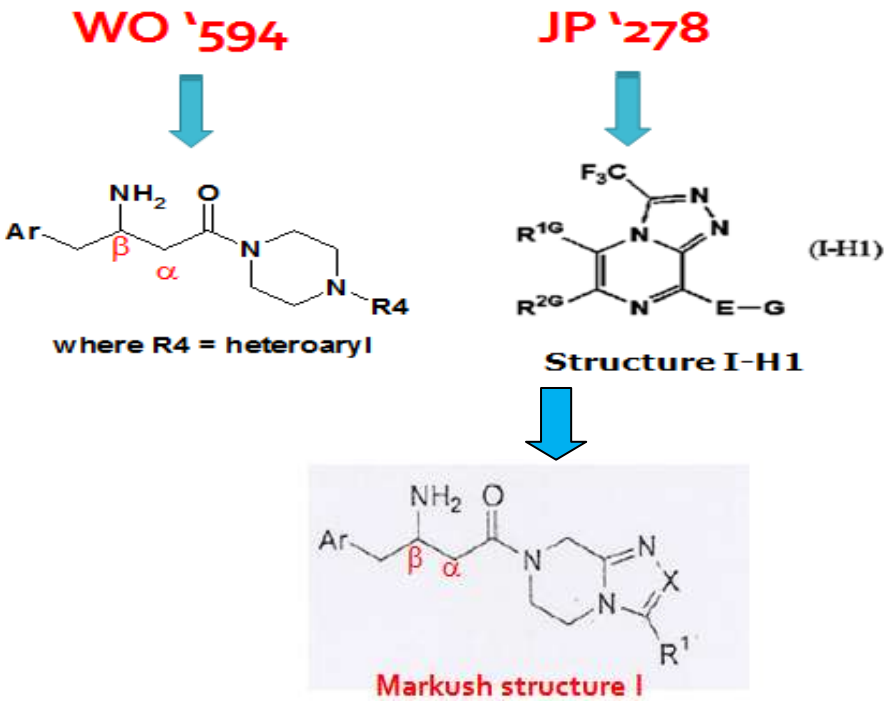
d) Any claim of the complete specification is not fairly based on the matter disclosed in the specification - **Section 64(1)(i)**;

e) The patent was obtained on a false suggestion or representation – **Section 64(1)(j)**;

f) Applicant failed to comply with Section 8 –**Section 64(1)(m)**;

79. As regards ground (a) is concerned, it is contended that suit patent is obvious to a person skilled in the art, in the light of various prior art documents, that is, (a) WO 01/34594 (b) JP 2000/319278 and (c) US 5,939,560 (d) EP 1406622.

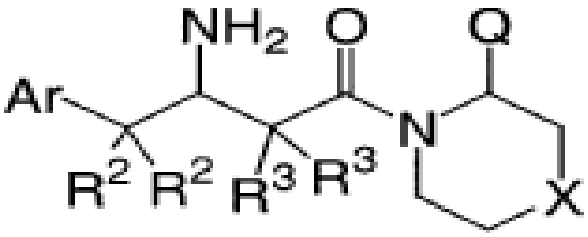
80. As per the defendant, on the basis of the teachings of WO 01/34594 read in the background of JP 2000/319278 – it would be obvious to a person skilled in the art to develop compounds that can be used for treatment of diabetes having the following structure:



81. It is further contended that claim 1 of US 5,939,560 further discloses that various substitutions can be made at different positions (n, m, X, A, Y

and R) of the Markush structure to develop compounds that would be useful in the treatment of diabetes. When the following substitutions are made i.e. n is 2, m is 1, X is NH, A is beta amino acyl group, Y is N and R is H, *inter alia* the following compound is obtained:

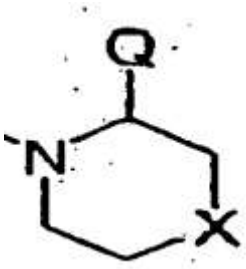
82. Thus, it is contended that the concept of Beta-amino derivatives as DPP-IV inhibitors was known before the priority date, that is, 6th July, 2001 of the suit patent. Thus, it would have been obvious to a person skilled in the art to reach the suit patent by working in the same field. It is further contended that PW2 Dr. Nichols in question to 177, 181-184 has admitted that US 5,939,560 relates to DPP-IV inhibitors and generally covers Beta amino acyl groups as DPP-IV inhibitors. He has further stated that Markush structure will embody a piperazine ring. It is further case of the defendant that EP 1406622 relates to a novel class of DPP-IV inhibitors. It includes pharmaceutically acceptable salts and pro-drugs, which are useful as therapeutic compounds, particularly in the treatment of type-2 diabetes. It is stated that EP 1406622 discloses the following structure:



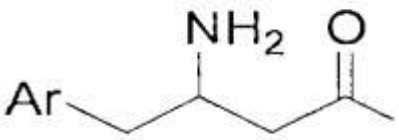
I

When the following substitutions are made such as Ar can be selected from the group consisting of:

I. phenyl;
II. napthyl;
III. thienyl; and
IV. bezothiophenyl



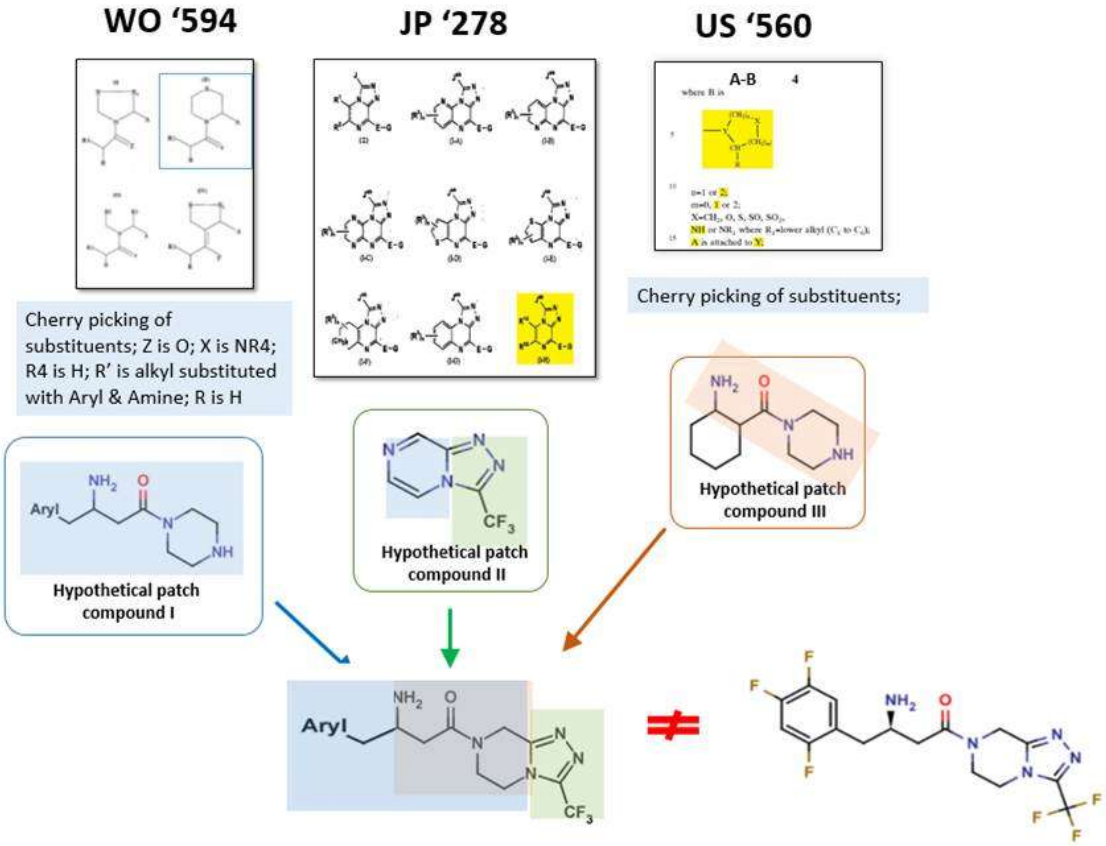
and X is selected from the group consisting of CH_2, O, and NR^7, and



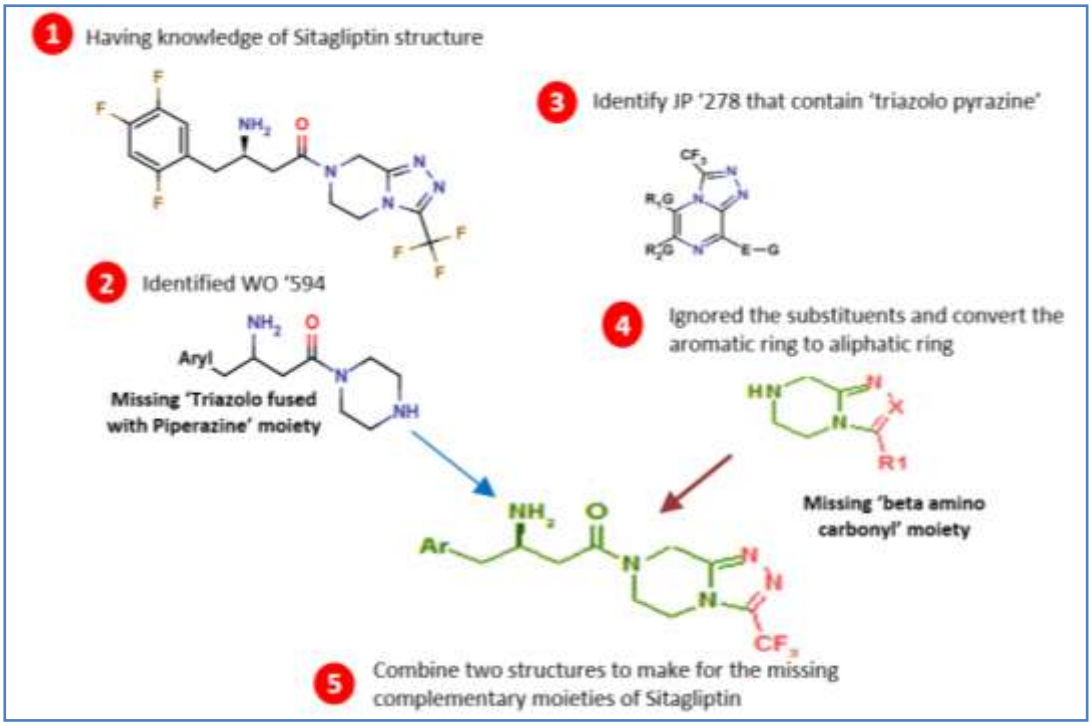
83. It is, thus, contended that similar structure would be obtained and it would be obvious to a person skilled in the art to develop DPP-IV inhibitor as claimed in the suit patent. DW2 Prof. Nangia analyzed the aforesaid

document in his affidavit and concluded in para 22 that based on the aforesaid prior art documents, there is sufficient disclosure available and known to a person skilled in the art before the priority date of the suit patent to work with beta-amino acyl derivatives that contain fused hetrocyclic ring for developing DPP-IV inhibitors. It is contended that Prof. Nangia has not been cross-examined on this point, thus, his statement to the above effect is deemed admitted.

84. Learned counsel for the plaintiff has contended that EP 1406622 is not a prior art as it was published on 3rd January 2003, that is, after the priority date of the suit patent. In the counter claim, a comparison of the structures of the Markush claim of the suit patent was carried out with respect to EP 1406622 only. No material facts have been pleaded in the counterclaim in relation to the relevance of WO 01/34594 in respect of obviousness analyses. In the replication, EP 140662 was dropped by the defendant and DW2 has led no evidence in relation thereto. The approach adopted by the defendant in relation to obviousness with respect to the three irrelevant prior art documents can be depicted as follows:



85. It is further contended that defendant has used Sitagliptin molecule as the blue prints to identify the prior art documents. Firstly, the Defendant has identified WO '594 document and arrived at the hypothetical patch compound I. Further having realized the missing parts in the hypothetical patch compound, the Defendant went hop-scotchsearching for documents to fill in the missing gaps as follows:-



86. In the hypothetical compound patch I created from WO '594, defendant admits that "triazolo is missing" which is present in the Markush structure of the suit patent and Sitagliptin that has a triazolo pyrazine core-structure; to fill this gap, defendant jumps to JP 2000/319278 without any logic, reasoning or by leading evidence and selected the formula 1-H1 from the nine disclosed Markush structures. Even after selecting formula 1-H1, defendant has ignored the other substituent's on the triazolo pyrazine ring and retained (CF3). Defendant further modified the aromatic ring to the aliphatic ring. Thus, defendant has failed to provide any reasoning as to why would POSA would arrive at hypothetical patch compound II and then

modify the hypothetical patch I using JP 2000/319278. Defendant then drops the pyrazine ring from Patch I compound and joins the unsaturated triazolopyrazine structure from Hypothetical patch II compound to arrive at the hypothetical suit patent compounds. Even this resulted hypothetical compound after fusion/ mosaicing is not the same as Markush structure of suit patent and Sitagliptin as the nature and position of the substituents is not contemplated.

87. Further contention is that credibility of DW2 on the issue of obviousness is suspicious, inasmuch as, in response to question no. 79 DW2 admitted that JP 2000/319278 does not relate to DPP-IV inhibitors. In response to question 74-78, DW2 admitted that the word 'diabetes', as stated in JP 2000/319278, was not emboldened in the Japanese version but was emboldened in its English translation by the defendant. In response to question nos. 86-96, he has stated that he was unaware of books known to POSA in the area of medicinal chemistry. In answer to question nos. 72-73, he has admitted that the prior art search conducted by him and Glenmark was based on hindsight by admitting to the fact that the background of his search object were the documents provided in para 4 of his affidavit which includes the suit patent. The suit patent governs the field of medicinal

chemistry and pharmacology. DW2 is neither a medicinal chemist nor has any experience in the drug discovery and development process which in fact has been admitted by him in answer to question nos. 5 and 7.

88. Learned counsel for the plaintiff has further contended that their independent expert PW2, based on the written statement and counter claim as also replication of the defendant in in para 76 to 115 of the affidavit by way of evidence, has extensively deposed on the three prior art documents, namely, JP 2000/319278, WO 01/34594 and US 5,939,560. PW2 has also deposed on EP 1406622 though it was not a prior art. In answer to question 182-186, PW2 has categorically deposed that a number of different types of compounds are covered by US 5,939,560 some of which are beta amino acids and some are alpha amino acid. The concept of inhibitor design provided by US 5,939,560 is different from that of Sitagliptin and the compound of the suit patent, while the compound of US 5,939,560 are dimeric bind to two different active sites of DPP IV, the compound of the suit patent including Sitagliptin binds only one active site of DPP IV. Further that the compounds of US 5,939,560 bear no structural similarity to Sitagliptin and are the compound covered by the suit patent. With regard to WO 01/34594, PW2 in answer to question 187-192 has deposed that there

are a number of different structures covered by WO 01/34594 with nothing to motivate the skilled person to arrive at the compound of the suit patent including Sitagliptin. PW2 categorically deposed that compound encompassed by structure II of WO 01/34594 would lead to so many possibilities that the moiety from WO 01/34594 which the defendant is envisioning reasonably occur if one first knew the structure of Sitagliptin and was through hindsight attempted to reproduce an element within structure of Sitagliptin. As regards JP 2000/319278 PW2, in answer to question 193-196, he has deposed that JP 2000/319278 is notable for its lack of focus on DPP IV inhibitor and focuses on effects on adhesion molecule, therefore, one skilled in the art searching for prior art examples relating to DPP IV inhibitor would never have come upon this document. Document was selected by the defendant only because it embodies a triazolopyrazine; meaning thereby it was a result of a hindsight analysis. Further, that even if a person skilled in the art search for 5:6 fused heterocyclic ring systems containing 4 nitrogen atoms, there are many such ring systems known. The fact that this specific ring system was brought up in the absence to any analogous reference to DPP IV inhibitor is one of the clearest examples of hindsight analysis which indicates that the document

was selected based on the structure of Sitagliptin. PW2 has concluded that there is no teaching in JP 2000/319278 that claimed compound would be useful to treat diabetes mellitus.

89. In Grain Processing vs. American Maize,840 F.2d 902, it is held that "care must be taken to avoid hindsight reconstruction by using the patent in suit as a guide through the MAZE of prior art references in the right way so as to achieve the result of the claims in suit". In Pfizer Inc. v. Teva Pharmaceuticals, (Federal Circuit 2014), it has been held that "a patent challenger, however, must demonstrate the selection of a lead compound based on its promising useful properties, not a hindsight-driven search for structurally similar compounds".

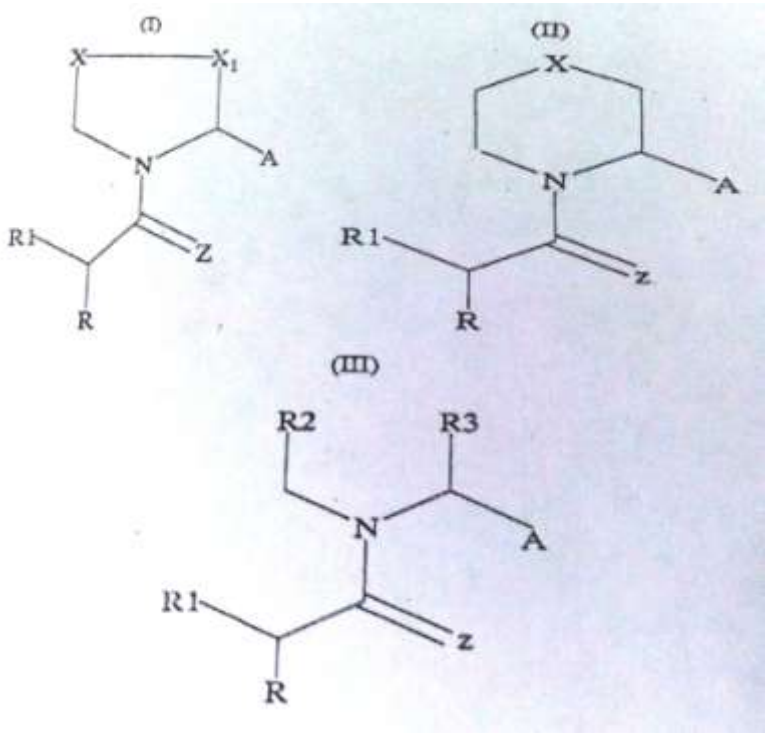
90. PW2, in his affidavit in para 88 to 113, after critically analyzing the prior art documents relied upon by the defendant, has made a categorical statement that suit patent was not obvious. His testimony on this point has remained unshattered in his cross-examination. What PW2 has stated in para 88 to 113 reads as under :-

> "88. The defendant states (page 4) that the "impugned suit patent is obvious in nature & thus lacks inventive step." As well as, "it was obvious to a person skilled in the art to reach the claimed invention in light of the following prior art documents:" Defendant relies on four prior art documents:

WO 01/34594, JP 2000/319278, US 5,939,560, and EP 1406622. I completely disagree with the assertion that any of these documents, taken either individually or in the aggregate, provide any teaching at all that would point to Sitagliptin, or that would contain teachings that the skilled person could use to arrive at Sitagliptin. I will now address the defendant's arguments with respect to these four documents.

WO 01/34594

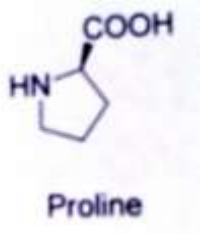
89. WO 01/34594 is titled "Dipeptidyl peptidage IV Inhibitors and methods of making and using dipetidyl peptidase IV inhibitors. It teaches three different Core structures, I, II, and III, as shown below:-



This nonorable court will immediately recognize that none of these structures is Sitagliptin.

90. Under "Detailed Description of Preferred Embodiments", WO 01/34594 states, "Preferably, the DPP IV inhibitors are pyrrolidlne-based compounds, and more preferably constitute or include proline or proline mimetics." Sitagliptin does not

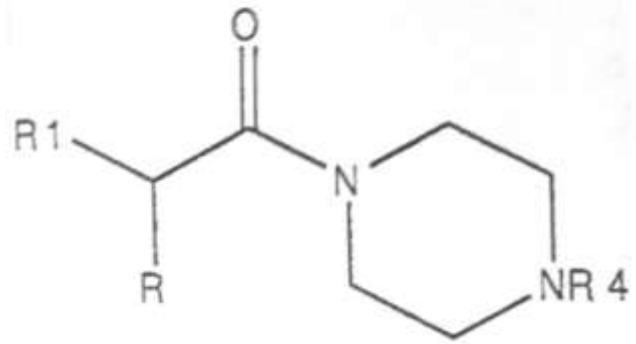
contain either proline or a proline mimetic. As demonstrated by Kim et al. (2005) [Exhibit PW2/7], it is the 2,4,5 trifluoromethylphenyl ring of Sitagliptin that binds to the DPP-IV active site that normally would bind to the proline residue of GLP-1. The structure of proline is shown below:



Proline

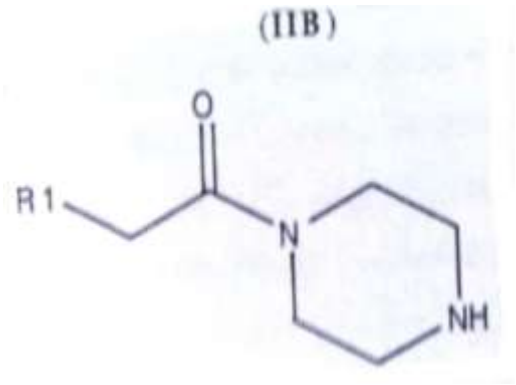
91. Defendant chooses only structure II from among the three claimed Markush structures and, considering the list of all of the possible atoms and groups that are specified in the patent for A,R, R1, X and Z, first creates "structure IIA" shown below. The Defendnt states on page 5 that this structure can be deduced from the disclosure when "When Z is O, A is H, and X is NR4." The defendant provides no explanation as to how the skilled person would know to select these particular moleties to be attached to structure II of the patent in order to arrive at structure IIA when so many possibilities are available from the teaching of the patent.

(IIA)

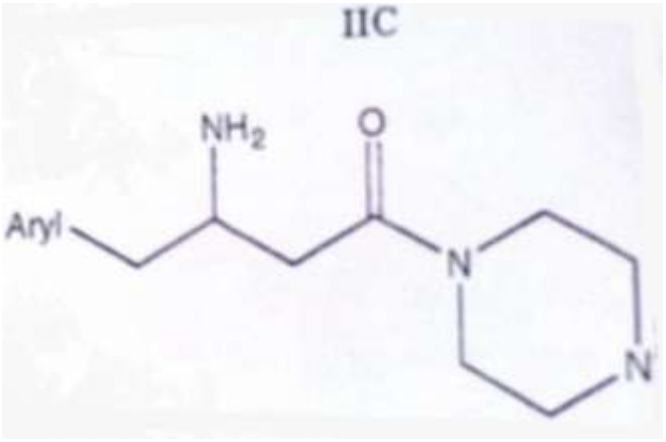


92. Next, the defendant takes structure IIA and transforms it into structure IIB, shown below. Defendnt recites part of the patent specification that R and R1 can be independently selected from a very large group of alkyl groups, wherein any

of the functional groups can be substituted with one or more aryl, or amino groups, and R4 is H. Once again, the defendant provides no motivation or logic for these specific choices. On what basis would the skilled person have made such choices? Obviously, the Defendant has some goal in mind, but at this point such goal would not be apparent to one skilled in the art at the priority date of IN'816.



93. Finally, the defendant chooses an ethyl group for R1 and attaches an aryl and amino group to it to provide structure IIC. Once again, the defendant offers no logic for the choice of these particular substituents from among the many possibilities offered by the teaching of the patent. Now, however, we can see that the defendant is trying to create a molecule that has some similarity to a portion of Sitagliptin. Obviously, moving in this direction with the selections that lead finally to structure IIC can be achieved only if one know the structure of Sitagliptin beforehand, i.e. through hindsight. Essentially, the defendant is saying, "I know the structure of Sitagliptin, so what can I find in the prior art that will allow me to select bits and pleces to create a molecule that resembles Sitagliptin?"



94. Defendant state that "the only different between the compounds claimed in the impugned suit patent and WO 594 is that the claimed compound has one additional functional group which is a pyrazole ring with a trifluoromethyl substitution." The absence of the pyrazole ring, however, is a serious one, and without it the skilled person will never get to Sitagliptin. Defendant also forgets to remind us that the aryl group is a phenyl ring substituted with fluorine atoms at the 2, 4, and 5 positions. The defendant's reasoning is baseless, and no skilled person would have any rational basis to make these choices.

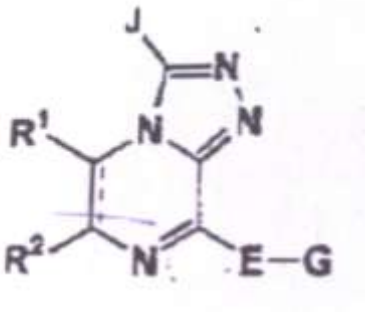
95. To conclude, the defendant states, "Thus, based on WO 594, it would be obvious to a person skilled in the art to develp a DPP-IV inhibitor as claimed in the impugned suit patent for treatment of diabetes." These leaps of faith, and absence of any rationale in going from II to IIA, then to IIB, and then to IIC and concluding that IIC only needs a couple of additional modifications, are completely nonobvious, and I am confident that no person skilled in the art could or would be able made these astonishing leaps as of the priority date of the IN816 patent. It is very cleary evident that such "reasoning" can only be accomplished if one knows beforehand the chemical structure of Sitagliptin.

JP2000/319278

96. JP 2000/319278 is a Japanese patent titled "CONDENSED PYRANZINE COMPUND AND

MEDICINAL AGENT HAVING THE SAME AS ACTIVE INGREDIENT. This patent is directed toward discovery of a new compound "..having inhibitory action against the expression of adhesive molecule, and useful for the therapy and/or prophylactic of various inflammatory diseases, rheumatoid arthritis, allergy, bronchial asthma, atopic dermatitis and the like."

97. At the very outset it must be emphasized that this patent has absolutely no relationship to GPP-IV inhibitors, nor do the inventors make any such claim in the patent specification. Thus, the very first question that must be asked is why one skilled in the art, and searching for novel GP-IV inhibitors as of the priority date, would even have found or considered this publication? The answer of course, is that when using hindsight, the defendant realizes that this patent contains at its core an imidazopyrazine moiety, shown below as (I):

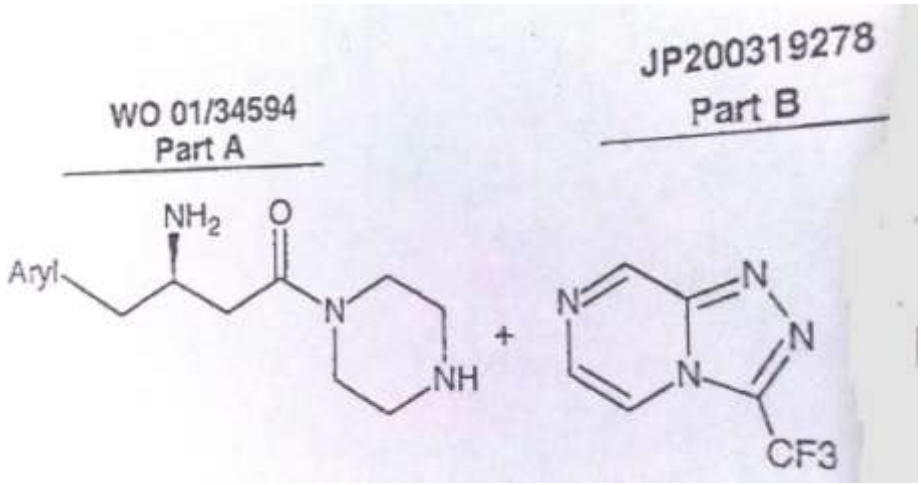


(I)

98. Defendant states on page 7, that "It would have been obvious to a person ordinarily skilled in the art to combine the teaching of WO 01/34594 and JP 2000-319278 to arrive at Sitagliptin as allegedly claimed in the impugned patent IN 209816." I completely disagree with this assertion. As I stated in 88 above, JP 2000-319278 has absolutely no relevance to DPP-IV inhibitors, the subject of IN'816. Thus, there would have been no motivation for one skilled in the art to seek out the JP 2000-319278 patent, and no motivation to somehow connect it with WO 01/34594 as two patents claim completely different types of biological activity. The only way that the defendant could possibly have found JP 2000-

319278 is by searching the scientific literature seeking any kind of molecule with an Imldazopyrazine moiety and the only way that culd be done is most clearly through hindsight.

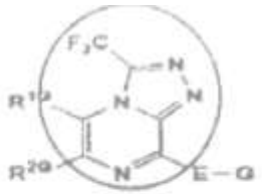
99. The defendant now creates a scheme in an attempt to show how the combination of WO 01/34594 and JP 2000-319278 leads one to envision Sitagliptin. In particular, on page 7 of the replication to counterclaim, defendant presents the following scheme:



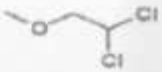
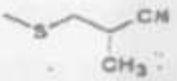
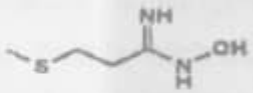
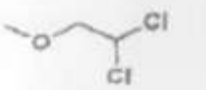
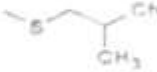
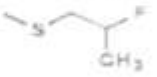
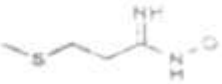
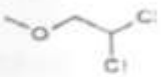
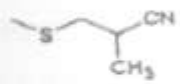
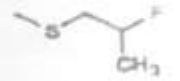
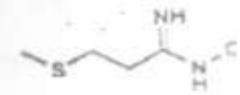
100. As I have discussed above in paragraphs 81 through 87, the defendant's so-called "part A" Sitagliptin was crafted by selectively choosing among the possible substituents listed in WO 01/34594 and placing them on one of the three core structures claimed in that patent, with no evident rationale or explanation. The defendant offers no reasoning to show how or why the skilled person would reach the structure of "Part A", and it is clearly evident that the selection of pleces used to construct "Part A" from among the many possibilities listed in the patent was driven by foreknowledge of the sturctue of Sitagliptin, i.e. hindsight.

101. The defendant has selected "Part B" from JP 2000-319278. But in fact, none of the compounds listed as examples in tables 2 though 32 of that patent bears any resemblance to Sitagliptin. Most of the compounds given as examples in this patent contain three fused heterocyclic rings and not two as are present in Sitagliptin.

102. In those examples where only a bicyclic imidazopyrazine ring system is present in JP 2000-319278, the pyrazine ring is not reduced as is the case in Sitagliptin, and the core structure has substituents attached at completely different locations from Sitagliptin, as for example illustrated in Table 28 from that patent, shown below.



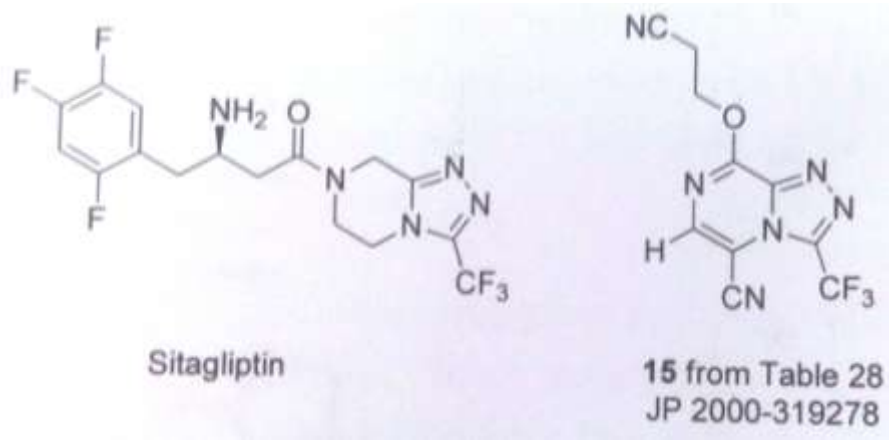
(I-III)

No.	R^{1G}	R^{2G}	-E-G
1	Et	H	
2	Et	H	
3	Et	H	
4	Et	H	
5	Et	H	
6	Et	H	
7	Et	H	
8	OMe	H	
9	OMe	H	
10	OMe	H	
11	OMe	H	
12	OMe	H	
13	OMe	H	
14	OMe	H	
15	CN	H	
16	CN	H	
17	CN	H	
18	CN	H	
19	CN	H	
20	CN	H	
21	CN	H	

103. As can be seen, none of the claimed examples from this patent resemble Sitagliptin to any significant degree. They do

not possess a single reduced fused pyridazine as in Sitagliptin, but rather have a fused pyrazine ring with appended groups at positions completely different from those in Sitagliptin.

104. Although the defendant has shown only the core structure of one of the many possibilities taught in JP 2000-319278, it is instructive to see Sitagliptin compared side-by-side with one of the complete structure from this patent, as below:



105. It is readily evident that the two molecules have very little in common when complete structures are compared. It is worth pointing out here that the biological activity of a molecule and its utility as a medicine is completely dependent on the structure as a whole. That is, each part of the molecule makes some contribution to the overall biological effect. Therefore, the contribution of the bicyclic tetrahydroimidazo[1,2-a] pyrazine ring system in Sitagliptin must play a very different role than does the imidazopyrzine ring system in the compounds of JP 2000-319278 and they cannot be seen to have parallel importance.

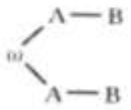
US 5,939,560

106. US 5,939,560 is US patent titled "INHIBIOTRS OF DP-MEDIATED PROCESSES, COMPOSITIONS AND THERAPEUTIC METHODS THEREOF. Markush formulas taught in this patent include several core structure, illustrated below:-

A-B (Groups I and II)

(1)

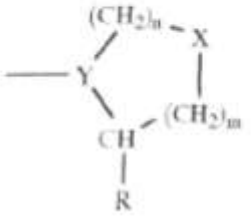
(2)



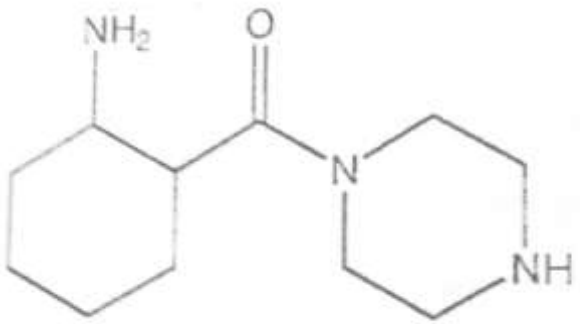
(3)

(Group III)

(4)



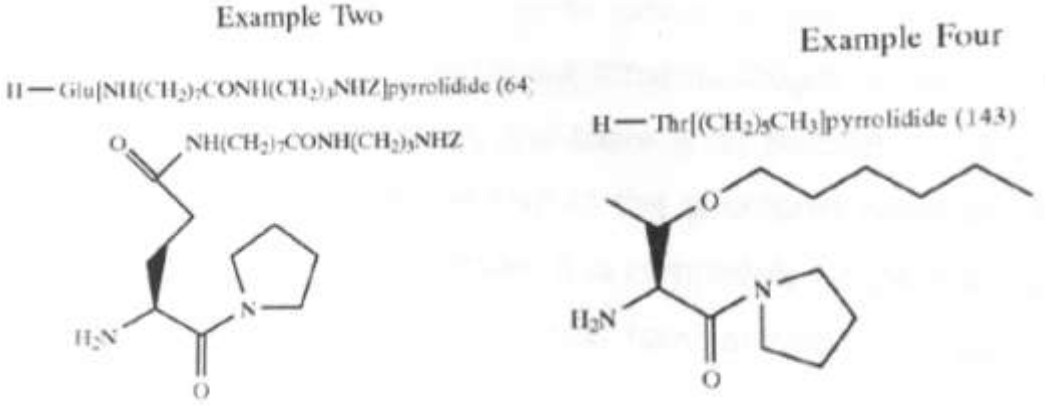
107. At the outset it will be noticed that none of these structures resemble in any way the structure of Sitagliptin. By carefully selecting from among the numerous substituents that are enumerated in the patent specification, however, the defendant arrives at the following structure :



108. Because this structure can be considered to be a beta-amino derivative, and because the impugned suit patent contains the phrase "Beta-Amino" in its title, the defendant therefore asserts that "....It would have been obvious to a

person skilled in the art to reach the impugned suit patent by working in the same filed". I completely disagree. There is no teaching in the US 5,939,560 patent that would lead the skilled person to arrive at Sitagliptin. Certainly, this patent teaches particular substituted beta-amino substituted molecule, but in fact there an infinite number of structures that one could create that contain a beta-amino moiety.

109. There is no example in the US 5,939,560 patent that is even close to the structure of Sitagliptin, and the vast majority of structures and examples taught in this patent have a five-membered pyrrolidine moety and not a piperazine. Examples 2 and 4 are illustrative of the teaching in US 5,939,560.



110. The Defendant takes the proposed analogy no further, apparently believing that the US 5,939,560 disclosure of DPP-IV inhibitors possessing a "beta-amino" function somehow renders the structure of Sitagliptin obvious to one skilled in the art. As I have discussed with respect to each of the defendant's claims regarding prior art documents, such a conclusion is an unwarranted leap of imagination, with no logic or reasoning to arrive there.

111. I have previously addressed Defendant's claim that EP1406622 renders IN'816 obvious, and my arguments are presented in paragraphs 69-78 above as a response to the same assertion in Defendant's Counterclaim.

CONCLUSION

112. In conclusion, none of the "prior art"documents cited by the Defendant, taken separately, or in the aggregate, would provide any motivation to the skilled person to envision Sitaglptin. As I have shown with respect to each prior art document, the defendant has "cherry picked" both core structures and attached substituents so as to arrive at structures that resemble to some extent Sitagliptin. In every case, the number of possible substituents taught in any of the documents that would lead to the structures proposed by the Defendant. In my opinion, it is completely impossible that any person skilled in the art could have arrived at Sitagliptin based on any prior art documents.

113. None of the cited prior art documents lists the exact structural pieces that can be combined or attached to any of the core structures in order to arrive at Sitagliptin and the Defendant admits as much by stating that the fragments they have crafted in their arguments will have to be combined, as illustrated for example in paragraph 91 above. Yet the Defendant never tells us what will motivate the skilled person to carry out this combining of substituents and fragments. In fact, the only obvious motivation could be knowledge of the structure of Sitagliptin beforehand, which clearly derives only from hindsight.

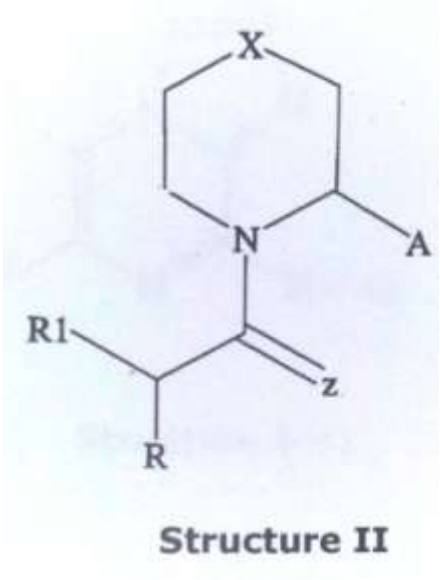
91. The above statement of PW2 has remained unshaken in his cross-examination. He stated that from the teachings prescribed in US 560, the structure claimed bore no structural similarity to Sitagliptin, inasmuch as, component of claimed compound bear no similarity to Sitagliptin. Concept of inhibitor design prosecuted was related to dynamic structure that would bind to two different active salts of DPP-IV, a concept that was not related

to DPP-IV inhibition by Sitagliptin**,** which is a single molecule that would bind only one active salt of DPP-IV. Similarly, in his answer in respect of WO 01/34594, though he admitted that it relates to DPP-IV inhibitor. However, he stated that all of the possibilities embodied in Markush structure II in WO 01/34594 would lead to so many possibilities that structure IIC at para 93 of his affidavit could only reasonably occur if one first know the structure of Sitagliptin, and was, through hindsight, attempting to reproduce an element within the structure of Sitagliptin. As regards JP 200319278, he has stated that it lacked focus on DPP-IV inhibitor. It related to effects on adhesion molecule. He stated that one skilled in the art searching for prior art examples relating to DPP-IV inhibitors would never have come up on this document. This document was selected only because it embodies a triazolopyrazine meaning thereby it resulted from a hindsight analysis.

92. DW2 in his affidavit from para 17 to 22 has deposed on the issue of obviousness as under:

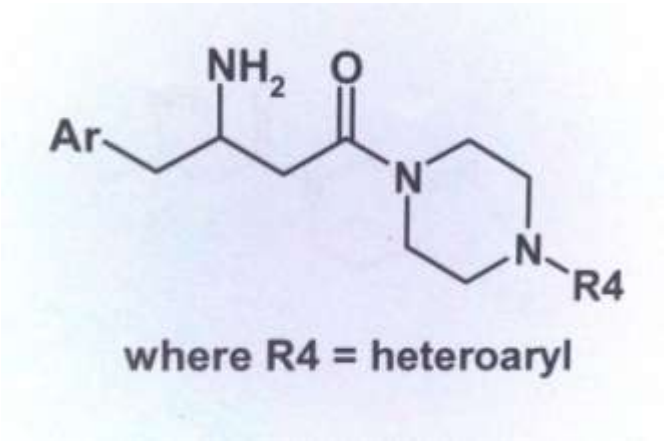
> 17. I will now answer the aforesaid question/issue number. I am aware that for the purposes of gauging obviousness, the knowledge and teachings available in the prior art as of the priority date are to be considered, which in the present case is July 6, 2001. WO 01/34594 (hereinafter referred as "WO 594") titled as DIPEPTIDYL

PEPTIDASE IV INHIBITORS AND METHODS OF MAKING AND USING DIPEPTIDYL PEPTIDASE IV INHIBITORS discloses and teaches inter alia various substituted amino compounds of structure I to IV. Structure II specifically discloses DPP IV inhibitors having the following core structure.



Structure II

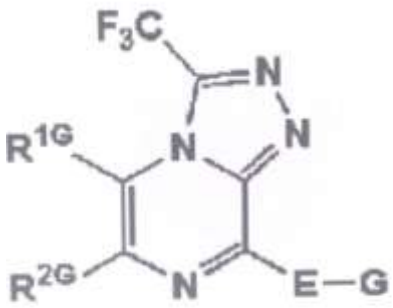
In the aforesaid Markush structure, when X is NR4 (R4 is heteroaryl group), Z is O, A is H, R is H and R is C_1 to C_9 straight chain alky substituted with one or more functional group including aryl and amino (NH_2), then compounds that have the following general structure are obtained.



where R4 = heteroaryl

18. Further, JP 2000/319278 (hereinafter referred as "JP 278") titled as CONDENSED PYRAZINE COMPUNDS AND

MEDICINAL AGENT HAVING THE SAME AS ACTIVE INGREDIENT discloses and teached certain compounds that are also capable of having effect against diabetes mellitus. JP '278 discloses the following as structure I-H1.

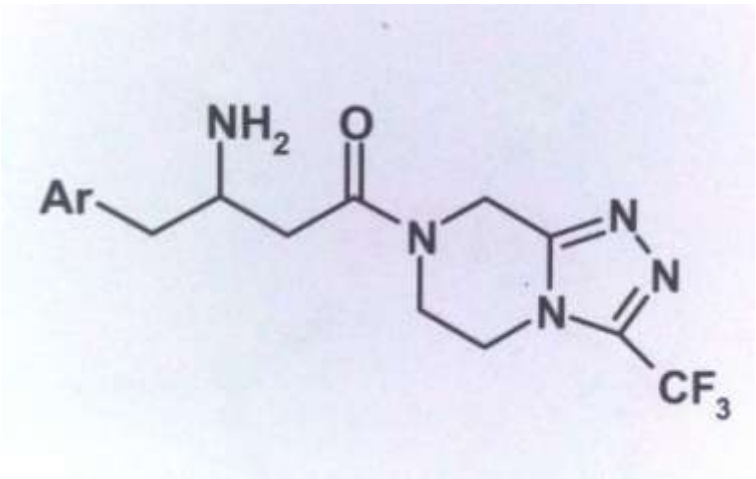


(I-H1)

Structure I-H1

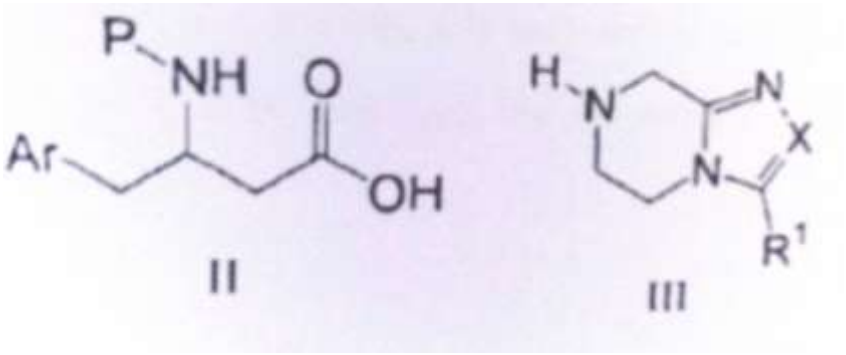
Thus, JP '278 disclosed and taught use of fused heterocyclic ring structure compounds for treatment of diabetes.

19. As a result, on the basis of the teachings of WO' 594 read in the background of jp ' 278, it would be obvious to a person skilled in the art to develop compounds that can be used for treatment of diabetes having the following structure.

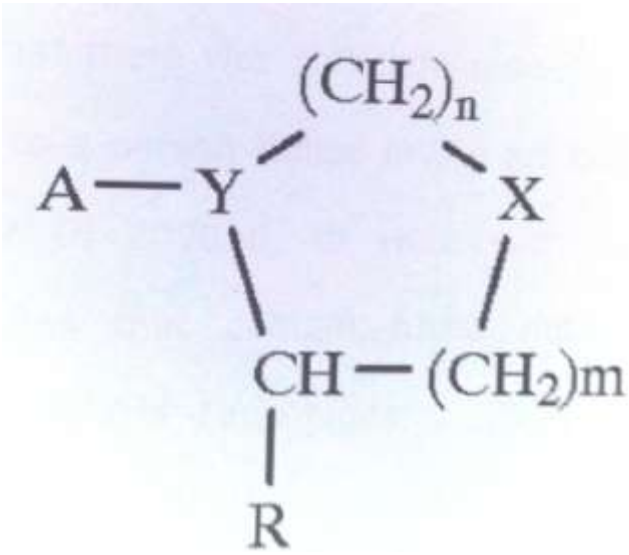


The above structure is the same as the markush structure disclosed in claim 1 of In 209816 i.e. beta-amino acyl derivatives which act as DPP-IV inhibitors. In fact, in the suit patent itself, the inventors have

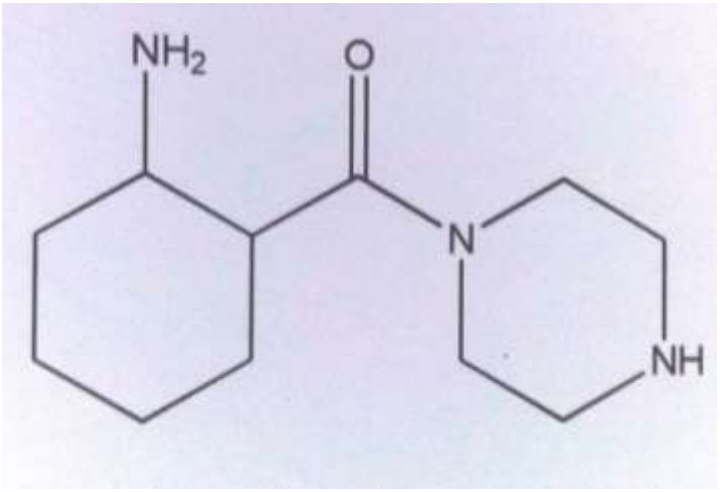
combined beta-amino acid (II) and terahydrotriazolopyrazine (III) by using standard peptide coupling conditions to reach the Markush structure I.



20. US 5,939560 (hereinafter referred as " US '560") titled INHIBITORS OF DP-MEDIATED PROCESSES, COMPOSITIONS AND THERAPEUTIC METHODS THEREOF discloses alpha and beta amino acyl compounds that can be used as DPP-IV inhibitors. US '560 specifically discloses and claims in claim 1 the following core structure:



21. Claim 1 of the US ' 560 further discloses that various substitutions can be made at different positions (n, m, X, A, Y and R) of the Markush structure to develop compounds that would be useful in the treatment of diabetes. When the following substitutions are made i.e. n is 2, m is 1, X is NH, A is beta amino acyl group, Y is N and R is, inter alia the following compound is obtained:



Thus, the concept of use of beta-amino acyl derivatives as DPP-IV inhibitors was know in the prior art and in fact it would have been known to a person skilled in the art that the aforesaid core-structure possesses DPP-IV inhibition activity.

22. As a result, based on the aforesaid prior art documents, I say that there was sufficient disclosure available and known to a person skilled in the art before the priority date of IN 209816, to work with beta-amino acyl derivatives that contain fused hetrocyclic ring for developing DPP-IV inhibitors. Thus, claim 1 of IN 209816 is obvious to a person skilled in the art and all the remaining being dependent claims are rendered obvious.

93. Onus to prove that invention in the suit patent was obvious to a person skilled in the art was on the defendant, which, in my view, defendant has failed to discharge by leading a positive evidence on record. Mere comparison of chemical structure is not sufficient, inasmuch as, picking up parts of chemical structures of different patents and clubbing them will also not be sufficient, as it appears to have been done, keeping in mind the molecule structure of the suit patent, as a hindsight analysis. A direct

question was put to DW2 that the methodology followed by him was typically referred to as hindsight analysis and is a prohibited methodology in patent law to which he answered thus : "I have no comments". He has not denied this suggestion. Instead has given a vague answer which is deemed admission on this point. Hindsight analysis is not permissible. Even otherwise, not much reliance can be placed on this witness, for the reasons already discussed in earlier paragraphs. Above all, PW4 inventor of the suit patent, was not confronted with these prior arts nor was any question put to her that, in view of the patent's cited, invention was obvious. Furthermore, PW2, for the detailed reasons, has categorically stated that suit patent was not obvious to a person skilled in the art. This contention of defendant is, thus, rejected.

Lack of industrial applicability

94. Learned senior counsel for the defendant has contended that suit patent lacks basic patent requirement, that is, industrial applicability and is liable to be revoked under Section 64(1)(g) of the Act. Defendant has contended that suit patent is limited to Sitagliptin Hydrochloride as exemplified in example 7. Suit patent even did not disclose Sitagliptin Free Base. The assertion that Sitagliptin and its pharmaceuticals acceptable salts,

as disclosed in the suit patent, cover Sitagliptin Phosphate Monohydrate is absurd. Only Sitagliptin Phosphate Monohydrate is commercially viable. Sitagliptin Free Base was not being manufactured on commercial scales in pharmaceuticals industries, inasmuch as, Sitagliptin Free Base or Sitagliptin Hydrochloride is incapable of being administered as finished formulations/medicinal products to patients as they are unstable in nature. Plaintiffs are selling Sitagliptin Phosphate Monohydrate and not the Sitagliptin Free Base or Hydrochloride. This itself shows that suit patent has no commercial utility. The purpose of granting patent is not for protection of mere ideas but for protection of actual innovative products, which can be used on commercial scale in the relevant industry. Sitagliptin Free Base or Sitagliptin Hydrochloride cannot be administered as a medicinal product and cannot be launched as a marketable product, inasmuch as, there is no industrial application associated with the same so as to establish that Sitagliptin Free Base was having therapeutic use towards inhibition of DPP-IV. Reliance has been placed on **F. Hoffman-La Roche Ltd and Anr. v. Cipla Ltd 2009 (40) PTC 125 (Del.) (DB)** wherein in para 33, it has been held thus: "it is hard to imagine that therapeutic efficacy of a pharmaceutical product could be tested without it even being able to be administered to a

sample population". It is further submitted that suit patent does not result in any 'product'.

95. Section 2(1)(j) of the Act defines "invention" as a new product or process involving an inventive step and capable of industrial application. As per section 2(1)(ac) 'capable of industrial application' in relation to an invention, means that the invention is capable of being made or used in an industry.

96. Section 83 of the Act reads as under :-

> **"Section 83: General principles applicable to working of patented inventions-**
>
> Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely;—
>
> a. that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
>
> b. that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
>
> c. that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;

d. that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;

e. that patents granted do not in any way prohibit Central Government in taking measures to protect public health;

f. that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and

g. that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public."

(emphasis added)

97. What can be deduced from the legal provisions quoted hereinabove is that invention in a patent shall provide a new product or process being capable of industrial application, that is, the invention is capable of being made or used in an industry. Such invention shall benefit the public and should be affordable. 'Product' has not been defined in the Act, therefore, its definition has to be looked elsewhere. As per WEBSTERS DICTIONARY product means "something produced, esp., something grown or manufactured, the number obtained by multiplying numbers together. (Chem) a new compound formed as a result of chemical change". As per

MERRIAM WEBSTER, medical definition of product means "a substance produced from one or more other substances as a result of chemical change". As per BLACKS LAW DICTIONARY: "with reference to property, term refers to producing; yields; income; receipts; return. Goods produced or manufactured, either by natural means, by hand or with tools, machinery, chemicals, or like. Something produced by physical labour or intellectual efforts or something produced naturally or as a result of natural process as by generation or growth". Thus, in my view, compound formed or a substances produced in terms of the suit patent will be a product. As regards clinical trials PW4, in answer to question no. 102, has deposed that "in fact initial clinical studies were done with a dry powder form of Sitagliptin in a capsule with no added excipients". This answer indicates that Sitagliptin Free Base was put to clinical trials.

98. While answering the issue of infringement, it has already been held that suit patent discloses Sitagliptin Free Base, inasmuch as, Sitagliptin Phosphate Monohydrate is generically covered in the suit patent. It is the Sitagliptin which has therapeutic utility; whereas Sitagliptin Phosphate Monohydrate has advantage over the Sitagliptin Free Base that it has got better physical and chemical characteristics so as to make it in tablet forms.

Sufficient literature has been placed on record to indicate that it is the Sitagliptin which is the DPP-IV inhibitor, inasmuch as, PW2 has also deposed that salt has no use inhibiting the DPP-IV. Indian Pharmacopoeia, a Government of Indian publication, also refers to Sitagliptin 100 mg as DPP-IV inhibitor. At the time when patent is granted it is not necessary that product is under manufacturing process. At that stage, invention as disclosed if made use of commercially subsequently is sufficient. It cannot be said that suit patent was/is not fit for industrial application or is not commercially viable. In fact, the drugs of the plaintiffs have been successfully working for inhibiting the DPP-IV and are used in treating type II diabetes, inasmuch as, defendant itself is manufacturing, marketing and selling Sitagliptin Phosphate Monohydrate of which Sitagliptin forms the bulk component and further that dosage of Sitagliptin 100 mg, 50 mg and 25 mg respectively have been prescribed for inhibiting the DPP-IV enzyme. I do not find much force in the contention of learned senior counsel that suit patent lacks industrial applicability.

Lack of sufficient disclosure and broad claiming

99. Learned senior counsel for the defendant has next contended that suit patent discloses Markush structure, which covers billions of compounds

having DPP-IV inhibitory activity. Suit patent discloses billions of compounds with 76 pharmaceutically acceptable salts, without even indicating or teaching that such salts would even exist or not. Such billions of compounds and their salts, as covered under the suit patent, can be used against treatment of 34 diseases. All such billions of compounds, as covered under suit patent, can be prepared as per the general teachings contained in schemes 1-6. Suit patent does not provide any specific reaction condition for the preparation of various compounds. Scheme 6 of the suit patent teaches preparation of salt and not the 'Free Base'. Suit patent discloses only 33 examples and all are either mono or di-hydrochloride salts. Example 7 of the suit patent discloses preparation of Sitagliptin Hydrochloride. Suit patent provides merely a range of IC_{50} value as opposed to specific data for individual compounds. In fact, specific data related to even the 33 compounds, that have been exemplified in the suit patent, is not given. Suit patent does not provide any characterization data of either Sitagliptin Phosphate Monohydrate or of Sitagliptin Free Base. Further, at the date of priority of the suit patent, claim 19 as it stands today was not present in the provisional specification as the same was added only after filing of the Sitagliptin Phosphate Monohydrate patent application.

Reliance has been placed on Teva Canada v. Pfizer Canada- 2012 SCC 60, wherein, in the context of insufficient of disclosure, Supreme Court has held as under :-

> "2…… The patent application did not satisfy the disclosure requirements set out in the Patent Act, R.S.C. 1985, c. P-4 ("Act "). The patent system is based on a "bargain": the inventor is granted exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge. Sufficiency of disclosure lies at the very heart of the patent system, so adequate disclosure in the specification is a precondition for the granting of a patent……
>
> The Act requires that the court consider the specification as a whole, which includes the claims and the disclosure, from the perspective of a person skilled in the art to determine whether the patent meets the disclosure requirements……
>
> In this case, the disclosure in the specification would not have enabled the public "to make the same successful use of the invention as the inventor could at the time of his application" because it does not indicate that sildenafil is the effective compound. Considering the specification as a whole, the use of sildenafil and the other compounds for the treatment of ED comprise one inventive concept. Even though a skilled reader will know that, when a patent contains cascading claims, the useful claim will usually be at the end concerning an individual compound, the claims in the patent ended with two individually claimed compounds. There was no basis for a skilled person to determine which of Claim 6 and Claim 7 contained the useful compound, further testing would have been required to determine which of those two compounds was actually effective in treating ED.
>
> Although s. 27 does not specify a remedy for insufficient disclosure, the quid pro quo underpinning the Act leads to the

> conclusion that deeming the patent invalid is the logical consequence of a failure to properly disclose the invention and how it works. If there is no quid — proper disclosure — then there can be no quo — exclusive monopoly rights. Even if s. 53 was not raised and its requirements were not met, this does not mean that the disclosure was adequate for the purposes of s. 27(3) . These provisions can be independent of each other.
>
> There is no question that sildenafil's utility had been demonstrated as of the time of filing of the patent application. This takes the invention out of the realm of sound prediction. As to the delay of 13 years between the filing of the patent and the challenge, the relevant question is whether the disclosure was sufficient as of the date of filing, so the delay is inconsequential……"
>
> (Emphasis added)

100. Learned counsel for the plaintiff has contended that Markush claims are well recognized and are common for pharmaceutical inventions. Markush format allows inventors of new chemical entities to cover 100's of closely related compounds which share at least one common trait and a common structure. Markush claims are not alien to Indian Patent Law and are acceptable both in law and practice. Even defendant and their independent expert (DW2) have applied for Markush claims. Ex.DW-1/P covers 9.5 billion compounds. It also provides general scheme of manufacturing and covers multiple diseases and conditions. It does not exemplify all compounds that are covered within the scope of the patent, inasmuch as, provide all general list of possible salts. Ex. DW 1/25 **c**overs

39 billion compounds out of which only one compound claim is Oglemistal. No compound covering general list of salt is provided therein. Ex. DW2/P2 **c**laims a Markush structure which covers nearly 268 trillion compounds. General scheme of manufacturing was provided in the said patent, inasmuch as, enhanced salts were claimed. Various types of cancers were mentioned and claimed to be treated with the compound, as envisaged in the patent. PW4, in answer to question no. 96, has stated that billions of compounds may seem as a very large number but chemical space is infinite. It is further stated that inspite of the claims of the suit patent being Markush, each and every compound claimed is novel, enabled and sufficiently described by the complete specification.

101. PW4, in her cross-examination, has deposed that the title of suit patent clearly indicates that the compound is for treatment of diabetes and diabetes is provided as an indication on internal page 14 and 24 of the suit patent. The structures and the preparations were disclosed in schemes 1-6 and examples 1-33 were provided to illustrate how the invention was reduced to practice. The forms that the compound might take, for example pharmaceutically acceptable salts etc are disclosed in the specification. Formulations and pharmaceutical compositions of the compound claims and

the oral route of administration have also been disclosed, inasmuch as, the dosages, that is, 25 mg, 50 mg and 100mg, which are the marketed dosage of Sitagliptin, have also been disclosed. IC 50 was provided as a range to show that the compound inhibits the enzyme DPP IV and, thus, had desired pharmacological effect.

102. I have considered the rival contentions of the parties. All the patent documents contain similar information and the suit patent is no different than the other patent documents placed on record, including that of defendant. Even the patent of defendant and that of Laurus Labs Private Limited of which DW2 is co-inventor, all contain compounds flowing from Markush structure, but the fact remains that claims have been specifically mentioned in the suit patent more particularly claim no. 19 which is Sitagliptin with its pharmaceutically accepted salts. IC 50 value has been given. It has also disclosed in the suit patent that the invention was meant for inhibiting DPP-IV enzyme and was helpful for treating type II diabetes. Examples as well as schemes have also mentioned. The disclosure in the suit patent is not for a lay person but is addressed to a person of ordinary skill in the art. It may further be noted that defendant itself has been successful in making Sitagliptin Phosphate Monohydrate, thus, it cannot be

said that suit patent is too wide and broad, inasmuch as, defendant itself has acknowledged in its patents, as discussed above, that Sitagliptin with pharmaceutically acceptable salt was disclosed in US patent of plaintiffs, which is equivalent to suit patent. Defendant cannot be permitted to blow hot and cold in the same breath. In my view, the patent cannot be revoked on this ground of 'insufficiently'.

103. Section 8 of the Act reads as under :-

> "8. Information and undertaking regarding foreign applications.—
>
> (1) Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application or subsequently within the prescribed period as the Controller may allow—
>
> (a) a statement setting out detailed particulars of such application; and
>
> (b) an undertaking that, up to the date of grant of patent in India, he would keep the Controller informed in writing, from time to time, of detailed particulars as required under clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.

> (2) At any time after an application for patent is filed in India and till the grant of a patent or refusal to grant of a patent made thereon, the Controller may also require the applicant to furnish details, as may be prescribed, relating to the processing of the application in a country outside India, and in that event the applicant shall furnish to the Controller information available to him within such period as may be prescribed."

104. Case of the defendant is that plaintiff no.1 had not disclosed multiple patents both in India and other jurisdiction relating to Sitagliptin Phosphate Monohydrate (5948/DELNP/2005, US7326708 & EP 1654263) and combination of Sitagliptin Phosphate Monohydrate along with Metformin Hydrochloride (2710/CHENP/2008, US 841492 & EP 1962827) to the patent office, during the prosecution of the suit patent, thus, plaintiff is guilty of non compliance of Section 8(1) of the Act. Even though, vide First Examination Report dated 28th July, 2006 patent office had asked the plaintiff no.1 to file details of patent applications filed in other jurisdiction along with their prosecution details but plaintiff no.1 did not disclose any of the subsequent applications to the patent office despite examination report of the patent office. Defendant's plea is that section 8 is mandatory and non-compliance thereof mandates revocation of suit patent under section 64(1)(j) of the Act.

105. Section 64 of the Act reads as under :-

"(1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds, that is to say—

(a) that the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of earlier priority date contained in the complete specification of another patent granted in India;

(b) that the patent was granted on the application of a person not entitled under the provisions of this Act to apply therefor:

(c) that the patent was obtained wrongfully in contravention of the rights of the petitioner or any person under or through whom he claims;

(d) that the subject of any claim of the complete specification is not an invention within the meaning of this Act;

(e) that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the, documents referred to in section 13:

(f) that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in India or what was published in India or elsewhere before the priority date of the claim:

(g) that the invention, so far as claimed in any claim of the complete specification, is not useful;

(h) that the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed, that is to say, that the description of the method or the instructions for the working of the invention as contained in

the complete specification are not by themselves sufficient to enable a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention, or that it does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection;

(i) that the scope of any claim of the complete specification is not sufficiently and clearly defined or that any claim of the complete specification is not fairly based on the matter disclosed in the specification;

(j) that the patent was obtained on a false suggestion or representation;

(k) that the subject of any claim of the complete specification is not patentable under this Act;

(l) that the invention so far as claimed in any claim of the complete specification was secretly used in India, otherwise than as mentioned in sub-section (3), before the priority date of the claim;

(m) that the applicant for the patent has failed to disclose to the Controller the information required by section 8 or has furnished information which in any material particular was false to his knowledge;

(n) that the applicant contravened any direction for secrecy passed under section 35 or made or caused to be made an application for the grant of a patent outside India in contravention of section 39;

(o) that leave to amend the complete specification under section 57 or section 58 was obtained by fraud.

(p) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;

(q) that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the

knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.

(2) For the purposes of clauses (e) and (f) of sub-section (1)—

(a) no account shall be taken of personal document or secret trial or secret use; and

(b) where the patent is for a process or for a product as made by a process described or claimed, the importation into India of the product made abroad by that process shall constitute knowledge or use in India of the invention on the date of the importation, except where such importation has been for the purpose of reasonable trial or experiment only.

(3) For the purpose of clause (1) of sub-section (1), no account shall be taken of any use of the invention—

(a) for the purpose of reasonable trial or experiment only; or

(b) by the Government or by any person authorised by the Government or by a Government undertaking, in consequence of the applicant for the patent or any person from whom he derives title having communicated or disclosed the invention directly or indirectly to the Government or person authorised as aforesaid or to the Government undertaking; or

(c) by any other person, in consequence of the applicant for the patent or any person from whom he derives title having communicated or disclosed the invention, and without the consent or acquiescence of the applicant or of any person from whom he derives title.

(4) Without prejudice to the provisions contained in sub-section (1), a patent may be revoked by the High Court on the petition of the Central Government, if the High Court is satisfied that the patentee has without reasonable cause failed to comply with the request of the Central Government to make, use or exercise the patented invention for the purposes of Government within the meaning of section 99 upon reasonable terms.

> (5) A notice of any petition for revocation of a patent under this section shall be served on all persons appearing from the register to be proprietors of that patent or to have shares or interests therein and it shall not be necessary to serve a notice on any other person."

106. A perusal of aforesaid provision makes it clear that it is not mandatory for the court to revoke the patent merely because any of the grounds mentioned in Section 64(1) are made out. It is the discretion of the court to revoke or not to revoke in the given facts and circumstances of a case. The word 'may' used in Section 64(1) of the Act makes it clear that it is the discretion of the Court to revoke the patent under this provision if any of the ground(s) stipulated therein are disclosed or made out. Learned senior counsel for the defendant has contended that word 'may 'be read as 'shall'. However, I am not in agreement with this contention. A Division Bench of this Court, vide judgment dated 7th November, 2004 passed in **FAO (OS) 16/2004 tilted Maj.(RETD.) SUKESH BHEL &ANR. V. KONINKLIJKE PHILLIPS ELECTRONICS,** has held that the power of court to revoke is discretionary. It was contended in the said case that having regard to the fact that section 8 is a mandatory provision and its non-compliance is a ground for revocation of the patent under section 64(1)(m), the world 'may' employed in section 64(1) should be construed to mean

imperative. This argument has been rejected by the Division Bench. It is further held that revocation would follow only if the court is of the view that omission to furnish the information was deliberate. No evidence has been led by the defendant to show that such non-disclosure of the information was deliberate and for malafide reasons. Accordingly, this argument is rejected. Arguments of the defendant about 'public interest' does not have much force in the facts and circumstances of the present case. Sitagliptin is not the only DPP-IV inhibitor for treatment of type II diabetes in the market and there are several other DPP-IV inhibitors, including the one manufactured and marketed by the defendant, that is, Teneligliptin. The invention of plaintiffs, that is, Sitagliptin improves the efficient management of the condition of a patient suffering from type II diabetes by inhibiting the DPP-IV enzyme. Merely because defendant, who is manufacturing generic version, is selling a tablet at a lower price than that of plaintiffs cannot be made ground to decline injunction against the defendant, who has been found to have been infringing the invention of the plaintiffs, is as much as, a competitor of the plaintiffs.

107. In view of above discussions, the above issues are answered in favour of the plaintiffs and against the defendant.

Issue No. 12

108. In view of the findings returned on the above referred issues defendant is restrained by a decree of permanent injunction from making, using, selling, distributing, advertising, exporting, offering for sale or dealing in Sitagliptin Phosphate Monohydrate or any other salt of Sitagliptin in any form, alone or in combination with one or more other drugs thereby infringing the suit patent no. 209816 of the plaintiffs. As regards damages are concerned, no issue has been framed in this regard, inasmuch as, only on the basis of the admission by DW1 regarding total sales and the percentage of the profits earned by the defendant, I do not find it justifiable to quantify the amount of damages. Plaintiffs shall, however, be entitled to actual costs of the proceedings. Decree sheet be drawn.

A.K. PATHAK, J.

OCTOBER 7, 2015

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