

## IP Hotline

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### PATENT PROTECTION IN INDIA? INTERIM INJUNCTION REFUSED FOR MSD'S PATENT

Delhi High Court has refused to grant an interim injunction in favor of Merck Sharp and Dohme (**MSD**) against Glenmark Pharmaceuticals (**Glenmark**) in relation to MSD's Sitagliptin patent in India. This rejection came very close to the Novartis order, leaving pharma industry wondering whether and how the patents can be obtained and enforced in India.

#### BACKGROUND

MSD filed a patent infringement suit in the Delhi HC on April 1, 2013 against Glenmark seeking permanent injunction and damages for infringing its patent on "Sitagliptin" by launching its products Zita and Zita Met. MSD also moved for interim injunction against Glenmark.

On April 4, 2013, after hearing both parties, the Delhi HC (Hon'ble Justice Rajiv Sahai Endlaw) refused to grant an interim injunction against Glenmark restraining it from launching its products Zita and Zita met.

MSD had been granted an Indian patent 209816 ('816 patent) on September, 6, 2007 covering Sitagliptin and '816 patent had not been faced with any pre-grant opposition, post-grant opposition or a revocation petition till date. Claim 1 of the '816 patent is a Markush claim. Claim 1 claimed both the R and S stereoisomers of Sitagliptin. The commercial product Januvia and Janumet consisted of R stereoisomer form of Sitagliptin.

#### MERCK'S ARGUMENT

MSD argued that its product JANUMET has pharmaceutical composition as "Sitagliptin Phosphate & Metformin Hydrochloride" and its exclusive licensee Sun Pharma's product ISTAVEL has its pharmaceutical composition as "Sitagliptin Phosphate" and Glenmark's product has a pharmaceutical composition as "Sitagliptin Phosphate Monohydrate". MSD relied on packaging of the drug products for this factual submission.

MSD argued that '816 patent covers Sitagliptin Phosphate Monohydrate. Thus, the act of manufacturing, selling and offering for sale Sitagliptin Phosphate Monohydrate by Glenmark directly infringed MSD's '816 patent.

Further, MSD submitted that Glenmark had been granted a process patent in US for preparation of R-Sitagliptin and its pharmaceutically acceptable salts wherein Glenmark had admitted that a US Patent on Sitagliptin had been granted to MSD.

#### GLENMARK'S ARGUMENT

Glenmark argued that its product comprises of three parts "S", "PD" and "DC" ( probably referring to Sitagliptin, dihydrogenphosphate salt and crystalline form). MSD had been granted a patent in India only for Sitagliptin, this was very much evident from the fact that MSD had filed separate patents in India for phosphate salt and crystalline form of Sitagliptin, which were denied and affirmatively abandoned in India by MSD. Further, in the US MSD has three different patents for Sitagliptin, dihydrogenphosphate salt and crystalline form.

Further, Glenmark argued that MSD in its patent application for Sitagliptin Phosphate (5948/DELNP/2005) had described that the combination of Sitagliptin and phosphate salt as a new discovery not covered by existing Sitagliptin patent. Thus, MSD cannot argue that Glenmark's combination of "Sitagliptin and phosphate salt" infringes MSD's '816 patent.

Further, Glenmark argued that since MSD's '816 patent did not cover Sitagliptin Phosphate, in order to prove that Glenmark was infringing its patent, MSD would have to show that the role of the addition element (i.e Sitagliptin phosphate) was not outweighed by the element covered by its patent (i.e. Sitagliptin). Glenmark submitted that the role of Sitagliptin Phosphate was outweighed by the role of Sitagliptin and thus they were not infringing MSD's patent.

#### MSD'S COUNTER TO GLENMARK'S ARGUMENT

MSD argued that under Section 3 (d) of the Patents Act a derivative of a known form of substance cannot be granted a patent. Thus, Sitagliptin Phosphate being a derivative of a known substance Sitagliptin cannot be patented in India and for this reason the patent applications was abandoned. MSD submitted that filling of a patent application for Sitagliptin Phosphate in India was misconceived and had been rightly rejected by the patent office and abandoned by MSD. Whereas in US Section 3(d) was not present, so MSD had obtained patents for all the three "S", "PD" and "DC".

MSD contended that no weightage ought to be given to the fact that the contents of the application for Sitagliptin Phosphate stated that it was a new discovery because it could not have been granted a patent under Section 3(d) of

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the Patents Act and had been abandoned by MSD.

MSD argued that '816 patent specifically covered Sitagliptin Phosphate Monohydrate and on the basis of this patent Glenmark can be restrained from selling its product Zita and Zita Met.

DELHI HIGH COURT'S DECISION

The court agreed that there is merit in the contention that '816 patent granted to MSD covers, "a pharmaceutically acceptable salt" of Sitagliptin and which may include Sitagliptin phosphate. However, the court held that the test to be applied here is whether the combination used by Glenmark embodies the inventive advance of the patent.

The court held that function of the patented Sitagliptin and Sitagliptin Phosphate was the same i.e. DPP-IV inhibitor. Thus, "if the infringing products are made with the same object in view which the patented article attains, then a minor variation does not mean that there is no infringement. Trifling and unessential variations are to be ignored. Conversely, a miniscule advancement could be recognized as an invention."

Thus, MSD in essence has to prove that Glenmark's product inspite of combining phosphate salt with MSD's patented Sitagliptin remained equivalent to Sitagliptin and that the role of phosphate was inconsequential in treatment of the disease. If the answer is in the affirmative then an interim injunction should be granted to MSD. The court concluded that MSD had not produced any evidence to that effect at this stage.

The court held that all submissions made by MSD were contending that pharmaceutical composition of MSD's drug i.e. Januvia was the same as that of Glenmark's drug Zita and Zita Met. The oral arguments and the pleading by MSD did not make out a case on which the interim relief should be granted i.e. Sitagliptin Phosphate was being made by the defendant with the same object as the patent of the plaintiff and the addition of Phosphate to the patented Sitagliptin did not embody any inventive advancement and the treatment of Type-II diabetes by Sitagliptin Phosphate was no different from treatment by Sitagliptin.

The court also emphasized on the fact that MSD had made a separate patent application for Sitagliptin Phosphate, considering it to be a new invention worthy of a separate patent and on this aspect in oral arguments MSD had said this was just an honest mistake but there was no pleading to this effect.

In view of these facts the court concluded that MSD's application for interim injunction should not be granted. However, the court directed Glenmark to maintain statement of accounts for the products in question and submit them quarterly with the court and also with MSD every quarter.

ANALYSIS

It is a fundamental principle in patent law that in order to prove infringement plaintiff has to compare the infringing product with the claims of the granted patent. Since, the invention lies in the claims granted and not the plaintiff's commercialized product.

Under Section (10) (4) (c) of the Indian Patents Act, 1970 claims define the scope of the invention i.e. the patent. Thus, the first step court should have undertaken is to construct the scope of the claims of MSD's '816 patent in order to determine whether the scope of the claims cover Sitagliptin Phosphate.

However, the court seems to have digressed a bit after it concluded that there was merit in the contention that MSD's patent could cover in addition to Sitagliptin also its salt form Sitagliptin Phosphate, if the answer was in affirmative, then the court should have granted an interim injunction to MSD. There was no need to go into the enquiry whether Glenmark's product inspite of combining phosphate salt with MSD's patented Sitagliptin remained equivalent to Sitagliptin and that the role of phosphate was inconsequential in treatment of the disease to grant interim injunction. This enquiry should arise only if the Sitagliptin patent did not cover Sitagliptin Phosphate.

The court seems to have also given weightage to the fact that MSD had filed a separate application for a patent in India and had later abandoned the application and also the fact that MSD had separate patent in the US for Sitagliptin and Sitagliptin Phosphate. These facts should not have been weighed in by the court in order to determine whether Glenmark was infringing MSD's patent or not.

Further, the court ought to have appreciated the fact that MSD's patent had not been challenged by any party either in pre-grant, post grant and even by Glenmark during these proceedings.

Section 3 (d) was inserted in the Act to prevent ever-greening. i.e. if the derivative of a known substance does not have significant enhancement of efficacy over the known substance, then the derivative should not be given a separate patent, thereby extending the monopoly period. But the claims of patent for original substance may still cover the derivate. In such cases, unless the patents for original substance are not interpreted appropriately, the patentees will have difficult time to enforce their patents in India.

- Ajay Chandru and Gowree Gokhale  
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