Ranjan Narula Associates
intellectual property attorneys

Merck refused interim injunction for the infringement of its patent on Anti Diabetic drug

The ambiguity over interpretation of section 3(d) just does not seem to die. In a yet another decision, the Delhi High Court refused to grant an injunction against Glenmark in a suit filed by Merck for the infringement of its patented anti Diabetic drugs marketed as Januvia and Janumet.

The infringement suit was filed by Merck alleging Glenmark for making anti diabetic drug known by non proprietary name 'SITAGLIPTIN'.The molecule 'SITAGLIPTIN' was invented by Merck and patented in 102 countries including India. The patent claims the base molecule SITAGLIPTIN in free base form and also 'pharmaceutically accepted salts thereof'. Merck also filed for a patent for SITAGLIPTIN phosphate which was abandoned later on in view of certain pre grant oppositions. However, the patent for the phosphate salt of Sitagliptin has been granted in USA.

The drug was approved for marketing in India on 28th March 2008. The plaintiff also granted a license in India to Sun Pharmaceutical Industries Limited (plaintiff 2) which sells the drug under the brand name Istavel & Istamet.

Glenmark launched SITAGLIPTIN phosphate monohydrate under brand name Zita & Zitamet on 28th march 2008.

Plaintiff filed a suit for injunction restraining infringement of patent and for other reliefs. Hence, the court had to decide whether the product SITAGLIPTIN phosphate monohydrate of the defendant infringes the plaintiffs' patents.

The honorable Judge decided on the enquiry as to on what basis an infringement is averred.

The Defendant's i.e. Glenmark argued that, as the validity of the patent of the plaintiffs has been challenged, therefore the question of grant of any interim relief to the plaintiff, does not arise until the said validity is decided by the court. Referring to the granted patent in USA for the phosphate salt and a separate application for same in India, they argued that phosphate salt is not a mere improvement patent but a distinct product which was also confirmed by the fact that plaintiff applied for a separate protection for the same in India and obtained a patent in USA. Further, the defendents argued that patent of the plaintiff Merck was not on the pharmaceutical composition as described in plaintiff's product but only on a part thereof. Thus, similarity of pharmaceutical composition of the products cannot be a ground for infringement. They also alleged Plaintiffs for suppression of the facts regarding the Indian patent application for the phosphate salt of the molecule.

While Plaintiffs argued that SITAGLIPTIN was the invention and SITAGLIPTIN phosphate was merely a derivative of the invention and therefore wasn't eligible for patent protection under Section 3(d). Referring to the package inserts information available with the defendant's product they argued that the pharmaceutical composition of their product is similar to composition of Glenmark's product Zita and hence the infringement is obvious. Merck's counsels also emphasized that "there is no price difference in the product of the plaintiffs and defendant" to allay the influence of Novartis supreme court decision. Probably this is the first case of differential pricing in India as the dug in India is available at a reduced price equivalent to 1/5 price of that is being charged in USA.

Regarding separate patent application in India on SITAGLIPTIN phosphate the plaintiff mentioned that it was misconceived and was not a subject matter of patent in view of section 3(d). Regarding the corresponding US patent they mentioned that as no such bar exists under US laws therefore need for applying for a second application for the phosphate salt arose. The plaintiff also referred to the patent obtained by the defendant for process of preparation of SITAGLIPTIN in US, mentioning that the defendant has admitted that SITAGLIPTIN phosphate is a pharmaceutically acceptable salt of SITAGLIPTIN.

The court held that if the combination by the defendant in its product, of SITAGLIPTIN (on which the plaintiff Merck undoubtedly has a patent) with phosphate salt, have a material effect upon the way SITAGLIPTIN works, then the product of defendant will be outside Merck's patent , but if it does not have any material effect then infringement will be proved. The mode of action of plaintiff's and defendants' product seems to be similar, the court therefore asked the defendant to show how phosphate salt of SITAGLIPTIN worked differently. However, no satisfactory answer was provided by the defendants.

The court ruled out that as only a part of patented molecule is being used by the defendant in its product, therefore similarity of products cannot be ground of infringement. Further referring to the lack of arguments from plaintiff pleading that SITAGLIPTIN and the SITAGLIPTIN phosphate are similar and that addition of phosphate to SITAGLIPTIN is not embodying any inventive advancement, the court contented that an interim injunction cannot be granted. It was categorically mentioned that it was for the Plaintiff to plead the circumstances in which its application for a separate patent in SITAGLIPTIN Phosphate was made and to explain the admissions made therein and reasons for abandonment of the same. The plaintiff has not done so, however it is open for them to do so at the trial. Therefore plaintiff's appeal for interim relief was dismissed.

Ranjan Narula Associates
intellectual property attorneys

Our Comments,

Though this is an interim order and final outcome is yet to come, we are of the view that this is yet another flawed decision in the sense that the plaintiff had a valid patent claiming the very product that is being clearly infringed. Even if the products are held to be 'different', the defendants'' product is 'equivalent' to the patented product. The subject matter of this case has lot in similar with the Roche Vs Cipla litigation over the drug 'Elrotinib' .We can only hope that as the case progresses, more clarity will emerge over the issues of patent validity and infringement of obvious variants of patented products.

Vatika Towers
10th Floor Block-B
Sector-54
Gurgaon-122002
National Capital Region (Haryana)
India

Tel. +91 124 4655999
Fax. +91 124 4045047
Email info@indiaiprights.com