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Delhi High Court grants permanent injunction in case of Sitagliptin

By **Sanuj Das**

Nearly three years after Merck (patentee) initiated an infringement action over its patented diabetics drug sitagliptin (Indian Patent 209816, sold under the brand names Januvia and Janumet), the Delhi High Court recently permanently restrained the defendant from the business of Sitagliptin.

Background

Order of Delhi High Court Single judge (First instance)

In April 2013, the patentee approached the Delhi High Court seeking a permanent injunction against the respondent for infringement of its patent for sitagliptin. Patentee alleged that respondent's product SPM infringed its patent for sitagliptin as the patent claims covered the active ingredient sitagliptin and any of its salts, including its various stereo isomeric forms. In addition to filing a counterclaim challenging the validity of the sitagliptin patent under Section 64 of the Patents Act 1970, the defendant argued that patentee was guilty of suppression and had failed to disclose that a separate patent application (5948/DELNP/2005) had been filed for a dihydrogenphosphate salt of sitagliptin, but subsequently abandoned.

The single judge vide his order dated April 5, 2013 held that on account of patentee's failure to explain satisfactorily its admission in the patent application for a dihydrogenphosphate

salt of sitagliptin, Patentee could not be granted an interim injunction.

Order of Delhi High Court Division Bench

The patentee appealed the single judge's order to the Division Bench. It argued that its non-disclosure of other applications for phosphate salts of sitagliptin in India and elsewhere was a minor detail and should not have influenced the decision as to whether Respondent had infringed its sitagliptin patent or been the basis for refusing an interim injunction. On the other hand, the respondent had argued that SPM was qualitatively different from sitagliptin *per se*, such that it had enhanced pharmaceutical qualities, and therefore the manufacture and sale of SPM did not violate the patent for sitagliptin. Further, the respondent had relied on a patent for SPM granted in the United States to assert its enhanced pharmaceutical qualities.

While dealing with the grounds for revocation asserted by the respondent, the Division Bench highlighted its limitations in addressing technical matters in an interim hearing and examined the three grounds for granting an interim injunction (i.e., a prima facie case, the balance of convenience and irreparable harm or injury).

The bench held that the following issues had to be considered in the case at hand:

- *Public interest* – The bench observed

that the price difference between the commercial products sold by the respondent and the patentee was not high. Hence allowing the respondent to sell the drug would not necessarily result in lowering of the price so as to increase access. The bench also held that it must be mindful of the need to enforce the act, particularly where a strong case of infringement is established.

- *Price* - An infringer who is allowed to operate during a trial may lower the price of the product since it has no R&D expenses to recoup but it does not apply to the patentee. Moreover, even assuming that the patentee can survive the financial setback during the trial, prices may not recover.
- *Challenge to validity of patent* - The bench observed that the respondent had released the drug without initiating revocation proceedings under the act, which would have obviated the need for an interim arrangement. Although the bench cautioned that the respondent's right to question the validity of the patent in an infringement was unaffected, it held that the manner of challenge was a relevant factor against it at the interim stage.
- The combination of the three primary factors (a *prima facie* case, the balance of convenience and irreparable harm or injury) – The bench held that the

patentee had established a *prima facie* case of infringement. Further, there existed an interim arrangement which secured the interests of both parties and maintained the public interest, and also ensured that the possibility of irreparable harm to the patentee was removed.

In light of this, the bench set aside the order of the single judge dismissing the application for grant of an interim injunction and granted the same in favour of patentee along with certain directions.

Before Supreme Court

On appeal by the defendant, the Supreme Court upheld the interim protection granted by the Division Bench of the Delhi High Court restricting the defendant from manufacturing and selling unfinished formulations of Sitagliptin and gave directions to complete the trial before the Single Judge within a stipulated time-frame.

Final Judgment by the Single Judge of the Delhi High Court

The Court observed that the onus to prove that the invention in the suit patent was obvious to a person skilled in the art, rested on the defendant and it had failed to prove the same. The Court said that mere comparison of chemical structure or picking up parts of chemical structures of different patents and clubbing them, is not sufficient to prove that the invention is not novel or obvious. Further, the defendant witness in this case is said to

have followed a methodology referred to as 'hindsight analysis' which is a prohibited methodology in patent law.

While answering the issue of infringement, two things that the court observed to be relevant were that, one Sitagliptin is the molecule with the therapeutic utility; whereas Sitagliptin Phosphate Monohydrate has advantage over the Sitagliptin Free Base, in that it has got better physical and chemical characteristics so as to make it in tablet forms. The court placed heavy reliance on the testimony of the Plaintiff's witness, being an independent witness, to rule 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 plaintiff's witness also stated in his cross-examination that Sitagliptin Phosphate Monohydrate is generically disclosed in the suit patent though not specifically. It was clarified to the court that DPP-IV inhibition was on account of Sitagliptin alone and it was irrelevant as to the form in which it was being administered, the same being done to merely enhance the availability of the drug in the body to facilitate further absorption and faster action.

On the issue of lack of sufficient disclosure and broad claiming, the court in this case observed that the disclosure in the suit patent is not for a lay person but is addressed to a person of ordinary skill in the art. Further, since the defendant itself has been successful in making Sitagliptin Phosphate Monohydrate, it cannot

claim that the patent in question is too wide and broad.

On the question of revocation on account of non-compliance with Section 8, the court observed that the provisions under Section 64 of the Patents Act make 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 and "may" cannot be read as "shall" as contended by the defendant.

With respect to the arguments made about "public interest", the court noted that Sitagliptin is not the only inhibitor for treatment of type II diabetes in the market and there are several other inhibitors, including the one manufactured and marketed by the respondent, called "Teneligliptin".

The present judgment is one of its kind judgment where the trial has been concluded within a period of three years. It remains to be seen what would be its implications in the pharmaceutical sector and what outcome it will have on the interface of patents & pharma.

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Ratio Decidendi

Trademarks - 'First in market' relevant over 'first to register'

The Supreme Court of India has upheld the interim injunction granted by the trial court on the basis of 'first in the market' test in a dispute where the defendant had filed for registration of the mark six years prior to the commencement of user by the Plaintiff, but had refrained from using the mark. The Court in this regard noted that though the Defendant-respondent had applied for the mark before, the user thereof had remained dormant for twelve years and that in the interregnum the Plaintiff-Respondents had not only applied for registration but had also commenced production and marketing of the similar drug and had claimed to have built up a substantial goodwill in the market. It was also observed that the factors, balance of convenience and an irreparable loss, were both in favour of the Plaintiff-Respondents.

The Court was of the view that Section 34 of the Trade Marks Act, 1999, which is to protect the prior user from the proprietor who is not exercising the user of its mark, was *prima facie* in favour of the Plaintiff-Respondent. It observed that the Act does not permit hoarding of or appropriation without utilization of a trademark and that legislative intent behind Section 47 was to ordain that a trademark applicant does not have a permanent right by virtue of its application alone.

While upholding the *prima facie* view, the Supreme Court observed that the Court

before whom the suit is pending has to look into the question as to whether the situation on the date of application for registration alone would be relevant, or whether the developments in the period between this date and the date of grant of registration would have any bearing on the rights of the parties. [*Neon Laboratories Ltd. v. Medical Technologies Ltd.* - Civil Appeal No. 1018 of 2006, decided on 5-10-2015, Supreme Court]

Title of a work is not 'work' – No copyright exists in title

The Supreme Court of India has held that copyright does not exist in the title of a work. The dispute revolved around the title 'Desi Boyz' used by the film producer (appellant). The Respondent who had shared the synopsis of a story with title 'Desi Boys' alleged copyright infringement as regards the title. There was no dispute about the story, synopsis etc., as the respondent had not seen the film and did not bring up these charges. Reasoning that title does not qualify for being described as "work" as it is incomplete in itself and refers to the work that follows, the Supreme Court held that it was not entitled to copyright protection. Further the words were commonplace words and their origin could not be traced to the person who created the title. The Court also observed that complainant is not entitled to relief except in an action for passing off or in respect of a

registered trademark comprising such title. [Krishika Kulla v. Shyam Vithal Rao Devkatta, Criminal Appeal 258/2013, Supreme Court decision dated 15-10-2015]

Trademarks – No exclusive use of mark ‘Eagle’ permissible

Delhi High Court has refused to grant interim injunction in a case involving exclusive appropriation of the word “Eagle”. The Court in this regard observed that there is not only one eagle in this world and ‘eagle’ as a name cannot be allowed to be appropriated exclusively by any one producer of any type of goods. It was further held that the device of a swooping eagle showing an eagle going towards earth (belonging to the plaintiff) cannot *prima facie* said to be identical or deceptively similar to an eagle which is taking off or flying higher (mark belonging to the defendant). No identity or deceptive similarity of the mark “American Eagle” with “Urban Eagle”, was also found by the Court though it was observed that the goods of both the parties are same. It was *prima facie* held that there was sufficient distinction between the two inasmuch as plaintiff itself had claimed exclusivity of the mark not on account of use of the word “Eagle” but because of the use of the word “American” along with the word “Eagle”, before the Registrar of the Trade marks.

The Court noted the absence of any public interest in the case where the goods were only clothing. It also held that the device of the swooping eagle was not entitled to copyright protection since it was not an original

artistic work. [Retail Royalty Company v. Pantaloons Fashion & Retail Limited - CS(OS) No.2872/2015, I.A. No.19847/2015 (Stay) and I.A. No.19848/2015 (under Order XXVI Rule 9 CPC), decided on 23-9-2015, Delhi High court]

Patents – Consideration of unregistered license agreement as evidence

The Delhi High Court has rejected the argument that the suit is not maintainable as an unregistered licence agreement cannot be admitted as evidence of title in view of Section 69(5) of the Patents Act, 1970. It opined that as per the amended Section 68 of the Act, it was not mandatory to register the assignment and the assignment was valid from date of execution. The defendant contended that the unregistered licence agreement of the plaintiff was not valid and had sought dismissal of the plaint under Order VII Rule 11 CPC which had not been granted. However, the Single Judge adjourned the matter *sine-die* to await the decision of the Controller on the application for registration filed by the plaintiff.

The High Court held that at the *prima facie* stage, the court can always refer to the assignment deed without formal proof thereof. The Single Judge’s Order to adjourn the matter *sine-die* was also set aside by the High Court observing that without forming an opinion in terms of Section 69(5) of the Act, the suit could not have been adjourned *sine-die*. [Sergi Transformer Explosion Prevention Technologies v. CTR Manufacturing Industries, Delhi High Court judgement dated 8-10-2015]

News Nuggets

Yoga sequence – Not moving towards copyright

While copyright may have less to do with appealing to the eye and beauty of movements etc, a ‘static and kinetic successions of bodily movement’ may be subject to copyright. However, recently, the United States Court of Appeals for the Ninth Circuit opined that the ‘Sequence’ of yoga poses and breathing exercises was not entitled to copyright protection. It observed that though copyright law had been amended to keep pace with technology or new understandings of creative expression, the idea/expression dichotomy had remained firmly in place. It stated that, brushing one’s teeth, churning butter or oil drilling also involved steps in succession and though the yoga sequence may fit the definition of dance for some, it was still a process which would not be copyrightable. The sequence, no doubt, was a result of selection of poses arranged in a particular way but it did not represent the original work of an author. Interestingly, in 2014, the High Court of Delhi opined that protection under Trademark Act or Copyright Act cannot extend to techniques,

processes or sequences and hence *pranic healing* and performance of the *asanas*, postures, communicating the same to public will not constitute infringement.

When imitation flatters the consumer

Copycat packaging may actually put a smile on the consumers’ face and help rather than hinder competition. The UK government, after conducting a review of the Consumer Protection from Unfair Trading Regulations 2008 (the CPRs) has decided that it will not exercise the option to empower business with civil injunctive power. The business did argue that the tort of passing off and remedies under trademark or copyright laws were at times inadequate. However, one of the most interesting aspects of the feedback - that consumers were actually happy to have bought goods at a lower price and were not ‘deceived’ by the packaging, seems to have carried a lot of weight. The report also records that use of such injunctive power is likely to be influenced by commercial considerations rather than consumer interest.

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