Dapagliflozin Patent Infringement - Delhi High Court Declines Injunction to Astrazeneca

written by Sanjay Kumar | November 3, 2020

The Delhi High in an order dated November 2, 2020, in the matter of *Astrazeneca Ab & Anr Vs Intas Pharmaceuticals Limited[1]* (Dapagliflozin Patent) declined to grant an injunction in favour of AstraZeneca ("Astra") and against Intas, Alkem, Emcure, USV and Micro lab ("Defendants"). The captioned applications were dismissed.

The court held that:

- Defendants will via their respective affidavits, to place on record the details, quantum, and value of drug manufactured and sold as also indirect and direct taxes paid on that behalf.
- This information will be placed on the Court's record every quarter.
- The defendants will also provide details of their assets [encumbered and unencumbered] which would include their location and current market value.
- The information given in the affidavits will be backed by a certificate of a statutory auditor.
- The defendants via their affidavits will also undertake to pay damages as and when called upon to do so by the court. These affidavits will be filed within a period of 3 weeks.

Facts - Dapagliflozin Patent Infringement

The matter principally concerns two patents of Dapagliflozin drug used in diabetes.

a) Indian Patent No. 205147

b) Indian Patent No. 235625

The first registered patent holder i.e. the grantee of these two patents is an entity going by the name Bristol Myers Squibb Company ("Bristol"). Bristol via an assignment deed dated 01.02.2014, assigned the rights in the aforementioned patents in favour of Astra Sweden. Astra has obtained the necessary statutory approvals for importing and marketing DAPA in India.

Issues

Whether the compound-in-issue i.e. Dapagliflozin ["DAPA"] which, according to the plaintiffs, is covered in IN 147 stands disclosed both, in law as well as on facts?

Contentions on Genus & Species of Patent

Astra claimed that DAPA is used worldwide to treat people suffering from type-II diabetes mellitus. Astra claimed that Markush structure, a patent

covering a group of compounds that disclosed the possibility of individual permutations and combinations that can run into several million structurally diverse compounds.

IN 147, is the genus patent claims which is a Markush structure that has 22 variables and, hence, can lead to millions and perhaps billions of possible permutations and combinations.

While the Markush structure claimed by the plaintiffs qua its genus patent i.e. IN 147 covers DAPA. This is the genus patent, which covers DAPA and is worked through commercialisation of the drug which was disclosed in the species patent. Therefore, this would not amount to an admission, as alleged or at all. A single product may cover thousands of patents. By way of illustration, reference was made to a mobile phone which is covered by multiple patents.

According to Astra, the defendants should be denied the relief of injunction for the following reasons.

- The defendants are either manufacturing or intending to manufacture DAPA and, therefore, infringement is admitted.
- DAPA is a man-made drug that is used for treating not only type-2 diabetes but is also approved for treating hypertensive heart failure in 2020.
- The species patent is an old and established patent and, therefore, carries with it the presumption of validity. This patent is in its 18th year of life cycle.

Analysis

Section 25(1) of the Indian Patent Act (“Act”) accords leeway to oppose grant of a patent once an application for the said purpose has been published. The grounds on which opposition can be filed are set out in subclause (a) to (k) of Subsection (1) of Section 25 of the Act.

Section 47 of the Act broadly, gives a right of exclusivity to the patentee whereby he can exclude third parties from acts of making [“act of using” in a process patent], using, offering for sale, selling or importing for the purposes indicated hereinbefore, that product [“that process” in the case of process patent] in India as long as they do not have the consent of the patentee.

Section 64 of the Act confers a right of revocation of a patent. Thus, any person interested [or the Central Government] can seek revocation of a patent by either moving the appellate board constituted under the Act or by filing a counter-claim in an infringement suit filed before any high court.

The court observed that the fact that the plaintiffs have taken out an infringement action both for IN 147 and IN 625 is a sufficient clue, at least at this juncture, that DAPA is claimed in both suit patents. It seems incongruous to the court that a patent holder can take out an infringement action for a patent and yet ever it is not disclosed.

In the present case, the Indian genus patent i.e. IN 147 bears the priority dates 12.10.1999 and 05.04.2000 whereas the Indian species patent i.e. IN 625 bears 20.05.2002 as its priority date. For the purposes of Section 64(1)(a) this ingredient is sufficient.

Therefore, as long as the defendant can establish that the inventions so far claimed in any claim of the complete specification [in this caseIN 625] was a valid claim of an earlier priority date contained in the complete specification of another patent [i.e. IN 147], a ground for revocation is made out.

Applying these principles, it can be said that the arguments of the plaintiffs that DAPA was not claimed in IN 147 seem to be untenable at this stage.

Concerning the balance of convenience and irreparable harm the court held that the defendants have been able to set up a credible challenge and/or establish, at least at the preliminary injunction stage, the vulnerability of the suit patents, even if the balance of convenience is in favour of the plaintiffs, the injunction cannot be granted.

On the other hand, if the plaintiffs had established a strong prima facie case for grant of a preliminary injunction, they would still have to satisfy the court as to whether or not the balance of convenience was in their favour and that denial of interim relief would cause irreparable damage.

In this background, the court examined the rival contentions made by the parties.

- The plaintiffs claim that the Indian genus patent i.e. IN 147 survived its full validity period and the Indian species patent i.e. IN 625 is in 18th year of its lifecycle.
- The plaintiffs' product is being sold in India since 2015 at reasonable prices.
- The defendants, according to the plaintiffs, should be asked to "clear the way" as contemplated in Merck Sharp and Dohme Corporation and Ors. vs. Glenmark Pharmaceuticals, MANU/DE/0852/2015 by following any of the following rules :

. i. Seeking voluntary license;
ii. Seeking compulsory license;
iii. Filing revocations;
iv. Filing pre-grant opposition and post-grant opposition; and
v. Filing a declaratory action for non-infringement.

The Court held that to decline injunction, in addition to what stated above, is also the fact that in this case, damages if proved at trial, appear to be compensable. The defendants have averred that the plaintiffs have, possibly, licensed their rights under the suit patents to two entities i.e. Sun and Abbott. The packaging of the products of the drug sold through these entities is indicative of this aspect.

The Court further observed that the plaintiffs, however, for reasons best known to them have not placed on record the agreements arrived at with these entities in support of their plea. Therefore, it has to be inferred that the said entities are licensees.

Further, the plaintiffs also aver that they are importing their drug into the country. Therefore, the plaintiffs seek to monetize their invention.

Thus, at the end of the trial, if they were to succeed, they could be granted damages, if proved, under the law.

The court further observed that *" Clearly, the difference in prices of drugs ranges between 250% to 350%. Therefore, as is apparent, if defendants were allowed to manufacture and market their drugs, it would be far cheaper. Concerns as to the quality, at this juncture, appear to be a self-serving argument*."

Conclusion

The market for dapagliflozin is at around Rs 360 crore and growing at the rate of 29% per annum. This judgement of the Delhi High Court gives tremendous business opportunities for generic brands and manufacturers in

India who already had launched the product and those who intend to launch.

[1] CS (*COMM) No. 410/2020 DHC)*

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