IP Hotline

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THE DELHI HIGH COURT RULES ON THE SCOPE OF THE BOLAR EXCEPTION

In a recent judgment[1], the Delhi High Court held that:

- In considering a situation where the plaintiff is opposing defendant's sale/export patented products under Section 107A, the court must examine whether the concerns of the plaintiff constitute a legitimate ground;
- Sale of a patented product for profit does not disqualify a party from claiming exception under Section 107A, so long as the product sold was ultimately used for research and development.

FACTS

- Merck Sharp and Dohme Corporation ("**Plaintiff**") is the owner of patent no. 209816 ("**IN 816**") which covers the drug Sitagliptin ("**Drug**"). IN 816 is valid till July 2022.
- The Plaintiff sought an injunction against SMS Pharmaceuticals Ltd. ("**Defendant**"), alleging that Defendant was infringing IN 816 on the following grounds:

  (i) The Defendant included the Drug on its website under the category of Active Pharmaceutical Ingredients ("**APIs**"); (ii) Sitagliptin Hydrochloride was listed under the "Current Product List" on the Defendant's website; (iii) Defendant was offering the Sitagliptin API through its business profile on various Indian ecommerce websites; (iv) an environmental impact assessment report filed by the Defendant claiming that its manufacturing capacity for Sitagliplin API would be 10 tonnes per month after its expansion; (v) export-import data of the Defendant showing that it had exported the Drug from 2017-2020; (vi) The Defendant offered to sell the Drug to an investigator appointed by the Plaintiff at INR 1 lakh per kg.
- Based on this evidence, the Delhi High Court ("**Court**") granted an interim injunction against the Defendant on October 21, 2020.
- The Defendant filed an application to modify the interim injunction to allow manufacture and export of Sitagliptin API in accordance with Section 107A (i.e. the Bolar provision) of the Patents Act, 1970 ("**Patents Act**").

DEFENDANT'S CONTENTIONS

- The Defendant was manufacturing and exporting Sitagliptin API for research and development purposes and therefore such manufacturing and export was exempted from the purview of infringement under Section 107A of the Patents Act[2].
- The Defendant's license under the Drugs and Cosmetics Act, 1940 ("**D&C Act**") for manufacture of Sitagliptin API was solely for the export of specified quantities.
- The Defendant was exporting the Drug to its group companies for conducting research and development for generic drugs.
- The quantities of the Drug exported by the Defendant were within the permitted quantities as specified under the approvals obtained by the Defendant under the D&C Act.
- Since IN 816 was due to expire in 2022, there was urgent necessity for research and development on the API to make the generic drug publically available affordably.

PLAINTIFF'S CONTENTIONS

- Section 107A has been frequently misused for commercial exploitation in the past, despite permission being granted only for research and development. Thus, permission to export under this section should not be granted as a matter of course, and must require a party to place sufficient evidence on record to prove its *bona fide*, as held in *Bayer Corporation v. Union of India.*
- Conditions laid down in the *Bayer Corporation* judgment had not been complied with by the Defendant. The *Bayer Corporation* judgment laid down factors that a court would have to adjudicate during an enquiry under Section 107A, including: (a) the patent granted; (b) nature of product sought to be exported; (c) quantity sought to be exported; (d) particulars related to end use of the product to establish the research and development requirement.
- The Plaintiff had no remedy against the entities purchasing the Drug from the Defendant in other jurisdictions, if the Drug was being commercially exploited by them.
- The Defendant could not claim any urgency in developing generic version of the Drug before expiry of IN 816, since it has been exporting the Drug since 2016. Further, the exports total almost 800 kg, which was so large that it could not be treated as being in relation to research and development.

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JUDGMENT

The Court allowed the Defendant's application seeking modification of the order of injunction to allow the Defendant to export the Drug based on the following:

- Following the judgment in *Bayer Corporation*, the Court held that exports of patented products are permissible under Section 107A as long as it is proved that such exports are reasonably related to research and development. The Court noted that while granting permission to export under Section 107A, the court must consider the *bona fides* of the party seeking to make such export.
- In the *Bayer Corporation* judgment, the court has held that volume of the patented product which may be required for research and development could not be prescribed by a single norm.
- The Plaintiff's difficulty in verifying whether the foreign entities receiving the Defendant's exports were commercially exploiting the drug, cannot be the basis to deny benefit under Section 107A to the Defendant.
- The Bolar exception under Section 107A would be rendered otiose if the court were to insist that exports under this section could only be made to sister concerns of the Defendant.
- A seller may export/sell a patented product at a profit without being disqualified under Section 107A, as long as the product is ultimately to be used for research and development. Commercial gain of a defendant cannot be a consideration while applying Section 107A.
- Defendant was directed to file an affidavit stating that it would only export the Drug to specific buyers, and that the export was for the purposes of research and development. The court also directed the Defendant to place on record undertakings from recipients of the export in foreign jurisdictions stating that the drug would be used only for research and development.
- The Plaintiff has permitted a third party, M/s Honour Lab Limited ("**HLL**"), to export the Drug pursuant to an order of the court allowing an application by HLL to export. Denial of a like benefit would place the Defendant at a disadvantage *vis-a-vis* HLL. The court must adopt a like approach to like situations.

COMMENTS

The Delhi High Court's present judgment is the most recent interpretation of the Bolar exception, and goes a long way in reiterating the judgment in *Bayer Corporation*.

The Court has once again reiterated that it is not the quantities exported but the conduct of the defendant which is relevant to determine if permission must be refused to sale/export under Section 107A. Patentees therefore must be able to establish through evidence that the defendant's sale/export is for commercial exploitation.

To protect their interests, entities exporting a patented product outside of India for purposes mentioned under Section 107A to an entity in another country should obtain appropriate representations backed by indemnities from the importing party to the effect that they will use the exported product solely for the purpose of obtaining regulatory approval and not for commercial exploitation. Interestingly, in this case, the court has also directed the foreign purchasers of the drug to provide undertakings that they would not commercially exploit the drug.

– Athira Sankar & Aparna Gaur
You can direct your queries or comments to the authors

[1] *Merck Sharp and Dohme Corp v. SMS Pharmaceuticals Ltd.,, CS (COMM) 463/2020*

[2] Section 107A (a) of the Patents Act states that: "*For the purposes of this Act,—*
(a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product;

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