IP Hotline

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EXPORT OF PATENTED PRODUCT BY A NON-PATENTEE FOR OBTAINING REGULATORY APPROVAL ALLOWED: DELHI HIGH COURT

The Delhi High Court has held that:

- Sale under Section 107A(a) of the Patents Act, 1970 includes export of a patented product by a non-patentee
- A non-patentee can sell (including export), use, etc. a patented product under Section 107A(a) so long as the end use and purpose of such sale, export, use, etc. is reasonably related to research and development of information in compliance with the relevant regulations in India or the importing country.

The Division Bench of the Delhi High Court has held that export of a patented product by a non-patentee for the purpose of obtaining regulatory approval is allowed under Section 107A(a) of the Patents Act, 1970 ("**the Act**") and therefore does not amount to infringement. The Court laid down guidelines to be followed by courts in an infringement action to determine whether a Defendant's exports are in fact for research purposes under Section 107A(a).

Section 107A reads:

> *107A Certain acts not to be considered as infringement. -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;*
> b. *importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product,*
>
> *shall not be considered as a infringement of patent rights.*

BACKGROUND

The judgment was a result of appeals against the combined judgment of the Single Judge passed in two separate actions by Bayer:

a. A writ petition[1] filed by Bayer seeking directions from the Court to direct Customs Authorities to seize all exports of Sorafenat made by Natco which formed subject matter of Bayer's Patent No.215758 and
b. a suit[2] filed against Alembic to injunct Alembic Pharmaceuticals Ltd. from making, selling, distributing, advertising, exporting, offering for sale and in any manner directly or indirectly dealing in "RIVAROXABAN' and any product that infringes Bayer's patent IN 211300.

The Defendant/Respondent in both actions alleged that export of the patented product was for the purpose of obtaining regulatory approvals in other countries and therefore did not amount to infringement under Section 107A(a) of the Act. It was argued that Section 107A(a) allowed sale of a patented product for research purposes and "sale" within the meaning of the provision includes export.

The Single Judge held that the "*language of Section 107A of Patents Act permits exports from India of a patented invention solely for uses reasonably related to the development and submission of information required under any law in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product.*"

KEY FINDINGS OF THE DIVISION BENCH:

A. "Sale" under Section 107A(a) includes "export"

Bayer's arguments:

i. **Section 107A(a) does not specifically mention "export"** - Section 84[3] and 92A[4] specifically mention exports whereas the legislature has excluded the term from Section 107A(a). Therefore, the intent of the legislature was to exclude exports of patented products from the purview of Section 107A(a).
ii. **Export can only be of information for obtaining regulatory approval and not of the patented product** - Section 107A(a) permits carrying out activities mentioned therein (sale, use, manufacture) in India for the purpose of generating data which may then be submitted before the regulatory authority in India or a country other than India. Therefore, according to Bayer's interpretation, the transfer from India to another country is only of information and not the patented product itself.
iii. **Section 107A(a) is an exception to Section 48[5] of the Act and therefore cannot be interpreted in a manner wider than Section 48** –Section 48 gives a patentee the right to sell in India only. Therefore, Section 107A(a) cannot be interpreted in a manner to grant an additional right to a non-patentee, i.e. export of the patented product.

Arguments by Natco/Alembic:

i. As per the plain meaning of the provision, export of the patented product itself is allowed solely for the purposes mentioned in Section 107A(a). Natco/Alembic relied on judgments to argue that "sale" would include "export". It was also highlighted that the laws of many countries require studies to be conducted within the country for obtaining regulatory approval. In such cases, non-patentees cannot rely on information from studies conducted in India for obtaining regulatory approval.
ii. Section 107A is not a proviso to or an exception to Section 48 but is an independent provision giving rights to a non-patentee.

Court's holding:

i. The Court held that "sale" under Section 107A(a) includes export. The Court rejected Bayer's interpretation of the provision and held that the provision cannot be interpreted in a restrictive manner to mean transfer of only information and not of the patented product itself from India to other countries. The Court held that the key is to determine the purpose of the sale, i.e. the objective of carrying on experiment, research and developing information. As long as the purpose of sale is research to prepare for obtaining regulatory approval, the provision cannot be interpreted in a restricted manner.
ii. Regarding express mention of the term "export" in certain other provisions of the Act, the Court noted that the objectives behind Sections 84 and 92A[6] are different – these provisions deal with compulsory licensing whereas Section 107A(a) deals with an exception when use of a patented product is for research purposes and therefore considering the different objects behind the provisions, the terms used therein cannot be interpreted in a similar manner.
iii. The Court also considered the history and the object behind enactment of Section 107A and held that Section 107A is an independent provision and cannot be read as a proviso to Section 48 and therefore, its scope cannot be limited.

B. Test to regulate the use of Section 107A(a) exemption

The Court noted that different countries have different requirements of quantities to be used in studies, where the studies are to be conducted and therefore there can be no rigid rule to determine whether section 107A(a) applies and each case will have to be decided on an analysis of the evidence including proof of the relevant regulatory requirements. The key is to determine the intent of use, i.e. it must be determined whether the use of the patented product is for commercial purposes.

The Court also laid down certain guidelines to be considered by courts to determine whether use, sale, etc. is "reasonably related" to the purpose of development of information to be used to obtain regulatory approvals. It was held that in a case where a plaintiff alleges infringement on account of exports or an exporter seeking a declaration of non-infringement on account of exports under Section 107A(a), courts should consider the following, and any other matter that may be relevant:

1. The patent granted;
2. The nature of the product or elements sought to be exported;
3. The details of the party importing the product;
4. The quantity sought to be exported;
5. Other particulars with respect to the end use of the product, to establish that it is solely for research and development of information to regulatory authorities in the other country;
6. All particulars regarding the relevant regulations, covering the kind and scope of inquiry, including the quantities of the product (i.e the patented product or compound, API or fine chemical needed). These details have to be provided by the exporter/seller of the product. The Court clarified that in case the defendant is not the seller, it should disclose who had purchased the product in the relevant quantities, to assist the court in impleading the relevant party in the proceedings;
7. If the regulations are in another language, the defendant must provide an authentic English

translation to facilitate a speedy resolution;

8. If necessary, court can order verification through the Indian mission (and its trade division) abroad regarding the authentication of the third party and/ or its facilities abroad.

It was further held that during adjudication of such matters, courts should issue appropriate interim orders requiring the Defendant to give an undertaking by way of affidavit to compensate the plaintiff, specifying the extent of such monetary compensation, in the event the court eventually held that the Defendant's acts amounted to infringement and the suit were to be decreed in favour of the plaintiff and the extent of such monetary compensation.

This affidavit should be:

a. of an authorized personnel;
b. kept alive during the pendency of litigation;
c. duly authenticated by the board of director or other controlling body of the defendant, and;
d. whenever the company or entity undergoes amalgamation or transfer, suitable undertaking from the successor organization should be obtained;

Lastly, to protect exporters of generic drugs against frivolous litigation by patentees, the Court held that if it is held by the court that the exporter is not involved in sale or export of any patented product, but a generic article, unprotected by patent law, when denying relief, suitable restitutionary relief should be awarded to the defendants in monetary terms, to preclude litigation that prevents trade or competition.

C. Disputes related to sale of patented products under Section 107A(a) are subject matter of civil suits

The Court held that since an adjudication under Section 107A(a) involves investigation into facts and could result in reliefs to private parties for enforcement of private rights, i.e. patent rights, such disputes cannot form subject-matter of writ proceedings but should be filed as civil suits.

The Court also noted that it cannot issue blanket directions of any kind to Customs authorities related to mandatory seizure, prohibition or labelling requirements since such aspects are within the domain of the executive and cannot be decided by courts.

KEY TAKEAWAYS FROM THE DECISION:

The judgment is a landmark decision in relation to use of patented products by non-patentees. While the Court has allowed exports for obtaining regulatory approval, the extensive guidelines laid down, including the requirement to provide an undertaking to compensate the plaintiff, will ensure protection of the rights of a patentee in the event patented products are being exported for commercial exploitation under the garb of Section 107A(a).

Patentees should conduct proper due diligence before filing an infringement suit against a non-patentee exporting a product covered by their patent. In the event in the infringement proceedings the defendant is able to prove that their product is not the patentee's patented product but is a generic drug, the patentees could be asked to compensate the defendant, as laid down by the court. To establish that the Plaintiff conducted proper due diligence before filing a suit, patentee can place on record reports of tests conducted on the defendant's product, if it is possible to obtain the product. Patentees could to the extent possible gather information about packaging material, export details including details of country of export, quantities exported to determine if the laws of such country require tests to be conducted in that country.

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.

– Aparna Gaur & Gowree Gokhale
You can direct your queries or comments to the authors

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[1] W.P.(C) No.1971/2014

[2] CS(COMM) No. 1592/2016

[3] Section 84 deals with compulsory licenses ("**CL**") – the grounds for grant of a CL; procedure to be followed and factors to be considered by the Controller for grant of a CL. Section 84(7)(a) mentions exports in the following manner:

(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied-

(a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,-

(i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or

(ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or

(iii) a market for ***export*** *of the patented article manufactured in India is not being supplied or developed; or*

(iv) the establishment or development of commercial activities in India is prejudiced;

[4] Section 92A deals with compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances.

[5] Section 48. Rights of patentees—

Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee—

(a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India;

(b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India

[6] *Sections 84 and 92A fall under Chapter XVI dealing with "Working of Patents, Compulsory Licenses and Revocation."*
