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## BOLAR PROVISION: A METICULOUS EXCEPTION TO PATENT MONOPOLY

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In a recent judgement, the Division Bench of the Delhi High Court (Court), decided on the two appeals filed by *Bayer Corporation (Bayer)* - one from the decision of the Learned Single Judge in a writ petition, filed by Bayer against the Natco Pharma Limited (Natco) (Bayer Corporation v Union of India & Ors, LPA No 359/2017)and the second, in a suit filed by Bayer against Alembic Chemicals Ltd (Alembic) (Bayer Intellectual Property GMBH & Anr v Alembic Pharmaceuticals Ltd, RFA(OS)(Comm) 6/2017)), both appeals involved identical issues pertaining to the interpretation of Section 107A of the Patents Act, 1970 (the Act), commonly known as the 'Bolar' provision.

### Background

Inventions pertaining to the pharmaceutical domain require certain pre-authorisations from different regulatory authorities before the product can be made available to the public. These pre-authorisations are granted upon the submission of the data obtained through clinical trials, for which the patented pharmaceutical product must be manufactured.

The Bolar provision is a defence for patent infringement wherein a patented invention (that is due to expire in the next three years) can be exploited by a third party solely for research and development purposes and to obtain the required regulatory approvals, while the patent is still valid.

India introduced product patents through the Patents Amendment Act, 2005 (Amendment Act). It was at this time that the Amendment Act also introduced Section 107A, mainly with an intent to ensure the availability of the drug (product patent) in the Indian market immediately after the expiry of the term of such a patent.

Section 107A of the Act provides an exception to patent infringement. It allows making, constructing, selling or importing of a patented invention solely for reasonable use related to research and development and for the submission of such information generated during the experimentation, before regulatory authorities for approvals. The intent of this exception was to ensure the prompt availability of patented products, particularly pharmaceutical products with the necessary regulatory approval for market launch, immediately after expiry of the term of the patent.

In the absence of Section 107 A of the Act, availability of patented products or their alternatives or substitutes from third party manufacturers, immediately after the expiry of the term of the patent would have been difficult to achieve. The reason for this is the lengthy process involved in pre-authorization of the pharmaceutical products which could in fact lead to the indirect extension of the patentee's monopoly over the

pharmaceutical product in question. To cater to this, the "research exemptions" or "Bolar exemption", was introduced in Section 107A by the Amendment Act which is in consonance with TRIPS (the Agreement on Trade-Related Aspects of Intellectual Property Rights).

### Brief facts

In Natco's case, Bayer filed a suit for injunction against Natco from making, importing, selling, offering for sale '*Sorafenib*', '*Sorafenib Tosylate*' (commonly known by its product name 'Nexavar') or any generic version or any other drug or product thereof which was a subject matter of Bayer's Patent No. 215758. While this suit was pending, Natco was granted a compulsory license by the Patent Office under section 84 of the Patents Act, 1970. The compulsory license granted was solely for the purpose of making, using, offering to sell and selling the drug covered by the patent within the territory of India. However, Natco manufactured the patented product under a compulsory license for export outside India against which Bayer filed a writ petition bearing Bayer Corporation v Union of India and others, WP(C) 1971 of 2014 on 25 March 2014. Bayer contested this on the grounds that the product did not qualify for the exemption contemplated under Section 107A of the Act and that such an act on part of Natco amounted to a commercial sale and hence a patent infringement. Bayer's interpretation of Section 107A of the Act was that the provision mentions the word "sale" and also "import", but the legislature consciously excluded the term "export" and thus such export by Natco was clearly an infringement of the patent held by Bayer. Natco, on the other hand, contended that Section 107A of the Act, also allowed 'exports' of the patented product for the purpose of drug development subject to laws of the country to where the products were to be exported.

In Alembic's case, Alembic was found manufacturing and exporting approximately 90 kg of *Rivaroxaban* worth INR 3 crores to the European Union. Bayer contended that such export amounted to an infringement and that Alembic could not take recourse to Section 107A of the Act. Thus, Bayer filed a suit against Alembic seeking an injunction against Alembic from making, selling, distributing, advertising, exporting, offering for sale and in any manner directly or indirectly dealing in *Rivaroxaban* and any product that infringed Bayer's Patent IN 211300.

Alembic denied the said contentions and stated that the exports effected by it were covered under Section 107A of the Act and that it had not commercially launched *Rivaroxaban* but had only exported it within the meaning of Section 107A of the Act.

Bayer did not succeed in both the above cases and hence appealed. In the appeal, the Division Bench primarily decided on the interpretation of Section 107A of the Act.

### Decision

The Court observed that Section 107A of the Act is not made subject to other provisions of the Act. On the other hand, Section 48 (governing 'rights of the patentee') is subject to the provisions of the Act including Section 107A of the Act. Section 107A of the Act is an independent provision which was enacted in compliance with TRIPS mainly to facilitate research and progress in the fields that are covered by patents. Hence Section 107A of the Act cannot be constituted as an exception to Section 48.

The Court held that, as per the provisions of Section 107A of the Act, a patented invention/product can be 'sold' for the purpose of carrying on research subject to regulatory laws of the country where it is exported. There cannot be an interpretation or any bar which narrows down the scope of the term 'sale' as used in Section 107A of the Act. The Court held that the term "exports" is used in different contexts in Sections 84, 90 and 92A of the Act; all of which in some way or the other primarily deal with compulsory licensing. This cannot be led to mean that the absence of the term 'export'

in Section 107A of the Act would in any way limit the sale of the patented invention/product for research purposes only to India.

The Court further held that neither the quantity used nor the place of research and development or information (i.e. within the country granting patent or on foreign soil) is *per se* conclusive that the claim to use the Bolar exemption or research exemption has to be rejected. The important aspect is the purpose of the sale i.e. the objective of carrying on the experiment, research and development of information. The expressions of Section 107A of the Act cannot be given a narrow interpretation in the case of sale, construction or use of the patented article, either within India or outside the territory of India. The question of infringement cannot arise if the object or purpose of that transaction is solely to experiment or research and develop information that is reasonably related to the requirements of the law (Indian or overseas).

***Comment***

The decision of the Court, arising out of the two pleas filed by Bayer, has created jurisprudence for deciding the scope of Section 107A of the Act.

The tenet of patent law is to provide exclusive monopoly to the patentee for 20 years, subject to certain provisions the Act. Thus, a patented invention can be exploited, without the consent of the patentee, only after the expiry of the term of the patent. However, the "research exemptions" or "Bolar exception", introduced under Section 107A of the Act allows use of the patented inventions/products for research and development.

The decision of the Court and its interpretation of the Section 107A of the Act i.e. Section 107A of the Act includes 'exports' of a patented invention/product to a third party outside India as long as the purpose of 'export' is the facilitation of research and it appears to be in harmony with various international laws. However, this kind of exemption may be misused and may affect certain innovator companies who invest significant amount of time and effort in research and development of a patent molecule or product. This decision is certainly hailed by local companies who are awaiting to enter the market immediately upon the expiry of a patent.

It would be interesting to see if the Supreme Court takes a different view in case the decision is sought to be tested.

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