

## ***Bolar Provision: An Experimental Use Exception to Patent Monopoly***

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### **Abstract**

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 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 Patent Act deals with Bolar provision, it's 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.

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.

This research paper through light on how the decision of the Delhi Court and its interpretation of the Section 107A of the Act has clarified certain issues, which there was no clarity previously. Paper also focuses on whether this decision is certainly hailed by local companies who are waiting to enter the market immediately upon the expiry of a patent.

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## 1. Introduction

A patent is an exclusive monopoly right, which most modern business owners leverage to optimize the commercialisation of their intellectual inventions. Indian patent law enables a patentee to exclude others from making, using, selling, offering for sale or importing their patented invention without their consent. The patentee is entitled to seek relief in case of an infringement, which includes an injunction, damages or an account of profits. However, certain acts of making, using, selling or importing a patented invention by a third party, even without the consent of the patentee, are not considered to be an act of infringement. Section 107(A) of the Patent Law – which is referred to as the ‘Bolar provision’ or ‘Bolar exemption’ – is a safeguard against patent infringement, especially significant to pharmaceutical drugs. The exemption was so named after the landmark US case *Roche Products v Bolar Pharmaceuticals*<sup>1</sup> wherein it was held that Bolar’s use of the patented compound for federally mandated testing was an infringement of the patent. However, soon after this judgment, the US Congress overturned the decision by enacting a law permitting the use of patented inventions in research to seek Food and Drug Administration approval.

While the provision had been sitting idly in the statute since 2003, it came into play after India embraced the product patent regime in 2005. The provision subsumes research exemption as a defence, according to which, the use of a patented invention in research to generate clinic trial data for regulatory approval is not considered an act of infringement. Before the expiry of the patent term, pharmaceutical patentees have, in general, monopolistic rights over patented drugs to restrain competitors from launching generic versions of the drug in the market.<sup>2</sup> This monopolistic exclusion in effect provided an opportunity to innovator companies to extend the term beyond 20 years until generic versions are launched in the market. Understandably, clinical trials with patients take several years, pursuant to which the data generated is submitted to the Central Drug Standard Control Organisation for the evaluation of safety and efficacy. Most generic drug manufacturers enjoy the safeguard of the Bolar exemption to formulate generic drugs prior to patent expiration. The Bolar exemption provides generic drug manufacturers ample time to conduct their research so that they can introduce their products into the market soon after the expiry of the innovator’s patents. In addition, the provision has been credited for ensuring continuous supply of life saving drugs in the market.<sup>3</sup>

## 2. Origin of the Bolar Exception Concept

The grant of a patent for an invention confers on the patentee or patent owner, where the subject matter of the patent is a product, the exclusive right to prevent third parties which do not have

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<sup>1</sup> 733 F.2d 858 (Fed. Cir. 1984)

<sup>2</sup> V.K. Ahuja, Intellectual property Rights in India ( 2nd ed. Lexis nexis 2015) 577.

<sup>3</sup> Ibid

permission from the act of making, using, offering for sale, selling or importing that product in a given country for a 20-year term from the date of filing the patent application in that country. However, once the term expires, the protected invention falls into the public domain and can be used by any third party for commercial purposes without the consent of the patentee or patent owner. Pharmaceutical products cannot be manufactured and marketed without the prior authorisation of the competent regulatory authority. The time taken for the grant of such approval may vary from country to country. If a producer of a generic or similar version is bound to wait until the final day of the patent term covering a pharmaceutical product, the patentee of expired patents will continue to enjoy a *de facto* additional period of monopoly, as long as a generic version of the product obtains marketing permission from the regulatory authority. The interface between the regulations for manufacturing and marketing approval of medicines and patent law justifies the need for what has been termed the 'Bolar exception'.

The Bolar exception derives its origin in the US Federal Circuit decision *Roche Products Inc v Bolar Pharmaceutical Co Inc* (733 F2d 858, (1984)). The Federal Circuit held that the experimental use exemption to patent infringement narrowly provided under US law did not allow for testing undertaken by Bolar Pharmaceutical to obtain marketing approval of a generic product.

To overturn the decision, the Bolar exception was introduced by the US Drug Price Competition and Patent Term Restoration Act 1984 (commonly known as the 'Hatch-Waxman Act'), which intended to strike a balance between the innovator and generic pharmaceutical producers (35 USC § 271(e)(1)):

*It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.*

Subsequently, many countries (including the United Kingdom, Germany, France, Ireland, Poland, Canada, China, Singapore and India) incorporated equivalent Bolar exception provisions in their IP laws<sup>4</sup>.

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<sup>4</sup> <https://www.worldtrademarkreview.com/bolar-exception-india>

### 3. Recent Stand by Delhi HC Pertaining to Bolar Exemption

India saw another tryst with the Bolar exemption recently, which culminated in a landmark judgment rendered by the Delhi High Court in *Bayer Corporation v Union of India (2019)*<sup>5</sup>, wherein an apparently liberal and flexible interpretation of the Bolar exemption was provided. Interestingly, Sorafenib was once again one of the drugs in question. This judgment was based on two appeals filed by Bayer against the decision of the single judge in the writ petitions filed by Bayer against Natco and Alembic Chemicals to injunct the respondents from making, selling, distributing, advertising, exporting and offering for sale any product that infringed Bayer's patents with regard to the drugs Sorafenib<sup>6</sup> and Rivaroxaban<sup>7</sup> respectively.

Natco had earlier secured a compulsory licence from Bayer with respect to Sorafenib through the Indian Patent Office. Natco applied to Bayer for permission to export 1 kilogram (kg) of the active pharmaceutical ingredient Sorafenib to China to conduct a clinic trial and research the development of the drug for regulatory purposes. Bayer rejected the application and filed a writ petition, arguing that the grant of such permission to Natco would be contrary to the provisions of Section 107A, as the transaction is a commercial activity and hence infringes Bayer's rights. The court rejected Bayer's plea and held that Section 107(A) covers any sale of a patented invention which is required for the development and submission of information under any law in a country other than India that regulates the manufacture or sale of any product. It was held that the sale of 1kg of Sorafenat to the Chinese company can be reasonably stated to be related to studies that are required to be conducted by the said company for obtaining the regulatory approvals, and hence fall within the exception under Section 107A.

The division bench of the Delhi High Court passed a common order on the legal interpretation of Section 107(A) of the Patent Law in the two cases.

It was argued by Bayer that the said provision is an exception and is subject to Section 48 of the Patent Law, which confers rights on the patentee. However, the court did not agree with this reasoning and observed that the Bolar exemption in the Indian statute is an independent provision with a specific history behind it. Bayer crucially argued that the word 'selling' used in the said provision does not include exports, since the Patents Act is territorial in nature and extends to the whole of India. It was submitted that the act regulates only those activities which take place within India. Natco contended that Section 107A read with Section 48 does not prohibit export if the person concerned satisfies the conditions in Section 107A(a). Natco emphasised that the export of the active pharmaceutical ingredient for the purposes reasonably related to the submission of information is legitimate. The court was of the opinion that once it is held that patented inventions can be sold for the purpose of conducting research which fulfils the regulatory requirements of India, there cannot be any bar or any interpretation narrowing the

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<sup>5</sup> 2019 (80) PTC 486 (Del)

<sup>6</sup> LPA No 359/2017

<sup>7</sup> RFA(OS)(Comm) 6/2017

scope of such sale. The court accepted that it is plausible that many nations may require experimentation or research to be conducted nationally to be able to supervise the process and oversee the outcome. It is therefore not possible to dictate the behavior and legal requirements of other nations by confining a research exception within the territory of India. However, the court was mindful that the Bolar exemption could be misused and therefore suggested that safeguards to check unregulated export activity should be adopted.<sup>8</sup>

The judgment ultimately held that under Section 107A, sale, use and construction of patented products for purposes both within India and abroad by third parties is authorised and legal, provided that the seller ensures that the end use and purpose of the sale or export is reasonably related to the research and development of information in compliance with India's laws or that of the importing country. Further, it also held that any dispute of such sale should be relegated to civil remedies and no writ petitions under Article 226 should be entertained.

#### **4. 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.

#### **5. Conclusion**

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<sup>8</sup> <https://www.iam-media.com/patent-infringement-defences-indias-bolar-story-so-far>

related to the research and development of information in compliance with India's laws or that of the importing country. Further, it also held that any dispute of such sale should be relegated to civil remedies and no writ petitions under Article 226 should be entertained. It's a very good stand by the Delhi HC but let us wait and watch what could be stand of SC in this connection.