VOLUME 6 | ISSUE 3

INTERNATIONAL JOURNAL OF ADVANCED LEGAL RESEARCH

INNOVATION VS. ACCESSIBILITY – AN ANALYSIS OF THE BOLAR PROVISION IN INDIA

- Lakshyta Singh*

Abstract

A person who owns intellectual property usually has exclusive rights over it;however, this isn't always the case. There are several circumstances in which these exclusive rights will be restricted and the innovation may be used by a third party for legal purposes that do not constitute infringement. Bolar provision is one such provision, which is covered in further depth in this research paper. 'Bolar Provision'is amongst the key provisions in the Patents Act. Essentially, the patent holder has a monopoly over the patent for a certain period of time because of their ingenuity. However, by preventing generics and other interested parties from entering the marketplace just after the expiration of patents, since marketing permission takes not less than a year or two, they often prolong their monopoly rights. This results in a de facto monopoly for the patentee. Hence, to represssuch activities as well as to safeguard the interests of generic producers, the idea of Bolar exemption was cultivated. After the 'Roche v. Bolar' decision, the United States was the first country to implement the bolar exception in the Hatch Waxman Act. The research article sheds light on the concept of Bolar provision under The Patents Act, 1970 and its impact on innovation and accessibility of generic drugs.

KEYWORDS:*Bolar provision, Patents Act 1970, Section 107 A, Drugs and pharmaceutical inventions, Patent infringement.*

INTRODUCTION

*LL.M., Hidayatullah National Law University, Raipur

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An inventor can obtain a patent which prohibit others to make, use, import, and sell the protected invention for a specifiedtime span—typically twenty years in most of the countries. Only after a lengthy review process with a chance to oppose in front of the competent authority or obligatory proceedings before the courts, a patent is granted to the innovator which motivates him to add to the reservoir of inventions. Whilst granting exclusive right over an invention to a patent holder, it is taken into consideration that there will be situations in which some humanitarian responsibilities have to be fulfilled. It is because of this reason that the patent laws around the world provides for certain exceptions. One of these exceptions is the "Bolar Provision," also known as the "Bolar Exception" or the "Regulatory Exception". Most of the countries entered into various accords as part of WTO over the 1990s. One among them is TRIPS, under which the World Trade Organization members have a general obligation to grant patents for inventions which qualify for patent protection, but they also have wider autonomy to incorporatecertain exceptions to it in their domestic legislations, as long as they comply with certain conditions. Member countries can make available adequate exemptions under Article 30 of the TRIPS Agreement[1] with regard to patent owners' interests.

The primary role of the bolar provision is to permit some developmental research on a product that is already patented. It is of great importance for ‘the pharmaceutical and/or biotechnology industries’ insofar as bringing a drug from the research lab to market takesa long time, and filing an application for patent that is the fruit of years of experiment, study and research is just an essential initial step that must be subsequent to at least three clinical trial phases and obtaining regulatory clearances when the required data has been submitted. Thus, some patented products must be allowed to be used exclusively for research purposes without any direct commercial interest so that at least the new product can be introduced into the market soon after the expiry of a patent.Sec. 107 A[2]is the ‘Bolar provision’ in India. It permits any interested party to use or market a newly manufactured medication or drug for additional research or development without fear of facing legal retribution. This paper will now delve into various facets of the bolar provision.

[1]WIPO, https://www.wipo.int/wipolex/en/text/305907#part2.5 (last visited March 06, 2026).
[2] The Patents Act, 1970, § 107A, No. 39, Acts of Parliament, 1970 (India).

REVIEW OF LITERATURE

1. 'Bolar Exemption – A good defence against pharmaceutical patent infringement under Indian Patents Act 1970', Priyanka Rastogi, Mondaq, April 2022.

The Article describes the 'Bolar Exemption' under the Patents Act, 1970. It deals with various clauses relating to the Bolar Exemption under the Act that relates to the issue of export from a country to any other for research and developmentpurposes of patented products. It also discusses several case laws in detail.

2. 'Bolar Provision: An Exemption to Patent Exclusivity', Anuja Saraswat.

This article talks about the meaning, significance, and background of the Bolar provision.It discusses about the case of*Roche v. Bolar*[3] after which the U.S. introduced the Bolar provision in the Hatch-Waxman Act. Furthermore,it provides an in-depth analysis of the landmark case *Bayer Corporation vs. Union of India*[4].

3. 'An expansive interpretation of India's Bolar exception: Critically analyzing the case of Bayer Corporation v. Union of India & Others', Urvika Agarwal, Manupatra.

This paper critically reviews the '*Bayer Corporation v. Union of India*' case. It analyses how India has interpreted the Bolar exceptionunder the Patents Act 1970. It discusses how "sale" was interpreted to include "export," and examines how Sections 48 and 107A interlink. It further highlights the importance for pharmaceutical patents and public health.

RESEARCH OBJECTIVES

1. To understand the concept of Bolar provision.
2. To trace the origin and background of Bolar Provision.
3. To analyze case laws related to Bolar Provision.
4. To analyze section 107 A of Patents Act, 1970.

[3]Roche v. Bolar,733 F.2d 858 (Fed. Cir. 1984).
[4]Bayer Corporation vs. Union of India, 162(2009) DLT 371.

RESEARCH QUESTIONS

1. What is the Bolar exception?
2. What is the background and origin of Bolar provision and how it impacts innovation and accessibility of generic drugs?
3. How section 107 A of Patents Act is interpreted?

RESEARCH METHODOLOGY

This research paper employs doctrinal methodology, characterized by its descriptive nature. The author has primarily relied on secondary sources of data. References include books, articles, and online databases such as Manupatra, Supreme Court Cases (SCC), and various law journals. A consistent citation style has been maintained throughout the paper .

BOLAR PROVISION – MEANING AND ORIGIN

A patent gives an inventor an exclusive legal right to use, sell or distribute a patented invention for a duration of 20 years. It gives a registered patent holder the ability to stop others from monopolizing his invention in the public sphere. However,this general rule has few exceptions, a situation where a third party may sell, use, or alter the protected inventions without violating the rights of the patentee. One of these exceptions is named as "Bolar Exemption" under the Patents Act of 1970.

Our country is known for its medicine over the globe. India produces and exports medicines worldwide and is a party to the TRIPS agreement that allows the nations to formulate fair patent exceptions (Article 30). Consequently, Section 107-A was incorporated as an exemption under The Patent Act. It is widely called as ‘Bolar exemption’.According to this section, any other third party is allowed to make, construct, use, sell or import a patented invention without any fear or concern ofpatent infringementto place on the market a freshly formulated item for further experiments or development in research.

The ‘Bolar provision’ is one of the vital in the Patents Act. The U.S.A. first introduced the ‘Bolar provision’ in the ‘Hatch Waxman Act of 1984’ as, "It will not be a demonstration of encroachment to make, use, offer to sell, or sell inside the United States or import into the United

States a protected creation exclusively for purposes sensibly related to the improvement and accommodation of data under a Federal law that directs the assembling, use, or clearance of medications or veterinary organic items."[5]

Patent holders obtain monopoly or the exclusive right over their invention for a limited time period. Approval to launch a drug in the market is just the beginning as it could get delayed due to various reasons such as regulatory holdups, supply chain issues and internal delays. Thus, it may prolong the monopoly rights of the patentee by preventing generic and thirdparty entrants to set foot in the market once the patent nears its expiry date. Such a situation thereby grants the patentees a de facto monopoly over their patent.For the purpose to prevent such acts and safeguard the interests of generic producers, the idea of bolar exemption or research exemption was developed.

In the case of *Roche Products Inc. v. Bolar Pharmaceutical Co.*the U.S. Court of Appeals for the Federal Circuit ruled that Bolar had infringed Roche's patent on its prescription drug, flurazepam hydrochloride, by using it to gain FDA clearance before the patent had expired. Bolar argued that the experimental use was too narrow to cover commercial purposes. However, the court rejected this argument and dismissed Bolar's defense. As legislative solutions, such as the Hatch-Waxman Act of 1984 were still pending, public policy arguments in favor of the availability of generic drugs were also rejected. The "Bolar exception" was eventually created as a result of this historic case which then allowed the restricted patent use for regulatory approval processes.

Since then,the Bolar provision has been incorporated by various countries. In India, section 107A was added through Amendment Act 38 of 2002 in The Patents Act, 1970, which is somewhat comparable to the research exemption provided under Canada's Bolar exemption. One of the main goals of licensing is to promote creativity and the creation of new innovations. In order to do thisIndia offers incentives to innovators such as market exclusivity this lasts for 20 years. To ensure general health the government must take a more comprehensive approach when awarding pharmaceutical licenses which includes encouraging new research and improving the affordability and accessibility of pharmaceutical goods and medications.

[5]Hatch Waxman Act of 1984, U.S.A.

The Bolar exception was incorporatedby giving consideration for the accessibility of pharmaceutical drugs, which helped to restrain the patentees' repressive commercial practices and market discrimination. The primary goal of this arrangement was to help nonexclusive pharmaceutical manufacturers. The arrangement was a crucial requirement since millions of people in developing countries continue to die from infections that may be treated with medication at once, and can be treated with generic medications which are even more affordable.

As far as how broad or restricted the provision is, the legislations of the European nations differ from one another. For example, the UK offers a more limited and restricted exemption, while others such as Germany and France provide a more expansive one. In the year 2012, UK Intellectual property office engaged with the Stake holders to find out if the law needs to be changed so as to give an exception from patent infringementfor operations linked to planning or performing clinical or field investigations concerning novel medications after which the amended guidelines were introduced that broadened the scope of bolar provision in the UK. The USA too has this exception, but solely for medical research and development, which is likewise managed at the state level under a federal framework. In contrast, India has a fairly expansive definition of bolar exemption that includes export, enabling nations to import the protected article for scientific study without the patentee’s approval. In this sense, it is necessary to investigate the underlying rationale behind the existence of this provision.

BOLAR PROVISION IN INDIA

One of the defenses against patent infringement is S. 107(A) of the Patents Act. This is especially important for drugs and pharmaceutical inventions from the perspective of the Indian Patent Act, 1970. This provision enables any generic drug producer to use or sell an innovation, such as newly created drugs, for research or development without fear of any legal action. Section 107 (A) read as –

"(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 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 authorized under the law to produce and sell or distribute the product], shall not be considered as an infringement of patent rights."[6]

In India, the Bolar exemption has a wider ambit. From the point of view of Section.107 A[7] which says, "…Development and submission of information required under any law for the time being in force in India." It would not be wrong to assume that this path can be used by the generic manufacturers and producers in the clinical development and trial and to file application for the generic products of patent protected medicines, since both the clinical trial and the market approvalapplication fall into gamut of the necessary information needed by the controller under the Acts like'The Drugs and Cosmetics Act, 1940 and the Rules, 1945'.

It's important to note that there aren't many case laws in India that relates to the Bolar exemption; in fact, there is just one case in which clinical trials are cited as part of the exemption i.e. *Bayer Corporation v. Union of India & Ors.*[8]where the Delhi HC stated that "Section 107(A) is in line with the TRIPS agreement, international guidelines, and Article 47, 21 of the Indian Constitution upholds export as a valid part of the bolar exemption. So, exporting for research and clinical trials comes under the scope of Section 107(A) as the bolar exemption and there will be no impairment of the patentee's rights."[9] Furthermore,the court held that the "export" of a protected medication is permissible as per Sec 107A(a), provided it is reasonably related to conducting experiments and submitting details to foreign regulative authorities. The case was then remanded to the trial court to decide the purpose behind 'Natco and Alembic's' export of plaintiff's drug, 'sorafenib tosylate.' What makes this ruling particularly interesting is that, despite the contested provision not explicitly mentioning "export," the Court has allowed it under specific conditions.

Bolar Provision is an exception to patent infringement. After an innovation has been invented, a third party may use it or sell it for particular uses to generate more funds to finance further research and development. This clause is so important to generic medication makers who want to

[6] The Patents Act, 1970, § 107A, No. 39, Acts of Parliament, 1970 (India).
[7] The Patents Act, 1970, No. 39, Acts of Parliament, 1970 (India).
[8]Bayer Corporation v. Union of India & Ors., 162(2009) DLT 371.
[9] Priyanka Rastogi,*Bolar Exemption – A good defence against pharmaceutical patent infringement under Indian Patents Act 1970*, MONDAQ(March 06, 2026, 11.23 pm), https://www.mondaq.com/india/patent/1185994/bolar-exemption-a-good-defense-against-pharmaceutical-patent-infringement-under-indian-patents-act.

gain more market share shortly after the patent has expired. By way of the Bolar clause, these producers are given ample space and room to carry out their product development when the patent is still in its ongoing state.

This Act, therefore, permits a drug which has patent to be employed for additional research and experimentation without the permission of the patentee if deemed necessary for society during the period of the patent. This gives drug manufacturers a chance to carry out studies even without waiting for the patent to expire. As per Sec. 48 of the Patent Act 1970, the patentee has the exclusive right of selling, using, distributing, or to monopolize the protected goods in the marketplace for the term of the patent. He also has the right of assigning his rights to any other person with his approval.

In the case of *Merck Sharp & Dohme &Anr v. Sanjeev Gupta & Ors*.[10] while deciding whether selling or producing a protected product for export constitutes infringement, Delhi HC held that Section 48 protects patents from being manufactured for export since the Patents Act of 1970 safeguards the rights of patent holders to limit the use of their patents by third parties without their consent, whether for sale, use, or any other purpose. It has, therefore, been decided through case law that Section 48 affords greater export protection, but still remained unclear whether such protection might extend to exports of protected goods used only in research. However, as discussed hereinbefore the judgement in the case of '*Bayer Corporation v. Union of India & Ors., and Bayer Intellectual Property GMBH &Anr v. Natco& Alembic Pharmaceutical Ltd.'*made this point clear.

CONCLUSION

According to Section 107 A of the Patents Act 1970, a product which is granted patent may be exported outside the country for further research, development or modification or clinical trials without consent from the patent owner. That means generic drug producers can use newly developed drugs for excellent research and testing. Even though such a product is legally protected, the manufacturer is free to use, sell, and dole out to the general people if needed. Although this provision is meant to benefit society, yet the rights of patent holders must not be

[10]Merck Sharp & Dohme &Anr v. Sanjeev Gupta & Ors.,CS(COMM) 823/2018

infringed upon or taken away entirely. The Bolar exemption is also very important because it reminds one that no one can produce patented goods only for financial gain or profit-making. People must be able to afford medications or patented technologies at low prices.All registered doctors ought to be directed by the Medical Association of India to prescribe generic drugs in order to reduce the burden of expenses on patients. In this regard, it can be said that the 'Bolar exemption' helps in providing strong protection against patent infringement for research and experiments. However, during deciding cases courts must apply reasonability test which guarantee that the use of a patented medication is non-commercial and restricted to research and testing in order to protect the patentee's rights. This broad reading of the section gives generic pharmaceutical companies a great deal of leeway to use the medicine anyway they see fit and create drug variations, provided that the usage is not for profit.