

ISSN: 2582-6433



INTERNATIONAL JOURNAL FOR LEGAL RESEARCH AND ANALYSIS

Open Access, Refereed Journal Multi Disciplinary
Peer Reviewed 6th Edition

VOLUME 2 ISSUE 7

www.ijlra.com

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PATENTABLE SUBJECT MATTER AND PATENTABILITY CRITERIA

AUTHORED BY - ABHISHEK NEMA

ABSTRACT

“The necessity is the mother of all Inventions”

With the rapidly growing economies and increase in the demands of people to continuously have an ease in the standard of living, inventions are the foremost factor of human existence. When there are inventions there is infringement and it is not necessary to have a substantial damage instead legal injury is bound to happen. Hence, law is required to safeguard the rights of people inventing something. With this vision, this paper focuses on the provisions of The patent act, 1970 relating to the invention, patents etc.

The legislation focus on picturing the rights and liabilities but the judiciary paves the way for that picture to come into existence. Therefore, the judgments of courts across nation have their own interpretation over the unending debate on the criteria of patents which is the prime focus of this paper and concluding by imposing remarks keeping in mind the will power of judiciary to make the laws enforceable!

Keywords: **invention, patentability, novel, industrial application,**

INTRODUCTION

With progress in science and technology, the range of IP continues to broaden. All intellectual property rights, including patents, copyrights, trademarks, industrial designs, etc., fall under its remit. When someone comes up with a novel concept, piece of technology, or innovation, they often go to intellectual property law to secure their rights to the creation. There are three main tenets of patent law: innovation, uniqueness, and practicality. The Patents Act of 1970, as revised by the Patents (Amendment) Act of 2002 and the Patents (Amendment) Act of 2005, is the primary piece of

An invention patent is an example of industrial property that falls under the purview of intellectual property today. If you come up with a new and valuable product, or if you improve an existing product, or if you come up with a new way to make those items, you may be eligible for a patent, which gives you the exclusive right to sell those products and make money off of them. Obtaining a patent for an innovation requires, it has to pass the test of:

- Foremost important Novelty,
- Distinguishing factor is Non-obviousness and
- Utility of the said invention.

The Paper intends to explain the meaning, objectives, terms, and advantages of a patent and the test imposed by statutes and judiciary that an invention has to undergo in India to get a patent.

RESEARCH QUESTIONS:

- What are the provisions of patentable criteria under The Patents Act, 1970?
- Whether the Patents Act, 1970 describes what are not inventions?
- Whether the judiciary has paved the way for multiple interpretations to provisions? Discuss with the help of landmark judgments.

WHAT ARE THE PATENTABILITY CRITERIA?

An invention is a qualified patentable subject matter if it complies with the following criteria—

It should be novel.

Innovation is an important criterion in determining the patent potential of an invention. Under the Patent Act,¹ a novelty or new Invention is defined as

“new invention” means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art”.

¹ The Patents Act, 1970, section 2(1), No. 29, Acts of Parliament, 1970 (India)

The definition of invention provides a wide scope of patentable subject matter, stating that an invention under the Act must be either a product or a process. To rephrase, an innovation must be either a product or a process to qualify for patent protection. There are no restrictions on the type of technology, industry, or other context in which a product or procedure can be patented. General patentability challenges are uncommon because every innovation is either a product or a process. However, the Patents Act includes a comprehensive list of non-patentable ideas that significantly contribute to the scope of what can be granted a patent.

The novelty criterion states, in essence, that a previously unpublished invention must be kept secret. It needs to be the most recent advancement in the field, with no analogues in the prior art.

It should have inventive step or it must be non-obvious.

Under the Patents Act, an inventive step is defined as

““inventive step” means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art”²

In other words, the idea must not be obvious to someone with expertise in the same field. It shouldn't require too much creativity or seem too obvious to someone with similar expertise.

Section 2(1)(j), which defines "invention," and Section 3, which provides a list of subject areas that are not innovations, can interact in ways that can be somewhat confusing. Comparing the scope and coverage of various topics that aren't deemed innovations under Section 3 with the criteria for evaluating inventions under Section 2(1) is redundant (j). However, the Supreme Court ruled in Novartis that deciding whether or not a patent infringes Section 2(1)(j) and whether or not it infringes Section 3 are two different and distinct inquiries. The Supreme Court's demarcation of assessment suggests that the outcome of one form of evaluation should not affect the other, although in many cases, this is easier said than done.

² The Patents Act, 1970, section 2(ja), No. 29, Acts of Parliament, 1970 (India)

It should be capable of Industrial application.

The industrial application requirement of Section 2(1) determines whether or not an innovation may be manufactured or put to industrial use (ac). A product is regarded industrially relevant if it has at least one use in a certain sector and can be mass-produced. To qualify, a procedure needs to be applicable to a given industrial setting. Use that is ambiguous, hypothetical, or otherwise not grounded in the present will not be accepted. The same holds true for applications that lack credibility or are otherwise insufficient.

The Delhi High Court noted that an innovation needs to be commercially viable in a case between Cipla and Roche³, after reviewing several Indian and foreign cases relating to the utility or industrial applicability criteria. Must have commercial value; proven success in the marketplace is not required. The invention must be useful in some way and accomplish what is claimed for it in the patent. There will be no more proof of utility needed to secure a patent.

The Delhi High Court found that the pharmaceutical compound Sitagliptin is industrially applicable in another case between MSD and Glenmark⁴ by applying the principles for industrial applicability set forth by the UK Court of Appeals. The principles cited by the Court are as follows:

- i) The patent has to disclose “a practical application” and “some profitable use” for the substance that is to be claimed, for the ensuing of monopoly “can be expected [to lead to] some ... commercial benefit”;
- ii) A “concrete benefit”, by the name of invention “use ... in industrial practice” must be “derivable directly from the description”, need to be in connection to common general knowledge;
- iii) the mere fact “speculative” use will not suffice, so “a vague and speculative indication of possible objectives that might or might not be achievable” will not do;
- iv) The general common knowledge and patent need to enable the skilled person “to reproduce” or “exploit” the claimed invention without “undue burden”, or having to carry out “a research programme”; ...”

The Court applied the aforementioned principles and determined that Sitagliptin is industrially applicable even though it cannot be used in practise due to an ineffective carrier.

³ Cipla Ltd. vs F.Hoffmann-La Roche Ltd. & Anr. (2008) 37 PTC 71 (Del)

⁴Merck Sharp And Dohme Corporation vs Glenmark Pharmaceuticals, 2015 SCC OnLine Del 8227

It should not fall within the preview of section 3 and 4 of the Patents Act 1970.

The Indian Patents Act of 1970, Sections 3 and 4, list the items that cannot be patented in India. In order to be granted a patent in India, one must first meet a number of requirements. They are:

- Whether or not the Invention is about something that can be patented is the primary concern. In the Patents Act, forbidden topics are outlined in Sections 3 and 4. Unless the Invention falls under one of the exceptions listed in Sections 3 or 4, it is patentable subject matter.
- It would appear that the range of patentable subject matter in India is narrowed by the extensive listing of non-patentable inventions. However, applicants have used, and will continue to use, interpretations of the statutory language of the subjects to separate patentable inventions from the scope of unpatentable ones.

WHAT SHALL NOT BE CONSIDERED AS INVENTIONS?

The following shall not be considered as inventions within the meaning of section 3(d) Act, -

“d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation.— For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy”⁵

Monsanto Case⁶

Gene sequences and methods for inserting such gene sequences into plant cells to express *Bacillus thuringiensis* (BT) Delta-endotoxin to provide Bollworm resistance in plants are covered by an Indian patent owned by Monsanto (Patent No. 214436, referred to as the "BT Patent") (Monsanto Technology LLC.). One set of claims in the granted patent is for the isolated, purified, and modified gene sequences themselves, while the other set of claims is for the methods used to insert the

⁵ The Patents Act, 1970, section 3, No. 29, Acts of Parliament, 1970 (India)

⁶ Monsanto Technology LLC v. Nuziveedu & Ors AIR 2019 SC 559

sequences into plant cells. The Indian Patent Office rejected the claims made in the patent application concerning transgenic plants, hybrid varieties, and seeds during prosecution.

Nuziveedu (Nuziveedu Seeds Ltd.) disputed the "trait fee" that Monsanto was charging as a licensee of the BT Patent owned by Monsanto, and subsequently contested the validity of the licence on the grounds that the BT Patent was invalid. According to Nuziveedu, Section 3(j) of the Patents Act prohibits patents for inventions relating to subject matter that is already known or obvious to the public, implying that Monsanto's BT Patent is invalid.

Specification

- Before receiving a patent, the inventor must file a patent application that includes a full description of their invention (Section 10). The specification's objective is to specify the scope of the invention and to provide the public with detailed information about the innovation and its implementation. A full explanation of the innovation, as well as its construction and usage, must be included in the specification. Drawings may be included in the written description to aid understanding of the invention. When filing for a patent, you may be required to submit a model or sample to the patent office to help show your idea.
- Furthermore, the specification must end with a claim or claims that define the scope of the invention for which protection is sought. The purpose of the claims is to define the boundaries of the invention that is the subject of the patent application. Specification claims should be brief, to the point, and focused on a single original concept. The claims must clearly define the territory for which the invention is claimed. The claims must explicitly explain the core idea of the invention, rather than relying on the specification as a whole. The claims of the patent must be compatible with the information in the specification.

PATENTABLE SUBJECT MATTER

The phrase "patentable subject matter" is taken from the US Patent Code and is not used anywhere in the Patents Act. The term "Patentable Subject Matter" has a broader meaning in the TRIPS Agreement than it does in this section. Topics that can and cannot be patented are both considered

patentable subject matter for the purposes of this chapter.⁷

This provision limits patentability to previously known configurations, applications, and properties. Regarding novel forms, the explanation provides an illustrative list of forms that are regarded as the same substance as the well-established one. To ensure that a new form is patentable, there is an efficacy-based exception clause. You can get a patent on a new formulation if it's more effective than the existing one. Although this is a small window of opportunity to meet the patentable subject matter requirement, it is nonetheless valuable. The Analysis of whether or not a new form of invention is patentable involves the following steps:

- Confirming the known substance;
- Confirming the known substance's purpose and efficacy;
- Identifying if the invention being claimed is a new form of the known substance;
- Confirming the efficacy of the new form; and
- Analysing and Comparing the efficacy of the new form with the efficacy of the known substance with respect to the purpose.

The new form has enhanced efficacy and is therefore patentable if its effectiveness in the context of the purpose for which the patent is claimed exceeds that of the known substance for the same purpose. Evidence of improved efficacy will not be strengthened by benefits provided by the new form that are unrelated to the substance's intended use.

According to the Supreme Court's decision in Novartis, the benefits of a new form, such as increased bioavailability and stability and decreased hygroscopicity, are insufficient to prove increased efficacy.

Novartis Case Brief⁸

Novartis AG, the Appellant here, submitted a patent application in 1998 for a crystalline salt form of Imatinib and its use in treating cancer. Imatinib mesylate, also known as Glivec or Glivec, was claimed in its beta crystalline form, which is non-needle shaped and has better flow properties, making it more amenable to processing and manufacturing, and less hygroscopic and thermodynamically

⁷ Linda L.Lee, Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India, Vol.23, BTLJ, 281-313 (2008).

⁸ Novartis A.G v. Union of India AIR 2013 SC 1311

stable, making it more amenable to storage. The beta crystalline form is distinguished from the needle shaped, alpha crystalline form by its lower melting point and higher X-ray diffractivity The beta crystalline form of Imatinib mesylate was also reported to have 30% greater bio-availability than the free base form of the drug.

The compound did not meet the requirements of Section 3(d), which excludes new forms of a known substance with known efficacy from the scope of patentability unless enhanced efficacy is shown, which is why the patent office and the Intellectual Property Appellate Board both rejected the application. The Appellate Board reasoned that because the compound in question was ineffective, it fell under the purview of Section 3(d) of the Act, citing the Madras High Court's decision that "enhanced efficacy" means "enhanced therapeutic effect". However, it did find that the compound did meet the other criteria for patentability, including industrial applicability, novelty, and inventive step. In this case, the Supreme Court of India ruled in favour of Novartis after the company appealed the Appellate Board's ruling.

PROMINENT JUDGMENTS ON PATENTABILITY CRITERIA

Bajaj Auto Ltd. v. TVS Motors Comp. Ltd (2010)⁹

Facts of the case

Bajaj auto claimed in this case that TVS Motors had violated their patents by using their patented technology without permission, prompting them to sue for an injunction. For this case, the court looked to the doctrine of pith and marrow to determine whether or not there was a true infringement of the patented technology at issue.

Issue involved in the case

Whether the defendants have infringed the technology that was already patented?

⁹ Bajaj Auto Limited v. TVS Motor Company Limited (2009) 9 SCC 797

Judgment of the court

The Supreme Court, in this particular case provide some guidelines that shall be followed in each and every IPR case. The following were the guidelines:

- Trial courts must hear IPR cases on a daily basis and render decisions in no more than 4 months from the date they were filed.
- Finally, the Madras High Court ruled that Bajaj Auto has a valid patent on the DTS-i technology and that the defendants, TVS Motors, are prohibited from using it. If they do, they will be held accountable for patent infringement.

Koninklijke Philips Electronics N.V. v. Rajesh Bansal and ors. (2016)¹⁰

Facts of the case

The plaintiff sued the defendants, claiming that they had copied and illegally used the patented technology found in the plaintiffs' DVDs. However, the defendants denied the claims, maintaining that they had not committed any violations.

Issue raised in the case

Whether there has been any infringement of patents on the part of defendants?

Judgment of the court

In this case, the court noted that the defendants' products made use of patented technology used by the plaintiffs in their DVDs, specifically enhanced forward-motion (EFM) and demodulation. The DVD technology patent held by the plaintiff was effectively infringed upon. The court found the defendants responsible, and they were ordered to pay the plaintiffs Rs 5 lakhs in damages.

CONCLUSION AND ANALYSIS

Intellectual property includes any intellectual product, such as an idea, invention, or piece of art, and the rights granted to the creator of such a thing are referred to as intellectual property rights. As a form of intellectual property, patents are protected ideas that can be copied and sold. If it does not fall under the category of non-patentable inventions, any invention that leads to the creation of a new product or service, or the production of an existing product using new means and technology, can be patented.

¹⁰ Koninklijke Philips Electronics N.V. v. Rajesh Bansal and ors. (2016) CS (COMM.) 24/2016

The Indian Patents Act, 1970, as amended in 2002 and 2005, is the law that applies to patents in India. For an invention to be granted a patent, it must adhere to a number of patenting requirements. Three primary criteria must be met: originality (or newness), practicality (or the ability to be applied in industry), and lack of obviousness. But the patent application can be rejected for a variety of reasons. The article has already presented these arguments.

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