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# Substantive requirements of patentability in India

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**Abstract**
All members of the World Trade Organisation (WTO) are bound by the obligations under the Agreement on Trade- Related Aspects of Intellectual Property Rights (The TRIPS). India is one of the founding members of the GATT and thus a member of the WTO from its inception from January 1, 1995, and is bound by the obligations under TRIPS Agreement like all other members of the WTO. In India, patents are governed by the Patents Act, 1970. This paper seeks to study the substantive requirements of patent law in light of the amendments to the Patents Act, 1970 in order to meet India's obligations under the WTO. The paper also delves into the legislative history of patent law in India. The subject matter of a patent is an invention. The Act defines the term invention as a new product of process involving an inventive step and capable of industrial application. In addition, the Act, specifically bars certain subject matter from being patented under sections 3 and 4. The paper focuses on the concepts involved in patentability of an invention and analyses judicial pronouncements in order to understand the various requisites of patentability namely; patentable subject matter, new invention, inventive step and capable of industrial application.

**Keywords:** invention, patent, new, inventive step, capable of industrial application

## Introduction

Patent is an exclusive right granted by the government of a country for a specific duration to an invention. In India patents are governed by The Patents Act, 1970 (The Act). The provisions of the Patens Act, 1970 govern grant of patents in India. Since its enactment, the Act has been amended on five occasions by:

- The Repealing and Amending Act, 1974 (Act 56 of 1974)
- The Delegated Legislation Provisions (Amendment) Act, 1985 (Act 4 of 1985)
- The Patents (Amendment) Act, 1999 (17 of 1999)
- The Patents (Amendment) Act, 2002 (38 of 2002)
- The Patents (Amendment) Act, 2005 (15 of 2005)

The first two amending Acts listed above were made to reflect the changes within India, while the later three amending Acts made substantive changes to the Indian patent laws in order to meet India's obligations under TRIPS.

At the time of Independence, India's patent regime was governed by the Patents and Designs Act, 1911, which had provisions both for product and process patents. It was, however, generally felt that the patent law had done little good to the people of the country. The way the Act was designed benefited foreigners far more than Indians. It did not help at all in the promotion of scientific research and industrialization in the country, and it curbed the innovativeness and inventiveness of Indians.

Shortly after Independence, therefore, in 1949, a committee was constituted under the chairmanship of Justice Dr. Bakshi Tek Chand, to undertake a comprehensive review of the working of the 1911 Act. The Committee submitted its interim report on August 4, 1949 and the final report in 1950 making recommendations for prevention of misuse or abuse of patent rights in India. The committee's recommendation prompted the Government to introduce a bill (Bill no. 59 of 1953) in Parliament, but the bill was not pressed and it was allowed to lapse.

In 1957, another committee came to be appointed under the chairmanship of Justice N. Rajagopala Ayyangar to take a fresh look at the law of patent [1]. Justice Ayyangar observed that the provisions of the Patent law have to be designed, with special reference to the economic conditions of the country, the state of its scientific and technological advancement, its future needs and other relevant factors, and so as to minimize, if not to eliminate, the abuses to which a system of patent monopoly is capable of being put. Bearing in view the matters set above, he recommended retaining the patent system, but with a number of improvements. One of the improvements suggested was to define, with precision, those inventions which should be patentable and equally clearly identify certain inventions, the grant of patents to which would retard research, or industrial progress, or be detrimental to the national health or well- being, and to make those inventions non-patentable [2]. Justice Ayyangar submitted a comprehensive Report on Patent Law Revision in September 1959 and the new law of patent, namely, the Patents Act, 1970, came to be enacted mainly based on the recommendations of the report, and came into force on April 20, 1972, replacing the Patents and Designs Act, 1911.

Following the Uruguay round of multilateral negotiations under the General Agreement on Tariffs and Trade (GATT), the Agreement on Trade- Related Aspects of Intellectual Property Rights (The TRIPS) was arrived at and it came into force on January I, 1995. The TRIPS Agreement is the most comprehensive multilateral agreement to set detailed minimum standards for the protection and enforcement of intellectual property rights, and aims at harmonizing national intellectual property systems. All members of the World Trade Organisation (WTO) are bound by the

obligations under the TRIPS Agreement. India is one of the founding members of the GATT and thus a member of the WTO from its inception from January 1, 1995, and is bound by the obligations under TRIPS Agreement like all other members of the WTO.

Prior to India's accession to the WTO, the 1970 Act, had been undisturbed for a period of 29 years. Beginning in 1999, a series of amendments were enacted in order to bring the 1970 Act into compliance with TRIPS. The first amendment came in 1999, to provide interim protection to inventions relating to pharmaceutical products by accepting mail box applications which would give priority to such inventions until the mail box opened in 2005 with the introduction of product patents in fields including pharmaceuticals [3]. The amendment also provided for the grant of exclusive marketing rights for such products [4]. The Act was again amended in 2002 to incorporate the second set of TRIPS obligations i.e. extension of term of patents to 20 years, reversal of burden of proof, etc [5]. and in 2005 for granting product patents in all fields of technology including chemicals, food, drugs and agrochemicals, etc [6].

The main aim of the Patent Act has been identified by the Supreme Court in *Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries* [7] as under:

The main aim of Patent law is to promote scientific research, new technology and industrial progress. Providing exclusive privilege to own, use or sell the meod or the product patented for a limited period, stimulates new invention of commercial utility.

The Act does not give a list of subject matter that is eligible for patent protection. It instead gives a list [8] of subject matter on which patent cannot be granted. The Act defines the term patent [9] as:

"patent" means a patent for any invention granted under this Act;

The definition of a patent makes it clear that the subject matter of a patent is an invention. However, the term invention may be different from the perspective of a scientist and that of the law. In order to qualify for patent protection, the subject matter on which patent protection is being sought must meet the legal requisites of the term invention. The term invention [10] is defined in the Act as invention" means a new product or process involving an inventive step and capable of industrial application.

This definition of an invention identifies what is ordinarily referred to as the requirements of patentability. In order to be granted patent protection, the applicant must satisfy the patent office that the product or process on which protection is sought is new, involves an inventive step and is capable of industrial application. The terms 'new invention' [11], 'inventive step' [12] and 'capable of industrial application' [13] have been defined under the Act. In addition to novelty, inventive step and capable of industrial application being an essential condition for patentability, lack of any of these requirements is also a ground to oppose the patent under section 25 and to challenge the validity of a patent under section 64 of the Act.

Once a patent is granted by the patent office nobody can make, use or sell the patented invention without seeking the permission of the patentee. The Act defines a patentee [14] as:

The person for the time being entered on the register as the grantee or proprietor of the patent. We will now look at the essential requirements of patentability.

**Patentable Subject Matter**

A patent is granted on an invention. But not all inventions are patentable. The Act does not name the products or processes which are patentable. The Act under sections provides an exhaustive list of subject matter which is not eligible for patent protection [15].

It may be noted that the works enumerated under the provisions of Section 3 of the Act seem to have been excluded primarily for four reasons. Firstly, certain works do not rise to the dignity of an invention for lack of novelty, inventive step or capable of industrial application and hence they are excluded. Such types of works are identified by clauses (a), (c), (d), (e), (f) and (p). Secondly, certain works are excluded from patenting for they are protected by other intellectual property regime like those enumerated in clauses (j), (k), (l) and (o). Thirdly, certain works are left entirely in the public domain particularly those enumerated under clauses (k), (m) and (n). Fourthly, certain works are excluded for reasons of policy particularly those specified under clauses (h), (i) and (j).

The Hon'ble Supreme Court in the matter of Novartis AG Vs. Union of India [16], recognising that the purpose of section 3(d) was to prevent evergreening of patents, observed as under:

We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant especially to deal with chemical substances, and more particularly pharmaceutical products. The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/ pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious ground

It was further held by the Apex Court in the case of medicines, efficacy means ―therapeutic efficacy‖ and physico-chemical properties of substances do not meet the requirement of ―therapeutic efficacy.

**Further section 4 of the Act provides**

No patent shall be granted in respect of an invention relating to atomic energy falling within sub – section (1) of section 20 of the Atomic Energy Act, 1962.

**Section 20(1) of the Atomic Energy Act provides**

No patent shall be granted for inventions which in the opinion of the Central Government are useful for or relate to the production, control, use or disposal of atomic energy or the prospecting, mining, extraction, production, physical or chemical treatment, fabrication, enrichment, canning or use of any prescribed substance or radioactive substance or the ensuring of safety in the atomic energy operation.

This exclusion is based on the principle of security of state and non – proliferation of atomic energy.

**Novelty**

**The Act defines the tern "new invention" [17] as under**

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 Thus, in order to qualify for patent protection, the product or process must not be a part of the state of the art. The Act does not define

the term state of the art. The U.S. Patent Act uses the term prior art in the context of novelty. The U.K Patent Act uses the word state of the art [18] as under:

An invention shall be taken to be new if it does not form part of the state of the art.

The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.

Prior art is any evidence that the invention was already known publicly or available, in whole or in part, before the effective filing date of your patent application. The concept of prior art varies from country to country. Prior art can include the following:

1. A product that was available for sale.
2. Commercial use of the invention.
3. Articles, publications or journals.
4. Presentation at public events.
5. Public knowledge or use of the invention.
6. A previously filed patent application, once the application becomes a published application or an issued patent.

Additionally, the information to be considers as prior art it must have been publicly disclosed or publicly available before the effective filing date of your patent application. The definition of new invention as given under the Act makes it clear that the critical date for determining if information qualifies as prior art is date of filling for patent application with complete specification. This is also indicative of the fact that India follows a first to file system of patent application as mandated by TRIPS.

The Bombay High Court in Alibhai Chakubhai Jariwala vs Chimanlal Chunilal [19] has identified the reason for novelty as a requirement of patentability as under:

The two features necessary to the validity of a patent are novelty and utility, but the real test is the novelty of the invention. Novelty is essential, for otherwise there would be no benefit given to the public and consequently no consideration moving from the patentee.

The Supreme Court in Bishwanath Prasad Radhey Shyam v. Hindustan Metals Industry [20] made the following observation with respect to novelty:

The fundamental principle of Patent law is that a patent is granted only for an invention which must have novelty and utility. It is essential for the validity of a patent that it must be the inventor's own discovery as opposed to mere verification of what was, already known before the date of the patent.

The Court further observed:

Whether the "manner of manufacture" patented, was publicly known, used and practised in the country before or at the date of the patent? If the answer to this question is 'yes', it will negative novelty or 'subject matter'. Prior public knowledge of the alleged invention which would disqualify the grant of a patent can be by word of mouth or by publication through books or other media. "If the public once becomes possessed of an invention", says Hindmarch on Patents (quoted with approval by Fry L. J. in Humpherson v. Syer, "by any means whatsoever, no subsequent patent for it can be granted either to the true or first inventor himself or any other person; for the public cannot be deprived of the right to use the invention..... the public already possessing everything that he could give.

In Monsanto Company v. Coramandal Indag Products (P) Ltd. [21], the Supreme Court observed as under:

Under sec. 64(e), a patent may be revoked if the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the date of the claim, etc.

To satisfy the requirement of being publicly known as used in clauses (e) and (f) of sec. 64(1), it is not necessary, that it should be widely used to the knowledge of the consumer public. It is sufficient if it is known to the persons who are engaged in the pursuit of the knowledge of the patented product or process either as men of science or men of commerce or consumers.

**Inventive Step**

The next requirement of patentability is inventive step. The Patents Act, 1970 and the Patents Act, 1977 of U.K uses the word inventive step. The U.S. Patent Act, uses the word non – obviousness [22]. TRIPS recognises that the term inventive step and non – obviousness can be used interchangeably [23].

The Patents Act, 1970 defines the term inventive step [24] as under:

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. The Supreme Court in Bishwanath Prasad Radhey Shyam [25] case made the following observations:

In order to be patentable, an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop `improvement, and must independently satisfy the test of invention or an inventive step. It must produce a new result, or a new article or a better or cheaper article than before. The new subject matter must involve "invention" over what is old. Mere collocation of more than one, integers or things, not involving the exercise of any inventive faculty does not qualify for the grant of a patent

**Referring to the test for determining inventive step the Court further observed**

Had the document been placed in the hands of a competent craftsman (or engineer as distinguished from a mere artisan), endowed with the common general knowledge at the 'priority date', who was faced with the problem solved by the patentee but without knowledge of the patented invention, would he have said, "this gives me what I want?" (Encyclopaedia Britannica; ibid). To put it in another form: "Was it for practical purposes obvious to a skilled worker, in the field concerned, in the state of knowledge existing at the date of the patent to be found in the literature then available to him, that he would or should make the invention the subject of the claim concerned?" Halsbury, 3rd Edn, Vol. 29, p. 42 referred to by Vimadalal J. of Bombay High Court in Farbwrke Hoechst & B. Corporation v. Untchan Laboratories.

The Madras High Court in Bajaj Auto Ltd. v. TVS Motor Co [26] interpreting the term obvious as used in the definition of inventive step observed as under:

Even though the term "obvious" has not been denied under the Patents Act, it can be safely stated to be a circumstance

where a person of skill in the field, on-going through the specification would complete the product. Therefore, even if any of the two ingredients, *viz*., technical advance or economic significance or both are available, if such invention enables a person of skill in the field, on going through the specification would complete the product, such invention can never be treated as an "inventive step" and consequently no patent can be validly issued. Therefore, it is clear that a patent must have the characters of novelty, non-obviousness and enablement, out of which, enablement being the concept of putting the novelty into action and all the above said ingredients must consecutively be present to have a valid patent.

Referring to the Rado v. John Tye & Sons Ltd. [27] the High Court further observed:

Whether the alleged discovery lies so much out of the Track of what was known before as not naturally to suggest itself to a person thinking on the subject, it must not be the obvious or natural suggestion of what was previously known.

The Delhi High Court in Cipla Ltd. v. F Hoffman – La Roche Ltd. [28] identified the characteristics of a person ordinarily skilled in the art as under:

The features of a person skilled in the art are that of a person who practices in the field of endeavour, belongs to the same industry as the invention, possesses average knowledge and ability and is aware of what was common general knowledge at the relevant date.

The Court also referred to the U.S. Supreme Court decision of Graham v. John Deere Co. of Kansas [29] which made the following observation:

In determining the level of ordinary skill in the art, you should first determine whether there was a number of people who regularly worked to solve the type of problem that the invention solved, and, if so, determine the level of ordinary skill of such people at the time the invention was made. You must consider the level of skill as to the time the invention was made. Among the factors that may be considered in your determination are:

1. The various ways that others sought to solve the problems existing;
2. The types of problems encountered;
3. The rapidity with which new inventions are made in this art;
4. The sophistication of the technology involved; and
5. The educational background of those actively working in the field.

The Court also referred to the triple test of obviousness has been laid down by the U.S. Supreme Court in KSR International Co v. Teleflex Inc. [30] i.e. teaching, suggestion, or motivation as under:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or no obviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

While determining patentability of the invention, an Examiner first conducts investigation as to whether the novelty of the claimed invention is established and then proceeds to conduct examination on whether the claimed invention involves the inventive step [31].

Accordingly, the following points need to be objectively judged to ascertain whether, looking at the invention as a whole, the invention does have inventive step or not:

1. Identify the "person skilled in the art", i.e. competent craftsman or engineer as distinguished from a mere artisan;
2. Identify the relevant common general knowledge of that person at the priority date;
3. Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
4. Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
5. Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of inventive ingenuity? [32]

**Capable of Industrial Application**

The last substantive requirement of patent eligibility is the subject matter i.e. product or process must be capable of industrial application. The Patents Act, 1970 and the Patents Act, 1977 of U.K uses the word capable of industrial application. The U.S. Patent Act, uses the word useful. TRIPS recognises that the term capable of industrial application and useful can be used interchangeably [33].

**The Patents Act, 1970 defines the term capable of industrial application [34] as under**

Capable of industrial application, in relation to an invention, means that the invention is capable of being made or used in an industry. The Delhi High Court in Merck Sharp And Dohme Corporation v. Glenmark Pharmaceuticals [35] referred to the decision of the UK Court of Appeal in Eli Lily v. Human Genome Sciences [36] where the Court of Appeals identified the following important elements of the term capable of industrial application:

1. The patent must disclose "a practical application" and "some profitable use" for the claimed substance, so that the ensuing monopoly "can be expected [to lead to] some ... commercial benefit";
2. A "concrete benefit", namely the inventions "use ... in industrial practice" must be "derivable directly from the description", coupled with common general knowledge;
3. A merely "speculative" use will not suffice, so "a vague and speculative indication of possible objectives that might or might not be achievable" will not do;
4. The patent and common general knowledge must enable the skilled person "to reproduce" or "exploit" the claimed invention without "undue burden", or having to carry out "a research programme".

The Examiner shall assess if the claimed invention is capable of use in any industry or made using an industrial process. Typically, the specification explains the industrial applicability of the disclosed invention in a self-evident manner. If it is not, a mere suggestion that the matter would be industrially applicable is not sufficient [37].

**Conclusion**

A patent is granted on an invention. A person seeking patent protection has establish to the patent office that the subject matter on which he seeks protection is an invention. Further, there is a difference between invention in the eyes of a scientist and in the eyes of law. Hence in order to receive patent protection an invention must be such as per the requirements of the Patents Act, 1970. Accordingly, an applicant for patent protection has to meet the four substantive requirements of patent law.

1. New Invention/Novelty: A product or process on which protection is sought must not be published or available in prior art of the country or elsewhere in the world before the date of patent filing.
2. Inventive Step: Invention which can be done by any ordinary skilled person is obvious and cannot be patentable.
3. Capable of Industrial Application/ Usefulness: invention must be capable of being made or used in an industry.
4. Patentable Subject matter: The Act under sections 3 and 4 specifically bars certain subject matter from patent protection. Therefore, even if a subject matter falls within the legal definition of invention, a patent will not be granted, if it falls within sections 3 and 4 of the Act.

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