

ORIGINAL RESEARCH ARTICLE

Indian Patents & Pharmaceutical Industries

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ABSTRACT

Patents are instruments which provide exclusive right for a limited period on the patentees for dealing with the product or process of his innovation and prevent others from using them without due authorization. These rights often result in monopolistic pricing of drugs making them unaffordable to large number of populations particularly from economically developing countries.

INTRODUCTION

The Indian pharmaceutical industry is one of the most vibrant knowledge driven industries in India it has witnessed spectacular growth over the past three decades currently over 90% of the modern medicine consumed in India is produced locally the industry manufacture almost entire range of therapeutic products and is capable of producing raw materials for manufacturing a wide range of bulk drugs.

Anything resulting from the exercise of human intellect is Intellectual Property and right of possession of the same is Intellectual Property Right (IPR). The trade related aspects of IPR (known as TRIPS) which are recognized by the agreement of World Trade Organization (WTO) are the following

Patents	Copyrights	Designs
Integrated Circuits	Trade	marks
Trade Secrets		
Geographical Indications		

But out of the above Patents, - Copy Rights, Designs and Trade marks are commonly used. Now we will take up a detail study of patents and its legal structure in India.

In late 50s when political and economic set up was being enhanced the Indian pharmaceutical industry was being dominated by the foreign multinational companies. The prices of the drugs with special mention to life saving drugs were too high. These prices were non affordable by

common people in India. The previous acts were not being able to meet needs and aspirations of a newly independent nation. After observing such chaos in the pharmaceutical sector the Indian Government in 1957 appointed a committee under the Chairmanship of Justice Raja Gopala Ayyangar. The committee started its work keeping in mind the changing scenario. The report was inspired by the Indian constitution which ensures social and economic justice. Article 21 of the Indian constitution which ensures the right to health to citizens was the guiding philosophy behind Ayyangar committee recommendations. This led to the structure for the 'Process Patenting' in India. This report was submitted in Lok Sabha (Lower House of Indian Parliament) in 1966.

The Patents Act (Act 39 of 1970) came into force on 20th April 1972. The Patents Act of 1970 was designed perfectly in tune with our then national ideology of planned development. This was the time when there was socialistic planning. Since then India has underwent an absolute economic enhancement. India has taken up the strands of globalization and liberalization. Today the country is gaining momentum ahead of the global economy. This process will not be complete unless the research and development is also integrated with global research and development. Also India has entered into an international framework after being the member of WTO. Thus it is in the legal obligation to fulfill all the

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statutory norms of the WTO. After signing the TRIPS agreement India is continuously updating its patent regime.

PATENTABILITY

The basic concept of patentability has often been challenged when they have been applied to life forms and biological material as living matter of capable of reproduction.

To start with a patent delivers protection to the innovator, thus protection is the sole aim of the system which is granted to promote industrial advancement in a country. This system does not confer absolute rights, on the contrary it gives right of monopoly for a specific period (according to TRIPS agreement this period is at least 20 years) this grant is from the state.

The invention means a voyage towards unknown, according to Section 2(I)(j) of the Indian Patents (Amendment)Act, 2002 it means a new product or process involving an inventive step and capable of industrial application.

The claim for invention does not fulfill the criteria of patentability. There are statutory obligations which have to be fulfilled besides this there are three broad requirements namely

- 1) Novelty
- 2) Utility
- 3) Inventive Step I Non obviousness

1) Novelty

Novelty comprises of the invention of unknown. The claim for novelty is only fulfilled when nothing of such order is present in the public domain i.e. the knowledge of inventor's invention and its outflow is not known by the world. The inventor should be the first one who introduces the same.

Thus novelty of the invention is determined by considering the following

(a) The knowledge available anywhere in the world in the relevant field at the time of filing the application for the patent.

(b)The invention should not have been made available to the public before the date of filing the application

2) Utility

This aspect includes society as a whole. The invention must be useful for the beings. Thus statutory obligation includes that an invention which is patentable must be capable of industrial application; the invention must have a practical

approach which is beneficial for the society. It is not at all necessary that invented has a concrete shape or is an absolute commercial success. The emphasis lies on the utility of the invention.

(3) Inventive Step and Non Obviousness

This measure is even more abstract in quality than novelty and utility. An inventor is said to have an inventive step if when compared to what is already known to the public the invention would not be obvious to someone with reasonably good knowledge and experience of the subject to which the invention relates. The invention thus should be technically advanced enhancing the science. The invention should not be so obvious that it comes automatically to anyone skilled in that field.

PATENT APPLICATION PROCEDURE IN INDIA

There are different types of Patents which can be secured in India under Indian Patents Act. These can be listed as

- 1) Ordinary Patents
- 2) Patent of Addition
- 3) Patent Granted under Convention Agreement

Ordinary Patents

An ordinary patent is one which is granted on the basis of general and ordinary procedure of application.

Patents of Addition

A patent of addition is a patent secured for an improvement or modification of an invention for which a patent has already been applied for or granted. A patent of addition remains in force only as long as the patent for the main invention remains in force.

Patent Granted Under Convention Agreement

A patent granted in respect of a convention application filed under Section 135 of the Act in respect of the same invention. According to the modified meaning of the term "Convention Country", it means a country of convention which is a member of a group of countries or a union of countries or an inter-governmental organization notified as such under sub Section (i) of Section 133 of the Act.

Patent Procedure

Under Indian Patents Act, 1970 Section 6 deals with person who could apply for patent claim

(1) Subject to the provisions contained in section J 34, an application for a patent for an invention

may be made by any of the following persons, that is to say.

(a) By any person claiming to be the true and first inventor of the invention;

(b) By any person being the assignee of the person claiming to be the true and first inventor in respect of the right to make such an application;

(c) By the legal representative of any deceased person who immediately before his death was entitled to make such an application.

(2) An application under sub-section (1) may be made by any of the persons referred to therein either alone or jointly with any other person.

The grant of patent assures the protection to the inventor for his invention. Thus when a monopoly right is given, it should follow a proper statutory track. Indian Patent Act has laid 3 full-fledged procedures to ensure the monopoly right to the inventor.

It comprises of four steps:

Step I

Application for the Patents

Step II

Examination of the Application

Step III

Opposition to the grant of Patent

Step IV

Grant & sealing of Patent

MARKETING RIGHTS

The Government of India in order to meet the obligations under Article 70(8) and (9) of TRIPs Agreement of WTO (These articles require the member states to make a provision for filing of Product Patents in case of pharmaceuticals and agrochemicals and also have provisions for the" granting of exclusive marketing rights as of 01.01.1995). The exclusive marketing rights are being granted to those patent applications Due to this requirement a new Chapter IV A was inserted in the Patents Act, 1970 on Exclusive Marketing Rights containing Section 24A - 24F by the Patents (Amendment) Act, 1999, with effect from January 1, 1995. Sections 24A - 24F are laid as under.

Section 24A - Application for Grant of Exclusive Rights

Section 24 B -Grant of Exclusive Rights

Section 24C-Compulsory Licenses in relation to Exclusive Rights to sell or distribute Section 24D

- Special Provision for selling or distribution

Section 24 E -Suits relating to infringements

Section 24 F - Central Government and its officers not to be liable

COMPULSORY LICENSE

EMR and licensing have been discussed in the previous chapter. Compulsory License is different from ordinary license; the Patents Act contains definite provision for providing compulsory license. The reason for providing such license in India is obvious from the fact that patents are granted to encourage invention. They are not granted merely to enable the patentee to enjoy a monopoly for the importation of the patented article. The patent system has to ensure that the inventions are worked in India on a commercial. Where patent has granted on something related to public interest like public health etc. the patentee is not supposed to keep the invention out of public without working it in the public. The patentee is expected to work the invention in the public and to make available the patented product to the public, that too at a reasonable price and without much delay. In fields related to socio - economic and technological development, especially relating to public health, the Government has to make sure that the patented products are accessible to the general public at a reasonable price.

Section 84 of the Indian Patents Acts deals with compulsory license which is given below:

(1) At any time after the expiration of three years from the date of the sealing of a patent. Any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely:

(a) That the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) That the patented invention is not available to the public at a reasonably affordable price, or

(c) That the patented invention is not worked in the territory of India.

(2) An application under this section may be made by any person notwithstanding that he is already the holder of a license under the patent and no person shall be stopped from alleging that the reasonable requirements of the public with respect to the patented invention are not satisfied or that the patented invention is not worked in the territory of India or that the patented invention is

not available to the public at a reasonably affordable price by reason of any admission made by him, whether in such a license or otherwise or by reason of his having accepted such a license.

(3) Every application under sub-section (1) shall contain a statement setting out the nature of the applicant's interest together with such particulars as may be prescribed and the facts upon which the application is based.

(4) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may grant a license upon such terms as he may deem fit.

(5) Where the Controller directs the patentee to grant a license he may as incidental thereto exercise the powers set out in section 88.

(6) In considering the application filed under this section, the Controller shall take into account,

(i) The nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;

(ii) The ability of the applicant to work the invention to the public advantage;

(iii) The capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;

(iv) As to whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit:

Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee.

But shall not be required to take into account matters subsequent to the making of the application

(7) For the purpose of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied -

(a) If by reason of the refusal of the patentee to grant a license or licenses on reasonable terms,

(i) An existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or

(ii) The demand for the patented article has not been met to an adequate extent or on reasonable terms; or

(iii) A market for export of the patented article manufactured in India is not being supplied or developed;

(iv) The establishment or development of commercial activities in India is prejudiced; or

(b) If by reason of conditions imposed by the patentee upon the grant of licenses under the patent or upon the purchases, hire or use of the patented article or process. The manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced, or

(c) If the patentee imposes a condition upon the grant of licenses under the patent to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing, or

(d) If the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable.

(e) If the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by

(i) The patentee or persons claiming under him;

(ii) Persons directly or indirectly purchasing from him;

(iii) Other persons against whom the patentee is not taking or has not taken proceedings for infringement.

Termination of Compulsory License

According to section 94 of Indian Patents Act

(1) On an application made by the patentee or any other person deriving title or interest in the patent, a compulsory license granted under section 84 may be terminated by the Controller, if and when the circumstances that gave rise to the grant thereof no longer exist and such circumstances are unlikely to recur: Provided that the holder of the

compulsory license shall have the right to object to such termination.

(2) While considering an application under subsection (1), the Controller shall take into account that the interest of the person who had previously been granted the license is not unduly prejudiced.

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