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Striking a Balance between Patent Laws and Public Health Issues with Special Emphasis on its Recognition in India

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ABSTRACT

The spread of various infectious diseases around the world and the lack of medicines and healthcare facilities necessitated to strike a balance between patent protection laws and the right to public health.

This article talks about the evolution of patent laws around the world with a special reference to their relevance in India from the pre-independence time to the post-independence era with greater emphasis on the provisions enumerated in the Patent Act relating to Public Health. The aim of this article is to establish a relationship between public health and patent laws while simultaneously trying to establish their growing importance by the day in the wake of deadly diseases and expensive cures. Furthermore, the article discusses various kinds of pharmaceutical patents recognized in India by the Indian Patent Office while seeking to analyse the concept of patent licensing in this regard and how transferability of pharmaceutical patents benefits a common man without any hinderance to the rights of the innovators.

Keywords: *public health, patent laws, pharmaceutical patents, transferability of patents, Indian patent laws.*

I. HISTORICAL BACKGROUND

Patent laws in India trace their roots back to the colonial period when for the first-time legislation relating to patent, i.e., the Act VI of 1856 was introduced.[3] Since then, the Act was amended many times to bring it in conformity with the UK patent laws. In the year 1911, the Indian Patent and Design Act came into force and replaced all the previous acts. However, in post- independence period, it was felt that the 1911 act failed to materialise its objectives and necessitated the enactment of comprehensive patent laws. Therefore, in the year 1949 under

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[3] *History of Indian Patent System*, INTELLECTUAL PROPERTY INDIA (Apr 29, 2021, 22:15 PM), https://ipindia.gov.in/history-of-indian-patent-system.htm.

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the chairmanship of Justice (Dr) Bakshi Tek Chand, a committee was formed to review India's patent laws. Based on their recommendations, certain changes were incorporated in the 1911 act. Subsequently, in the year 1957 another committee headed by Justice N. Rajagopala Ayyangar was formed. One of the major recommendations of this committee was the grant of only process patent relating to invention of drugs, medicines, food and chemicals.[4] Based on the report of this committee, a bill was then tabled before the joint parliamentary committee and the Patent Act 1970 was passed which came into force on 20th April 1972.

For a very long time the development of patent laws in India remained at a nascent stage. India being a signatory to TRIPS agreement had an obligation to ensure that the domestic laws on intellectual property are in consonance with the minimum standard set forth in the TRIPS agreement, to ensure the same, various amendments were made in the Patent act of 1970. However, a turning point came in the year 2005, when major amendments were introduced in the patent act. Now with the availability of process patent, the product patent was also incorporated in the act. Section 5 of the 1970 act, which provided limited term process patent was removed and the amendment provided for 20 years of protection for all categories of invention excluding those provided under section 3 of the act.[5] The definition of the term 'Patent' was amended. The compulsory licensing system under the act was also given a boost, section 92A (1) was inserted which expanded the scope of compulsory license for manufacturing and export of patented pharmaceutical products. All these amendments acted as a boon for India to move a step forward in complying with the standards set in TRIPS agreement.

II. PATENT AND PUBLIC HEALTH

Patent sought to protect the invention of an individual or group of individuals from infringement. It provides right to the patent holder to exclude others from an unauthorised access of the patented product/process. The pharmaceutical industry is also one such industry which is driven by the creation of minds of people. It involves intensive research which can be highly expensive and unpredictable and may result in the creation of a new product or method that can be useful. In such a situation, it becomes imperative to provide protection in order to promote further invention, to protect the rights of the patent holder and for the benefit of public at large from that invention. However, a major challenge which is often discussed both at

[4] Fathima Mehendi, *An Analysis of Development of Patent Law in India*, LEGAL BITES (Apr 29, 2021, 22:56 PM), https://www.legalbites.in/analysis-of-the-development-of-patent-law-india/.
[5] Ayush Verma, *Patents and the Right to Healthcare in India*, IPLEADERS (Apr 29, 2021, 22:59 PM), https://blog.ipleaders.in/patent-right-healthcare-india/.

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international and domestic level, is to maintain a balance between public health and patent protection.

Right to health is considered as a basic human right which should be guaranteed to every individual without any discrimination. However, even after development in healthcare technologies, the ground reality is that, in the entire world around 2 billion people do not have access to rudimentary medicines.[6] Each year over 13 million people die because of infectious diseases.[7] One of the major reasons which impede the people to have access to medicines is their exorbitant prices, which is the direct result of the patent protection granted over the medicines.it leads to creation of monopoly and allows the patentee to keep the prices high. At the international level, this major challenge concerning patent and public health was discussed at length in the Doha Declaration on TRIPS agreement and public health which took place in 2001, pursuant to which efforts were made to balance the grant of patent to pharmaceutical companies in relation to the public health needs. Paragraph 4 of this declaration gave primacy to the public health over the intellectual property rights.

III. INDIAN SCENARIO

Under the Indian Constitution, Right to Health is not expressly provided as a fundamental right but there are multiple references in the constitution and various judicial pronouncements to support right to health.

Directive principles of state policy incorporated under part IV of the constitution contains certain provisions to protect right to health. Article 47 cast a duty on the state to raise the nutrition level and improve public health, Article 39(E) directs the state to protect the health of workers. Apart from this, the Supreme Court in the case of Bandhua Mukti Morcha vs Union of India,[8] interpreted right to health as a part of article 21 of constitution of India.[9]

For several decades, India has witnessed various health crisis, the situation became worst due to the unavailability of medicines and inadequate health infrastructure. Based on such scenarios, it becomes essential that the patented medicine shall be provided at a reasonable rate by pharmaceutical companies.

While dealing with the public health crisis and developing a robust system for public health,

[6] *Access to Medicines: Making market forces serve the poor*, WORLD HEALTH ORGANIZATION (Apr 29, 2021, 23:01 PM), https://www.who.int/publications/10-year-review/medicines/en/.
[7] Anuradha Chadha, *Intellectual property rights vis a vis right to health: A critique*, SSRN, pg. no. 3, 2014.
[8] Bandhua Mukti Morcha v Union of India, (1997) 10 S.C.C. 549 (India).
[9] Nishant Sirohi, *Declaring the right to health a fundamental right*, OBSERVER RESEARCH FOUNDATION (Apr 29, 2014, 23:13 PM), https://www.orfonline.org/expert-speak/declaring-the-right-to-health-a-fundamental-right/.

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the Indian Patent Act 1970 incorporated certain provisions to strike a balance between public health and the rights of the patent holder. The provisions are listed as follows:

1. Section 47 of the patent act, imposes certain conditions on the grant of patent and empowers the government to import or make use of any patented product or patented process for the purpose of welfare of public at large. Clause 4 of section 47 further stipulates that, in case of patent in respect of any medicine or drug, the government has the power to make use of such patented product or for its distribution in any dispensary, hospital or any medical institution.
2. Section 83 enumerates that grant of patent should not impede the protection of public health and also ensure that the patented product is available for public at affordable prices. The objective behind granting patent to the patentee is to encourage further invention and to protect any form of exploitation of the rights of patent holder but such grant should not act as a hindrance rather, act as an instrument to promote public interest.[10]
3. Section 84 provides for compulsory licensing after the expiry of three years from the date of grant of patent. This section seeks to protect public interest and lays down certain conditions in which any person can apply for the license by making an application to the controller. The grounds for the same are as follows:
   (i) *"that the reasonable requirements of the public in respect to the patented invention has not been satisfied,*
   (ii) that the patented invention is not available to the public at affordable prices,
   (iii) that the patented invention is not worked in the territory of India."[11]
4. Section 92 is yet another provision which stipulates that in case of any emergency or for public non- commercial use, the government can waive off the time period of 3 years given under section 84, in order to give primacy to the protection of public interest.
5. Section 102 empowers the government to acquire any patented invention, when it is satisfied that, it is necessary to do so for public interest.

In its landmark decision[12], the Supreme Court held that: "*The object of patent law is to encourage scientific research, new technology and industrial progress. Grant of exclusive*

[10] Avanee Tewari, *Commercialising a pandemic – how to balance patents and public health emergencies*, LAW BUSINESS RESEARCH (Apr 29, 2021, 23:15 PM), https://www.iam-media.com/commercialising-pandemic-how-balance-patents-and-public-health-emergencies.
[11] Section 84, The Patents Act 1970, No. 39, Acts of Parliament, (India).
[12] *Bishwanath Prasad Radhey Shyam v Hindusthan Metal Industries* AIR (1982) SC 1444 (India).

privilege to own, use or sell the method or the product patented for a limited period, stimulates new inventions of commercial utility. The price of the grant of the monopoly is the disclosure of the invention at the Patent Office, which after the expiry of the fixed period of the monopoly, passes into the public domain."[13]

Therefore, it is clear as a picture that public health plays an essential role as a part of the patent laws in India. Ease of access of pharmaceutical products to the public at minimal rates not only provides flexibility to the public but rather balances out the need for an essential commodity.

IV. TYPES OF PHARMACEUTICAL PATENTS IN INDIA

Being one of the most relevant intellect centric sector, the pharma industry can be very expensive and unpredictable in terms of research and findings. The outcomes of a pharmaceutical research can vary from being new, inventive to being productive. Undoubtedly, such a sector can be extremely competitive and therefore, it is essential to give a medium of protection against any unregularized commercial use to the pharmaceutical companies w.r.t to their inventions by use of patent rights. Several categories of these public health patents as defined by the Indian Patent office are as follows:

(A) Drug Compound Patents

In this category, the chemical composition of a drug compound, having the widest possible protection, is claimed as a patent. Also known as the Markush Type claims, it is a claim which is capable of having several 'functionally equivalent' chemical units taking place in more than one part of the concerned compound.

By way of this patent, other similar companies are not allowed to invent or produce the similar drug both directly or indirectly before the expiry of the concerned patent.

(B) Formulation Patents

Technology used for the formulation of the key ingredients of a drug can be claimed under this patent category. This is to imply that the exceptional combination used for the preparation of an active drug ingredient for formation of its dosage that shall be administered to the patient can be protected under this category.

(C) Synergistic Combination Patents

When more than one drug interacts with one another that is expands or widens the effects of the drugs concerned, then this process is referred to as 'Drug Synergy'.

[13] Id.

For example- a synergistic combination of roflumilast and salmeterol was claimed in the Indian patent no. 206328[14] as follows:

"A medicament comprising a PDE inhibitor, which is to be administered orally, from the PDE4 inhibitors group combined with a G2 adrenoceptor agonist in fixed or free combination, wherein the PDE inhibitor is roflumilast, a pharmacologically tolerable salt of roflumilast and/or the N-oxide of roflumilast and the G2 adrenoceptor agonist is salmeterol or a pharmacologically tolerable salt thereof.[15]"

(D) Technology Patents

There can be various innovative techniques which can be used by companies to resolve specific tech-problems and therefore, such innovations require considerable protection, too. That's where technology patents come into the picture. Solutions like stabilization, increased solubility, taste masking, etc can be protected under this category.

V. TRANSFER OF THE PATENT RIGHTS

As a form of property, owned by its inventor or innovator, a patent right can be transferred to any person via the patentee through assignment or licensing. As per the Indian Paten Act, such a transfer done by assigning or licensing must be carried out in written form and must clearly mention all the conditions covering the duties and liabilities of the parties involved.[16]

VI. PATENT ASSIGNMENT

In layman terms, assignment can be understood as the transfer of ownership of the property belonging to one person the another. Therefore, patent rights can be assigned by transferring partially or entirely the patent rights, title and interest in the patent to some other person, thereby, defining such person as the assignee.

A patent assignment usually takes place within the company and employee dynamics. Suppose an employee upon being hired signs a patent assignment that any inventions that he comes up with within the R&D facilities of that company shall be transferred in the name of that company only, although the name of the employee as the patentee can be retained.

[14] Jain B. Ayurvedic Antiretroviral composition for treatment of Acquired Immuno Deficiency Syndrome. Indian Patent IN 203986, 2007.
[15] Id.
[16] Vipin Mathur, *Patenting of Pharmaceuticals: An Indian Perspective*, IMEDPUB LTD. (Apr 29, 2021, 23:29 PM), https://www.ijddr.in/drug-development/patenting-of-pharmaceuticals-an-indian-perspective.php?aid=4994

VII. PATENT LICENSING

The process of patent licensing enables plethora of related rights to be transferred to other people such as geographical zones, field of use, time, etc. Such licensing may be compulsory or voluntary.

(i) Voluntary license: When another person is transferred the right to use the patented invention by a voluntary action on the wish of the patentee by a written agreement, it is known as voluntary license. The Central Government or the Indian Patent Office do not play any role in this procedure.

(ii) Compulsory license u/s 84: A provision relating to compulsory licensing is provided under the Indian Patent Act. Any person who wishes to work the patented invention can apply for a compulsory license once three years from the date of the sealing of the patent have expired. Upon such application, the patent holder may be directed by the controller of patents to grant the license based upon relevant terms and conditions.

In a landmark decision[17], the controller of patents granted the issue of first ever compulsory license in India on the grounds for the grant of compulsory license mentioned under section 84 of the Patents Act, 1970:

a. *"Reasonable requirements of the public with respect to the patented invention were satisfied since only 2% of the total kidney and liver cancer patients were able to access the Bayer's drug.*
b. *The Controller determined that the patented invention was not available to the public at a reasonably affordable price because Bayer was charging about Rs 2.8 lakhs for a therapy of one month of the drug.*
c. *The Controller also found that the patented invention was not worked in the territory of India since Bayer was not manufacturing the product in India rather it was importing it from outside India."*[18]

VIII. LICENSES OF RIGHTS

The Indian Patent Act, apart from compulsory licensing, also has a provision for 'licenses of right.'[19] In such category, after three years of the sealing of the patent, the Central Government has the power to apply for a patent to be categorized as a license of right on the grounds that

[17] Natco Pharma Ltd., India v Bayer Corporation, USA C.L.A No. 1 of 2011., Mar. 9, 2012.
[18] Id.
[19] Section 91, The Patents Act 1970, No. 39, Acts of Parliament, (India).

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the public related reasonable requirements have not been met w.r.t to the concerned patent invention or that the said patent is simply not available to the public at a reasonable price. Usually, items which can be categorized as food or drug items but do not generally fall under the tag of the same can be endorsed with the term 'license of right' once three years expire after the sealing of the patent. The effect of such endorsement is that any interested person in India can request the patentee to grant them a license. After such request, the license can be granted either upon mutually agreed terms between the parties or at the terms as laid down by the controller of patents.

IX. CONCLUSION

Apart from being a member of the World Trade Organization, India is also a signatory to the TRIPS Agreement (modified by the Doha Declaration) while also being a signatory to the Paris Convention 1883. Pursuant to this, India enacted the Patent Act 1970. The purpose of this Act is to create a mutually beneficial environment for those in a health crisis as well as the inventors of pharmaceutical products.

Aimed at balancing the interests of the public at large as well as the innovators, the Indian Patent Act plays a huge role in meeting the requirements of the patent legislation scenario in India. Undoubtedly, a vast range of pharmaceutical inventions can be protected under the aegis of a patent, however, it is highly recommended that the innovators should conduct due research as to which category best fits the protection of their innovation. As far as transferability of patents is concerned, on one hand it meets the objective of sharing the inventions in the public domain by giving due recognition to the patentee's rights while on the other hand it also ensures that public health being a common interest shall be available to a common man without the hinderance of unreasonable prices and other like factors.

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