A CRITICAL STUDY ON COMPULSORY LICENSING OF PATENTS UNDER THE INDIAN PATENTS ACT, 1970

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ABSTRACT

In order to address the problem of monopoly created by the patent system, there is a holy provision in the Indian Patents Act 1970 known as compulsory licensing. It may be considered as heart and soul of the Indian Patents Act 1970. Compulsory licence is an authorization granted by a legal authority to grant a licence without or against the permission of the title holder for the use of a patent-protected subject matter. Finding a balance between the interests of the innovator and the general well-being of society is the primary goal of patent issuance. However, the current patent system primarily safeguards technological advancements and innovation at the expense of the general welfare of consumers. It is now seen as a crucial instrument for fostering creativity

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Introduction

According to World Intellectual Property Rights, a patent means an absolute exclusive right granted for novel innovation, which is a process or product it involves a novel remedy to an issue or, more generally, a creative method of producing something. Technical details of the invention must be made public in a patent application to receive the patent[2]. The current Patent Act granted the inventor an exclusive right to use his invention, so long as it met the Patents Act's standards for patentability, which include being inventive, having an industrial application, and being non-obvious. The state has granted the monopoly for a span of 20 years, to be exact. "The innovators may benefit momentarily from their creation during the tenure of patent. Consumer must,however, wait for the patent to expire before they can benefit from the patented invention. Customers can benefit from the patented drugs once the patent has expired. It confers social gains by making inventions lucrative and encouraging innovators to continue their cost-cutting efforts, but it also imposes social losses by making customers wait longer for the competitive price drop, according to F.M. Scherer[3].

Finding a balance between the interests of the innovator and the general well-being of society is the primary goal of patent issuance. However, the current patent system primarily safeguards technological advancements and innovation at the expense of the general welfare of consumers. It is now seen as a crucial instrument for fostering creativity. When the patented drug is released into the commercial sector by the patent holder, For those who can afford it, it is a more effective option. Because of the patentee's strict monopolistic policy or control, the cost of these patented medicines increases. As a result, those in need have the choice to purchase generic drugs, less expensive drugs, or no drugs at all.

They are left with the choice to pay for poor medical care because they cannot afford better medicines. The conclusion of such a patent is neither ideal nor acceptable from a societal and moral standpoint. However, there won't be any novel drugs available on the market if there isn't a patent system in place. The best course of action for society, without endangering the interests of the patentee, would be to provide a special relief that permits to sell patented medicines on the market at a reduced cost in extreme crisis situations. If patent protection is reduced it may be a disincentive to innovator or if patent protection is absolutely permitted it may be threat to the individual's life interest. So, this situation necessitates to enact a socio welfare legislation

[2] Available at https://www.wipo.int/en/web/patents/ , accessed on 28.10.2024 at 12.37.p.m
[3] Scherer .F.M , The Economic effects of compulsory patent licensing, 1st edition(New York University, Graduate School of Business Administration, Center for the Study of Financial Institutions, 1977)

in accordance with Article 31 of the TRIPS Agreement. Under the heading of "Other Uses Without Authorization of Right Holders," Article 31 of TRIPS addresses the idea of compulsory licensing. It describes the circumstances such as national emergencies, public health emergencies, and anti-competitive behavior under which compulsory licenses may be issued. Compulsory licensing, in general, is a legal mechanism that enables governments to allow other persons to utilize patent ideas without getting consent from owner. It meets needs in public interest, such as promoting competition or providing access to necessary medications[4].

Compulsory licensing under the Patent's Act, 1970

The Patents Act contained the laws pertaining to compulsory licensing. The Patents Amendment Act of 2002 subsequently updated this chapter. Prior to the modification, the chapter was made up of Sections 82 through 98 and included clauses known as "licencing for rights" as stated in the title. However, it was left out of the 2002 Patent Amendment Act. These provisions referred as "working of patents, compulsory licenses, and revocation of patents for non-working[5]." As per the provisions of the TRIPS Agreement, this law was modified[6]. As per Section 84, the Patents Act of 1970, anyone who is interested in obtaining a compulsory license, including an existing licensee, may apply to the controller for the award.

Concerning the timing of the application, Section 84 states that a request for the issuance of a compulsory license may be submitted at any point after three years have passed after the patent was granted[7]. Section 84(1) of the Patents Act of 1970 states that any interested party may request a compulsory license for a patent from the Controller at any time after three years have elapsed from the date of the patent's award for any of the following reasons:

As the patented product has not been effective in operating inside Indian territory, and the patented invention is not reasonably priced, or as the patented product has not lived up to the reasonable expectations of the public.

Who can apply for compulsory licensing

If the patent hasn't been developed in India, an interested party may ask the controller to seek

[4] Available at https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm accessed on 28.10.2024 at 12.50.p.m
[5] Sections 82 to 94 of the Patents Act
[6] Feroz Ali Khadar, *The Law of Patents with Special Focus on Pharmaceuticals in India,* (New Delhi: Lexis Nexis Butterworths,1st Edition 2009), p.707
[7] Section 84 of the Patents Act, 1970

a compulsory licensing. Patent requirements and patent operation are not synonymous. Both mean different things. The patent owner's ability to limit competition is the only factor affecting the patent invention's functionality in India. The granting of the required patent license is completely connected to the operation of the patent. The Indian Patents Act of 1970 discusses the objectives of compulsory licensing and stipulates that the broad justifications listed in the section must be considered before granting a compulsory license[8]. According to chapter XVI, there are various circumstances under which a compulsory license may be sought. Sections 84, 91, 92, and 92A go into depth on the steps that must be taken when awarding a compulsory license as well as the conditions under which it may be issued.

The following factors will be taken into account when evaluating whether to award compulsory licenses when using the authority granted by this Act[9].

1. Promoting ideas and ensuring that inventions are manufactured economically and, to the extent that it is practical, on Indian soil are the main goals of patent issuance. For a patent to continue to be successful, its operation is more important. Patents must be created as quickly and efficiently as feasible, possibly by manufacturing the patented drug locally[10].
2. The sole purpose of patents is not to give the patentee the exclusive right to import patents. Implementing the patented idea on Indian soil is the aim of a patent grant.
3. The defense and upholding of patent rights promotes technological innovation, transfer, and diffusion.
4. Granting patents should not obstruct the protection of the public's nutrition and health. The general public will also benefit from this in terms of economic and technological growth.
5. When the union government taken particular actions to enhance public health, patents shouldn't be conferred. Further information on these subjects can be found in the Doha Declaration on TRIPS and Public Health principles[11].
6. Actions unduly restrict commerce or obstruct the transfer of technology should be avoided, as this lead to the monopoly of patent rights.
7. The main reason patents are conferred on the patentee is to enable the general public to profit from patented inventions at affordable prices.

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[8] Elizabeth verky, intellectual property law 1st edition(eastern book company) p444
[9] Section 83 of the patents Act, 1970
[10] Section 84 of the patents Act, 1970
[11] Para 6 of the Doha Declaration on the TRIPS Agreement and Public health

Applications for the grant of compulsory licences

Applications for the issuance of compulsory licenses generally fall into four categories. Specifically Section 84, Section 91, Section 92, and Section 92A applications. The applicant must show the prima facie case in order to receive a compulsory license. Section 87 requires the controller to certify that the petitioner has shown the prima facie case[12]. The controller is then the only one with the authority to issue an order. If the Controller finds that there is a prima facie case for issuing an order after reviewing an application under section 84 or section 85, he will direct the applicant to serve copies of the application to the patentee and any other people listed on the register who might be interested in the patent for which the application is made. He will also publish. If the patentee or anybody else wants to object to the application, they can notify the Controller of their objection within the allotted period or during any further time the Controller permits on the application made before or after the time limit has passed.

A statement detailing the reasons for opposing the application must be included in each such notice of opposition. The Controller will notify the applicant and provide both parties a chance to be heard before rendering a decision if the notice of objection is duly delivered.

All applications submitted under sections 84, 85, 91, and 92(1) are subject to section 87. If the application is submitted under sections 92(3) and 92A, the prima facie case does not need to be proven[13]. The controller will issue a compulsory license if the applicant meets the requirements of section 92A. In some severe circumstances, exporting patented medicinal products requires a compulsory license. If a country has granted a compulsory license or permitted the importation of the patent by notification or another means, then compulsory licenses will be available for the manufacture and export of patented medicines to any country with inadequate or no pharmaceutical manufacturing capacity to address public health issues. The Controller must provide a compulsory license exclusively for the production and export of the relevant pharmaceutical product to that country under the terms and circumstances he may specify and publish after receiving an application in the proper manner. Subsections (1) and (2) have no bearing on the extent to which pharmaceutical products manufactured under a compulsory license may be exported in line with any other provision of this Act.

An application for a compulsory license may be submitted by anyone interested in the patented drug. An application for a compulsory license may also be submitted by a patent license holder.

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[12] Feroz Ali Khader, the law of patents with a special focus on pharmaceuticals in India (lexis nexis butterworths wadhwa, 1st edition),p 712

[13] Feroz Ali Khader, the law of patents with a special focus on pharmaceuticals in India (lexis nexis butterworths wadhwa, 1st edition),p 712

The license holder cannot be turned away because he already holds a patent, whether through a license or another method. For the reasons listed in section 84(1) of the Patents Act, the license holder's acceptance of such a license will not be a barrier to their ability to apply for a compulsory license[14]. To secure a compulsory license, the interested party must submit an application to the patent controller. Rule 96 of the Patent Rule 2003 specifies the type of interest the applicant has, the terms and conditions of the license, and additional formalities that the applicant is willing to accept. The applicant is required to submit an application outlining the nature of his or her interest as well as the relevant information[15].

Crucial elements that the controller must take into account while awarding a Compulsory license

Section 84 (6) goes into great detail on the key elements that the controller must take into account when awarding a compulsory license[16]. After lapsing three years from the date of the patent grant, the scope of the invention and the steps taken by the patent owner or licensee to properly utilize it must be taken into account by the controller.The capacity of the applicant to use the invention for the benefit of the public. After the license is granted, the applicant must assume the risk of funding and running the invention. If the applicant made an effort to obtain a patent from the patentee but failed to do so within a reasonable amount of time that is not more than six months. If there is a national emergency, other dire circumstances, public non-commercial use, or the patentee exhibits anti-competitive activity, the controller may waive the fourth requirement. The applicant always has the burden of proving that the requirements for providing a compulsory license are met in his favor.

Reasonable public requirements

The Patents Act's Section 84(7) outlines the following situations when it will be assumed that the legitimate needs of the general public have not been met.

(a) If the patent holder declines to issue a license or licenses on fair terms

(b) The formation or growth of any trade or industry in India is hampered if the patentee places restrictions on the patentee by issuing licenses for patented drugs, their purchase, rental, use, or process, or by manufacturing patented inventions that are not covered by the patent.

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[14] Section 84(1) of the patents Act, 1970

[15] Section 84(3) of the Patents Act 1970

[16] Therma – tru corp's patent (1997) RPC 777, p 793

(c) To avoid objections to the patent's validity or coercive package licencing, the patentee may impose a condition on the patent grant by licenses under the Patents Act to offer the exclusive grant back.

(d) If the invention is not being made to the greatest degree that it is commercially feasible within the borders of India

Impact of refusal by the Patentee to grant licences

When an applicant requests a patent licence and the patentee refuses on reasonable conditions, it results in the public's reasonable requirements not being met, resulting in the following circumstances.

(a) Prejudice to trade or commerce or industry
(b) Demand for patented inventions not satisfied
(c) Prohibition of export of patented invention results in failure to supply in the local market
(d) Detrimental to the commercial activity

The controller is vested with the following powers to pass an order under section 88 of the patents Act as follows

1 Power to grant licences to applicant customers
2. Power to cancel or amending the existing licences
3. Power to grant licences for other patents
4. Power to revise the terms and conditions

Special compulsory licenses

If certain special circumstances exist, if the central government thinks fit, Section 92 of the Indian Patents Act allows it to give a compulsory license to use the patented innovation. In order to implement Article 31(b) of the TRIPS Agreement , by publication in the official gazette, the central government has been given the authority to declare that to implement the innovation in the following cases, a compulsory license must be granted for any active patent:

1. In case of National Emergency
2. In case of extreme public urgency
3. In case of public non- commercial use.

After the patent has been awarded, an application under Section 92 may be filed at any time.

The applicant is not required to wait the required three-year term following the date of issuance of the patent before filing an application. It is possible to file a patent application immediately after the patent is granted. If any person submits an application to the controller after receiving the notification, the controller may award a licence under the patent on the terms and conditions that he deems appropriate. But provision of relaxing three year period can be possible only after then, the central government may proclaim in the official gazette that this is the case. The procedures ,rules and principles for granting licences under section 92(1) are similar to the provisions of section 84.

Fast relief procedure are mentioned in section 92(3). In the case of an application filed under Section 92, the controller has the authority to deviate from the method set forth in Section 87. The following prerequisites must be met in order to proceed:

a. The applicant must prove a strong case in order to proceed.
b. The copies of the application should serve on the patentee by the applicant
c. It is necessary that the application shall be published in the official journal. On receiving such application the patentee mar raise an objection to the applicant by giving notice of opposition.
d. If any opposition received the controller shall give notice of opportunity to both parties before deciding the case.

(b) Section 92(3) also lists national emergency, extraordinary urgency, and public non - commercial use as special conditions.

Under the provision public health crisis are broadly interpreted. The expression public health crisis includes the following Acquired Immuno Deficiency Syndrome (AIDS), Human Immuno- deficiency Virus (HIV), Cancer, Tuberculosis, Malaria or other Epidemics.

Conclusion

The primary goals of establishing patents were to benefit the national economy as well as the innovator.[17] According to the code of Federal Regulations of US that the Patent by its very nature is affected with the public interest. In the words of Michael Kern "one should not forget that patents represent an interventionist instrument ultimately for the sake of community welfare. Thus intervention to restrict some of the effects of patents may be required when the community welfare is no longer served". The grant is given to patentee as a bargain for

[17] Justice N.R.Rajagopala Ayyangar committee report on the revision of Patents Law

disclosing patented invention to the society[18]. Apart from the patent holder the largest beneficiary of that patented invention is ultimately public. Hence the patented invention should be made available to the public. But there is always a threat that the patentee has chance to abuse patent monopoly conferred on him by way of exercising patent monopoly right. Such monopoly can be exercised by way of refusing licence to third party or imposing arbitrary terms upon the licensee or imposing restrictive negative conditions on the use of the patented articles or products.

The government grants compulsory licenses to increase access to patented products and services in order to accomplish numerous public goals. The Paris Agreement, which was recognised as an international convention protecting intellectual property rights, and the TRIPS Agreement both include a compulsory licence for a patented invention. Various international accords, such as the Paris Convention for the Protection of Industrial Property and the TRIPS Agreement, recognise the transnational nature of compulsory licencing. Even though compulsory licencing as a policy choice is explicitly allowed by the TRIPS Agreement, there is still a problem of differing opinions on its rules. This must be addressed in a way that provides developing countries the greatest degree of freedom in interpreting and applying the provisions. Members must have explicit and accepted guarantees that the TRIPS Agreement does not prohibit or limit their commitment to preserve public health and respond effectively to disease outbreaks or pandemics, as well as other health goals, in the context of access to medicines. Parallel import recognition is becoming more common in poor countries, which have enacted explicit statutory provisions incorporating international patent exhaustion into their national legislation in order to ensure their residents' access to lower-cost medications. It is also crucial for developing country to be able to formulate national policies so that they do not find themselves in situations of unpredictability, such as being forced to use the WTO's dispute settlement system. Furthermore, effective compulsory licencing should promote generic competition and local manufacture of life-saving medications

[18] Patent is a quid pro quo contract between the patentee and government.