COMPULSORY LICENSING OF PATENTS IN INDIA

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Patent is an important criterion as it gives the inventor a monopoly over their invention and restricts the use of the invention by others as it confers exclusive rights on the patent holder. In some cases, the rights patented may be exploited. The Indian Patents Act provides for the prevention of misuse of compulsory licensing provisions. Compulsory license allows a third party to use, sell, and make the patented invention without the patent holder's consent. This paper will cover the compulsory licensing concept and the significance of the case of Bayers in India. And the statutory provisions on compulsory licensing under the Indian Patents Act.

I. INTRODUCTION

INTRODUCTION

Patent is the exclusive right granted to a person who invents a product or process that is also new and useful. Patent provides a monopoly right for 20 years to the patent holder to prevent others from exploiting the invention[1]. Patent is a reward for the inventors for their skills, efforts and resources to foster innovation. The patent is granted by the government instead of being fully disclosed by the inventor. Without the presence of a patent system the inventor will not be encouraged to disclose his invention and may prefer to keep it as a trade secret, which may lead to sluggishness in the research and development of new technologies[2].A patent is a legal contract between the patentee and the government, wherein, the government provides right of protection of the invention for a limited period of time after full disclosure of the invention by the patentee[3].

The grant of the patent is a statutory process governed by the patent regulation of the country concerned, subject to the general conditions of patentability viz. Novelty, inventiveness and industrial applicability. In India patents are governed by the 1970 Indian Patent Act. In order to comply with TRIPS (Trade Related Aspects of Intellectual Property Rights) agreement, India introduced a series of amendments in its patent law in 1999, 2002 and 2005. Now under the law, the patent proprietor has the exclusive right to use, sell, manufacture and import their product and process patents to exclude a third party until the expiry of the patent. . In certain specific circumstances, a third party may use the patent without the patent holder's permission, which is called compulsory licensing. . It is the authorizations given to a third-party by the Government to make, use or sell a particular product or use a particular process which has been patented, without the need of the permission of the patent owner.[4] Under the Indian Patent Act 1970, the provisions of

[1] Gupta R. Compulsory Licensing under TRIPS: How afar it Addresses Public Health Concerns in Developing Nations. Journal of Intellectual Property Rights, 2010; 15: 357-363.
[2] http://ipindia.nic.in/ipoNew/compulsory_License_12 032012.pdf (accessed 20 January 2016)

[3] Vipin Mathur, Dr. B. P. Nagori & Dr. Mahendra Tiwari,A comparative study of patent opposition in US,Europe,China and India
[4] https://blog.ipleaders.in/concept-compulsory-license-patents-act-1970/

the compulsory license specifically granted under Chapter XVI. The requirements for granting a compulsory license under Sections 84 and 92 of the Act to be fulfilled.

COMPULSORY LICENSING IN INDIA

Patents are exclusive legal rights granted by the government to a innovation by company / individual. Patents are time - bound in nature, for example in India patents are granted for a period of 20 years from the date of filing of the patent application. The patents are valid only in the territory where they were granted. There are two types of product and process patent. A product patent protects the product that has been synthesized or made by the inventor and nobody else can make the same product. And only the process or method developed by the inventor to make the article / product is protected by a process patent. The inventor can only use it to make that particular article or product. But using different processes, the public can use the same product. The primary purpose of the patent grant is to promote innovation and ultimately result in development. In these circumstances, patents grant the patentee a monopoly power there is a chance of abusing patent rights. In India, also too, CL's grant provision has been made to restrict anti - competitive practices and strike a balance between the rewarding patentees and simultaneously inventing and making new products, particularly drugs, available to a large population at cheaper and affordable prices. The compulsory licenses can be used to avoid such abuse. Compulsory licensing is where a government authorizes another person to produce a patented product or process without the patent proprietor's consent or plans to use the patented invention itself. It is one of the flexibilities in the field of patent protection included in the WTO's agreement on intellectual property — the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement.[5]

The World Trade Organization (WTO) defines compulsory licensing as a practice in which the government permits another person to produce the patented product or use the patented process without the patent proprietor's consent. . It is one of the flexibilities on patent protection included in the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement.[6] In India's present Patents Act, 1970 entered into force in 1972, amending and incorporating existing patent and design laws in India in 1911. The2005 Patent (amendment) Act came into force on 1 January 2005, bringing changes to India's previous patent system in which product patents were extended to all subjects of food, drugs and chemicals technology. In addition, in 2005, Section 3(d) introduced the said amendment act and for the first time introduced patents for pharmaceutical products in India. in 2005 Patent (amendment) Act defines what an invention is and makes it clear that it is not possible to patent any existing knowledge or thing. The provision defines a standard of ' novelty ' - which together with ' non - obviousness ' or ' inventive step ' and industrial activity. In fact, ' discovery ' refers to finding out something that already existed in nature but was unknown or unknown. Therefore, discoveries are excluded from patent protection under section 3 of the Indian Patent Act 1970.[7] Chapter XVI Sections 82 to 94 were inserted in accordance with the Indian Patent Act, 1970 and in 2002 amendment and Section 84 specifically provides for the grant of CL after a period of 3 years from the date of grant of the patent on an application filed by an interested person before the patent controller.

[5] https://www.wto.org

[6] Kaur A, Chaturvedi R. Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma. Journal of Intellectual Property Rights, 2015; 20): 279-287

[7] https://www.lexology.com

REQUIRMENTS FOR COMPULSORY LICENSING

Compulsory licensing provisions are laid down in both the 1970 Indian Patent Act and the TRIPS International Law Agreement between all WTO Member States. Chapter XVI of the Indian Patent Act, 1970 deals with compulsory licensing while the conditions which need to be fulfilled for the grant of a compulsory license are laid down under Sections 84 and 92 of the Act.[8] Pursuant to Section 84(1) of the Indian Patent Act 1970, any interested person may apply for a compulsory license on the grounds that the patented invention has been granted after three years of granting a patent:

1. The reasonable requirements of the public have not been satisfied

2. The patented invention is not available to the public at reasonable affordable price, or

3 .The patented invention is not worked in the territory of India.[9] .

Section 84(7) of the Patents Act sets out a list of circumstances in which, if any of these circumstances occur, the reasonable requirements of the public are treated as not being met. These are the circumstances - (A) the patent proprietor refuses to grant a license resulting in harm to trade, industry or commercial activities in India ; or the non - compliance with the patented article or the non - development of the patented article in export ;(B) The patent proprietor imposes unreasonable conditions on licenses that are detrimental to trade and industry development in India(C) The patent proprietor imposes conditions of exclusive grant reimbursement, prevention of contestation of patent validity or coercive package licensing(D) the invention is not worked in India on commercial scale to an adequate/ fullest extent in a reasonably practicable way(E) The commercial functioning of the invention in India is prevented by the importation from abroad of the patented article.

The Controller while determining a “reasonably affordable price” may take into account various factors such as the purchasing power of Indian public/ end user(s) of the patented product, cost of the production, availability and affordability of any substitute of the product etc[10]. Under section 83 of the Patents Act, general principles applicable to the "working of patented inventions" are laid down. And Sec 83(b) is one of the general principles granted to patents not only to enable patentees to enjoy a monopoly on imports of the patented article into India. Therefore, for a patented invention to be treated as “worked in the territory of India” the invention shall be manufactured to a reasonable extent in India. [11]Further, the patentee must not mistreatment his patent rights by adopting any anticompetitive activity, or resort to practices which unreasonably restrain trade/ adversely affect the international transfer of technology (section 83(f))[12]

Pursuant to Section 92 of the Act, the Controller of Patents may also issue compulsory licenses on suo motu shall be subject to a notification issued by the Central Government where there is either a "national emergency" or "extreme urgency" or "public non - commercial use". The said section allows the Government of India to notify such extreme circumstances to the public, whereupon any interested person may apply for a compulsory license and in such a case the Controller may grant the applicant a patent license on such terms and conditions as he deems appropriate.

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[8] http://www.mondaq.com
[9] https://www.lawyerscollective.org
[10] Gopalakrishnan NS, Anand M. Compulsory License Under Indian Patent Law. In: Liu KC, Hilty RM, editors. Compulsory Licensing: Practical Experiences and Ways Forward. London. Springer Verlag Berlin Heidelberg; 2015. Ibid., p. 26 The Patents Act
[11]Indian patent Act 1970, section 83
[12] Ibid, section 90

Procedure for grant of compulsory license under section 84

Before applying for a compulsory license under Section 84, the applicant should attempt to obtain a voluntary license from the patent proprietor in order to make use, sell or import the patent proprietor's invention. If the patent holder refuses to give consent and grants a voluntary license on reasonable terms and conditions resulting in applicants failing to obtain a voluntary license, the interested person may apply for a compulsory license under Section 84(1) before the patent controller. Then t controller will examine the initial application for the compulsory license to determine whether the application actually reveals sufficient facts and incidents that can support the raised reasonable grounds. The patentee is desire to oppose the application may, within such time as may be prescribed(two moths) or within such further time as the Controller may on application (made either before or after the expiration of the prescribed time) allow, give to the Controller notice of opposition[13]. Here both applicant and patentee have the opportunity to be heard before deciding the case.

INDIA'S FIRST COMPULOSORY LICENCE

I first compulsory license in India was granted to Natco Pharma Ltd. by the Patent Office for the production of a generic version of the patented medicine of Bayer Corporation, sorafenib tosylate used in the treatment of liver (Hepato cell carcinoma [HCC]) and kidney cancer (Renal cell carcinoma [RCC]) at advanced stages. In 2007, Bayer was granted a sorafenib tosylate patent. By pricing it at Rs. 2, 84,000 per patient per month, Bayer marketed this medicine in India. On 2010, Natco Pharma requested a voluntary license from Bayer to manufacture and sell Bayer's patented drug Nexavar in India at a price below Rs.10,000/month of therapy compared to the price of Rs.2,80,428/month charged by Bayer. Since Bayer refused to grant Natco a voluntary license and rejected Natco's request, Natco applied to the Patent Controller requesting that a compulsory license be granted, i.e. without Bayer's consent, to manufacture and sell the patented drug sorafenib tosylate from Bayer in India. . The patent controller considered Natco's application for compulsory license under section 84. According to section 84, while any of the above three grounds might be necessary to grant a Compulsory License, on all three grounds, the Patent Controller decided against Bayer. The Controller's decision was based on section 84 of the Patents Act. Here the Controller found that the public's reasonable requirements with respect to the patented invention had not been met, as only 2 percent of total patients with kidney and liver cancer had access to the Bayer's drug. And the patented invention was not accessible to the public at a reasonably affordable price, as Bayer charged one month of drug therapy for Rs. 2.8 lakhs. Another observation was the patented invention is not worked with in India.

Rational behind the decision

The decision of the IPAB was motivated by its inclination towards the public health needs and recognition of the right to health and life guaranteed under the Constitution of India.[14] This referred to TRIPS Article 8, which recognizes the Member States ' obligation to uphold national interests. The IPAB placed all its reliance on Sec. 84(1) and held that the reasonable requirement test was not met because it did not sell in India and it was so highly priced that it was out of reach of the ordinary public.

Bayers submission was in India, only 4004 patients with kidney cancer in terminal stage and 4838 patients with liver cancer in the terminal stage required sorafenib tosylate for the treatment. The Bayers Company

[13] http://rajdeepandjoyeeta.com/compulsory-licensing-in-india/
[14] Gujan chawla, THE CURIOUS CASE OF COMPULSORY LICENSES IN PATENTS

issued only 2 percent of the patients with the drugs compared to an eligible 8842 patients. . The cost of 2.8 lakhs of medicine a month again fails to test reasonable affordable prices under sec 84(1)(b). . The Patent Controller therefore concluded that the Patent Controller concluded that since 2008 Bayer had only been able to supply sorafenib tosylate to just over 2% of patients in India. And the excessive amount of medicine also creates a burden to reach the medicines for the patients. Bayer Company fails to meet the test's first requirement. .

The Bayer imported sorafenib tosylate into India and were unable to provide substantial grounds for failing to produce the drug in India. Despite having facilities in India to manufacture other drugs, the Patent Controller maintained that Bayer had failed to work the invention on India's territory. The IPAB specifically referred to the history of the TRIPS negotiations and argued that if India meant manufacturing in the territory to a reasonable extent. Bayer had failed to do this, as well as granting a volunteer license under S. 84 (1) (c). The IPAB ordered the payment of royalty by Natco at 7% of the net sale made by them in India instead of the initial 6% royalty ordered by the Controller[15]. Furthermore, under the compulsory license Natco will only produce and market a generic version of sorafenib tosylate at a price of Rs.8,800 per patient per month in India, which is 97 percent lower than Bayer's sorafenib price. In some more cases related to grant of compulsory license in pharmaceutical industry, the controller rejected the grant on various grounds like failing to prove prima facie case, not applying for a license of patent prior to applying for compulsory license and failure to prove public use of the product sought to be use by the compulsory license.[16]

OTHER CASES

After the grant of compulsory license to Natco , two or more pharmacy companies filed applications for the compulsory license. But the applications were rejected by the controller.

In March 2013, BDR Pharmaceuticals applied for a compulsory license to generate a generic version of Dasatinib anti - cancer drug patented in India by Bristol - Myers Squibb. The Controller rejected BDR's plea stating that the applicant did not make reasonable efforts to persuade the patent proprietor to grant a voluntary license before making the application for a compulsory license and therefore the applicant failed to find a prima facie case for issuing a compulsory license under the Patents Act.[17]

In June 2015, Lee Pharma, an Indian company based in Hyderabad, applied for a compulsory license to produce and sell the drug Saxagliptin used in the treatment of type II diabetes mellitus. .Saxagliptin is patented and marketed by Bristol Myers Squibb in India. The Controller rejected the request stating that the applicant had failed to fulfill any of the reasons set out in section 84(1) of the Act.

CONCLUSION

As India is also a member of TRIPS; India has a legally, administratively and judicially compliant TRIPS framework to protect IPRs. Under the Doha Declaration on the TRIPS Agreement, each member is entitled to grant compulsory licenses on the grounds set out in the Act. In certain circumstances, such as public health emergencies, India may grant such licenses and have the right to grant compulsory licenses to ensure

[15] The Financial Express, *Patent Appellate Board rules against Bayer in cancer drug case* , March 27, 2014
[16] http://www.khuranaandkhurana.com/2017/08/03/compulsory-licensing/
[17] Vipin Mathur1, Dr. B. P. Nagori2 and Dr. Mahendra Tiwari, COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS IN INDIA: A RESEARCH STUDY

access to affordable products. For a underdeveloped or developing country, compulsory licensing is significant. Because in nature the patented drugs are always expensive, a common man cannot afford such drugs. There may be a role for compulsory licensing here. In India, many applications for the compulsory license were submitted after the nexavor case, but the controller refused those. For the compulsory license, India needs a liberal approach towards compulsory licensing.