COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS IN INDIA: ISSUES AND CHALLENGES

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Abstract

The relevance of patents to various facets of human life, particularly to health care& pharmaceuticals is well achieved through grant of patents to medicines and its allied processes. Patents are governed by Indian Patent Act 1970, wherein it allows the patent owner to explore the commercial benefits of his inventions exclusively by him. Needless to say, that such monopolistic right encourages innovation and research. Indian Patent Act does not discriminate between pharmaceutical and non-pharmaceutical subject matter for grant and licensing of patent. Though, the pharmaceutical patent does involve technicalities and rapid technical advancement which at times burden the judiciary with litigation. It is essential to consider that the grant of pharmaceutical patents never aims to create any barrier to availability, accessibility and affordability of medicine which is contrary to the notion of monopoly right. This creates a tussle between patent owners right to commercially explore pharmaceutical product versus the right to have access to affordable medicines by the citizens. In such situations, the Indian Patent Law allows compulsory licensing aspect. Since the inception of patent law in India, only one compulsory license has been granted. Therefore, does it mean that all pharmaceutical medicines are easily accessible to the people and hence no need of compulsory license or does it mean that this provision is inserted just as a formality which nobody wants to use at all. Therefore, this paper will focus on all such issues related to compulsory licensing of pharmaceuticals in India.

Keywords: *Pharmaceutical Patent, Right to Health, Compulsory Licensing, Grant of Patent, Access to Medicine*

Introduction

Property created by use of human intellect has legal recognition since time immemorial. The specification of such property as private in general or public in peculiar circumstances is well known. Justification and constitutional-legal safeguards of these properties, lies in manifestation of rights of creator, his personality[1], the efforts put in, and / or the social-commercial value of it. Such property is defined as an intellectual property. Statutory recognition, regulation and protection to such property is guaranteed with relevant factors such

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[1] Justin Hughes, *"*The Philosophy of Intellectual Property*"*,77 *Gr. W.L.J.* 287 (1988).

as subject matter of the work, its nature, content and sociological, commercial, technology-based reflections of such property. The various forms that such property may take are copyright, patents, designs, trade secret, trade-marks, traditional knowledge, GI etc. Creation of such intellectual property is usually associated with disclosure for its legal protection, especially patents. "Patent is an award for the inventor for his intellectual effort". It serves as a motivation for creator to let the world know about the invention made by him. In order to make the optimum utilisation of this invention, the sovereign authority grant patent protection in the form of monopoly right to the inventor so that he will make the invention available to the people for use without any fear of losing the benefit. Protection of an invention by patent rights gives rise to multiple legal incidences which leads to conflict of rights between public and private person, duty upon government for protection of rights, adherence to monopoly of patentee and balance of these aspects with constitutional rights of public at large. This study shall discuss specific aspects of patents in relation to pharmaceutical products and compulsory licensing of such invention.

Concept of Patent and Pharmaceutical patent

A "*Patent is a legal right*", granted to an inventor as a quid pro quo for unveiling his invention in public. It is statutory right for creation of new and useful article or improvement of existing article or new proceed of making article.

WIPO mentions, "*A Patent as exclusive right granted by a government for invention, which is a product or a process that provides, in general, new way of doing something, or offers a new technical solution or offers a new technical solution to problem*"[2].

Basically, a patent officially allows its holder a monopoly to dominate the market and fetch the commercial benefits, which is justified against disclosure of invention by patentee to public at large[3]. Owner enjoys such exclusivity for specified term. After end of this fixed term, invention can be availed in general without fetters. A patent has territorial feature and is enforced on the basis of its registration in each country.[4]Accordingly, if the patent holder does not disclose his invention then it shall result into an abuse of the monopoly right granted to him and gross denial of public good.

[2] World Intellectual Property Organization, available at https://www.wipo.int/patents/en/, (Last visited on Jan 20, 2023)
[3] P. Narayanan, *Patent law, (*Eastern Law House, Fourth edition, 2017) pp 1-4
[4]*Ibid*

Domain for patent has been multi-dimension since its inception. All fields except few[5] wherein innovation takes place, does have an opportunity to get the grant of patent. Therefore, Pharmaceutical companies which has capability of developing new medicines that can increase life expectancy and can cure diseases that affect people globally does apply for the grant of patent for their inventions as well. Protective rights are critical to these drug companies owing to guarantee of profit and make resources of time and cost so engaged for new drug rewarding. Drug patents are particularly important as new and enhanced drugs are being introduced to the market every year. The pharmaceutical sector has advanced over the years, which has led to the introduction of several drugs that have saved the lives of millions. These drugs have also generated a significant amount of revenue for their commercial benefits.

For pharmaceuticals, invention is often a new molecule or family of molecules for the treatment (or prevention) of a particular disease (protected by what is known as a "product" or "substance patent"), or a method of producing a drug (protected by what is known as a "process" or "methods" patent. "*The pharmaceutical patent is granted for product patent, product by process, process patent and formulation patent[6]. Pharmaceutical product means any patented product , or product manufactured through a patented process, of pharmaceutical sector needed to address public health problems & shall be inclusive of ingredients necessary to their manufacture & diagnostic kits required for their use[7]. "*

When such rights are attached with processes and product relating to medicine, medicinal processes, molecules of medicines, vaccines etc these are referred as pharmaceutical patent. The patenting of pharmaceutical products directly relates to availability, accessibility and affordability of medicine to public at large and concerned patients in particular. Hence there is a clear, active and well-established relation between such pharmaceutical patents, right to life and health of a person under Article 21[8] and article 19 (1)(g)[9] i.e. freedom of trade, profession, and business of an individual under the Constitution of India, 1950.

In consideration to the fundamental rights and nature of patent, as its subject matter provides monopoly to the inventor over his invention and restrict others to use the invention providing

[5] Indian Patent Act, 1970, Act of Parliament, 1970 (India) s. 3.
[6]Dr. G.B. Reddy's, "*Intellectual Property Rights And The Law*", (Gogia Law Agency 2012)
[7]V.K.Ahuja, "*Law Relating To Intellectual Property Rights*" (LexisNexis Third edition 2017); pg, 577, Annex 7, Importation of Para 6 of Doha Declaration on TRIPS Agreement & Public Health, Para 1 Subpara(a), (30/08/2003)
[8]The Constitution of India. Art 21, Read as: "Protection of life and personal liberty: No person shall be deprived of his life or personal liberty except according to procedure established by law".
[9]The Constitution of India. Art 19 (1) cl g Read as: "All citizens shall have the right to practise any profession, or to carry on any occupation, trade or business."

exclusive monopoly right to the patentee. The monopoly may lead to amplification of the cost of patented pharmaceutical products / processes. This can create a serious problem to the developing countries due to lack of resources or funds to ensure availability such exorbitant patented products. In order to create equilibrium of interest, both right holder and society at large, there is this concept of "Licensing of Patents[10]" which means by licensing the patentee can fell secure about his rights by way of grant of patent and the society will get the fair benefit of using the innovation/invention which will help then in safeguarding their life.

Concept of Licensing of Patent

The notion of licensing patents incepts in 18th century with the operation of Paris Convention, 1883 and considering its significance later this notion got introduced in other domestic and international legal instruments across world as well. "Compulsory licence is not an unmentionable word. Under a different name, it exists in the TRIPS (Trade-related Aspects of Intellectual Property Rights) too where it is called, 'Other use without authorization of the right holder'..."[11]. Theoretically, licensing is "*An act of granting or sharing patent related rights under a legal arrangement is known as licensing*". Transfer of bundle of rights which are restricted or limited by various factors like geographical area, time span or area of use, is done through patent licensing. Such an act shall in no way transfer ownership of the invention, but other rights for example right to usage, make products, sell product etc. Licensing shall be ideally a voluntary effort by patent holder to share rights with another person in consideration for royalty for the same. But wherever it is not so affected voluntarily, government may step it to exercise its constitutional and legal power to grant such license to another person, on specified grounds under Patent act and without the will of patentee. License can be a contractual arrangement by will of patentee and license holder i.e. Voluntary license, or it could be the one granted by government irrespective of consent of patentee i.e. compulsory license. There had been lot of hue and cry around the licensing practices relating to patents and therefore, this study will limit its focus on the practices and issues related to compulsory licensing in India.

Compulsory Licensing for Pharmaceutical Patents

India has a wide pool of population and variety of patients waiting for affordable medicines and thereby it becomes State's responsibility to provide affordable health care of its people.

[10]Indian Patent Act, 1970, Act of Parliament, 1970 (India), Chap XVI, ss 84- 94.

[11] Agreement on Trade Related aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement] Article 31.

With life threating and pandemic situations during COVID-19, a need was felt that the provisions of compulsory licensing shall be proactively implemented in public interested. Theoretically, the term compulsory licensing means, "When the government permits other interested parties or itself to make use of patented invention for manufacture and sell without the consent of the patent holder. It is a statutorily created license that allows certain people to pay a royalty and use an invention without patentee's permission"[12]. Rights arising out of such compulsory license are presumably considered as rights so granted by patentee itself. Grant of such licence serves as reasonable restriction upon rights of the patentee. Such restriction is against a guarantee of compensation to the patent holder.[13]Such interference with intellectual property rights of the patentee or we can say the conflict of his interest is justified when it is done in a statutory way that too with the intention of social welfare.

According to Robinson, "*Patent privilege differs from an odious monopoly in that it does not deprive the public of an existing right but rather prevents only the exercise for limited time of the new direction marked out by the inventor*"[14]. This justification of patents and the said restrictions becomes relevant while understanding the requirement to grant patents to the other interested parties *via* licensing. As these rights are granted and recognized by sovereign authority, the restrictions so imposed on legal, moral or social grounds becomes valid. The apparent application of natural law theory on the rights of an inventor reflects that an inherent right of exclusivity is granted to the inventor for his intellectual conception which otherwise would not have been recognized and protected by the Sovereign[15]. However, can we employ the same natural law application on the tenure of grant of patent because though the patents allow monopoly but it allows only a reasonably limited monopoly for a term of 20 years term[16]. Further, the question to be discussed here is that does the grant of patent for 20 years means that this patented invention cannot be used by anybody in any reasonably required situation like COVID-19? If it is permitted to be used in exceptional circumstances that, how is it permitted and through which provision it is justified? The researchers want to put forth an argument here that, the utilitarian approach towards patent which includes contractual rationale behind patent system, profit sharing, limited period monopoly can be executed through

[12] (Bryan A. Garner (Editor in Chief), Black's Law Dictionary, 1003, Ninth Edition, (West Publishing Co. 2009)
[13] TRIPS Agreement, Apr 15, 1994, Article 31 (h), 33 I.L.M. 1125 (1994);
[14]Robert A. Choate and William H. Francis, *Patent Law, Trade Secrets- Copyrights-Trademarks,* (West publishing Co. Second Edition 76, 1981)
[15]W.J. GORDON, "A Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property", 102 *YALE LJ* 1533-1609 (1992)
[16] Patent (Amendment) Act, 2002, No. 38, Acts of Parliament, 2002, (India) s.53.

compulsory licensing. This also will help in reducing the issue related to scarcity of pharmaceutical resources for safeguarding the lives of humans on this planet.

Inherency of patent rights and in turn its protection by state is considered through recognition which may be applied by the will of the government supporting compulsory licensing of patents. It shall not lead to a conclusion that reward or prospect approach towards patent rights deny confirmation of rights by a sovereign. Hence, compulsory licensing through other approaches of patent rights also justifies restrictions so insisted. Nevertheless, the power so available with State for compulsory licensing of patent shall not be haphazardly used and must fulfil the requirement of constitutional mandate of eminent domain[17]. In such situations, government is an ultimate owner of patented invention and such ownership necessarily arises out of ensuring public good. It is certainly implemented against rights of patentee but legal constitutional mandate for the same shall override private rights of patentee as a valid restriction.

Need for Compulsory Licensing of Pharmaceutical Patents

The rational proving need for the grant of compulsory licence lies in this utilitarian approach which means the benefit for all. Certainly, in fulfilling "benefit for all approach" there may arise a tension or conflict of interest between the inventor and the user. There is always a tension between IP protection and access to health and this has been the subject of a number of international commissions. The UN Secretary-General's High-Level Panel on Access to Medicines in 2016[18]recommended the need for adoption and use of compulsory licensing legislation by the under developed and developing countries. The panel recommends that,

> "*Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and particularly with regards to essential medicines. The use of compulsory licensing must be based on the provisions found in the Doha Declaration and the grounds for the*

[17] The constitution of India Art 300-A, Read as: "No person shall be deprived of his property save by authority of law,"1950

[18] Carlos M. Correa and Reto M. Hilty (eds.) *Access To Medicines And Vaccines, Implementing Flexibilities Under Intellectual Property Law,* (Springer publication, 2019) p.74.

issuance of compulsory licenses left to the discretion of member governments"[19].

It is in this context that compulsory licences and government use provisions in IP law are advanced as both important safeguards against abusive practices by IP rights holders, and enablers of the public's right to access medicines at affordable prices.

The purpose of grant of patent should not hold back the aspect of protection of public health, whereas it must act as an instrument to assist public interest in healthcare. Article 47[20] of the Constitution of India, obligates the State, "to improve public health" along with Panchayats and Municipalities[21] and for this at times it becomes necessary for the State to a permit or allow the use of patented invention by the other interested partied for manufacturing the pharmaceutical drugs. Further, considering the vast requirement of pharmaceutical drugs and financial struggles of common man, patent is granted with an intention to make the benefit of the patented product/article[22] only at reasonable price which is affordable to a large section of public. Therefore, in order to provide wide access to such medicines with economical pricing, compulsory licence was introduced as a superlative tool under the patent regime.

Compulsory Licensing for Pharmaceutical Patents: Legal Landscape

After discussion the Constitutional validity to the grant of compulsory license to pharmaceutical patents, the Indian Patent Act, 1970 does provide provisions for consideration of compulsory licenses in India. Grant of compulsory licence aims unquestionably to prevent abuse of patent by patentee. Hence it is imperative that patentee must exercise his invention for benefit of society[23]. Such requirement is always a part of consideration for grant of patent.[24] It is an inevitable positive incident of the grant hence licensing of patents is closely associated

[19] The United Nations Secretary-General's High-Level "Panel on Access To Medicines" (Sept 2016), p.27 Recommendation 2.6.1 (b). In addition, recommendation 2.6.1 (c) urges the revision and adoption of the Doha Declaration paragraph 6 decision. https://www.politico.eu/wp-content/uploads/2016/09/HLP-Report-FINAL-Sept-2016.pdf (last visited on Jan 12, 2023)

[20]"Duty of State to raise the level of nutrition and the standard of living and to improve public health: The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary dues and, in particular, the State shall endeavour to bring about the prohibition of the consumption except for medical purposes of intoxicating drinks and of drugs which are injurious to health".

[21]Art 243-G, r.w. 11th Schedule, Entry 23, 1950.

[22] Indian Patent Act, 1970, S. 2(1)(o), No. 39 Acts of Parliament,1970 (India) ," patented article means an article in respect of which a patent is in force", S. 82, No. 39 Acts of Parliament,1970 (India) ," patented article includes an article made by patented process."

[23]V.K.Ahuja, *Law Relating To Intellectual Property Rights,* (LexisNexis, Third edition 2017) p. 567.

[24]*Bayer Corporation V. UOI,* W.P. NO. 1323, Bombay High Court, 2014

using i.e. working of patents. Following are some important provisions under Patent Act, 1970 discussed with relevance to pharmaceutical patents.

a. Section 82-94, Indian Patent Act, 1970:

Law attempts to provide monopoly to patentee and contrive public access to inventions as needed. To put forth general principles of working of patent[25], main object is to ensure encouragement to innovations, and use of such inventions on commercial scale[26] in India without delay. With due consideration to all the other factors mentioned under section 83 of the Indian Patent Act[27], a discretionary power is specified to the Controller of Patents if such invention does not satisfy "reasonable requirement of public", or "is not available and reasonably affordable to public', or "not worked within territory of India". The Controller may grant compulsory licence to interested person-applicant, with a mandate of expiry of 3 years from date of grant of patent[28]. There is clear legislative intention to grant monopoly for first 3 years to enable recovery of cost of research and development reflects the harmonious construction between the rights of the patentee and State's obligation to provide affordable health care.[29]. However, the act permits that in exceptional circumstances the mandate of expiry of 3 years-time period need not be adhered to and Central government may issue compulsory license by notification [30].

b. Implementation of Compulsory Licensing of Pharmaceutical Patents:

With the blend of legal provisions (i.e. section 84) of compulsory licensing and judicial interpretation of the same, few pointers can be noted as relevant for compulsory licencing of pharmaceutical patents in India, such as-

- The courts must examine the primary required technicalities like the conduct and intention of the applicant. The applicant must justify his requirement for the grant of compulsory license in a way that it does not unnecessarily affect the patentee to compromise his right to get commercial benefit from his invention[31].

[25] Indian Patent Act, 1970, S.83, No. 39 Acts of Parliament,1970, (India)
[26]Glaverbal S.A. v. D. Rose, 2010 (43) PTC, 630 (Del) "That the product is put to commerce, it must have sales arising out of exploitation of product."
[27]Indian Patent Act, 1970, S.83, No. 39 Acts of Parliament,1970 (India)
[28] Indian Patent Act, 1970, S.84, No. 39 Acts of Parliament,1970 (India)
[29]*F. Hoffmann-La Roche V. Cipla Ltd.* 2009 (40) PTC125 (Del) pg152; V.K.Ahuja, *Law Relating To Intellectual Property Rights*, (LexisNexis, Third edition 2017) , p.570.
[30]Indian Patent Act, 1970, No. 39 Acts of Parliament, 1970, s.92
[31]Indian Patent Act, 1970, No. 39 Acts of Parliament 1970, (India), s. 84(6) (iv).

- The reasonable requirement of public welfare is met or not- Before identifying a product/process patented invention for compulsory licensing, care must be taken to verify about its availability in the form of drug/medicine in the market to the persons in need. Whether any alternative drug is available for the same disease which could be made available to the public at a reasonable cost or not. If not, then if the local patented drug is available to the public through manufacture or import by the patentee (commercial working in India) at a reasonable cost. Also, it is essential to consider the cost comparison of pharmaceutical product originally and proposed after being compulsorily licensed so that the inventor must not face any unreasonable losses due to compulsory license.

- According to section 146[32] of the Act, it is important to diligently file yearly statement for working patents (Form 27)[33], irrespective of the existing status of working in India. In case of non-working pharmaceutical patent, submission of recent future roadmap for non-working patent will suffice.

- Affordability shall be considered in pricing policy of such products. Further, it must be evidently clear that the chances of obtaining voluntary license with just terms and due time is significantly failed.

- Non-exclusivity of rights is the prime essential condition for the grant of compulsory licence. The rights of patentee must co-exist and functions in tune with the rights of the applicant of compulsory license.

c. *Powers of Central government to issue a compulsory licence for the manufacture and export of patented pharmaceutical products*:

The central government is assigned with the power to grant the compulsory licenses for pharmaceutical product/process in situations when any country which lacks in pharmaceutical resources and have scarce manufacturing units with regards to pharmaceutical sector for a particular product. Of-course, there is prior mandate that the said country has primarily granted the imports or such license from India. The receipt for the same shall be submitted to the Controller and he may then grant a

[32]Indian Patent Act, 1970, (Power of Controller to call for information from patentees.) No. 39 Acts of Parliament 1970, (India), s. 146.
[33]Indian Patent Act, 1970, No. 39 Acts of Parliament 1970; s. 146(2), Patent Rules 2003, R. 131 (1).

compulsory license only for the purpose of manufacture and export of a particular product patented in the pharmaceutical sector, prescribing certain terms and conditions, as may be required.[34]

After refereeing to the above-mentioned provisions of the Indian Patent Act it can be said that the act does provide extensive provisions for compulsory licensing with reasonable limitations. Whereas, it is equally important to refer relevant international instruments dealing with compulsory licensing of pharmaceutical patents particularly the WTO's *Trade- Related Aspects of Intellectual Property Rights (TRIPS) Agreement*.

d. TRIPS and Compulsory Licensing of Pharmaceutical patents:

With the advent of WTO and implementation of TRIPS from 1995 led to extensive multilateral treaties in the field of patents. Being member State, India is obliged to inculcate and amend Indian Patent Act in conformity with TRIPS from 1994-2005, especially to strengthen position for pharmaceutical patents. Post trips, patent laws in India were amended to include longer protection term, EMRs, product patent for pharmaceuticals within its preview etc. as well as compulsory licensing. Alike all other international instruments, TRIPS also conform with principles of National Treatment[35] and Most Favoured Nation[36]. To form a ground for national treatment in India for implementation of TRIPS, if compulsory license is granted to a national applicant, equal treatment is to be ensure to foreign applicants as well. Here, capacity of Indian financial and legal system is highly questionable.

Indian Patent Act, 1970 already grants wide discretionary authority to Central Government & Controller for grant of pharmaceutical compulsory license. It shall be obvious to look into vertical as well as horizontal application of provisions of TRIPS, yet it is seldom practical to approach to the situation where it shall allow such licensing for all at length or to only few based upon the requirement. Provisions of compulsory licensing under TRIPS[37] are operative since drafting of TRIPS, so along with the same compulsory license to countries which are

[34] Indian Patent Act, 1970, No. 39 Acts of Parliament 1970 (India), s. 92A.
[35] TRIPS Agreement, Apr. 15,1994, Art 3, Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property".
[36] TRIPS Agreement, Apr. 15,1994, Art 4, With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. ". "Relevant exception such as international agreements on judicial assistance / law enforcement, Berne/Rome convention provisions. Related rights, agreements prior to WTO shall be considered."
[37]TRIPS Agreement, Apr 15, 1994, Art 30 & Art 31.

incapable to manufacture pharmaceutical products was introduced as an outcome of Doha Declaration, 2001[38].

Compulsory Licensing of Pharmaceutical Patents and Judicial Trends in India

Despite of the fact that compulsory licensing does have sufficient legal provisions in India, still there is just a single incidence wherein the court has granted compulsory licensing. Therefore, introspection of this single case becomes vital. In Natco Pharma Limited vs. Bayer Corporation[39] the Controller General of Patents granted a compulsory licence to Natco Pharma to manufacture and sell Bayer AG's patented anti-cancer drug sorafenib tosylate (Nexavar), a drug for kidney and liver cancer patients, in India[40].Initially the above drug was not produced in India and therefore was ended high-priced in India and was not level-headedly obtainable to patients at large. The litigation went through IPAB & Bombay High Court, finally with the Supreme Court's dismissal of Bayer's special leave petition against the Bombay High Court's decision resulting into the case on the first-ever grant of Indian compulsory licence. The court identified three grounds from Section 84 for upholding the Bombay High Court's decision of granting compulsory licensing. These 3 grounds were:

I. The derisory supply of this patented drug is the primary reason as only 2% from the long list of desired patients get access to this drug[41].

II. The uneconomic pricing of this drug i.e. Rs.2,80,428/- per month makes its out of the reach of common man as compared to Rs. 8800/- per month proposed by Natco after licensing in its favour[42].

III. This was a non-working of the patented drug in India as there was mere importation[43].

Further in this present case, the IPAB revised the royalty rates from 6% to 7% while granting the compulsory license and held that it must be subjectively decided on case-to-case basis whether any importation of drug constitutes working of patents or not. The court further said

[38] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)DEC/1,41 ILM 746,2002 Para 6. (Hereinafter Doha declaration)
[39]CLA No. 1 of 2011, IPO, decided March 9, 2012
[40]*Bayer Corpn.* v. *Union of India*, 2014 (60) PTC 277 (Bom)
[41]Indian Patent Act, 1970, No. 39 Acts of Parliament,1970(India), s. 84 (1)(a).
[42]Indian Patent Act, 1970, No. 39 Acts of Parliament,1970(India), s.84 (1)(b).
[43]Indian Patent Act, 1970, No. 39 Acts of Parliament,1970(India), s. 84 (1)(c).

that "We must bear in mind that these proceedings are in public interest; they are neither against the inventor, nor in favour of the compulsory licensee." [44]

In the case of Lee Pharma Co. V Astrazeneca[45],Lee Pharma corporationapplied for grant of a compulsory licence for manufacturing and selling the drug Saxagliptin used in the treatment of type-II diabetes mellitus, medicine patented by Bristol Myers Squibb (AstraZeneca) in India.Application was rejected by controller quoting that applicant failed to satisfy any of the grounds as specified in the section 84(1) of the Act. It did not prima facia satisfy the need for licensing[46]. Similarly, cancer drug such as "Dasatnib[47]", Roche's *Herceptin* case[48](*Trastuzumab),* lost the battle for compulsory license.

From the above discussion, it can be said that the success rate of pharmaceutical compulsory licensing in India is extremely less which may lead to the assumptive conclusion that either there is no need for these drugs or the prices of these imported drugs are too economical so that it does not need compulsory licensing. Unfortunately, both these assumptions are not true and unjustified. Therefore, it becomes necessary to trace out the issues and challenges related to compulsory licensing in India which may lead to the less allot of compulsory licenses in India.

Compulsory Licensing of Pharmaceutical Patents in India: Issues and challenges

Compulsory licensing is known as a justified effective tool against patentee's monopolies whereas cartels agreements is a more promising and affordable way which provides accessibility to pharmaceutical products. For pharmaceutical patents it is not possible to follow across the board blanket approach. The implementation of law needs a balancing approach between public health rights and IP's exclusive right based approach. It surely ensures economic growth and further research incentivization, still there are few conceptual, procedural and technical issues related to compulsory licensing which needs attention.

i. Compulsory licensing of invention in turn is a denial of ownership right of patentee. There is no clarity in law about the future of compulsorily licensed

[44] *Bayer Corporation v UOI and Ors*; IPAB; Order No. 45/2013 ; *Natco Pharma Limited vs. Bayer Corporation*; *Bayer Corporation vs. UOI* OA/35/2012/PT/MUM decided March 04, 2013 IPAB ; *Bayer Corporation vs. UOI &Ors.* Writ Petition No.1323 OF 2013 decided July 15, 2014 Bom HC

[45]AB, C.L.A.1, 2015.

[46]*Lee Pharma Limited vs. Lee Pharmaceuticals (12.07.2019 -DELHC) available at* https://indiankanoon.org/doc/187917013/ (Last visited on Jan 5, 2023)

[47] *Bristol Myers Squibb v. Hetero Drugs Ltd.* Del HC Ex Parte Order on 19 December 2008, *available at* https://indiankanoon.org/doc/33406881/ *(*Last visited on Jan 1, 2023

[48]*Roche Products (India) Pvt Ltd vs Drugs Controller General Of India,* CS(OS) No.355/2014, 2016; *available at* https://indiankanoon.org/doc/68170451/(Last visited on Jan 1, 2023)

patent under Section 92[49] if due to the change of circumstances, patent is no more warranted for use.

ii. It is to be analyzed that if grant of compulsory licensing is denial of basic fundamental rights and human rights of the patentee. An unwilling arrangement to share patented invention may operate as gross denial of rights guaranteed under Article 19[50]. Still right to life of person or public at large being in contrast to patentee's monopolistic right, grant of compulsory license shall serve as a reasonable restriction and not denial of patentees' rights to fulfill greater good of greater number. It shall serve as legitimate limitation or reasonable restriction.

iii. Grant of compulsory license is permitted only for non-functional patents. The functionality approach needs to be further clarified, if a pharmaceutical product is easily available, accessible but not affordable, shall it lead to compulsory licensing only or alternate measure can be resorted to, as situation does not completely confirm to non-functional patent.

iv. Considering the procedure for grant of compulsory licensing, firstly, no compulsory license can be granted 3 years before the date of sealing of patent. It poses a question on time lost in grant of patent, resorting to very limited time for patentee against compulsory licensing application in some cases.

v. Any interested person may file an application for compulsory licensing, but basis of infrastructural and financial capacity of such person is not mentioned. Such attribute may differ on case-to-case basis but basic foundation is yet to be mentioned. Also, such application may serve as means to harass and cause mental agony to patentee in absence of proof of intention.

vi. The mandate of failure of voluntary licensing can resorted as delay tactics by patentee. Fixed negotiation time period, with specifications as to stages of negotiation may lead to delay is filing of viable compulsory licensing application.

vii. The application of Section 92 dilutes provision of Section 84 but such clear mention is absent under the provisions leaving room for ambiguity.

[49]Indian Patent Act, 1970, No. 39 Acts of Parliament,1970(India) s. 92, Read as: "Special provision for compulsory licences on notifications by Central Government.

[50] The Constitution of India, *Art* 19 (1) cl g, Read as- "Right to practice any profession, or to carry on any occupation, trade or business."

viii. Finally, if a patentee is dissatisfied with the royalty or compensation, he may challenge the same at high court. This has led to increased judicial burden and delay in disbursement of amount due to procedural compliances.

ix. There is no doubt that law is underutilized for compulsory licensing in general and with respect to pharmaceutical patents in particular. Government has shown proactive approach in legislating for and implementation provisions relating anti-competitive practices, regulation of corporations against abuse of dominant position etc but has passive approach for licensing provisions irrespective of the fact that there is always high time requirement of pharmaceutical products owing to population and diseases in India. There might be lack of political will but according to researcher the primary concern lies with "The developed and developing nations' saga". Develop countries insist upon strong and strict licensing provision, same is not the scenario with the developing countries. There is notable pressure of unilateral and unwelcoming sanctions on developing countries by developed countries if such provisions are extensively used.

x. It shall be understood that there is no cost effectiveness of royalty. Pharmaceutical products are research intensive, unpredictably time consuming and involves extremely high expenditure. The royalty / compensation so granted does not match with the resources spent on the product that leads to failure of licensing attempts. Such inadequate compensation may discourage research endeavors.

xi. Considering the international approach, the question comes forth is whether universality and absolute harmony is possible with patents. Every Member state is diverse in resources, political approaches, political stability, jurisprudential system and thereby has a different need for specific drug, its quantity. Flexibilities and transitional provisions shall cater to such problem but it does not identify possibility of optimum harmonization.

xii. One of the worst situations that may arise against patentee is a threat created in his mind for compulsory licensing of his patent due to which he may give up patent rights under coercion. There is no process identified in India, which allows the patentee to negotiate the pricing for compulsory licensing with the Government. It is always the later who decides the pricing for compulsory license patented drug. This factor may demotivate the interest of patentee to allow their patent to get compulsorily licensed.

Conclusion

Procedural drawbacks under patent laws, conceptual notions and technical barriers so posed have led to premature death of compulsory licensing provisions under domestic laws as well as internationally. As technology transfer is avoided under compulsory licensing, irrelevance of such invention even after licensing is becoming prominent. It is pertinent to make transfera part of compulsory licensing. There is need of more mindful and social use of patents. It is not a trade related issue but a serious constitutional, jurisprudential and policy-based concern for all the developing countries. There is a need that government shall ensure a research friendly environment through funding and subsidies for CL. Protection of monetary interest of patentee can be addressed by fixing a consolidated amount to be paid and further payment as per each case. Among other things, passive approach of government to implement the provision even in time of urgent need of implementation of such provisions is a collective effect of all the factors discussed above.

Way Forward

These issues can be addressed with basic amendments and socially responsive than monopolistic basis of patents. TRIPS is an effective instrument for harmonization of patent law to curb problems arising due to diversity, yet clarity of individual responsibility for member states is much needed. The criteria of affordability as per income strata, adherence to social responsibility by patentee for availability and affordability of pharmaceutical products, incentivizing mechanism by government will surely lead to better use of patent licensing provisions. Provisions relating to compulsory licensing can be very well used as instrument of social change by government with its co-operation with other laws relating to drug price policy control, competition control and DPSP and it is high time to realize importance of compulsory licensing and come over passive approach for the same. Any act of licensing or refusal to license shall not be at the cost of oversighting public interest and a paramount fundamental right to health. As an alternative, patent pooling, patent linkage, parallel importations shall be encouraged. An aspect of voluntary programmes conducted by patentee corporation for betterment of health of patients and public is also very viable solution to curb problem of non-accessibility of medicine. Last but not the least, judicial activism is the key to give life and breath to the law. Hence, impact of judicial interest, interference, initiatives shall surely result into effective implementation of licensing provisions.