RIGHT TO HEALTH UNDER PATENT REGIME IN INDIA

Adhikarla Shraddha, BA LLB (H.) & Vaishnavi Viswanath, BBA LLB (H.), Amity Law School, Mumbai

ABSTRACT

The right to health which consists of right to access to healthcare and medicine is a fundamental right guaranteed under Article 21 of the Indian Constitution. It is a fundamental right and is endowed with the status of being supreme law. On the contrary, patent rights are considered to be economic rights which are granted by the government to patent holders to encourage innovation within the Country. Therefore, there can be no doubt that the fundamental rights should prevail over patent holder's right in case of conflict.

However, the situation is not so clear. Patent rights play an essential role in developing the Indian Economy. It provides encouragement to inventors and investors to develop new products and improve existing products. Therefore, we can conclude that the patent regime is a necessary evil even if there is a conflict between fundamental rights and competition laws.

The government needs to maintain a fine balance between protection of economic rights of patent holders and the fundamental rights of individuals. It has provided monopolistic rights to patent holder which allows them to sell, distribute and produce the product which is patented.

The protective rights persist for a period of 20 years but are provided with certain safeguards for the benefit of the public. The patent must be worked upon for commercial purposes within the territory of India, the general public must have access to the patented product at a reasonably affordable price, it must not impede public health and should instead promote public health.

In addition, it has also implemented laws such as compulsory licensing, bolar exception, parallel importation and disallowing evergreening to keep a check on the monopoly of the patent holders. Thus, we can infer that the Indian legislature has tried to provide for a balanced legislation which protects the interests of both parties. In this article, This paper aims to throw light on some of the provisions safeguarding public interest in patent regime consisting of compulsory licensing, disallowing evergreening and parallel importation.

Keywords- Right to Health, Right to Access to medicine, Pharmaceutical companies, Compulsory Licensing, Evergreening of Patent, Parallel Importation.

Introduction

Under the constitution of India, health has been recognised as a fundamental right and has found its stepping under the Article 21 and the courts have made it very evident from the various judicial pronouncements[1]. access to the medicines becomes the very part of the right to health. From several reports it is observed that there has been a teetering access to the medicine in the developing countries where around two billion people and one-third of the global population do not get the access to the medicine[2]. An inflexible patent regime is seen as an hindrance to such a right. India a developing country, the access to the patented medicines is restricted and highly regulated as an outcome of high prices of the medicines. A monopolistic patent is seen as an issue to be in conflict with the financial gains of the companies and the very human right to access the medicine. Hence, it Can be said that it has obstructed the access to the medicine in two [3]manner-

- By granting companies which have the monopoly which very usually raise the prices of the medicines to an unimaginable level.
- By encouraging the research for developing the medicines which only serves the needs of the people of the developed countries and for those who can afford to purchase such expensive medicines.

As the Indian pharmaceutical industry is a high-tech based industry and over the decade it has seen steady growth in the field the respective field. It is seen that the current pharmaceutical industry is under the control of some of the big shot pharmaceutical companies, which intends that they have monopoly in the respective field due to the government policies favouring them and a limited interference from the international market holder and players[4].

It is believed that the human rights are soft laws in the field of international law as it is presumed that it is difficult to implement those laws in its entirety. The different countries implement and interpret it very differently in accordance with tier countries socio-economic conditions and so it makes it very difficult to bring a balance between the human right to health which is access

[1] Parmanand Katara v. Union of India, (1989) 4 SCC 248; Paschim Banga Khet Mazdoor Samity v. State of West of Bengal, (1995) 6 SCC 213.
[2] Lisa Forman, *Trade Rules, Intellectual Property, and The Right to Health*, IATP, Microsoft Word - Document2 (iatp.org).
[3] Laurence R. Helfer & Graeme W.Austin, Human Rights And Intellectual Propertymapping The Global Interface 90, Cambridge University Press (2011).
[4] Nilesh Zacharias & Sandeep Farias, *Patents and Indian Pharmaceutical Industry*, NISHITH DESAI ASSOCITION, Patents_and_the_Indian_Pharmaceutical_Industry.pdf (nishithdesai.com).

to the medicine and the patent rights[5]. It is often argued by the states that grant of the patent to such monopoly is done as the patent laws have a structure and a framework within in itself that deals with the issues such as the patent relating to the essential medicines and drugs[6].When pondered upon the recent judicial pronouncements, it has encouraged even more such patenting.

The Patent Act And Compulsory Licensing-

Issuance of the license of patent varies from countries to countries and is dependent on the factors such as the health status, disease burden and the development status and the innovation of the capacity. India is still developing and has more than 1 billion of people living in the country. Under the Indian scenario, compulsory licensing becomes very important as India[7].

Even though under the TRIPS agreement there is no provision of compulsory licensing, compulsory Licensing of the innovation was done to keep a check on the use of the invention due to moral obligation towards the citizens is based on the TRIPS agreement[8].

Compulsory licensing is known to be a process of granting the license to the third person by governmental institutions in order to use the patent and the other form of intellectual property without the consent of the patent holder, it allows the regulator to break a patent holder. It limits the power and the control a monopolised pharmaceutical company may have over the market[9].

The Act that deals with the patenting of the invention is under the Indian Patent Act, 1970 which was first amended in 1999, the second in 2002 and the third time being, in the year 2005. The third time the Act was amended, it looked more into the aspect of compulsory licensing which is mentioned under the Act in section 84 to 92 of the said Act[10]. Earlier, the Acts included the process of agriculture or horticulture, process for the medicinal, surgical, curative, prophylactic or other treatment of the human beings, animals or plants or the substances that are produced by a mere mixture. Patent was granted to the process of manufacturing of the

[5] 4 Atharva Sontakke, *Right to Health and Access to Patented Medicines: Towards constitutionalisation of IPR*, (PDF) Right to Health and Access to Patented Medicines Toward Constitutionalisation of IPR (researchgate.net).
[6] Supra note 5.
[7] Harish Chander, Vaibhav Choudhary & Vikas Kumar, *Current Scenario of Patent Act: Compulsory Licensing 47,* IJPER 2013, ijper_47_3_5.pdf.
[8] Amanpreet Kaur& Rekha Chaturvedi, Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma 20, J INTELLECTUAL PROPERTY RIGHT 279, 279 (2015)Microsoft Word - ipr-246.doc (niscair.res.in).
[9] Ibid.
[10]Supra note 8.

substance which can be used as food, drugs or medicines or any such substance that is chemically produced and so pharmaceutical products are not being granted the patent.

The product patenting regime was under the patent and design Act, 1911, but when the government had introduced the new patent Act, it had cut out the pharmaceutical industry and the agrochemical products. the exclusion was made in order to make India independent and to slowly bring an end the importation of the drugs and the formulation and to develop a self-reliant pharmaceutical industry. This had benefitted the pharmaceutical industry in India which had led to a considerable increase and development of the expertise in the reverse engineering of the drugs that are patentable as the products throughout the world but unprotectable in India[11].

This resulted in the robust growth of the pharmaceutical industry which made the cheaper version of various drugs that are patented for the domestic market and later moved towards the international market with the generic drugs once the international patent had expired[12].

The granting of the license is done any time after the term of 3 years has expired from the date of the sealing of the patent is done. One could apply for licensing and once the parties have mutually agreed upon the terms, the license could be provided. If the consensus is not reached in respect to the terms of license, one could apply before the controller of the patents to arrive at the settlement of the terms[13].

The very first compulsory license was made by the Natco Pharma. In order to manufacture and export the Roche's anti-cancer drug Erlotinib to Nepal, however, the patent application got rejected. Later it filed a second application for the compulsory licensing in the Indian patent office in order to manufacture and produce and export Sunitinib (Sutent), even this was not granted[14].

On 9th march 2012, Indian had granted its very first compulsory licensing to Natco for Bayer's drug Nexaver, after being convince that it had fulfilled all the necessary conditions present under the section 82 of the Indian Patent Act. the Indian generic Manufacturer is now selling the Sorafenib tosylate at comparatively cheaper prices when compared to Nexaver. Now Natco

[11] *TRIPs and Pharmaceuticals: Implications for India*, http://www.cuts-india.org/1997-8.htm#Pharmaceutical%20Industry%20in.
[12] Supra note 10.
[13] Supra note 4.
[14] Supra note 7.

is paying its royalties to Bayer quarterly. In the year 2013, the ministry of health of India had recommended three anti-cancer drugs-trastuzumab, ixabepilone and dasatinib for the compulsory licensing. It will give an opportunity to the government to make the generic versions of medicine that are patented and will sell them at lower prices[15].

As the procedure of producing the medicine is usually patented, it can be defined as patents that protect the way in which the medicine is produced. Patent does not protect the medical device which are a part of the medical procedure. One of the examples could be surgical and therapeutic methods are secluded from the patent protection and only diagnostic models were considered to be patented[16].

Patent protection has always been in dispute when considering the human right and the competition law aspect as well, but it is a necessary evil in order to cater to innovation. There could arise an instance where the right of protection of invention is not given a stand as it may go against the interest of the public. Since the basic principle of compulsory licensing is to issue the license to a company, an individual or a governmental agency to use the patent without any consent of the patent holder[17]. The concept had developed in when there was an outbreak of diseases such as HIV or AIDS as the issue of the access to necessary medicines[18].

Impact of compulsory Licensing-

There are some of the major areas which get affected by compulsory licensing[19]-

- Innovation-

  There are instances where compulsory licensing around the globe would result into decline of innovation as it will pose as a hindrance to the interest of the pharmaceutical companies of the developing countries to research as they could later on become the generic medicines and be sold at a marginalised price.

- Competition and cost-

[15] *Health ministry recommends compulsory licensing of three anti- cancer drugs*, 2013 Jan 16, http:// www.livemint.com/Companies/F3Rn5jCkKjCJNYzhtuQseO/Health-ministryrecommends -compulsory-licensing-of-three-ant.htm
[16] Sanjana, *India:An Overview on Patenting of Medical Procedures*, MONDAQ, An Overview On Patenting Of Medical Procedures - Patent - India (mondaq.com).
[17] E. Durojaye, *Compulsory licensing and access to medicines in post doha era: what hope for Africa?*, 18 Journal of Intellectual Property Law, 35 2011.
[18] Muhammad Zaheer Abbas, *Pros and Cons of Compulsory Licensing: An Analysis of Arguments*, IJSSH 3, 239-D00013.pdf (ijssh.org).
[19] Supra note 7.

Compulsory licensing will result into increase in the competition as more and more generic companies and may also acquire the high market share. This will reduce the prices and ensure the easy access of the medicines and will force the innovators to lower their prices. The patients can also be seen to be benefitting from it.

It can be deduced from the above that compulsory licensing could be proven to be an obstacle for the patent holder to enjoy his right over his invention. This may result into depletion in number of inventions as royalties in no manner going to financially benefit the patent owner and hence it is often discouraged by many countries. On the other hand, it can also be seen that it is a tool for the underdeveloped countries for making sure that they avail essential medicines in their countries. It gives them the right to have the access over the intellectual property of the advanced nations in this respect[20].

Evergreening-

Evergreening refers to the practice of making slight modifications to the original patent and seeking patent protection for this slightly modified product. It is prevalent practice used by Pharmaceutical companies to maintain their profit by maintaining their monopoly but does provide any proportionate benefits to the public in general[21].

The basic aim of any patent law is to balance the interests of the patent holders and right of an individual to have access to the medicines and overall health care. But the process of evergreening is all about gaining profits and can even be said to detrimental for innovation. The purpose behind evergreening is economic benefits for the company and mostly doesn't involve any significant therapeutic advantage to the patients[22].

The companies justify their practice of evergreening in one of the following ways:

- They want to maintain their market and use that for R&D.
- These incremental changes gradually lead to development of a superior medical treatment.

[20] Supra note 18.
[21] Alkhafaji, A.A., Trinquart, L., Baron, G. et al. *Impact of evergreening on patients and health insurance: a meta analysis and reimbursement cost analysis of citalopram/escitalopram antidepressants.* BMC Med 10, 142 (2012). https://doi.org/10.1186/1741-7015-10-142.
[22] Roger Collier, *Drug patents: the evergreening problem*, CMAJ : Canadian Medical Association Journal, 2013 Jun 11; 185(9): E385–E386, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/.

- They need to recuperate the huge investment spent on the development of the drug. The clinical testing of a drug takes huge amount of time, money and resources.

But these arguments cannot be considered to be completely valid. Firstly, In India patent protection is grated period of 20 years which is a reasonable time to recuperate the investment and in addition earn profits. Secondly, in most cases, the modified versions do not give enough advantage to the patients in comparison to the generic version of the original medication.[23]

It is also noticed that the companies spend considerable amount of time, effort and money in false marketing the mainstream use of the new modified expensive drugs which claims to give better results. It results in the widespread use of these expensive drugs by medical professionals. It forces the common man to buy these expensive modified drugs and obstructs the common man's access to cheap and affordable generic version of the drugs. Therefore, patents should only be granted in cases where it actually provides noticeable benefits to the users and actually contributes towards medical advancements [24].

It must be highlighted that the provisions of Patent Act, 1970 clearly specify that evergreening of patents is not allowed within India. Moreover, the position of evergreening was clearly clarified by The Hon'ble Supreme Court in the case of Novartis v. Union of India & Ors.[25].

The Court in this case analysed the provisions of S3(d) of the Patent Act with reference to clauses (j) & (ja) of S2(1) of the Act. It stated that there are higher standards for patentability for pharmaceutical products. S3(d) defines the scope of patentability[26].

- The discovery of new form of substance patentable only if it provides increased efficacy.
- The discovery of new use/property of a known substance can't be patented.

The Court held that for pharmaceutical products, the patentability depends upon the therapeutic efficacy. But the Court refused to answer as to what can be defined as therapeutic efficacy and conditions required to prove the same[27].

[23] *Ibid*.
[24] Supra note 20.
[25] Novartis v. Union of India & Ors Civil Appeal No. 2706-2716 of 2013.
[26] Patent Act, 1970, S3(d), Acts of Parliament, 1970 (India).
[27] Supra note 23.

The judiciary has taken a right step by curbing the exploitative practice of evergreening. It also is a huge step in facilitating right to access to medical treatment by enabling the access to affordable generic medicines to the public.

On the other hand, we must also recognised the requirement of comprehensive legislation which specifically deals with the rampant practice of evergreening within India. The legislature must form detailed guidelines for the clinical trials and testing required to prove the efficacy of any drug or treatment procedure. The pharmaceutical companies in order to get a patent must tender proof which clearly depicts how the modified medications increase the efficiency of treatment, reduce the side effects, etc. Even the registrar must be very carefully consider each application for patent and must approve only true inventions.

Therefore, we can conclude that it is only with the help of the co-operation and coordination of the legislature, executive and legislative can India effectively deal and minimise the threat of evergreening by pharmaceutical companies.

PARALLEL IMPORTATION

Patent is a double-edged sword. On one hand, it encourages the pharmaceutical companies to invest on developing medicines and treatments. But on the other hand, the sky high prices of these same companies causes the common man to be unable to have access to these medicines and treatments. It is observed that the majority of the people in developing countries are unable to afford the patented medicine and are forced to suffer[28].

Parallel importation is one practice which may force the pharmaceutical companies to sell the medications at a slightly lower prices. It is a thorn in the side's of the pharmaceutical companies but a blessing to the ailing patients and their families.

Parallel importation can be defined, to be the practice of legally acquiring the patented good in a foreign market and selling the goods in the domestic market or vice versa. It is known to be the "grey area" and is considered as an effective tool to promote a healthy competition as it keeps a check on the monopolistic rights of the patent holders.

[28] PARALLEL TRADE IN PHARMACEUTICAL INDUSTRY: COMPARISION BETWEEN INDIA AND US, https://indianbarassociation.org/wp-content/uploads/2013/02/Parallel-trade-in-pharmaceutical-industry-Comparision-between-India-and-US.pdf.

The Article 28 and Article 6 of TRIPS read with Article 5(d) of the Doha declaration provide that the legality of the practice of parallel importation depends upon the domestic laws of the country and the countries have the freedom to frame it in anyway suitable for their economy[29].

In India, S.107A(b) of the Patent Act declares the practice of parallel importation to be legal within India. The section states that it will not be considered as infringement of IPR if there is importation of patented products by a person who has legally acquired it from a person who is "*duly authorised under law*" to produce, distribute and sell.[30] There was much debate concerning the specific meaning of the term "*duly authorised under law*" as it would determine the applicability of the section mentioned above.

India clarified it's position about parallel import during a trade policy review conducted by WTO in the year 2011[31]. It stated that India follows the principles of International exhaustion which states that patent holder loses rights over the goods once they have been sold anywhere in the world. It further states that "*under the law*" in S107A(b) means the domestic laws of the country where the transaction takes place. It means that if sale transaction is legally completed as per the law of the land, then the import or export of patented goods will be allowed[32].

CONCLUSION

The very basic essence of right to health which has been included under the constitution of India under the Article 21 n is the right to have access to medicine. Every human being has this right as an inherent right irrespective of whether this has been bestowed under any of the grants[33]. In order to cater to the right of an individual to have access to medicine and overall health care, some of the companies and the government adopt certain practices some of which is to benefit themselves and to the others being to benefit the overall public. The practices included here are compulsory licensing, evergreening of the patent and parallel importation of the medicines.

[29] Supra note 28.
[30] Patent Act, 1970, S107A(b), Acts of Parliament, 1970 (India).
[31] Trade Policy Review India Record of The Meeting, WT/TPR/M/249/Add.114 (2011).
[32] Aastha Sharma and Krishnaja Saseendran, *PARALLEL IMPORTATION" Under The Indian Patent Act,* Mondaq, (13/5/2022, 16:00), https://www.mondaq.com/india/patent/1148718/parallel-importation-under-the-indian-patent-act.
[33] Justice Prabha Sridevan, Patent and Right In Covid-19: Is The Right to Exclusivity a Hamlet Question?, Patent and Patient Rights in COVID-19: Is the Right to Exclusivity a Hamlet Question? | NewsClick..

When considering compulsory licensing, it has increased over the last decade after the Doha declaration in the developing countries and seems to be favouring the developing countries. As a result of constant growth in the amount of compulsory licensing it is believed by many of the experts that it would have a bad impact on the inventions, research and the development aspect of the big Pharmaceutical companies[34].When considering evergreening is a practice of patenting a slightly modified version of the original drug. It is primarily practiced to maintain the profits of the company and doesn't provide any proportional therapeutic advantage. It is a practice which often used to exploit the patent legislature. Therefore, it must be granted after due consideration of the proof provided for establishing therapeutic efficacy. When considering parallel importation is legal within India and is used to encourage healthy competition within the pharmaceutical industry. It ensures that the consumer can access the patented products at a comparatively lower-prices.

Therefore, the objective of the patent regime is to balance out the rights of the inventors and the right of the individuals. We find that the sky-high prices of the patented medical treatment and drugs has negatively impacted the right to access to healthcare and consequently right to affordable healthcare.

[34] Supra note 7.