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Research Article on

ACCESS TO ESSENTIAL MEDICINES: IS IPR A HANDICAP?

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ABSTRACT

Right to good health and access to essential medicines is one of the basic human rights guaranteed to every living being on this planet. However, the majority of the developing nations in the world do not have access to essential medicines, thereby, leading to the public health crisis. One of the main reasons for lack of access to the essential medicines can be attributed to the high drug pricing which can further be ascribed to the monopoly created in the Pharmaceutical industry because of strong Intellectual Property (IP) protection. Affordability is generally regarded as the core and central to the accessibility of essential medicines. There is a huge conundrum between the need for protection of rights of innovators under IP regime and the basic human rights in terms of access to medicines, thereby necessitating the creation of sustainable balance. In light of this notion, the authors in this article aim to critically analyze the provisions of the Indian Patent law and the shortcomings in the Agreement for Trade Related Aspects of Intellectual Property Rights. The authors also reflect the changes brought by the product patent regime in the Indian pharmaceutical industry including the measures which are taken by the Government of India for complete regulation of drug prices. Since the Covid-19 pandemic has highlighted the disparities in people's access to medicines and healthcare across the world, therefore, his article will also suggest few solutions for better implementation of the International IP regime and access of essential medicines to the public at large in light of the ongoing Covid-19 Pandemic.

Keywords: Essential medicines, accessibility, Intellectual Property Regime, Public Health, Patent Law.

INTRODUCTION

Infectious diseases kill over 17 million people every year and 90% of these people are from developing countries[1]. This has drawn attention to the fact that the majority of the developing world doesn't have access to essential medicines. More than 2 billion peoples in Low- and Middle-Income Countries lack access to essential medicines[2]. Essential medicines are those that satisfy the priority healthcare needs of the population of a country. They are chosen after effective consideration of several factors like- quality and efficacy, healthcare relevance, cost effectiveness. These medicines are intended to be available at all times within the context of working of a healthcare system, in adequate amounts, proper dosage form, assured quality, relevant information and at prices which are affordable by the community at large[3].

The lack of access to medicines can be because of several reasons however, one of the major reasons is high prices of the drugs. Prohibitive drug prices which are the result of strong Intellectual Property protection, are one the major barriers to the needed treatment. Intellectual Property in simplest sense means the creation of mind[4]. Affordability is generally regarded as central to the accessibility of essential medicines. It has been argued that low drug prices are detrimental to pharmaceutical innovations. Any pharmaceutical innovation or drug development requires expenditure both in terms of human resources and monetary thus, low prices of the drugs wouldn't fetch the innovators maximum profits. This has led to the huge conundrum between intellectual property and human rights. However, there has been a growing pressure on the pharmaceutical companies to contribute to easy access of essential medicines. It is therefore essential to build a sustainable balance between the interests of the pharmaceutical innovators along with alleviating the health-related sufferings. These are easy to reconcile however, there must not be unduly simplification of the relationship between price of drugs and their accessibility.

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[1] World Health Organization, https://www.who.int/news/item/01-01-1996-infectious-diseases-kill-over-17-million-people-a-year-who-warns-of-global-crisis (last Visited March 4, 2021)

[2] World Health Organization (WHO) (2004) Access to Essential Medicines. In: The World Medicines Situation 2004. Geneva: WHO.https://www.who.int/en/ (last visited March 4, 2021).

[3]WHO|Essential Medicines, https://www.who.int/topics/essential_medicines/en/ (last Visited March 4, 2021)

[4] WIPO, https://www.wipo.int/about-ip/en/ (last Visited March 5, 2021)

HISTORICAL DEVELOPMENT OF THE IP REGIME AND ITS IMPACT ON THE PHARMACEUTICAL INDUSTRY

The history of the development of the Intellectual Property regime can be traced back to the Paris Convention for Protection of Industrial Property in 1883. The objective of this convention was to provide procedural advantage and right to priority application upon the nations having real and effective Industrial Property however, the provisions under this convention did not confer any rights upon the patent holders or provide any explicit scope for them. This was left upon the discretion of the domestic legislation of the respective countries[5].

The Indian Patent and Design Act, 1911 also provided for Compulsory Licensing which was inserted in the Act after consideration of the report of the Tek Chand Committee. The Ayyangar Committee was established in 1957 to review the then Laws on Industrial Innovations. The recommendations of this committee led to the enactment of the Patents Act, 1970[6]. This Act also provided for the compulsory Licensing clause under Section 84 of the Act[7]. This Act was based on the premise of the process patent regime[8]. Under this regime, food, pharmaceutical and chemical industries were granted patent protection only upon the process of their innovation. They didn't have any rights over the end products thereby, allowing others to manufacture the same products through a different process. The rationale for this was to prevent monopolies in the pharmaceutical companies so as to ensure the access of medicines to all at reasonable prices.

In the year 1995 upon signing of the Trade-Related Aspects of Intellectual Property Agreements (TRIPS), the process patent regime was shaken which came to an end in the year 2005[9].

With the long-term objective to lay down the uniform standards of IP laws among nations, TRIPS was presented in the Uruguay round of the General Agreement on Trade and Tariffs (GATT). The discretion as provided under Paris Convention upon the nations to define the scope and rights of the patent holders through domestic legislation was eliminated in 1995.

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[5] Seth M. Reiss, Commentary on the Paris Convention for the protection of industrial property, Lex-IP.com, (last visited March 5, 2021) http://www.lex-ip.com/Paris.pdf

[6] Department for Promotion of Industry and Internal Trade, https://ipindia.gov.in/history-of-indian-patent-system.htm (Last Visited March 5, 2021)

[7] The Patents Act, 1970, § 84, No. 39, Acts of Parliament, 1970(India).

[8] The Patents Act, 1970, § 5, No. 39, Acts of Parliament, 1970(India).

[9] The Patents (Amendment) Act, 2005, No.15, Acts of Parliament, 2005(India).

After TRIPS immense pressure was put upon the developing countries to implement the provisions by the developed countries in form of TRIPS- plus Agreements[10]. This was in the dawn era of globalization where in the developed nation followed the imperial ideologies by subjecting the signatories of the TRIPS to global isolation, who refused to implement the provisions in order to prioritize the public health[11].

The TRIPS Agreement however, allows the nation states to adopt the compulsory licensing scheme during the national emergency or other reasonable circumstances. It has been argued that the scope of such compulsory licensing is subjective and has not been imposed strictly. The loopholes under the compulsory licensing system both under TRIPS and Indian Patents Act, 1970 are examples of imperialism. Under Article 31 of the TRIPS, the nations are also allowed to manufacture the generic medicines without the permission of the patent holders. This Article is beneficial for the nations having the manufacturing capacities however, the nations without any financial or mankind power to manufacture medicines remain under the threat without access to proper medicines as there is no provision for export[12]. The Doha Declaration however, provides for the exports of Pharmaceutical innovations in cases of national emergencies or urgent circumstances. The Doha Declaration iterates the flexibility among member nations to ensure easy access of medicines[13].

SCOPE OF STUDY

India's policy on Patents has been "The idea of a better world is one in which medical discoveries will be free from patent and there will be no profiteering from life and death." This was also declared by Indira Gandhi in 1981[14]. In this article authors aim to critically analyze the impact of Indian Patents (Amendments) Act, 2005 and the shortcoming of the TRIPS Agreement in order to bring a balance between the public health in terms of access to essential medicines and the protection of the rights of the Patent holders. In this article, the authors will also suggest

[10] Nadia Natasha Seeratan, The negative impact of intellectual property patent rights on developing countries: An examination of the Indian Pharmaceutical Industry, 3 SCHOLAR 339 (2001)
[11] *Ibid*
[12] Raadhika Gupta, Compulsory licensing under TRIPS: How far it addresses public health concerns in Developing Nations, 15 JIPR 358, 357-363 (2010)
[13] Bayer Corporation v. Union of India, Writ Petition No. 1323 of 2013 decided by Bombay High Court on 15th July, 2014.
[14] TALWAR SABANNA, WTO AND INTELLECTUAL PROPERTY RIGHTS 21(Serials Publications 2008)

few solutions for better implementation in the International regime and access of essential medicines to the public at large in light of the ongoing Covid-19 Pandemic.

THE CONUNDRUM BETWEEN THE RIGHT TO HEALTH AND RIGHTS OF THE INNOVATORS

The Right to good health has been guaranteed to every living being of this planet under Article 25 of the Universal Declaration of Human Rights. This Article guarantees everyone a standard of living which is health for individuals and their families, including good food, and medical care thereby, making right to health one of the fundamental rights of the person[15]. The International Covenant on Economic, Social and Cultural Rights (ICESCR) has also recognized the right to health by laying duties upon the member states to ensure that this right is fulfilled. Both UDHR and ICESCR have acknowledged the right to health and this can be achieved only through the easy access and availability of essential medicines at affordable prices[16].

Indian Constitution guarantees various Fundamental Rights under part III- right to life and personal liberty, right to equality, right to non-discrimination and alike. While interpreting Article 21, the Supreme Court of India has also included the right to good health within the umbrella of right to life in the case of ***CESC Ltd. v. Subhash Chandra***[17] . This decision was also reiterated in the case of ***ESI corp. V. Francis De Costa***[18]. In the case of ***Vincent Panikurlangara v. Union of India***[19], it was held that a healthy body is the very foundation of all human activities.

Article 13 of the TRIPS Agreement gives exclusive rights to the patent holders subject to limitations and exceptions in certain cases which do not conflict with the normal exploitation of the work and do not unreasonably prejudice the interest of the rights holder[20]. Further Article 28 of the TRIPS Agreements confers exclusive rights upon the patent holder to authorize the sale

[15] Universal Declaration of Human Rights, United Nations, (last visited March 6, 2021) https://www.un.org/en/universal-declaration-human-rights/

[16] Tommaso Soave, Three ways of looking at a blackbird political, legal, and institutional perspectives on pharmaceutical patents and access to medicines, 8(1) TRADE L. & DEV. 137 (2016)

[17] 1992 (1) SCC 411

[18] 1993 Supp(4) SCC 100

[19] 1987 AIR 990

[20] Part II — Standards concerning the availability, scope and use of Intellectual Property Rights, World Trade Organization, (last visited March 6, 2021) https://www.wto.org/english/docs_e/legal_e/27-trips_04_e.htm

and import of the patented product[21] which has been incorporated in the Section 48 of the Patents Act, 1970. This concept is referred to as parallel importation; which basically means that the patented products are exported with the authorization of the patent holder[22].

Another Important principle in relation to parallel importation is the principle of exhaustion. This principle means that the patent holder has the first right to sell or authorize export to other countries. Once he has made this sale, his right to the same gets exhausted[23].

The two major International Agreements; UDHR and TRIPS are in contradiction with each other which has been harmonized by the Doha Declaration of 2002. Article 6 of the TRIPS Agreement read with the Article 5(d) of the Doha Declaration provides the member states a freedom to enact their own laws on exhaustion[24].

In lieu of the exception under Article 6, Section 107A(b) of the Patents Act, 1970 provides for the parallel importation. Section 107A(b) of the Patent Act states that any person can import the patented products provided the person exporting this product is duly authorized by law for exporting the said product and for the subsequent sale and distribution[25]. The "authority duly authorized by law" under this provision is subjected to interpretation. Further this provision can be read as an exception to the Section 48 of the Act which provides the exclusive rights to the patent holders to prevent third parties from using, making, selling or importing the patented products in India.

The legislative intent of this Section 107A(b) is to provide access to the medicines through importation at affordable prices. However, it can be argued that the exemption under Article 6 is limited to the exhaustion of rights. If the patent holder has not sold his product in the Indian Markets or not exhausted his rights, the exhaustion principle is not applicable, the flexibility under Article 6 will not be applicable and this importation will be contrary to Article 28 of the TRIPS agreement as the right to import of the patentee is violated[26]. Thus, the

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[21] *Ibid*

[22] Shamnad Basheer and Mrinalini Kochupillai, TRIPS, Patents and Parallel Imports in India: A Proposal for Amendment , 2 IJIPL 63 (2009)

[23] Part I— General Provisions and Basic Principles, Article 6, World Trade Organization, (last visited March 6, 2021) https://www.wto.org/english/docs_e/legal_e/27-trips_04_e.htm

[24] Declaration on the TRIPS agreement and public health, World Trade Organization, (last visited March 6, 2021) https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[25] The Patents Act, 1970, § 107A(b), No. 39, Acts of Parliament, 1970(India).

[26] Shamnad Basheer, India's Tryst with TRIPS: The Patents(Amendment)Act,2005, 1 The Indian Journal of Law and Technology 16 (2005)

provision which aims to find the loophole in the TRIPS Agreement and provide for access to the essential medicines bores the loophole itself.

THE CRITICAL ANALYSIS OF THE CONCEPT OF COMPULSORY LICENSING UNDER THE TRIPS AGREEMENT AND THE PATENTS ACT, 1970

Compulsory Licensing basically means a license provided to a third party by the government to use the patented product without the permission of the patent holder in exchange of novelty[27]. The concept of compulsory Licensing is based upon the rationale that public health should be given the priority over the rights of the patent holders[28].

The TRIPS Agreement under Article 31 lays down the criteria when a compulsory licensing can be granted which are National Emergency, epidemic, legitimate interests of the public is affected by the monopoly right of the patentee[29]. The Doha Declaration however, clarified that these criterions are applicable for granting license without the permission of the patent holder. Both TRIPS and Doha Declaration have recognized the importance of voluntary as well as compulsory Licensing upon the public health.

Section 84-92 under chapter XVI of the Indian Patents Act, 1970 deals with the provision for compulsory licensing. These provisions were part of the Indian Patents Act, even before India became a signatory of the TRIPS.

Section 84(1) provides for who can apply for and the exhaustive list of circumstances when a compulsory license can be granted after expiration of 3 years from the date of the grant of the patent. An application for the compulsory license can be made before the Controller by any person of interests on any the followings grounds:

a. The reasonable requirement of the public hasn't been fulfilled
b. The patented product is not available to the public at affordable price
c. The patented product has not been worked in the territory of India[30]

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[27] Compulsory licensing of pharmaceuticals and TRIPS, World Trade Organization, (last visited March 6, 2021) https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm
[28] Namrata Dawar and Pooja Kumari, Compulsory License for Pharmaceuticals in IndiaBalancing the Conflict of interest 6 IJIPL 136 (2013)
[29] Part II — Standards concerning the availability, scope and use of Intellectual Property Rights, World Trade Organization, (last visited March 6, 2021) https://www.wto.org/english/docs_e/legal_e/27-trips_04_e.htm
[30] The Patents Act, 1970, § 84(1), No. 39, Acts of Parliament, 1970(India).

The criteria for the granting the patents also indicate that the provision aims at prioritizing the requirements of the public and accessibility of the innovation by the public at affordable prices. The controller of the Patents in the case of ***Lee Pharma Ltd. v. Astrazeneca AB***[31] held that the reasonable requirements under Section 84(1)(a) means whether the demand of the medicine can be met by the supply of not. In the case of ***F. Hoffmann-La Roche Ltd. v. Cipla Ltd.***[32], it was held that the question of availability of drugs at affordable price in India was provided by compulsory Licensing. It can be established that the legislators have given a period of 3 years for the innovators to recoup the investment and cost incurred. A similar observation was made in the case of ***Telefonaktiebolaget LM Ericsson (Publ) v. Competition Commission of India***[33], wherein the court stated that the parliament in its wisdom thought it fit to grant this minimum period for patentee, to reasonably ensure that his patent is worked in India and the invention is available at reasonable and affordable prices. The Question of reasonably affordable by the public was dealt with in the case of ***Bayer Corporation v, Union of India***[34], wherein the court was of the view that the patents Act, 1970 didn't bestow any power upon the authorities to investigate with regards to reasonable affordable price therefore, the authorities do not have the withal to carry out the same. The evidence led by the parties and impeached by the other side would form the basis of determining the affordable price. This reasonable affordable price has to be determined by relative comparison between the prices offered by the applicant for compulsory licensing and those of the patent holder.

The Section 84(6) also lays down the essential factors that the controller needs to take into consideration before granting compulsory license which are as follows:

a. the nature of the invention and the time that has elapsed from the time of grant of license, utility of the invention to the patentee
b. the ability of the applicant to work the invention to the public advantage,
c. the capability of the applicant to utilize the invention, the capital and resources that the applicant has

[31] CLA No. 1 of 2015 before the Controller of Patents, Mumbai
[32] 2009 (40) PTC 125(Del.)
[33] W.P.(C) 464/2014 & CM Nos.911/2014 & 915/2014
[34] Writ Petition No. 1323 of 2013 Decided by Bombay High Court on 15th July 2014.

d. the measures taken by the applicant to obtain voluntary license from the patentee and such efforts have to be successful within reasonable period; not ordinarily exceeding 6 months[35].

The reasonable requirements of the public mentioned in Section 84(1) are explained in clause 7 of the said Section. This clause provides a list of circumstances where the patent holder hasn't fulfilled the reasonable requirement by refusal to grant voluntary license. Few of these circumstances are

a. If any existing, developing, established or of any class/person's trade of Industry is prejudiced
b. If the demand of the patented product is not meant to an adequate extend
c. Market for export of patented article manufactured in India is not developed
d. The establishment or development of commercial activities is prejudiced.
e. The patentee has not commercially utilized or exploited the patented article[36].

The Honorable Bombay High Court, in the case of ***Bayer Corporation v, Union of India***[37], stated that Section 84(7) provides a deeming fiction which deems that reasonable requirement of the public is not satisfied if the demand of patented product is not meant to an adequate extent. The court observed that the parliament has deliberately used the words "adequate extent" as the realms would vary from article to article. In case of medicine the adequate extent has to be 100% i.e., fullest extent. Access and availability of medicine to every patient is the penultimate requirement which cannot be sacrificed for the rights of the patent holder. The further said that this is the mandate of the parliament by providing for compulsory license.

In brief the main principle in this Section is that the patent should not be given and protected for products which are to be kept as a Secret from the public and not used or exploited for the purpose they were created. The same principle is adopted in the Section 85 of the Act which deals with the revocation of patent for non-working in India after 2 years of the grant of compulsory License[38].

[35] The Patents Act, 1970, § 84(6), No. 39, Acts of Parliament, 1970(India).
[36] The Patents Act, 1970, § 84(7), No. 39, Acts of Parliament, 1970(India).
[37] Writ Petition No. 1323 of 2013 Decided by Bombay High Court on 15th July 2014.
[38] The Patents Act, 1970, § 85(1), No. 39, Acts of Parliament, 1970(India).

Even though the courts have observed that three years limitation before granting compulsory license is to create a sustainable balance between the access to public health and interests of the patent holder. It has been observed that in developing countries, people require 2nd and 3rd Generation drugs which are not available due to this locked up period therefore these drugs are inaccessible without the consent of the patentees for a period of three years and the lack of access to proper medicines a prolonged issue of concern[39]. In addition to this, the controller under Section 84(6) is required to ensure all the factors are considered in depth which also causes delay in access to essential medicines to the public. Also, applicants are required to approach the patentee for voluntary license and wait for a reasonable period of 6 months as mentioned under Section 84(6). In the case of ***M/s BDR Pharmaceuticals International Pvt. Ltd. v. M/s Bristols Myers Squibb Co.***[40], the court observed that the compulsory licensing application should be the last resort after all the deliberations and efforts for voluntary licensing have failed, thereby, increasing the procedural requirements and also the issue of public health. Section 84(7) in addition adds to the administrative difficulty of the Controller who has to investigate the practices and the distribution methods used by the Patentee to determine whether they are utilizing the product to the fullest and if they aren't then the reason and the justification for the same.

Further Section 86 provides for an additional time period of 12 months (in addition to the 3 years) to be granted to the patentee before granting compulsory License, if the Controller is of the opinion that reasonable time to exploit the product as mentioned under Section 84(7) (d) has not lapsed and the Patentee can still maximize his utilization and commercially exploit the invention[41]. Section 87 of the Act provides for procedural compliance by informing the patent holder of the application for compulsory license and ensuring a chance of hearing to both the parties[42]. It is undisputed that *Audi Alteram Partem* forms an essential feature of the principles of Natural Justice however, it must be noted that the application for compulsory licensing is applied for only after the voluntary license has been rejected thus, these procedural compliances only add to the hinderance to the access and availability of essential drugs. In ***Imperial Chemical***

[39] Dipika Jain and Jonathan J Darrow, An Exploration of Compulsory Licensing as an effective policy tool for Antiretroviral Drugs in India, 23 Health Matrix 425
[40] CLA No. 1 of 2013 before the Controller of Patents, Mumbai
[41] The Patents Act, 1970, § 86, No. 39, Acts of Parliament, 1970(India).
[42] The Patents Act, 1970, § 87, No. 39, Acts of Parliament, 1970(India).

Industries Ltd v Controller of General Patents, Designs and Trademarks (1978)[43], the delay of the hearing was so extreme that the original patent period of 20 years expired before the final decision on the case was delivered and the issue was resolved. Delays like this may cause great harm to patients who are suffering from serious illness and in dire need of the medicines[44].

Section 88 of the Act provides for the terms and conditions given by the controller at the stage of granting the license along with the time period for which it can be used[45]. To ensure that the medicines are available to the public at affordable prices the license must be granted for a longer duration of time and the terms and conditions must be changed with the changing circumstances. However, under this provision the applicant is allowed to request for such changes only twice. This adds to the procedural drawbacks under the Patents Act.

Section 90 also provides for the terms and conditions to be adhered by the licensee. Some of these terms are royalty that can be charged, time period of licensing, the affordable prices at which the products can be sold, exporting or importing rights of the licensee etc.[46]. In order to maintain a balance between the rights of the patent holder and the needs of the public the controller as a neutral person is required to decide the royalty paid to the patent holder. Along with this licensee is not allowed to authorize import of the patented article, any kind of importation would amount to infringement of the rights of the patent holder.

Another important provision under the Act is Section 92, wherein the government notifies patents on which compulsory licenses can be granted and this is limited to circumstances of national emergency, urgency or for public non-commercial use and in these cases, the applicant can approach the Controller and the license is granted[47]. However, it is essential to comply with the provisions of section 83, 87,88,89,90[48].

In certain exceptional cases such as national emergency, urgency or for public non-commercial use including Public Health Crisis relating to HIV, AIDS, Tuberculosis, Malaria and other epidemics as mentioned under Section 92(3), the procedural compliances under Section 87 are not required to be adhered with. It is however, imperative to inform the patentee of such non

[43] AIR 1978 Cal. 77
[44] Dipika Jain and Jonathan J Darrow, An Exploration of Compulsory Licensing as an effective policy tool for Antiretroviral Drugs in India, 23 Health Matrix 425
[45] The Patents Act, 1970, § 88, No. 39, Acts of Parliament, 1970(India).
[46] The Patents Act, 1970, § 90, No. 39, Acts of Parliament, 1970(India).
[47] The Patents Act, 1970, § 92(1), No. 39, Acts of Parliament, 1970(India).
[48] The Patents Act, 1970, § 92(2), No. 39, Acts of Parliament, 1970(India).

adherence as soon as practicable[49]. This Section provides for easy access of medicines in situations relating to public health crises.

Section 92A was inserted in the Act by the 2005 Amendment Act[50] to comply with the changes brought in form of Article 31(f) of the TRIPS Agreement in the year 2003[51]. The Compulsory License shall be available for manufacture and export of patented products to the countries which don't have any manufacturing capacity to address public health problems if such country has been granted the compulsory license or for, they have by notification, allowed importation of the patented product[52]. This is an important provision to enable the access of medicines to the public however, the controllers are skeptical to grant the same, fearing loss of investment from international pharmaceutical companies.

ISSUES OF THE EVER-GREENING OF PATENTS

Ever-greening of patents is a corporate, legal, business and technological strategy for extending the term of any granted patent in a jurisdiction that is near its expiration date, in order to reserve royalties from them, by taking out new patents. In India, patents are granted for a maximum term of 20 years. Post the expiry of the patent, the invention is free for use, manufacture, sale or import since it becomes available in public domain. However, occasionally the patentees of pharmaceutical companies attempt to extend their monopolized right beyond the period of 20 years. When the term of the patent is nearly over, these pharmaceutical companies make piffling variations to the already existing patented invention and files for a new patent, thereby extending their monopoly. This act is known as ever-greening of a patent.[53]Ever-greening is a major concern of generic drug manufacturers, since it seeks to gain protection for another 20 years on the basis of trivial changes in the present composition of existing drugs. The process does not generally produce any increase in the therapeutic efficacy of the drug. Multiple countries qualify for patent extension with products having minor reformulations and this results

[49] The Patents Act, 1970, § 92(3), No. 39, Acts of Parliament, 1970(India).
[50] The Patents (Amendment) Act, 2005, No.15, Acts of Parliament, 2005(India).
[51] Part II — Standards concerning the availability, scope and use of Intellectual Property Rights, World Trade Organization, (last visited March 6, 2021) https://www.wto.org/english/docs_e/legal_e/27-trips_04_e.htm
[52] The Patents Act, 1970, § 92A, No. 39, Acts of Parliament, 1970(India
[53] Shilpi Kumari, India: Ever-Greening of Patents: An Introductory Brief (last visited March 14, 2021) https://www.mondaq.com/india/patent/974246/ever-greening-of-patents-an-introductory-brief#:~:text=In%20India%2C%20section%203(d,a%20known%20process%2C%20machine%20or

in preventing competition in the market and is also considered harmful to the market and consumers.

When the term of the patent is over and generic competitors enter the market, the price of the drug drops massively. This lower price of the generic drugs motivates more consumers to shift from the branded drugs. Most of the Multi-National Pharmaceutical Companies earn their major revenues from a number of blockbuster drugs. When a blockbuster drug loses its market exclusivity there occurs an inevitable drop in revenue for that country. Since companies want to retain their monopoly over such drugs, ever-greening has emerged as a major strategy towards this end. The pharmaceutical companies invest huge sums of money in drug research and it is estimated that of every thousand potential drugs screened, barely four to five make it to the clinical trials and among them only one gets market approval. Therefore, these companies obtain market exclusivity rights and recover the cost of research and development through pricing mechanisms. However, they do not limit profit making to reasonable standards but rather exploit the loopholes in the regulatory system to unduly extend their monopoly over the market in order to retain their revenues.

The controversy relating to the issue of ever-greening of pharmaceutical patents has been decisively settled by the historic judgment of the Supreme Court in ***Novartis AG v. Union of India &Ors***[54]. The judgment given by the Hon'ble Supreme Court in this case was to prevent the ever-greening of patented products and also to give relief to those who cannot afford the life-saving drug as these pharmaceutical companies sell such life-saving drugs at an enormous high rate, thereby making it unaffordable for the common man. The apex court in its judgment made it clear that India is a developing country and the availability of medicines at a cheaper rate was necessary for the lives of 1 million people. Section 3(d) of the Patent Act, 1970 prevents obtaining secondary patents by introducing minor changes in the existing technologies from these big pharmaceutical companies[55]. Novartis failed to prove that the therapeutic efficiency of the beta crystalline form of imatinib mesylate is more as compared to the therapeutic efficiency of imatinib mesylate. So, the application filed by Novartis for the grant of patent was rejected by the Supreme Court. However, the law with regard to anti-evergreening, upheld and clarified by Indian courts, remains in the books, its application by the IPO has been far from satisfactory.

[54](2013) 6 SCC 1
[55] The Patents Act, 1970, § 3(d), No. 39, Acts of Parliament, 1970(India).

IMPACT OF 2005 AMENDMENTS ON THE INDIAN PHARMACEUTICAL INDUSTRY

The Product Patent regime came into effect through the 3rd Amendment leading to the Patent (Amendment) Act, 2005 and the examination of mailbox application commenced thereafter. The Act omitted Section 5 of the Indian Patent Act, which included process patents for food, medicines, and other drug substances. thereafter, product patents became available in all fields of inventions. The Act also introduced Section 92 (A) which deals with the compulsory licensing of pharmaceuticals for export purposes. This was meant to facilitate the Indian pharmaceutical industry to continue supplying cheaper generic versions of patented drugs to those Least Developed Countries who are lacking adequate domestic manufacturing capabilities[56]. Thereby from 2005 onwards India provided product patents for pharmaceutical substances. After the 2005 Amendment, product patents could be granted under the Patent Act of 1970. So, the generic companies could no longer reverse engineer the drug or medicine as the end product was protected under the patent law. Any such act of reverse-engineering would amount to infringement of the patent. Therefore, the only option that was available with the generic drug companies was to wait for the patent to expire. So, once the patent expires, it comes into the public domain and then anyone can manufacture the same medicine and sell it at a lower price than the patented medicine. The generic companies sell the same medicine at a lower price than the patented medicine as there is no investment that the generic companies have done with regards to research and development as well as marketing the drug or medicine. Hence, generic drugs are allowed for sale after the patent on the original drug expires. This enables multiple generic drug companies to produce and sell the same drug which increases the competition and drives the price down even further. Therefore, the price remains regulated due to the competition and the company which previously held the patent is forced to reduce the price if it wants to continue in the market. However, there are many latches in the 2005 Amendment that supersedes the benefits of the amendment. Since Indian pharmaceutical companies gained their status by selling generic drugs in a market which was previously dominated by the Multi-National Companies, post the 2005 amendment it became difficult to sustain their growth, with the introduction of product patents. Many companies are either exiting or investing in other sectors like financial services, energy etc. because their base was founded in

[56] The Patents Act, 1970, § 92(A), No. 39, Acts of Parliament, 1970(India).

a protected market where generic production was their only source of revenue collection. After the 2005 amendment, it was clear to them that they had to face and compete with the international companies even when they had less resources to spend on research and development. It was impossible to grow in the market without having a structured marketing chain by selling only generic drugs. They lacked the money, infrastructure to produce new, original drugs on a mass scale. With many Indian companies bailing out, there is a possibility of a hike in the low-cost generic drugs in the Indian as well as global market. Another factor leading to enumerable exits of Indian pharma companies is the recent Drug Price Control Order (DPCO 2013) which seems to have increased the number of bulk drugs from 74 to 348.[57] As Indian companies are facing competition from other generic medicine producers from various developing countries, selling only generic drugs will not yield enough for the growth and sustenance of those Indian pharmaceutical companies.

DRUG PRICING REGULATIONS AND DRUG PRICE CONTROL ORDER

Although India has one of the lowest drug prices in the world, many Indians are deprived of life-saving drugs. The price controls have not been adequate to bridge this gap. The price of medicines has been a delicate subject in India, where more than 55 million people are rammed into poverty every year due to expensive healthcare expenses. Over 50 percent of one's income is spent on purchasing expensive medicines. For availing medical treatment by all sections of the people and particularly by the poor people of the country affordability plays a crucial role. It is in the hands of the government to make drugs affordable to all sections of people in a country by price control. The Health Ministry, in consultation with the experts draw up a National List of Essential Medicines after every few years, and the medicines which are deemed essential for the treatment of common conditions, automatically come under price control under the Drug Price Control Order. Prior to 2013, the Drug Price Control Order followed a cost-based pricing mechanism which was based on the costs involved in manufacturing a medicine along with reasonable profit margins. However, after 2013 the Drug Price Control Order follows a market-based pricing mechanism.[58] In healthcare sectors, innovation is crucial in order to reduce drug

[57]Current Issues in Indian Pharmaceutical Industry, (last visited March 15, 2021) https://blog.ipleaders.in/current-issues-in-indian-pharmaceutical-industry/

[58]How drug prices are regulated in India, (last visited March 16, 2021) https://www.moneycontrol.com/news/business/explainer-how-drug-prices-are-regulated-in-india-4606751.html

prices. New compositions, formulations and molecules have proved to be more effective and less expensive and therefore which are tools used to have universal healthcare. The present price control framework does not encourage innovation that is the cornerstone of healthcare provision for the poor and for the neglected diseases. Even if there exists an unexpected expenditure which mainly consists of costs of medicines, the rest of the burden is significant and tends to rise as healthcare providers seek to substitute loss in drug margins by hiking consultation fee, diagnostic and hospitalization charges. However even after imposing a price cap for medical devices there is enough evidence that indicates that there has not been any significant improvement in accessibility.

It is essential that robust healthcare infrastructure is created which not only values patient safety but also encourages innovation and reduces costs. Research based organizations must be encouraged to operate in India. India must move towards a centralized procurement which would give the state a stronger negotiating power and greater burgling clout. Apart from these health insurance schemes e, cross subsidization and state financing of essential drugs are the other solutions that have worked in various Geographic areas. With the use of these multiple solutions the state will be able to make healthcare affordable to all sections of the people in a society and this will also give our state the accessibility to latest technology.[59]

CONCLUSION AND SUGGESTIONS

There is a gross violation of fundamental rights of the people living in the developing countries like India because of the way healthcare is organized and provided to them. Majority of the population living in India do not have access to basic minimum health care thereby violating the principle of justice. The future of public health in India largely depends upon the way pharmaceutical industries respond to the TRIPs agreement. Manufacture of the patented product or an application of the patented process in any local industry is most commonly called as" local working of patent". Inventive activity should result in innovation, which thereby leads to the development of technology as well as the economic and industrial welfare which is possible only through local working of various patented inventions. The monetary interest of Multi-National Companies in the drug industry remains under a constant threat to the axis of life saving drugs at

[59]India's drug price fix is hurting healthcare, (last visited March 16, 2021) https://www.livemint.com/politics/policy/india-s-drug-price-fix-is-hurting-healthcare-11572334594083.html

moderate prices in India. Innovation and patents are like two sides of the same point wherein innovations should be for serving humanity especially in the field of medicine and patents should not have only one objective to a mass profit.[60]

With a few reforms we can optimistically foresee a picture where people are free from incurable diseases and poverty has not become a major hindrance in their path of leading a merry, cheerful and disease-free life. A few suggestions which might pave the way to such a glorious and disease-free future would be such where patent regulations can be molded to improve access to medicines, particularly by the poor as it is an important public health objective. Each country while recognizing its international obligations must shape its patent law as per the socio-economic needs and objectives inclusive of public health. In cases of emergency, including an epidemic crisis a health sensitive legal regime must allow Governments to act efficiently. The Government should also create a framework for pharmaceutical patenting with special emphasis on regulation of accessibility of life saving drugs. Parallel import of some of the essential life-saving drugs should be permitted and an easy process must be formulated for the grant of compulsory licensing.

The world has been fighting against the Covid-19 pandemic since November, 2019. Safe and effective vaccines are available and accepted at a rapid pace, providing a new way to protect people from the virus in addition to conventional public health measures. The vaccines manufactured in India for the global vaccine access programme COVAX have been made available in various countries. As of 7th March, 2021, 225 million doses of the vaccine were administered globally. The vast majority have been concentrated in a few wealthy countries that produce vaccines, whilst the majority of low- and middle-income countries have watched and waited. A self-centered strategy may serve short-term political goals, but it is self-defeating and will result in a long recovery of trade and travel suffering[61]. Every chance to defeat the virus should be seized. New strains are emerging that are more transmissible, lethal, and vaccine resistant. The danger is clear: as long as the virus is circulating, it has more chances to mutate, potentially jeopardizing vaccine effectiveness worldwide. A vaccine equity declaration has already been signed by heads of state, international agencies, and civil society organizations,

[60]Pharmaceutical Patents And Healthcare: A Legal Conundrum, (last visited March 16, 2021) https://www.scconline.com/blog/post/2019/09/03/pharmaceutical-patents-and-healthcare-a-legal-conundrum/

[61]Waive Covid vaccine patents to put world on war footing, World Health Organization, (last visited April 8, 2021) https://www.who.int/news-room/commentaries/detail/waive-covid-vaccine-patents-to-put-world-on-war-footing

calling on governments and manufacturers to speed up regulatory processes and increase manufacturing. Manufacturing would not, however, increase on its own. The world is in a penultimate state and it is imperative for the nations to make most of it. The need is to take out all the stops, whether it's dose sharing, technology transfer, voluntary licensing (as the WHO's COVID-19 Technology Access Pool initiative encourages), or waiving intellectual property rights, as South Africa and India have proposed[62].

[62] *Ibid*