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With this thought, we hereby present to you

“EVERGREENING PATENT ON LIFE SAVING MEDICINES-A CRITICAL STUDY WITH REFERENCE TO DEVELOPING COUNTRIES”

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Abstract

Lifesaving medicines which are created by the pharmaceutical industries that invest a lot on the inventors are invented with the aim to eradicate deadly diseases and are an output of intellectual labour of a group of scientists who put all their mind and soul to extract the formula of the same. Once such medicine is invented, patented and circulated to the public after testing, further improvements can be made to the existing life saving medicine so as to bring increased efficacy as stated in NOVARTIS AG vs UNION OF INDIA, thereby providing it with an another patent and on subsequent repetition, becoming evergreen patent. The establishment of such evergreening patent would grant monopoly over the life saving medicine over a particular industry thereby not only increasing the efficacy but also the price of the same. Practically, with only luminant pharmaceutical giants investing on such life saving medicines when it comes in concern with the developing countries, the serious question of affordability raises as the people over these areas in the world are most affected by such deadly diseases due to comparatively poor hygienic conditions and most of the population living under the minimum standards of life thus, poverty. This paper aims to analyses whether the evergreen patent issued in developing countries hinders the competition by others and also proposes theories so as to bring better life saving medicines with increased efficacy and also about its affordability in the developing countries.

Keywords: *Developing countries, Evergreen patent, Affordability, Competition.*

1. INTRODUCTION

The value of life is precious and the same has been realized, thanks to the worldwide spread pandemic COVID-19. Millions of people all over the globe lost their lives leaving behind their surroundings in panic and fear. And this is the time by which the entire Earth came to know the importance of medicine, particularly that of life saving medicines. Once the pandemic broke out, the entire world had no answer and there was great pressure on the Pharma industries to find something to prevent the spread of the deadly disease and if possible to cure them. The pharma industries invested millions of dollars on the scientists in order to invent the same. The scientists strived hard for months to produce a vaccine which kept in check the spread of the deadly pandemic. The cost incurred to find the same is quite a huge one. Now with vaccine being invented, it was patented as it falls under drug invention. Patenting these kinds of lifesaving medicines is not a big issue in the present context, but when considering the view of the next generation after 20 years, it becomes a big threat to local pharmaceutical industries. Starting as a competition between the patent owners and the indigenous industries, it slowly transforms into a subject affecting national economy of a country especially that of developing ones.

The patent ensures monopoly over the invention for the given period of time. But, the pharma industries in this case, tend to extend this period, so as to gain profit selling the lifesaving medicine at high price. The nature of the patent right is that it cannot be breached and also applicable globally. So, using this as advantage, the pharma companies try to obtain evergreen patents which had been the talk not only now, but for many years. With this issue growing, the need for addressal of the above as become an immediate need, so that the life of the people who are affected should not be lost on behalf of the account of the conflicting interests mentioned above.

This study deals with the aspects of the evergreening of patent and how it affected the local companies of the developing nations. At the end, there is a list of issues faced and the suggestions provided to tackle the same. To start with, the definitions of the most commonly used time phrases in the work are given as follows.

1.1 PATENT

A patent can be defined as an exclusive right which is granted for an invention, for a limited period of time, which is nothing but a process or product that provides a new way of doing certain things or a new technical solution to a problem¹. To obtain a patent, the patent application must disclose technical information about the invention. Patents are a cornerstone of intellectual property rights that play an important role in supporting inventions, encouraging investments and driving economic growth.

A patent serves two main functions; protects the rights of the inventors and promotes the development of an invention. They grant the inventors exclusive rights to their ideas and innovations for some fixed time period, typically 20 years as in the case of India. Without this exclusivity it would not be possible for an inventor to disclose their innovations publicly as there is a prevailing risk of someone duplicating and owning their hard work. With a patent it would be impossible for anyone who does not own the patent to make, sell, use or import the patented innovation without the permission of the owner. It is generally done for the economic profiting.

The exclusivity that a patent provides fosters a culture of innovation, as the inventors are encouraged to invest in research and development since they can expect a profit out of their investment through the exclusivity. This leads to the creation of new technologies, services and products which can potentially improve the quality of life and drive economic growth.

1.2 EVERGREEN PATENT

The innovator might want to increase the lifespan of the patents to have the monopoly in the market for his invention. It is in this case the concept of evergreening of patents comes into effect. It is a business strategy to hold the patent to the invention which would otherwise be expired after the agreed period of 20 years. After this period, the invention would be available to the public as a whole where it becomes open to companies, firms and individuals to sell, import or manufacture in case of normal patent.

¹ WORLD INTELLECTUAL PROPERTY ORGANIZATION, <https://www.wipo.int> (last visited Sept. 20, 2023)

The evergreening of patents involves the practice of making advanced changes or improvements to an existing patented innovation and then new patents are obtained for the some modifications which increase the efficacy of the same. The sole intention of extending a patent is to prevent the competition from generic or bio similar manufacturers, which thereby increases profit.

The pharmaceutical industry is the most prominent user of patents and evergreening. A drug company generally seeks to extend the lifetime of the patents after making minor alterations to the medicine. This could be really minor alterations like changing its formulation or dosage. For instance, secondary patent Bedaquilinewas applied by J&J Company to sustain the monopoly. For better understanding of evergreening, a much evident example, Apple Inc. regularly applies for a number of continuation patents related to its core products, such as iPhones and iPads, to extend the duration of intellectual property protection for these products in the long term.

1.3 LIFE SAVING MEDICINES

Lifesaving medicines stand as a testament to the remarkable progress humanity has made in the field of healthcare. These are drugs that are critical for the treatment of certain life threatening conditions and to make a comeback of the body in a healthy condition. These are pharmaceutical interventions that are specifically designed to treat, prevent or manage life-threatening diseases.

These types of medicines include antibiotics for some deadly infections, chemotherapy for cancer, antiviral drugs for diseases like HIV and hepatitis, treatments for chronic conditions like diabetes and hypertension and vaccines that protect against deadly pathogens. The manufacturing of such medicines are complex and resource-intensive also very expensive. It includes clinical trials, regulatory approvals and rigorous research. The researches have to understand the disease at a molecular level and identify potential drug targets.

1.4 DEVELOPING COUNTRIES

The term ‘developing countries’ was coined during the 1950s and 60s. After the world war, many countries faced financial problems and barriers to living postwar period. To bring back a better standard of living, international aid such as development aid concentrated on countries that needed funds for postwar reconstruction of the country.

Developing countries in the world are determined by many factors. They are countries that are short of practical government, economic stability and human rights protection of the country than developed countries. There are 152 developing countries in the world as stated by the International Monetary Fund (IMF)². Developing countries incorporate the whole of Central and South America, the whole of Africa, almost all Asian countries, and numerous other island states. Most commonly, the developing countries are decided by the use of a metric known as the Human Development Index. The United Nations will consider a country as a developing country if any country's outcome is less than 0.80. Another method for deciding a developing country is Gross Domestic Product. A developing country is considered when the country's GDP falls below the estimated country's standard of living.

The concept of developing countries used to face many criticisms as the category of developing and developed countries was not practical to scrutinize the international development of the world. Most developing countries face problems such as poverty, insufficient infrastructure, literacy level, and so on.

2. UNFOLDING OF EVERGREEN PATENT

Evergreen patent is a concept which is barely accepted, acknowledged and put into practice. Only few countries, law have approved the concept of evergreening of patent. Developing countries perceive this concept as a threat to the domestic industries which may ultimately lead to the downfall in economy. The concept of patent arose to stop the infringement of the newly developed inventions and to give credit to the owner for a particular time till it becomes a generic product available to all people at market. The evergreen patent fulfills only the first half of the definitions to make it advantageous to the inventor while ignoring the second half. Though inventors invent the product, it is the investors who invest a lot in the same and thus have a right to claim patent over it. The investors who invested in the same with a motive to get profit after the invention of the medicines tend to stick to the concept of evergreen patent.

² WORLDDATA.INFO, <https://www.worlddata.info> (last visited Sept.20, 2023)

2.1 REASONS

The developed countries offer a supporting hand to the MNCs for the evergreen patent as they tend to uphold their interests. They have a significant reason to do so. The patent holders claim improved efficacy at the end of expiration of the patent so as to get additional patent with just a small modification and this fashion continues as evergreen patent. This prevents the life saving medicines from becoming a generic product in the market. These countries claim many justifications to have the same and they are listed as follows.

- ❖ The main reason which stands as a perfect defense for the evergreen patent is the due recognition for the intellectual labour behind the life saving medicines. In order to invent a new life saving medicine, the scientists apply a lot of labour which is not physical but intellectual in nature. They spend months or even years inside the laboratories suggesting new methods and new ingredients in order to discover the final product with the desired outcome. In this process, they also have to test the same on various mediums until it gets the tick right in all the boxes in order to ensure the credibility of the same. Only after this it gets tested on animals and finally on human beings, before obtaining the patent. Obviously the effect put in to yield the product is immense. Also the cost incurred on the same is very expensive. The pharma industries invest millions of dollars on the scientists and researchers who work on these fields in order to produce the life saving medicines of a disease which is considered incurable. New recognition must be given to the inventors of the medicines which could possibly save a life which is invaluable. Keeping this as defense, the pharma industries obtain patent, and not only stopping with that, they file for the subsequent patent of same kind that allows the patent holders to extend the life on the inventions which is the key principle of evergreen patents.
- ❖ The other claim put forth is that, the newly invented life saving medicines has to be protected and to be kept in observations to study the behavioral patents of the same. In the process the formula of the same can be stolen and also misused. To prevent the same the industries use the weapon “non-disclosure” which is a supporting key for evergreen patent indirectly.
- ❖ The ulterior intentions to obtain the evergreen patent is to have monopoly of a crucial product needed to mankind is obvious due to the adamancy of the developed countries. Once an evergreen patent is obtained over a lifesaving medicine, the industry gets a special power during the patent period and tends to have it all times and exploited the produce. With these

industries belonging to developed nations, these nations aspire to have a control over the same in order to be established as a super power. Once evergreen patent is issued as product patent, no one can reproduce the product and with this having increased efficacy, it stays ahead of the indigenous medicines thereby incurring a huge profit without competition worldwide. That is one of the substantial reasons why developed countries support evergreen patent.

2.2 DRAWBACKS

Talking on evergreen patents which confer monopoly to the industry, they tend to have a handy amount of drawbacks than compared to the positives. What is the biggest scandal is that, this concept of evergreening is itself a selfish approach to the area of intellectual property and has less to do with the benefit of the public. Apart from this, this corrupts the main motive of the invention of public use. If an invention is patented and not served for public use, there is no benefit of the invention apart from having it in papers. So the list of disadvantages is here as follows.

- ❖ It confers absolute monopoly to the industry. The monopoly conferred allows the industry to exploit the invention for their prestige. The industry prefers to advertise the invention in order to get fame of the company and credits to its inventors rather focusing on public welfare.
- ❖ The invention may not reach the motive of its invention. For instance, a lifesaving medicine which is capable of curing cancer is invented with a motive of curing cancer. But giving evergreen patent to the same would only make the invention in papers and not in public use due to issues of affordability.
- ❖ The affordability of the evergreen patent is very high and thus it always does not reach the needed class. The industries set the price of these products so high so that it is not affordable by the middle class and obviously the poor people.
- ❖ Products which obtain evergreen patent are less seen in the market, arising the question of commercialization which is an essential for grant of patent.
- ❖ The availability and accessibility of the products in market of all countries is not achieved as it is the decision of the industry to decide its market. Even if the people other than the targeted sector desire to have the product, it is barely available and also confers very huge costs in order to purchase the same.
- ❖ The concept of evergreen patent prevents competition in the market and thus other industries don't come forward with a better idea of the same one. It hinders the possibility of increased

efficacy of the product as time evolves.

- ❖ Also non-disclosure or incomplete disclosure is often associated with evergreen patent. This leads to secrecy of the product and even a person having an ordinary skill in the art being unable to reproduce the same.
- ❖ Evergreen patent associated with secrecy of formula always affects the R&D sectors of other industries which deal with the same subject matter. This curbs innovation, newness and improved efficacy of the products. The young minds ready to work for the same will lose their raw material they work upon.

3. PROCESS PATENT AND PRODUCT PATENT AND ITS RELATION TO EVERGREEN PATENT

The patent in its earlier form was only in the form of a process patent and yes, it was legitimate. But in the later stages of globalization, a new method of patenting called the product patent appeared, which facilitated the creation of an evergreen patent. Talking about process patents and product patents, Justice BP Jeevan Reddy explained the two. If the result of a new process is a new article or a better article or a cheaper article than that produced by an old method that process is patentable and is called process patent. And for product patent, the grant of monopoly right to produce that product which necessarily means preventing any other person from producing the same product whether improved or otherwise and even by adopting a different or new process for the period of patents.³

After the product patent was introduced, there was a problem between the two, with the process patent favouring the local industry, and other, in the side of the multinational companies. The above question of product patent protection and process patent protection is very important for pharmaceutical inventions. Granting a patent for a product means that the product could be manufactured by a completely new and different method, and in this case the patentee has the exclusive right as a guarantee or license to use or apply the process or method in the country who granted the patent. Granting a product patent prevents a person from commercially exploiting the method developed to produce the product without obtaining a license from the owner of the product's patent. This is because the moment a person manufactures a product using a process entirely developed by the person; the person would be infringing the rights of the patent holder of the product. It should be noted that a new

³ 17 KRISHNA IYER, V.R., "HUMAN HEALTH AND PATENT LAW" 14-27 (Frontline 2000).

method can be patented if it meets the criteria of patentability. If the developed alternative process is very efficient and the product is very useful and has good commercial potential, the patent owner of that invention can come together and enter into a joint agreement called a cross license and bring the product to market and share the profits among them. The process patent would certainly continue even after the introduction of the product patent regime.⁴

The introduction of product patents is a huge advantage in the age of evergreen patent, because it backs up all its claims. In the case of food and pharmaceuticals in particular, this would drastically affect generic drug manufacturers, as most local pharmaceutical firms can grow faster without the product patent system. With the exception of a few major players, many could change their strategy from arms and license producers to marketing partners to innovators of new technologies and eventually move to evergreen governance.

4. EVERGREEN PATENTS AND PHARMA INDUSTRIES IN DEVELOPING COUNTRIES

Before the era of globalization, each country was able to have its own laws according to its wish without the interference of other countries' interest. Therefore it was only the wish of the local government to decide the patent laws. When looking into that time, there was no term called 'evergreen patent'. And it was the local industries which were producing pharma products with the local medicine techniques which evolved from the indigenous region.

Apart from this, due to colonization the colonies had the medicines from their respective colonizing countries. There were also examples of import and export of medicines between states. However, there was none of the law spoke about evergreen patent over a pharma product although there were traces of regular patent laws. All these patent laws were mostly brought at the influence of the colonizing countries whereas a very few number of nations which could be counted by fingers, had their own patent laws.

⁴ SUBBARAM.N, "WHAT EVERYONE KNOW ABOUT PATENTS" (Pharma Book Syndicate 2003)

It all took a turn when globalization started. This process removed all the barriers of economic integration and made the world countries to become economically inter-dependent. So, now there came a link between the developed countries and the developing countries. As the scenario prevails, the developing countries went powerless against the global finances and were unable to control its movement within their own national boundaries. With no other go, the developing countries introduced and made amendments in the existing laws also enacted new laws to meet the demands of the global markets.

The impact of globalization in economic sphere is very significant and has greater emphasis on privatization and opening of economy for foreign capital. Also, it was the time when individualism is re-emphasized in recognition of not only a form of individual's freedom of creating wealth and property but also as a living a life of dignity that entitles availability of basic necessities like food, water and shelter.⁵ It was the right time for the MNCs that dealt with pharmaceutical products to obtain patent and they did no mistake. Not stopping there, they wanted monopoly over the products and so, they stressed upon the concept of evergreen patent.

In this process, the rich nations with their superior financial power started controlling the economic sphere and the poor and developing nations were forced to integrate by surrendering their economic independence knowing fully well what they are forced to accept, which was really a prejudicial to their interest. Thus with MNCs patenting their drugs, the whole world was colonized by the global finance and the transnational corporations supported by the neocolonial structure of the existing support pillars such as the World bank and World Trade Organization which were controlling the financial situation worldwide.

The treaties and conventions which were initiated by the developed countries, had provisions facilitating evergreen patents without actually mentioning them. Also, the developed countries tried their level best to prevent the issuance of compulsory license to the product patents obtained by the MNCs. By following the above strategies, they wanted the establishment of Evergreen patent.

⁵ PUSKAR RAJ, GLOBALIZATION AND HUMAN RIGHTS (PUCL Bulletin 2002)

Now, most of the developing countries stand strongly opposing evergreening of patent but in reality though not actively existent, when it comes to pharma industries, evergreen patent traces are seen in developing countries.

4.1 IMPACT OF TRIPS

The WTO established the TRIPS agreement, which entered into force on January 1, 1995. And it was a turning point in the history of patents around the world, and especially in developing countries. The completion of the Uruguay Round of Multilateral Trade Negotiations and the signing of the Agreement of the Trade Related Aspects of Intellectual Property is an important landmark in the development of intellectual property rights. The purpose of the TRIPS Agreement was apparently to reduce distortions and barriers to international trade and to consider the need to promote effective and adequate protection of intellectual property rights. It also recognizes that intellectual property rights are private rights and that the underlying public policy goals, including developmental and technological goals can be achieved by the above means. It continues to recognize the special needs of least developed countries for maximum flexibility in the national implementation of laws and regulations to enable them to establish a stable and functional technological base.

One of the most debated agreements of all time, the TRIPS agreement, became a reality in a very short time with its implementation in the pharmaceutical industry and healthcare system, especially in developing countries. The comprehensive document, which contains 73 articles, provides guidance for the enforcement of intellectual property rights worldwide. Most of the provisions of the TRIPS Agreement concerning medicines and health care were considered less favorable to developing countries. Adherence to this agreement can lead to serious problems in the field of medicine and health care and lead to adverse consequences such as shortage of essential medicines and high affordability of life-saving medicines, etc. Some of the negative features of the TRIPS Agreement, especially in the context of the pharmaceutical industry⁶, is that the granting of a product patent affects the production of many medicines, which are other ways may be available freely in the market, the patent protection is extended for an unlimited period, taking into account the conditions prevailing in the market of developing countries. In addition, there are no special regulations on mandatory authorization in the food and pharmaceutical industries.

⁶ G.B.REDDY, INTELLECTUAL PROPERTY RIGHTS AND THE LAW 193(2017)

This TRIPS Agreement appears to be adversely affecting technological activity in the developing countries by choking the knowledge spillovers from industrialized countries to developing countries. Furthermore, the implementation of the provisions of TRIP Agreement threatens poor people access to and affordability of lifesaving medicines by pushing up their prices.

4.2 STATUS IN INDIA

In India, there is no provision in the law expressly for evergreen patent but the essence of the same is derived from the landmark judgements and also some basic provisions that speak about the patent. The history of the patent rights with respect to that of the pharma industries must be known in order to have better understanding about the evergreen patenting of the life-saving medicines.

4.2.1 EARLY ERA (1947 - 1991):

Before the process of globalization, Indian pharmaceutical companies manufactured bulk drugs and could supply drugs to the common man at affordable prices. In 1954, the Government of India had established Hindustan antibiotic Ltd. (HAL) and later on Indian drugs and Pharmaceutical Ltd. (IDPL) was established. Setting up of production units, the Government of India provided incentives to MNCs and the year 1970 was an important step to promote the same. The government has also introduced some regulatory norms like Drug Price Control Ordinance (DPDO), Foreign Exchange Regulation Act (FERA), High Import Tariff and also Indian Patent Act (IPA) to boost the growth of domestic pharmaceutical industry. This led to a decrease in the market shares of international companies of 80 % at the time.⁷ An important factor here was the absence of product patent and the introduction of a process patent in 1971, which facilitated domestic production. R&D costs were also low, allowing the industry to price drugs at reasonable prices, effectively low costs. During this period until 1991, domestic manufacturers competed with international companies for drugs and dosage forms.

4.2.2 THE TURNING POINT (1991 -2005):

In 1991 the liberalization policy was introduced and with it came many changes in various economic fields. With this, multinational companies increased their influence in the Indian market by bringing

⁷ K.UMA DEVI, THE LAW OF INTELLECTUAL PROPERTY RIGHTS: VARIOUS DIMENSIONS 122(Regal Publications 2013)

their proprietary products to India. Compared to Indian domestic manufacturers like Ranbaxy, Nicholas etc., these companies outsource larger and compound requirements. The WTO-administered Washington Treaty of 1989 was signed by India, followed by the Patent Cooperation Treaty of 1998 in December 1998. The TRIPS Agreement entered into force in January 1995. As a signatory to all such international agreements, India has faced international pressure to improve its intellectual property rights and management. As a result, India had a transitional period until 2005 to bring its intellectual property rights into line with its commitments to the World Trade Organization.

According to the same, the Patent (Amendment) Act was passed in March 1989 amending the earlier Patent Act of 1970. Not only stopping with that, The Patent (Amendment) Bill, 1999 was introduced in December 1999 and was signed into law as Patent (Amendment) Act, 2002 to provide exclusive marketing rights (EMRs). With the Patent (Amendment) Ordinance, 2004 and the Patent (Amendment) Rules, 2005 and Indian Patent (Amendment) Act 2005, with the view to allow product patterns for food medicine and drugs as well as substances prepared by chemical process was initiated by the Government of India. This was a very crucial decision in the history of pharmaceutical industry of India lending all the rights to MNCs indirectly in the context of abiding with the WTO's TRIPS Agreement.

4.2.3 THE IMPACT OF LAW AND JUDICIARY:

Although laws were amended in accordance to the international treaties, none of the laws were in support of the evergreen patent concept. The laws facilitated the entry of foreign industries in the Indian market but ensured that Indian industries are protected. For instance, the amended patent law's section 3(d) [Indian Patent (Amendment) Act, 2005] states that mere discovery without giving justice to the given product would not be patentable.

This was reflected in *Novartis AG vs. UOI*⁸, one of the landmark mark judgments. Here, Novartis, a Swiss based pharmaceutical giant filed an application to grant patent to an anticancer drug Glivec which is used to treat Leukemia. It had already been patented outside India. The Indian law states that a known substance can be patented only if its new forms prove to be "more effective" as stated in the section above. The Patent Office did not find Glivec effective and therefore found it not patentable

⁸Novartis AG vs. Union of India, (2013) 6 SCC 1

under section 3(d) of the 2005 Act. Novartis argued that Section 3(d) is constitutionally invalid and inconsistent with the TRIPS Agreement. But, Novartis could not provide evidence to support its claim of greater efficacy compared to the parent compound, thus Novartis' application did not meet the patentability requirements of Section 3(d). In addition, the Supreme Court of India has said that the enhanced efficiency standard is consistent with the features and flexibility of the TRIPS framework.

In spite of this landmark judgment, many faults and flaws are still prevalent in India in the form of industries and companies. Nevertheless, there remain loopholes in the law which the foreign industries use to their own advantage.

4.2.4 ECONOMIC IMPACT:

As a result of globalization, MNCs in India have mostly started importing drugs from the country where they are produced. Very soon, most of the drugs and pharmaceutical patents in India were held by foreign MNCs. Until now, the multinational companies that controlled more than 80 percent of the market did not make financial and technological investments to help and set up their production centers in India. So they considered India as their supply market and not as a production unit.

Earlier, the establishment of Hindustan Antibiotic Ltd. (HAL) and Indian Drugs Pharmaceutical Ltd. (IDPL) units and the Drug Policy of 1978 led largely to the availability of drugs and medicines at relatively cheaper prices in India. However, the prices of many life-saving medicines rose sharply during this period when transnational corporations took over. The government reduced the tax on foreign imports which caused a very big loss to the Indian pharmaceutical industries. Many Indian pharmaceutical manufacturers have become viable in the Indian market compared to foreign products. Indian companies stopped production because the price in the international market was cheaper than the cost of production in India. For example, Sarabhai Chemicals closed its Vitamin C plant for this reason. Apart from these drugs like ampicillin, amoxicillin, paracetamol etc. are available cheaply from abroad in India due to low customs duties. As a result, the Indian factories producing them were closed and the Indian industry became dependent on foreign supplies for medicines. Public sector pharmaceutical companies like Hindustan Antibiotic Ltd. (HAL), Indian Drugs Pharmaceutical Ltd. (IDPL) and Bengal Chemicals and Pharmaceutical Ltd. are marginalized. HAL's largest penicillin plant was privatized and the streptomycin plant was leased to a private company to manufacture other

drugs and this list continues and continues.

Indian pharmaceutical companies earn by producing drugs similar to the patents of MNCs outside India without paying them royalties until 2005. But this is not possible as of now, due to the introduction of product patent and amendment in laws. So, now many major companies have now started focusing on getting generic products as their main source of income. The generic drug market offers stiff competition to the rest of the companies.

4.2.5 RESEARCH AND DEVELOPMENT SEGMENT

R&D is much less developed in India, and programs for both new drug development studies and new drug delivery systems can be done at very competitive rates. India has a well-established network of research laboratories and professional research staff. The success of a few companies in this era can be seen in the rest of the industry, which invests in research and development and generates handsome returns.⁹ Research and development are negatively affected by a lack of funds, an inadequate regulatory framework associated with many issues such as an outdated and inadequate laboratory animal patent office, a long delay in obtaining necessary permits for experiments, to name a few issues.

5. ISSUES IN EVERGREEN PATENTING

Evergreening itself a problem when it comes to pharmaceutical industry. It is impossible to make something immortal, and the same applied here. Evergreening patent rights or exclusive ownership are unrealistic in nature. Making a particular drug in the hand of one industry, without outsourcing it or without making into the public domains are the subsequent major issues that arise out of evergreening patent. Green patent made sense after the advent of TRIPS agreement and it precisely exercised its provisions all over world via local laws. Meanwhile endless patent are meaningless innovations of an eager and hunger to make profits out of lifesaving medicines. Mainly when it comes to health industry, it does not focus on welfare of the people rather only on profits of the private industries.

⁹ K.UMA DEVI, THE LAW OF INTELLECTUAL PROPERTY RIGHTS: VARIOUS DIMENSIONS 131(Regal Publications 2013)

5.1 TWEAKING

Tweaking means simply adding a value to the existing product and claiming it to be a new product. Tweaking is the core issues in matter of question whether such modified product is patentable or not. A lot of industries use tweaking as a key to hold their monopoly in their hands. Tweaking seems mere changes in their product without fulfilling the essentials of efficacy. Even it becomes worse in some countries, where some industries make alterations on labels of the drugs which are already expired so that they can use of it again for commercial purpose. Adversely, it brought an evolved idea of evergreening patent through slight modification. Evergreening a drug through increasing efficacy was challenged before various courts of India and many patents were rejected even after it took many appeals beyond its powers.

5.2 PHARMACEUTICAL DEBRIS

Pharmaceutical debris is waste and unused medicine reaches out of increasing efficacy i.e. new one arises out from older one. The questions which arises here is that what will happen to the old drugs; are they overlooked from this universe; the answer is no, they form unblemished cycle of debris among the minds of doctors and people. In the end of the course, pharma debris are been accumulated often. For every drug in India has two names, i.e. brand name and generic name, provided, brand name has commercial importance. For example: Bedaquiline fumarate is the brand and generic name is SIRTURO. As far as health medicines were considered in early times, they equally implies being signatories for constituencies of subject in the world. Due to globalization and by integrating our economy with world economy we can witness drastic changes over development in both positive and negative way.

5.3 AFFORDABILITY

Developing countries, children's health is affected by the fact that basic life-saving medicines are not available in public health facilities and medicines are not affordable in private pharmacies. In India, more number of children are prone to deadly diseases likely HIV, AIDS, TB and cancer. According to the latest United Nations estimates, seven million children and young people will die (India) in 2021, which equates to one in every 4.4 seconds.¹⁰ A major barrier to the use of essential medicines in India is its low availability to the ones who are in need of it. In India, where there is a large

¹⁰ UNICEF, <https://unicef.org>(last visited on Sept. 20, 2023)

proportion of poor economic groups, financial constraints related to booking medicines is a major reason for lack of access to essential medicines.

5.4 COMPETITION

Evergreen patents, which have existed for several decades, have received more attention because they can affect innovation and the availability of important medicines. While some argue that these patents are necessary to encourage research and development, they have been criticized for their potential to stifle competition and raise prices for consumers.

Evergreen patents can raise drug prices and reduce the availability of essential drugs, especially in developing countries where patients rely on generic versions of drugs to treat their illnesses. In addition, evergreen patents can reduce industry innovation because companies focus on pursuing secondary patents to maintain their monopoly over a particular product or process, rather than developing new drugs or making significant improvements to existing ones.

Companies applying for evergreen patents argue that developing a new drug is an expensive and time-consuming process, and that they need to recoup the investment to fund future research. However, applying for multiple patents on small changes to the original product reduces competitors' incentives to innovate and create new products, leading to a lack of competition and stunted industry growth.

A major concern is the effect of evergreen patents on competition, as extended patent protection allows the original patent holder to maintain a monopoly on the product, which limits competition and raises prices. This can create barriers to entry for new competitors, further reducing innovation and limiting the availability of essential medicines.

6. SUGGESTIONS

It is the role of the government to look into these issues and resort to solve them. But one of the current existing laws provide an active solution for the same.

- ✓ The concept of compulsory licensing as per section 84 of the Indian Patent Act is the best suited one to overcome the issues of affordability and availability of products that had obtained patent. This section comes into play when the reasonable demands of the public were

not met by the invention, the patented invention is not available to the public at a reasonable cost raising the question of affordability and the patented invention is not being worked on in the Indian Territory.

- ✓ The same was the issue and resolved in Bayer Corporation vs. Natco Pharma, a 2013 case¹¹ in which the court granted the first compulsory license in India. Also, Article 5(A) (2) of the Paris Convention justifies this reasoning i.e. each country has the right to grant a compulsory license to benefit the general public. Thus, compulsory license can come to the rescue of the people and also answers the question of affordability and accessibility of the public. Also, the domestic pharma industries can manufacture the products under compulsory license thereby preventing them from closure.

Apart from this, there must be changes in the government policies and the international conventions to ensure that the problems of evergreening of patent never arise again. Some of the ideas include,

- Bringing back the concept of process patent in pharma industries and eradicating product patent with respect to the pharmaceutical industries.
- The government should take over the sector of medicine completely in its hands which also includes the drugs manufacturing industries.
- Converting the private right of the industries as a public right for medicines as it has to deal with the life of people in an international way.

7. CONCLUSION

Evergreening is an effective way for companies to extend the life of their inventions by strategically using new sustaining patents and protecting themselves from potential infringers for a longer period of time. However, it should be noted that this process has both advantages and disadvantages, which must be carefully considered before adopting such a strategy in order to minimize potential risks and maximize potential benefits at the same time. Evergreening, if used correctly, can be an effective method for companies seeking maximum legal protection for their inventions in the long term without fear of competition entering the market too quickly.

¹¹Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), available at <http://www.ipab.tn.nic.in/045-2013.html> (Last visited on Sept. 20, 2023)

The local pharmaceutical industries are the most affected by the evergreen patent. With the establishment of the above concept, they have to come forward with new challenges to face the gigantic MNCs and have to sort the problem with the help of the suggestions as mentioned above. History has already answered the above question at various circumstances. Be it India, its pharmaceutical industry received a fillip during the first world war and the same continued for years but by then, India had managed to climb back to the place where it sits now as the 'PHARMACY TO THE WORLD'¹².

The problem of evergreen patent is not over by the Novartis case. The developed countries like US, are sure to assert pressure on all developing countries particularly India to enact a change in the legislation and amend the existing laws so as to facilitate the evergreen patent practice. There may also arise a new convention in the future which voices out for evergreen patent to be established universally. It is the local industries who will have to adapt for the conditions by the help of R&D sectors to equally fight the growing foreign MNCs. Apart from this, as section 84 of the Indian Patent Act enables, it must be made a voice for the issuance of compulsory license for the life-saving medicines in order to make it available in market at adequate level at an affordable price.

It is the fact that the needs and wants of a common civilian is completely undermined and underestimated in the global context. But looking in fact it is the individual who stands as a backbone for a countries' economy. So, understanding this and proceeding will help the human race achieve the next level.

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¹² ANKITA SHARMA, INVEST INDIA, JULY 31, 2020, <https://www.investindia.gov.in/siru/india-pharmacy-world>