



**EVERGREENING OF PATENTS: A
BARRIER TO NEW INVENTIONS**

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ABSTRACT

Pharmaceutical companies tend to implement the strategy of evergreening of patents in order to increase their period of patent protection upon a particular drug before expiration of the primary period of protection i.e. 20 years. The pharmaceutical companies invest in research and development process for a great extent with the sole intention to develop a by-product of their already patented drug. This is done in order to apply for new patent protection of their recently developed drug so that they retain the monopoly right over that product and also restricting the manufacturing process of generic companies. The provisions of evergreening if not amended, it will lead to abuse of patent protection and will affect the society at large, as majority of people will not be able to bear the high costs of these life-saving drugs. The ideal concept of a society is to have equilibrium between patients and patents. Public health is to be kept at highest pedestal since right to life is one of the basic fundamental rights for people all over the world. The researchers would take a supplementary vestige in analysing and deliberating upon the various aspects of evergreening with special emphasis on the steps taken by India along with other countries with respect to evergreening. The paper is also an attempt to envisage the role of the various regulatory authorities with regard to evergreening of patents clubbed with the exertion to align them with the international and ethical standards.

INTRODUCTION

The procedure acquired by the patentees through which they are able to extend their period of patent protection when the primary period expires after 20 years is known as Evergreening. This period helps to prevent the patent from coming into the public domain so that it cannot be exploited by anyone. This strategy of extending the period of patent protection is mainly adopted by pharmaceutical companies to protect their drugs and other pharmaceutical products. The patentee seeks to extend the patent protection for any by-product of the already patented drug, which resulted from the minor changes of the patented drug. These changes are made at the time of or sometime before the expiration of the patent, so that the patent holder can lengthen the period of protection. The patent can secure for the method of manufacturing or even the colour of the product, therefore the patent holder tries to acquire separate patents for different features of a single product. Thus, the condition when patentee tries to get patent for the several attributes of a single product to use it for extending the term of protection beyond the period of 20 years can be called as 'Evergreening of Patents'.

It can be understood that the use of evergreening provisions will lead to the misuse of intellectual property protection, as the innovator company will look to make only trivial changes to extend the term of protection for the patented drug and then charge unreasonable price for it, stating that they had to incur huge expenditure on research and development of the patented drug. This will affect the society at large, as majority of people will not be able to bear with the high costs of these life-saving drugs. The process of evergreening is also



considered to be against the competitive strategies, as it creates a need for generic manufacturers to negotiate with the innovator company on monetary terms or else they have to wait until the patent of the drug expires for accessing the subject matter of the patent. Due to the provisions of evergreening, the area of concern for the pharmaceutical companies will only be to make minor changes in the drug to get it patented. Thus, it would be highly unlikely for the innovator company to do some risky or heavy research and development for the new drug as they can gain high rewards with lower risks.

The entire principle of protection of intellectual property is to promote and educate the society regarding the importance of innovation yet the provisions of evergreening allows the patent holder of a drug to add more patents to it, regardless if such improvements are necessary or not for that particular drug. This makes the competitors and generic drug manufacturers unable to manufacture or carry out any sort of inventions or innovations on the subject matter of that patent even though the term of 20 years is expired. If the competitors or the generic producers make an effort to create or invent the patented drug then they will be burdened with the payment of court fees and all the related costs. In order to evergreen their drugs, the innovating company will come up with what are euphemistically called "*the life-cycle management plans*" which not only comprises of patent policies but have a whole range of policies which aim at slowing down or holding up the arrival of a new

generic drug into the market. The pharmaceutical companies create a bullet proof patent portfolio which surrounds the valuable drug molecules, by using the complex procedures of patent prosecution. Evergreening as a patent prosecution and management strategy helps in extending the patent term by developing a portfolio of patents which surrounds a basic invention. The attributes of drug which were qualified for patenting in the 1980s were mentioned by the Generic Medicines Associations of Europe: (i) Primitive usage; (ii) Intermediates and Processes; (iii) Transparency of formulations; (iv) Composition of matter and (v) Bulk Forms.¹ However, the list swiftly expanded to accumulate patents over auxiliary features like (i) Compounds consisting of more than two drugs; (ii) Action mechanisms; (iii) Dose-ranging and Pathway for inserting the drug in the body; (iv) Delivery profiles; (v) Processes of Screening; (vi) Various process for treatment (vii) Packaging; (viii) Various process in Chemistry; (ix) Targets in Biology consisting of older molecules; (x) Field of use.²

Evergreening of patents is considered as any other business strategy in several countries and thus, it is permissible by law to implement such methods in those countries. Whereas, in India there are provisions which aim at preventing the method of evergreening and safeguard the interests of various new innovators. The verdict of Novartis Case exhibited that the growth pattern of manufacturing and usage of the technology has been shifted. Earlier, the laws protecting

¹Arun Kumar and Arun Nanda, Ever-greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries, Pharmaceutical Regulatory Affairs: Open Access., (9th May, 2020, 6:45 AM),

<https://www.hilarispublisher.com/open-access/evergreening-in-pharmaceuticals-strategies-consequences-and-provisions-for-prevention-in-usa-eu-india-and-other-countries-2167-7689-1000185.pdf>
²*Ibid.*



the rights of intellectual property in India were very weak since we were the user of technology invented by others. Gradually, since India started to innovate and produce, we are not totally dependent on the technologies of others. Therefore, there has been an urgent need to strengthen our laws in relation to IPR.

I. Indian Patent Law Post 2005 Amendment Act

Pharmaceutical companies with the help of evergreening used to lengthen the term of protection for the patented drug by making insignificant or trivial changes. Indian laws were not strict enough to deal against the method of evergreening which acted as an advantage for the innovative company. This created a need for a more rigid patent law to prevent the process of evergreening. Evergreening of patents can only be restrained by negating any patents on the grounds of trivial or insignificant changes in the original patented product.

In India the patenting of products was established under the Indian Patents (Amendment) Act, 2005 which pronounced the inception of new patent system which intended towards securing the rights of the patent holders. The Act was in attainment of India's adherence to the World Trade Organization (WTO) on matters relating to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)³. The Agreement harmonious to the Amendments

Act came up with few essential issues in relation to patents:

- Acquiring annotations of 'pharmaceutical products';
- Eliminating the 'Findings of new form of a recognized product' and 'new applications of the already recognized product'.
- Fabricating the substances which might be provided with protection in the new patent rule.⁴

Moreover, the Act came up with the annotations of the phrase 'new invention' and also established limitations to the purview of patenting under Section 3(d). It also specified various grounds on which the protection will be provided⁵.

The Amendment Act, 2005 was the last step taken by India to adhere towards the TRIPs agreement. The step was taken to balance out the interests of the competitors such as several shareholders including local manufacturers, civilian groups who have the ingress to medicines, the community of R&D, overseas companies.

India while establishing a new patent system also had the obligation to adhere by the TRIPs Agreement. To curb the negative aspects of evergreening, India introduced certain amendments under which the drugs were subject to patent protection only if they are not the new forms or have no new uses of the same original drug. Further, the

³Annex C, Agreement on Trade Related Aspects of Intellectual Property Rights, WTO (10th May, 2020; 10:23 am), http://www.wto.org/english/docs_e/legal_e/27-trips.doc

⁴Biswajit Dhar, Post 2005 TRIPS Scenario in patent protection in the pharmaceutical sector: the case of

generic pharmaceutical industry in India, *iprs online* (11th May, 2020; 3:45 pm), https://unctad.org/en/PublicationsLibrary/ictsd-idrc2006d2_en.pdf

⁵ Section 3(d) of The Patents (Amendment) Act, 2005



amendments were by way of interpreting the term ‘new invention’ as mentioned under the Section 2 of the IPA in a stringent manner. This provision can be explained as any new creation or technology which has not been formerly published in India or any part of the world prior to the filing of application with total specifications, i.e., the essentials have not been exposed to the public or that it never forms a part of the state of the art⁶. It is necessary that the term ‘new invention’ call for “absolute novelty” of the patentable subject matter. As a result, it will cause a hindrance for the patent holders to acquire the patents by virtue of frivolous or petty changes in the recognized product. Further, in Section 2(1) (ja) the term ‘inventive step’ talks about such attributes of the creation that requires technical advancement in comparison to the knowledge which is already in existence, which can make the innovation not so evident for a man who is already proficient in that particular art⁷. The main purpose of this section is that only those ideas which are innovative and have the capacity to be created into a new product are subject to patentability. The primary concern is that only those inventions which are not obvious are allowed.

The TRIPs Agreement through its aims and objectives looks forward to achieve a socio-economic balance for each of its member countries by authorizing them to implement an appropriate patent law system. Hence, after six years of validation of the TRIPs Agreement, WTO members conceded urgency of the indigent countries to be provided with reasonable healthcare facilities

and therefore, introduced the Doha Declaration on TRIPs and Public Health⁸. Though, after acquiring Doha Declaration, the pharmaceuticals companies were not able to lower the costs of the antibiotics, specifically for the medications of illness such as cancer or HIV/AIDS. It manifested that the overseas associations were unsuccessful in addressing the health issues concerning the prospering countries. Thus, every policy which was supposed to aid the availability of drugs at a nominal price for the needful, around the world has turned out to be futile.

The Reports of 2006, allows the countries to acquire legislation and several examining guidelines required to check the level of inventiveness to prevent evergreening of patents. The report further states that all the WTO members have been given the authority to ascertain barriers which are required for the ‘inventive step’⁹.

II. *Novartis v. Union of India: Section 3(d) An Aid Against Evergreening*

The verdict of the Apex Court of India, in the case of *Novartis AG v Union of India* is considered to be one of the historical verdicts of the Supreme Court. The verdict came as an aid to several persons around the globe as it allowed the people to obtain medicines at nominal rates, hence restraining the pharmaceutical companies from using the method of evergreening.

In the case a Switzerland based pharmaceutical company named Novartis, claimed patent protection for one of its cancer

⁶ Section 2(1) of Indian Patents Act, 1970

⁷ Section 2(1)(ja) of the Indian Patents Act, 1970

⁸WTO Doha Ministerial Declaration, WT/MIN (01)/DEC/2, 20 November 2001

⁹WHO Public Health, Innovation and Intellectual Property Rights Report, 2006



medication drug called *Glivec* which can be used for curing Chronic Myeloid Leukemia (CML) and also Gastrointestinal Stromal Tumor (GIST) upon the grounds that it created the beta crystalline salt form (imatinib mesylate) of the free base, imatinib¹⁰. This drug has been patented around the globe in 35 different nations. During that time, the patent laws in India were not strong enough and therefore, could not grant patents to any pharmaceutical or agrochemical medicines.

During the year of 2005, the patent laws in India were in accordance with TRIPs Agreement and thus drug products were subject to patent protection. India then subsequently brought in the amendments under its Patent Act and commenced with the patent granting to the pharmaceutical drugs. Later in the year 2006, the application for patent grant by Novartis for patenting its drug *Glivec* was revoked by the Madras Patent Office, on the grounds that it did not display any remarkable change in its therapeutic effectiveness as compared to its pre-existent form, which has already been patented outside India. As mentioned under Section 3(d) of Amendment Act, 2005 that says any recognized product is subject to patentability only if its new form displays “enhanced efficacy”. The Madras Patent Office failed in finding any “enhanced efficacy” in its new form of the drug called *Glivec* and hence, under Section 3(d) of the Act, it was not subject to patentability.

In the same year, under the Article 226 of the Indian Constitution, Novartis filed for two

writ petitions in the Madras High Court appealing against the decision of Patent Office in Madras for revoking the patent application and the other against the validity of Section 3(d) of Patents Act, 1970 stating that it was not in accordance with the TRIPs and hence inconsistent and in contrast with Article 14 of the Constitution.

Novartis in the High Court of Madras filed two writ petitions which was rejected on the basis that the court lacked the jurisdiction to ascertain whether the national law is inconsistent with the worldwide agreement, which means the court could not establish whether Section 3(d) is in accordance with the TRIPs. The main purpose of amending the Patents Act was to restrain the pharmaceutical companies from using the method of Evergreening and to make the life-saving drugs easily available for the citizens of the country. Hence, the amended section is not considered to be in contrast with Article 14 of the Constitution.

The Intellectual Property Appellate Board is an appellate body of patent controller¹¹, which considered that the beta-crystalline form of imatinib mesylate as new and inclusive of inventive step¹² but revoked the patent application of the drug named *Glivec* due to the Section 3(d) of the Act. Novartis then filed for Special Leave Petition in the Apex Court of India.

The Supreme Court in its verdict held that the main purpose of enacting Section 3(d) is to restrain the pharmaceutical companies from using the method of evergreening and

¹⁰Harsha Jeswani, Analysis Of Novartis A.G. vs. Union Of India, Ipleaders (11th May,2020; 1:18 pm) <https://blog.ipleaders.in/analysis-novartis-g-vs-union-india/>

¹¹*Ibid.*

¹²*Ibid.*



therefore, no patent will be granted to the invented drug until it fulfills the test under Section 3(d). Further, the court said that this verdict will not mean that Section 3(d) doesn't entertain any incremental inventions. In the cases of life-saving drugs, a substantial amount of care and caution needs to be taken to defend the Right to Life of the public. For the people who are unable to afford such costly medicines created by the pharmaceutical giants, this verdict came as a great relief for those people. The high prices of these patented drugs prevent the poor people from purchasing it and thus, putting their lives in danger. Therefore, the patent applications of companies such as Novartis were rejected by the court as they were trying to obtain a monopoly over their invented drugs which would endanger the life of the people who cannot afford these drugs. The Apex court of India was very clear in its verdict that availability of medicines at reasonable price is necessary considering the population of the country. The Supreme Court is therefore, justified in its order to forbid the non-restrictive manner of granting of patents and granting it only to authentic inventions.

III. Comparative Analysis of Evergreening in Foreign Countries

The concept of patent evergreening signifies a strategy through which multiple numbers of patents are obtained for various aspect of the same product, when the patent is about to expire by developing it to a similar improved by-product.¹³ It is permissible under the

patent laws to procure patent protection on improved products by industries and among it evergreening is found to be the most sought after process.

In USA, it is considered by many that since the procedure for extension of patent is available at the USPTO, it involuntarily tends to promote the evergreening strategy. The court put a stop to the USPTO regulations that might have resulted in putting an end to the evergreening process by stating that the regulations are outside the power of the authorities. "*The Hatch-Waxman Act*" came into force in early 1984 with an aim to formulate a balance between the generic and brand medicine industry.¹⁴ This act compels the drug development companies to single out the patent applications that relate to their medicinal products. The information is then collected and published in book known as the "*Orange Book*" by FDA. When a generic firm is about to sell a brand name pharmaceutical in its own version, in that scenario the generic firm must go through the "*Orange Book*" for patents relating to the product before going for "*Abbreviated New Drug Application*" (ANDA).¹⁵ In case where a similar patent exists and the generic firm is not ready to wait for the end of prevailing patent protection then the generic firm must put forward its opinion against the validity of the existing patent or for the reason why their product does not violate the patent protection.

¹³Shivendra Mishra, Evergreening of Patents, Mike Legal (7th May,2020, 6:23 PM), <https://medium.com/mikelegal/evergreening-of-patents-7bacd0eccc33>

¹⁴Hatch-Waxman Letters, Abbreviated New Drug Application (ANDA), FDA Gov(7th May, 2020, 7:23 PM),

[fda.gov/drugs/abbreviated-new-drug-application-anda/hatch-waxman-letters](https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/hatch-waxman-letters)

¹⁵*Ibid.*



The Act prohibits FDA from providing marketing permission to the generic firm for duration of 30 months if the brand name pharmaceutical company files for patent infringement. This period is provided for resolving dispute between the parties before the generic medicine comes into market. And, if the claim is successful then the generic pharmaceutical manufacturer is awarded a period of 180 days in which they have to increase their sale of product in the market. This period is also awarded to benefit the generic manufactures by allowing them enough time to develop generic form of the branded medicine.

Before the amendments of 2003 under “Medicare Prescription Drug Improvement and Modernization Act 2003” (US),¹⁶ the “Hatch-Waxman Act” gave the brand name manufactures power to obtain more than 30-month period stay in a single time. There were numerous critics that regularly held their voice against the process of obtaining numerous patents on a product for a long duration of time which effectively extended the exclusivity right owned by the patent holder. According to them it resulted in forming a dominant structure by the brand name firms and it slowed down the chance for generic companies to get introduced into the market which proved to have a negative effect upon the United States public healthcare. The amendments mollified the distress against evergreening of patents.

¹⁶Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Amendments: H.R.1-108TH Congress (2003- 2004) (7th May, 2020, 6:23 PM), <https://www.congress.gov/bill/108th-congress/house-bill/1/amendments?searchResultViewType=expanded&KWICView=false>

¹⁷Thomas A Faunce and Joel Lexchin, Linkage pharmaceutical evergreening in Canada and Australia,

The change in the legislative now allows a 30-month stay order only for claim regarding infringement of patents that are mentioned in the “Orange Book” during the time of filing the ANDA. Since a follow up patent does not act as an indicator for additional thirty-month blockage period, they remain valid proprietary rights against generic firm. Therefore, the amendment of 2003 did not defeat the enticement that evergreening possess.

After the introduction of “Hatch-Waxman Act” in 1984, the pharmaceutical companies followed “linkage” form of patent evergreening to extend their profits over high revenue pharmaceutical products.¹⁷ The act was formed with the intention to aid the generic drug manufactures with an easy introduction in the market while providing an extension to patent period for brand name manufactures as a compensation for taking so much time providing regulatory approvals. The brand name firms were always wary of generic availability as its low cost allowed them to capture most of the market once their patent protection got expired.

“The North American Free Trade Agreement” or NAFTA induced Canadian NOC “Notice of Compliance” linkage regulations which prevented the authorization of market entry until the expiry of brand name product patent protection.¹⁸ Also it made sure that whenever a generic

NCBI, (8th May,2020, 7:50 PM), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1894804/>

¹⁸North American Free Trade Agreement (NAFTA), Office of the United States Trade Representative, (7thMay, 2020, 9:30 PM), <https://ustr.gov/trade-agreements/free-trade-agreements/north-american-free-trade-agreement-nafta>



company in Canada filed for approval of product for license it must send along a “*Notice of Allegation*” or NOA to the owner of the patent stating that no patents were violated. The owner of the patent can file for an order to restrict the issue of NOC to the generic firms for a duration of twenty four months, the owner have 45 days to file for this motion.

The *linkage* regulations were codified by the Canada Industry and were authorized by the “*Office of Patented Medicines and Liaison*”. The Minister of Health has the responsibility to manage the Patent Register. The patent list is comprised of eligible NOC issued pharmaceutical products. The power to refuse adding and removing of information from the patent list lies with the Minister only.

The linkage regulations have been subject to various conflicts between the generic firm and brand name firm. The “*Canadian Generic Pharmaceutical Association*” or CGPA puts up an allegation against Canada’s patent rules stating that it is responsible for making sure that the public is forced to pay high price for brand name drugs for an extended duration.¹⁹ The CGPA pointed out that the brand name firms follow a vile practice of filing new patents on products to trigger a new NOA and along with it an extension to the stay period for generic firms to get introduced in the market to make sure that there is a delay in competition against them.

According to “*The Office of Patented Medicines and Liaison*” there are supposed to be about 44% of 419 medicines mentioned in the Patent Register to be covered by a single product. The Canadian federal government on October 2006 accepted the fact that the brand name firms were using the NOC regulations in their favour in a negative manner. The new regulation prevented the brand name firms from applying fresh patent applications for products that have been submitted by the generic firm for approval. This amendment made sure that the patents that have no therapeutic application cannot be used to delay the approval filed by generic firm. The Canadian Supreme Court also identified the abuse of NOC by the brand name firms by filing unnecessary patent applications.

In Australia before the enactment of “*Australia-United States Free Trade Agreement*” or AUSFTA evergreening of patents by the pharmaceutical companies faced only a minute attention. Justice Kirby in the case of *Aktiebolaget Hassle v Alphapharm* stated that the strategies used by the brand name firms to minimize the competition from generic firms represent a serious issue for a developing world. He also put forward that the court restrain itself from proving any fail-safe contingency for unsought extension of ownership right safeguard that are not clearly sustained by law.

It is clear from the provision of the AUFSTA²⁰ that one of its articles if gets enacted might facilitate the growth of patent

¹⁹Generic Drugs.Same Quality. Lower Price, Canadian Generic Pharmaceutical Association (CGPA), WHO (8th May, 2020, 12:12 PM), <https://www.who.int/intellectualproperty/events/en/CGPA.pdf>

²⁰Australia Free Trade Agreement (AUFTA), U.S. Customs and Border Protection (9th May,2020, 10:25 PM), <https://www.cbp.gov/trade/free-trade-agreements/australia>



evergreening. *Article 17.10.4 of the AUFSTA* stated that the Australia's "*Therapeutic Goods Administration*" or TGA have to formulate a process through which a brand name firm would be notified once a generic firm is aiming to come into the market with the generic product of the brand name pharmaceutical drug, so that the brand name firm can prevent the marketing approval of the drug.

There were various amendments that were brought in the *Therapeutic Goods Act of 1989*. One of such amendment resulted in addition of *Section 26B* in the aforementioned act. This section compelled the applicants before applying for market approvals, to certify that their products were not infringing any patent protection and also that the patent owner have been duly notified. Along with this *Section 26C* was also inserted in the act which made sure that the patent owners while filing for infringement of patent their intent was not of malice. These sections are considered to be anti-evergreening in nature as they aimed towards stopping the brand name firms to use strategies to delay the entry of generic drugs into the market

The US was not particularly happy with the enactment of *Article 17.10.4* in the AUFSTA and was also wary of the amendments that were brought in "*Therapeutic Goods Act of 1989*".²¹ US was concerned that the amendments made sure that patent owners incur penalties while enforcing their patent rights along with it the amendments provided the patent owners with additional burden that are not justifiable and also a bit discriminatory. The US challenged the

validity of these amendments and requested the Australian Government to review its enactments from the perspective of its international obligations. Similar to the provision of *Article 17.10.4* of the AUSFTA, the US faced similar scenario with *Article 18.9.4* of KORUSFTA (Korean-United States Free Trade Agreement) which was considered to be a significantly more advanced provision.

On comparative study of the Canada and Australian involvement with linkage form of evergreening have indicate need to form a regulatory agency like the Office of patented Medicines and Liaison. The Koreans are closer to achieving this development. Along with this no time should be wasted for implementing the WTO disputes resolution proceedings for issues relating to pharmaceutical policies. The debate on approval of fast track trade agreements between the US Trade representatives and US Democrats may result in curving out the form of linkage evergreening from US bilateral trade agreements.

The patent laws prevalent in the European Union or EU are still tolerant as they are not many laws in relation to the evergreening process. Under the "*Treaty on Functioning of the European Union*" or TFEU, *Article 102* states that evergreening is a process of abusing one's dominant position. Those who were convicted under this article challenged the article on the ground that the provision lacks clarity and a community law like this cannot challenge an evergreening patent laws that are specific to a country.²² It is an absolute right of a patent holder to enjoy its patent protection for monopoly. The article

²¹Therapeutic Goods Act 1989,Federal Register of Legislation, Australian Government (6th May,2020,

10:45 PM),
<https://www.legislation.gov.au/Details/C2019C00066>

²²Arun Kumar, supra note 1.



should have a definite aim so to accommodate the definition of evergreening in a more compact manner since the preceding definition is open to numerous exploitations.

In country like Japan, the new law states that the subject matter needs to be absolutely novel and clearly different from the original drug in order to achieve patent protection.

IV. Safeguarding the Interest of Patients over Patents

The pharmaceutical companies avail the process of evergreening so that they can continue to reap the benefits of a patent protection by exploiting the monopoly right that they have on the product which is under protection. There was a need to destroy this practice and create a harmonious environment between the patent laws and their provisions for extension with respect to fixing a low price of patented drugs so that everyone can afford the medicines²³.

There are many critics who stated the process of evergreening promotes the notion of benefiting a company's economic value rather than making any serious improvement in the drug. According to the brand name firms, they apply for increasing the period of their patent protection so that their investment in R&D process in order to make the quality of the drugs better remains protected under patent protection.

During time of pre-TRIPS regime, India was one of frontrunner country for distribution of medicines in an affordable price to countries

that were in dire need. Prior to the conclusion of the "TRIPS Agreement", India was one of the leaders in supply of cheap and affordable drugs globally. When India had a product patent regime, 85 percent of its medicine requirement was met through importing from other countries. A shift in the regime, i.e. from product regime to process patent regime saw India's medicine requirement met by its own products itself.²⁴ From the early 1970's the pharmaceutical companies in India reached to a significant level and became main suppliers of drugs at affordable prices to various countries.

Under the process patent regime, India benefitted from manufacturing generic medicines at relatively lower price. But to satisfy the guidelines of "TRIPS Agreement", India again had to shift to product patent regime. Various amendments were brought in to curb the negative impact of product patent. The scope of non-patentable products was widened by the amendment and also *Section 3(d)* was completely redrafted. It was taken as one of the most significant amendment brought in as it directly prevented evergreening of patents related to pharmaceutical products.

In India, since the decision of the Supreme Court to refuse the application for patent protection on a recent developed form of the drug Glivec filed by the Novartis company, evergreening came into major limelight. Novartis stated that the recent developed form of the drug gets absorbed into the blood very easily. According to them since the drug

²³Sushmita R.Evergreening: An Abuse of the Patent System, (10th May, 2020, 9:15 AM), <https://www.lawctopus.com/academike/evergreening-an-abuse-of-the-patent-system/>

²⁴ Dr. Lisa P. Lukose, Patent Ever Greening : Law And Ethics, International Conference on Information Law and Ethics, (10th May, 2020, 9:15 AM), https://icil.gr/download.php?fen=years/2016/downloads/speakers/0028-lukose-full_text-en-v1.pdf



was to cure leukemia, it was a very positive advancement in the characteristic of the drug which needed to be protected.

Compulsory License and Mutual Benefit Programs were the two methods that were recognized in order to minimize the price of patented medicine. The process through which non-patent owners are permitted to manufacture certain patented products is known as compulsory licensing.²⁵

In India, Natco pharmaceutical company was granted compulsory license for the very first time for the manufacturing of the patented product *Nexavar* of Bayer Corporation. This medicine was used for curing kidney and liver cancer. The price in which the Bayer Corporation used to sell was way too high and therefore not affordable by every sectors of society. The Indian Government on seeing that all the essentials of “*Section 84 of the Patent Act of 1970*” were met granted compulsory license on the grounds of public welfare.²⁶

There are numerous cases related to approval of compulsory license. In some scenario, the controller denied the application on the basis of having no prima facie case, not filing for a patent license before filling for compulsory licensing and also on failing to provide with a reasonable justification of the public use of the product by compulsory license.²⁷ According to the patent laws, it not satisfactory only to have a registration of a patent, there is a need for the court to look at the case as a whole, along with the strength

of the claim by the patentee and that of the defendant.

Indian courts in some case stated the laws relating to compulsory licensing should be read with the provisions surrounding the anti-competitive practices as both of them are not in exclusion to one another. The controller has the authority to decide whether the patentee has taken up any anti-competitive practices but if the CCI has already given its decision that the patentee has adopted anti-competitive means then the Controller has to follow the decision and stop the grant for license.

The category of cases suggests Judicial Inclination in favour of compulsory licensing, however owing to its nature, compulsory licensing remands for a fine system of checks, to ensure optimum scale of balance between the right of society to access pharmaceutical products and rights of pharmaceutical companies to exploit their intellectual property so as to recover the economic and other resources invested in developing such pharmaceutical products.

Giving due attention to the conflicting interests, the conundrum that what constitutes reasonable monopoly rights and in favour of whom the balance of convenience lies surface up, the answer to these questions are difficult to be put in a straightjacket formula and will majorly depend on legal regime as well as facts and circumstances of an individual case.

²⁵*Ibid.*

²⁶THE PATENTS ACT, 1970 (10th May,2020, 9:30 PM), http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf

²⁷Roger Collier, Drug patents: the evergreening problem, NCBI (10th May,2020, 10:15 PM), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/>



For underdeveloped countries compulsory license is the only ray of hope for patients with low economic support. The challenge in front of India is that to progress with the method of compulsory licensing with respect to international guidelines of protection of patents on one side and creating a structure of public welfare on the other.²⁸

One of the most important fundamental rights of a person is right to health. The WHO encourages its member states to promote the best standards of public health. Right to health signifies the right to access the best possible health care conditions like good quality food, proper sanitation, decent living conditions, etc.²⁹ A person has a right of mental and physical health. The idea behind right to health is that, it's the responsibility of the government to provide its citizen with conditions in which every one of them can live and prosper. These conditions include providing of adequate health services along with adequate housing and nutritious food and also safe and healthy working conditions.

CONCLUSION

The procedure acquired by the patentees through which they are able to extend their period of patent protection when the primary period expires after 20 years is known as Evergreening. This strategy of extending the period of patent protection is mainly adopted by pharmaceutical companies to protect their drugs and other pharmaceutical products. The patentee seeks to extend the patent protection for any by-product of the already patented drug, which resulted from the minor

changes on the patented drug. These changes are made at the time of or sometime before the expiration of the patent, so that the patent holder can lengthen the period of protection. It can be understood that the use of evergreening provisions will lead to the misuse of intellectual property protection, as the innovator company will look to make only trivial changes to extend the term of protection for the patented drug and then charge unreasonable prices for it, stating that they had to incur huge expenditure on research and development of the patented drug. This will affect the society at large, as majority of people will not be able to bear with the high costs of these life-saving drugs. To combat with the issues in relation to evergreening, there was a dire need of robust patent laws in the country. Thus, India came up with the Indian Patents Amendment Act, 2005 which established patenting the products in India and marked the inception of a new patent system which intended towards securing the rights of the patent holders. The Act was in attainment of India's adherence to the World Trade Organization (WTO) on matters relating to the Agreement on TRIPs. The Amendment Act came up with the definitions of the term 'new invention' [Section 2(1)], 'inventive step' [Section 2 (1) (ja)] and also established limitations as to the purview of patentability under Section 3(d). After the gap of only one year, the provisions of section 3(d) were put under scrutiny in the case of *Novartis AG v Union of India* which is considered to be one of the most historical verdicts of the Supreme Court. Switzerland based pharmaceutical company named

²⁸Compulsory Licensing In India, Mondaq (11th May,2020 11:00 PM), https://www.iiprd.com/compulsory-licensing-in-india/?utm_source=Mondaq&utm_medium=syndication&utm_campaign=LinkedIn-integration

²⁹ Compulsory licensing of pharmaceuticals and TRIPS, IIPRD (10th May, 2020, 11:30 PM), https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm



Novartis, claimed patent protection for one of its cancer medication drug called *Glivec* which got rejected. The Supreme Court in its verdict held that the main purpose of enacting Section 3(d) is to restrain the pharmaceutical companies from using the method of evergreening and therefore, no patent will be granted to the invented drug until it fulfills the test under Section 3(d). The verdict came as an aid to several persons around the globe as it allowed the people to obtain medicines at nominal rates, hence restraining the pharmaceutical companies from using the method of evergreening.

there is a need to balance the patent rights with the right to public health.

In the author's viewpoint, there is a predominant demand for maintaining equilibrium between the patients and the patents. Since, the most important fundamental right of a person is right to health. The WHO encourages its member states to promote the best standards of public health. Right to health signifies the right to access the best possible health care conditions like good quality food, proper sanitation, decent living conditions, etc. Each person has a right of mental and physical health. The idea behind right to health is that, it's the duty of the government to provide its citizen with conditions in which every one of them can live and prosper.

The paper has been an endeavor to extensively bring up the negative aspects of the evergreening process and the necessary steps taken by numerous countries to curb the patent extension essentials with respect to the ambit pertaining to the rights of a patent holder. The researchers believe that the amendments are old in themselves as there have been huge stride in development process by pharmaceutical companies and

