Acceptability of Ever Greening Method in India

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Evergreening refers to the diverse ways wherein patent owners take undue advantage of the law and associated regulatory processes to extend their IP monopoly particularly over highly lucrative "blockbuster" drugs by filing disguised/artful patents on an already patent-protected invention shortly before the expiry of the parent patent . These artful patents tend to protect delivery profiles, packaging, derivatives and isometric forms, mechanism of action, etc. for the same old molecule. This provides the innovator companies sufficient time to recoup their controversially estimated R&D costs. Patent monopolies thus should be designed to function to function at an optimum level wherein maximum incentive is accorded to investment in research followed by simultaneous accessibility of the protected inventions to the public. The TRIPS compliance has compelled pharma industries of the developing countries, such as India, to innovate in order to cater to the requirement of current and future drugs. This study covers aspects of evergreening, its impact in the pharma IP domain and identifies means adopted for limiting evergreening. Further, the concepts have been understood with the help of the Hoffman La Roche and Novartis cases.

I. INTRODUCTION

A patent is described in the Indian Patents Act, 1970 as "*a grant or a right to exclude others from making, using or selling one's invention and includes right to license others to make, use or sell it*". It has been defined as an official document conferring a right or a privilege, letters patent, writing securing to an inventor for a term of years the exclusive right to make, use and sell his invention, the monopoly or right granted[2]. This monopoly right is given only for a certain number of years. After the expiration of this duration, this right is taken away from them and the technology or the product becomes easily accessible to any other person and he may not earn any more profit from his own creation. In recent times, it has become a practice by a number of innovator companies to extend the patent term of their innovative molecules to maintain market dominance.

Under chapter II of the Indian Patent Act, 1970, Section 3 deals with what is not patentable. Sub-section (d) which reads "*the mere discovery of a new form of a known substance or mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant*".

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[2]Webster's Ninth New Collegiate Dictionary.

This provision aims to prevent evergreening and protect the genuine innovators. This was demonstrated in the judgment of Novartis case which shows that there is a shift in the development pattern of usage and production of technology. Earlier India was just a user of the technology hence its laws provided weak protection to the intellectual property. But gradually India became a producer of technology, thus providing a strong protection to intellectual property.

Further, it must be kept in mind that TRIPS recognizes that members have the right to use/adopt measures to protect public health so long as they are consistent with TRIPS. Policy makers in developing and developed countries need to base their implementation of intellectual policy rules on these pro-public health and pro-access principles. The language of the Doha Declaration emphasizes the importance of implementing and interpreting the TRIPS Agreement in a way that supports public health.

II. HISTORICAL BACKGROUND

India's pharmaceutical industry is considered as the 3rd largest in the world in terms of volume and the 14th in terms of its value. With China, Brazil and Russia, it led a group of seventeen high-growth pharmaceuticals markets also called "pharmerging countries" which are expected to contribute to nearly 50% of the annual pharmaceutical market growth in 2013[3]. Given its capacity to produce large quantities of drugs at cheap, affordable prices, India is known to many as the "Pharmacy of the Developing World" as it has become a leading supplier of generic medicines to many developing countries[4]. For example, India's production of HIV/AIDS medications has helped lower the cost of treatment dramatically from as much as USD $10,000 per year in 2000 to USD $150 per year in today's date[5].

Innovation and invention have speeded up in myriad ways in the last few decades and India had committed itself to the obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter referred to as the 'TRIPS' Agreement) in 2005. Therefore, it was necessary for India to revisit its patent law. Hence, in 2005, the Indian Patents Act was amended, Section 3(d) being one of the amendments. It was the basis for the Novartis case.

For well over 30 years, the Indian government did not allow product patents for pharmaceutical inventions, paving the way for Indian generics companies to freely produce medicines created by foreign drug companies at a fraction of the cost. Process patents, on the other hand, were recognized as they were seen as an incentive for domestic manufacturers to develop "cheaper methods of making expensive patented products", and a way for the Indian government to keep drug prices low. In 1995, India became a member of the World Trade

[3]http://www.imshealth.com/portal/site/ims, last accessed on 06/03/2019.
[4]Ncbi.nlm.nih.gov/pmc/articles/PMC3884017, last accessed on 22/04/2019.
[5] Id.

Organization (WTO), and was compelled to revise its patent laws following a ten-year transition period in order to comply with the TRIPS Agreement. Thus, January 1st, 2005 saw the "implementation of substantially enhanced patent protection for pharmaceuticals" in India, in that drug products were now able to become patentable[6].

What is evident is that India has had a mixed approach towards the implementation of the TRIPS Agreement, availing itself to the full transition period for product patent protection, and delaying other commitments[7]. It also stalled on a second required measure that involved exclusive marketing rights – that is if a state allows the new drug to be marketed, the firm that invented the pharmaceutical has the right to exclusively market the drug for a period of time. This strategy of delay suggests strongly that India, while committing to the spirit of the TRIPS Agreement, has also sought to ensure that its interpretation and implementation is in line with domestic preferences.

India's domestic patent provisions have been contested by the international pharmaceutical industry. For example, provisions in its domestic law that ban 'evergreening', a process in which minor reformulations to a pre-existing drug can be used to extend patents (a common practice among pharmaceutical companies in developed countries); and second its criteria for 'compulsory licensing', a clause permissible under the TRIPS Agreement, which under extenuating circumstances, permits a country to "force a firm to license a patented drug to a generic company".

India at present is seeking to interpret its obligations under TRIPS in a manner that still permits the production of generic medicines and keeps medicine prices as low as possible to facilitate access to essential medicines..

III. THE PROCESS OF EVER GREENING

"Evergreening" is an aspect of patenting that leads to patent life cycle enhancement technique largely employed by the pharmaceutical organizations to develop bullet proof patent portfolios around lucrative drug molecules. This is done in an artful manner by protecting a large number of inventive aspects over the basic invention by avoiding any imminent double patent rejection and eventually leading to extension of patent terms to a further 20-year term for a single drug product. In other words, it is referred to the practice whereby pharmaceutical firms extend the patent life of a drug, by obtaining additional 20-year patents for minor reformulations or other iterations of the drug without necessarily increasing the therapeutic efficacy, for a longer duration than would normally be permissible under the law[8].

Drug patent ever greening is the single most important strategy that multinational pharmaceutical companies

[6]Bansheer S., Reddy TP, '*The efficacy of Indian Patent Law: Ironing out the Creases* in Section 3(d)', 2008, Pages 232-266.
[7]Redwood H.*New Horizons in India: The Consequences of Patent Protection*, England, Oldwicks Press, 1994.
[8]Nopr.niscair.res.in/bitstream/, last accessed on 03/03/2019.

have been using. One form of ever greening occurs when the original manufacturer "stockpiles" patent protection by obtaining separate 20-year patents on multiple attributes of a specific product. These patents can cover everything from aspects of the manufacturing process to tablet color or even a chemical produced by the body when the drug is ingested and metabolized by the patient.

The ultimate consequence could be that the genetic equivalents of the drug would be prohibited from entering the market so the price of the drug of the innovator Company will be higher even after the patent expiry in absence of competition from generic drug makers. Further, ever greening many be used by manufacturers of a particular drug to restrict or prevent competition from manufacturers of generic equivalents to that drug. The main arguments in favor of governments regulating against ever greening are rapid entry of multiple generic competitors after patent expiry is likely to lower prices and facilitate competition.

Lastly, it has become a practice in the pharmaceutical industry where on one hand innumerable patients struggling to afford the high priced patented drugs, while on the other hand innovators struggling to give immortal value to their creation.

Evergreening strategies that have been usually followed by the pharmaceutical industries involve:

(a) Redundant extensions and creation of next generation drugs which result in superfluous variation to a product and then patenting it as a new product,

(b) Prescription to OTC switch,

(c) Exclusive partnerships with cream of generic players in the market prior to patent expiry thus significantly enhancing the brand value and interim earning royalties on the product,

(d) Defensive pricing strategies practice wherein the innovator companies decrease the price of the product in line with the generic players for healthy competition and

(e) Establishment of subsidiary units by respective innovator companies in generic domain before the advent of rival generic players.[9]

IV. EVER GREENING UNDER INDIAN PATENT ACTS

When India amended its patent law to comply with the TRIPS agreement, it also added a controversial provision intended to curtail evergreening of pharmaceutical patents. The provision, Section 3(d), bars companies from patenting new forms of known substances unless the new form demonstrates a significant enhancement in efficacy. However, Section 3(d) does not define 'efficacy', it is still questionable as to what constitutes sufficient improvements in a drug to qualify as substantial increase in efficacy.

[9]Hunt M I, *Prescription Drugs and Intellectual Property Protection*, NIHCM Foundation, (2000) 1-12.

Section 3(d) of the Patent Act lists what are not considered 'inventions'. It goes as follows:

"The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."

Section 3(d) of the Indian Patents Act, 1970 (hereinafter referred to as "the Act") prevents "Ever greening" of a drug. It is clear that unless the enhanced efficacy as mandated by Section 3(d) of the Act was demonstrated, a patent could not have been granted for a known substance.

The Act allowed patent grants to only processes but not products and further encouraged R & D and domestic competition while protecting interests of the patent holders. To create a foothold in the international market, the Patents (Amendment) Act, 2005 came into effect which was TRIPS compliant. The TRIPS compliant patent system encouraged third parties interested in the product to file pre- and post- grant oppositions. The definition of patentability was also modified to prevent evergreening and further fresh patents would not be granted for new indications for drug use.

The applicability and acceptability of 'evergreening' in India may best be understood by discussing the following two landmark cases:

F. Hoffmann-La Roche Ltd. &Anr. v. Cipla Ltd.[10]

This case related to the Hon'ble High Court deciding that social welfare must be supreme to all economical attributes.

Facts: OSI jointly owns a patent with Pfizer Products Inc. in respect of a small drug molecule popularly known as "Eriotinib". It is claimed that the said drug marked a major breakthrough and innovation in the treatment of cancer. It is administered in the form of a tablet and sold under the trademark name 'Tarceva', which is registered in the name of Roche. It is claimed that Eriotinib and Tarceva have been approved by the U.S. FDA (2004) and by the EU (2005). Patent in respect of Eriotinib was granted by the Controller General of Patents, New Delhi and recorded as on July 6, 2007.

In 2008, media reports alleged that Cipla announced its plan to launch a generic version of Tarceva (Eriotinib) in India under the name of 'Eriocip'. On hearing of this, the plaintiffs alleged infringement and violation of patent owner's rights by claiming that the drug had been developed after a long sustained research and after incurring enormous expenditure. Roche claimed before the Single Judge in Hon'ble High Court of Delhi to restrain Cipla from manufacturing the said drugs, so that their business of drugs would not be affected.

[10]F. Hoffmann-La Roche Ltd. &Anr. v. Cipla Ltd,I.A. 642/2008 IN CS (OS) 89/2008

Cipla gave the argument before the Court that the Patent was hit by Section 3(d) of the Act as Eriotinib was a derivative of a known patent 'Quinazoline' and that there were at least three EU patents dating back to 1993 which disclosed the Quinazoline derivative. Roche had not if there was "any improved efficacy of the said drug". They further contended that Roche's drug costsRs. 4800 and Cipla's costs just Rs. 1600 and in the context of life saving drugs, it was in the public interest that the drug should be made available at cheap and affordable prices.

The Hon'ble Single Judge rejected the application for interim injunction prayer by Roche opining that invention in the patent was obvious to the unimaginative person skilled in the art and that the court could not be unmindful of the general access to life saving products and that irreparable injury would be caused to the public.

In the Division Bench of the High Court of Delhi, Cipla further relied on the fact that Roche did not yet hold a patent for Polymorph B in India (application was pending consideration). US patent granted Roche in May 2005 stated that Eriotinib was a mixture of two polymorphs A and B and that it was necessary to separate and purify the B to get the claimed compound for acceptable efficacy and, therefore, the patent granted defeated the inventive step of the alleged invention. However, reports showed that it was wholly Polymorph B.

Judgment: The division bench finally stated that there was no infringement as the patent which was in question was a mixture of Polymorphs A and B, whereas the drug Tarceva drug consisted of only Polymorph B. The point here to be noted was that Roche had applied for patent of Polymorph B but was denied by the Indian Patent office as it did not satisfy the criteria of Section 3(d) and the test of patentability was not satisfied. Moreover, the court considered the intent of the legislature in enacting Section 3(d) and anti-ever greening laws and held public interest above everything. The court realized that in here a lifesaving drug was in question, and hence the drug which was made available by Cipla was three times less priced than the drug which was manufactured by Roche.

Critical Analysis: The main question was whether denying infringement to the drug of Roche was correct or not, as it highlighted ever greening of patent which has been expressly denied under the section 3(d) of the Indian Patent Act.

If we carefully analyze Section 3(d) of the Act we can see that it clearly lays down denial of patent in three circumstances:

- **Mere discovery**: Mere discovery According to the Webster's Third International Dictionary of the English Language, the expression "discovery" refers to "the act, process or an instance of gaining knowledge of or ascertaining the existence of something previously unknown or unrecognized."

Therefore, discovery would mean simply finding out something which is known in the world whereas innovation involves an inventive step.

- **New form of a known substance**: This would mean that the existence substance is being presented in a different manner or in other words other derivatives of a known substance. This would not be patentable unless it is proved that they differ significantly about efficacy.
- **Does not increase efficiency:** Meaning thereby that a new form of a known substance will be allowable only when it is shown that they differ in properties and that this difference has led to enhanced efficacy. The efficacy can be in the form of enhanced stability or freedom from specific disadvantages or even perhaps increase in bioavailability but it should not be an eye-wash increment in efficacy but a significant increment.[11].

The intent of the legislature behind such a Section was clearly to make Anti- Evergreening laws by restricting obvious forms and substances.

In the case of **Garham v. John Deere Co**.[12] the U.S Supreme Court had laid down few steps to check whether the patent involves an inventive step or not:

- The scope and content of prior art.
- Whether there is a difference between prior art and the claim which has been made.
- The level or an ordinary skill which is involved in the pertinent art.

The term has nowhere been defined in the Act, but the fact that it was common for a person who is an expert in the field would be sufficient to make the claim fall under the connotation of prior art.

The intent of the legislature behind inserting an anti- Evergreening section in the Patents law was to do away with the practice in the medical field where the pharmaceutical companies had a habit to change a small component and gain the patent again, after the expiry of 20 years of the patent term.

In the present case the court quoted that "A mere difference in physical property is a well-known conventional variation of the same pure substance not showing unobvious properties. Therefore, the changes alleged by the applicant are in the physical properties and not in the therapeutic efficacy. This clearly amounts to Evergreening tendency which has been denied by Section 3(d).

Section 3(d) basically keeps a check on the over ever-greening as it in turn affects the public health of a country, as the manufactures may charge heavy prices which are not affordable by the public at large and

[11]http://www.ip-watch.org/2007/06/01/scope-implications-of-section-3d-of-the-indian-patents-act-1970-as-amended/, last accessed on 03/03/2019.
[12]Garham v. John Deere Co, 383 U.S 1(1966)

continue to enjoy their monopoly and this is completely against the concept of patents. In the present case also, it is quite evident that the drug which was being made available by Roche was three times more expensive than the drug which was available by Cipla. While granting patent and passing injunction orders what is more important to see is the public benefit at large.

Section 3(d) promotes subsequent expansion of existing chemical substances, compounds, technologies which are helpful in fulfilling the health requirement of the public and balance public goods.[13]

Novartis Ag v. Union Of India &Ors.[14]

In this case, it was seen that Section 3(d) was interpreted as to the therapeutic efficacy of the drug and not just the improvements in the physical characteristics or stability of the product. Supreme Court stated that even if the bioavailability of the drug was improved, it did not demonstrate enhanced efficacy and that Glivec was not patentable. Further, this case illuminates how India is interpreting international law to fit domestic public health needs.

Facts: Glivec, produced by the Swiss pharmaceutical giant Novartis, is used to treat Chronic Myeloid Leukemia (CML) and Gastrointestinal Stromal Tumours (GIST), and is patented in 35 countries across the world. According to Lee[15], studies have shown that Glivec is "almost ten times more effective than traditional interferon therapy", due to its ability to target specific cancer proteins. For patients, the drug needs to be taken lifelong. For this reason, along with the fact that 95% of Indians do not possess private health insurance, its pricing plays a critical factor in cancer patients' ability to access a continuous supply of Glivec for effective treatment. There is a significant price gap between the patented version of Glivec and its generic copy, as a monthly dose of the former can cost as much as USD5,000 in the U.S., whereas a monthly dose of the latter can be purchased for just USD 200 in India.

In 2006, the Indian Patent Office rejected Novartis' patent application for Glivec under Section 3(d) of the Indian Patents Act, stating that the drug was a modification of an existing substance, imatinib, and therefore represented a case of 'evergreening'. Section 3(d) articulates that reformulations of pre-existing drugs, which do not improve the efficacy of the product, are ineligible for extended patents. Unfortunately, "neither the Indian patent statute nor its implementing rules define 'efficacy'", and there are no available guidelines for companies like Novartis seeking second-generation patents (i.e., extended patents on modifications of previous products). Thus, the interpretation of the word "efficacy" is central to this case.

[13]Kant A, Section 3(d): 'New' *Indian Perspective, Journal of Intellectual Property Rights*, 14 (9) (2009) 385-396.
[14]*Novartis Ag v. Union Of India &Ors*, Civil Appeal No. 2728 Of 2013.
[15]Lee L., Trials and TRIPS-regulations: Indian patent law and Novartis AG v. Union of India, Berkeley Technology Law J., 2008, Pg. 281-290.

Judgment (along with the obiter of the Hon'ble Supreme Court of India): The court first analysed the question of "prior art" by considering Zimmerman patent and the related academic publications. It was clear from the Zimmerman patent that imatinibmesylate itself was not new and did not qualify the test of invention as laid down in section 2(1)(j) and section 2(1)(ja) of the Patents Act, 1970. Now, the beta crystalline form of ImatinibMesylate being a pharmaceutical substance and moreover a polymorph of ImatinibMesylate, it directly runs into section 3(d) of the Act with the explanation appended to the provision".[16]

In applying 3(d) of the Act, the Court decided to interpret "efficacy" as "therapeutic efficacy" because the subject matter of the patent is a compound of medicinal value. Court acknowledged that physical efficacy of imatinibmesylate in beta crystalline form is enhanced in comparison to other forms and that the beta crystalline form of imatinibmesylate has 30 per cent increased bioavailability as compared to imatinib in free base form. However, as no material had been offered to indicate that the beta crystalline form of imatinibmesylate will produce an enhanced or superior efficacy (therapeutic) on molecular basis than what could be achieved with imatinib free base in vivo animal model, the court opined that the beta crystalline form of imatinibmesylate, does not qualify the test of Section 3(d).[17]

Thus in effect, Indian Supreme Court upheld the view that under Indian Patent Act for grant of pharmaceutical patents apart from proving the traditional tests of novelty, inventive step and application, there is a new test of enhanced therapeutic efficacy for claims that cover incremental changes to existing drugs.

The Court also took care to state the decision was intended to be narrow: "We have held that the subject product, the beta crystalline form of ImatinibMesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be a grave mistake to read this judgment to mean that section 3(d) was amended with the intent toundo the fundamental change brought in the patent regime by deletion of section 5 from the Parent Act. That is not said in this judgment."[18]

Case Comment: The main contention which was raised in this case was that Section 3(d) ought to be removed as it was against the TRIPs agreement. But what the court instead said was that the main aim of the patent system is to provide benefit to the inventor for a period of 20 years but restrict the expansions of such term once the term has expired. The Court said that the Amendment was intended to:

- Prevent ever-greening;
- To provide easy access to the denizens of this country for life saving drugs; and

[16]Novartis v. Union of India, Para. 158.
[17]Novartis A.G. v. UOI &Ors., Hon'ble Justice AftabAlam's Swansong, RudrajyotiNath Ray, RDA, April 8, 2013.
[18]Novartis v Union of India, Para 191.

- To discharge their constitutional obligation of providing health care to its citizens.

What is to be noted in the present case and in cases which involve the drug is that 'Right to health' is a cause of concern in major parts of the world specially Africa and Asia and in such situations price plays a key role. If the price of these lifesaving drugs are allowed to be fixed at a higher rate by allowing monopoly and not restricting Evergreening then companies will keep on creating drugs which are thrice as expensive. In such cases what is of most important is public concerns which are to be given a upper hand.

Criticism for the Novartis Judgment: RanjitShahani, vice-chairman and managing director of Novartis India Ltd. is quoted as saying "This ruling is a setback for patients that will hinder medical progress for diseases without effective treatment options."[19] He also said that companies like Novartis would invest less money in research in India as a result of the ruling.[20] The Indian government and the Indian courts have come down on the side that doesn't recognize the value of innovation and the value of strong intellectual property, which we believe is essential."[21]

V. EVERGREENING IN OTHER COUNTRIES

Canada: An extensive investigation by the Competition Bureau revealed problems with drug patent "evergreening" arising from the Patented Medicines (Notice of Compliance) Regulations in 1993 required as an obligation of entering the North American Free Trade Agreement ("NAFTA"). It found that over 200 legal actions involving "evergreening" claims had been brought and that this was having an adverse effect on the sustainability of the Canadian generic drug industry and drug prices in the country[22].

Australia: Patents Act 1990, already permits non-use-related patent extension for up to five years for delayed pharma marketing approval but AUSFTA has "locked-in" this monopoly protection and for the preservation and promotion of the so-called 'anti-evergreening' amendments were passed by the Australian Parliament.[23]

Israel: Endorses a demanding non-obviousness requirement for patentability. Pharma companies run the risk of developing a drug therapy that is genuinely innovative, but that is denied patent protection by the Court system. Also, Israel has a strong domestic market and it pushed the development of the generic pharma industry in order to provide healthcare to its citizens at the cheapest possible cost. Israel's Patent Office Guidelines for Examination indicates that an "inventive step" requires a "quantum" advancement over the prior art. A similar requirement is provided for under Section 5 of Israel's Patent Act.[24]

[19]Shift in Novartis Strategy, The Telegraph, April 2, 2013.
[20]Gardiner Harris and Katie Thomas, "*Top Court in India Rejects Novartis Drug Patent*", The New York Times, April 1, 2013.
[21] Gardiner Harris and Katie Thomas, "*Top Court in India Rejects Novartis Drug Patent*", The New York Times, April 1, 2013.
[22]Faunce TA, Lexchin J, "*Linkage, Pharmaceutical Evergreening in Canada and Australia*", Australia and New Zealand Health Policy, June 1, 2007.
[23] Ibid.

VI. SUGGESTED MEASURES

Just describing the problems caused by the strict patent laws or evergreening of the patent is not enough. It is also important to prescribe a solution for these problems. There are ways that can help in the reduction in the price of patented drugs.

Compulsory Licensing

By providing for compulsory licensing, permission is granted to non-patent holders of the drug to manufacture that drug. In this way, prices of these drugs though patented are kept low and they are within reach of the poor sections of the society.

Mutual Benefit Programs

The government should ensure proper health care is available to all the sections of the society. Because in India, there are problems like low income and inadequacy of healthcare facilities. The common man has very limited access to essential drugs and it does not matter whether the drug is patented or not. Even if the drug is not patented, access to such crucial drugs is very less. Hence, the government should ensure access to basic health facilities.

VII. CONCLUSION

The amendment of 2005 showed that India has adopted an IP regime that showcased the spirit of WTO, but at the same time keeps a provision for prohibiting 'Evergreening' by making available expensive medicines available at nominal rates by encouraging market competition. What has been showed by the Indian judiciary through cases like Novartis and Cipla is that Section 3(d) is acting as a guard against Evergreening of patens as the pharmacy companies have a habit of simply changing just one component which does not in any manner change the efficacy of the product and re apply for product, this basically restricts the research and development pace and leads to the downfall of the country. Secondly what has been made clear through these cases is that while granting and considering patents applications what will be of at most importance is the Public benefit at large. Had the patent been granted to Roche by the Controller of Patent in New Delhi then the medicine for treating Cancer would have been out of reach for numerous patents because of the cost of the medicines.

Patent laws in India encourage inventions but are against providing absolute rights, they provide a restrictive right whereby encouraging more research and development and development of better medicine in the market.

[24]Is evergreening a cause for concern? A legal perspective.http://www.ipatent.co.il/the-novartis-decision-evergreening-and-the-future-of-generics/, last accessed on 06/03/2019.