PATENT EVERGREENING AND ACCESS TO MEDICINES: A LEGAL DILEMMA

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ABSTRACT

One of the most disputed problems in modern pharmaceutical patent law has become the socalled patent evergreening, especially in developing nations such as India when the access to affordable medicaments is one of the burning issues of the population. Evergreening is the practice used by pharmaceutical firms to make a minor modification on a previously existing drug, whether in form, dose or combination; without any significant breakthrough in its therapeutic effect in order to keep the patent alive. On the one hand, the idea of patent protection is meant to encourage innovation by giving a person a 20-year monopoly, but on the other hand, this concept may be applied to withhold the introduction of effective generic medicines due to the necessity to secure patent protection.

This paper is a critical analysis of the legal issue on drug innovation versus access of essential drugs by the people in the Indian context. It discusses the legal context of the Patents Act, 1970, especially the Section 3(d) that aims at eliminating patenting of minor modifications unless they can prove an improved therapeutic effect. This is an exclusive provision by India in balancing the rights of the individual and the objective of the health of the population.[1]

The paper also examines some of the landmark judicial decisions that have informed the debate on evergreening. In Novartis AG v. Union of India.[2] The Supreme Court took a very stringent view on efficacy and established a world-wide precedent against non-serious patent extensions. Likewise, Bayer Corporation v. Natco Pharma ltd. [3] emphasized the importance of the compulsory licensing as a means of accessing life-saving drugs, and Roche ltd v. Cipla ltd emphasised the role of the public in the enforcement of patents.

Arguments of evergreening and anti-evergreening have also been put forward in the paper. In its proponents believe that incremental innovations

[1] The Patents Act 1970, s 3(d) (India).
[2] Novartis AG v Union of India (2013) 6 SCC 1 (India).
[3] Bayer Corporation v Natco Pharma Ltd (2014) 6 SCC 534 (India).

should be offered protection, and help recuperate high research and development expenditures. However, critics see evergreening as an artificial expansion of monopolies and thus limiting access to affordable medicines and ethical issues particularly in low- and middle-income countries.

Placing the problem in a comparative context, the article shows that India has a tighter patent system than other countries of the United States and the European Union in terms of its adherence to the concept of public health. Finally, the article proposes a moderate legal solution that could nourish outstanding innovation but will eliminate the exploitation of patent rights. It points out why the judicial vigilance and consistent policy action are necessary to make sure that the patent system benefits the commercial interest as well as the larger aim of fair healthcare access.

INTRODUCTION

The clash of patent law and public health has come into the limelight of contemporary pharmaceutical environment, especially in the developing countries such as India. The practice of patent evergreening is one of the most controversial topics in this field, as it is a strategy used by pharmaceutical firms that allow extending the time taken by patents through slightly changed drugs. Such changes can be in form of change of dosage forms, new combinations or change in delivery mechanisms, which in most cases may not make a significant change in therapeutic value. Although these practices might be under the technical aspects of the patent law, they could be of great concern on competition, affordability and access to medicines.[4]

The very nature of patent protection is the incentive of innovation by allowing those that create inventions to have exclusive rights on their inventions within a certain duration of time which is usually 20 years. This monopoly position is only temporary enabling pharmaceutical companies to recoup the huge expenses incurred during the research and development, clinical trials and regulatory approvals. Yet, this system needs a delicate balance between the promotion of innovation and protection of the interest of people as well. When patents are evergreened exceeding their intended duration, this balance is upset, and such evergreening will tend to postpone the introduction of generic medicines that are less expensive and more widely available.

The patent law in India attempts to achieve this balance of delicate provisions in the statutory

[4] Carlos M Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (Oxford University Press 2007).

law. Safeguards on protection of patent rights against abuse are contained in the Patents Act, 1970, which has been amended to suit the requirements of establishing the international obligations in the TRIPS Agreement. One of the important requirements in this connection is the Article 3(d) which directly limits the patentability of new forms of known substances unless they lead to a noticeable increase in therapeutic efficacy. This is based on the policy decisions of India to ensure that trivial inventions do not get the protection of patent and thus, put a check on the evergreening practice and enhance the availability of crucial medicines.[5]

The Indian judiciary has been very instrumental in the interpretation and implementation of these principles. The cases have shed light on the restriction and usage of patent law in the pharmaceutical industry, specifically, evergreening and the interests of the populace. The courts have stressed that minor or even incremental changes that do not substantially contribute to the effectiveness of a drug should not receive a patent, therefore, strengthening the purpose of legislature in Section 3(d).Simultaneously, other means like the compulsory licensing have been identified as relevant to unlock the access of patented medicines when the need arises in the society.[6]

Patent evergreening is also a problem that can be approached with wider ethical and policy implications. On the one hand, pharmaceutical corporations justify that due to incremental innovations they need to enhance the performance of a drug and retain the interest in research. Conversely, the critics argue that evergreening tends to become a business tactic to extend the existence of monopolies, limit competition and ensure high drug prices, especially among vulnerable groups in the developing world.

It is on this background that this current article tries to discuss the patent evergreening legal dilemma in India. It examines the conflict between novelty and availability, scrutinised the legislative and judicial system and discussed the greater impact to the community health. In such a way, it tries to emphasize the necessity of a fair and equal strategy that will not only preserve the integrity of the patent system but also underline the basic right to affordable medications.

[5] The Patents Act 1970, s 3(d) (India).
[6] Novartis AG v Union of India (2013) 6 SCC 1 (India).

SIGNIFICANCE OF PATENT PROTECTION

The patent protection is one of the core principles of the intellectual property law existing to encourage innovation by providing exclusive rights of the inventors on their works within a specific term. The protection of patents in the form of a legal right is especially relevant in the pharmaceutical industry as it ensures legal protection and economic incentives that are used to develop new medical technologies and drugs. Patent law can ensure that inventors and pharmaceutical firms will not have their invention, patented or not, made, used, sold, or imported by other parties without their consent. This monopoly is essential towards promoting investment in research and development which is usually costly, time consuming and uncertain in its results.[7]

The normal term of patent protection, which is recognized at the international level under the TRIPS Agreement and is enforced in the domestic legislations like the Patents Act, 1970 is a period of 20 years since the date of the patent application filing. The patent holder has the exclusive commercial right in this period and therefore he or she is free to charge prices and control distribution of the patented product. This narrow monopoly has been considered on the basis that it allows the inventor to compensate the high costs of innovation, which include lab researches, clinical trials, regulatory compliance and marketing. Lack of this protection would easily lead to other companies copying the invention and selling it cheaply to deter actual innovation.[8]

Nevertheless, patent protection is not the right that is absolute or has no restrictions. It is working under a larger legal framework that aims at harmonizing the interests of the people and the welfare of the people. The reason why patents are given is not simply to award inventors but also to make sure that the society is ultimate beneficiary of the new and useful inventions. This equilibrium is especially essential in the pharmaceutical industry whereby the availability of medicines can directly influence the population health and life. High drugs costs and shortage could be caused by excessive or protracted protection of patents particularly in developing countries where a good proportion of the population might not be able to afford

[7] W Cornish, D Llewelyn and T Aplin, Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights (9th edn, Sweet & Maxwell 2019).
[8] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1994, art 33; The Patents Act 1970 (India).

high-priced medicines.[9]

Thus, tension between two conflicting goals, which is the process of patent protection, is intrinsically rooted in the necessity to promote innovation and protect the interests of the people. On the one hand, there is a need to have a good patent exploitation to motivate pharmaceutical firms to invest in the formulation of new and better drugs. Conversely, these rights have to be controlled to avoid abuse, including the so-called evergreening, which artificially extends the monopoly of patent rights without any real invention. The legal systems have tried to achieve this balance in a number of ways, such as rigorous requirements of patentability, short-term protection and the existence of compulsory licensing in matters of national emergency.[10]

This balance is well incorporated in the Indian context by having a legislative and judicial action capable of guaranteeing that the protection of patents does not threaten access to vital medicines. Even though innovators are allowed to enjoy exclusive rights over a specified time, such rights are limited to ensure that they are not abused and to encourage competition. Therefore, the concept of protecting patents can be perceived as more than a means of individual benefit, but a regulatory system that attempts to align the interests of the inventor with the social benefit on the whole.

INDIAN LEGAL FRAMEWORK

The Indian legal system that regulates patent evergreening and access to medicines is mainly based on Patents Act, 1970 which has been well developed to create a balance between innovation and protection of health. The Indian attitude towards pharmaceutical patents is related to socio-economic reality of the country, especially the necessity to provide affordable access to necessary medicines to a great number of population. Although India had revised its patent law in the year 2005 so as to maintain the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), it had taken steps to provide certain protection to avoid abuse of patent right, particularly through evergreening.[11]

[9] Carlos M Correa, Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options (Zed Books 2000).
[10] Bayer Corporation v Natco Pharma Ltd (2014) 6 SCC 534.
[11] The Patents (Amendment) Act 2005 (India); Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1994.

The main characteristic of this framework is the provision of the Patents Act, Section 3(d) that literally limits the patentability of new forms of known substances unless they prove a noteworthy improvement in therapeutic effect. It was added to deal with the increasing fear that drug-related companies were using patents on small alterations of the current medications, i.e. a change in form, dosage, or chemical structure, without their clinical performance improving in any significant way. Section 3(d) provides a measure against artificial extension of patent monopolies by making a patent only to real innovations through the imposition of the requirement of enhanced therapeutic efficacy.[12]

The explanation to Section 3(d) further explains that, derivatives like salts, esters, polymorphs, metabolites and other such forms of the known substances will be regarded as the same substance unless they vary substantially in properties with regard to efficacy. This renders the patent regime in India especially strict in contrast with most other jurisdictions because it increases the bar of patentability in the pharmaceutical industry. This is not to eliminate innovation, but to weed out insignificant or cosmetic change that may not add any value to the therapy.

Besides Section 3(d), the Indian patent system has other legal mechanisms which favour the interest of the people. The Patents Act has provisions concerning compulsory licensing that enable third parties or the government to exploit a patented invention in specific conditions which include when the patented product is not at a reasonably affordable price or is not adequately available to the populace. This can be an effective check on the monopoly given to patent holders and thus, no consideration of the health of the population is sacrificed.[13]

Communities in India have not been left behind in creating and strengthening this legal structure through the Indian judiciary. The courts have always applied the patent law in a way that is more concerned about the interests of the people and at the same time the rights of the innovators must not be ignored. With reference to the legislative intent of Section 3(d), judicial rulings have stressed that the protection of patents should not be given on the incremental changes which cannot be substantively effective.

Altogether, the Indian legal system can be defined as a well-balanced system, which aims to avoid the misuse of patent rights in a form of evergreening and promotes substantial

[12] The Patents Act 1970, s 3(d) (India); Novartis AG v Union of India (2013) 6 SCC 1 (India).
[13] The Patents Act 1970, ss 84–92 (India); Bayer Corporation v Natco Pharma Ltd (2014) 6 SCC 534 (India).

pharmaceutical innovation. India has tried to find a balance between innovation, affordability, and access to medicines by establishing a model which tries to balance the competing interests of the three into one with the introduction of stringent standards of patentability and public interest protection.

LANDMARK JUDICIAL INTERPRETATION

Judicial interpretation has had a major influence in the question of evergreening of patents and access to drugs in India, where courts have played a important role in pitting the rights of patent owners versus the greater good. With the help of a sequence of landmark rulings the Indian judicial system has not only made it clear under what circumstances the concept of patent protection can apply to the pharmaceutical industry but it has also strengthened the idea of what should be able to be done to counter the misuse of patent law and its application to lengthen monopolies.

Roche v. Cipla (2009),[14] is one of the first and most significant cases in this case. The implementation of the patent right to a life saving cancer drug dealt with Cipla (2009). The case brought up serious issues concerning the award of interim injunctions on patent infringement matters, particularly where the public health interests are concerned. Although the court acknowledged the patent holder's rights, it refused to grant an injunction in view of public interest of the patent owner, denied an injunction that would have limited the presence of a cheaper generic form of the medication. The case made it clear that there is no absolute implementation of patent in India that needs to be balanced with the necessity to provide access to necessary medications. It was a change towards a more balanced and publicly interested attitude in patent disputes.

The other important ruling is the case of Bayer Corporation v. Natco pharma ltd (2014),[15] was the first case in India to award a compulsory license on a patented drug. The treatment of cancer was done with the help of the patented medicine that was of a price that was unaffordable to most of the patients. The government gave a mandatory license to Natco Pharma, which permitted it to produce a generic form and market at a much lower cost. This was affirmed by the court as it stated that the Patents Act allows such action in those cases when the reasonable needs of the people are not fulfilled, or when the patented invention is not offered at a

[14] F Hoffmann-La Roche Ltd v Cipla Ltd 2009 (40) PTC 125 (Del).
[15] Bayer Corporation v Natco Pharma Ltd (2014) 6 SCC 534 (India).

reasonable cost. The necessity of mandatory licensing to enhance the national health system and to avoid the misuse of patents monopolies was reiterated in this case.

The case Novartis AG v. Union of India[16] the most high-profile and internationally important case that concerns patent evergreening. This was a patenting case where the claim was on a derivative version of an established anti-cancer drug. The patent application was rejected because under Section 3 (d) of the Patents Act the new version had to prove increased therapeutic effectiveness and this was not the case. The Court took a literal view of the word efficacy and believed that improvements in the properties of the property e.g. stability or bioavailability do not suffice unless they will lead to a beneficial therapeutic effect. The case was a precedent in the fight against evergreening and it strengthened the Indian resolve to stop empty patent extensions.

The outcome of Novartis has had far reaching consequences, both in the domestic and international front. It set a rigorous standard of patentability in the pharmaceutical industry and made a very strong message that patenting in India would not be offered to the minor innovations that do not bear significant therapeutic benefits. The decision has been generally seen as a major move towards access to affordable medicines especially in developing nations.

In Merck Sharp & Dohme Corp. v. Glenmark Pharmaceuticals Ltd.,[17] the dispute concerned the anti-diabetic drug Sitagliptin. Merck alleged patent infringement, while Glenmark challenged the validity of the patent on grounds including lack of inventive step. The Delhi High Court refused to grant an interim injunction in favour of Merck, emphasizing that public interest and accessibility of affordable medicines must be considered alongside patent rights. The case highlighted judicial caution in granting injunctions where it may restrict access to essential drugs.

In F. Hoffmann-La Roche Ltd. v. Cipla Ltd.,[18] the court dealt with patent infringement relating to a lung cancer drug (Erlotinib). While the patent was held valid, the court declined to grant a permanent injunction against Cipla and instead allowed continued sale of the generic version subject to payment of royalties. This decision reinforced the principle that public health

[16] Novartis AG v Union of India (2013) 6 SCC 1 (India).
[17] Merck Sharp & Dohme Corp v Glenmark Pharmaceuticals Ltd 2015 (61) PTC 257 (Del).
[18] F Hoffmann-La Roche Ltd v Cipla Ltd 2015 (225) DLT 391 (Del).

considerations can justify limiting strict enforcement of patent exclusivity.

In Biocon Ltd. v. Bristol-Myers Squibb Co.,[19] the issue involved the cancer drug Dasatinib. Biocon sought to launch a generic version, while the patent holder opposed it. The court refused to grant an interim injunction, noting that the patent's validity was under serious challenge and that delaying generic entry could adversely impact patients. The ruling underscored the judiciary's balanced approach between patent enforcement and access to affordable treatment.

In Natco Pharma Ltd. v. Bristol-Myers Squibb Co.,[20] the Intellectual Property Appellate Board (IPAB) revoked the patent for Dasatinib on grounds including lack of inventive step and failure to meet patentability standards. This decision further strengthened India's strict scrutiny of pharmaceutical patents and demonstrated resistance to weak or incremental patent claims.

In Glenmark Pharmaceuticals Ltd. v. Merck Sharp & Dohme Corp.,[21] the Delhi High Court ultimately upheld Merck's patent and granted a permanent injunction against Glenmark. However, the court also reiterated the importance of balancing patent rights with public interest, showing that while genuine innovations are protected, such protection is not absolute and must be carefully applied.

All these court rulings indicate that the Indian courts have always put the interest of the society first when they interpret patent laws. Through a relatively conservative and balanced stance taken by the judiciary, the patent system has not been availed to the disadvantage of the popular health. These determinations remain as principles of reference to deal with the legal problems of patent evergreening.

RATIONALE SUPPORTING PATENT EVERGREENING

Patent evergreening, as a common practice, has been controversially supported by a number of legal and economic as well as innovation-based claims. The advocates argue that evergreening is not an abusive practice per se but an exercise in the primary use of patent rights as provided in the intellectual property law. Analysed through the prism of the pharmaceutical innovation and industry dynamics, evergreening may be regarded as a valuable tool to keep research going,

[19] Biocon Ltd v Bristol-Myers Squibb Co 2013 (56) PTC 350 (Del).
[20] Natco Pharma Ltd v Bristol-Myers Squibb Co (2013) IPAB Order No 27 of 2013.
[21] Glenmark Pharmaceuticals Ltd v Merck Sharp & Dohme Corp 2015 (63) PTC 257 (Del).

enhance drug productivity, and guarantee further investment in the healthcare sector.[22]

The other main point that is made to argue in support of evergreening is that it promotes incremental innovation. The pharmaceutical industry does not see breakthroughs because in many cases, improvements have been made to an already existing drug instead of an entirely new drug. These can be in the form of improved formulations, improved delivery systems, less side effects, improved stability or better patient compliance. Even some slight changes can help considerably to enhance quality of treatment and patient outcomes. The proponents suggest that denying patents of such innovations would deter firms to invest on the refinement and optimisation of the already known drugs and in the end reduce the rate of development in the medical field.[23]

The other important reason is the recuperation of research and development (R&D) expenses. The new drug development process is very costly, time and risky. Pharmaceutical firms spend vast amounts of resources in clinical trials, regulatory approvals and post-market surveillance. A significant percentage of the term of the patent is regularly lost during testing and approval of a drug even after it has successfully been developed, leaving little room to commercially exploit it. The evergreening by further patenting better versions gives the companies the opportunity to generate more years of market exclusivity in addition to recovering their investments. This is an essential financial drive towards maintaining innovation especially where the research is continuous as it is in the case of the chronic and complex disease.[24]

Evergreening is also justified as a legit and legal business practice that exists within a scope of the patenting law. In so far as the changes comply with the legal requirements of patentability, including novelty, innovative step, and industrial applicability, companies have a right to apply the patent protection. In this light, evergreening is not an abuse of the system, rather it is the expression of the manner in which intellectual property rights are supposed to work. Companies attempt to compete in the market by strategically managing their patent portfolios and these strategies are not unique to the pharmaceutical industry.

Also, proponents state that evergreening may cause the diversification of treatment options.

[22] F Scott Kieff, 'Property Rights and Property Rules for Commercializing Inventions' (2001) 85 Minnesota Law Review 697.
[23] John F Duffy, 'Inventing Invention: A Case Study of Legal Innovation' (2007) 86 Texas Law Review 1.
[24] Joseph A DiMasi, Ronald W Hansen and Henry G Grabowski, 'The Price of Innovation: New Estimates of Drug Development Costs' (2003) 22 Journal of Health Economics 151.

The drug itself can be formulated in different ways that can serve different needs of a patient,

i.e., it can be used in adults or in children, or it can offer alternative routes of administration,

e.g. as an extended-release tablet or transdermal patch. These differences can be used to increase access and convenience, thus, increasing treatment compliance.

CONCERNS REGARDING PATENT EVERGREENING

Evergreening of patients has become a highly criticized practice, especially with regard to its effects on both the overall health of the population and medication access. Opponents of evergreening contend that the practice of evergreening contravenes the very purpose of patent law as it provides pharmaceutical firms with the ability to keep a monopoly longer than originally planned without any actual innovation. It may seem that instead of scientific progress, it is also regarded as an instrument of strategic control to retain the market dominance and profit maximisation at the cost of the consumer.[25]

Arguably one of the most widely cited reasons against evergreening is that it contributes to the artificial expansion of rights to monopoly. The patent law provides exclusivity rights over a set time usually of 20 years in order to balance between giving recognition to innovation and ultimately opening it to public accessibility in a system of generic competition. Nonetheless, pharmaceutical companies can easily extend their exclusivity by patenting minor changes, like new forms or dosages or combinations of already- patented drugs. These other patents might not reflect any important advancement in therapy, but they will postpone the end of the intellectual monopoly in the market, thus undermining the balance of the patent system.

Also strongly connected to this is the fact that evergreening causes the delay of the appearance of generic medicines which are cheaper. The generic producers are important in lowering drug prices and making them more accessible, particularly in the developing nations. The market is dominated by expensive patented drugs, when the entry can be blocked or delayed by using evergreening strategies. It has a direct impact on patients who are dependent on affordable options of treating important conditions. This lack of timely generic competition leads to high

[25] Carlos M Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (Oxford University Press 2007).

prices that are maintained, and some parts of the population cannot access life-saving drugs.[26]

The other major criticism has its basis in the public health and ethical issues. Universal health care access to medicines is generally considered to be a fundamental element of the right to health. The promotion of evergreening implies a high level of commercialism at the expense of the common good and has serious ethical implications. Patients in the low and middle income countries can not always afford patented drugs and therefore suffer and lose their lives which could be prevented. Opponents state that the idea of making companies be able to extend patents without the therapeutic meaning is not aligned with the larger objectives of healthcare systems and social justice.

Moreover, evergreening is considered to be the abuse of the patent system. The patent legislation aims at compensating true inventions that entail novelty and inventive step.

Nevertheless, when petty or cosmetic alterations have been patented, it erodes the quality of patents and it overloads the system with feeble or superfluous assertions. This not only leads to a legal uncertainty but also heightens litigation and therefore, the generic manufacturers find it more difficult to attack doubtful patents.[27]

Finally, opponents point out that evergreening may not be as effective in encouraging innovation as it claims to be. Pharmaceutical firms can spend less on the development of completely new and breakthrough therapies by concentrating on the life cycle extension of already developed drugs. Such change of priorities may slow down the long-term science development and predetermine the lack of new approaches to new health issues.

IMPLICATION ON ACCESS TO MEDICINES

The idea of patent evergreening has drastic consequences to the availability of medicines, especially in the developing countries where affordability and availability still pose significant challenges. Evergreening affects the supply, distribution and prices of the essential medicines directly by extending the patent protection period with minor alterations to the old drugs. This imposes a big hump on patients who rely on cost-effective means of treatment, and,

[26] Ellen ‘t Hoen, The Global Politics of Pharmaceutical Monopoly Power (AMB Publishers 2009).
[27] Frederick M Abbott, ‘The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health’ (2005) 99 American Journal of International Law 317.

consequently, casts serious doubts on the health and equity of the population.[28]

The secondary impact of evergreening is that the cost of medicines remains high. In cases where the pharmaceutical companies have exclusive rights to a drug even after the expiry of the original patent, they control the price of the drug. Drug prices are usually at a very high level, where generic manufacturers do not have competition. It is especially a problem in low- and middle-income countries with a significant portion of the population being under insured or uninsured to cover the high costs of drugs. This leaves a large number of patients with no access to treatment or high financial cost of treatment.

The other devastating effect is procrastination of generic drugs into the market. Compared to a brand name, generic drugs are usually significantly cheaper and they are important in enhancing access to healthcare. Nevertheless, even the strategies of evergreening can introduce legal and procedural barriers to the entry of generic manufacturers, which cannot enter or have to wait longer. The delay prevents competition and continues to hold prices high, which eventually reduces the supply of life-saving drugs to the population.[29]

The consequences of evergreening are especially drastic in the environment of developing countries, where the healthcare systems do not always have many resources. Access to affordable medicines is closely connected with more global problems of social justice and economic disparity in such settings. When the prices of the basic medicines are kept artificially high as a result of prolonged patent protection, governments might struggle to supply the necessary drugs within a public health program. Therefore, evergreening has the potential to widen the intrinsic healthcare access and outcome disparities.

The right to health is another related issue to the problem, and it is described as a basic human right pursuant to multiple international and constitutional conventions. The right to accessible medicines is also part of this right since people will have access to the required treatment without discrimination and monetary strain. This right can be undercut by evergreening practices which limit access to low cost medicines and hamper the achievement of the universal healthcare objectives. This poses some significant ethical and legal issues regarding how much the individual intellectual property rights can be permitted to supersede the considerations of

[28] World Health Organization, Equitable Access to Essential Medicines: A Framework for Collective Action (WHO 2004).
[29] Carlos M Correa, Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options (Zed Books 2000).

the health of the people.[30]

In addition, evergreening is not restricted to individual patients but has an overall effect on the healthcare system. The cost of the drugs is high, and as a result, this adds financial strain on the governments, insurance companies, and health institutions. This may restrict the capacity of the public health programs to serve a broader population or investing in other important services.

COMPARATIVE PERSPECTIVE

Looking at patent evergreening from different places around the world shows how theres no single way everyone agrees on balancing new drug ideas with making sure people can get medicines they need. Countries all follow the basic rules from the TRIPS Agreement but then they shape their own patent laws based on what matters most to them locally like economy or health needs. India the United States and the European Union kind of stand out as examples of really different ways to handle this especially when it comes to stopping companies from just tweaking old drugs to keep patents going longer.[31]

India does something pretty specific to fight evergreening and its interesting how they put it right into their laws. In their Patents Act from 1970 section 3d sets a tougher bar for getting patents on new versions of drugs that already exist. It is not just about being new or inventive or useful like usual but for things like new forms or salts or polymorphs you have to show it actually helps people more in treatment. This stops patents for small changes that dont really do much unless there is clear better results in how the drug works for patients. I think this hits right at the heart of evergreening because companies can't just file for every little adjustment to stretch out their control.[32][33]

The reason India goes this way ties back to their situation with so many people and not a lot of money for fancy healthcare. They are a developing country so keeping drugs cheap is huge and their companies make tons of generic versions that go all over the world to places that can't afford the brand name stuff. By blocking those extra patents India lets generics come in right

[30] United Nations Committee on Economic, Social and Cultural Rights, General Comment No 14: The Right to the Highest Attainable Standard of Health (2000).
[31] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1994.
[32] The Patents Act 1970, s 3(d) (India); Novartis AG v Union of India (2013) 6 SCC 1 (India).
[33] USC Ss. 101–103 (United States Code); Gerald J Mossinghoff, 'Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process' (1999) 54 Food and Drug Law Journal 187.

after the main one ends which pushes prices down through more competition. This helps folks at home get medicines easier and it even plays into bigger global efforts by keeping supplies steady for poorer areas. Sometimes it feels like India's setup is more about real life needs than just protecting ideas.

Over in the United States it is a different story they lean toward letting more things get patented to keep innovation rolling. There is nothing like India's section 3d so they stick to the basics novelty non obviousness and utility but they interpret those pretty loosely. That means small steps forward like new ways to deliver a drug or use it get their own patents pretty often. Companies end up with these big collections of patents around one medicine which basically keeps them in charge of the market way past when the first patent runs out. It creates this layered protection that makes it hard for others to jump in.[33]

The US also has extras that kind of help this along without saying it outright. For one they give extra time on patents to make up for delays in getting approval from regulators and then there is data exclusivity where generics can't use the original testing info for a while. All that stacks up to slow down cheaper options coming out and yeah it keeps prices high longer. People say it's worth it because developing drugs costs billions and the country wants to lead in new treatments so strong patents push companies to spend on research. With good insurance and hospitals there it softens the blow for some but still affordability is a big issue even for Americans. It seems like they prioritize the big picture of progress over quick access sometimes.

The European Union sits somewhere in between not as tight as India but not as open as the US. They let patents go for those incremental changes if they pass the usual tests but they have tools like Supplementary Protection Certificates to deal with pharma specifics. These add up to five years extra to cover time lost in approvals so companies get a fair shot at profits. It is meant to balance things out but it does mean longer exclusive selling rights which can feel like evergreening in practice.[34]

Still the EU watches out for overreach with their competition rules. They go after deals where drug makers pay generics to stay out like those pay for delay setups and they've fined companies for it. So even though patents can be broad there is this oversight to keep markets

[34] Regulation (EC) No 469/2009 concerning supplementary protection certificates for medicinal products (European Union).

fair and open. It is not perfect but it shows they try to mix protection with not letting things get abused. Compared to the US where it is more hands off or India where it is strict from the start the EU approach has these checks that step in when needed.[35]

These setups really show how a country's money situation and health systems shape the laws. Places like the US and EU with strong economies focus on sparking new inventions even if drugs cost more because they have industries that crank out advanced stuff. India though has to think about a huge diverse group of people so they clamp down to make sure basics are available without the extras blocking the way. Courts play into this too in India judges stick close to that section 3d idea and reject patents for what they call minor tweaks. In the US and EU it is more about checking the technical side though other laws can jump in if theres foul play. This judicial difference makes outcomes vary a lot across borders.[36]

On a bigger scale what these countries do affects everyone. India tough line means they supply cheap generics to Africa and Asia helping with fights against HIV or TB or even cancer which is huge for global health. Meanwhile the US and EU drive a lot of breakthroughs in medicine that save lives down the line. It is this ongoing pull between pushing for new drugs and getting them to people who need them now. No one's way works everywhere since each spot has its own challenges but India's example suggests you can tighten up on patents without killing off good ideas entirely. They set higher bars and add guards against tricks which might give other developing places something to look at.[37]

Wrapping this up the ways evergreening gets handled differ because of what each area values most whether its innovation or access or a mix. The US and EU go heavy on IP to build their pharma power while India holds back to protect health for the masses. All this points to how tricky it is and why laws need to fit local realities without ignoring either side of the coin.

CONCLUSION

The issue of patent evergreening is a problem. It involves intellectual property rights and public health. This article shows that patent protection in the sector is important. It encourages companies to invest in drug development. A 20-year monopoly is an incentive for companies.

[35] European Commission, Pharmaceutical Sector Inquiry Final Report (2009).
[36] Novartis AG v Union of India (2013) 6 SCC 1 (India); 35 USC §§ 101–103 (United States Code).
[37] Ellen 't Hoen, Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines (Health Action International 2016).

They invest a lot of money in research and development.[38]

However the misuse of this system through evergreening practices is a challenge. Minor changes are made to extend patent life. This hurts the balance that patent law tries to achieve.

In India the Patents Act of 1970 tries to prevent this misuse. Section 3(d) requires proof of therapeutic efficacy for new forms of known substances. The law ensures that only real innovations get patent protection. Courts have supported this approach in cases. They stress the importance of interest and access to medicines.[39]

Some arguments support evergreening. Incremental innovations do improve existing drugs. Pharmaceutical companies need to recover their investments. Evergreening can be a business strategy. However the issue is to distinguish between innovation and manipulation of the patent system. When evergreening delays competition and keeps prices high it undermines patent protection.

The impact of evergreening on access to medicines is significant in developing countries.

Affordability is a concern. Delayed entry of drugs and high prices restrict access to life-saving treatments. This affects the right to health. A regulatory framework that prioritizes welfare and supports innovation is needed.[40]

A comparison with the United States and the European Union shows that India's approach is stricter. These countries allow patent protection for incremental innovations. India prioritizes health and access to medicines.

In conclusion addressing patent evergreening requires an approach. Legal provisions must prevent abuse while allowing innovation. Judicial vigilance, policy direction and evaluation of patent standards are essential. The goal is to make essential medicines accessible and affordable, to all. The patent system should serve both innovators and the public interest.[41]

[38] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1994, art 33.
[39] The Patents Act 1970, s 3(d) (India); Novartis AG v Union of India (2013) 6 SCC 1 (India).
[40] United Nations Committee on Economic, Social and Cultural Rights, General Comment No 14: The Right to the Highest Attainable Standard of Health (2000).
[41] Carlos M Correa, Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options (Zed Books 2000).