EVERGREENING PRACTICES: AN ABUSE OF THE PATENT SYSTEM

by

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ABSTRACT

A patent is 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 is 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. After the expiration of the stipulated term or duration, the right comes in public domain, the technology or the product becomes easily accessible to any other person and the patentee becomes ordinarily barred to earn any more profit from his own creation. However, the life of the patented process or product is dubiously extended by a general practice of evergreening. It is in a way doing something which may be legitimized by innovation, modification, or manipulation of a patented product or process by the patentee but much to the detriment of the public at large. This paper is an attempt to evaluate the scenario in the light of balancing between the legitimate interest of the patent holders and the people in need of health care. The paper argues that Indian law is better placed in terms of preventing evergreening practices by pharmaceutical companies but needs to follow the best practices in some developed countries to get the desired result and achieve the global target of universal access to affordable essential drugs for public health.

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Keywords: evergreening, compulsory licence, public health, Novartis dictum, Doha declaration.

I. INTRODUCTION

One of the most important Intellectual Property Rights covered under industrial property rights is the specie of patents which is a monopoly right given under the Patent Law. Patent is a grant or licence conferring a right or title for a set period, especially the sole right to exclude others from making, using, or selling an invention. A patent is a form of intellectual property that gives its owner the legal right to exclude others from making, using, or selling an invention for a limited period of years in exchange for publishing an enabling public disclosure of the invention. In most countries, patent rights fall under private law and the patent holder must sue someone infringing the patent in order to enforce his or her rights. In some industries patents are an essential form of competitive advantage; in others they are irrelevant.[1] In pharmaceutical industry patents are of utmost importance as it involves the interplay of technological and innovative techniques to create a new product or a new process giving birth to a patentable product or a process. Any modification or change in the process or procedure of manufacturing or producing new products becomes an important add-up generally referred to as an 'inventive step' which is far more significant in terms of its commercial value or competitive advantage. It requires billions of dollars to produce a new patentable drug or medicine by corporate undertakings and needs to be recouped at the earliest by invoking the provisions of Patent law. But the practice of evergreening resorted to by the corporate giants obfuscates the legitimate user of patentable drugs in terms of accessibility for public health and hygiene. Thus, there remains a tussle between the practitioners of evergreening techniques and the legitimate beneficiaries i.e., the public at large. There are some grey areas where the drug manufacturing companies make a misuse of patents rights touching upon the non-patentable domain.

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II. WHAT ARE NOT PATENTABLE

Under section 3 of the Indian Patent Act, 1970 the subject-matter of what is not patentable is exclusively covered[2]. It covers a whole gamut of inventions that have been excluded from the

[1] WIPO Intellectual Property Handbook: Policy, Law and Use, chap.2nd : Fields of Intellectual Property Protection, available at: https://en.wikipedia.org/wiki/Patent#cite_note-WIPO_Handbook_Ch_2-1

[2] What are not inventions. -The following are some of the inventions within the meaning of this Act, -
(a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;
[(b) an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;]
(c) the mere discovery of a scientific principle or the formulation of an abstract theory [20] [or discovery of any living thing or non-living substances occurring in nature];
(d) 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 discovery of any new property or new use for a known substance or of the

purview of patentability depending on the nature, effect or its impact on the public purpose. Amongst the excepted items sub section (d) dealing with 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 discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus, is a well recognised legal principle. Its exception could be when such known process results in a new product or employs at least one new reactant[3]. Despite this clear legal provision, the pharmaceutical companies are taking benefit by effecting marginal changes in patented drugs, here and there, to claim its extension beyond the stipulated period of 20 years. This practice referred as evergreening purports to defeat the stated legal position[4].

III. THE DOCTRINE OF EVERGREENING

"Evergreening," 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. However, 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[5].

Evergreening of pharmaceutical patents has emerged as a serious challenge for access to affordable drugs as it aims to delay the generic competition by extending the length of the exclusivity period beyond the legitimate patent term without any considerable improvement in therapeutic benefits of the already patented pharmaceutical drug.[6]

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…
(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;
(f) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way ···
(i) any process for the medicinal, surgical, curative, prophylactic [23] [diagnostic, therapeutic] or other treatment of human beings or any process for a similar treatment of animals [24] [***] to render them free of disease or to increase their economic value or that of their products…

[3] The explanation appended to sub-section (d) makes it abundantly clear that salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

[4] See Nuziveedu Seeds Ltd. And Ors. vs Monsanto Technology Llc And Ors. on 11 April, 2018

[5] Available at : https://www.lawctopus.com/academike/evergreening-an-abuse-of-the-patent-system/

[6] See Mohamad Z Abas, Evergreening of Pharmaceutical Patents: A Blithe Disregard to The Patent System , available at: https://journals.sagepub.com/doi/full/10.1177/1741134319848797,

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In India the position has become clear that mere discovery of a known substance or adaptation of a new process albeit novel, may not be available for evergreening in terms of sub-section (d) of section 3. It is in this context that the apex court has upheld the provision as constitutional, as it is done purportedly to prevent ever- greening of patents and protection of the genuine innovators. This was demonstrated in the judgment of *Novartis* case[7] which is similar to that of *Hoffman La Roche Ltd. Verses Cipla Ltd* [8] showing thereby that there is now a shift in the development pattern of the Indian usage and production of technology. Earlier India was just a user of the technology hence its thinking and laws were consumers oriented which provided weak protection to the Intellectual Property. But gradually now India has grown to a producer of technology too, thus providing a strong protection to Intellectual Property as compared to what it earlier did[9].

IV. UNDERSTANDING THE NOVARTIS CASE

Understanding the facts and judgment of the Novartis case is very important in order to analyze whether it is an abuse or not. In 2005 when India inserted a condition in the section 3 (d) of its patent Act regarding the efficacy of the drug, it was interpreted as the therapeutic efficacy of the drug and not just the improvements in the physical characteristics or stability of the product. The letter and spirit with which India transitioned into new patent regime has been put to the litmus test by Novartis. Patents granted in India could have implications worldwide because several developing countries depend on the generic medicines manufactured in India. However, the Supreme Court rejected the appeal of Novartis on the basis that the drug did not provide any new therapeutic efficacy and hence the consumers cannot be forced to pay higher price for basically the same drug[10].

But the petitioner (Novartis) prayed the court to declare section 3(d) of patent (Amendment) Act 2005 as non complaint with the TRIPS agreement and violative of Article 14 of the Constitution of India, besides being arbitrary based on discretionary power vested in the Patent Controller, in determination of enhanced efficacy. The aim of the patent system is to discourage the extension of the patent term so as to provide other firms chance to enter in the production and marketing of the drug, after the expiry of legitimate patent term. This way the drug can become cheaper but

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[7] Novartis Ag vs Union Of India & Ors on 1 April, 2013 available at : https://indiankanoon.org/doc/165776436/
[8] F. Hoffmann-La Roche Ltd. & Anr. vs Cipla Ltd. on 24 April, 2009
[9] See for example various decisions stating the obvious: Nuziveedu Seeds Ltd. And Ors. vs Monsanto Technology Llc And Ors. on 11 April, 2018; Novartis Ag vs Union Of India & Ors on 1 April, 2013; Asian Electronics Ltd. vs Havells India Limited on 19 April, 2010; Cipla Ltd. vs F.Hoffmann-La Roche Ltd. & Anr. on 27 November, 2015
[10] http/www.redif.com/money/interview

eventually cause a decrease in its price and a loss to the MNC. Hence a deep analysis into the judgment of the Supreme court in the Novartis case, can dispel the doubt about the resultant effect of patent law in India especially in the backdrop of TRIPS Agreement mandate. It will be appropriate to cull out the important observations by the apex court delineated as under:

a. Preventing ever-greening;
b. provide easy access to the denizens of this country for life saving drugs;
c. discharge their constitutional obligation of providing health care to its citizens

It is important to note that the judgment was not in contradiction to the patent laws, neither did the judgment say that new forms cannot be patented. All that it meant was that it ought and it cannot be patented unless the said drug proves to be therapeutically more effective. The Indian court has remarkably factored public interest while deciding the case[11]. The right to health is a cause of concern in many parts of the world, one third population of world does not have access to basic medicines and among this one third majority of population lives in African and Asian continent. Since price is one of the major factors in accessibility, this decision is of great significance, it allows many poor countries to access the patented drug at affordable prices.

V. ITS EFFECT ON THE ECONOMY OF DRUGS

This judgment has undoubtedly contributed to the affordability of drugs, be it cancer or not in the future. It is quite obvious that after this direction of the court obtaining patents will become more difficult in future. But should be remembered that until and unless compulsory license is granted to the non patent holder to manufacture the drug, the drugs which are under product patent will be in future highly priced. Thus, it is not the fact that India is undervaluing the patents, she recognizes it and hence will take all steps needed to protect it.

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VI. INDIA'S INTERNATIONAL COMMITMENTS

India has favored the public interest in the Novartis decision. Let us examine the various international conventions in this regard. India has always aimed at the need to promote innovation and to improve and strengthen the national intellectual property systems with a view to providing an effective response to the challenges created by knowledge-based society and the introduction of new technologies. This is well emphasized in the numerous bilateral treaties of India with

[11] Roche verses Cipla is another such case were a court in India has heavily considered public interest while granting temporary injunction.

Australia, Germany, USA and many other countries[12]. Most of the MOU'S intend to cooperate for benefit of industry, research and citizens. Every bilateral agreement of India touches aspects of public awareness, human resources management in field of IP. It encourages Innovation and also supports public welfare in all means. For instance, the MOU between India and Switzerland [13] provides for setting up a joint committee mainly that aims at:

1. Protection of IP at national level
2. Exchange of experiences between the countries
3. Development of continuous cooperation

The MOU provides that the joint committee shall be obliged to discuss strategies aimed at preventing the manufacture, distribution, sale and consumption of counterfeit and pirated products, as well as, raising public awareness of damages caused by counterfeit and pirated products[14].

A. The patent cooperation treaty

The PCT is another treaty[15] to which India is signatory that inter alia aims at the following:

1. Desiring to make the contribution to the progress of science and technology,
2. Desiring to perfect the legal protection of inventions,
3. desiring to facilitate and accelerate access by the public to the technical information contained in documents describing new inventions.

A close examination into various India's international commitments reveals the importance given to the aspect of public welfare in the context of new inventions. A contribution towards science and technology has been given predominance but not at the cost of public health and welfare. The aspect of evergreening clearly affects the public health and welfare as a result India being a welfare country bound by the duties as enshrined in the Indian constitution concerning public health decided against the concept.

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[12] Available at : www.patentoffice.nic.in
[13] Memorandum of understanding between ministry of commerce and Industry of India And The Federal Department of Economic affairs of Switzerland on Intellectual property 7th August 2007
[14] Article 1 of MOU between Ministry of Comerce and Industry of India and the Federal Departement of Economic Affairs of Switzerland on Intelectual Property 7th August 2007
[15] patent cooperation treaty done at Washington on June 19 1970 amended on September 28, 1979, modified on Febaruary 3 1984 and on October 3 2001

When we examine the situation of pre-Novartis case, we realize that, the Indian patents (Amendment) Act,2005 introduced product patents in India and thus, marked the beginning of a new patent regime, aimed at protecting the intellectual property rights of patent holders. The act was in fulfillment of India's commitment to the world trade Organization (WTO) on matters relating to the agreement on trade related aspect of Intellectual property Rights (TRIPS)[16]. The TRIPS compatible Indian patents (Amendment) Act, 2005 addressed few important issues regarding patent of products:

1. Adopting the definition of 'Pharmaceutical substance'
2. Exclusion of 'mere discovery of new form of known substance' and the 'new use for a known substance';
3. Manufacturing the products which may be granted patent protection in the new regime'[17].

Furthermore, the Act brought in new definition of the term new invention and also introduced restrictions in the scope of patentability (section 3(d)), it is explicitly mentioned in section 3 (d) that patents would not be granted on the following grounds:

1. The mere discovery of a known substance, which does not result in the enhancement of the known efficacy of that substance.
2. The mere discovery of any new property or new use for a known substance, and
3. The mere use of a known process, machine or apparatus, unless such known process results in a new product or employs at laser one new reactant.

The Indian Patents (Amendment) Act 2005 was India's final step towards attaining TRIPS compliance. It is an attempt to balance the competing interest of its variety of stakeholders which include domestic generic manufacturers, civil society groups concerned with access to medicines, the research and development community, foreign multinational companies and the intellectual property lawyers.

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However, this legislative effort catapulted to international significance because of introduction of pharmaceutical patents and the subsequent threats to an internationally famous generic industry that has, so far, guaranteed the supply of affordable drugs. Hence, India while complying with the

[16] WTO agreement on trade Related aspects of Intellectual property Rights ,annex C, available at http:/www.wto.org/English/docs_e/legal_e27-trips.doc, visted on May 26,2008

[17] . biswajit Dhar post 2005 TRIPS scenario in patent protecntion in the pharmaceutical sector the case of generic pharmaceutical industry in India available at http:/iprsonline.org/unctaictsd/docs/dhar/20India available at http://www.iprsonline.org/unctadoctsd/docs/dhar/20 pharma/ 20 November

TRIPS agreement and introducing a product patent regime for new drugs that were invented, also added a safeguard enabling refusal of patents on discovery of new forms or new uses of old drugs (i.e., preventing ever-greening). It is noteworthy that the TRIPS Agreement provides in its objectives and principles[18] that each country can introduce a patent regime that is more suited to its socio-economic context.

Consequently, after six years of enacting the TRIPS agreement, WTO Members recognized the needs of the poor countries to combat public health problem and came up with Doha Declaration on TRIPS and Public Health[19]. However, even after the adoption of Doha Declaration, the Pharmaceutical companies have failed to reduce the prices of the medicines, especially for the treatment of diseases, like cancer, HIV/AIDS. This demonstrates that the multinational corporation do not address the health problems of the developing countries adequately. Hence, the health policies that must foster the availability of drugs at an affordable price to all those needy worldwide, has been proven ineffective. Property Rights Report, 2006 supports the fact that countries can adopt legislation and examination guidelines requiring a level of inventiveness that would prevent ever-greening patents from being granted. It further states that the TRIPS agreement gives freedom to WTO members to determine the hurdle required for the inventive step.

VII. A BALANCE BETWEEN THE PATIENTS AND PATENTS

Just describing the problems caused by the strict patent laws or evergreening of the patent is not enough. But it is also important to prescribe a solution for these problems. As the research paper is both descriptive and prescriptive, in this last part we aim to look for solutions in order to create balance between the patent laws and their extension while keeping a low price for the patented drugs. So that it is affordable by the common man of India and around the world. There are other ways available which can help in the reduction in the price of patented drugs.

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A. Compulsory licensing

By providing 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 still kept low and within reach of the purchasing power of common and poor section of the society.

[18] Article 8 specially states that member countries may adopt measures to protect their public health and nutrition and to promote public interest in sectors of vital importance to their socio- economic and technological development
[19] WTO Doha Ministerial Declaration, WT/MIN (01) DEC/2,20 November 2001.

B. Introducing mutual benefit programs

Other important step to be taken by the Indian Government is to ensure proper health care which should be available to all the sections of the society. Because in India, the very critical problem of economic factors like that of low income and low purchasing power exists coupled with poor health of the public and inadequacy of insurance facilities[20]. 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 some of such crucial drugs is very low by the poor and the underprivileged section of the society, hence just making apart rules, regulations and laws are not what should be done by the Government of a country. The government of a country ought before to make laws or granting license or freedom from patents, ensure the basic amenities are provided to the public. In this regard India can usefully follow the model adopted by some developed countries. Some of the patent laws and systems of developed countries are studied in the next section.

VIII. NEED FOR A GLOBAL APPROACH

The need to strike a balance between innovators and patients in not a concern isolated to India. Such issues, and concerns over potential abuses of ever greening, are widespread throughout the global community, including in the United States[21]. However, the balance is struck differently in each jurisdiction [22]. This aspect of balancing between the innovators and generic companies is very important.

A. AUSTRALIA

Prior to the introduction of the AUSFTA[23], it was possible to engage in a practice so-called evergreening and indeed to seek an extension of protection for the terms of the basic patent. Limited term extension for drug patents had been a feature of the Patents Act 1990[24] with the ability to apply for extensions of up to five years for pharmaceutical substance patents[25]. This

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[20] WHO Public Health, Innovation and Intellectual Property Rights Report 2006
[21] see, E.g . discussion of the United States Federal Commissions 2002 inquiry into *evergreening abuses: Thomas Faunce, the Awful Truth Evergreening, the Age (Melbourne), August 2004, 9*
[22] see e.g the comparative regulatory discussion in Anita Nador And Melanie Swears, comparing Canadian Notice of Compliance (NOC) regulations for patented medicines with corresponding United States and European Union Provisions (4 march 2002) Bearskin and Parr Intellectual Property law
[23] Australia –United States free trade agreement opened for signature 18 May 2004, ATS 1 (entered into force 1 January 2005)
[24] Intellectual Property laws amendment Act 1998 (cth)sch1 div 2.
[25] patents act 1990 (ctj)ss 70-9A

specific extension is regarded as some compensation for the extended regulatory approval process and safety trials to which new drugs are subjected, and is common element of many patent system. However, this extension was never available for a 'use' claim. The Australian government was of the view that new application must meet all the requirements for patentability in its own right, and will only receive protection to the extent its claims are valid. As Karin Innes states, 'patent evergreening will still be permitted to the extent that it does not transgress the law' [26]. She asserts that the practice of evergreening was 'effectively endorsed[27] by the high court of Australia in Aktiebolaget Hassle vs. Alpha pharm pvt. Ltd[28].

B. UNITED STATES

US also has had numerous debates about the dangers of evergreening and have attempted to strike a balance between the interests of originator and generics drug companies which provides drugs at an affordable price. This is done primarily within the framework of the Hatch-Waxman Act. This Act introduces a procedure for obtaining regulatory approval for generic drugs. An 'Abbreviated new drug Application (ANDA) can be made to the US Food and Drug Administration (FDA) by generic drug manufacturers seeking approval for the release of their competing drugs. The rationale underlying this system is that if the original drug had already received regulatory approval then, in order to gain marketing approval for their drugs, all a generics company should be required to do is to demonstrate bio- equivalency with the original drug, that is to say, an identical biological effect rather than demonstrate safety and efficacy independently. In order to balance the interests of the originator industry, the Hatch-Waxman Act requires an acknowledgment to make one of four certifications in relation to the patent status of the competing generic drug. The options are:

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1. The drug is not patented;
2. Relevant patents have expired;
3. Relevant patents will expire by the time the generic drug hits the market
4. The patent won't be infringed or
5. is invalid [29].

[26] Karin Innes the impact of the Australia- United States free trade agreement on pharmaceuticals patents (July 2005)
[27] ibid.
[28] Aktiebolaget hassle Verses Alpha pharm Pvt. Ltd. (2002) CLR 41
[29] Federal Food, Drug and Cosmetics Act, 21USC 355(b) 2004

The Hatch- Waxman Act contains several other important elements[30]. Firstly, it makes provision for periods of data exclusivity (for example, to an originator listing a new molecular entity). Secondly, it also grants patentees a more expeditious mechanism for obtaining status on generic product releases and Finally, it further provides for term extensions in order to make up for delays caused by regulatory process. Overall while the Hatch- Waxman Act was not stacked completely in favour of the originator drug company interests, its basic structure especially as it came to be used over time also ensured to be balance friendly to that sector.

IX. CONCULSION

The patent law in India has been amended to adopt the changes mandated by TRIPS Agreement but with certain reservations related to public health. The Novartis decision has signaled to the world that India has chosen to adopt an IP regime that keeps with the spirit of WTO, however, keeping a provision for inexpensive access to medicines by prohibiting patent 'evergreening'. It has implications for global companies seeking to utilize the R&D and commercial opportunities in India, as well as, for Indian generic companies seeking to develop innovative products for both domestic and international markets. India can incorporate any of systems of other developed countries only to ensure accessibility of life saving drugs to millions of patents, so that its support to an evergreening regime remains intact. The Novartis decision will definitely go down in the annals of history as representing a milestone in patent jurisprudence in India.

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[30] Evergreen or deciduous Australian Trend in relation to the evergreening of patents