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**INTERNATIONAL JOURNAL OF  
 ADVANCED RESEARCH (IJAR)**

Article DOI: 10.21474/IJAR01/9276  
 DOI URL: <http://dx.doi.org/10.21474/IJAR01/9276>



### RESEARCH ARTICLE

#### EVERGREENING OF PATENTS: REVIVAL OF COLONISATION AND MONOPOLY.

Preeti Uttam.

#### Manuscript Info

##### Manuscript History

Received: 12 April 2019  
 Final Accepted: 14 May 2019  
 Published: June 2019

#### Abstract

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#### Introduction:-

##### Concept of evergreening

An attempt to “stockpile” the patent protection by original manufacturers by obtaining several patents on multiple forms of the same product can be termed as “ever greening”.<sup>1</sup> As per “the Age”, “ever greening refers to a variety of legal, business and technological strategies to extend the term of patent protection of those which are about to expire for a longer periods of times than provided under legal framework”.<sup>2</sup> Ever greening is not a formal concept of patent law rather it is a social idea to refer various ways in which the patent owners use the law and all related regulatory processes so as to gain monopolistic control over the given product which is known as “intellectual monopoly privileges”.<sup>3</sup> It is generally used by the drug industry to develop “bullet proof patent portfolios” so as to block a possible entry into the domain of innovator, or to protect their “IMP”<sup>4</sup> upon highly-profitable drugs which are considered as “blockbuster drugs”.<sup>5</sup> There is a lot of ‘hue and cry’ for the much talked “evergreen resolution”<sup>6</sup> which refers to the concept which is often resorted to by huge companies to extend the term of protection of their products just before the patent is about to expire. For example: a company ‘A’ manufactures a drug ‘D’ and shortly before its expiration, ‘A’ files a new patent to revise or extend the term of patent protection of ‘D’, this is all about the concept of “ever greening”. Hence, ever greening refers to increasing the life of the patent or term of patent protection so as the manufacturing company may reap its benefit for longer period than it has been granted ordinarily, i.e, 20 years term of patent protection. Now-a-days, ‘drug patent ever greening’ can be seen emerging as most common and often used form of ever greening which is continuously being used as an important strategy by huge multinational companies to ‘stockpile’ patent protection on multiple attributes of a single product . Hence, ever greening in a way is the main cause behind the development of “generic industry” in pharmaceutical arena.<sup>7</sup> John R. Thomas has mentioned: “Patent ever greening” is a potentially pejorative term that generally refers to the strategy of obtaining multiple patents that cover different aspects of the same product, typically by obtaining patents on

<sup>1</sup> Prachi Gupta(Adv.), “Evolution of Patent Law of India”.

<sup>2</sup> Thomas Faunce, “The Awful Truth About Evergreening” available at: [www.theage.com/au/articles/2004/08/06/1091732084185.html](http://www.theage.com/au/articles/2004/08/06/1091732084185.html) last accessed on April 1, 2016.

<sup>3</sup> Greg Martin, *et.al*, “Balancing Intellectual Monopoly Privileges and The Need for Essential Medicines, Globalization and Health” (2007).

<sup>4</sup> *Ibid.*

<sup>5</sup> Apoorva Sristi, “Evergreening of Patents”.

<sup>6</sup> Uttam K. Shukla, “Ever Greening of Patents” available at: [nopr.niscair.res.in/bitstream/123456789/12535/1/SR%2048\(8\)%2031-34.pdf](http://nopr.niscair.res.in/bitstream/123456789/12535/1/SR%2048(8)%2031-34.pdf) last accessed on April 4, 2016.

<sup>7</sup> *Ibid.*

improved versions of existing products. Although the patent system allows improvement patents to be obtained in any industry, evergreening is said to be most common in the pharmaceutical industry”.<sup>8</sup>

### Meaning And Definition Of Evergreening

The literal meaning of the term “evergreen” is that doesn’t change colour in the fall or something that is timeless.<sup>9</sup> Evergreening is a term, used primarily by detractors of the alleged practice, to describe the acquisition of secondary patents on reformulations or minor modifications of pharmaceutical products in order to unfairly extend the monopoly over the drug beyond the life of the initial patent.<sup>10</sup> Evergreening refers to a variety of legal, business and technological strategies by which producers extend their patents over products that are about to expire, in order to retain royalties from them by either taking out new patents, or by buying out or frustrating competitors, for longer period of time than would normally be permissible under the law.<sup>11</sup> Patent Evergreening is a potentially pejorative term that generally refers to the strategy of obtaining multiple patents that cover different aspects of the same product, typically by obtaining patents on improved versions of existing products. Although the patent system allows improvement patents to be obtained in any industry, evergreening is said to be most common in the pharmaceutical industry.<sup>12</sup> Evergreening is the strategic extension of the duration of a temporary monopolistic or market dominant position by means of IP strategies, and in practice patent strategies particularly.<sup>13</sup> Alkhafaji, Trinquart et.al. defines evergreening as a way “that allows owners of pharmaceuticals products using numerous strategies, such as patent law and minor drug modifications, to extend their monopoly privileges with their products”. According to Bansal ever greening refers to “different 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 expiry of the ‘parent’ patent”. Granstrand describes ever greening as a strategy by which “effective patent protection is prolonged from a continually renewed patent portfolio”. The European Generics Association describes ever greening as a “common form, occurs when the brand name manufacturer literally ‘stockpiles’ patent protection by obtaining separate 20-year patents on multiple attributes of a single product.... To evergreen their products, the originator company will develop what are euphemistically called ‘life-cycle management plans’ composed not only of patent strategies, but an entire range of practices aimed at limiting or delaying the entry of a generic product on to the market”. Hence, Granstrand provides a tentative definition of IP based ever greening which is as follows:

IP based ever greening is the business strategy to extend the duration of the effective protection derived or derivable from a portfolio of IPRs in order to increase the appropriability of an innovation or a set of business related innovations or technologies.<sup>14</sup>

### Generic Drugs

After giving elaborate introduction to the concept of “evergreening of patents” alongwith its definition and meaning also, it is quite pertinent that evergreening is the main cause behind the evolution of “generic drug” industry. To deliberate further on the topic it is important to know the meaning of ‘generic drugs’. A generic drug is a drug defined as a “drug product that is comparable to a brand or reference listed drug product in dosage form, strength, quality or performance characteristics and intended use.<sup>15</sup> It has also been defined as a term referring to any drug marketed under its chemical name without advertising<sup>16</sup> or to the chemical makeup of a drug rather than to the advertised brand name under which drug is sold.<sup>17</sup> Generic drugs are named according to the main chemical or salt

<sup>8</sup> John R.Thomas, “Patent Evergreening: Issues in Innovation and Competition” *available at*: [www.ipmall.info/hosted\\_resources/crs/R40917\\_091113.pdf](http://www.ipmall.info/hosted_resources/crs/R40917_091113.pdf) (last accessed on April 4, 2016).

<sup>9</sup> Evergreening *available at*: [www.gourdictionary.com/evergreen](http://www.gourdictionary.com/evergreen) (last accessed on April 5, 2016).

<sup>10</sup> Janice M. Mueller and Donald S. Chisum, “Enabling Patent Law’s Inherent Anticipation Doctrine”, 45 *Hous. L. Rev.* 1101-1106 (2008); Dorothy Du, “Novartis AG v. Union of India: Evergreening, TRIPS and Enhanced Efficacy under Section-3d”, 21 *J. Intell. Prop. L.* 223 (2013-2014) *available at*: <http://heinonline.org> (last accessed on January 20, 2016).

<sup>11</sup> *Supra* note 2.

<sup>12</sup> *Supra* note 8.

<sup>13</sup> Ove Granstrand and Frank Tietze, “IP Strategies and Policies for and against Evergreening”, Centre for Technology Management Paper Series ISSN 2058-8887 April, 2015.

<sup>14</sup> *Supra* note 13.

<sup>15</sup> Generic Drugs, Centre for Drug Evaluation and Research, US Food and Drug Administration.

<sup>16</sup> Definition of Generic Drugs *available at*: [www.medterms.com](http://www.medterms.com) (last accessed on April 16, 2016).

<sup>17</sup> [www.ndrugs.com](http://www.ndrugs.com) (last accessed on April 16, 2016).

present in the drug. These drugs are not given fancy brand names by different pharmaceutical companies and patented in the market, rather they are sold under their manufacturer's name. Generic drugs may look or taste different from brand name drugs, but have same chemical composition as their. This makes them identical in efficacy, potency, route of administration, strength and dosage. Generic drugs are cheaper than their branded equivalents as they are not patented or advertised and involve the cost of manufacturing only, hence they often prove to be a better choice.<sup>18</sup> Most nations have a requirement for generic drug manufacturers that they need to prove that their formulation exhibits bioequivalence to the innovator product.<sup>19</sup>

Hence it can be said to avoid the purchase of high-priced drugs and also to escape the colonisation and monopolistic practices of giant pharmaceutical companies, many pharmaceutical companies have taken a step ahead to manufacture generic drugs so that people can have access to such affordable medicines which also possess same curative quality as that of in the high-priced patented drugs manufactured by such giant pharmaceuticals companies and also in those drug modifications which the companies also got patented via evergreening of patents obtained in the "parent drug".

### Evergreening And Trips

The TRIPS Agreement provides for the negative monopoly over competitors or rivals from using patented invention without consent of the patent holder for a term of 20 years irrespective of the field of technology.<sup>20</sup> TRIPS provides that patent shall be available for any inventions, whether product or processes, in all fields of technology without discrimination, subject to normal tests of novelty, inventiveness and industrial applicability. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced.<sup>21</sup> TRIPS Agreement recognises that members have the right to use/adopt measures to protect public health so long as they are consistent with TRIPS. Therefore the implementation of IP laws should be based on "pro-public health" and "pro-access" principles.<sup>22</sup> Doha Declaration is an affirmation of the flexibilities provided under the TRIPS Agreement. But the language of the Doha Declaration laid emphasis on the importance of implementing and interpreting the TRIPS Agreement in a way that supports public health.<sup>23</sup>

There arise several questions regarding adherence to the TRIPS Agreement in pharmaceutical sector especially by developing and least developed countries concerning public health. N. Lalitha poses such questions as follows:

1. Would the TRIPS Agreement and product patent regime affect access to medicines for the public?
2. What are the options available for the countries that face health crises?<sup>24</sup>

Doha Declaration has simplified access to medicines by simplifying "compulsory licensing" clause. The Declaration responds to the concerns of developing countries about the obstacles they faced when seeking to implement measures to promote access to affordable medicines in the interest of public health in general, without limitations to certain diseases. The Doha Declaration refers to several aspects of TRIPS, including the right to grant compulsory licenses and the freedom to determine the grounds upon which licenses are granted, the right to determine what constitutes a national emergency and circumstances of extreme urgency, and the freedom to establish the regime of exhaustion of intellectual property rights.<sup>25</sup> So as to understand the flexibility provided by TRIPS regarding public health and then affirmation of Doha Declaration on the TRIPS, we need to look into the provision pertaining to that flexibility and such provision is Art. 27 which reads as: patents shall be available for any inventions whether products or processes in all fields of technology provided they are new, involve an inventive step and are capable of industrial application- and shall be available and patent rights shall be enjoyable without discrimination as to the place of invention, field of technology and whether products are imported or locally produced". The text of TRIPS Article 27.1 can be divided into two components. The first states that: "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and

<sup>18</sup> *Ibid.*

<sup>19</sup> Generic Drugs *available at*: [https://en.m.wikipedia.org/wiki/Generic\\_Drug](https://en.m.wikipedia.org/wiki/Generic_Drug) (last accessed on April 16, 2016).

<sup>20</sup> Inderjeet Singh Bansal, Deeptymaya Sahu, *et.al*, "Evergreening: A Controversial Issue in Pharma Milieu", *JIPR* 299-306 (2009).

<sup>21</sup> The Trade Related Aspects of Intellectual Property Agreement 1994, Art. 27.1.

<sup>22</sup> Prabha Sridevan, "Defending India's Patent Law", *available at*: [m.thehindu.com](http://m.thehindu.com) (last updated on May 12, 2014).

<sup>23</sup> *Ibid.*

<sup>24</sup> N. Lalitha, "Doha Declaration and Public Health Issues", *JIPR* 401-413 (2008).

<sup>25</sup> The Doha Declaration on the TRIPS Agreement and Public Health *available at*: [www.who.int](http://www.who.int).

are capable of industrial application."<sup>26</sup> This section lays out the basic premise that patents must be available for "all fields of technology" subject to the three basic requirements of novelty, utility, and non-obviousness. No other requirements are named, giving rise to a possible negative inference that no other patentability requirements are permitted.<sup>27</sup> The second component states "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."<sup>28</sup> This component is known as the "non-discrimination clause" of TRIPS because it appears on its face to contemplate non-discrimination among different fields of technology.<sup>29</sup> Hence, we can say that TRIPS and Doha Declaration both provide for the basic parameters and object of "patent law" that is "openness" and "accessibility" among which affordability is more important and the flexibilities provided by it are concerned for this aspect only and also for public health. Under the TRIPS Agreement companies enjoy monopoly for a fixed period of time. Pharmaceutical organisations pour their resources in the development of a pharmaceutical which is subjected to various uncertainties. Maximizing such certainty that a research based manufacturer can obtain, enforce, defend and make full legitimate use of his IP rights is very essential or else the promise of pharmaceutical innovation can be lost.<sup>30</sup> However this in no way implies that evergreening of patents should be promoted. Hence what is required is to strike a balance between innovations and affordability.<sup>31</sup>

### Evergreening and indian patents act, 2005: prevailing controversy

#### Development of indian patent law

Having given the brief description of how the concept of evergreening has been taken into consideration under the TRIPS Agreement, the deliberation should move forward to discuss the national law regime of India regarding "patents" and its compliance with the provisions of TRIPS Agreement and also the amendments made in "Indian Patent Law" so as to comply completely with the standardised provisions incorporated under the TRIPS Agreement. In this regard the development of Indian Patent Law needs to be discussed. The development of Indian Patent Law can be discussed by dividing it into three categories which can be as follows:

1. India's Colonial Era to 1970: Recognition of Need to Reform Indian Patent Law to Increase Patent Filing and Stimulate Innovation.
2. 1970-1986: The India Patents Act of 1970 Prohibits Patents on Pharmaceutical Products, Stimulating India's Generic Drug Manufacturing Industry.
3. 1986 to Present: An Uncertain Future for Generic Drug manufacturing after India Reforms Patent Law to be TRIPS Compliant.<sup>32</sup>

Hence, the following flowchart briefly mentions the development of Indian Patent Law which incorporates into it all the legislations which came up in line of bringing the contemporary Patent Law in India.

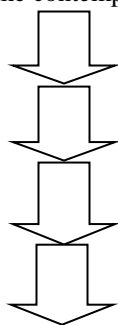
**Protection of Inventions Act, 1856**

**Modified in 1859**

**The Patents and Designs Protection Act, 1872**

**Protection of Inventions Act, 1883**

**1872 Act +1883 Act**



<sup>26</sup> Agreement on TRIPS Art. 27, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, Legal Instruments-Results of the Uruguay Round, 31 *ILM* 81 (1994).

<sup>27</sup> *Ibid.*

<sup>28</sup> *Supra* note 26.

<sup>29</sup> Dorothy Du, "Novartis AG v. Union of India: Evergreening, TRIPS and Enhanced Efficacy under Section 3d", 21 *J. Intell. Prop. L.* 223 (2013-2014).

<sup>30</sup> Carlos M. Correa, "Implications of the Doha Declaration on the TRIPS Agreement AND Public Health-Health Economics and Drug Series No. 012, WHO (2002)(4/5/2013) available at: <https://apps.who.int/medicinedocs/en/d/Js2301e/#Js2301e.19> (last accessed on April 18, 2016).

<sup>31</sup> *Supra* note 5.

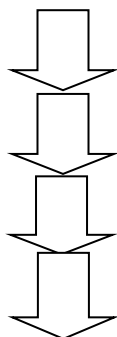
<sup>32</sup> Janice M. Mueller, "The Tiger Awakens: The Tumultuous Transformation of India's patent System and The Rise of Indian Pharmaceutical Innovation, 68 *U. Pitt. L. Rev* 491-495.

**Inventions and Designs Act, 1888**

**Indian Patents and Designs Act, 1911**

**Patents Enquiry Committee, 1948  
(to review the Patents law in India)**

**Patents Bill, 1953  
(based on UK Patents Act, 1949)**



**Justice Rajagopala Iyengar + Justice Tekchand Committee**

**The Patents Act, 1970  
(w.e.f. April 20, 1972)**

After the enactment of the Patents Act, 1970 several changes have been introduced in the legislation via three major amendments of 1999, 2002 and 2005 respectively. The requirement to grant exclusive marketing rights to medicines or drugs as an alternative to product patent protection during the transition period<sup>33</sup> was the main reason to amend the Patent Act and hence 1999 Amendment introduced Chapter IVA relating to exclusive marketing rights for medicines and drugs during the transition period. The chapter pertaining to “EMRs” was omitted in the 2005 Amendment Act after the expiry of transition period given to India. After the Amendment in 1999, numerous changes were made to the Indian Patent Act in 2002 through the Patents (Amendment) Act of 2002.<sup>34</sup> The transition period given to India under the TRIPS Agreement ended in December 2004 and the Indian Parliament passed the Patents (Amendment) Act, 2005 in order to bring the Indian Patent Law in conformity with the Agreement on TRIPS Agreement. In addition to provisions directed to the TRIPS Agreement, the amendment also modified and incorporated other provisions in the Act.<sup>35</sup>

The most important is the 2005 Amendment which came into force with retrospective effect from January 1, 2005. But it was also added that Ss. 37(a)(ii) and (b), 41, 42, 47, 59-63 and 74 shall come into force on such date as the Central Government may appoint by notification in the Official Gazette.<sup>36</sup> The most important change made via this amendment is that “section-3(d) of the Act was substituted by a new clause, which provided that discovery of a new form, property or use of a known substance was not patentable unless it results in “enhanced efficacy”.

### **Section-3(D) Of The Patents Act, 1970**

Section 3(d) stipulates “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 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, is not patentable”.<sup>37</sup> The provision has posed two conditions falling into ambit of which will make the subject-matter non-patentable. They are as follows:

1. Mere discovery of a new form of known substances, and
2. Mere Discovery of Any New Use of Known Substance.

The main objective of this section is to prevent several pharmaceutical companies from obtaining patents on old medicines which are just a mere increment or trivial improvement of the known substances and also a refusal to the

<sup>33</sup> India was given transition time until 2005, under the Agreement on Trade Related Aspects of Intellectual Property rights (TRIPS) to provide for the grant of product and process patents to all inventions including drugs and medicines, The TRIPS Agreement, 1994, Art. 70 Para 9.

<sup>34</sup> Kalyan C. Kankanala, Arjun K. Narasani, *et.al.*, *Indian Patent Law and Practice*, 4-6 (Oxford University Press, New Delhi, 2010).

<sup>35</sup> *Ibid.*

<sup>36</sup> Feroz Ali Khader, *The Law of Patents-with a Special Focus on Pharmaceuticals in India*, 16 (LexisNexis Butterworths, New Delhi).

<sup>37</sup> The Patents Act, 1970, Sectio-3(d).

patent on discovery of new form or new use of old drugs.<sup>38</sup> Hence, section-3(d) introduces pharmaceutical product patents in India for the first time. The Patent (amendment) Act 2005 defines what invention is and makes it clear that any existing knowledge or thing cannot be patented. The provision defines that a 'novelty' standard - which, along with 'non-obviousness' or 'inventive step' and industrial applicability, are the three prerequisites for 'patentability'. "Discovery" essentially refers to finding out something which already existed in nature but was unknown or unrecognised. Therefore, discoveries are excluded from patent protection under section 3 of the Indian Patent Act 1970.<sup>39</sup> The provision under section 3(d) has been approved by WHO Public Health, Innovation and Intellectual Property Rights Report, 2006, that countries can adopt legislation and examination guidelines requiring a level of inventiveness that would prevent **ever-greening patents** from being granted.<sup>40</sup> Section 3 (d) aims to prevent ever-greening, a process by which a company introduces minor modifications in the patented product and then gets a new patent for its product on the strength of the alterations. By applying for secondary patents over related or derivative technologies, prior to the date of expiry of original patent, these companies seek to extend the life of patent by additional 20 year periods for different attributes of the same drug. The changes made may add little therapeutic or clinical value to the original patented product, but the patents granted for them ensure that the patent holders do not lose out market shares to the generic versions of its patented drug. Thus, company can enjoy lengthy monopoly over the drugs and profit from their R&D investment.<sup>41</sup>

The practice of ever-greening has anti-competitive effects as it enables the pharmaceutical MNCs to eliminate competition from the generic manufacturers and charge exorbitant prices for their patented drugs over a prolonged period of time. This in turn is detrimental to public interest since many essential drugs become inaccessible to the general public on account of prohibitive pricing. It was India's concern for public health issues that compelled her to exclude from patentability 'incremental innovation' or modifications on existing drug molecules unless they satisfied the enhanced efficacy requirement under Section 3(d). Prior to India's membership in the WTO, India had developed a highly successful generic pharmaceutical industry producing cheaper versions of patented drugs. This became possible on account of its patent regime which allowed protection only on the process and not the product. After the introduction of patent protection for products, it was feared that such a move would jeopardize the position of Indian generic drug manufacturers in the global pharmaceutical market. Moreover, there was growing apprehension that the sharp rise in the price of life-saving drugs which would take them beyond the reach of common man. By incorporating the enhanced efficacy requirement in Section 3(d), it sought to allay the fear regarding patent evergreening through incremental innovation, and at the same time implemented its obligations under TRIPS.<sup>42</sup>

### **Criticisms Against Section-3(D) Of Patents Act, 1970**

Having deliberated over the provisions contained under section-3 (d), the other face of the coin is that the incorporation of section 3 (d) was widely criticized also in the terms that:

1. It does not comply with the TRIPS Agreement
2. The "enhanced efficacy" was not envisaged under Art. 27.1 of the TRIPS
3. It falls beyond the flexibilities in TRIPS since it limits patentability to only "new chemical entities and excludes "new forms of known substances lacking enhanced efficacy".

To answer the questions we need to look into the relevant provisions of TRIPS. Art. 27.1 provides that "patent shall be available for any inventions, in all fields of technology, provided that they are new, involves an inventive step and are capable of industrial application". The language of this provision is very broad as it does not define any of the terms hence it allows the member countries to design their patent laws as per their convenience so long as they satisfy the broad patentability criteria. Another aspect of concern is that of flexibility regarding public health and in this regard Art. 8 of TRIPS is of vital importance which provides that "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public

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<sup>38</sup> Ayush Sharma, "India: Section-3(d) of Indian Patents Act, 1970: Significance and Interpretation", *available at*: [www.mondaq.com/india/x/295378/Patent/Section+3D+OF+Indian+Patents+Act+1970+significance](http://www.mondaq.com/india/x/295378/Patent/Section+3D+OF+Indian+Patents+Act+1970+significance), (last updated on February 26, 2014).

<sup>39</sup> *Ibid.*

<sup>40</sup> *Ibid.*

<sup>41</sup> Section-3 of the Indian Patents Act *available at*: [www.lawteacher.net/free-law-essays/commercial-law/Section-3-of-the-Indian-Patents-Act-Commercial-law-essay.php](http://www.lawteacher.net/free-law-essays/commercial-law/Section-3-of-the-Indian-Patents-Act-Commercial-law-essay.php) (last accessed on April 19, 2016).

<sup>42</sup> *Supra* note 41.

interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement”.<sup>43</sup>

Art. 7 of TRIPS states “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to balance of rights and obligations”.<sup>44</sup>

Art. 27.2 of TRIPS states “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law”.<sup>45</sup> Hence it can be said that though TRIPS does not provide any definition to the terms “invention”, “inventive step” and “industrial application” and it left this to member countries to accordingly define the limits of patentability criteria as per their socio-economic need. So, it can be said that there is nothing which prevents section 3 d of Indian Patents Act, 1970 to adopt the criteria of “enhanced efficacy” which can be considered as higher level of defining inventiveness of “new form of known substances” hence it can be said that Indian Patent Act has heightened the non-obviousness criteria provided by TRIPS in full compliance of it and hence can very well be considered as “TRIPS PLUS” and not in contravention of TRIPS.<sup>46</sup>

More importantly, Article 8 gives considerable leeway to the developing countries to design a patent system which is conducive to the protection of environment and public health. Article 27.2 enhances the scope of this flexibility by permitting member nations to exclude certain inventions from patentability for protecting public interest.<sup>47</sup> It has been said that in fact none of the member nations has utilised the flexibilities provided by TRIPS but section 3d of Indian Patents Act, 1970 is one of those few provisions of patent legislations which has actually utilised the flexibilities provided by the TRIPS as the Doha Declaration also states that “we agree that TRIPS Agreement does not and should not prevent Members from taking measures to protect public health”<sup>48</sup> Thus we can see that Doha Declaration also envisages in it some sort of flexibilities for developing countries to deviate from the normal patentability criteria so as to ensure public health of their citizens.<sup>49</sup>

While reading literatures pertaining to this paper I came across to a very interesting fact that though section 3d of Indian Patents Act, 1970 found no parallel of it in any other patent legislation of any other country but interestingly it has been copied from a European Directive<sup>50</sup> dealing with drug safety regulation which defines “generic medicinal products” as a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.<sup>51</sup>

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<sup>43</sup> *Ibid.*

<sup>44</sup> The TRIPS Agreement, 1994, Article-7.

<sup>45</sup> *Id.*, Article-27.2.

<sup>46</sup> *Supra* note 41.

<sup>47</sup> *Ibid.*

<sup>48</sup> Para 4 of Doha Declaration.

<sup>49</sup> *Supra* note 41.

<sup>50</sup> Directive 2004/27/EC, Article-10(2)(b).

<sup>51</sup> Directive 2004/27/EC of the European Parliament and of the Council of March 31, 2004 amending directive 2001/83/EC on the Community Code Relating to MEDICINAL Products for Human Use (2004) O.J.(L136)34; Shamnad Basheer, “India’s Tryst With TRIPS: The Patents (Amendment) Act, 2005”, 1 *Indian J.L. & Tech.* 15 (2005) available at: <http://heinonline.org> (last accessed on April 22, 2016).

Shamnad Basheer then contests that “If the intention behind this provision is to heighten the obviousness standard and weed out frivolous and fairly obvious patents, this seems a rather illogical result, as a new use for a new form is certainly more inventive than a mere showing of an increase in known efficacy.”<sup>52</sup> But conclusively it can be said that section 3d made an effort to find a balance between grant of patents and accessibility and affordability of low priced generic drugs by patients and consumers by not allowing the practice of “ever greening” which could potentially delay low priced generic drugs from reaching to low income consumers and patients.<sup>53</sup> And since WTO Dispute Settlement Body (DSB) would consider that section 3d of Patents Act, 1970 has used flexibilities of TRIPS validly and hence it should be taken as a proposal to clarify TRIPS while addressing the concerns about “ever greening”.<sup>54</sup> And hence it can be contested that Section- 3d of the Indian Patents Act, 1970 is an anti-ever greening provision which by incorporating “enhanced efficacy” criteria has in one hand heightened the non-obviousness criteria of patentability complying with the basic requirements of patentability provided under the TRIPS and on the other hand has sought a balance between grant of patents and affordability of low priced generic drugs and hence a balance can be seen between public health and intellectual property rights. The controversy regarding section-3d hence seen to be resolved and it can very well be said that it can be a proposed universal solution of the problem of “ever greening of patents” which can be considered as a means of colonisation and monopolistic control by giant MNCs in pharmaceutical sector, which is the next part of this paper to be dealt with.

### Meaning Of Colonisation And Its Effect

Colonization or colonisation is an ongoing process of control by which a central system of power dominates the surrounding land and its components. The term is derived from the latin word *colere*, which means to “inhabit”. The history of colonisation can be traced long back to times of maritime nations such as city-states of Greece and Phoenicia, they used to establish colonies to farm and also with the intent of regulating and expanding trade throughout the Mediterranean and Middle East. The Vikings of Scandinavia also carried out a large scale colonisation, they also established colonies to began trading. While reading literature pertaining to colonisation I came across an emerging concept of “hypothetical colonisation” which interlinks different fields with the concept of colonisation such as “ocean colonisation”, “space colonisation” etc.<sup>55</sup> And hence the paper is also dealing with another type of hypothetical colonisation which is “market colonisation” pursued by giant MNCs in pharmaceutical sector via process of “ever greening of patents”. The advent of colonialism in India produced major upheavals in the economy causing disruptions in production, trade and agriculture. Before being colonised by British, India was a major supplier of manufactured goods to the world market and after colonisation she became a source of raw materials and agricultural products and consumer of manufactured goods largely for the benefit of industrialising England. At the same time new groups entered the trade and business sometimes in alliance with existing communities and in some cases by forcing them out.<sup>56</sup>

In industrialised nations, historic colonialism is rarely equated with “economic globalisation”. Yet as MNCs assert rights over nation-state sovereignty, globalisation increasingly looks like a highly-evolved form of colonialism, re-subordinating the economies of newly industrialised countries, as well as labour markets of developed nations.<sup>57</sup> Colonialism means “the policy or practice of a wealthy or powerful nations maintaining or extending its control over other countries, especially in establishing settlements or exploiting resources”.<sup>58</sup> As per Collins English Dictionary, colonialism means “the policy and practice of power in extending control over weaker peoples or areas”.<sup>59</sup> While

<sup>52</sup> Shamnad Basheer, “India’s Tryst With TRIPS: The Patents (Amendment) Act, 2005”, 1 *Indian J.L. & Tech.* 15 (2005) available at: <http://heinonline.org> (last accessed on April 22, 2016).

<sup>53</sup> Zoe Lynn Turrill, “Finding the Patent Balance: The Novartis Glivec Case and the TRIPS Compliance of India’s Section-3d Efficacy Standard”, 44 *Geo. J. Int’l. L.* 1555 (2012-2013).

<sup>54</sup> *Supra* note 53.

<sup>55</sup> Colonisation available at: <https://en.m.wikipedia.org/wiki/colonization> (last accessed on April 23, 2016).

<sup>56</sup> Colonialism and the Emergence of New Markets available at: [www.sociologyguide.com](http://www.sociologyguide.com) (last accessed on April 23, 2016).

<sup>57</sup> Anna Manzo, “Rethinking Colonisation” available at: [www.thirdworldtraveler.com](http://www.thirdworldtraveler.com) (last accessed on April 23, 2016).

<sup>58</sup> American Heritage, Dictionary of the English Language (Houghton Mifflin Harcourt Pub. Co., 5<sup>th</sup> edn. , 2011).

<sup>59</sup> Collins English Dictionary- Complete and Unabridged edn. , (Harper Collins Publisher, 12<sup>th</sup> edn., 2014).



dealing with the concept of colonialism, “neo-colonialism” is another worth mentioning concept which means “control of its former colonies by economic pressures”.<sup>60</sup>

Colonialism, colonisation, imperialism and neo-colonialism all these terms refer towards control of stronger over the weaker and this control can be in any manner and in any sphere. Conventionally, these terms have always been talked in the political sense but an attempt has been made to link these concepts with one of the concept relating to Intellectual Property rights which is the concept of “ever greening of patents” wherein the huge MNCs try to control the economy of newly industrialised companies by getting their patent protection renewed over the products manufactured by them just by making small modifications and hence this process leads to the price inflation of such products which cannot be easily afforded by the low-income consumers. The next part of the paper talks about this very interconnection that how these multinational companies are colonising the economy of newly settled or small companies by using this concept of “ever greening” which is in a way not only affecting the right to trade and commerce of small enterprises in the concerned spheres but also adversely affecting the rights of consumers to have access to those products and in case of pharmaceutical product affecting the rights of patients to have access to generic version or cheaper drugs.

### **Evergreening Of Patents: Reason Of Colonisation And Monopoly**

As the concepts of “ever greening” and “colonisation or colonialism” have been deliberated in quite detail, the basic idea which can be gathered about these concepts is that the term “ever greening” refers to the renewal over the patent production before its expiry just by introducing trivial modifications over the patented products. And the term “colonisation or colonialism” refers to the strategy of control of stronger over the weaker ones. Hence we can very well say that ever greening of patents is nothing but a main cause behind the colonisation and the increasing monopoly by huge giant MNCs pharmaceutical countries as they continuously practice this practice of getting their patented products or drugs renewed by making trivial modifications in their composition which results in the inflation of prices of drugs and medicines as they have to extract all the expenditure which they had bear while research and development and also to secure the finance for further research regarding modifications to be made in the patented products such as drugs or medicines. The process of ever greening is a double-edged sword because it hampers interest of two classes of the society such as the newly emerged pharmaceutical companies dealing in the manufacturing of generic medicines because by getting their patented product’s protection renewed MNCs in that field trying to bring “market colonialism” in which they try to control the economy of these newly emerging companies in pharmaceutical sector who are trying to bring some generic version of high-priced drugs or medicines which could not be afforded by low-income consumers or patients by increasing their monopolistic tendency of getting their patent renewed just by making small modifications in the patented products and secondly, the affordability aspect of the patients because due to evergreening of patent over the drugs and medicines, there is a rise in the price of those secondarily patented drugs and medicines which could not be afforded by the low-income consumers or patients. But today, India still has a thriving domestic generic drug industry that competes directly with brand-name drug manufacturers from the U.S. and Europe. Indeed, India and Japan are the only two countries where generic drug manufacturers dominate over multinational corporations." The domestic industry is itself divided between several large companies (such as Ranbaxy, Cipla, and Dr. Reddy's Laboratories), which engage in some original research and development in addition to generic drug production, and hundreds of smaller companies, which exclusively reverse engineer and manufacture generics.' Both segments rely heavily on export markets.<sup>61</sup>

Hence, the fragmented Indian pharmaceutical industry has led to a wide disparity of interests with respect to patent protection. Not only do multinational drug companies want enhanced patent protection, but some domestic companies-primarily those who have significant research and development operations-also want a stronger patent regime.<sup>62</sup> Other domestic companies, however, fervently oppose patent law reform, fearing that it would lead to patent-based monopolies and destroy their imitation-based business models.<sup>63</sup>

On the basis of above analysis, it can very well be said that ever greening is nothing but a means of increasing “market colonisation” and the enhanced monopolistic patent regime.

<sup>60</sup> Based on wordnet3.0, Farlex elipkart collection, Princeton Univ., Farlex Inc., 2003-2012.

<sup>61</sup> *Supra* note 32 at 532-33 & 537-40; Linda L. Lee, “Trials and TRIPS- Ulations: Indian Patent Law and Novartis AG v. Union of India”, 23 *Berkley Tech. L. J.* 281 (2008) available at: <http://heinonline.org> (last accessed on January 15, 2016).

<sup>62</sup> *Supra* note at 540.

<sup>63</sup> *Id* at 539-40.

### Measures To Restrict Evergreening In India

As it has been deliberated in detail a lot about the concept of “ever greening”, it means nothing but a process to get a “secondary patent” on a new form of product which has been granted patent protection for the term of 20 years. Hence, it is a tendency to gain a new term of patent protection just by making trivial modifications. But in India, the Patent (Amendment) Act, 2005 has brought insertion of a very important provision in the form of Section-3d which importantly aims at prevention of the process of ever greening of patents by preventing grant of patent protection on minor modifications of already known and patented product such as drugs and medicines etc.. It has introduced the “enhanced efficacy” clause which says that no “secondary patent” can be granted to any trivially modified product until and unless it shows some enhancement in the efficacy of that already known combination and which also enhances the value of earlier known combination of drugs. In a way section-3d<sup>64</sup> also prevents new use of known substances and hence it also increased the patentability criteria by raising the non-obviousness standard for granting patent.

Another important measure which has been taken in India is in the form of definition of “inventive step”<sup>65</sup> and “new invention”<sup>66</sup> which have been construed in a stricter manner. According to which any invention will be considered new only if firstly, it has not been anticipated and secondly, it does not form part of prior art, and hence the provision demands the criteria of “absolute novelty” to be fulfilled. Hence, this provision has made it difficult to obtain patent on trivial changes made in any earlier existing patent. Next measure can be discussed via discussing section-2(1)(j) which defines “inventive step” which talks about “non-obviousness” criteria of patentability which means patent should not be granted for anything which is obvious to the person ordinarily skilled in the art. It signifies that the intention of the incorporation of this provision in the Indian Patent legislation is that minor and changes merely for namesake in earlier patents will not be permissible.<sup>67</sup>

Hence, it can be said that the amended provisions are the sufficient measures which can restrict the very trending process of ever greening of patents so that “market colonialism” streaming by MNCs and also the enhanced monopolistic patent regime could be controlled.

### Conclusion:-

Starting the paper with the research question that what is the concept of ever greening of patents which has been answered by providing various definition and meaning provided by various dictionaries, the author has moved forward to clear the concept of “generic drugs” which are the cheaper version of high-priced patented drugs or medicines. Then the paper dealt with the provisions of TRIPS which in some manner deal with the concept of ever greening in the form of Art. 27 and also the flexibilities provided by the same have also been talked about. Moving ahead the provisions of Indian Patents Act, 1970 as amended by amendment of 2005 has also been discussed in detail wherein a detailed discussion revolved around section-3d and also the prevailing controversy regarding whether the provision is in compliance with TRIPS or not has also been discussed, the conclusion of what can be mentioned in the manner that since TRIPS has left it to the member countries to adopt any manner so as to define the patentability criteria hence in no manner it can be said that Section-3d is not in compliance with the provisions of TRIPS rather it has provided a universal suggestion which need to be incorporated in TRIPS as well as in other national patent legislations so as to combat the “ever greening of patents”. Though the scope of the paper is to deal the concept of ever greening as the main root cause of “market colonialism” and increasing monopolistic trend in patent regime by the huge giant MNCs in the pharmaceutical sector hence the paper dealt with the concept of colonisation or colonialism which can be understand as the process of gaining control over the weaker ones and unconventionally the author has attempted to interlink the concept of colonialism with that of the trending concept in the IPR regime. Moving on the line of “hypothetical colonialism” it can be said that yes ever greening leads to “market colonialism”. Then lastly, certain measures to restrict evergreening which are incorporated under the Indian Patent Law regime in the form of section 3d and 2(1)(j) and also the definition of “new invention” have been talked about and all of which intend only to the concept that no patent protection should be granted over the obvious form of already existing patented product and hence absolute novelty has been made a stricter criteria of patentability. Hence, the author concludes by stating that ever greening should not be appreciated as it not only threatens the economy of newly established domestic drug manufacturers but also in some or the other ways hampers the right of

<sup>64</sup> Patents Act, 1970, Section-3(d).

<sup>65</sup> Supra note 64, Section-2(1)(j).

<sup>66</sup> Definition of “new invention” incorporated under Section-2 of the PATENTS ACT, 1970

<sup>67</sup> Supra note 1

patients to have access to the medicines which they require for their concerned treatment because ever greening always leads to inflation of prices of drugs or medicines. As a suggestion the author wants to mention that the “enhanced efficacy” standard should also be adopted by other national patent law legislations so to ensure that ever greening may not only be eradicated from India but it could be combated globally so as to harmonise the balance between the IPRs and affordability on the part of the consumers.

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