
Email:editorijless@gmail.com Volume: 4, Issue 1, 2017 (Jan-Mar.)

Impact Factor 4.1 (IB Factor)

# INTERNATIONAL JOURNAL OF LAW, EDUCATION, SOCIAL AND SPORTS STUDIES (IJLESS)

**www.ijless.kypublications.com**

**ISSN:2455-0418 (Print), 2394-9724 (online)**



www.kypublications.com

# STRATEGIES FOR OBTAINING PATENTS BY PHARMACEUTICAL COMPANIES AND EVERGREENING OF PATENTS

RESEARCH ARTICLE

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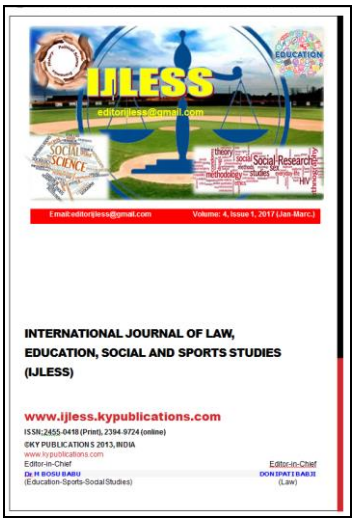


**ABSTRACT**

The limitations on monopoly right under the patent law is vital in helping preserve the policy underlying the Patent Act of promoting innovation while still allowing the intellectual property to enter the public domain. Ever greening through patent strategies allows the branded drug companies to hold its exclusive right to market the drug. Strategies to extend the monopoly and control by branded pharmaceutical companies' in order to avoid generic competition are formulated as soon as the product is ready for patenting. Under the patent law no distinction is sought between inventions consisting of brand new products and inventions relating to improvements, as the same criteria for patentability apply. Secondary patents can thus act as a barrier to generic competitors. The author in this paper argues that the ever greening strategies employed by the big pharmaceutical companies as a tactics to bypass the existing patent laws and limit generic competition in the market is not just limited to the patent related strategies but also extends to other means such as aggressive litigation etc. for limiting the generic competition in the market. Hence the frequency of such strategies demands strong patent interpretations that are protective of the spirit of patent laws.



Patent strategies like evergreening differently impact the developing world. The practice of evergreening not just refer to extending the original patent, but also includes strategies and practices used to protect a cluster of related, but unoriginal, technologies through the filing of secondary applications.[1]This contributes to increased medical costs by keeping lower-cost generic alternatives out of the marketplace.[2] This chapter gives an overview of the evergreening strategies that are employed by branded pharmaceutical companies as a tactic to bypass existing patent laws and limit generic competition in the marketplace. The frequency of such strategies demands strong patent interpretations that are protective of the spirit of patent laws.[3]

## I.RATIONALE FOR PHARMACEUTICAL COMPANIES TO ENGAGE IN EVERGREENING STRATEGIES

The giant pharmaceutical companies do not wait for the expiry of their patent to start with the evergreening process. Strategies to extend their monopoly and control, and avoid generic competition are formulated as soon as

[1] S See Edson Beas Rodrigues, Junior. & Bryan Murphy, Comment, Brazil's Prior Consent Law: A Dialogue Between Brazil and the United States Over Where the TRIPS Agreement Currently Sets the Balance Between the Protection of Pharmaceutical Patents and Access to Medicines, Vol.16 Albany Law Journal of Science and Technology, 423-431, 2006.

[2] Declaration on the TRIPS Agreement and Public Health, Nov. 20, 2001, World Trade Organization, Ministerial Declaration of 14 November 2001, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm Last Visited on May 3, 2014.

[3] Gaurav Dwivedi, Sharanabasava Hallihosur, Latha Rangan, Evergreening: A deceptive device in patent rights, Vol. 32, Technology in Society, 324–330, 2010.

the product is ready for patenting. These life cycle management plans cover not just the patent related strategies, but other practices such as aggressive litigation etc., for delaying or limiting generic competition in the market.[4]

**A. EFFECTIVE MARKET EXCLUSIVITY**

One rationale for evergreening is the effective market exclusivity enjoyed by the patent holder may be less than the full 20 years of patent length because patents applications are generally filed in the development process of the product and the term of 20 years of patent is granted from the date of filing of the application. Pharmaceutical products then undergo various clinical testing, as well as governmental regulatory review, before they are being introduced in the market. However, these delays are mitigated by stipulations in the Hatch-Waxman Act that add FDA regulatory review time back into the effective patent life, which can extend the market exclusivity once a product is approved.[5]

**B. BRANDED VERSUS GENERIC DRUGS**

Under the patent law no distinction is sought between inventions consisting of brand new products and inventions relating to improvements as the same criteria for patentability apply. Taking the advantage of this existing loophole in patent law, patent applications for the developments or modifications is not just filed by the original product developer but also by other companies including generic companies. One the one hand the branded companies advertise to customers their brand value and reliability, and on the other hand they try to cast generics negatively on the basis of poor replication, or unsatisfactory testing before commercial production of the original formula. However, the argument put forth by branded companies is that they enable the development of a non-infringing competitor product thereby channeling "designing around" the patent.[6]

A monopoly right that is suitably limited is vital in helping preserve the policy underlying the Patent Act of promoting innovation while still allowing the intellectual property to enter the public domain.[7]

**II.EVERGREENING STRATEGIES**

**A. DELAY THE LAUNCH OF GENERIC PRODUCTS/ 30 MONTH PERIOD OF STAY PROVISION**

In US, innovator drug companies have been able to use provisions of the Hatch Waxman Amendments to the Federal Food, Drug and Cosmetics Act, 1984 to delay or restrict the launch of generic competitor products. The innovator pharmaceutical company has been allegedly using the listing of additional patents in the 'Orange Book ' to try to benefit from more than one 30-month period of stay of the Food and Drug Administration (FDA's) approval of the abbreviated new drug application (ANDA) and in this way extend its period of protection from generic competition.[8]

Under the Act, a generic drug manufacturer wishing to make generics of a brand-name drug must file an ANDA with the FDA. The ANDA needs to satisfy the FDA that the generic is a bioequivalent of the brand-name drug. Furthermore, the generic must not be in violation of any patents on the brand name drug. If the generic manufacturer certifies to the fourth option (called a "paragraph IV certification") that is the patent is invalid or will not be infringed by the generic then it must immediately send a notice to the patent holder informing its intent to market a generic. A paragraph IV certification triggers the right of the brand-name company to challenge the generic manufacturer in court within 45 days on the basis that the generic is in violation of a patent listed in the Orange Book. If the brand decides to litigate, the statute automatically prevents FDA approval of the generic for 30 months or until the litigation is resolved or the patent lapses, whichever occurs first.[9]

Companies have misused this provision and sometimes even list bogus patents in the Orange Book to gain time by litigation. Merely challenging the generic in the court of law gives the brand an automatic extension of two and a

[4] Id

[5] Aaron S. Kesselheim, Intellectual Property Policy in the Pharmaceutical Sciences: The Effect of Inappropriate Patents and Market Exclusivity Extensions on the Health Care System, Vol. 9(3), The AAPS Journal, 2007 Available at http://www.aapsj.org Last visited on March 5, 2014.

[6] Gaurav Dwivedi, Sharanabasava Hallihosur, Latha Rangan, Evergreening: A deceptive device in patent rights, Vol. 32, Technology in Society, 324–330, 2010.

[7] Gaurav Dwivedi, Sharanabasava Hallihosur, Latha Rangan, Evergreening: A deceptive device in patent rights, Vol. 32, Technology in Society, 324–330, 2010.

[8] Scott Parker and Kevin Mooney, Is 'Evergreening' A Cause for Concern? A Legal Perspective, Vol. 13(4), Journal of Commercial Biotechnology, 235–243, 2007

[9] Gaurav Dwivedi, Sharanabasava Hallihosur, Latha Rangan, Evergreening: A deceptive device in patent rights, Vol. 32, Technology in Society, 324–330, 2010.

half years. The brand could litigate saying that the generic violates one of the patents listed in the Orange Book and get a 30 month extension, irrespective of whether the challenge was correct or whether the patent was valid. Hence with 'n' number of patents listed in the Orange Book, the brand could go on litigating for 30n months or till the patent lapses by initiating a separate litigation for each listed patent.[10]

***The case of Bristol-Myers Squibb(BMS) and Taxolc***

Bristol-Myers Squibb (BMS) sells paclitaxel, used to treat ovarian, breast and lung cancer, under the brand-name Taxol. Paclitaxel was developed by the National Cancer Institute and placed in the public domain and hence was not patentable. The drug was approved by the FDA in December, 1992. BMS was given a five-year market exclusivity over sales of paclitaxel as Taxol until December, 1997.[11]

Before expiration of the five-year period, BMS obtained two patents on paclitaxel for methods of administering it as an anti-tumor agent and sought to extend the five-year exclusivity[12]. Upon expiration of the five-year term in December 1997, a number of generics tried to enter the market. BMS challenged many of them based on its patents listed in the Orange Book and got an extended monopoly for 30 months after 1997. This prevented the entry of generics into the market until 2000. However the courts ruled that the BMS patents were invalid, except for specific parts which by themselves could not have blocked the entry of generics into the market. Also in June 2002 attorneys general of 29 US states filed a lawsuit against BMS alleging that in 2000 it started the process all over again by acting in collusion with a California-based company, America Bio Science. As per the Attorneys the two companies filed sham lawsuits with the intent of further delaying the entry of generics into the market, once again with the aid of the 30 month extension.[13]

**B. 180 DAYS PERIOD OF MARKET EXCLUSIVITY**

The Hatch-Waxman Act, 1984 encourages generic drug companies to challenge the patents on brand name drugs by awarding the first generic challenger 180 days of generic marketing exclusivity. By challenging a patent it automatically triggers patent infringement litigation from the brand name firm. Exclusivity is awarded as long as the generic firm does not lose that patent infringement suit. In such a case stakes are really high as 180 days of generic exclusivity is worth millions of dollars for major pharmaceutical drugs. In response to the increased numbers of patent challenges, brand name firms have adopted an "evergreening" strategy that is filing for multiple patents for each drug hoping that the generic firm will not be able to successfully challenge all of the patents and that the continued validity of just one of them will prevent generic entry.[14]

**1. *Response of the generics***

Evergreening unavoidably results in patents of different strengths. Generics have responded to this strategy by challenging only the weaker patents on a drug and then filing for a stay of the subsequent patent infringement lawsuit until the strong patents are about to expire, which is often many years in the future. Generics seek these stays because an early litigation victory would grant a period of exclusivity that they could not use because the strong patents continue to block generic entry. Brand name firms also favor stays because by delaying the generic's exclusivity period, the stay also ultimately delays full competition. Courts are split on whether to grant the motions but have not addressed the anticompetitive consequences of stays.[15]

**2. *"Failure to market" forfeiture provision***

Even if the generic firm were to prevail in the resulting patent litigation, however, the strong patent would continue to block FDA approval of the generic drug product for the duration of the strong patent's term. Thus, there is a risk that the generic firm might win the patent litigation too early, resulting in a premature period of exclusivity during which the generic firm still cannot feasibly enter the market. In such a case, the generic firm would ultimately forfeit exclusivity under the Hatch-Waxman Act's "failure to market" forfeiture provision.[16]

[10] Id
[11] Id
[12] Whitehead B, Jackson S, Kempner R, Managing generic competition and patent strategies in the pharmaceutical industry, Vol. 3(4), Journal of Intellectual Property Law & Practice, 226-235, 2008.
[13] Gaurav Dwivedi, Sharanabasava Hallihosur, Latha Rangan, Evergreening: A deceptive device in patent rights, Vol. 32, Technology in Society, 324–330, 2010.
[14] Michael R. Herman, The Stay Dilemma: Examining Brand And Generic Incentives For Delaying The Resolution Of Pharmaceutical Patent Litigation, Columbia Law Review, Vol. 111, 1788-1832, 2011
[15] Id
[16] Id

Many of these patents do not cover the compound at issue. Rather, they are ancillary patents on chemical variants, alternative formulations, methods of use, and relatively minor aspects of the drug. Many such patents tend to be weak. Even though they are weak, they have the effect of extending the total duration of protection for a brand-name drug, compared to the protection offered by the compound patent alone. Accordingly, these weak patents have a deleterious effect on social welfare.[17]

**C. AGGRESSIVE LITIGATION**

Most evergreening strategies involve prolonged litigation. Although giant pharmaceutical companies are in a superior position to litigate than most of the generic drug manufacturers, it is still a financial burden for them. Despite this fact when evergreening strategies are well planned and executed in a proper manner they seem to work well for branded drug majors. Delay in market entry will be caused, by litigation procedures in certain countries which frustrate the attempts of generic companies to clear blocking patents out of the way.[18]

Patent litigation in the pharmaceutical industry is risky and resource intensive, and becomes all the more when more patents and claims are involved. Such litigation may take several years to resolve. It is still possible that a weak secondary patent that is invalidated after litigation could produce years of valuable exclusivity.[19] Further, litigation as a means to invalidate weak secondary patents is a far less reasonable policy outcome in countries without strong incentives for generics to undertake the expense of challenging these patents. Insofar as the policy response to the rise of secondary patents relies on litigation and rigorous patent examinations as a means to ensure that only truly inventive secondary patents issue, the countries with limited resource settings are likely to be at a considerable disadvantage.[20] This helps us explain to a certain extent as to why India sought to adopt clear statutory bars on certain types of secondary patent claims, even if those bars are not always consistently implemented during patent examination.[21]

**D. STOCKPILE/LINE EXTENSION/PATENT THICKET**

A form of evergreening occurs when the branded drug manufacturers "Stockpile" patent protection by obtaining separate patents on multiple attributes of a single product. Here, the brand-name companies "stockpiles" patent protection by obtaining separate 20-year patents on multiple attributes of a single product. The expiration of these patents can extend market exclusivity by several years in addition to the period of the primary patent. Line extension refers to such strategies where companies attempt to buy additional period of exclusivity by gaining patents on modifications to the drugs or their method of use.[22]These patents can cover everything, right from manufacturing aspect to tablet colour, or even a chemical produced by the body when the drug is ingested and metabolized by the patient.[23]

A related charge that is sometimes made against innovator companies is that they file numerous patents on multiple attributes of a single product so as to create a patent thicket that so complicates third-party research that it strangles innovation, or that they are guilty of what is sometimes referred to as strategic patenting.[24]Implicit in these charges is that the only reason for filing these patents is maintenance of market share for as long as possible after the expiry of the patents covering the originator product itself.[25]

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[17] Id

[18] Scott Parker and Kevin Mooney, Is 'Evergreening' A Cause for Concern? A Legal Perspective, Vol. 13(4), Journal of Commercial Biotechnology, 235–243, 2007

[19] Amy Kapczynski , Chan Park, Bhaven Sampat, Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of ''Secondary'' Pharmaceutical Patents, Vol. 7(2),Yale Law School, December 2012.

[20] Amy Kapczynski, Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector, Vol. 97(6), California Law Review, 1571–1649, 2009

[21] Sudip Chaudhuri, Chan Park, K.M. Gopakumar, Five Years into the Product Patent Regime: India's Response, United Nations Development Programme, December 2010.

[22] Gaurav Dwivedi, Sharanabasava Hallihosur, Latha Rangan, Evergreening: A deceptive device in patent rights, Vol. 32, Technology in Society, 324–330, 2010.

[23] Shanti Kumar, Dr. Nitin Shukla, Tanushree Sangal, Evergreening of Patents and the Indian Patent Law, Electronic copy available at: http://ssrn.com/abstract=1420003 Last visited on March 23, 2014

[24] Gopakumar K. M., Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime, Vol. 3(2), The Law and Development Review, Special Issue: New Voices From Emerging Powers Brazil and India, Art. 11, 325-368, 2010

[25] Scott Parker and Kevin Mooney, Is 'Evergreening' A Cause for Concern? A Legal Perspective, Vol. 13(4), Journal of Commercial Biotechnology, 235–243, 2007

As generic drug manufacturers became more aggressive in their efforts to gain share in markets formerly dominated by branded products, companies with significant brand franchises tried to protect their revenues by going after line extensions, defending patents, and reallocating their product portfolios.[26]

**E. SECONDARY PATENTS/ ME-TOO DRUGS**

Evergreening is defined as further patenting by the originator company of variations on the original Active Pharmaceutical ingredient (API). Patenting of variations on the original API by entities other than the originator company is referred to as secondary patents. A related issue is "me-too" drugs. These are drugs developed by competitors in response to the development of a block-buster API by an originating firm. The motivation is to obtain a share of a large and lucrative market. The company developing the me-too drug is looking for similar therapeutic effect, but with some variation in the chemistry, dosage, administration, formulation or method of treatment so that the "new" drug meets the very low inventiveness threshold for a patent grant. On some occasions these variations on the original theme may be more efficacious and/or more efficient, such as decreases in side effects. In others they offer no advantages.[27]

These patents are generally termed secondary because they are assumed to come later in the sequence of innovation, and to offer less robust protection than a chemical compound claim.[28]Some possible types of secondary patents could be Composition patents, Patents for new polymorphs, Patents for new formulations, Synthesis patents, Patents for new therapeutic regimes, Patents for metabolites or pro drugs, etc.

***The case of Pfizer and Viagra***

In 1991 and 1992 Pfizer obtained patents on a series of compounds which acted as selective inhibitors of phosphodiesterases (PDEs). The patented compounds included sildenafil citrate, marketed by Pfizer under the brand-name Viagra. The patents stated that these compounds were useful in the treatment of angina and hypertension. Subsequently, several research articles were published in 1992 and 1993 signifying that PDE inhibitors could be useful in the treatment of impotence and male erectile dysfunction (MED).Pfizer followed this by filing for new patents in 1994 which covered the same compounds patented in 1991 and 1992 but claiming that these products could be used to treat impotence and MED. The claim stated that this use had been found “unexpectedly” and had the added advantage of being administered orally as opposed to existing medication which needed to be injected. Lily ICOS, a joint venture of ICOS Corporation and Eli Lilly, challenged this patent saying that in view of the articles published in 1992–1993 the invention was invalid for obviousness. Pfizer defended by arguing that the patent was inventive in the respect that the articles did not suggest the compounds as an oral treatment.[29]

When matter reached the court in 2000 the judge found that the only difference between prior art and the claims was the suggestion of oral use, which did not constitute inventiveness. He declared the patent invalid. When Pfizer appealed against the decision, the Court of Appeal upheld the decision. The court observed that while there was reason to doubt that PDEs could administer orally to treat impotence and MED, simply deciding to try it out was not inventive. Also there was nothing in the specification which suggested that there were any difficulties in oral administration which needed to be overcome by adapting the compound for oral use. It was obvious to try and any skilled person carrying out routine procedures would have been successful[30]

**F. FRANCHISE EXTENSION TO SUCCESSOR DRUGS**

The struggle between the brand and generics now has taken a leap beyond. Brand makers are extending their patents beyond the expiration dates by creating euphoria about the most original and enhanced drug effects based on

[26] Gaurav Dwivedi, Sharanabasava Hallihosur, Latha Rangan, Evergreening: A deceptive device in patent rights, Vol. 32, Technology in Society, 324–330, 2010.

[27] Hazel V J Moir , Luigi Palombi, Patents and Trademarks: empirical evidence on 'evergreening' from Australia, 4th Asia-Pacific Innovation Conference College of Law, National Taiwan University 6-7, Session 2B: Patenting Strategy, available at https://digitalcollections.anu.edu.au/bitstream/1885/11418/1/Moir%20%26%20Palombi%20Patents%20and%20trademarks%202013.pdf Last Visited on January 10, 2014

[28] European Commission Pharmaceutical Sector Inquiry: Final Report, Competition Enquiry into the Pahrmaceutical Sector, Brussels: European Commission, 2009; Burdon M, Sloper K (2003) M. Burdon, K. Sloper, The Art of Using Secondary Patents to Improve Protection, Vol.3(3), Journal of Medical Marketing, 226–238, 2003; Furrow ME, Pharmaceutical Patent Life-Cycle Management after KSR v. Teleflex, Vol. 63(1), Food and Drug Law Journal, 275–320, 2008.

[29] Gaurav Dwivedi, Sharanabasava Hallihosur, Latha Rangan, Evergreening: A deceptive device in patent rights, Vol. 32, Technology in Society, 324–330, 2010.

[30] Id

brand reliance and constant improvisation in the chemical composition which they ought to get it re-patented, thus an effort to curtail the generics entering the market. This strategy of "patent to patent" is being used to retain market shares by presenting consumers with a new, supposedly improved, drug line to replace the original drug whose patent is about to expire. This kind of switching of patients to the new drug line minimizes market share loss by attrition of consumers and at the same time dissuades generic drug manufacturers from entering the market with a generic for the original drug since most patients have already transitioned to the new drug. Such a large scale franchise extension requires promotion on a huge scale therefore companies invest huge amounts of money to launch massive campaigns to popularize the successor drug among patients. Doctors' offices are flooded with sales representatives offering them gifts of money and kind for prescribing their drug. In most of the cases the successor drugs offer very little advantage over the original drug but the advertisement campaigns do succeed in convincing both patients and doctors otherwise.[31]

***The case of AstraZeneca and Prilosec***

Omeprazole is proton pump inhibitor used in the treatment of dyspepsia, peptic ulcer and gastro esophageal reflux disease. It was patented by AstraZeneca which marketed it under the brand-name Prilosec.[32]

Prilosec is a race mate containing equal quantities of both the S and R enantiomers. In most patients, except those that are "poor metabolizers", the race mate undergoes a chiral shift in vivo to form the S enantiomer, which is the active form of the drug. Before the patent on Prilosec could lapse AstraZeneca developed a new drug branded Nexium which was nothing but the S enantiomer, or the active component of Omeprazole. The company executives surmised that this formulation could be more effective against erosive esophagitis as compared to Prilosec. The company sanctioned four different studies to compare the efficacy of Nexium with Prilosec in patients with this condition.[33]

Of the four studies two concluded that Nexium did not surpass Prilosec even with the increased dose. But the two studies found Nexium better than Prilosec. The results of the favorable studies were published while those of the other two studies were not released. At the end of the study Nexium seemed to outdo Prilosec only marginally that is a healing rate of 90% against 87%. This study was used to convince doctors that Nexium was indeed better than Prilosec. AstraZeneca quickly got FDA approval for Nexium in February, 2001, a few months before the patent on Prilosec was to expire. At the same time AstraZeneca exploited the federal provision of pediatric exclusivity in the US which gives a six month extension on existing market exclusivity for conducting tests on effectiveness of a drug on children. This extended the exclusivity of Prilosec fending off the generics for a further six months. The extra time gained was used to campaign for the drug.[34]

In AstraZeneca v Canada, the Canadian Supreme Court said the commercialization of generic medicines should be accepted insofar as they are not in the realm of the original patent. This mechanism shows substantial flaws. First, one wonders why patents are being allowed on additional characteristics in the first place, if they would not be enforceable in the end. Second, the factual situation of the case and the way the decision was linked to it makes the mechanism to be applicable in a limited number of cases only.

**G. ROLE OF TRADEMARKS IN EVERGREENING**

Trademarks play a crucial role in evergreening by establishing branding distinctions. These are used by sales forces to encourage prescribing doctors to shift from the original branded medicine to the evergreened branded medicine, reinforcing any existing brand loyalty while developing new loyalty in the evergreened brand and extracting a price premium beyond the original patent period. Where a variant of the original API is introduced the original brand will be cannibalized by the new brand . Loyalty in the old brand for which the relevant patents are about to expire is thus transferred to the new brand whose relevant patents won't expire for many years. The objective is to retain a patent-provided price premium over a much longer period. Typically such variants are enantiomers, metabolites, salts, esters or similar closely similar versions of the original API.[35]

[31] Id
[32] Id
[33] Id
[34] Id
[35] Hazel V J Moir , Luigi Palombi, Patents and Trademarks: empirical evidence on 'evergreening' from Australia, 4th Asia-Pacific Innovation Conference College of Law, National Taiwan University 6-7, Session 2B: Patenting Strategy, available at

The trade mark for such improvement drugs typically uses the original brand augmented by letters, such as 'XR' (extended release), or phrases, such as 'Plus' conveying a superior version of the original brand. An example of this kind of evergreening is venlafaxine (EFEXOR) to venlafaxine extended release (EFEXOR-XR) and FOSAMAX to FOSAMAX PLUS.[36]

Differences in the appearance of generic and originator products may cause confusion, reduce adherence and increase prescription/dispensing errors, with adverse consequences for patients. However, the current jurisprudence suggests that trademarks for tablet colour or shape are not registrable since the colour and/or shape of a tablet has an important function because patients often rely on the colour, size and shape of medication for reassurance that they are taking the right pill.[37]

**H. PHARMACOGENOMICS**

'Pharmacogenomics' is the fusion between pharmacology and genomics and is a growing field of scientific endeavor that seeks to untangle the complex connection between genotype and phenotype, particularly to unlock its capacity to improve the development and prescription of pharmaceutical drugs.[38]The issue here is that the possibility that the connection between drugs and genetic tests might be exploited by pharmaceutical patentees in their attempts to 'evergreen' 'blockbuster' drugs. Pharmacogenomics suggests a new strategy to the would be available to an evergreener that is a drug's exclusivity might be extended by developing and patenting an associated pharmacogenomic test. This strategy will be termed 'genetic evergreening.'[39]

Insofar as it relates to genetic evergreening, a pharmacogenomics method claim does not occur in a vacuum, but in the context of an originator pharmaceutical company's attempt to extend its monopoly over drug X. Consequently, although Claim A speaks of 'a method for using drug X to treat a patient suffering from condition Y, it can be assumed that there is no novelty in drug X's use to treat condition Y(such use having been disclosed previously in drug X's base patent). Instead, the claim's novelty lies in the discovery that the safety and/or efficacy of this previously-known use of drug X can be improved by pre prescription genetic testing for marker Z. Having thus concluded that a pharmacogenomics method can be the subject of a valid patent, the next step is to consider whether such a patent will be infringed by the market entry of a generic equivalent of that drug. Infringement under the Patents Act can be classified under three main heads: direct infringement, infringement by authorization and contributory infringement. This section examines these three principles and their respective applicabilities in the genetic evergreening context. The bulk of the discussion is devoted to contributory infringement, since it is likely to be of most assistance to the genetic evergreener. In summary, therefore, a pharmacogenomics method patent is likely to provide an effective means of evergreening a drug under Australian law. In particular, such a patent is likely to be valid, despite the potential for objections on the 'law of nature', 'medical treatment method' and 'lack of threshold inventiveness' grounds.[40]

Evergreening through patent strategies allows the branded drug company to hold its exclusive right to market the drug. Secondary patents can thus act as a barrier to generic competitors. Hence this forces the generic manufacturers to choose between the options of simply waiting for all the patents to expire or enter into a legal battle and risk the associated costs and delays. No matter how much investment is made in improving the world's patent offices some patents will be granted which should not have been.[41] Governments should, hence, apply rigorous criteria of inventive step and thereby reducing the scope of speculative or strategic patenting.

https://digitalcollections.anu.edu.au/bitstream/1885/11418/1/Moir%20%26%20Palombi%20Patents%20and%20trademarks%202013.pdf Last Visited on January 10, 2014

[36] Id

[37] The Trans-Pacific Partnership Agreement: Implications for Access to Medicines and Public Health, UNITAID, World Health Organization, March 2014

[38] Lars Noah, 'The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients' Genetic Profiles' Vol. 43 Jurimetrics1-18, 2002

[39] John Altin, Pharmacogenomics: A New Frontier For The Evergreening Of Pharmaceutical Drugs, A thesis submitted for the Bachelor of Laws degree of the Australian National University October, 2007

[40] Id

[41] Scott Parker and Kevin Mooney, Is 'Evergreening' A Cause for Concern? A Legal Perspective, Vol. 13(4), Journal of Commercial Biotechnology, 235–243, 2007