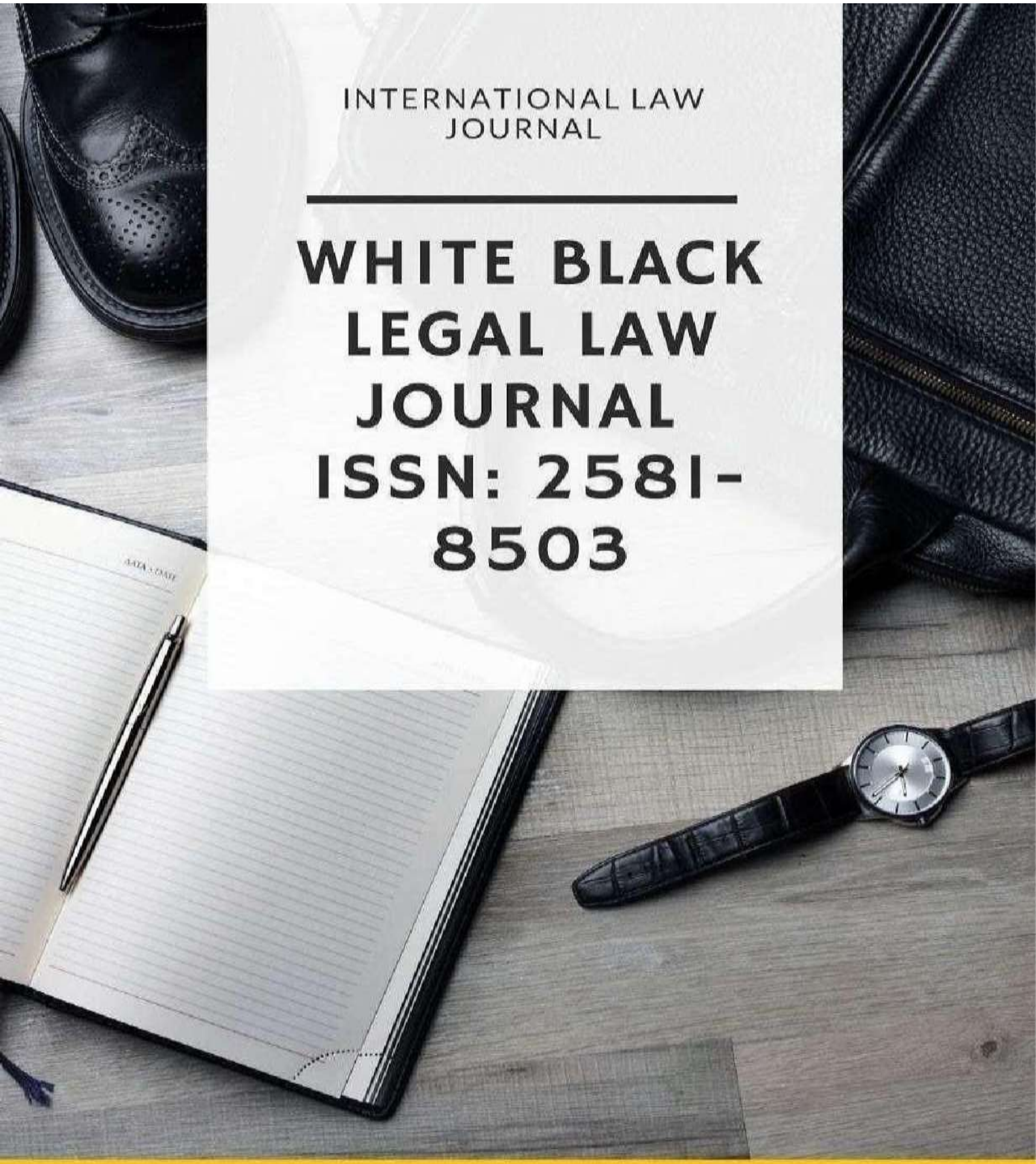

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## *ABOUT US*

WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal providededicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

# PHARMACEUTICAL PATENT AND EVERGREENING: WHERE DOES ONE DRAW THE LINE BETWEEN INNOVATION AND PROFITEERING?

AUTHORED BY - VARSHA BABU VATUL

No one can deny the extent to which the Pharmaceutical has progressed from, since the late 1850's where key conglomerates, such as Pfizer (1849); Bayer (1863); and Merck (1827)[1] made massive scientific headway during both world wars and were responsible for great scientific breakthroughs, such as discovery of Penicillin. India has been on a remarkable standing with respect to the regulations laid down by the TRIPS Agreement in 1995 and the Patent laws in the country underwent significant changes to keep stride with international standards. This led to an overhaul in understanding intellectual property and also the various ways it manifests under it – be it a patent or a trademark.

## Evergreening

To qualify for patenting of pharmaceutical innovations, it goes through the same criteria as many other inventions;-

i. Novel or Innovative
ii. Non obvious
iii. Practical and useful
iv. Capable of Industrial Application[2]

The WHO Commission on Intellectual Property, defined Evergreening as *"a term popularly used to describe patenting strategies when, in the absence of any apparent additional therapeutic benefits, patent holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term".*[3]

[1] Unknown, "History of the Pharmaceutical industry", (2020) https://pharmaphorum.com/rd/a_history_of_the_pharmaceutical_industry

[2] Correa, C., (2007) Trade related aspects of intellectual property rights: a commentary on the TRIPS agreement. OUP Catalogue. See World Trade Organization. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). Art. 27

[3] World Health Organization (2006) Public Health Innovation and Intellectual Property Rights. World Health

Evergreening, is a tacit methodology adopted by Pharmaceutical companies to renew their intellectual property claim over the drug/process by adding on newer elements but ironically do not substantially change the nature of the product to be innovative by mere improvement. Evergreening places a particular threat to accessibility of drugs as non-patented manufacturers do not necessarily overprice the drug owing of lower costs of production. However, patented drugs are priced higher to recover the costs invested into Research and Development (R&D) of the drug.

Evergreening practices lay down the following fundamental problems:-

i. Pharmaceutical products do not fulfil the test of novelty and innovation on the basis of mere improvement of a product/process of drug creation;
ii. They increase monopolization rights for an organization to appropriate the value of drug patented, which can have appreciable adverse economic consequences;
iii. Reduce access to larger masses, on the sheer basis of patenting of drug.

## Manifestation of Evergreening in the Pharmaceutical Industry

While the notion of Evergreening has been explained previously, the following would highlight the methodologies through which it is carried out. There are primarily four ways through which it is done –

**a) Evergreening on the basis of new compositionality of drugs[4]**

This would relate to the re patenting of the same drug but would reinforce a newer and improved version of formulation that would yield better results. However, this need not establish breakthroughs necessarily.

**b) Evergreening on combination of drugs**

To extend the longevity of the patent, manufacturers would create a new drug that is a synthesis of different compounds which are used to combat/treat the same disease.[5]

Organization.

[4] FM't Hoen, E., (2016) Private patents and public health: Changing intellectual property rules for access to medicines (Health Action International,2016)

[5] FM't Hoen, E., (2016) Private patents and public health: Changing intellectual property rules for access to medicines (Health Action International,2016)

**c) Patenting new application for an established Drug**

This would recall the usage of a patented drug in a completely new format, previously unestablished.[6] While many would argue that this would qualify as advancement in terms of scientific breakthroughs, one needs to remember that you cannot extend patenting of a drug, into a larger bracket when it is granted exclusivity via patent only for certain usage. Creating larger brackets for applicability of a drug component in multiple formats beats the ideation of exclusivity and inhibits fair competition with respect to drug sales.

Example:-

Viagra and Revatio was found to have versatile applicability and was subsequently advertised for the same by Pfizer. However both bear the same base compound known as *"Sildenafil Citrate"* and were discovered to treat Erectile Dysfunction and Pulmonary Artery based Hypertension respectively. There was no substantial breakthrough as much as an auxiliary conclusion that was reached, coincidentally during clinical trials.[7]

**d) Patenting of drugs for different administration format**

This would relate to renewing of patent owing to a different methodology of drug administration based on dosage format (Liquid or pills), frequency and efficacy. While this may have led to innovation, it lacks practicability to renew patents time and again for the sole reason on sheer improved administration.[8]

## Patent Laws in India regarding Evergreening of Pharmaceutical products

The Indian Patent Act amended itself in three phases following the years 1999, 2002 and 2005 to incorporate its allegiance to the TRIPS agreement. Certain provisions inserted, would lay as a counter balance to ensure that unfair practices would not take place in the granting of exclusive Intellectual

[6] FM't Hoen, E., (2016) Private patents and public health: Changing intellectual property rules for access to medicines (Health Action International,2016)

[7] Kappe, E., (2014) Pharmaceutical lifecycle extension strategies. In Innovation and Marketing in the Pharmaceutical Industry

[8] Ho, C.M., (2014) Should All Drugs Be Patentable: A Comparative Perspective. 17Vanderbilt Journal of Entertainment and Technology Law

Property.

**Section 3(d) of the Indian Patent Act, 1970** would state, *"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"*[9]

The above provision is used as a test, time and again to understand the extent of efficacy for a drug that is in the process of being patented. **Section 83**[10] would go on to give specific criteria's highlighting the general principles of a working patent. The following judgements lay great precedential value of the provisions as mentioned before.

**Novartis vs Union of India**[11]

The above is a landmark case that showcases the efficacy of Section 3(d) of the Indian Patents Act. In the year 2006, Novartis, a Pharmaceutical conglomerate would have applied for patenting of Imatinib Myselate, specifically for its beta structure for application in Chemotherapy and Cancer treatment however the IPAB (Intellectual Property Appellate Board) would reject the application. Novartis did not produce any substantive nor compelling evidence to showcase the efficacy of the beta form of the drug Imatinib Myselate, which at best was a derivative and not a new innovation. This led to Novartis contending the provision Sec 3(d) of the Patent Act 1970, being infringing on the provisions of the TRIPS Agreement. The Supreme Court, looked into the Zimmerman patent and later laid down that the drug did not pass the "Innovation Test" as laid down under Section 2 (1)(j)[12] and Section 2 (1) (ja)[13] of the Patent Act. Considering that the beta form of Imatinib Myselate is a polymorph of the same, it directly runs contravene to Section 3(d) where the court would have interpreted the term "Efficacy" to be that of "Clinical Efficacy" where Novartis would have to prove the ground breaking effects of the drug form in question. Seeing as it fails on both prongs of

[9] Section 3(d), Indian Patent (Amended) Act, 1970
[10] Section 83, Indian Patent (Amended) Act, 1970
[11] Novartis vs Union of India and ors., [2013] 13 SCR 148
[12] Section 2 (1) (j), Indian Patents Act, 1970
[13] Section 2 (1) (ja), Indian Patents Act, 1970

innovation and efficacy, the Supreme Court would uphold the ratio held by the Madras High Court in this instance.

**Boehringer Ingelheim v The Controller of Patents[14]**

In the case of Boehringer Ingelheim v The Controller of Patents, the Delhi High Court addressed the concept of *"plurality of inventions"* and the conditions for accepting a divisional application for an additional invention claimed in the parent application.

The Court emphasized that the determination of plurality of inventions revolves around the claims rather than the specification. The scope of the invention is defined by the claims, and even though they must be based on the specification, one can identify the invention by examining the claims independently. Unity or plurality of inventions and their formation into a single inventive concept should be assessed through a careful examination of the claims.

The crucial legal test established by the Court stated that if the subject matter of a divisional application is not present in the claims but only in the specification, the divisional application cannot be granted. This aligns with a fundamental rule of patent law, asserting that what is not claimed is considered disclaimed.

Applying this legal framework, the Court rejected a divisional application in this specific case. The original DPP IV inhibitor, though disclosed in the specification and mentioned in examples, was not claimed as a product in the parent application. The parent application exclusively contained method claims, while the divisional application sought claims for products (medicaments or their combinations). Consequently, the Court concluded that the parent application's claims did not encompass a plurality of inventions, leading to the denial of the divisional application. The court also upheld Section 3(d) interpretation strictly as well in this instance.

[14] Boehringer Ingelheim v The Controller of Patents

**Novartis vs Cipla**[15]

The Division Bench of the Delhi High Court had delivered a significant judgment with far-reaching implications for the Indian pharmaceutical industry, which is a major player in the production of cost-effective generic drugs and is poised to become a leading exporter of generic pharmaceutical products.

The case centres around a patent held by Novartis for the respiratory drug *Indacaterol*, used to treat *chronic obstructive pulmonary disease (COPD)* and marketed in India under the trademark ONBREZ. Cipla, an Indian pharmaceutical company, faced restrictions on selling products containing Indacaterol due to Novartis' patent. Cipla argued that as Indacaterol was not manufactured in India and was imported in limited quantities by another company, Lupin, it did not meet the patient demand in India. Additionally, Cipla contended that the price of Novartis' drug was significantly higher than its own.[16]

Cipla's defense included the assertion that it should be allowed to sell Indacaterol as Novartis was not effectively working the patent in India. They claimed that public interest should be a consideration in granting an injunction, and allowing it would not serve the demands of patients in India. Novartis countered by stating that even though the drug was not manufactured in India, it was being adequately worked through imports to meet the needs of COPD patients. The court rejected Cipla's statistics on COPD patients, stating that the number was large, and Novartis accused Cipla of bad faith for attempting to pass off Novartis' trademark in a previous suit.

The court held that patents are granted to encourage inventions on a commercial scale, and the patentee's rights should not be overlooked in the name of public interest. Importantly, the court clarified that a patent need not be worked in India through manufacturing; imports can also satisfy the working requirement. The court cited a previous decision, emphasizing that the key factor is the availability of a sufficient quantity of the drug through imports, not necessarily its local manufacture. In the specific case, the court determined that the extent of imports and whether it met the demands of COPD patients in India would be a matter of evidence at trial.

[15] Novartis vs Cipla, 2017 (70) PTC 80 (Del)
[16] Ankit Ratogi, "Cipla va Novartis AG", (2017), https://indiancaselaw.in/cipla-limited-v-novartis-ag-and-ors/

The court found that Cipla failed to prove that granting the injunction would be against public interest and had not effectively challenged the validity of the patent. Consequently, the Division Bench upheld the order restricting Cipla from selling Indacaterol, emphasizing the importance of protecting intellectual property rights in the pharmaceutical sector.[17]

## Conclusion

Considering all of the above, India has the unique juxtaposition to create a safe harbour for innovation incrementally while also being able to combat any contravent practices against fair markets and usages as per public policy. This robust system although in nascent stages, is sure to become a lot more robust in the coming years as India's economy develops. This would also lead to concurrent application of the competition act, 2002 to ensure that adverse economic practices are curbed in the spirit of granting monopoly over product or process patenting. Thus, it would only allow ownership and claim but not abuse of such rights by the owner of patent.



[17] Gautam Kumar, "Cipla vs Novartis: Import Qualifies as working of patent" (2017), https://www.mondaq.com/india/patent/598434/cipla-v-novartis-import-qualifies-as-working-of-patent