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Dolo Turn Gold: Evergreening Effect of Pharmaceuticals

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ABSTRACT

Creation of mind in today's world creates a global impact in various industries. Especially in space of pharmaceuticals whereby few minor modifications to the existing drugs helps the company to acquire patent rights without any legal difficulty. According to WTO Intellectual property rights are the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time. In India The Patents Act, 1970 provide security against evergreening effect but there is always an exception in law based on which we observed evergreening of drugs in recent case of DOLO. Whether the process behind the making of such drug can be patented? again a question arises. This research paper will analyze the effect of Patent, evergreening effect; considering DOLO as Case Study along with analyzing the evolution of history of IPR in India w.r.t the pharmaceutical industry in India. This research paper will try to analyze the current loopholes and ambiguities in law and to overcome the same. This research paper also emphasizes on the aspect that how can exploitation can be curbed with certain potential and sustainable solutions.

Keywords: *Intellectual Property Rights (IPR), Evergreening Effect, Indian Patent Laws, Sustainable Solutions, Critical Analyses.*

I. INTRODUCTION

Renaissance in Italy and special privilege which was provided while constructing of model mills to store grain led to the need of Laws that may govern Intellectual Property Rights (IPR). Initially inventions were kept secret in order to protect them later on due to exponential advancement in technology as the matter of National Prestige inventions were exhibited. In year 1867, Germany received the first genuine recognition as an industrial nation at an exhibition held at Paris. The conflict between United States of America and Germany led to the absence of USA from participating in Vienna Exhibition in 1873, in order to protect their inventions from German Nation. Hence came the Paris convention for protection of Intellectual Property Rights. In India during 1856 Act VI of on protection of invention based on the British Patent Law of 1852 was established. Whereby the manufacturers were provided certain privileges for

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 [ISSN 2581-5369]

14 years. In 1859, the Act was modified as Act XV in which making, selling, using of inventions in India and authorizing others to do so for 14 years from the date of filing the specifications. In 1872, the act was re-named as The Patents and Design Protection Act, in 1883 and then a modification in year 1888 followed by 1911. The Indian Patents and Designs Act of 1911 was the first comprehensive patent legislation in India. This act provided patent protection for inventions, including pharmaceuticals. However, the act had several limitations whereby the patent terms were relatively short, ranging from 5 to 14 years. The act did not provide for the grant of patents for "methods of treatment" or "medicinal substances."[2] In the post-World War II era, India began to engage with international organizations, such as the World Intellectual Property Organization (WIPO). This exposure led to increased awareness about the importance of patent protection for promoting innovation. The 1911 Act did not establish a centralized registry for patent applications. This led to confusion and difficulties in tracking patent applications. Also creating ambiguities in the registration process. Patent applications were not formally examined for novelty, inventiveness, or utility. This increased the risk of invalid patents being granted. The 1911 Act did not provide for product patents for pharmaceuticals. Only process patents were allowed, which limited the scope of protection for pharmaceutical inventions. The Act did not provide for the grant of patents for methods of treatment, which limited the scope of protection for medical inventions. The 1911 Act did not provide for compulsory licensing, which would have allowed the government to grant licenses to third parties to exploit a patented invention in certain circumstances. The Act provided limited remedies for patent infringement, including damages and injunctions. However, the remedies were not always effective in preventing infringement. The 1911 Act did not provide for international cooperation in the field of patents, which limited India's ability to participate in international patent systems. These shortcomings limited the effectiveness of the 1911 Indian Patents and Designs Act and hindered the development of India's patent system. The Act was eventually repealed and replaced by the Patents Act, 1970, which addressed many of these limitations. India's association with BIRPI (United International Bureaux for the Protection of Intellectual Property) and WIPO (World Intellectual Property Organization) played a significant role in shaping India's patent laws and providing safeguards to the pharmaceutical sector. India became a member of BIRPI in 1947 and later joined WIPO in 1975, when BIRPI merged with WIPO. Membership in these organizations exposed India to international best practices in intellectual property protection. India's association with BIRPI

[2] THE INDIAN PATENTS AND DESIGNS ACT,1911
(ipindia.gov.in/history-of-indian-patent-system.)

 [ISSN 2581-5369]

and WIPO influenced the development of Indian patent laws, particularly the Patents Act, 1970. This act introduced significant changes to India's patent system which includes introduction of "Process Patents". It also provided for limited product patents, which restricted the scope of protection for pharmaceutical products. Along with compulsory licensing provisions, allowing the government to grant licenses to third parties to produce patented medicines in certain circumstances. The Patents Act, 1970, enabled Indian pharmaceutical companies to produce affordable generic medicines, increasing access to essential medicines for the Indian population. This act also encouraged domestic innovation in the pharmaceutical sector by providing a framework for process patents and limited product patents. India's membership in WIPO allowed the country to take advantage of flexibilities in patent laws, such as compulsory licensing, to address public health concerns. India's membership in WIPO helped the country navigate the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement, which introduced stricter intellectual property standards. "Evergreening" is a practice where pharmaceutical companies extend the life of a patent by making minor modifications to the original invention. The TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement, which came into effect in 1995, has had a significant impact on the pharmaceutical industry. While the agreement aimed to strengthen intellectual property protection, it also introduced measures to prevent "evergreening". The evergreening is an emerging challenge in the current world w.r.t pharmaceuticals industry whereby certain drugs which already exists whereby minor modifications of those drugs increases the patent tenure. Along with-it certain modifications are made in already existing Medicines whereby minor modification in the compositions of drugs or by just increasing the power of the drug by certain Mg (Milli Grams). India's Supreme Court made a landmark decision, refusing to grant Novartis a patent for its cancer drug Gleevec (imatinib mesylate), also known as Glivec. Novartis argued that the new version of the drug was more easily absorbed into the blood, making it a significant improvement in treating leukemia. However, India's trade and industry minister, Anand Sharma, defended the decision, stating that it was justified under Indian law, which does not allow "evergreening" - the practice of extending patent life through minor modifications. Whereby it was held by Supreme Court of India that evergreening is not legal in India especially when the drug is that important that it should be available for generic purpose and on low rates. Although the efficiency is very much important because in that case the drug becomes very much important to be manufactured by same manufacturer.[3]

[3] *Novartis AG v. Union of India & Others (Supreme Court of India, 1 April 2013)* Prepared by UNCTAD's Intellectual Property Unit Also available at https://main.sci.gov.in/jonew/judis/40212.pdf, The key takeaways

II. CRITICAL ANALYSIS ON DOLO-650

Bengaluru-based Micro Labs, which makes drugs for cardiac diseases, diabetes, ophthalmology, dermatology, and pain management, among others. The company, with annual revenues in excess of Rs 4,000 crore, runs 17 manufacturing facilities across the country and also runs operations across 50 countries. But what has catapulted Company to national fame over the last few years is a small tablet, which costs Rs 30 for a pack of 15, and has emerged as a choice for physicians during the third wave of Covid-19 in the country. The Dolo-650 tablet, a successor to the Dolopar tablet, contains paracetamol, which prevents the release of prostaglandin, which causes sensations of pain, inflammation, and fever; it also reduces body temperature in cases of fever. By many estimates, Micro Labs has sold over 350 crore tablets of Dolo-650 since the Covid-19 outbreak in 2020, earning revenues of Rs 400 crore in a year. Micro Labs sold about 7.5 crore strips of Dolo-650 annually before the pandemic began, according to market research firm IQVIA. A year later, that increased to 9.4 crore strips, before touching 14.5 crore strips, almost double the 2019 figure, by the end of 2021. That's perhaps why, since the Covid-19 pandemic began, Micro Labs has seen its revenues and profits skyrocket, and it isn't likely to subside anytime soon, especially since the tablet has become one of the most common choices of medication for Covid-19 symptoms. Between March 2019 and March 2021, its revenues have jumped 25 percent and profits 244 percent. Almost 60 percent of the company's revenue comes from the domestic market.[4] Crocin, a popular pain reliever medication in India, typically contains 500mg of paracetamol. DOLO 650, on the other hand, contains 650mg of paracetamol. By increasing the dosage strength, the manufacturer, Micro Labs, may have aimed to provide a more effective pain relief option for patients. However, as you astutely pointed out, the active ingredient remains the same, which raises interesting questions about the patentability and innovation aspects of DOLO 650. This scenario is often referred to as "evergreening" or "patent thickening," where a company makes minor

from this case are:

- Enhanced Efficacy: The court emphasized that enhanced efficacy refers to therapeutic efficacy, not just physical or chemical properties.
- Section 3(d): This section of the Indian Patents Act requires that new forms of existing substances must demonstrate significantly enhanced efficacy to be patentable.
- Evergreening: The court's decision reinforces India's stance against evergreening, ensuring that patents are granted only for genuine innovations.

The interpretation of the term "efficacy" will be decisive in this context. TRIPS leaves Members free to define efficacy in a broader sense (including non-therapeutic/physical efficacy, such as improved methods of drug administration) or in a narrow sense, as applied by the Indian Supreme Court (limiting the definition to therapeutic efficacy). Many drug derivatives will pass a broad test of physical efficacy, while failing a test of therapeutic efficacy.

[4] Read on "https://www.ipa-india.org/article/how-micro-labs-struck-gold-with-dolo-650-during-covid-19/"

modifications to an existing product to extend patent life and maintain market exclusivity.[5] While Micro Lab's success with Dolo 650 is impressive, it also raises questions about the evergreening effect in the pharmaceutical industry. Dolo 650's patent exclusivity contributed to its success. However, this also highlights the potential for evergreening, where pharmaceutical companies employ strategies to extend patent life and maintain exclusivity.

- **Higher prices:** By maintaining market exclusivity, Micro Labs charges higher prices for DOLO-650, making it less accessible to price-sensitive consumers. These challenges clearly states that price-sensitive consumers will be impacted in long run of the same.

- **Limited generic competition:** The lack of generic competition limit choices for consumers and reduce the incentive for manufacturers to innovate or reduce prices. Limited competition can reduce the incentive for innovation, as the originator company may not face pressure to improve the medication or develop new treatments. Limited generic competition can exacerbate health inequities, as patients who cannot afford the originator medication may be forced to go without treatment or seek alternative, potentially less effective, options.

- **Misleading marketing:** Consumers might be misled into believing that DOLO-650 is a significantly improved product, rather than a minor modification, leading to unnecessary spending. Exaggerating the benefits of the 650mg dosage strength compared to the 500mg version, creating the impression that DOLO-650 is a significantly improved product. Whereby both plays an equal role the difference is very minimal. Suggesting that DOLO-650 is a new or innovative product, when in fact it is a minor modification of an existing medication which can also be termed as implying innovation. Selectively presenting or misinterpreting clinical trial data to create the impression that DOLO-650 is more effective or safer than other paracetamol products. Using marketing tactics that create fear or anxiety about pain or fever management, making consumers more likely to choose DOLO-650 over other options as it is observed that DOLO-650 is given by every pharmacist when asked for pain relief or fever relief medication eliminating other options. Directing marketing efforts towards vulnerable populations, such as the elderly or those with limited health literacy, who may be more susceptible to misleading claims.

- **Reduced access to affordable alternatives:** Patent thickening/evergreening can limit access to affordable generic alternatives, exacerbating health inequities and reducing access to

[5] Crocin's active ingredient and dosage strength:
- Cipla's official website: (search for Crocin)
- MedlinePlus: (search for Paracetamol/Acetaminophen)

 [ISSN 2581-5369]

essential medicines. Unaffordable medication can lead to reduced adherence, compromising treatment outcomes and potentially worsening health conditions.

Even after the covid-19 wave consumption of DOLO-650 has not reduced instead it is the common medicine whereby majority of people when they get fever, they consume Dolo-650 to cure the same. Medical pharmacist uses the same Dolo in various compositions that they provide to the persons.

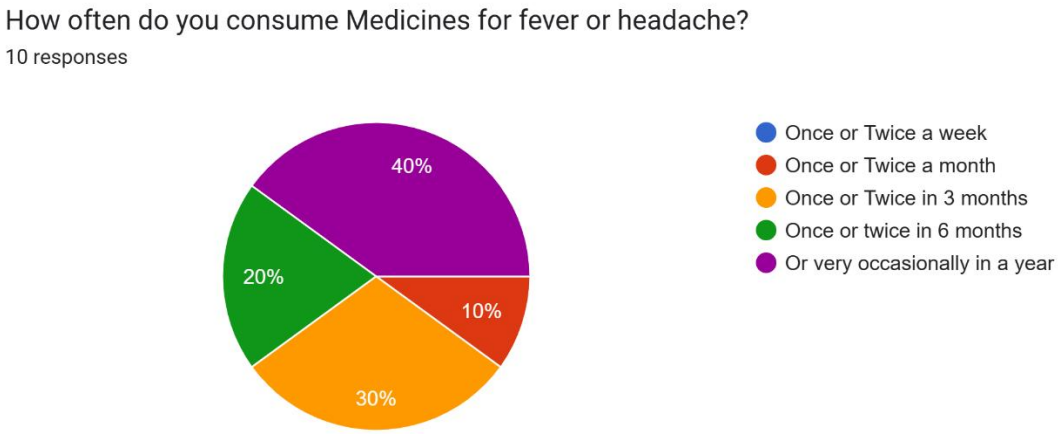

Figure 1: Frequency of consumption of paracetamol drugs[6]

Here in the above figure, we can observe that how out of 10 people 6 people consume paracetamol drugs often within 6months which proves the importance of paracetamol drugs in India.

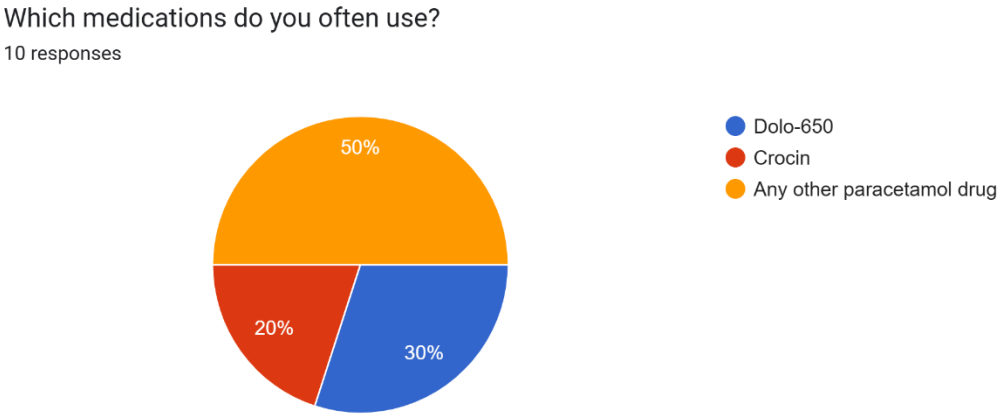

Figure 2: Out of the most consumed medicine for fever and headache 30 percent people consumes DOLO-650 tablets.[7]

[6] A survey conducted by researcher considering wide range age groups https://docs.google.com/forms/d/1Xn-ZKrlwd_WlzYVmZ4A_MKaj8s0O8z-jqMJsp7Amx_w/edit#responses

[7] A Survey conducted by researcher consider different age group of people as a sample

What we can observe here is that 30 percent people are consuming DOLO-650 in case of fever or headaches that means a big market size is captured by DOLO-650.

Regular consumption of DOLO-650 can lead to a cumulative effect, where the liver is consistently exposed to higher levels of paracetamol, increasing the risk of liver damage.[8] High-dose paracetamol may increase the risk of bleeding, particularly when combined with other medications that affect blood clotting. Individuals who consume alcohol regularly may be more susceptible to liver damage from high-dose paracetamol. People with malnutrition may have impaired liver function, making them more vulnerable to liver damage from high-dose paracetamol. High-dose paracetamol may increase the risk of adverse effects in pregnant or breastfeeding women. [9]

III. LOOPHOLES AND AMBIGUITIES

Under section 3(d) of The Patents Act, 1970 provides protection w.r.t evergreening of pharmaceuticals patents but it also imposes certain ambiguities and disparity in existing legislation. Whereby new form of substance is invented for patenting. Unless these new forms significantly enhance the "known efficacy" of the substance. The other aspect is new properties or uses of known substances whereby certain changes leads to change in properties of the substance. Unless these new properties or uses result in a new product or employ at least one new reactant. Along with-it similar processes, machines, or apparatus should not be used again as patenting to avoid evergreening of pharmaceuticals exception to the same is unless these known processes result in a new product or employ at least one new reactant. The exceptions discussed here provides the loopholes which depends on the discretion of court if challenged and also on the interpretation.

- **Lack of Clarity on "Significantly Enhanced Efficacy"**

The term "significantly enhanced efficacy" is not clearly defined in the Patent Act, leading to subjective interpretations. This ambiguity creates uncertainty for patent applicants, examiners, and courts, making it challenging to determine whether a new form of a known substance meets this criterion.

- **Ambiguity Around "New Properties or Uses"**

The Act does not provide clear guidelines on what constitutes a genuinely new property or use of a known substance. This ambiguity leaves room for patent applications based on minor

https://docs.google.com/forms/d/1Xn-ZKrlwd_WlzYVmZ4A_MKaj8s0O8z-jqMJsp7Amx_w/edit#responses

[8] See "National Kidney Foundation" report.

[9] See report "Paracetamol use in breastfeeding" by the Australian Breastfeeding Association

 [ISSN 2581-5369]

modifications, such as:

New indications or uses that are not substantially different from existing ones instead of chloride using bromide or any other halogen which is actually not creating much difference in efficacy. Minor changes to the dosage form, delivery mechanism, or packaging. Combinations of known substances that do not demonstrate synergistic effects

- **Unclear Definitions of "New Product" and "New Reactant"**

The terms "new product" and "new reactant" are not clearly defined in the Act, leading to confusion and inconsistent application of the law. For instance:

What constitutes a "new product"? Is it a new chemical entity, a new formulation, or a new dosage form?

What is a "new reactant"? Is it a new chemical compound, a new intermediate, or a new catalyst? Whether the catalyst or new reactant used is creating a different product also creating a visible change in efficacy.

Exceptions for Derivatives of Known Substances

The explanation provided in the Act lists various derivatives (e.g., salts, esters, ethers) that are considered the same substance unless they differ significantly in properties regarding efficacy. However, this creates a loophole for applicants to argue that their derivative is significantly different, despite being a minor modification.

For example:

A patent applicant may argue that a new salt form of a known substance has improved bioavailability or stability, even if the difference is minor. An applicant may claim that a new ester derivative has enhanced efficacy or reduced side effects, even if the evidence is limited or based on minor modifications.

These loopholes and ambiguities can be exploited by patent applicants to obtain patents that do not meet the required standards, leading to evergreening and limiting access to affordable medicines.

There are various landmark case laws which raised the same concern w.r.t definitions some of those are:

Novartis AG v. Union of India (2013)

The Supreme Court of India rejected Novartis' patent application for Glivec, citing Section 3(d) of the Patent Act. The court held that the new form of the substance (beta-crystalline form) did

not demonstrate significantly enhanced efficacy.[10]

Bayer Corporation v. Union of India (2013)

The Intellectual Property Appellate Board (IPAB) revoked Bayer's patent for the anti-cancer drug Sorafenib, citing lack of inventive step. The IPAB held that the patent application did not demonstrate a significant enhancement in efficacy.[11]

Pfizer Products Inc. v. Rajesh Kumar (2013)

The Delhi High Court revoked Pfizer's patent for the drug Sildenafil (Viagra), citing Section 3(d) of the Patent Act. The court held that the new form of the substance (sildenafil citrate) did not demonstrate significantly enhanced efficacy.[12]

Roche Products (India) Pvt. Ltd. v. Cipla Ltd. (2015)

The Delhi High Court allowed Cipla to manufacture and sell a generic version of Roche's anti-cancer drug Tarceva. The court held that Cipla's product did not infringe Roche's patent, citing lack of clarity on the patent claims.[13]

Merck Sharp & Dohme Corp. v. Glenmark Pharmaceuticals Ltd. (2015)

The Bombay High Court allowed Glenmark to manufacture and sell a generic version of Merck's diabetes drug Sitagliptin. The court held that Glenmark's product did not infringe Merck's patent, citing lack of clarity on the patent claims.[14]

These case laws highlight the concerns around ambiguities and loopholes in the Indian Patent Act, particularly with regard to Section 3(d) and the definition of "inventive step". Inventive step refers to the requirement that a patent application must demonstrate a non-obvious improvement or innovation over existing technology or knowledge. In other words, the invention must be significantly different from what is already known or available. The Indian Patent Act defines inventive step as a "feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both" whereby it is

[10] "*Novartis AG vs Union of India 2013*" Supreme Court of India 1st April 2013 Also see Annex 2 of United Nations Trade and Development (UNCTAD) website https://unctad.org/ippcaselaw/sites/default/files/ippcaselaw/2020-12/Novartis%20AG%20v.%20Union%20of%20India%20%26%20Others%20Indian%20Supreme%20Court%202013_0.pdf

[11] *"Bayer Corporation Vs. Union of India and Others"* (Bayer v. Natco) Before the Indian Intellectual Property Appellate Board (IPAB) Decision Date: 04.03.2013 Also see summary prepared by Prepared by UNCTAD's Intellectual Property Unit

[12] *"Pfizer Products Inc. v. Rajesh Kumar (2013)",* SC website

[13] *"Roche Products (India) Pvt. Ltd. v. Cipla Ltd. (2015*)", SC website

[14] High Court of Delhi, India [2015]: *Merck Sharp & Dohme Corpn. v Glenmark Pharmaceuticals, FAO(OS) 190/2013*
See http://164.100.69.66/jupload/dhc/SRB/judgement/06-07-2015/SRB20032015FAOOS1902013.pdf

open to interpretation. The Act does not provide clear guidelines on what constitutes a "technical advance" or "economic significance". This ambiguity leads to inconsistent application and subjective judgments. The ambiguity surrounding inventive step creates uncertainty for patent applicants, examiners, and courts. The lack of clear guidance leads to inconsistent decisions, which can be frustrating for stakeholders. The ambiguity can compromise patent quality, as patents may be granted or rejected based on subjective interpretations rather than objective criteria. In conclusion, the concept of inventive step in the Indian Patent Act is not properly defined, leading to ambiguity, inconsistent application, and subjective interpretations. This can have significant consequences for patent applicants, examiners, and courts, ultimately compromising patent quality which in return also leads to evergreening.

IV. RECOMMENDATIONS

1. Clarifying and Refining Definitions:

By providing explicit explanations which will include detailed explanations and examples to illustrate the intended meaning of each definition. Profound elaboration of specific terms in the Illustrations. Also using precise language while avoiding use of vague or open-ended terms that can be misinterpreted. Again, it is equally important to define key terms so that clear definition key terms and phrases are used in the definitions to prevent confusion.

2. Establishing Clear Guidelines and Criteria:

Developing of guidelines to create guidelines that outline the criteria for assessing inventive step, novelty, and non-obviousness. Providing examples w.r.t to certain inventions whereby including examples of inventions that meet or do not meet the criteria to help illustrate the guidelines. Ike certain pharmaceutical drugs how they were produced and what modification help them to get new patent. Establishing a framework whereby developing a framework for evaluating patent applications that ensures consistency and transparency.

3. Implementation Mechanism for Consistent and Transparent Evaluation Process:

Specialized Training program examiners, to provide training to patent examiners to ensure that they understand the refined definitions and guidelines to create a better interpretation skill. Using a standardized evaluation process so that we may implement a standardized process for evaluating patent applications to ensure consistency and transparency. Providing feedback mechanisms whereby establishing the mechanisms for applicants to receive feedback on their

 [ISSN 2581-5369]

applications and for examiners to receive feedback on their evaluations. Rather to create a separate feedback portal.

4. Reviewing and Revising Definitions Periodically considering the change in pharmaceutical industry:

Regularly reviewing definitions so that the periodical review ensure that they remain clear and effective and in consideration of the change. Revise definitions should be made specific so that the interpretation of it does not create any ambiguities.

5. Strengthening Patent Laws and Enforcement:

Amendment under Section 3(d) of the Indian Patents Act should provide a specific clarification of the definition of "inventive step" to prevent trivial modifications from being patented. Enhancing patent examination so that it ensures that the patent examiners receive regular training to identify and reject frivolous patent applications. Also making patent applications and examination processes more transparent to facilitate public scrutiny and opposition/objections.

6. Addressing Public Health Concerns:

Prioritizing public healthcare to ensure that patent laws and policies prioritize public health concerns, particularly for essential medicines. Also, Compulsory licensing shows that implementation of compulsory licensing mechanisms to allow generic manufacturers to produce patented medicines during public health emergencies.

7. International Cooperation and Knowledge Sharing

Collaboration with international organizations/working with organizations like the World Health Organization (WHO) and the World Intellectual Property Organization (WIPO) to share best practices and address global health concerns along with their recommendations through various Reports. Encouraging collaborative research and development efforts between Indian pharmaceutical companies, academia, and international partners to develop new and innovative medicines with generic options or affordable options.

8. Defining the Therapeutic Efficacy profoundly:

So, that it explains the ability of the new form to produce a desired therapeutic effect, such as reducing symptoms, improving quality of life, or increasing survival rates. Considering Pharmacokinetic Parameters whereby the new form's absorption, distribution, metabolism, and excretion (ADME) properties, which can impact its efficacy are calculated accordingly. Pharmacodynamic Parameters should be added in a way that the new form's mechanism of action, receptor binding affinity, and potency, which will influence its efficacy. Conducting

 [ISSN 2581-5369]

clinical trials and creating Clinical Endpoints so that the new form's ability to achieve specific clinical endpoints, such as improved blood pressure control, reduced blood glucose levels, or enhanced tumor response should be considered accordingly.

9. Creating Quantitative and Qualitative Measures:

Quantitative Measures: Using numerical values to assess efficacy, such as:

- Percentage change in symptom severity
- Mean change in biomarker levels
- Response rates (e.g., complete response, partial response)

Qualitative Measures: Use descriptive measures to assess efficacy, such as:

- Patient-reported outcomes (e.g., improved quality of life)
- Clinician-assessed outcomes (e.g., improved disease control)
- Observational studies (e.g., real-world evidence)

10. Creating Comparative Analysis:

To conduct comparative studies so that head-to-head comparisons between the new form and existing forms of the known substance is considered. Conducting systematic reviews and meta-analyses of existing studies to assess the efficacy of the new form.

11. Composition and Mechanism of Action

To know that what are the "Active Ingredients"/ "Drug Composition", Mode of Action, Usage based on which one can determine that whether the Inventive Step is involved or not. Mere Increase in the "power of drug (i.e. mg)" and slight change in usage or effect will not cause a drug to be termed as a "New Invention" under Indian Patent Act, 1970;

Active Ingredient:

Dolo-650 contains "Paracetamol (also known as Acetaminophen)"as its key therapeutic component, with each tablet comprising 650 mg of the drug. Paracetamol is widely recognized for its ability to reduce pain and lower fever.[15]

Chemical Profile:

The molecular formula of "Paracetamol is $C_8H_9NO_2$". It belongs to the class of aniline derivate-

[15] Official Website of Apollo Pharmacy Depicting Image of Dolo-650 Wrapper; https://www.apollopharmacy.in/otc/dolo-650mg-tablet-15-s?srsltid=AfmBOoqCoxy6zUnUC3aNEYMbLG4SX7pUYgfurbCcb5T1L1iPHj2Gll2s

ives and is categorized as an analgesic and antipyretic agent. Unlike non-steroidal anti-inflammatory drugs (NSAIDs), Paracetamol does not possess significant anti-inflammatory properties.[16]

Mode of Action

Paracetamol primarily works by inhibiting the synthesis of prostaglandins, chemicals in the body that contribute to pain and fever. It is believed to exert its effects mainly through selective inhibition of the COX-3 enzyme in the central nervous system, which enhances its pain-relieving and fever-reducing capabilities without affecting peripheral inflammation.[17]

V. CONCLUSION

The case of Dolo-650 offers a compelling lens through which the broader issue of evergreening in the pharmaceutical industry can be examined. While on the surface, Dolo-650 may appear to be an innovation, a deeper analysis reveals that it represents a strategic repositioning of an existing molecule Paracetamol through a mere increase in dosage strength from the standard 500 mg to 650 mg. Despite its commercial success, particularly during the COVID-19 pandemic, Dolo-650 does not demonstrate the degree of innovation required under Indian patent law to qualify as a *New Invention*.

The core issue lies in the *exploitation of legal ambiguities* especially those in Section 3(d) of the Indian Patents Act, 1970. This section was designed to prevent trivial modifications from being treated as patentable inventions unless they show a significant enhancement in therapeutic efficacy. However, due to lack of precise legal definitions for terms like "significant efficacy," "new product," or "new reactant," companies can present minor variations as substantial improvements to secure or extend market exclusivity. This dilutes the spirit of innovation and leads to limited access to affordable generic medications, especially in a country like India where healthcare affordability is crucial.

As illustrated in the Dolo-650 example, the active ingredient (Paracetamol), chemical composition ($C_8H_9NO_2$), and mechanism of action (COX-3 inhibition) remain unchanged. A slight increase in dosage does not alter the therapeutic mechanism or provide substantial additional benefits to the patient. This underscores the principle that mere changes in dosage

[16] Official Website of Apollo Pharmacy Depicting Molecular Formula of Paracetamol 500 mg; https://www.apollopharmacy.in/medicine/paracetamol-500mg-tab-1000-s?srsltid=AfmBOor8Ug_5dpktNmANDy1nNLJqinwdsvdBInyEy6VZKVXaj2xIhTjw

[17] Official Website of Yashoda Hospitals; https://www.yashodahospitals.com/medicine-faqs/dolo-650/

 [ISSN 2581-5369]

strength, formulation, or delivery mechanism—without demonstrable enhancement in clinical efficacy—do not constitute genuine innovation.

Furthermore, the ethical ramifications of such practices are significant. By promoting a product as newer or better based solely on a dosage increase, companies engage in misleading marketing, often targeting vulnerable populations. This not only compromises consumer choice but also reinforces healthcare inequality by keeping prices elevated through artificial exclusivity.

The Indian judiciary, through landmark cases like ***Novartis AG v. Union of India (2013)*** **and** ***Bayer v. Union of India (2013)***, has taken commendable steps to uphold the integrity of the patent system and resist evergreening tactics. However, as this research shows, implementation gaps and interpretative ambiguities still persist, allowing companies to navigate around regulatory intent.

Final Remarks

To curb evergreening and ensure a robust patent regime:

A. Legislative clarity must be introduced regarding the definitions of "efficacy," "inventive step," and "therapeutic benefit."

B. Patent examiners should be equipped with better training and structured evaluation guidelines to assess incremental pharmaceutical claims.

C. Public health interests should remain central to any innovation-related decisions, and compulsory licensing mechanisms must be strengthened and readily deployable.

D. In conclusion, innovation must be distinguished from modification. The pharmaceutical industry thrives on genuine breakthroughs, not on the strategic repackaging of old molecules. As demonstrated by Dolo-650, minor adjustments to drug properties such as dosage or non-functional derivatives cannot and should not be granted new patent protection, as they do not satisfy the statutory and ethical standards required for recognition as a new invention. Upholding this principle is essential not only for ensuring equitable access to medicines but also for sustaining the credibility and purpose of the patent system.

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 [ISSN 2581-5369]

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 [ISSN 2581-5369]