## **Evergreening Strategy: Extending Patent Protection, Innovation or Obstruction?**

"Evergreening" in the context of intellectual property (**IP**), especially in the field of patents, refers to a strategy that companies often use to prolong their commercial exclusivity. This strategy is particularly common in the pharmaceutical industry, where companies secure patents for minor modifications, improvements, or new applications of existing products. Often, these patents are based not on entirely new technical solutions but rather on minor changes to previously protected products or processes. The purpose of these modifications is to extend patent exclusivity without the necessity to create a completely new product.

"Evergreening" has become a heated, controversial topic. Supporters, often from within the pharmaceutical industry, argue that it encourages innovation and allows companies to recoup their research and development costs. However, opponents, including consumer groups and healthcare advocates, contend that it stifles competition, elevates drug prices, and restricts access to affordable treatments.

What are the advantages and disadvantages of "evergreening"? Which fields can apply "evergreening" strategies? This discussion will also cover the benefits and challenges of "evergreening" in the pharmaceutical field. Furthermore, we will explore how Vietnamese law regulates this issue. KENFOX IP & Law Office will provide analysis and interpretation to help IP rights holders and related parties understand and shape their IP protection strategy in Vietnam in an appropriate and legal manner.

# 1. "Evergreening": Improving or Blocking the Path to Innovation?

Evergreening is a widely debated topic in <u>the pharmaceutical industry</u> and other technology sectors, eliciting conflicting opinions from various interest groups, namely:

#### 1.1. Advantages:

- Encouraging continuous innovation: "Evergreening" ensures that companies have the incentive to
  invest in incremental improvements by providing patent protection, which helps recoup research and
  development costs. This promotes ongoing enhancements to existing products.
- **Improving product quality**: Evergreening initiatives often lead to enhanced product efficacy and safety, such as by reducing side effects or improving dosage management. These improvements can directly benefit consumers by increasing treatment effectiveness and comfort.
- **Economic investment protection**: Pharmaceutical companies must spend billions of dollars on research and development of new products. Evergreening ensures they have sufficient time and resources to recoup these investments, supporting continuous innovation and product quality improvement.

#### 1.2. Disadvantages:

- Interfering with competition: "Evergreening" may restrict fair competition by preventing the market entry of more affordable generic products. This practice can keep drug prices high and limit consumer choices
- Rising healthcare costs: High drug prices, maintained by blocking generic products, directly increase
  overall healthcare costs. This impact is particularly critical for public health systems and low-income
  patients.
- **Limiting real innovation**: While "evergreening" may spur ongoing minor enhancements, it often leads companies to focus solely on incremental improvements to extend patent protection, rather than pursuing new, groundbreaking innovations. This shift can stifle the development of significant and transformative breakthroughs.
- **Ethical issues**: There are concerns that "evergreening" constitutes an abuse of the patent system by extending exclusive rights without substantial contributions to science or society, which could be considered unethical.

# 2. Evergreening: In Which Fields Is It Applied?

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"Evergreening" is a strategy that can be applied in many different sectors, although it is most commonly associated with the pharmaceutical industry. Below are some areas where evergreening is utilized:

- [i] **Pharmaceutical industry**: This is the most common area for "evergreening", where companies extend patent rights to drugs through improved formulations, new methods of use, or combinations of active ingredients.
- [ii] **Technology and software**: In the technology sector, companies can use evergreening by regularly updating or upgrading <u>software and technology</u>. These improvements not only enhance the product but also help extend the life cycle of relevant patents.
- [iii] **Medical devices**: Similarly to the pharmaceutical industry, evergreening in the medical device sector may involve inventing improvements to existing devices, such as enhanced designs, materials, or software.
- [iv] **Consumer electronics industry**: Companies that manufacture consumer electronics products, such as smartphones and computers, can use "evergreening" to extend product life cycles through hardware updates and software updates.
- [v] **Chemical products and materials**: In the chemical industry, "evergreening" may involve inventing new formulations, developing innovative production methods, or discovering new applications for existing chemicals or materials.
- [vi] **Food and agriculture**: In the agricultural sector, "evergreening" may involve developing new plant varieties, improving farming methods, or advancing food preservation technologies.

In the above fields, evergreening is used as a method to increase commercial value and prolong product or technology exclusivity. However, it also faces significant criticism for creating barriers that restrict competition and innovation.

## 3. "Evergreening" In the Pharmaceutical Field: What Are the Benefits and Challenges?

A company may patent a new drug and then, just as the original patent is about to expire, receive a patent for an improved version of that drug, such as a new production method, a new dosage form, or a different dosage. Although these improvements might be minor, they can extend the company's monopoly in the market. Below are some evergreening tactics used to extend the exclusivity period of inventions in the pharmaceutical field

- **Pharmaceutical innovation**: Pharmaceutical innovation often involves changing the dosage form of a drug, such as converting tablets to liquids, or developing a delayed-release version of the drug.
- **Drug Combination**: Creating a new product by combining an existing active ingredient with one or more other active ingredients, and then patenting this combination.
- **New indications**: inding a new application for a previously approved drug and applying for a patent for this new use.

#### 4. Evergreening: How Does Vietnamese Law Regulate It?

Vietnam's IP law has not established any regulations that prohibit owners from developing and improving existing technical solutions and registering them for intellectual property protection, as long as the improvements meet the statutory standards for patent protection. In other words, the "evergreening" tactic is still legal in Vietnam. If an effective and well-directed "evergreening" strategy is implemented, patent owners can achieve extended protection for their technical solutions and prolong the exclusivity period beyond what is offered by the original patent alone.

However, it's important to note that with the evergreening strategy, changes or improvements, no matter how minor, must still meet the basic patentability requirements: they must be novel, non-obvious, and not merely common knowledge. Preferably, they should represent a significant technical and economic advancement to warrant a new patent. Otherwise, new applications may be <u>refused</u> due to lack of novelty and inventiveness, as previously disclosed by the original patent, leading to a waste of time and resources. Furthermore, related parties can utilize the "<u>opposition</u>" or "invalidation" mechanisms to challenge or invalidate a patent, even after it has been registered in Vietnam

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Therefore, patent holders should carefully weigh the benefits and risks before deciding to adopt an evergreening strategy.

#### **Final thoughts**

It seems that the struggle to redefine the boundary between "innovation" and "fair competition" will become increasingly fierce in industries that rely on patents. Experts predict that relevant parties will increasingly resort to legal tactics such as filing for "opposition" or "invalidation of patents" to protect their interests. This not only sparks lengthy legal battles but also consumes significant time and resources, plunging companies and inventors into a vicious cycle of disputes and litigation. Whether there is a way to balance innovation with fair competition remains an unanswered question.

For effective protection of your invention in Vietnam, please contact KENFOX IP & Law Office. Our team, with extensive practical experience and expertise in intellectual property law, is committed to providing accurate advice and dedicated service, ensuring your invention is fully protected against legal challenges in Vietnam.

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