#### Cannabis and Pharmaceutical Inventions in Vietnam: To Protect or To Reject?

In many developed nations, pharmaceutical products containing active ingredients extracted from cannabis are ushering in a new era of treatment for conditions ranging from epilepsy and chronic pain to supportive cancer therapy. Inventions in this field are continuously being granted patents in the **United States**, **Europe**, and **Japan**. In a global context witnessing a profound shift in the perception of medical cannabis, a critical legal question arises in Vietnam: Why is a trend considered a medical innovation in many parts of the world impeded by what is deemed "contrary to social ethics and public order" under Article 8.1 of the Intellectual Property Law? Does the Vietnamese legal system have specific grounds for this strict interpretation and application of the provision, and what are the implications for the future of the domestic pharmaceutical industry?

KENFOX IP & Law Office provides in-depth analysis of the current regulations and offers recommendations concerning the protection of inventions containing cannabis in Vietnam.

### **Legal Basis**

To understand why the path to <u>patent protection</u> for pharmaceutical inventions containing cannabis is effectively barred in Vietnam, it is necessary to examine a legal mechanism arising from two distinct yet mutually reinforcing statutes: (i) the specialized law on narcotics control and (ii) an overarching principle of the Intellectual Property Law.

## The Specialized Law on Narcotics Control: Cannabis as a Substance Absolutely Prohibited in Medicine

Vietnamese law, through a stringent framework underpinned by the Law on Drug Prevention and Control and Decree No. 57/2022/ND-CP, establishes a resolute and unequivocal position. Pursuant to Decree 57, Cannabis (*including the plant, leaves, flowers, and resin*) and its primary active ingredient, Delta-9-tetrahydrocannabinol (**THC**), are classified under Schedule I – List of Narcotic Substances Absolutely Prohibited from Use.

The definition of Schedule I explicitly states these are "Narcotic substances absolutely prohibited from use <u>in</u> <u>medicine</u> and social life". The phrase "<u>absolutely prohibited from use in medicine</u>" carries critical legal significance. It erects an insurmountable barrier to the development, marketing authorization, and commercialization of any pharmaceutical product containing these substances.

This provision leaves no room for interpretation. It affirms that, from a medical standpoint, these substances possess no recognized therapeutic value in Vietnam. Consequently, a pharmaceutical product containing these components is *de jure* illegal and <u>cannot be licensed for circulation</u>, prescribed, or utilized in any healthcare facility.

Meanwhile, the purpose of granting a patent is to bestow upon its owner the right of commercial exploitation. However, if a product cannot be legally commercialized, granting a patent for it would be rendered futile and would create a legal contradiction: the state would be simultaneously prohibiting a substance while granting an exclusive right to exploit a product containing that very substance. This constitutes an untenable legal paradox.

### The Overarching Principle of the Intellectual Property Law

Article 8.1 of the Intellectual Property Law stipulates that the State shall "not protect intellectual property subject matters which are **contrary to** social ethics and public order".

This is not an ambiguous provision. "Public order" is understood as the adherence to and respect for the nation's entire prevailing legal system. Given that the Law on Narcotics <u>has absolutely prohibited the use of cannabis in medicine</u>, the act of granting a patent for a cannabis-based pharmaceutical <u>would be deemed to contravene "public order"</u>. Such an act would not only undermine the efficacy of the narcotics control law but could also be viewed as indirectly legitimizing a prohibited substance, running counter to the consistent public policies and efforts undertaken by the State for decades.

Thus, the crux of the issue lies in the direct and irreconcilable conflict between the objective of intellectual property law (to encourage innovation) and the objective of narcotics control law (to protect public health and social security).

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# An Alternative Viewpoint: Is It Time to Re-evaluate the Stance on Patent Protection for Inventions Containing Cannabis in Vietnam?

Is the current interpretation overly rigid? The foregoing legal argument is sound and coherent. However, viewed from a **scientific** and **developmental perspective**, a different debate must be initiated. The question is whether the current interpretation is causing Vietnam to <u>miss significant opportunities for its medical and economic sectors</u>.

## Is "Social Ethics" an Immutable Concept?

How should the concepts of "social ethics" and "public order" be interpreted to best serve the interests of the people? Is it an "unethical" act for a pediatric patient with drug-resistant epilepsy to be treated with a pharmaceutical product derived from cannabis? Or is it the refusal to grant access to a potential new treatment method that is, in fact, "unethical"?

The law must <u>clearly distinguish</u> between the abuse of cannabis for recreational <u>purposes</u> (which harms society) and the strictly controlled use of cannabinoids in medicine (which aims to save lives). Equating these two concepts strips medicine of its core humanistic value. "Social ethics" should be about protecting human health and life, and science is the very instrument to fulfill that mission.

#### The Cost of Scientific and Economic Lag

While research institutes and pharmaceutical companies around the world (such as in the United States, Japan, and Europe) are generating numerous valuable <u>intellectual property assets</u> from cannabis, Vietnam remains on the sidelines. The absolute prohibition, extending even to controlled research, is creating a significant void in knowledge and technology. We are forfeiting the opportunity to: (i) Develop new "Made in Vietnam" medicines based on this potential medicinal source; (ii) Establish a high-tech agricultural sector for cultivating hemp for medical and industrial purposes, thereby generating economic value and employment; and (iii) Attract foreign investment in the biotechnology and pharmaceutical sectors.

#### The Purpose of a Patent: To Foster the Future or Merely Reflect the Present?

A patent does not merely protect what is already authorized for circulation; it serves as a commitment to protect investment in the future. A pharmaceutical company might be willing to spend millions of dollars to conduct rigorous clinical trials to prove the safety and efficacy of a new cannabis-derived drug. However, they will only do so with the knowledge that, if successful, their invention will be protected.

<u>Denying patent</u> issuance from the outset extinguishes the motivation for R&D investment. This creates a vicious cycle: without patent protection, no one will invest in research, and without research, there is no scientific data to persuade lawmakers to amend the regulations.

#### Recommendations – A Prudent and Feasible Roadmap for Vietnam

A genuine conflict exists between social security and developmental opportunities. Instead of maintaining a rigid stance or implementing abrupt changes, Vietnam can construct a phased, controlled, and science-based roadmap.

## 1. Immediate Recommendation: Establish a "Sandbox" (Pilot Regulatory Framework) for Scientific Research.

The first and most secure step is to create a special legal corridor (a controlled trial mechanism – a sandbox) for medical cannabis research.

- Content: Amend relevant Decrees to permit designated leading research institutes, universities, and
  hospitals to import or cultivate cannabis/hemp in limited quantities, under the absolute security
  control of the Ministry of Public Security and the scientific supervision of the Ministry of Health.
- **Objective:** To gather "Made in Vietnam" scientific data on the efficacy and safety of cannabinoids in the Vietnamese population and to evaluate plant strains suitable for local conditions. This will create an invaluable evidence base for future policymaking.

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#### 2. Medium-Term Recommendation: Reclassification and Establishment of Standards.

Based on the research outcomes from the "sandbox," the Government can proceed with the reclassification of substances within Decree 57.

- For Cannabidiol (CBD): CBD is one of many cannabinoid compounds found in the cannabis plant. Unlike THC, CBD does not produce addiction or psychoactive effects. It is necessary to separate CBD (with a THC concentration below 0.3%) from the list of controlled narcotics and to develop a set of National Standards (TCVN) for CBD used in cosmetics, dietary supplements, and pharmaceuticals. This would immediately open a new market and permit the protection of CBD-related inventions.
- For THC: Instead of widespread legalization, a special Schedule should be created for pharmaceutical products containing THC that have been proven effective through clinical trials and are licensed by the Ministry of Health as strictly controlled prescription drugs. This would allow the "medicine" to be circulated while the "narcotic" remains prohibited.

#### 3. Long-Term Recommendation: An Inter-Ministerial Roadmap and Legal Harmonization.

An inter-ministerial steering committee should be established, comprising representatives from the Ministry of Health, the Ministry of Public Security, the Ministry of Science and Technology, the Ministry of Agriculture and Rural Development, and the Ministry of Justice. This steering committee shall be tasked with the following duties:

- To study international experiences (particularly the successful and failed models in Thailand, Canada, and Germany).
- To develop a comprehensive roadmap for the development of a medical cannabis industry in Vietnam, from cultivation, extraction, and <u>pharmaceutical</u> production to licensing and post-licensing management mechanisms.
- To propose synchronous amendments to the legal system (e.g., the Law on Pharmacy, the Law on Intellectual Property, the Law on Drug Prevention and Control) to ensure consistency, prevent conflicts, and simultaneously control risks while leveraging developmental opportunities.

#### **Final thoughts**

Vietnam stands at a critical juncture: to maintain a conservative stance by absolutely prohibiting all cannabisrelated inventions, or to proactively build a modern, flexible legal framework where medical innovation is guided by science, not constrained by outdated prejudices.

No one denies that narcotics are a menace requiring strict control. Yet, it is equally undeniable that from compounds once deemed taboo, global medicine has discovered breakthrough treatment solutions. While developed nations such as Japan, the United States, and those in Europe have clearly demarcated between "narcotics" and "pharmaceuticals", Vietnam remains cautious and hesitant - and is at risk of missing the opportunity to lead in a nascent medical and economic field.

The protection of inventions containing cannabis, if implemented selectively, under strict control, and based on rigorous scientific data, is not a compromise with risk. Rather, it is a powerful declaration of the maturity of the legal system—one where social ethics are understood as the paramount protection of human health and life.

It is time to shift from a posture of "rejection due to apprehension" to one of "proactive control and shaping the future". A rational roadmap will not weaken public order; on the contrary, it will position Vietnam to lead in the research, development, and protection of new medical solutions, simultaneously safeguarding the community while embracing humanistic values, innovation, and sustainable economic growth.

The future of Vietnam's pharmaceutical industry lies not in standing outside the global medical revolution, but in knowing how to guide it with intellect, fortitude, and a long-term vision.

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