

IP KNOWLEDGE EXTRACT



UNDERSTANDING EXCLUDED MEDICAL METHODS UNDER VIETNAMESE IP LAW

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What's New

1. [Overview](#)
2. [In Details](#)
3. [Conclusion](#)



Overview

In Vietnam, the regulation surrounding the patentability of medical methods for preventing, diagnosing, and treating diseases—referred to as "excluded medical methods"—is outlined in Article 59.7 of the Vietnam Intellectual Property Law. This provision, rooted in humanitarian principles, seeks to enhance access to advanced medical services for all segments of society and aims to improve public health by eliminating barriers associated with patent ownership. However, this approach presents notable challenges for patent holders attempting to secure intellectual property rights for their medical method inventions.

To better understand this framework, it's important to clarify what constitutes excluded medical methods, how these methods can be identified, and whether there are any viable solutions for protecting such inventions despite the existing constraints.

In Details

According to Article 5.8.2.9 of the Guideline on Patent Examination Procedure, certain medical methods are not eligible for patent protection in Vietnam. This includes:

1. **Disease Diagnosis Methods:** These methods involve processes designed to identify and determine the causes or sources of diseases in living humans or animals. They share two primary characteristics: first, they are performed on living organisms or in vitro specimens, and second, their main objective is to diagnose the disease or health condition present in the individual or animal.
2. **Treatment Methods:** These processes are aimed at preventing, reducing, or eliminating the causes or sources of diseases, with the goal of restoring health, alleviating pain, or improving the overall condition of humans or animals.
3. **Surgical Methods:** This category encompasses treatment methods that involve creating wounds or conducting interventions in living humans or animals. Surgical methods may include activities such as incisions, cuts, sutures, and tattoos, and are executed using a variety of specialized tools.

Understanding these distinctions is crucial for those involved in medical innovations and patent applications within the regulatory framework of Vietnam.

First of all, according to Article 5.8.2.9 of the Guideline on Patent Examination Procedure, there are several approaches to identifying medical methods that may be excluded from patent protection. The following outlines these methods of identification.

One of the key criteria for identifying medical methods that are excluded is that these methods are conducted on living organisms or in vitro specimens derived from humans or animals. It is essential to evaluate this characteristic alongside other critical aspects outlined in sections below to accurately determine whether these medical methods fall under the exclusion criteria.

a) Based on the intended purpose of the method

- **Preventive Methods:** Techniques aimed at preventing diseases before they develop into serious issues—such as immunization, contraception, and



strategies designed to control the spread of infectious diseases—are not eligible for patent protection.

- **Diagnostic Methods:** Methods that directly assess or diagnose the health status of humans or animals using imaging technologies like MRI, X-ray, and ultrasound, as well as blood and cellular testing, do not qualify for patent protection.

- **Curative Methods:** Approaches that focus on treating or eliminating the underlying causes of diseases—including surgical procedures, medical treatments, pharmacotherapy, and psychological interventions—are also ineligible for patent protection.

This framework outlines the criteria that exclude various medical methods from being patented, emphasizing the legal boundaries in the context of public health and welfare.

b) Based on the practical of the method

- Methods Involving Wound Creation, in which:

- Curative surgical methods are not eligible for patent protection as stated in Article 59.7 of the law.
- Non-curative surgical methods are similarly excluded due to a lack of industrial applicability.

- Methods Not Involving Wound Creation, in which:

- Methods performed for the purposes of diagnosing, preventing, or treating diseases are also ineligible for patent protection.

This framework ensures that certain medical and surgical techniques remain accessible for public use and advancement in healthcare.

c) Based on the effectiveness of the method of the method

When assessing the eligibility of a medical method for patent protection, it's important to note that methods designed to directly identify or treat a specific disease are generally not eligible for such protection. Evaluation of a medical method's eligibility involves considering several factors. If the method includes a characteristic outlined in the sections above, it is likely categorized as an excluded medical method and would be ineligible for patent protection.



On the other hand, when developing or owning medical inventions that encompass both excluded and non-excluded subject matters, it is important to note that while methods for preventing, diagnosing, or treating diseases in living humans and animals are generally not eligible for patent protection, applicants can still pursue patent registration for other applicable subject matters. This approach allows them to maximize the benefits and rights related to their intellectual property. Below are some recommendations that applicants may consider when formulating a patent protection strategy.

Firstly, when drafting patent claims, it is essential for the applicant to select subject matters that are likely to be accepted for patent protection while avoiding those that fall under the excluded categories.

a) Acceptable Subject Matters

- **Medical Devices and Tools:** This includes medical instruments, devices, and pharmaceuticals utilized in medical procedures, as they do not involve direct interaction with living organisms in a diagnostic or treatment capacity.

- **Non-invasive Methods:** These encompass methods that do not interfere directly with living organisms, such as:

- Manufacturing processes for prosthetic limbs.
- Breeding techniques for livestock.
- Cosmetic methods.
- Procedures designed to enhance the comfort or satisfaction of healthy individuals.
- Methods for eliminating pests (e.g., bacteria, viruses, lice, fleas) on humans or animals, provided they do not involve wounds or infected areas.
- Techniques aimed at achieving intermediate results where immediate diagnosis of a health condition is not feasible based solely on those results.

- **Animal Slaughter Methods:** These methods are applicable to non-human animals.

- **Methods on Non-living Organisms:** This includes procedures performed on human or animal corpses.

b) Subject Matters to Avoid

- **Disease Diagnosis Methods:** It is advisable not to claim methods that are applied to living organisms or conducted on in vitro specimens (such as test tubes). This also includes methods that lead to immediate diagnosis of diseases or health conditions through diagnostic or testing steps.

- **Treatment Methods:** Claims should avoid methods intended for treatment purposes or those with a curative nature, as well as methods focused on disease prevention or immunogenic actions.

- **Surgical Methods:** Applicants should not select claims related to surgical techniques, regardless of whether they are curative or non-curative in nature.

By carefully considering these guidelines, applicants can enhance the likelihood of successfully obtaining patent protection for their innovations.



Secondly, when drafting a patent specification for a medical method that serves both curative and non-curative purposes, it is important for the applicant to take specific steps.

- **Clearly State Non-Curative Intent:** The applicant should explicitly mention that the method is designed for non-curative purposes. This aspect is crucial as it emphasizes the additional benefits of the method, including improvements in overall health, rehabilitation, or cosmetic applications.

- **Avoid Curative References:** The applicant should refrain from mentioning or describing the method's potential curative effects within the patent specification. Including such references could jeopardize the application, potentially leading to rejection during the examination phase, as the subject matter may not align with the necessary protection criteria.

By following these guidelines, applicants can enhance the clarity and focus of their patent applications while safeguarding against rejection.

Furthermore, in Vietnam, inventions that pertain to methods for preventing, diagnosing, and treating diseases in living humans and animals are not eligible for patent protection due to humanitarian considerations. However, patent owners have the option to pursue protection in other countries or jurisdictions that permit registrations for these types of inventions. Consequently, if patent owners recognize regions with viable opportunities for commercialization that align with their resources, they can move forward with patent registration and exploit their inventions in those areas.

Conclusion

Developing and safeguarding medical inventions is a crucial and intricate process that necessitates a thorough understanding of the legal regulations governing patent protection. To effectively register medical inventions—particularly those that pertain to methods for diagnosing, preventing, and treating diseases in both humans and animals—patent holders must be well-versed in the specific medical methods that are excluded from patentability under Vietnamese law.

It is essential for inventors to carefully select the subject matter for their claims. Additionally, crafting a clear and detailed invention specification is vital. This document should explicitly outline the invention's intended non-diagnostic and non-treatment purposes. By doing so, inventors can significantly reduce the risk of objections during the patent application process, ultimately enhancing the chances of achieving successful patent registration.

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