# Medical method inventions: What should be done to obtain patent protection in Vietnam?

In Vietnam, methods of preventing, diagnosing, and treating diseases in humans and animals, known as "excluded medical methods", are not eligible for patent protection under Article 59.7 of the <u>Vietnam Intellectual</u> <u>Property Law</u>. This regulation, established based on humanitarian policies, aims to facilitate access to advanced medical services for all societal classes, thereby improving public health by removing patent ownership barriers. However, it poses significant challenges for patent owners seeking to protect intellectual property rights for their medical method inventions. So, what are the excluded medical methods? How to identify these methods? And are there any available solutions for protecting these methods?

## 1. What are the excluded medical methods?

According to Article 5.8.2.9 of the Guideline on Patent Examination Procedure, subject matter of medical methods that are not protected as inventions in Vietnam include:

Disease diagnosis methods: refer to processes used to identify and determine the cause or source of diseases in living humans or animals. These methods have two main characteristics: (i) they are conducted on living organisms or in vitro specimens of humans or animals, and (ii) their primary purpose is to diagnose the disease or health condition of such humans or animals.

*Treatment methods:* refer to processes intended to prevent, reduce, or eliminate the causes or sources of diseases, aiming to restore health, alleviate pain, or improve conditions in humans or animals.

*Surgical methods:* are treatment methods involving that involve creating wounds or interventions in living humans or animals. These methods include actions such as incisions, cuts, sutures, and tattoos, and are performed using various tools.

### 2. How to identify excluded medical methods?

Based on Article 5.8.2.9 of the Guideline on Patent Examination Procedure, several ways for identifying excluded medical methods can be derived, as outlined below.

#### 2.1 Identify excluded medical methods based on the object to which the method is applied.

First, one of the important features for identifying the excluded medical methods is that these methods are performed on living organisms or in vitro specimens of humans or animals.

In addition, to accurately determine whether medical methods are excluded, it is necessary to combine the aforementioned feature with other important features described in items 2.2 to 2.4 below.

#### 2.2 Identify excluded medical methods based on the purpose of the method

- *Preventive purpose:* if methods are performed to prevent disease before it progresses into a significant problem, such as immunization, contraception, or medical methods aimed at preventing the spread of infectious diseases, etc., then they are not eligible for patent protection.

- *Disease diagnosis purpose:* if methods are performed to directly determine the disease or health condition of living humans or animals, utilizing imaging techniques such as MRI, X-ray, ultrasound, or blood and cell testing methods, etc., then they are not eligible for patent protection.

- *Curative purpose:* if methods are performed to treat or eliminate the cause of the disease, including surgery, medical procedures, pharmacotherapy, or other psychological treatments, etc., then they are not eligible for patent protection.

#### 2.3 Identify excluded medical methods based on the implementation of the method

- *Method involving wound creation (surgical method):* wherein (i) curative surgical methods are excluded under Article 59.7 of the Vietnam Intellectual Property Law; and (ii) non-curative surgical methods are rejected due to a lack of industrial applicability.

- *Method not involving wound creation:* wherein if the methods are performed for diagnosing, preventing, or treating a disease, then they are not eligible for patent protection.

#### 2.4 Identify excluded medical methods based on the immediate effectiveness of the method

If the immediate effect of a method is to directly identify or treat a specific disease, then it is not eligible for patent protection.

In general, to determine whether a medical method is excluded, it's necessary to evaluate it based on various factors. If the method in question possesses a feature mentioned in section 2.1 and at least one of the features mentioned in sections 2.2 to 2.4, it can be concluded that it falls under the category of excluded medical methods and would not be accepted for patent protection.

# 3. Which solutions are possible?

When inventing or possessing medical inventions that involve both excluded and non-excluded subject matters, even though methods for preventing, diagnosing or treating diseases in living humans and animals are not eligible for patent protection, applicants can still proceed with patent registration for other suitable subject matters to obtain the maximum benefits and rights regarding their intellectual property. Below are some suggestions that applicants may consider when building a patent protection strategy.

**3.1 Selecting subject matters to be claimed:** When drafting claims for a patent specification, the applicant should carefully choose subject matters that may be acceptable for patent protection and avoid subject matters belonging to the excluded subject matter group. Specifically:

Should choose subject matters to be claimed, such as:

- Medical devices and tools (which are not methods): Examples include medical instruments, devices, or drugs used in medical procedures.
- Methods that do not directly interfere with the living organisms of humans or animals (do not cause wounds) and are not intended for diagnosis or treatment: Examples include methods of manufacturing prosthetic limbs; methods of breeding livestock; methods are cosmetic in nature; methods aimed at enhancing the comfort or satisfaction of non-sick individuals; methods for eliminating bacteria, viruses, lice, or fleas on the human or animal body (excluding wounds and infected sites); and methods aimed at obtaining intermediate results where immediate diagnosis of disease or health condition cannot be obtained based on these intermediate results.
- Methods of slaughtering animals other than humans;
- Methods are performed on non-living organisms, including human or animal corpses.

Should not choose subject matters to be claimed, such as:

- Disease diagnosis methods: Do not choose subject matters of methods applied to living organisms or conducted on *in vitro* specimens (in test tubes), or methods that involve diagnostic or testing steps (if diagnostic steps are absent), wherein the diagnosis of a disease or health condition can be immediately obtained based on the acquired diagnostic or testing information along with medical knowledge in the art and the information disclosed in the application.
- Treatment methods: Do not choose methods intended for treatment purposes or possessing a curative nature; disease prevention methods and immunogenic methods.
- Surgical methods: Do not select subject matters of surgical methods, including both curative surgical methods and non-curative surgical methods.

**3.2 Appropriately draft a patent specification:** If the medical method can serve both a curative purpose and a non-curative purpose, when drafting a <u>patent specification</u>, the applicant:

<u>Should:</u> Clearly state in the patent specification that the method is intended for non-curative purposes. This helps highlight other effects of the method, such as improving overall health, rehabilitation, or cosmetic applications.

<u>Should not:</u> Avoid mentioning or describing the method serving as a curative purpose in <u>the patent</u> <u>specification</u>. This may lead to the possibility of the patent application being rejected during examination because the claimed subject matter does not meet the protection criteria.

# 4. Other suggestion: Seek patent protection in the appropriate country or jurisdiction

Inventions containing claimed subject matters of methods for preventing, diagnosing, and treating diseases in living humans and animals are not granted protection in Vietnam due to humanitarian reasons. However, patent owners can seek protection in other countries or jurisdictions that accept registrations for these subject matters. Therefore, if patent owners identify areas with potential for exploitation and that are suitable for their resources, they can proceed with patent registration and exploit inventions there.

# **Final thought**

Developing and protecting medical inventions is extremely important and complex, requiring a deep understanding of the legal regulations related to patent protection. To successfully register medical inventions, especially those involving methods of diagnosing, preventing, and treating diseases in humans and animals, patent owners must comprehensively understand the medical methods excluded from patent protection under Vietnamese law. They also need to carefully select the subject matters to be claimed. Additionally, preparing a clear and detailed invention specification, that explicitly states the invention's non-diagnostic and non-treatment purposes will minimize the risk of <u>objections to the patent application</u>, thereby increasing the likelihood of successful patent registration.

Contact KENFOX IP & Law Office for advice on effectively protecting your invention in Vietnam. KENFOX's team, with extensive practical experience and expertise, deeply understands intellectual property law and is committed to providing you with dedicated and accurate advice, ensuring that your patents overcome legal barriers and receive comprehensive protection in Vietnam.

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