**New Developments in Patent Examination and Enforcement in the Field of Medical Devices in Southeast Asia**

**Patent Examination and Enforcement in the Field of Medical Devices**

**Patent Examination and Enforcement in the Field of Medical Devices**

*The medical device sector in Southeast Asia is witnessing unprecedented innovation, accelerating development and reshaping healthcare across the region. This progress, however, introduces new challenges for patent protection, making it essential for inventors and companies to stay informed on evolving regulations and enforcement mechanisms.*

*KENFOX IP & Law Office offers expert insights into the key trends shaping the patent landscape for medical devices in Southeast Asia, covering the latest advancements in examination practices, enforcement strategies, and the significant issue of second medical use claims.*

### 1. **Emphasis on Novelty and Inventive Step**

Patent offices across Southeast Asia are increasingly emphasizing the demonstration of "novelty" and "inventive step" for [medical device patents](https://kenfoxlaw.com/medical-method-inventions-what-should-be-done-to-obtain-patent-protection-in-vietnam). This stricter approach has significant implications for patent applicants.

To secure patent protection, applicants must provide compelling evidence and detailed explanations that clearly differentiate their medical device innovations from existing technologies. This includes demonstrating that the invention is not only new but also involves an inventive step that would not be obvious to a person skilled in the art.

This heightened scrutiny aims to prevent the patent system from being overwhelmed with trivial inventions that do not significantly advance the field of medical technology. By focusing on novelty and inventive step, the patent system incentivizes substantial innovations that offer tangible benefits over existing solutions.

### 2. Focus on Second Medical Use Claims

“Second medical use” is very important and, yes, sometimes controversial aspect of patent law. Please see our article titled “[***Second Medical Use Claims in Patent Protection in Southeast Asia – Why it is important and controversial?***](https://kenfoxlaw.com/second-medical-use-patents-promoting-development-or-hindering-the-pharmaceutical-industry-in-southeast-asia)”

**Thailand: Patenting New Medical Uses for Known Substances**

* **Legal Framework**: Section 9(4) of the Thai Patent Act excludes methods of diagnosis, treatment, or cure from patentability, focusing instead on protecting the technological aspects of medical devices without monopolizing treatment methods.

This standard exclusion is a common feature in many patent laws globally to avoid monopolization of medical and veterinary treatment techniques.

Although the Patent Act excludes treatment methods, it does not specifically exclude “new uses” of known substances.

* **Patentability Criteria**: However, according to the 2019 DIP guidelines, new medical uses of known substances **can be patented** if they demonstrate novelty, inventive step, and industrial applicability, provided they are not “*methods of treatment*”.
* **Claim Format**: Swiss-type claims are permissible under Thai law to patent new therapeutic uses of known substances, although such claims must carefully avoid including dosage or therapeutic steps.
* **Key Consideration**: Claims should not directly or indirectly include dosage or therapeutic steps that describe how the product is applied to the body to provide treatment efficacy. Such descriptions could render the claim as a method of treatment, thus falling under the exclusions of Section 9 (4).

**Indonesia: Second Medical Use**

* **Article 4(f) Exclusions**: New uses of known products and new forms of existing compounds without enhanced efficacy are not patentable as stated in the Patent Law No. 13 of 2016.
* **Historical Context**: Swiss-type claims were previously accepted before 2016, despite Article 7(b) prohibiting patenting methods of treatment.
* **Current law**: Law No. 65 of 2024, which is the third amendment to Law No. 13 of 2016 on Patents, was enacted on **October 28, 2024**. The new law **removes** the exemption on Article 4(f) for patenting “new uses” and “new forms” of existing products or compounds, allowing patents for the “second medical use” of known pharmaceutical products or compounds.

**Patent Examination and Enforcement in the Field of Medical Devices**

Article 9(b), relating to any method of examination, treatment, medication, and/or surgery applied to humans and/or animals, remains in effect with no amendments made to it.

**Vietnam: New Medical Uses for Known Substances**

* **Non-Patentable subject matters**: Method claims for prevention, diagnosis, and treatment; use claims (claims beginning with “Use of”); and claims carrying a nature of use (such as those in the form "product X for use in...") [are not accepted in Vietnam](https://kenfoxlaw.com/patent-refusal-in-vietnam-reasons-suggestions-for-applicants).
* **Legal Background**: The reasons can be found based on the interpretation of Vietnamese IP law, namely:

Method claims: Pursuant to Clause 7, Article 59 of Vietnamese IP Law, *“Methods of prevention, diagnosis and treatment for humans and animals”* shall not be protected.  Thus, method of treatment claims or claims carrying the nature of treating disease are not accepted under invention in Vietnam.

Use claims (*claims commencing with “Use of”*): Pursuant to Article 4.12 of Vietnamese IP Law, the subject matter eligible for invention must be “product” or “process”. Because “use” is not considered as "product" or "process", thus, medical use claims are not accepted under invention in Vietnam.

Claims carrying nature of use (claims in form of *"product X for use in...")*: Although this type of claim (Swiss-type claim) may pass the formality examination stage, it will be rejected during the substantive examination. This is because the use-related features are regarded as functional or utility characteristics of the subject matter. As per Point 16.5.d(i) of Circular 23/2023/TT-BKHCN, functional and utility features are not considered essential technical features. Consequently, when assessing novelty and inventive step, these features are ignored, and only the feature "known substance" is evaluated. Since the substance is already known, the claim is deemed neither novel nor inventive. Therefore, new uses of known medical substances or medical device (including first and second medical use claims) are not patentable in Vietnam.

* **Key Consideration**: Claims should not refer to or imply methods for prevention, diagnosis, and treatment, or the use of medical substances/devices, to avoid rejection by IP Vietnam based on the above legal background. Instead, they should focus on instruments or devices used in therapeutic methods, as well as substances or materials for use in such methods, which are considered patentable.

**Philippines: Second Medical Use for Drugs and Medicine**

* **Non-Patentable Discoveries**: Section 22.1 of the Philippine Intellectual Property Code explicitly excludes the patentability of second medical use, including new forms or new uses of known substances that do not enhance efficacy.
* **Legislative Background**: These exclusions were strengthened by the Cheaper Medicines Act of 2007 to maintain affordability in healthcare.
* **Guideline Adjustments**: The 2018 IPOPHIL QUAMA Guidelines introduced the concept of "inherency" in assessing patentability, allowing some flexibility for patenting new uses if they are not obvious from the prior art.
* **Current Understanding**: Despite guideline adaptations, the prevailing legal interpretation continues to restrict second medical use patents to support affordable medicines.

### 3. **Streamlining Examination Processes**

Streamlining patent examination processes is crucial for fostering innovation and economic growth in Southeast Asia. Recognizing this, countries in the region are taking proactive steps to enhance efficiency. Singapore, for instance, has simplified its process by eliminating the need for International Search Reports, making it easier and faster for applicants to navigate the system. Thailand is prioritizing medical innovation with a fast-track examination process, aiming to grant patents within 12 months. These reforms signify a commitment to reducing the time and cost associated with securing patent protection, ultimately facilitating quicker market entry for [innovative products](https://kenfoxlaw.com/evergreening-strategy-extending-patent-protection-innovation-or-obstruction) and promoting a more vibrant intellectual property landscape in Southeast Asia.

**4. Enhancing Patent Enforcement in Southeast Asia**

**Patent Examination and Enforcement in the Field of Medical Devices**

* **Specialized IP Courts**: Some Southeast Asian countries (Vietnam to be set up in 2025) are establishing specialized courts solely dedicated to handling IP disputes, including patent infringements. This specialization enhances the judicial process by involving judges and legal professionals with expert knowledge in IP law, leading to more informed and quicker resolutions.
* **Stricter Penalties**: To deter infringement effectively, countries are revising their legal frameworks to impose harsher penalties on those found guilty of patent violations. This includes higher fines and, in severe cases, stricter criminal sanctions. These measures aim to increase the risk associated with violating IP rights, thus reducing the incentive for such actions.
* **Improved Border Control Measures**: Recognizing the importance of preventing the entry and exit of counterfeit medical devices, customs authorities are being equipped with better tools and training to identify and seize counterfeit goods. Enhanced cooperation between IP offices and customs authorities is also being emphasized to enforce IP rights more effectively at the borders.
* **Regional Collaboration**: There is an increasing trend towards regional cooperation to combat IP infringement. Southeast Asian countries are collaborating more closely through information sharing and joint enforcement initiatives, which helps in creating a unified front against [patent infringement](https://kenfoxlaw.com/how-to-cope-with-patent-infringement-allegations-in-vietnam) across borders.
* **Impact on Medical Devices**: For the medical device sector, these enforcement measures are crucial as they ensure that innovations are protected from counterfeiting and unauthorized use, which is vital for both the health safety of the public and the economic well-being of companies investing in medical technology

### Typical patent cases:

* [Filing Patent Infringement Lawsuits In Vietnam – What Businesses Stand To Learn?](https://kenfoxlaw.com/filing-patent-infringement-lawsuits-in-vietnam-what-businesses-stand-to-learn)

# [Joint Liability Confirmed in Thai Patent Infringement Case](https://kenfoxlaw.com/joint-liability-confirmed-in-thai-patent-infringement-case)

### 5. **Harmonization of Patent Laws**

Southeast Asia is moving towards a unified approach in patent examination through the **ASEAN Common Guidelines**. This initiative aims to standardize patent prosecution processes across member states, ensuring uniform practices and standards and creating a more predictable and consistent IP landscape for medical device innovators.

<https://asean.org/wp-content/uploads/2023/03/ACG-PE-final-version-for-publication_edit-03mar.pdf>

### **6. Pharmaceutical** Patent Landscape in Cambodia and Myanmar

Both Myanmar and Cambodia are among the least developed countries that have been granted waivers from certain obligations under the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This exemption, which has been extended until 2033, allows them not to grant patent protection for pharmaceutical products during this period. This measure is intended to facilitate access to essential medicines and promote public health.

**Strategies for Protecting Second Medical Use Inventions in Southeast Asia**

Patent protection for second medical uses of pharmaceuticals and medical devices faces certain challenges in some Southeast Asian countries. To overcome these challenges and effectively protect intellectual property rights for such inventions, applicants can consider the following strategies:

* **Choose the right jurisdiction:** Carefully research the patent laws of each Southeast Asian country to identify those that permit second medical use claims.
* **Draft strong patent applications:** [Applications must clearly and precisely](https://kenfoxlaw.com/how-critical-is-the-vietnamese-translation-of-a-patent-specification-for-invention-protection-in-vietnam) demonstrate the novelty, inventive step, and industrial applicability of the new use, with compelling evidence of non-obviousness to a person skilled in the art.
* **Consideration of Alternative Forms of IP Protection:** In cases where patent protection for second medical use is unavailable or undesirable, applicants should explore other forms of intellectual property protection, such as trade secrets or design patents, to safeguard their innovations.
* **Monitoring Legal Developments:** Intellectual property law, especially patent law, is constantly evolving. Applicants should closely monitor new legislation, guidelines issued by IP offices, court decisions, and industry practices to ensure their IP protection strategies remain effective and compliant.

**Patent Examination and Enforcement in the Field of Medical Devices**

* **Collaboration with IP Experts:** Consulting with experienced IP lawyers or patent attorneys who possess in-depth knowledge of the relevant laws and practices in the chosen jurisdiction is crucial for navigating the complexities of patent protection and enforcement in Southeast Asia.

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.

**QUAN, Nguyen Vu | Partner, IP Attorney**

**PHAN, Do Thi | Special Counsel**

**NGA, Dao Thi Thuy | Senior Patent Attorney**

**Contact**

**KENFOX IP & Law Office**

Building No. 6, Lane 12/93, Chinh Kinh Street, Nhan Chinh Ward, Thanh Xuan District, Hanoi, Vietnam

**Tel:** +84 24 3724 5656

**Email:** info@kenfoxlaw.com / kenfox@kenfoxlaw.com