

Second Medical Use Patents: Promoting Development or Hindering the Pharmaceutical Industry in Southeast Asia?

The pharmaceutical landscape in Southeast Asia is undergoing a dynamic shift, with second medical use claims emerging as a crucial battleground. These claims, which protect the use of a known medical substance or device for a new therapeutic application, are gaining traction, but not without controversy. KENFOX IP & Law Office provides you with the importance and contentious nature of second medical use claims in Southeast Asia, examining the varying approaches across the region.

Second Medical Use Claims: What They Matter?

Developing new drugs and therapies requires significant investment in research and development (R&D). Second medical use claims provide pharmaceutical companies with an avenue to recoup these costs and incentivize further research into new applications for existing products, particularly after the original patent has expired. This fosters a continued drive towards medical advancement.

Protecting new uses encourages the development of treatments for conditions that might otherwise be neglected. This can lead to a wider array of therapeutic options, potentially [improving patient](#) outcomes and addressing unmet medical needs.

For companies, second medical use claims can breathe new life into existing products. By securing protection for new applications, they can extend market exclusivity, maintain competitiveness, and potentially generate new revenue streams.

The Controversial Side

Critics argue that second medical use claims can be exploited to ["evergreen" patents](#), artificially extending monopoly rights and delaying the entry of more affordable generics. This practice can lead to higher drug prices and hinder access to essential medicines, particularly in price-sensitive markets.

There's concern that broad second medical use patents might stifle further research and development by other companies. This could discourage exploration of related applications and limit the development of alternative therapies.

The aggressive pursuit of second medical use claims raises ethical questions about prioritizing profit over patient well-being. It could potentially incentivize the promotion of off-label use without sufficient clinical trials to support safety and efficacy for the new indication.

The Diverse Landscape in Southeast Asia

Southeast Asian countries are adopting varied approaches to second medical use claims, creating a complex and evolving legal landscape:

- **Thailand:** Embraces second medical use claims, with explicit guidelines allowing "Swiss-type" claims that focus on the use of a substance or product for a specific new therapeutic purpose. However, claims must carefully avoid including dosage or therapeutic steps to prevent being classified as non-patentable "methods of treatment".
- **Indonesia:** Recently amended its patent law to explicitly allow second medical use claims. This marks a significant shift from its previous stance, which excluded "new uses" of known products to prevent evergreening. The change signals a move towards greater protection for [pharmaceutical innovation](#).
- **Vietnam:** Maintains a restrictive approach. Use claims, method claims for treatment, and claims indirectly implying medical use are not patentable. This stance prioritizes access to affordable medicines and avoids potential evergreening.
- **Philippines:** Explicitly excludes second medical use patents under its Intellectual Property Code, reinforced by the Cheaper Medicines Act of 2007. While recent guidelines introduced some flexibility, the prevailing interpretation remains restrictive to ensure affordability.

Closing thoughts

Second medical use claims are a critical and contentious issue in Southeast Asia. While they hold the potential to incentivize innovation and improve public health, concerns remain about evergreening, potential impacts on research, and ethical considerations. The diverse approaches across the region requires the ongoing struggle to find the optimal balance between fostering [pharmaceutical](#) innovation and ensuring access to affordable medicines.

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