# Freedom to Operate (FTO) in Vietnam: Why and How you can conduct an FTO before product launching?

Launching a product in Vietnam without an FTO check is like driving at night with the headlights off, possible, but risky and expensive. Vietnam recognizes utility solutions (utility models), a powerful doctrine of equivalents in infringement analysis, and broad "Bolar"-style regulatory approval exceptions. Knowing which of these helps you, and which hurts you, often decides whether your launch flies or stalls.

For foreign enterprises considering entry into the Vietnamese market, conducting a Freedom-to-Operate (FTO) search is not a simple administrative box to check; it is a critical, proactive tool for risk mitigation and strategic business planning. In a rapidly evolving economic landscape where Vietnam is increasingly integrated into global supply chains and attracting significant foreign direct investment (FDI), an FTO search is indispensable. A failure to undertake this diligence can expose a company to substantial legal and financial risks, including <u>patent infringement</u> lawsuits and reputational damage. This is because FTO is fundamentally a defensive strategy, designed to avoid infringement on the patent rights of others, which is a completely different goal from obtaining a patent yourself.

## 1. What is Freedom-to-Operate?

A Freedom-to-Operate (FTO) search, also known as a clearance or infringement search, is a thorough investigation to determine whether a product, process, or technology can be commercially manufactured, used, or sold in a specific country without infringing upon the valid, enforceable patent rights of others. Unlike other patent searches, an FTO analysis focuses on "active rights," which include patents that are still in force and pending applications that could mature into enforceable patents in the future. The primary objective is to assess and mitigate the risk of infringement before market entry or product launch.

The FTO process is far more than a legal formality; it is a fundamental business strategy. Waiting until a product is fully developed to conduct an FTO is a risky mindset that can lead to significant financial investment in a venture that may be blocked from the market by an existing patent. A company that integrates FTO analysis into the earliest stages of research and development can use the findings to adjust their design, alter their product roadmap, or innovate around potential conflicts before they become insurmountable obstacles. Furthermore, a well-executed FTO search is a crucial element for attracting investment. Savvy investors scrutinize FTO reports to reduce perceived risks during due diligence, which can build confidence and accelerate the fundraising process.

#### 2. Why Vietnam deserves a tailored FTO approach?

A tailored FTO approach is indeed critical for Vietnam's intellectual property landscape, which presents specific complexities that differ from other jurisdictions.

#### Two blocking rights, not one:

Vietnam protects both **invention patents (20-year term)** and **utility solutions (10-year term)**. Because utility solutions have a **lower inventiveness threshold**, they're easier to obtain, and easier to overlook if your screening only covers "patents". A Vietnam-ready FTO must search and review both right types to avoid false comfort.

For a foreign company, this duality means a comprehensive FTO search must screen for both types of protection titles. A search focused only on traditional patents could easily miss a valid utility solution that may still block market entry, creating a hidden and significant infringement risk.

#### The Doctrine of Equivalents and Its Application:

Vietnamese authorities often lean on <u>expert assessments (formerly VIPRI, now NIIP)</u> that apply a **function** - **way** - **result (F-W-R)** lens when comparing accused products/processes to claims, so "small tweaks" may still infringe.

In infringement assessments, Vietnamese authorities and courts, particularly the National Institute of Intellectual Property (NIIP), rely on expert assessments that employ a "function-way-result" (F-W-R) analysis. This doctrine of equivalents means that even if a product or process does not fall within the <u>literal wording of a patent's claims</u>, it can <u>still</u> be found to be infringing if it performs "substantially the same function in substantially the same way to yield substantially the same result" as the patented invention.

This approach is crucial for an FTO analysis because it means that minor design "<u>tweaks</u>" or modifications intended to "<u>design around</u>" a patent may still be considered an infringement. The expert opinions provided by the NIIP carry significant persuasive weight in legal proceedings.

## No Patent-Term Extension (PTE):

Unlike some other jurisdictions, Vietnam does not have a legal provision for a general patent term extension (**PTE**). While an invention patent is valid for 20 years from the filing date, the time spent during the examination process can reduce the effective commercial life of the patent. However, in a notable development, Decree 65/2023/ND-CP does provide a limited compensation mechanism for patent owners in the pharmaceutical sector who experience delays in obtaining marketing authorization. This is an important consideration for <u>pharmaceutical companies</u> when timing product launches and modeling their market exposure.

A copy-paste FTO from PCT/US/EU won't do. In Vietnam, you need a dual-right search, an NIIP-style F-W-R equivalence analysis, and pharma-specific timing models without PTE. Build those three into your workflow, and your clearance decisions will reflect how risk is actually measured and enforced on the ground.

## 3. The Vietnam-Specific 7-Step FTO Method

A comprehensive and accurate FTO search in Vietnam cannot be conducted without the expertise of a reputable, local intellectual property law firm. This is not merely a recommendation; it is a strategic necessity. Firms like KENFOX IP & Law Office possess proprietary, internal databases and employ experienced professionals, including former VNIPO examiners, with technical expertise and deep local knowledge that public search engines lack. This partnership is a foundational step that mitigates key procedural challenges and ensures the search is based on the most complete and accurate information available.

A professional FTO search in Vietnam is a methodical process that goes far beyond a simple keyword search. It requires a tailored approach that accounts for the specific legal and institutional landscape of the country. A typical workflow for a comprehensive FTO search includes the following seven steps:

<u>Step 1</u>: Define: Begin by meticulously defining the product or process to be analyzed. This involves decomposing its features and mapping its parts or process steps to <u>potential patent</u> claim language. This foundational step ensures that the search scope is both broad and precise.

<u>Step 2</u>: Search the appropriate databases: The search must be conducted from multiple sources, which may include but are not limited to:

- The online publication platform of IP VIETNAM (WIPOPublish): the most commonly used database for searching patent applications and patents filed in Vietnam.
- The Industrial Property Gazette issued and published by IP VIETNAM: review annuity records published by IP VIETNAM to determine legal status.
- Published Patent/Utility Solution Certificates (issued monthly): review the contents (full text) of granted certificates to identify their scope of protection.
- ASEAN IP Register: check legal status through a regional database covering multiple ASEAN member countries, including Vietnam.
- WIPO's PATENTSCOPE: search PCT applications, many of which designate Vietnam.

<u>Step 3</u>: Cast a wide net: Vietnam's IP system has two blocking rights - invention patents and utility solutions, so the search must cover both to be effective. Searches should be conducted using multiple criteria, including <u>International Patent Classification</u> (IPC) codes, keywords in both English and Vietnamese, titles, abstracts, filing dates, priority dates, applicant/patentee names, etc., to ensure a comprehensive and

accurate capture of inventions falling within the potential scope relevant to the subject matter under search..

<u>Step 4</u>: Check legal status & term: An FTO search is only as valuable as the current status of the patents it finds. A crucial step is to verify the legal status of any relevant patents, including whether they are granted or pending, and if their annual annuities have been paid to remain in force. Since the maximum term of a patent in Vietnam is 20 years and there is no patent term extension (PTE) mechanism, a Freedom-to-Operate (FTO) search may focus on applications/patents filed or granted within the 20 years preceding the search date. In addition, it should be noted that much crucial information may not be available in public databases (either because it has not yet been published, or due to administrative regulations that only allow partial disclosure), therefore, the expertise of an IP attorney in Vietnam is invaluable.

<u>Step 5</u>: Read the claims (and Equivalents): This is the core of the FTO analysis. The legal team must meticulously read the claims of any identified patents, as these define the legal scope of protection. The analysis must go beyond a literal reading to consider the **Doctrine of equivalents**, applying the function-way-result (F-W-R) approach used by the National Institute of Intellectual Property (NIIP, formerly VIPRI). Preparing a comparison table between the technical solution (product or process) under search and the claims of the relevant prior documents is a common and effective practice.

<u>Step 6</u>: Account for exceptions & defenses: A thorough FTO report considers all potential defenses to a claim of infringement. Key exceptions in Vietnam include:

- Bolar / Regulatory approval: While the Bolar exception for pharmaceuticals is common internationally,
  Vietnam's legal framework provides a limited compensation mechanism for patent owners who face
  regulatory delays, which is a key consideration for companies in the pharma, medical, and device
  sectors.
- Provisional rights: An applicant who has a published patent application may have the right to claim
  reasonable compensation from a party that uses their invention after being notified, provided the patent
  is eventually granted.
- Parallel import (Exhaustion): Vietnam applies an international exhaustion of rights mechanism. This means that once a patented product is legally sold anywhere in the world by the patent owner or with their consent, the patent owner cannot prevent its resale or import into Vietnam. This is highly relevant for products that may be sourced from different markets.
- **Prior user rights:** A party that was using an invention in good faith before the patent application filing date has the right to continue using it within the scope and volume of its prior use.

<u>Step 7</u>: Risk-rate & mitigate: The final step is to synthesize all findings into a clear risk assessment (e.g., high, medium, low) and provide strategic recommendations. Mitigation options may include: redesigning the product to "design around" the patent, seeking a license from the patent holder, or challenging the validity of the blocking patent. The 2022 <u>amendments to the IP Law</u> have added new grounds for patent invalidation, such as issues with enablement or claims that go beyond the original scope of the disclosure, which can be leveraged as part of a strategic defense.

# 4. Addressing Vietnam's FTO Landscape: Key Structural Challenges

- Data transparency limitations: Vietnam's public patent databases (e.g., IPVN) offer basic bibliographic information but lack reliable data on legal status, whether a patent is active, expired, or abandoned, as well as the full texts of pending patent applications. This gap makes public searches insufficient for FTO purposes. The most accurate and up-to-date records are typically restricted to authorized agents or examiners. As a result, partnering with a reputable local IP firm is not optional, it's essential. Without access to proprietary databases and local verification, foreign investors risk making FTO decisions based on incomplete or outdated information.
- Language and translation risks: All patent filings in Vietnam must be submitted in Vietnamese, and
  enforcement decisions rely solely on the Vietnamese version of the specification. NOIP examiners are
  not obligated to validate foreign-language translations. A mistranslation, however minor, can
  undermine the enforceability of a patent or distort its scope. Therefore, even when an FTO search
  flags a potential infringement, a deeper review of the Vietnamese text may reveal reduced or

eliminated risk. This emphasizes the need for an <u>IP partner</u> with not only legal and technical expertise, but also fluency in both languages and mastery of legal terminology.

# 5. Lessons from the Front Lines: Case Studies & Strategic Precedents

Civil litigation for patent infringement in Vietnam has long been viewed as a secondary enforcement tool, a battleground fraught with obstacles: lengthy procedures, a lack of technical expertise among judges, and difficulties in proving damages. This often left IP holders on the defensive, hesitant to engage. But recent cases are rewriting that narrative. Vietnamese courts are increasingly willing to engage with complex IP disputes, accept foreign expert evidence, and issue meaningful remedies.

The following case studies illustrate how litigation is evolving from a theoretical option to a viable enforcement strategy. Each case not only resolved a dispute but also set strategic precedents that reshape how rights holders, especially foreign patent owners, can approach enforcement in Vietnam. These cases reveal that with the right approach, IP holders can now achieve decisive victories and hold infringers accountable.

Case Name	Legal issue	Outcome	Strategic Lessions Learnt
Bayer SAS v. Công ty TNHH Thương mại Nông Phát	Patent infringement	Court ordered defendant to cease manufacturing and distributing infringing products. The plaintiff only requested lawyer fees as compensation.	Civil litigation can be effective, even if the damages awarded are limited.
European Pharma v. Vietnamese Infringer	Pharmaceutical patent infringement	Court ruled in favor of plaintiff, ordering destruction of products, payment of maximum statutory damages, and public apology.	Courts are willing to accept foreign expert opinions and will not tolerate delaying tactics.

A European pharmaceutical company discovered a Vietnamese firm infringing its patent for a crystalline form of a pharmaceutical active ingredient. The company's evidence was based on an X-ray diffraction test conducted in France, as Vietnam lacked the capability. The defendant used delaying tactics by filing an invalidation request for the patent.

The court ruled in favor of the plaintiff, setting several crucial precedents. It was the first time a Vietnamese court accepted expert opinion from abroad as evidence in a legal proceeding. It was also the first time a court awarded the maximum statutory damages of VND 500 million (approximately \$21,600). Most importantly, the court did not suspend the civil case while awaiting the administrative decision on the patent invalidation request, signaling that such delaying tactics would not be effective in derailing court proceedings. This case illustrates that the civil court system is becoming a more effective and reliable channel for IP enforcement, and that Vietnam is actively addressing its historical limitations.

## **Conclusion: Vietnam FTO Requires a Localized, Risk-Managed Roadmap**

Vietnam's Freedom to Operate (FTO) landscape is shifting toward a more pragmatic and granular approach. Businesses can no longer rely solely on traditional public searches to ensure legal safety at launch. With two layers of potentially blocking rights - patents and utility solutions - the Function–Way–Result (F–W–R) equivalence lens, mandatory reliance on the Vietnamese-language specification in examination and enforcement, and limited transparency in public legal-status data, an effective FTO demands a structured process and the right multidisciplinary team.

When executed properly, FTO is not merely defensive; it is a strategic lever. Companies can proactively screen risks early, verify legal status on the ground, implement design-around strategies, and prepare parallel civil-litigation or <u>administrative-enforcement</u> options where appropriate.

KENFOX IP & Law Office is one of the leading IP firms in Vietnam, with deep expertise across patents, trademarks, industrial designs, and copyright. Our team, comprising attorneys and technical specialists with multi-disciplinary backgrounds and robust litigation/enforcement experience, helps clients make decisions

based on locally verified Vietnamese data rather than assumptions, and handles complex mandates from FTO searches and legal-status verification to courtroom representation and licensing negotiations.

QUAN, Nguyen Vu | Partner, IP Attorney
PHAN, Do Thi |Special Counsel
NGA, Dao Thi Thuy | Senior Trademark 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

 $\textbf{Email:} \ \underline{info@kenfoxlaw.com} \ \underline{/ \ kenfox@kenfoxlaw.com}$