

# Pharmaceutical IP and competition law in Vietnam: overview

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A Q&A guide to pharmaceutical IP and competition law in Vietnam.

The Q&A gives a high-level overview of key issues including patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, visit [Medicinal product regulation and product liability in Vietnam: overview](#).

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## Patents

1. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

## Conditions and legislation

Patents are regulated by the:

- Law on Intellectual Property No. 50/2005/QH11(as amended in 2009 and 2019).
- Civil Code 2015, in particular Chapter 13.
- Decree No. 103/2006/ND-CP dated 22 September 2006, Detailing and Guiding the Implementation of a Number of Articles of the Law on Intellectual Property regarding Industrial Property.
- Decree No. 99/2013/ND-CP dated 29 August 2013, on Administrative Penalties in the Area of Industrial Property.
- Circular No. 01/2007/TT-BKHHCN dated 14 February 2007, Guiding the Implementation of Decree No. 103/2006/ND-CP.

Circular No. 11/2015/TT-BKHHCN dated 26 June 2015, Guiding the Implementation of Decree No. 99/2013/ND-CP. There are currently two types of patents for technical solutions in Vietnam: patents for inventions and patents for utility solutions (also referred to as petty patents). Both types are granted for an invention or a group of inventions that fulfil the unity requirements. The claimed invention must satisfy the following criteria.

**General formality requirements.** The claimed invention must:

- Be a technical solution in the form of a product, substance, or process to solve a specific problem by using the laws of nature.
- Comply with Article 8.1 of the Law on Intellectual Property, which means it must not be contrary to social morality and public order or detrimental to national defence and security.
- Not be on the list of unpatentable subject matter (*see below*).

**Specific substantive requirements.** An invention patent must:

- Be globally novel.
- Involve an inventive step.
- Be capable of industrial application.

A utility solution patent must:

- Be globally novel.
- Be capable of industrial application.

Generally, it is impossible to patent a health care procedure because methods of human disease prevention, diagnosis or therapy are not patentable subject matters. However, inventions relating to organisms, genetic sequences and biological material are patentable in Vietnam. Registered drugs containing active ingredients can be protected by patent.

At least two years before expiry of the invention protection period for a drug, a drug registration establishment can apply for registration for circulation of generic drugs. The application must clearly state the drug registration establishment's request for registration, and include documents showing that the validity period of the protected drug is due to expire.

## Scope of protection

Patents can protect products or processes, except the following:

- Discoveries, scientific theories and mathematical methods.
- Schemes, plans, rules and methods for performing mental acts, training domestic animals, playing games, doing business, and computer programs.
- Presentations of information.

- Aesthetic solutions.
- Plant and animal varieties.
- Essentially biological processes for the production of plants and animals, except microbiological processes.
- Methods of disease prevention, diagnosis and treatment for humans or animals.

## 2. How is a patent obtained?

### Application and guidance

Applications to register a patent are made to the Intellectual Property Office of Vietnam, formerly known as the National Office of Intellectual Property (NOIP). Guidance on the application procedure is provided on the IP Office's website in Vietnamese ([www.noip.gov.vn](http://www.noip.gov.vn)).

Although there are two types of patents for technical solutions in Vietnam, procedures to obtain an invention patent or a utility solution patent are only materially different in the timeline indicated in legal regulations. Other requirements in the dossier are the same. In fact, due to the backlog at the IP Office, the timelines are not different in practice.

There are three patent application types in Vietnam:

- First filed patent application.
- Application claiming priority under the WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention).
- Patent Cooperation Treaty 1970 (PCT) application.

While the dossier requirements and timelines differ, the IP Office will treat all patent applications similarly.

### Process and timing

First, a patent application dossier is filed at the IP Office and is given a filing date and application number. Generally, an application dossier must include the following:

- Vietnamese version of the specification.
- Petition requesting the grant of a patent with International Patent Classification (IPC) symbols, name, address and nationality of the applicant and inventor, and information about priority application (if any).
- Power of attorney granting authority to the agent filing the patent.

- Priority document (not required in a PCT application).

After filing, the patent application is examined as to formal requirements:

- If the results are positive, the IP Office will issue a decision of acceptance of a valid application.
- If the IP Office considers that the application has defects, it will issue an office action requiring the applicant to remedy the defects. After the defects are remedied, the IP Office will issue the decision of acceptance of a valid application.

When the application passes the formality examination and the decision of acceptance of a valid application is issued, it is published in the *Industrial Property Gazette*. A request for substantive examination must then be filed at the IP Office within 42 months from the priority date or the filing date (if the application does not claim any priority right).

The patent application is then substantively examined:

- If the results are positive, the IP Office will issue an invitation to pay the granting fee and first annuity.
- If the results are negative, the IP Office will issue an office action and applicants must file amendments/arguments. The IP Office may then issue the invitation to pay the granting fee and first annuity or a further office action. In practice, there may be many further office actions.

After the fees indicated in the invitation to pay the granting fee and first annuity are paid, the patent will be issued.

Vietnam is a party to the Paris Convention. The patent priority system in Vietnam complies with the relevant provisions of the Paris Convention. During prosecution, any third party can submit opinions to the IP Office to challenge the patentability of a pending patent application. The existence of a patent dispute does not prevent the regulatory review of an application for approval of a pharmaceutical.

3. How long does patent protection typically last? Can monopoly rights be extended by other means?

## Duration and renewal

**Invention patent.** Protection starts from the issue of the patent and lasts for 20 years from the date of filing.

**Utility solution patent.** Protection starts from the issue of the patent and lasts for ten years from the date of filing.

## Extending protection

There is no procedure for extending patent protection.

4. How can a patent be revoked?

A patent can be entirely revoked in the following cases:

- The applicant has no right to registration or was not assigned such a right.
- The invention does not satisfy the protection requirements at the grant date of the patent.

*(Article 96, Law on Intellectual Property.)*

A request for revocation of a patent can be made at any time during its entire period of protection.

A patent can be partially revoked if it partly fails to satisfy the protection requirements. In addition, a patent can be terminated in the following cases:

- If the owner has not paid the annuities for maintenance as prescribed.
- If the owner relinquishes the rights conferred by the patent.
- If the owner no longer exists.

*(Article 95, Law on Intellectual Property.)*

The patent holder can request termination of the use right where the grounds for licensing no longer exist and are unlikely to recur, provided this is not prejudicial to the licensee.

5. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

## Conditions for infringement

The unauthorised use of a patent during its term of validity will constitute infringement of the patent (*Article 126, Law on Intellectual Property*). Slightly more detailed provisions for determining infringement are set out in Article 8.1 of Decree 105/2006/ND-CP as amended and supplemented by Decree 119/2010/ND-CP and Article 11 of Circular 11/2015/TT-BKHCHN, which provide that infringement occurs when the product or a product part is identical or similar to a product or product part within the invention's scope.

A similar definition of infringement is found in Decree 105 in relation to processes. Specifically, a process used by an alleged infringer is an infringing process if it is "identical or similar to the process [of the invention]". Vietnam applies the doctrines of equivalent and literal infringement. Therefore, patent infringement can take any of the following forms:

- A product or part (component) of a product that is identical or equivalent to a product or part (component) of a product within the scope of protection of an invention patent.
- A process that is identical or equivalent to a process that is protected as an invention.
- A product or part (component) of a product that is manufactured by a process that is identical or equivalent to a process protected as an invention.

In practice, most patent infringement cases in Vietnam involve literal infringement. Therefore, the courts in Vietnam have not had much practice applying the law on equivalent infringement.

Using an invention means to carry out the following acts:

- Manufacturing the protected product.
- Applying the protected process.
- Exploiting the protected product or a product obtained by the protected process.
- Circulating, advertising, offering for sale, or stocking for circulation a protected product or a product obtained by the protected process.
- Importing the protected product or a product obtained by the protected process.

*(Article 124.1, Law on Intellectual Property.)*

The following defences are available in patent infringement actions:

- Prior use right.
- Fair use.
- Parallel importation.
- Compulsory licence.
- Use to maintain the operation of a foreign vehicle in transit or only temporarily entering into Vietnam.
- Statute of limitations.

*(Article 125.2, Law on Intellectual Property.)*

## Claim and remedies

**Administrative action.** A patentee brings an administrative action by filing a complaint with the competent Inspectorate specialised in Science and Technology, such as the Inspectorate of the Ministry of Science and

Technology. The proceedings, final decision on the case, and enforcement of the decision are set out in Chapter IV of Decree 99/2013/ND-CP and Chapter III of the Law on Handling of Administrative Violations.

In a typical patent infringement case, administrative remedies often include:

- A fine of up to VND500 million.
- Confiscation and destruction of the infringing products.
- Recovery of illicit profits by the State Treasury.
- Suspension of the infringer's business for up to three months.

**Court action.** As an alternative to administrative action, a patentee can bring a court action to enforce its patent rights. The proceedings and court's judgment/decision are set out in the Code of Civil Procedure. The enforcement of the court's judgment/decision is regulated by the Law on Enforcement of Civil Judgment 2008.

Remedies include the following:

- Termination of the patent infringement.
- Public rectification and apology.
- Performance of civil obligations.
- Compensation for damages.
- Destruction, distribution or putting to use for non-commercial purposes of goods, materials and implements the main use of which is the production and trade of goods infringing patents (provided that such distribution and use does not have an impact on the exploitation of rights by the patent holder).

In principle, attorneys' fees can be recovered from the losing party in a civil action.

**Border control measures.** Border control measures, particularly customs seizure, are another specific measure of administrative action that can be used.

No criminal actions are available for patent infringement.

## Dispute resolution and settlement

Infringement allegations can be resolved by conciliation. Conciliation is carried out by intellectual property lawyers and specialists. The lawyers and specialists help the parties to reach a negotiated resolution by providing them with legal advice or a specialist opinion on the issue in question. In patent infringements, IP lawyers may send warning letters or meet with infringers to persuade them to stop the infringing acts. In practice, this is often effective as many infringers do not realise that their acts are infringing, and often stop infringing acts unilaterally on receipt of a warning. By establishing contact with the infringer, the patent owner may gain access to valuable information that may be used if a formal action is brought later on.

## Relevant international patent instruments and processes

Vietnam is a party to the following international treaties:

- Paris Convention.
- PCT.
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS) (Vietnam is a member country of the WTO).

In the case of conflict, the following sources will take precedence in order of priority:

- International treaties.
- Laws and codes, which are adopted by the National Assembly.
- Decrees, which are introduced by the government.
- Circulars and joint circulars, which are issued by ministers of the relevant ministries.

However, in practice, the enforcement authorities usually give more weight to circulars and joint circulars, as they often contain detailed guidelines and regulations on applying the laws.

6. Are there non-patent barriers to competition that protect an originator's monopoly over an authorised medicinal product?

There is a regulatory data protection mechanism for drugs, which lasts from the date the trial data is filed until the date of expiration of the five-year marketing authorisation. However, protection is not very effective in practice.

Organisations can apply for authorisation for generic drugs two years before the expiry of patent protection for the branded medicine. There are no further barriers to generic competitors.

7. Are any restrictions placed on licensing or transferring patents to foreign parties? Are intellectual property transfers for inventions funded, or partially funded, by public investment restricted?

The authors are not aware of any restrictions placed on licensing or transferring patents to foreign parties, or on intellectual property transfers for inventions funded, or partially funded, by public investment.

## Trade marks



8. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

## Legislation and scope of protection

The legislation applicable to trade mark registration in Vietnam includes:

- Law on Intellectual Property.
- Law No. 36/2009/QH12 Amending and Supplementing a Number of Articles of the Law on Intellectual Property.
- Decree No. 103/2006/ND-CP.
- Circular 01/2007/TT-BKHCHN.

Brand owners can seek trade mark registration through either the national registration system or the Madrid System. The IP Office applies the same basic conditions and legislation for both procedures. However, in practice, the IP Office only issues trade mark certificates for national trade mark registrations, and decisions of acceptance for international registration.

## General conditions and specific rules for naming medicines

To be eligible for protection, a mark (a sign used to distinguish the goods or services of different organisations and individuals) must be:

- A visible sign in the form of letters, words, drawings, or images, including three-dimensional images, or a combination of these, represented in one or more colours.
- Capable of distinguishing goods or services of the mark owner from those of other undertakings (that is, it must be distinctive).

A mark is considered to be distinctive if it is both:

- Created from one or several easily perceptible and memorable elements, or from many elements forming an easily perceptible and memorable combination.
- Not included in the list of signs not registrable as trade marks under Article 74.2 of the Law on Intellectual Property. This list of indistinctive signs includes a wide range of exclusions, such as simple geometric figure signs, descriptive signs, and signs that are identical or confusingly similar to the registered or well-known marks of others.

Article 73 of the Law on Intellectual Property also lists various signs that cannot be registered as trade marks, including:

- Signs that are identical or confusingly similar to:
  - national flags or emblems;
  - names of state agencies;
  - names of Vietnamese or international national leaders, heroes and famous people; and
  - certification seals of international organisations.
- Signs liable to mislead, confuse or deceive consumers as to the origin, nature, intended purposes, quality, value or other characteristics of the goods or services.

A medicinal brand can be registered as a trade mark if it satisfies the conditions set out above. The Ministry of Health encourages a drug registration applicant to register IPRs. The Ministry of Health can refuse to grant a registration number or marketing authorisation for a drug if there are sufficient grounds to show that the drug may infringe another party's protected IPRs.

Common reasons for refusal of protection of a medicinal brand include:

- The mark is considered generic or descriptive due to indicating the purpose or the ingredients/composition of the drug bearing the mark, or is partly or wholly derived from the international non-proprietary name (INN).
- The mark is confusingly similar to a previously filed/registered mark.

9. How is a trade mark registered?

## Application and guidance

Applications for trade marks are filed at the IP Office through paper applications or online (the IP Office has recently adopted an online system that enables online filing of trade mark applications). Guidance on the application procedure for trade mark registration is provided on the IP Office website in Vietnamese ([www.noip.gov.vn](http://www.noip.gov.vn)).

The Drug Administration of Vietnam also reviews the intellectual property aspects of proposed trade marks when reviewing drug registration applications.

## Process and timing

**National trade mark registration.** A national trade mark registration dossier is filed at the IP Office and is given a filing date and an application number.

Under the law, the time frame for prosecuting a trade mark application from filing to the grant of registration is 12 months. This includes the following stages:

- **Formality examination (one month from the filing date).** At this stage, the IP Office will examine the necessary formalities of the application such as the power of attorney, classification of goods/services, and so on.
- **Notification of formality acceptance.** The IP Office will issue this if all formalities are complied with. Alternatively, an office action is issued and the applicant has one month to respond to the office action.
- **Publication (two months from the date of formality acceptance).** The application is published in the *IP Gazette*.
- **Substantive examination (nine months from the publication date).** At this stage, the IP Office will examine the availability of registration for the applied mark.
- **Notification of granting certificate.** If the trade mark meets all the required protection criteria, the IP Office issues a notification of granting certificate and requests the applicant to pay the registration fee within one month. Otherwise, the IP Office will issue a notification of substantive examination results that provisionally refuses protection of the mark. The applicant will have two months to respond to the IP Office's refusal.
- **Certificate of trade mark registration (one or two months from paying the registration fee).** If the trade mark meets the protection criteria, the certificate of registration is issued within one or two months from the date of payment of the fees.

In practice, if the case goes smoothly, the whole process for a trade mark to obtain registration may take about 14-15 months (because of a backlog of applications at the IP Office).

The requirements for a national application dossier are:

- Five representations of the trade mark or an image file of the trade mark.
- If the trade mark is three-dimensional, a photograph or perspective view, or different side views of the trade mark are required (if necessary).
- A request for trade mark registration with:
  - the name, address, and nationality of the applicant;
  - the list of goods/services covered by the mark and their classification according to the WIPO Nice Agreement Concerning the International Classification of Goods and Services;
  - a description of the mark (meaning, colours claimed, transliteration into Roman letters if the mark consists of characters not in English).
- A power of attorney executed by the applicant.

- A certified copy of the priority document (if Paris Convention priority is claimed).

**International trade mark registration designating Vietnam.** Within 12 months from being informed by the WIPO, the IP Office will automatically examine the trade mark registration. The following apply:

- If the trade mark owner does not receive any feedback from the IP Office through the WIPO after 12 months, the international trade mark registration is accepted in Vietnam and the trade mark is protected in Vietnam.
- Otherwise, the IP Office will issue a provisional refusal to accept the international trade mark registration and send it to the WIPO.
- After receiving the provisional refusal through the WIPO, the owner can assign a Vietnamese IP agent to file an appeal at the IP Office.
- The IP Office will re-examine the trade mark and, if the result is positive, will withdraw the refusal and issue a decision of acceptance of the international trade mark registration in Vietnam. The trade mark is then protected in Vietnam. The IP Office will issue a trade mark certificate on the owner's request.

10. How long does trade mark protection typically last?

Trade mark protection begins when the trade mark is registered and lasts for ten years from the date of filing the application. Protection can be renewed indefinitely for consecutive terms of ten years each.

11. How can a trade mark be revoked?

In Vietnam, a trade mark can be revoked through either cancellation or termination of validity. In the event of cancellation, the trade mark rights are considered to have never been acquired. In the case of termination of validity, the trade mark rights become invalid as of the termination date.

**Cancellation.** A trade mark can be cancelled in the following situations:

- The applicant for registration did not have or had not been assigned the right to register the trade mark.
- The trade mark failed to satisfy the protection conditions at the time of registration.

*(Article 96, Law on Intellectual Property.)*

**Termination of validity.** This can occur in the following situations:

- The brand owner fails to pay the stipulated validity maintenance or extension fee.
- The trade mark owner no longer exists, or the owner is no longer engaged in business activities, and does not have a lawful heir.
- The owner relinquishes the trade mark.
- The owner of a collective trade mark fails to supervise or ineffectively supervises the implementation of the regulations on use of the collective mark.
- The owner of a certification mark violates the regulations on use of the mark or fails to supervise or ineffectively supervises the implementation of such regulations.
- The trade mark has not been used legally for five consecutive years prior to a request for a termination of validity. This does not apply where use has commenced or resumed at least three months before the request for termination.

12. How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

## Conditions

The unauthorised use of signs confusingly similar or identical to a protected trade mark for the same or similar goods/services during the valid term of a trade mark will constitute trade mark infringement (*Law on Intellectual Property, in particular Article 129.1*).

Use of a trade mark means to carry out any of the following acts:

- Affixing the protected trade mark to goods, packages of goods, means for conducting business, means for supplying services and transaction documents in business activities.
- Circulating, offering for sale, advertising for sale, or storing for sale goods bearing the protected trade mark.
- Importing goods or services bearing the protected trade mark.

(*Article 124.5, Law on Intellectual Property*.)

## Claim and remedies

The claims and remedies are the same as for patent infringement (*see Question 5, Claim and remedies*).

In addition, trade mark infringement, particularly trade mark counterfeiting, can be subject to criminal charges under Article 226 of the Penal Code of 2015, as amended and supplemented in 2017.

## Dispute resolution and settlement

See [Question 5, \*Dispute resolution and settlement\*](#).

## Relevant international trade mark instruments and processes

See [Question 5, \*Relevant international patent instruments and processes\*](#).

13. Outline the regulatory powers and enforcement action against counterfeiting in the pharmaceutical sector.

## Regulatory powers

In the pharmaceutical sector, a trade mark owner can request the Ministry of Health to withdraw the certificate for circulation of the counterfeit product.

## Enforcement action

Brand owners can rely on the following actions to enforce their IPRs.

**Administrative action.** Administrative actions are both cost-effective and time-efficient. This is the most common route in Vietnam for companies if their main priority is to stop the ongoing infringement.

To initiate the action, the trade mark holder must file an application with the competent authorities such as the police, the Inspectorate of the Ministry of Science and Technology, and the Market Control Force. The authority examines the request within one month from the filing date. When the request and its accompanying documents are found to be satisfactory, the competent authority will then raid and seize infringing goods without prior notice to the infringer. If an infringement is found, the competent authority will impose sanctions on the infringer.

**Civil action.** The trade mark holder can take civil action to claim remedies available under law, such as a compulsory order to stop the infringement, a public apology, and compensation for the infringement. After an administrative action, the trade mark holder can also commence civil litigation to claim damages based on evidence collected in the administrative action.

**Criminal action.** The new Penal Code of 2015, as amended and supplemented in 2017, which took effect on 1 January 2018, establishes criminal measures as a viable alternative to administrative and civil measures, with the possibility of imposing the most serious penalties. The new Penal Code clearly states the financial thresholds in terms of illegal profit generated or loss incurred by the trade mark owner. It is expected to make enforcement easier than the provisions of the old Penal Code of 1999, as amended and supplemented in 2009.

Criminal charges can be brought against IP counterfeiting under Article 226 of the Penal Code. However, the effectiveness of the new provisions may not be guaranteed in the near future, due to a lack of actual enforcement experience of authorities (including the police and prosecutors).

In practice, the competent authorities often use other articles of the Penal Code to prosecute counterfeiters, including the following crimes:

- Article 188 (smuggling).
- Article 190 (producing and trading in prohibited goods).
- Article 191 (storing and transferring prohibited goods).
- Article 192 (producing and trading in counterfeits).
- Article 193 (producing and trading in counterfeits which are food or food additives).
- Article 194 (producing and trading in counterfeits which are medicines for treatment or prevention of diseases).
- Article 195 (producing and trading in counterfeits which are animal feed, fertiliser, veterinary medicines, pesticides, plant varieties, and livestock).

**Border control.** The trade mark owner can seek a customs seizure of infringing shipments on the borders of Vietnam.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, visit *Medicinal product regulation and product liability in Vietnam: overview*.

## IP and competition law issues

14. Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector. In particular, the competition authorities and their regulatory powers, key legislation, whether pharmaceutical investigations are common, key recent activity and case law.

The key legislation in the competition law framework includes the:

- Law on Competition No. 23/2018/QH14 adopted by the National Assembly on 12 June 2018 and in force since 1 July 2019.
- Decree No. 116/2005/ND-CP of the Government dated 15 September 2005, guiding the implementation of certain provisions of the Law on Competition (as amended and supplemented by Decree No. 119/2011/ND-CP on 16 December 2011).

- Decree No. 71/2014/ND-CP of the Government dated 21 July 2014 on sanctions in the field of competition.
- Decree No. 35/2020/ND-CP of the Government dated 24 March 2020 elaborating on several articles of the Law on Competition.

The following legislation specifically applies to IP-related competition issues, particularly misleading trade indications and cybersquatting:

- Law on Intellectual Property.
- Decree No. 99/2013/ND-CP.
- Circular No. 11/2015/TT-BKHCHN.

Since the adoption of the Law on Handling of Administrative Violations in 2012, the Competition Authority under the Ministry of Industry and Trade is no longer entitled to deal with misleading trade indication cases. These cases now fall under the jurisdiction of the competent IP authorities, such as the courts and the Inspectorate of the Ministry of Science and Technology.

In the pharmaceutical sector, the issue of misleading trade indications stands out from other competition issues. However, there have not been many cases on this issue in the past few years. In these cases, the offenders often imitate the packaging of a widely used drug for the purpose of trading on the goodwill of the product. The competent authorities for this kind of case include the courts and the administrative authorities, such as the Inspectorate of the Ministry of Science and Technology.

15. Briefly outline the competition issues that can arise in relation to commercial contracts and other business arrangements relating to medicinal products? What compliance issues do parties to pharmaceutical technology licences and pharmaceutical distribution agreements need to consider?

Currently, competition issues in the IP field only involve misleading trade indication and cybersquatting (see [Question 13](#)). There are no specific regulations on competition in licensing and technology transfer.

Although there is a compulsory licensing regime, the competent authorities have not ruled on any compulsory licensing in Vietnam.

16. Are there competition issues associated with the entry of generic pharmaceuticals in your jurisdiction?



Vietnam has not laid down any specific regulations on competition relating to patents (see [Question 13](#)). IP-related competition issues only include misleading trade indication and cybersquatting.

In certain situations, the purchase of patents for destruction or prevention from use of the patent could trigger some anti-trust remedies, in accordance with Decree No. 71/2014/ND-CP.

17. Have abuse of dominance issues arisen in the pharmaceutical sector in your jurisdiction?

To the best of the authors' knowledge, abuse of dominance issues have not arisen in the pharmaceutical sector in Vietnam.

18. Have parallel imports of pharmaceuticals raised IP and competition law issues in your jurisdiction?

Parallel imports are legal in Vietnam under IP law (particularly Articles 20 and 125.2 of the Law on Intellectual Property). The conditions for parallel imports of pharmaceuticals are further detailed in Decision No. 1906/2004/QĐ-BYT of the Ministry of Health.

Many pharmaceutical manufacturers, however, are understandably concerned that parallel importation could lead to diminished profits, thereby reducing research and development efforts, and leading to a slowdown in the innovation of new drugs. In certain situations, parallel imports could also put public health at risk.

A recent case brought these issues to the forefront. A major European pharmaceutical innovator learned that a Vietnamese company was importing diabetes drugs into Vietnam that the company had manufactured for the Turkish market. While these drugs were "genuine" products of the manufacturer, and drugs under the same brand name had been authorised for circulation in Vietnam, the markets were not truly "parallel". Turkey requires different standards for storage than Vietnam, and the quality of the drugs could deteriorate more rapidly in Vietnam's tropical climate. With a view to protecting public health, the authorities decided to prohibit the distribution of the parallel imports by relying on regulatory aspects, especially labelling regulations, including imposing a monetary fine and seizing the products. They also brought the issue to the attention of the Drug Administration of Vietnam, which may lead it to take further precautions in granting licences for parallel importation.

In its recent practice, when weighing the decision to grant a parallel import licence, the Drug Administration of Vietnam has focused on the price and the name of the drugs, but not the quality or any special characteristics of the original market.

19. Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body? Are there any formalities or other requirements that must be complied with to make the licence enforceable?

There is no requirement that remittance of royalties payable under a patent or trade mark licence agreement to a foreign licensor be approved by a regulatory body.

The registration of a patent or trade mark licence is not compulsory in Vietnam. A patent or trade mark licence is valid and legally effective against any third party on registration with the IP Office.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, see [Medicinal product regulation and product liability in Vietnam: overview](#).

## Contributor profiles

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**Professional qualifications.** LLB, Bachelor of Pharmacy

**Areas of practice.** Life sciences; regulatory affairs; intellectual property.

#### Recent transactions

- Advised two international pharmaceutical companies on issues of patent and data exclusivity in Vietnam in light of the Trans-Pacific Partnership.
- Prepared arguments/explanations to submit to the Drug Administration of Vietnam to successfully declare a biologic drug as an original brand-name drug which will be allowed to join drug tenders for original brand-name drugs in hospitals in Vietnam.
- Analysed the patent claims, drafted claim charts, and obtained professional conclusions on patent infringement from the Vietnam Intellectual Property Research Institute in several patent infringement cases concerning patented human drugs.

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**Professional qualifications.** BSc in Pharmacy

**Areas of practice.** Life sciences; regulatory affairs.

**Recent transactions**

- Prepared, submitted, and followed up on dossiers to obtain registration licences for pharmaceuticals in Vietnam.
- Converted global labelling for both drugs and medical devices to Vietnamese labelling to meet stringent requirements for Vietnam.

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