

# Pharmaceutical IP and competition law 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.
- Law No. 36/2009/QH12 Amending and Supplementing a Number of Articles of the Law on Intellectual Property.
- Decree No. 103/2006/ND-CP of 22 September 2006, Detailing and Guiding the Implementation of a Number of Articles of the Law on Intellectual Property regarding Industrial Property.
- Circular No. 01/2007/TT-BKHCN of 14 February 2007, Guiding the Implementation of Government Decree No. 103/2006/ND-CP of 22 September 2006.

At present, there are two types of patents for technical solutions in Vietnam: patents for invention and patents for utility solutions (also referred to as petty patents). Both types are granted for an invention or a group of inventions which 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.
- Have its subject matter capable of industrial application.

A utility solution patent must be:

- Globally novel.
- Have its subject matter capable of industrial application.

The following subject matter cannot be patented:

- 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 varieties, animal varieties.
- Processes of essentially biological processes for the production of plants and animals, except microbiological processes.
- Prevention, diagnostic and therapy methods for treatment of the human or animal body.

Registered drugs containing active ingredients still within the period of intellectual property protection 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.

### 2. How is a patent obtained?

#### Application and guidance

Applications to register a patent are made to the National Office of Intellectual Property (NOIP). Guidance on the application procedure is provided on the NOIP 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 get an invention patent or 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 NOIP, in practice even the timelines are not different.

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 (PCT) application. Though the dossier requirements and timelines differ, the NOIP will treat all patent applications similarly.

#### Process and timing

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

- Vietnamese version of the specification.
- Petition requesting the grant of a patent with International Patent Classification (IPC) symbols, name, address and nationality of 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 PCT application).

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

- If the results are positive, the NOIP will issue a decision of acceptance of a valid application.
- If the NOIP 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 NOIP 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*. Then, a request for substantive examination must be filed at the NOIP within 42 months from the earliest 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 NOIP will issue an invitation to pay the granting fee and first annuity.
- If the results are negative, the NOIP will issue an office action and applicants must file amendments/arguments. Then, the NOIP may 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.

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

#### Duration and renewal

**Invention patent.** Protection begins from the issue of the patent and continues for 20 years from the date of filing.

**Utility solution patent.** Protection begins from the issue of the patent and continues 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 (*Article 96, Law on Intellectual Property*):

- The applicant has neither a right to registration nor has been assigned such a right.
- The invention in the patent does not satisfy the protection requirements at the grant date of the patent.

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 in part fails to satisfy the protection requirements. In addition a patent can be terminated in the following cases (*Article 95, Law on Intellectual Property*):

- 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.

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, IP Law*). 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]".

The use of an invention means to carry out the following acts (*Article 124. 1, IP Law*):

- 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 of a protected product or a product obtained by the protected process.
- Importing the protected product or a product obtained by the protected process.

The following defences are applicable to patent infringement actions (*Article 125.2, IP Law*):

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

#### Claim and remedies

**Administrative action.** A patentee brings an administrative action by filing a complaint with the 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 under Chapter IV of Decree 99/2013/ND-CP on administrative sanctions in the industrial property field and Chapter III of the Law on Handling of Administrative Violations.

**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 under the Code of Civil Procedure. The enforcement of the court's judgment/decision is stipulated under the Law on Enforcement of Civil Judgment 2008.

**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.

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The following remedies are available in a patent infringement case:

**Administrative remedies.** These are:

- Warning or monetary fine.
- Suspension for a limited term of relevant business activities.
- Destruction of the infringing elements/goods.
- Compulsory recovery to the state treasury of the illicit earnings from the patent infringement.

**Civil remedies.** These include the following compulsory orders:

- Termination of the patent infringement.
- Public rectification and apology.
- Performance of civil obligations.
- Compensation for damages.
- Destruction or 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 influence the exploitation of rights by the patent holder).

Attorney's fees, in principle, could be recovered under the civil action.

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## 6. Are there non-patent barriers to competition to protect medicinal products?

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There is a regulatory data protection mechanism for drugs in Vietnam, which lasts from the date the trial data is filed to the date of expiration of the five-year validity of a drug marketing authorisation granted to the applicant with the confidential trial data. However, the protection mechanism 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.

## TRADE MARKS

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### 7. 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?

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#### Conditions and legislation

The applicable legislation to trade mark registration in Vietnam includes:

- Law on Intellectual Property No. 50/2005/QH11.
- Law No. 36/2009/QH12 Amending and Supplementing a Number of Articles of the Law on Intellectual Property.
- Decree No. 103/2006/ND-CP of 22 September 2006, Detailing and Guiding the Implementation of a Number of Articles of the Law on Intellectual Property regarding Industrial Property.
- Circular 01/2007/TT-BKHCN issued on 14 February 2007, Guiding the Implementation of Government Decree No. 103/2006/ND-CP of 22 September 2006.

Brand owners can seek trade mark registration by either the national registration system or the Madrid System. The National Office of Intellectual Property (NOIP) applies the same basic conditions and legislation for both procedures. However, in practice, the NOIP only

issues trade mark certificates for national trade mark registrations, and decisions of acceptance for international registration.

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 subjects (that is, it is 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 in the list of signs not registrable as trade marks under Article 74.2 of the IP Law. This list of indistinctive signs includes a wide range of exclusions that range from simple geometric figure signs, to descriptive signs, to signs which are identical or confusingly similar to the registered or well-known marks of others.

Article 73 of the IP Law also sets out a number of types of signs which 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.

#### Scope of protection

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 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.

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## 8. How is a trade mark registered?

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#### Application and guidance

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

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## Process and timing

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

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

- **Formality examination (one month from the filing date).** At this stage, the NOIP 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 NOIP will issue this if all formalities are accepted. 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 then published in the *IP Gazette* if it is accepted in terms of form.
- **Substantive examination (nine months from the publication date).** At this stage, the NOIP will examine the availability of registration of the applied mark.
- **Notification of granting certificate.** If the trade mark meets all required protection criteria, the NOIP issues a notification of granting certificate and requests the applicant to pay the registration fee within one month. Otherwise, the NOIP will issue a notification of substantive examination results which provisionally refuses protection of the applied mark. The applicant will have two months to respond to the NOIP's refusal.
- **Certificate of trade mark registration (one or two months from paying the registration fee).** If the trade mark meets the protection criteria, this is issued within one or two months from the date of paying the fees.

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

The requirements of the 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).
- Request for trade mark registration with:
  - name, address, and nationality of the applicant;
  - 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;
  - 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 designated into Vietnam.** Within 12 months from being informed by the WIPO, the NOIP will automatically examine the trade mark registration:

- If the trade mark owner does not receive any feedback from the NOIP 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 NOIP 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 NOIP.
- Then, the NOIP will re-examine the trade mark and if the result is positive, the NOIP 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 NOIP will issue a trade mark certificate on the owner's request.

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## 9. How long does trade mark protection typically last?

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

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## 10. How can a trade mark be revoked?

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In Vietnam, a trade mark can be revoked by either cancellation or termination of validity. Cancellation will result in a scenario in which the trade mark rights are considered to have never been acquired. Termination of validity will lead to a situation in which the trade mark rights become invalid as of the termination date. Before the termination date, however, the trade mark rights are still considered valid.

**Cancellation.** A trade mark can be cancelled in the following situations (*Article 96, IP Law*):

- The applicant for registration neither had nor had been assigned the right to register the trade mark.
- The trade mark failed to satisfy the protection conditions at the time of the registration.

**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 marks.
- 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.

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

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### 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 (*IP Law, in particular Article 129.1*).

Use of a trade mark means to carry out any of the following acts (*Article 124.5, IP Law*):

- 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, of goods bearing the protected trade mark.
- Importing goods or services bearing the protected trade mark.

### Claim and remedies

The claims and remedies are the same as for patent infringement (*see Question 3*).

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

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

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### 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 for 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 rendering 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 (like 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, due to border control measures.

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

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## 13. 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.

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The key legislation in the competition law framework includes the:

- Law on Competition No. 27/2004/QH11 adopted by the National Assembly on 3 December 2004. At present, the Vietnamese regulator is working on a draft law which is expected to entirely replace the current Law on Competition in the near future. Five drafts have been made available to the public so far, the latest dated 8 March 2018.
- 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.

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

- Law on Intellectual Property No. 50/2005/QH11 adopted by the National Assembly on 29 November 2005 (as amended and supplemented in 2009).

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- Decree No. 99/2013/ND-CP of the Government dated 29 August 2013 on administrative sanctions in the industrial property field.

- Circular No. 11/2015/TT-BKHCN of the Ministry of Science and Technology dated 26 June 2015 guiding certain provisions of Decree 99/2013/ND-CP.

Since the passage 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. Such 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.

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#### **14. Briefly outline the competition issues that can arise on the licensing of technology and patents in a pharmaceutical context**

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Currently, competition issues in the IP field only involve misleading trade indication and cybersquatting (see *Question 13*). There have been 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.

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

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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 remedies relating to antitrust, in accordance with Decree No. 71/2014/ND-CP.

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#### **16. Have abuse of dominance issues arisen in the pharmaceutical sector in your jurisdiction?**

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

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

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Parallel imports are legal in Vietnam in terms of IP law (particularly, Articles 20 and 125.2 of the IP Law). Parallel imports of pharmaceuticals are further detailed in Decision No. 1906/2004/QD-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. Even worse, in certain situations, parallel imports could 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 sanction 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.

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#### **18. 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? How is such a licence made enforceable?**

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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 NOIP.

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*.

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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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**Areas of practice.** Commercial transactions and M&A; corporate services; life sciences.

#### Recent transactions

- Seconded for six months to Vietnamese offices of multinational pharmaceutical, medical device and consumer goods company to temporarily fill a vacant in-house counsel position.
- Advised multiple foreign pharmaceutical companies in Vietnam on business structuring options for compliance with new pharmaceutical legislation.
- Advised one of the world's largest foreign research-based pharmaceutical companies as external counsel in Vietnam.



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**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.