

Indonesia

Contributing firm
Rouse



Author
Brett McGuire

Indonesia's geography and unique socio-economic conditions create a number of challenges for pharmaceutical companies seeking to do business there. As one of the fastest-growing markets in the region, Indonesia also presents significant opportunities. Success is possible through a robust strategy, as well as strict and transparent compliance with Indonesia's regulatory regime.

Selection, clearance and registration

Regulation

Trademarks are registered with the Trademark Office. However, all drugs intended for distribution in Indonesia must also be approved by and registered with the Food and Drug Monitoring Agency (BPOM) before they are imported, marketed or sold in Indonesia.

It usually takes between two and three years for a trademark registration certificate

to be issued. Once an application is filed, the Trademark Office checks whether all formalities have been complied with and whether there are any prior conflicting marks. If objections are raised, the office will issue an office action and the applicant has 30 days in which to respond. If the application is accepted by the office, it will be published in the *Government Gazette*. At any time within three months of publication, the application may be opposed by third parties on various grounds, including the similarity of the mark to prior registered marks.

The issuance of an office action will delay the grant of a registration certificate by six to 12 months. An opposition to a trademark application can delay registration by 12 to 18 months.

Once registered, a trademark is protected in Indonesia for 10 years from the date of filing. The registration can be renewed for subsequent periods of 10 years. Applications for renewal may be filed up to 12 months before expiry of the then-current registration period.

Classification

The Trademark Office applies the Nice Classification. However, the office does not require the strict classification of goods or services covered by a trademark. For example, it is possible to apply for the class heading or a general category of goods, such as "vaccines" in Class 5.

This can cause problems for applicants, as it is impossible to amend a trademark application once it has been filed, except by deleting words from the goods or services specification. For example, if an application has been filed for "vaccines for human use" in Class 5, the trademark applicant cannot subsequently restrict the goods to "vaccines for human use in the treatment of avian influenza".

Confusion with other marks or INNs

Generally speaking, any trademark can be registered provided that:

- it is distinctive;
- it is not descriptive; and
- it is not similar to an earlier registered mark.

With regard to the World Health Organization's international non-proprietary names (INNs), a proposed trademark should be acceptable for registration as long as it is not confusingly similar to an INN. The Trademark Office takes a slightly less strict approach when considering similarity and the distinctiveness of trademarks for goods in Class 5.

Non-traditional trademarks

Indonesia does not allow the registration of non-traditional trademarks, such as single colours, shapes, tastes or sounds. The Trademark Law defines a 'trademark' as a sign in the form of a picture, a name, a word, letters, figures or a composition of colours. Therefore, single colour trademarks are not registrable, but – at least theoretically – it is possible to register a composition of colours.

The law is currently under review; it is proposed to extend the classification of trademarks to include three-dimensional marks.

Trademark use requirements

Once registered, a trademark must be used in exact accordance with the mark as registered. If a trademark is not used commercially for a consecutive period of three years from the date of registration, or any consecutive three-year period thereafter, a third party may apply to the court for the cancellation of the mark on the grounds of non-use. There are divergent views in the Indonesian courts as to what constitutes 'use in accordance with registration'.

Trademark licences

The Trademark Law states that unless a licence agreement has been recorded at the Trademark Office, it will have no effect on third parties. However, as of the beginning of 2009, the regulations on licences have not yet been implemented and it is not possible for licences to be recorded. It is recommended that trademark licences be informally deposited with the office to put the licensor and licensee in the best possible position. The use of a mark by a licensee is deemed to be use by the owner of the mark. A licensee, as well as the trademark owner, can commence infringement proceedings.

Anti-dilution and unfair competition

Indonesia is obligated under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and Article 10(1)*bis* of the Paris Convention for the Protection of Industrial Property to implement national legislation providing for trade dress/unfair competition protection. However, Indonesia

has no specific trade dress/unfair competition law. Technically, it is possible to file a lawsuit based on unfair competition-type arguments under the Criminal and Civil Codes. However, these general provisions are not tailored to provide adequate or effective IP protection, as they are almost impossible to harness in practice. Accordingly, court actions based on unfair competition have been rare, and none has been successful.

Similarly, Indonesia is required under the TRIPs Agreement and Article 6(1) of the Paris Convention to provide effective protection to well-known marks. In particular, Article 16(3) of the TRIPs Agreement prohibits the registration or use of a mark similar to a well-known mark for goods dissimilar to those for which the well-known trademark is registered.

While the Indonesian Trademark Law provides that an application to register a mark may be rejected if the mark is similar in principle or in entirety to a well-known trademark owned by another party for dissimilar goods or services, the relevant provision, Article 6(3), requires that certain conditions, as further provided in a government regulation, be met. However, this regulation remains unimplemented.

The law contains no provision to prevent the use of a trademark similar to a well-known mark for goods dissimilar to those for which the well-known mark is registered. This violates Article 16(3) of the TRIPs Agreement, which makes such anti-dilution protection mandatory. There is no apparent intention on the part of the Indonesian government to deal with this issue.

Parallel imports and repackaging

Preventing parallel imports is largely a matter for pharmaceutical companies and their distributors – except in the case of illegal imports (smuggled goods).

Parallel imports are permissible *per se* under the law, as there is no specific provision on the matter. Under Article 4 of the law, the registration of a trademark gives "the exclusive right granted by the state to the owner... to himself use said mark or to grant permission to another party to use it".

In the case of illegal imports, such goods will usually breach Indonesia's drug registration and labelling requirements. With the assistance of BPOM, illegal imports can be seized and destroyed.

Anti-counterfeiting and enforcement

Counterfeits

The prevalence and circulation of illegal drugs in Indonesia has reached alarming

levels in recent years. It is estimated that 40% of drugs are counterfeit or distributed without a licence.

According to the University of Indonesia's Institute for Economic and Social Research, in 2005 the total losses suffered in terms of taxes exceeded \$65.4 million. Accordingly, the increase in counterfeit drugs is a commercial issue for Indonesia and the region as a whole, as well as a significant health and public safety concern.

In July 2007 the police uncovered 16 containers' worth of illegal drugs in two warehouses, representing an estimated 53 million units. At the time, this was the largest seizure of illegal medicine in the world. Among the medicine found were drugs for the treatment of coronary disease and cancer, as well as over-the-counter (OTC) drugs. In addition, all types of medicine were found (eg, OTC, generic and prescription drugs).

The Drug Anti-counterfeiting Subcommittee of the International Pharmaceutical Manufacturers Group estimates that 10% of drugs sold in Indonesia are counterfeit. According to the Indonesian Anti-counterfeiting Society, around 60% of counterfeits are imported – predominantly from China. The remaining 40% are produced locally.

Counterfeit drugs found in the Indonesian market fall into the following four categories:

- drugs with no active pharmaceutical ingredient;
- drugs with an inadequate level of active pharmaceutical ingredient;
- drugs with a 'different' chemical ingredient; and
- drugs with substandard product quality due to significantly inferior production practices.

Illegal drugs are predominantly sold on the black market at unauthorized outlets. However, illegal drugs can also be found at authorized outlets.

A number of factors contribute to the high prevalence of illegal drugs in Indonesia:

- a low health literacy, coupled with low awareness;
- inadequate law enforcement and non-deterrent fines; and
- the country's complicated geography and distribution channels.

Access to drugs through the Internet has increased cross-border trade and represents another opportunity for counterfeiting.

Illegal drugs are typically offered at lower prices. Lower prices are usually explained as being possible by virtue of:

- direct sources;
- shorter distribution chains;
- large quantities resulting in a discount; or
- lower profit margins.

Socio-economic conditions make pharmaceutical products, especially new molecules, unaffordable to most Indonesian consumers. This lack of access makes low-priced counterfeit products very attractive.

A significant contributing factor is the lack of compliance with the law, which requires that prescription medication be distributed only with a prescription. Studies show that 89% of counterfeit drugs are sold through small unregistered outlets with no prescription.

Enforcement

There have been great improvements in the ability of IP rights holders to enforce their rights, particularly in copyright enforcement. However, taking action against infringers is still difficult and expensive.

Corruption and lack of transparency remain significant problems within the police and the Attorney General's Office. Underfunding of the police means that rights holders are required to assist with the police's operational costs. However, the inability of the police to provide transparency in terms of reporting operational costs often means that rights holders cannot proceed.

Similarly, corruption within the Attorney General's Office means that cases are often not prosecuted. The lack of adequate reporting structures precludes officers from being held accountable, thereby exacerbating the problem.

While great improvements have been made by the Indonesian courts in recent years, corruption is still a problem.

Criminal enforcement strategies

If the level or impact of a counterfeit product is low, cease and desist letters can be a simple and cost-effective step against the counterfeiters. It is usually possible to secure a settlement pursuant to which the infringer provides a written undertaking and details of supply and customers, among other things. Delivery up of infringing goods and compensation is possible, although uncommon at this stage.

If the level of counterfeiting is high and the location where the counterfeiting is conducted is known, a raid can be carried out to seize the counterfeit goods. The raid is generally initiated by the registered owner of the trademark by filing a complaint with the police. The police have the power to seize infringing goods and arrest infringers.

Trademark owners must work closely with the police during the raid.

If a trademark owner pursues its complaint after a raid, the police will complete their investigation and then transfer the case to the public prosecutor. If the public prosecutor finds that the investigation and the evidence are sufficient, a criminal prosecution will be filed with the District Court. If there is a conviction, the infringer will have to pay a fine and/or be sent to prison. However, penalties are often low. Moreover, corruption remains problematic in the Indonesian legal system. Prosecutions should be pursued only as part of a broader long-term strategy.

Civil proceedings

If a cease and desist letter fails or a police raid or criminal prosecution are inappropriate, a case can be brought in the civil courts. Available remedies include:

- injunctions;
- search and seizure orders; and
- damages.

An application for a preliminary injunction must be accompanied by a bank or cash guarantee. If the court ultimately decides that a case has no merit, the order for the preliminary injunction will be discharged and the guarantee forfeited to the infringer as compensation. Although this remedy is well known abroad, it was introduced in Indonesia only in 2001, so is still relatively new. Few have been granted so far.

Damages can be claimed, although the plaintiff needs to prove actual loss and/or a method of quantifying that loss.

Customs recordal

There is no Customs recordal programme in Indonesia. Consequently, seizures are rare and generally made on the basis of intelligence provided by trademark owners. Under the Customs Law, Customs officials have an *ex officio* power to seize a consignment if they have reason to believe that the goods are counterfeit.

Warrants

Theoretically, a trademark owner can apply to the court for a warrant ordering the seizure of consigned goods that infringe its IP rights. However, the government regulation specifying the procedural requirements is yet to be implemented.

Advertising

Drug registration

All drugs must be registered with BPOM

before they are advertised in Indonesia. A new drug registration is required for the following types of products or product changes:

- a new active ingredient;
- a new derivative or combination; and
- a new dosage form, strength or indication.

The following changes to a drug registration must be notified to BPOM:

- licence holder, trade name, manufacturing site or factory name, or importer;
- inactive ingredients or excipients;
- specification or method of analysis; and
- packaging or labelling.

Marketing and labelling

Marketing authorization licences are valid for five years. Drugs produced for export only are not required to have labels in Indonesian. However, all drugs produced or sold in Indonesia must have Indonesian labelling.

Generic substitution

Generic substitution is not in itself regarded as trademark infringement in Indonesia, as there is no unlawful reproduction or use of a registered mark. Arguably, the substitution of a generically equivalent drug amounts to passing off. However, Indonesia's passing off and consumer protection laws are not well-developed and are rarely used in this context.

Online issues

While the police acknowledge that the distribution of illegal drugs via the Internet is an issue, distribution of drugs through e-pharmacies or bulk resellers makes up only a very small part of the Indonesian market. However, this will become an important issue as the penetration of the Internet accelerates. [WTR](#)

Biographies

Rouse

Rouse

7th Floor, Wisma Pondok Indah 2,
Jalan Sultan Iskandar Muda, Pondok Indah,
Jakarta 12310, Indonesia

Tel +62 21 769 7333

Fax +62 21 769 7505

Web www.iprights.com

**Brett McGuire**

Executive, Indonesia country manager
bmcguire@iprights.com

Brett McGuire is an executive of Rouse and country manager of Rouse's Indonesian office. He graduated with an LLB-BA from Otago University, New Zealand. He deals with almost all aspects of IP law in Indonesia. His areas of particular experience include strategic planning to combat counterfeiting and IP theft generally. He is an adviser to the International Pharmaceutical Manufacturer Group on strategies for addressing parallel imports and counterfeit drugs.