Indonesia

Contributing firm
Rouse

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Indonesia's rapidly growing domestic market presents significant opportunities for pharmaceutical companies seeking to do business in the country. However, its geography and unique socioeconomic conditions also present a challenge. 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 (TMO). 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 has been filed, the TMO will examine it to check that all formalities have been complied with and that there are no prior conflicting marks. If objections are raised, the TMO will issue an office action and the applicant then has 30 days in which to respond. If the application is accepted by the TMO, it will be published in the *Government Gazette*. At any time within three months of publication, it may be opposed by third parties on various grounds, including similarity of the mark to prior registered marks.

The issuance of an office action will delay the issuance of a registration certificate by six to 12 months. The opposition of 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 10-year periods. Applications for renewal can be filed up to 12 months before expiry of the then-current registration period, but not afterwards.

Classification

The TMO applies the International Classification of Goods and Services. However, the TMO 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, as it is not possible to amend a trademark application once it has been filed, except by deleting words from the goods or services specification, as the case may be. For example, if an applicant is 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, INNs

Generally speaking, any trademark can be registered, provided that it is distinctive, is not descriptive and is not similar to a prior registered mark. With regard to the World Health Organisation's international nonproprietary names (INNs), as long as a proposed trademark is not confusingly similar to an INN, it should be acceptable for registration.

The TMO takes a slightly less strict approach when considering similarity and the distinctiveness of trademarks in Class 5.

Non-traditional trademarks

Indonesia does not allow for the registration of non-traditional trademarks, such as colours, single shapes, tastes or sounds. The Trademark Law defines a 'trademark' as a sign in the form of a picture, name, word, letters, figures or composition of colours. Colour trademarks are not registrable, although it is at least theoretically possible to register a composition of colours. The Trademark Law is under review and it is proposed that the classification of trademarks be extended 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 for any consecutive three-year period thereafter, a third party can apply to the court for revocation 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 TMO, it will have no effect on third parties. However, as of 2008, the regulations for licences had not been implemented and it is not yet possible for licences to be recorded. It is recommended that trademark licences be informally deposited with the TMO to put the licensor and licensee in the best possible position. The use of a mark by a licensee is deemed to constitute use by the owner of the mark. A licensee, as well as the trademark owner, can commence infringement proceedings.

Anti-dilution and unfair competition

Under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and Article 10(1)*bis* of the Paris Convention, Indonesia is obliged to implement national legislation providing for trade dress/unfair competition protection. However, as yet 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 in practice they are almost impossible to harness. Accordingly, court actions based on unfair competition are rare and none has been successful.

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

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

The Trademark Law contains no provisions that prevent the use of a mark that is similar to a well-known mark, but is used on goods dissimilar to those to which the well-known trademark is applied. This violates Article 16(3) of TRIPs, which makes such anti-dilution protection mandatory. There is no apparent intention on the part of the Indonesian government to deal with this issue.

While great improvements have been made by the courts in recent years, inconsistent, contradictory and illogical decisions are still sometimes issued, precluding effective action to remove incorrectly registered rights from the relevant official registers. This hinders the ability of rights holders to take action against infringement.

Parallel imports and repackaging

Preventing parallel imports is largely an issue for pharmaceutical companies and their distributors, except in the case of illegal imports (smuggled goods).

Parallel imports are permissible *per se* under the Trademark Law. There is no specific provision on parallel imports in the Trademark Law. Under Article 4 of the law, 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 have 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 in one year. Accordingly, this is a commercial issue as well as a significant health and public safety issue for Indonesia and the region as a whole.

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

- drugs with no active ingredient (API);
- drugs with an inadequate level of API;
- drugs with a different chemical ingredient; and
- drugs of sub-standard product quality due to significantly inferior production practices.

According to MIAP, around 60% of counterfeits are imported, predominantly from China. The remaining 40% are produced by local 'home industries'.

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

The following factors contribute to the high prevalence of illegal drugs in Indonesia:

- low health literacy, coupled with low awareness;
- inadequate law enforcement and non-deterrent fines; and
- Indonesia'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. These lower prices are usually explained as being possible as a result of 'direct sources', 'shorter distribution chains', 'bulk purchases' or 'lower profit margins'.

Socioeconomic conditions also make pharmaceutical products, especially new preparations, unaffordable to most Indonesian consumers. This lack of access makes low-priced counterfeit products attractive.

A significant contributing factor is the lack of compliance with regulations that require prescription medication to be distributed only with a prescription. Studies show that 89% of counterfeit drugs are sold without prescription through small, unregistered outlets.

Enforcement

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

Corruption and a lack of transparency are still significant problems in the police and the Attorney General's Office. Under-funding means that rights holders must assist with the police's operational costs. The inability of the police to ensure 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, thus exacerbating the problem.

Criminal enforcement strategies

If the level or impact of a counterfeit product is low, a cease and desist letter can be a simple and cost-effective step against counterfeits. It is usually possible to secure a settlement, pursuant to which the infringer provides a written undertaking and details of supply, customers and so on. Delivery up of infringing goods and compensation are also possible, although still uncommon.

If the level of counterfeiting is high and the location is known, a raid can be conducted to seize the counterfeit goods. Such raids are generally initiated by the registered owner of the trademark by filing a complaint with the police. The police have the power to seize and destroy infringing goods and arrest infringers. For the reasons discussed above, rights holders must work closely with the police during the raid.

If a rights holder 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 at the district court. If there is a conviction, the infringer will have to pay a fine and/or will be sent to prison. However, poor understanding of economic crimes means that penalties are often low. As mentioned above, corruption is a problem 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 is not appropriate, 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 the case has no merit, the order for a preliminary injunction will be discharged and the guarantee forfeited to the infringer as compensation. Although well known abroad, this remedy was not introduced in Indonesia until 2001, so is still relatively new. Few have yet been granted.

Damages can be claimed, although actual loss and/or a method of quantifying that loss must be proved.

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 product or product changes:

- a new active ingredient;
- a new derivative or combination; or
- 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; or
- packaging or labelling.

Marketing and labelling

Marketing authorisation licences are valid for five years in Indonesia. Drugs produced for export only need not 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, because there is no unlawful reproduction or use of a registered mark. It could be argued that 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 online distribution of illegal drugs is an issue, the distribution of drugs through e-pharmacies or bulk resellers makes up only a very small part of the Indonesian market. However, this issue will grow in importance as internet penetration accelerates. WTR

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Kin Wah Chow previously practised in Singapore and Hong Kong, having acted in both contentious and non-contentious IP matters. He began his career practising litigation in the Singapore courts, handling various notable IP cases, including a major patent dispute between two international airlines.

Mr Chow has advised various multinationals in anti-piracy campaigns in Indonesia and the region. Clients include media/merchandising businesses, luxury car manufacturers, and enterprises in the liquor and industrial equipment sectors. His work includes advising on reclaiming well-known marks registered by local parties in Indonesia. He also oversees the patent filing/prosecution practice in Indonesia.