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Selection, clearance and registration

Marketing approval under the Pharmaceutical Affairs Law

Under the Pharmaceutical Affairs Law, sellers must obtain approval from either the Ministry of Health, Labour and Welfare (MHLW) or the prefecture in order to market pharmaceutical products, including drugs (defined in Article 2(1) of the law). Approval must be obtained for each product. In practice, with regard to drugs which require the MHLW's approval, the approval review is conducted by the Pharmaceutical and Medical Devices Agency (PMDA). Applicants must submit a written application, specifying the brand name of the drug. The MHLW notice provides that such brand names must cause no risk to health (eg, should not cause confusion) and be dignified. This notice also provides that

brand names for prescription drugs must, as a general rule, contain information regarding the dosage and the content (or concentration) of the active ingredients.

The Pharmaceutical Affairs Law states that the Ministry of Agriculture, Forestry and Fisheries is responsible for drugs intended for animals.

Trademark registrations with the Japan Patent Office

Pharmaceutical companies must file an application for trademark registration with the Japan Patent Office (JPO) in order for a drug's brand name to be protected under the Trademark Law. The examination for registration generally takes about six months from application. Thus, pharmaceutical companies should file an application with the JPO before applying to the MHLW for marketing approval.

Under the Trademark Law, a trademark application may be rejected if the mark lacks distinctiveness (eg, it is a generic term, is descriptive of designated goods or services or is simple and commonplace) pursuant to

Article 3(1) of the law. Even if a mark is sufficiently distinctive, after a time it may become generic if it is used continuously as a term for the goods themselves by many and unspecified traders, as was the case with the mark SEIROGAN. Also, even if a trademark is sufficiently distinctive, an application will be rejected if it falls under one of the various bars to registration provided in Article 4(1). These bars include trademarks that:

- are misleading as to the quality of the goods or services;
- conflict with a prior registration; or
- cause confusion with respect to the source of the goods or services.

Brand names that consist solely of a mark indicating the quality or ingredients of the drug will be refused by the JPO due to a lack of distinctiveness or a risk of confusion. In the past the Tokyo High Court has upheld a JPO trial decision which rejected a trademark application for the mark D-FRACTION for a tumour-suppressing agent. The term 'D-fraction' is generally used

to refer to the ingredient extracted from *Grifola frondosa*, which is the raw material used in tumour-suppressing agents.

Generally, the likelihood of the trademark causing confusion is assessed from the point of view of consumers and traders. In some cases the Japanese courts have considered that consumers of prescription drugs include not only healthcare professionals, but also patients.

Confusion with international non-proprietary names

Although the JPO guidelines do not clearly refer to the confusion of trademarks with international non-proprietary names (INNs), an application for a trademark that is identical or similar to an INN will be rejected by the JPO for a lack of distinctiveness or for likelihood of confusion. The Tokyo High Court has upheld a JPO trial decision that rejected a trademark application for the mark CEFLAGINE because the term recalled the INN Cefradine and was thus likely to be misleading.

Non-traditional marks

Three-dimensional (3D) trademarks are permitted under the Trademark Law. In the *Mini Maglite* case, the IP High Court ruled that although the 3D shape of a product is usually chosen for reasons of function or aesthetics, and thus barred from registration under Article 3(1)(3) of the law due to lack of distinctiveness, it can be registered if it has acquired distinctiveness, as required under Article 3(2). In the *Coca-Cola Bottle* case, Article 3(2) was applied to a 3D container of goods. Although it is the authors' understanding that there have been no cases in which the JPO has accepted an application for a 3D trademark for a pharmaceutical product, the shape of the actual drugs or the container holding the drugs may be registered as a trademark if it is sufficiently distinctive. On the other hand, trademarks for colours or tastes alone are not permitted, while marks consisting of characters, figures, signs or 3D shapes, or any combination thereof with colours, are permitted.

Unregistered marks that are well known to consumers or traders, as well as certain configurations of goods, are protected under the Unfair Competition Law. In the *Selbex* case, the IP High Court held that trademarks for colours only may be protected under the Unfair Competition Law. In the *Alinavig* case, the Osaka District Court ruled against a company that used a mark similar to the famous mark ALINAMIN, the brand name of a drug manufactured by Takeda Pharmaceutical Company Ltd, on the grounds that the company was negligent

in using this mark under the Unfair Competition Law. The court ruled that, due to the similarities of the marks and the package designs, the company's intent was to take a free ride on Takeda's credibility.

Parallel imports and repackaging

In *Fred Perry*, the Supreme Court held that the parallel import of goods bearing a registered trademark does not constitute infringement, provided that the following requirements are satisfied:

- The trademark was duly affixed with the authorisation of the foreign trademark owner;
- The foreign trademark owner is identical or substantially identical to the Japanese trademark owner; and
- The Japanese trademark owner is in a position to exert influence, directly or indirectly, on the quality of the goods, so that there is no substantial difference between these goods and the goods on which the registered trademark is affixed by the owner, in terms of the quality assured by that registered trademark.

Even if these requirements are satisfied, importers must be aware that a MHLW licence for marketing must be obtained in order to import drugs commercially for the purpose of marketing those drugs under the Pharmaceutical Affairs Law. An increasing number of individuals have been importing drugs which are not approved in Japan through import agencies on the Internet. Consequently, the MHLW has tightened regulations on agencies that import drugs without a licence or that advertise unapproved drugs in violation of the Pharmaceutical Affairs Law.

In cases where imported goods bearing a registered trademark are repackaged into smaller quantities, the Japanese courts have been inclined to treat the parallel import as an infringement, without considering whether the goods are genuine. In the *Viagra* case, the Tokyo District Court held that the import and marketing of repackaged Viagra that was manufactured by Pfizer, Inc and then repackaged into smaller quantities could not be classed as a parallel import of genuine goods, due to the unauthorised repackaging. As a result, the imported Viagra was found to have infringed Pfizer's trademarks.

Anti-counterfeiting and enforcement

Border measures

Under the Customs Law, Customs has the *ex officio* authority to suspend the import

or export of goods suspected of infringing IP rights or violating the Unfair Competition Law, where there is *prima facie* evidence of infringement. However, in most cases Customs exercises its authority based on an application submitted by the rights holder (and in the case of a registered trademark, any registered exclusive licensees) to suspend the release of the suspected goods.

Following the lodging of an application, Customs reviews the validity of the IP right and examines whether the evidence is sufficient to prove the alleged infringement before determining whether to accept the application. If Customs suspects that certain goods are infringing after inspecting them, it may suspend their release and notify both the importer/exporter and the rights holder of the commencement of the identification procedures, together with the name and address of the other party. After examining the opinions and evidence submitted by both parties, Customs will determine whether the suspected goods infringe any IP rights and thus whether to prohibit their release. Customs will confiscate goods identified as infringing IP rights once the period in which the parties can seek an administrative remedy has elapsed. On average, the identification procedure takes about one month from when the customs notice is issued.

Enforcement

A criminal investigation involving counterfeit goods typically starts when the rights holder brings a case to the police, although no complaint from a rights holder is necessary in the case of infringement of a registered trademark or a violation of the Unfair Competition Law. Since only intentional infringements or violations are subject to criminal penalties, the police and public prosecutor must examine the evidence carefully to determine whether they can establish criminal intent before opening an investigation or pressing charges.

Under the Trademark Law, an infringer may be subject to imprisonment for up to 10 years and/or fines of up to ¥10 million. Under the Unfair Competition Law, an infringer may be subject to imprisonment for up to five years and/or fines of up to ¥5 million. In addition, the Customs Law provides that anyone that intentionally imports or exports counterfeits may be subject to imprisonment for up to seven years and/or fines of up to ¥7 million.

The rights holder may take legal action against alleged infringers to seek civil remedies. Normally, rights holders send a warning letter to alleged infringers and wait

a week or two for a reply before commencing legal proceedings. Under civil proceedings, rights holders may seek the following remedies:

- permanent injunction;
- destruction of the counterfeits and removal of the facilities used to commit the infringement;
- compensatory damages (in the case of negligent or intentional infringement);
- restitution for unjust enrichment as a result of the infringement; and
- measures to restore the brand's reputation, including corrective advertising (in the case of negligent or intentional infringement).

Advertising

Regulatory framework and considerations

Pharmaceutical advertising is mainly regulated by:

- the Pharmaceutical Affairs Law;
- the Unjustifiable Premiums and Misleading Representations Law;
- related government regulations; and
- codes of conduct issued by industry groups.

MHLW guidelines state that 'advertising' is defined as something that:

- is clearly intended to induce consumers;
- specifies the name of particular medicinal products; and
- is capable of being acknowledged by the general public.

Although the Pharmaceutical Affairs Law regulates pharmaceutical advertising, it sets out no detailed provisions. The MHLW issued its Standards for Fair Advertising Practices Concerning Medicinal Products in order to help companies to comply with the Pharmaceutical Affairs Law. In the event of a breach of standards, the prefectural government begins an investigation and instructs the party in question to stop or change such advertising voluntarily. Fines and/or imprisonment may be imposed if these instructions are not followed.

The Unjustifiable Premiums and Misleading Representations Law prohibits false and exaggerated advertising. The scope of advertising is not limited to 'advertising' as defined above and broadly covers various kinds of representation.

In addition to the above legal regulations, there are several codes of conduct. The Code of Practice for Promotion of Ethical Drugs and the Fair Competition Code on Restrictions on Premium Offers in the Ethical Pharmaceutical Drugs Marketing

Industry provide clarifying guidelines to ensure fair competition and fair dealing with medical institutions and patients.

Although pharmaceutical advertising need not be approved by the government authorities, the competent prefectural government may be consulted.

Generic substitution

Generic substitution is permitted. Due to the financial pressure to reduce medical costs, the government encourages medical institutions and physicians to use and prescribe generic drugs.

Online issues

Online infringement

The Trademark Law provides that the 'use' of trademarks includes use on the Internet in some manner. Further, protection under the Unfair Competition Law extends to online acts and covers unregistered marks in Japan.

In *Cialis*, the Osaka District Court held that the following acts regarding the online marketing of a counterfeit of the drug Cialis, manufactured by Eli Lilly, infringed the rights of Lilly ICOS LLC, a Japanese affiliate company of Eli Lilly:

- providing advertisements of such counterfeit drug, to which marks similar to Lilly ICOS LLC's trademarks were affixed, on the Internet; and
- affixing marks similar to Lilly ICOS LLC's trademarks to packages of the drug.

E-pharmacies

Under the Pharmaceutical Affairs Law, regulations concerning e-pharmacies apply to the mail-order marketing of non-prescription drugs. Through the amendment of the law's Enforcement Regulations in 2009, non-prescription drugs are categorised into three classes, according to the degree of risk of adverse effects. As a general rule, non-prescription drugs must be sold face to face by pharmacists or registered sales representatives. The amendment allows only non-prescription drugs in Class III, which have the lowest risk of adverse effects, to be sold by mail order. In addition, the amendment prohibits companies from selling non-prescription drugs in Classes I and II by mail order, including via e-pharmacies. In 2009, two companies that had sold Class II non-prescription drugs sued the government, claiming that the amendment was unconstitutional. However, on March 30 2010 the Tokyo District Court declared that the amendment was constitutional. The companies have appealed the ruling to the Tokyo High Court.

Domain names

The Unfair Competition Law protects rights holders by providing that non-rights holders may not obtain, keep or use in bad faith a domain name that is identical or similar to a registered trademark. Since the Trademark Law does not address the registration and retention (without use) of domain names, protection under the Unfair Competition Law is particularly important to rights holders. In connection with disputes over domain names in the top-level country-code domain '.jp', arbitration at the Japan IP Arbitration Centre, which is swifter than a lawsuit, is also available.

Preventive measures/strategies

IP rights holders enjoy legal protection under laws other than the Trademark Law in Japan. However, they should carefully investigate the facts and analyse the legal situation before taking action against third parties. In addition, companies that deal with pharmaceutical products should be aware of the various different laws and regulations. In this regard, IP rights holders, including foreign owners of trademarks relating to pharmaceutical products, should consider using local law firms in Japan, in addition to their own affiliated company or branch office in Japan, if any, for their brand management. [WTR](#)

Kaedeo Takagi, associate, and Yoko Kasai, associate, assisted in the preparation of this chapter.

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