Finland

Contributing firm
Backström & Co Attorneys

Author
Petri Eskola

Selection, clearance and registration

National and international bodies

The primary bodies dealing with pharmaceutical trademarks are those involved in granting and administering registrations for trademarks. Marks concerning the territory of Finland can be registered nationally, in the form of an international registration or as a Community trademark.

The National Board of Patents and Registration is responsible for national trademark registrations, as well as the other industrial property rights capable of registration.

Finland has been a party to the Madrid Protocol (administered by the International Bureau of the World Intellectual Property Organization) since its creation. The Trademarks Office of the National Board of Patents and Registration examines, at a national level, international registrations designating Finland under the Madrid System. In many cases, trademark holders decide to protect their rights with a single registration covering the entire European Union.

Registration requirements

Material requirements for granting national and international registrations designating Finland are the same. If the mark is intended for pharmaceutical products, there is no practical difference in this regard.

The National Board of Patents and Registration examines whether the mark is distinctive for the intended goods and makes an *ex officio* search for earlier confusingly similar marks covering identical or similar goods. Lack of distinctiveness forms an absolute ground for refusal to register a mark, whereas confusingly similar earlier trademark registrations or other relevant earlier rights, such as trade names, are of relative character. Relative grounds preventing registration can be circumvented where the holder of the earlier right gives consent for registration.

In the field of pharmaceuticals, a later registration with only a slight potential to cause confusion with an earlier mark is unlikely to be registered under the Trademark Office's current *ex officio* examination system. However, this is typically more a matter of enforcement than registration, as all applications should be handled similarly – regardless of the goods covered. The holder of an earlier mark may, if the later mark has been accepted by the registration authority for publication, submit an opposition against the registration within 60 days of such publication.

Pharmaceutical regulatory bodies

Marketing pharmaceutical products requires an authorization. In the European Union, marketing authorizations for medicinal products are granted either by the competent national authorities (under a national procedure, a mutual recognition procedure or a decentralized procedure) or by the European Medicines Agency (EMEA) (under a centralized procedure).

The relevant national Finnish body involved in granting marketing authorizations is the National Agency for

> **“An application for a marketing authorization can be submitted ... in Finnish, Swedish or English, [but] must include a proposal for a summary of product characteristics in Finnish”**

Medicines (NAM). It has issued an administrative regulation concerning labelling and packaging leaflets for medicinal products. The regulation requires that the trade name be used as the name of the medicinal product, which should be followed by the strength and pharmaceutical form of the product (ie, capsule, cream or powder).

More specifically, the regulation states that the trade name may be:

- an invented name;
- a common name (generic name) combined with a trademark;
- the name of the manufacturer, marketing authorization holder or its representative; or
- a scientific name combined with a trademark, or the name of the manufacturer, marketing authorization holder or its representative.

The invented name must not be confusingly similar to a common name, nor may it be otherwise exaggerating or misleading (eg, in a therapeutic or pharmaceutical sense). Neither can an invented name be identical nor confusingly similar to the name of a medicinal product that has a different composition and is currently on the Finnish market or has been in recent years. The applicant for marketing authorization or registration is responsible for the protection and registration of the trade name.

In practice, NAM's assessment of the trade name pursuant to the above criteria is rather formalistic and narrower than that made under the Trademarks Act between two confusingly similar trademarks. This means that even if the trade name for a medicinal product would be considered as confusingly similar under trademark law, it may pass the criteria under NAM's administrative regulations.

As for the application, which can be submitted to the board in Finnish, Swedish or English, it must include a proposal for a summary of product characteristics in Finnish. The applicant must also draft proposed:

- packaging leaflets in Finnish and Swedish; and
- labelling for each type of package.

The detailed guidelines for labelling and packaging are set out in administrative regulations.

Confusion with INNs

As mentioned above, NAM takes generic names into consideration when examining applications for marketing authorizations. NAM has particular awareness of and information on generic names in the field of pharmaceuticals and takes such information into account as part of its procedure. The commercial name is, in many cases, very close to the generic name.

The National Board of Patents and Registration takes international non-proprietary names (INNs) into consideration during the trademark examination process. The board will reject the registration should its examination for distinctiveness reveal that the proposed registration is identical or too close to an INN.

Non-traditional trademarks

In most cases, non-traditional marks such as shapes and colours are considered to lack distinctive character. Such marks require evidence of extensive use before they can be considered to have gained distinctive character and thus become eligible for registration.

Shape or three-dimensional marks tend to be the main non-traditional marks applied for by pharmaceutical companies.

Some attempts have been made to register the form or appearance of a tablet as a trademark. Such applications have usually been rejected on the grounds that they lack distinctiveness.

Parallel imports and repackaging

Several companies in Finland are actively involved in the parallel importation of medicinal products. However, a regulative policy on pricing and compensation of purchase prices to consumers of pharmaceuticals might have decreased the number of parallel-imported products, as well as the volume of such activity.

A parallel-imported medicinal product may be sold to the general public or otherwise released for consumption only if:

- either NAM or the EMEA has granted an authorization for the product; or
- NAM has registered such a product.

NAM's Administrative Regulation on the Parallel Import of Medicinal Products sets out the prerequisites for an application for marketing authorization for a parallel-imported medicinal product. A parallel-imported product must comply with the regulations on labelling and packaging. In practice, this means that a parallel-imported medicine must be repackaged in order to meet the relevant criteria.

The administrative regulations provide that repackaging may be carried out only in a pharmaceutical factory that has obtained an authorization for the industrial manufacture of medicinal products. Furthermore, repackaging must be undertaken within the European Union. The products to be parallel imported must originate from either the European Union or the European Economic Area.

In most cases, the trademark used on the parallel-imported product is the same as

that used for the original product in Finland. However, the administrative rules also allow the use of the trademark which was on the original product in the country of importation.

The parallel importer must give prior written notification to the marketing authorization holder for the original product on the national market. This notification must be made at least one month before the proposed importation and must be included in the marketing authorization application. Prior notice must also be given to the trademark proprietor, but there is no actual and specific time limit for this. The prior notice should give the proprietor a reasonable chance to study the matter.

The European Court of Justice (ECJ) has issued a significant amount of guidance in the field of repackaging and parallel importation, and trademark holders frequently bring infringement cases against parallel importers, claiming that the relevant packaging does not fulfil the criteria set out by the ECJ. Due to the control carried out during the marketing authorization process, trademark infringement claims against parallel importers are seldom based on the poor quality of the repackaging or other similar reasons.

National case law does not add any specific aspects which should be observed in relation to the repackaging and parallel importation of pharmaceuticals. In general, the legal practice in the field is in favour of parallel importers as long as the trademark proprietors' reasonable interests have been observed. However, whenever issues which are not yet covered by the ECJ and can reasonably be argued by rights holders arise, parallel importers may face difficulties.

Anti-counterfeiting and enforcement

The EU Customs Regulation (1383/2003) harmonizes and specifies customs actions and measures available in cases where suspected infringements of IP rights are found or traced. The regulation forms the basis for effective enforcement at the border.

The vast majority of seizures carried out by Customs on the basis of the regulation have been for suspected trademark or copyright infringements.

Following a seizure, the rights holder should – within the relatively short time period provided by the regulation – initiate either a civil or a criminal procedure in order to obtain a court's decision on the merits of the case.

It is difficult for the average consumer of pharmaceutical products to determine at first sight whether the product he or she is buying is legal. As the vast majority of medicines are available on prescription only in Finland, the risk of buying counterfeits is reduced, but not eliminated: counterfeit medicines have been found in pharmacies on several occasions.

Bearing in mind the dangers that counterfeit medicines pose to health, it is crucial that enforcement be effective. *Ex parte* injunctions are a fast remedy available in situations where counterfeits were not seized at the border and have entered the market.

General remedies, together with a final injunction, consist of an award of damages and/or costs, and an order to destroy the infringing goods.

Advertising

Advertising of medicinal products must encourage people to use the products appropriately in accordance with the Medicines Act. The advertising of medicinal products must not be improper or induce people to use the products unnecessarily. NAM monitors the advertising of medicinal products.

NAM acts against illegal advertising of medicinal products on the basis of a defect or fault in such advertising. The process can be initiated by a complaint submitted to NAM.

According to the Medicines Act, medicinal products supplied by prescription or containing narcotic drugs or psychotropic substances must not be marketed to the general public. Advertising targeted at the general public must:

- mention at least the name of the medicinal product and the generic name if the medicinal product contains only one active substance;
- contain the information necessary for the correct and safe use of the medicinal product; and
- encourage in clear language the user to read carefully the separate instructions for use of the medicinal product.

Medicinal product advertising must not include groundless health statements or be targeted at children. Neither can it otherwise give an exaggerated or misleading picture of the effects of a medicinal product. It is forbidden to distribute medicinal product samples to the general public for sales promotion purposes.

Generic substitution

Generic substitution of pharmaceuticals is widespread and supported by the prevailing legislation. The issue concerns patents rather than trademarks. Pharmacists are obliged to substitute a prescribed drug with the cheapest corresponding medicine of the same pharmaceutical substance included in the list of substitutable medicines issued by NAM. The prescribing physician may decline generic substitution for medical or therapeutic reasons. Drugs protected by analogy method patents are currently excluded from the list of substitutable medicines, but this will change when new regulations come into force later in 2009.

The generic substitution system had no legal effect on local trademark laws.

Online issues

While no law explicitly forbids the sale of pharmaceuticals online, NAM has so far been conservative in its approach to the issue, for safety reasons. NAM's main concern is that electronic prescriptions are not currently available – and will not be available nationwide until 2011. Problems have also arisen from Section 57 of the Medicines Act, according to which pharmacists must offer instruction and consultation regarding their products, alongside the sale of the products themselves.

The future of online pharmacies is in the hands of NAM, which has prepared a bill on the matter on behalf of the Ministry of Social Affairs and Health. This bill will be introduced into Parliament later in 2009. WTR

Backström&Co
ATTORNEYS

Biographies
Backström & Co Attorneys

Backström & Co Attorneys
Kasarmikatu 44,
00130 Helsinki,
Finland
Tel +358 9 668 9940
Fax +358 9 668 99410
Web www.backstrom.fi

Petri Eskola
Partner
petri.eskola@backstrom.fi

Petri Eskola graduated in 1992 from the University of Helsinki. He has a wide experience in IP law and practice, and frequently advises clients on all IP matters. He represents clients in related litigation and arbitration. In addition, he advises in all major areas of business law, including contract, corporate, distributorship and competition law.

Mr Eskola joined Backström & Co in 1998 and is a partner of the firm. He was admitted to the Finnish Bar in 2001. He speaks Finnish, Swedish and English.