Finland

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Selection, clearance and registration

Trademark bodies

In Finland, pharmaceutical trademarks are governed by national trademark legislation and relevant EU directives and regulations. In addition, international trademark registrations designating Finland must comply with the Madrid Protocol, to which Finland acceded on April 1 1996. Pharmaceutical trademarks must also comply with pharmaceutical legislation and some sector-specific regulations.

Pharmaceutical trademarks are registered through the same bodies as other types of trademark. Trademarks for which protection can be sought in Finland can be registered:

- nationally;
- in the form of an international trademark designating Finland through the Madrid Protocol; or
- as a Community trademark.

The body responsible for national registrations is the National Board of Patents and Registrations (NBPR), which is also responsible for examining international registrations that designate Finland. International and national applications undergo the same *ex officio* examination during which the trademark, company name and surname databases are checked in order to find possible similar signs. If similar prior registrations or other rights are found, the NBPR will deem them an obstacle to registration. In addition, if the mark is considered to be descriptive or otherwise contrary to trademark legislation, the registration will be refused.

Confusion between different medicines can potentially be far more dangerous than confusion between other goods or services. However, the NBPR does not take national health issues into consideration when assessing the similarity between a pharmaceutical trademark application and a prior trademark registration. Thus, pharmaceutical trademarks do not receive any special attention from the NBPR.

The above-mentioned possible obstacles can be overcome by submitting a letter of consent from the owner of the prior registration, submitting evidence of the establishment of trademark rights or restricting the list of goods accordingly. The obstacles can also be surmounted by arguing and presenting evidence that the prior mark and the applied-for mark are sufficiently different from each other in order to eliminate the risk of confusion among the public. The applicant can file an appeal to the Board of Appeal and further to the Supreme Administrative Court.

Lastly, Community trademarks, which are registered at the Office for Harmonisation in the Internal Market, are automatically valid in Finland.

Pharmaceutical regulatory bodies

A valid marketing authorisation is required before a pharmaceutical product can be placed on the market in Finland. The

marketing authorisation is granted either by the Finnish Medicines Agency (FIMEA) or by the European Medicines Agency (EMA). FIMEA's main task is to improve and supervise pharmaceutical services for the public, as well as ensuring the safety, appropriateness and economy of pharmacotherapy. FIMEA also provides the general population and other interested parties with impartial information on medicinal products.

The national procedure to obtain a marketing authorisation may be used when an application is filed for the first time in the European Union. The national procedure may also be used to extend the marketing authorisation of a product already approved nationally – for example, to a new strength or pharmaceutical form. The centralised EU procedure (through the EMA) is used when a marketing authorisation is sought within the entire European Union for new biotechnological and other innovative medicinal products.

The marketing authorisation system was created to ensure the safety of pharmaceutical products and to protect public health. The safety of pharmaceutical products is assessed prior to granting the marketing authorisation. In addition, the safety of the medicine is continually reassessed once the authorisation has been granted. When assessing the safety of pharmaceutical products, FIMEA also takes into consideration whether the trade name of the pharmaceutical product can create a public health concern or safety risk.

According to FIMEA's Administrative Regulation (1/2009), the name of a pharmaceutical product for which a marketing authorisation is sought may, for instance, be an invented name or a generic name combined with a trademark. However, the invented name should not be confusingly similar to a common name or otherwise be exaggerating or misleading – for example, in a therapeutic or pharmaceutical sense. Neither can an invented name be identical or confusingly similar to the name of a medicinal product that has a different composition and that is currently on the Finnish market or has been on the market in recent years.

FIMEA's evaluation is made from the public health perspective. Thus, a decision by FIMEA regarding a product name can differ from that of the NBPR, and vice versa.

Confusion with international non-proprietary names

The NBPR takes international non-proprietary names (INNs) into consideration during the examination of a trademark application. Marks that are identical or too similar to an INN are considered to lack distinctiveness and thus cannot be registered as trademarks. Otherwise, the examination and registration procedure for trademarks in Class 5 (for pharmaceutical preparations) and trademarks covering other classes is the same.

Non-traditional trademarks

According to trademark legislation and practice, any kind of mark that can be represented graphically and by means of which goods marketed in business can be distinguished from those of others may be registered as a trademark. Words, personal names, figures, letters, numerals and the shape of goods or of their packaging are examples of traditional trademarks. In addition, colours, slogans and sound marks can also be represented graphically and thus be registered as trademarks. Even a scent can be registered as a trademark, provided that there is a way to represent it graphically.

However, most non-traditional trademarks are considered to lack inherent distinctive character. Thus, the trademark applicant should provide evidence of extensive use of the mark in order to show that the mark has acquired distinctive character through use. The evidence should prove that the mark has acquired a secondary meaning in a sense that end users recognise the mark as the trademark applicant's sign. The NBPR requires very extensive and long-term use in order to prove that trademark rights have been established through use.

Parallel imports and repackaging

Pursuant to Section 21(d) of the Medicines Act, an application for a marketing authorisation regarding the parallel import of a medicinal product can be made, provided that the original product already has a valid marketing authorisation in Finland. The national body granting the authorisation is FIMEA, but the authorisation may also be obtained through the centralised procedure of the European Union through the EMA. The pharmaceutical product must also have a valid marketing authorisation in the country of acquisition, which must be a member of the European Union or European Economic Area.

FIMEA has issued a specific regulation regarding the parallel import of medicinal products. According to this regulation, the parallel-imported product and the original product must be similar to the extent that they can be considered the same medicinal product. The medicinal products need not be identical in all respects, but they must use the same active ingredient and their formulations must be similar to the point that formulation variations do not give rise to differences in the therapeutic efficacy or safety of the products.

Repackaging must be carried out at a factory that has obtained authorisation for the industrial manufacture of medicinal products and must occur within the European Union/European Economic Area. The product name used on a parallel-imported medicinal product may be the same as, or different from, the product name used on the original medicinal product on the market. The product name may also differ from that used in the country of acquisition. Consequently, the immediate packaging may bear two different product names; this must, however, be specifically mentioned on the outer packaging.

In addition, the above-mentioned conditions regarding the product name used on a pharmaceutical product for which a marketing authorisation is sought also apply to parallel-imported products.

The pack size and type of the parallel-imported medicinal product may also differ from the pack size and type of the medicinal product on the market in Finland, provided that the differences are not likely to pose a threat to public health.

Anti-counterfeiting and enforcement

The counterfeiting of medicinal products is a growing problem for public health, as well as pharmaceutical companies in Finland. In terms of the enforcement of trademark rights, the EU Customs Regulation (1383/2003) is applicable in Finland. In accordance with that regulation, pharmaceutical companies can file an application for customs surveillance with the customs authorities. By filing the application, pharmaceutical companies can provide additional information on both possible counterfeits and the original goods. This improves Customs' ability to identify counterfeits and stop them before they enter the market.

An application for customs surveillance can be made either nationally or for two or more EU member states. National applications may include both national and Community trademark registrations; multinational applications can cover only Community trademark registrations.

The customs authorities can also take action independently – that is, without an

application for action – if they notice that goods entering the country are obviously suspicious. In the event of an *ex officio* seizure, the rights holder shall determine within three working days whether the goods are infringing.

If Customs is informed in due time that the goods are counterfeit or if an application for customs surveillance is in force, the rights holder has 10 business days (three days in the case of perishable goods) to file a claim with the district court, to file an application for customs or police investigation, or to settle the matter. This 10-day period may be extended by 10 additional business days. If the rights holder takes no action within the time limits, the goods will be released onto the market.

Advertising

The advertising of pharmaceutical products is regulated by the Medicines Act and monitored by FIMEA. Pursuant to Section 91 of the Medicines Act, the advertising of pharmaceutical products must encourage end users to use the products appropriately. In addition, the advertising must not be improper or incite people to use the products unnecessarily. Prescription medicines or medicines without a valid marketing authorisation may not be advertised to the public at all under the Medicines Act. In addition to the requirements of the Medicines Act, the advertising of pharmaceutical products must comply with the regulations of the Act on Unfair Business Practices.

If the regulations are breached, FIMEA can intervene on the basis of a defect or fault in advertising. The process can be initiated by a complaint submitted to FIMEA. The complaint may be submitted by a legal person or a private individual.

FIMEA will then send a reprimand to the pharmaceutical company concerning fraudulent marketing or a clarification request and a copy of the submitted complaint. The pharmaceutical company that allegedly used illegal marketing is given the opportunity to submit a rejoinder, on the basis of which FIMEA will then decide on the need for further action. If further action is required, the company will be informed in writing and has a right to submit a further rejoinder. Both the company and the complainant will be informed of the actions taken and of the conclusion of the proceedings.

Generic substitution

Generic substitution by pharmacists was introduced in Finland on April 1 2003. Since then, pharmacists have been obliged to inform customers of the availability of cheaper generic products and to substitute the prescribed medicine with a cheaper generic product if the customer requires the substitution and the medicines belong to the same reference price group. In order to be substituted in compliance with the Medicines Act, the products must be pharmacologically and clinically substitutable – that is, they must contain the same active substance in the same amount and pharmaceutical form. In addition, the products must be bioequivalent. FIMEA publishes a list of medicines that are substitutable. However, the prescribing doctor may prevent the substitution on medical or therapeutic grounds.

The Pharmaceuticals Pricing Board confirms the reimbursement status and reasonable wholesale prices for medicinal products, clinical nutritional preparations and basic ointments reimbursed under the health insurance scheme. The 'reasonable wholesale price' is the maximum price at which the preparation can be sold to pharmacies. The reimbursement payable under health insurance, pursuant to the Health Insurance Act, is based on the wholesale price confirmed by the Pharmaceuticals Pricing Board. A pharmaceutical product for which a marketing authorisation has been granted can be sold without a confirmed wholesale price, but in that case it is not entitled to reimbursement.

Before a generic drug comes into competition with an original product, the price difference between the original and the parallel-imported drug is negligible. The reasonable wholesale price is discontinued after a generic comes onto the market and the medicine is allocated to a reference price group. The confirmed price in the reference price group is usually significantly lower than the previously confirmed wholesale price.

Each of the medicines in a reference price group carries the same price regardless of its market price. Thus, if the products belong to a certain reference price group, the generic products are at an advantage as the pharmacy personnel are obliged to offer to substitute the prescribed product with a similar but cheaper one. This process usually means that trademark owners make little profit from their branded pharmaceuticals once competing generic drugs have entered the market if they do not lower the price of their products to (or near) that of the generic drugs.

Online issues

Selling pharmaceuticals online (ie, through e-pharmacies) is permitted under Finnish legislation, provided that all requirements are met. Wholesale trade in medicinal products is subject to a licence – hence, a licence is also needed to run an e-pharmacy. FIMEA issues licences for pharmacies, hospital pharmacies and dispensaries, and monitors the lawfulness of their activities. Electronic prescriptions are also legal in Finland. WTR

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Ben Rapinoja has broad experience in pharmaceutical patent litigation, disputes relating to IP rights, as well as in commercial disputes and arbitration proceedings involving IT and high-tech companies. Mr Rapinoja's area of particular expertise is the representation of clients from the pharmaceutical and life science sectors, as well as from the electronics and high-tech industries, and the provision of advice on business law-related issues such as contractual and licensing arrangements, commercial disputes and corporate transactions.

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