Sweden

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Selection, clearance and registration

Trademark bodies

In Sweden, pharmaceutical trademarks are governed by trademark law and also, to some extent, by sector-specific regulation.

Primarily, the bodies dealing with the registration of pharmaceutical trademarks are those involved in granting registrations for all kinds of trademark. Trademarks for which protection is sought in Sweden can be registered:

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

The Swedish Patent and Registration Office (PRV) is the responsible authority for national trademark registrations. Sweden acceded to the Madrid Protocol on December 1 1995; the PRV is responsible for examining Swedish designations of international trademark registrations. It conducts these examinations in the same manner as for national trademark applications. In addition, Community trademarks are valid in Sweden.

The examination of Swedish trademark applications for pharmaceutical preparations and the like in Class 5 is, in some respects, more stringent than for trademark applications covering other classes. Swedish trademark practice and doctrine hold that, due to the risks of confusing different medicines, the examination regarding similarity should be stricter than in other matters. One might say that trademark examiners in Sweden take into account the special circumstances regarding use of pharmaceutical trademarks before granting any rights. Usually, the main purpose of a trademark right is to ensure that the rights holder has the sole right to the name of a product or a service; however, in the case of trademarks covering Class 5, the importance of safe and effective drugs and pharmaceutical preparations is also given consideration.

Pharmaceutical regulatory bodies

In order to place a pharmaceutical product on the Swedish market, authorisation by the Medical Products Agency (MPA) or the European Medicines Agency (EMA) is required. The main task of these regulatory bodies is to ensure that both individuals and healthcare professionals have access to safe and effective drugs and pharmaceutical preparations.

The MPA's activities include:

- the issuance of permissions for conducting clinical trials of pharmaceuticals on humans and/or animals;
- government inspections; and
- the preparation of centralised standards.

With regard to trademarks, the MPA conducts a similarity search from a public health perspective when reviewing a new application from a pharmaceutical company. A name for a medicinal product

will not be allowed on the Swedish market if it could create a public health concern or potential safety risk.

The EMA can grant EU-wide approvals for the marketing and use of pharmaceutical products. The examination is conducted by certain committees and each member state has two appointed examiners. A preliminary decision is prepared by one of the committees, but before any final decision is taken, each member state examines the application on the basis of national law and practice. A final decision is taken after opinions have been submitted by member states. If the proposed name for a drug is rejected by one member state, the procedure has to start all over again. Permission is obtained either for all countries or for none. The procedure can thus be time consuming.

Like the PRV, the MPA looks at visual, phonetic and associative similarities with existing marks. In addition, it considers the similarity between handwritten versions of the proposed mark and existing marks, since it is still usual for doctors to write patient prescriptions by hand.

The main difference between the examinations by the two authorities is the objective – the MPA considers the public health aspects, while the PRV safeguards the sole right for the owner of a trademark registration.

Confusion with international non-proprietary names

The PRV will take international non-proprietary names (INNs) into consideration during the examination procedure of a trademark application. Marks that are identical or too close to an INN will not obtain registration in Sweden due to lack of distinctiveness.

The MPA accepts INNs for use as names for pharmaceutical products on the Swedish market.

Non-traditional trademarks

In most cases non-traditional trademarks, such as shapes, colours and flavours, are considered to lack distinctive character *per se*. It is necessary to show extensive use and that the mark has acquired distinctiveness as a trademark in order for it to qualify for registration.

Pharmaceutical companies may wish to register three-dimensional marks, such as the shape of a tablet or packaging, as a trademark. As mentioned above, it is often necessary to show that the shape has acquired secondary meaning through extensive use and consumer education. Given the restrictions regarding advertising of pharmaceuticals, it can often be difficult to demonstrate such use.

One option might be to seek to register the shape as a design instead of a trademark.

Parallel imports and repackaging

A parallel-imported pharmaceutical product may be sold to the public in Sweden provided that it has been granted authorisation by either the EMA or the MPA. In order to place a parallel-imported medicinal product on the Swedish market, the importer must be able to show that the product has been granted a marketing authorisation in the country of export. Pharmaceuticals sold in Sweden may not originate from any countries other than EU member states, or Iceland, Lichtenstein and Norway (European Economic Area countries).

The MPA has adopted an administrative regulation on the use of parallel-imported products in Sweden. The MPA liaises closely with the relevant authorities in the country of export in order to ensure that only products that comply fully with the regulations on labelling and packaging are granted a licence for use in Sweden, as well as in the country of export. The packaging and labelling requirements for pharmaceutical products differ from country to country and the parallel-imported products must comply with the corresponding Swedish regulations before the product can be marketed in Sweden. As a consequence, quite often a parallel-imported medicine must be repackaged in order to meet the relevant criteria of the MPA. Repackaging can be carried out only by an approved pharmaceutical manufacturing facility.

The parallel-imported product need not be fully identical to the original product; minor differences are thus accepted by the MPA. Differences that have no impact on the therapeutic properties – such as the colour, size and shape of the product – are also accepted.

The parallel importer is required to notify the holder of the authorisation in the country of origin before beginning to market the parallel-imported product in Sweden. The notification must be in writing and a copy must be attached to the application for approval of sale and marketing filed with the MPA.

The European Court of Justice (ECJ) has ruled on, and given guidance in, a number of infringement cases regarding parallel-imported goods and repackaging. In general terms, the case law regarding parallel imports is predominantly in favour of the parallel importer, as long as the trademark holder's rights are respected. Rights holders frequently claim that parallel-imported repackaged products infringe their trademark rights and the claims are often based on the fact that the relevant packaging does not comply with the criteria established by the ECJ. The ECJ recently handed down a judgment regarding parallel importers' repackaging (C-400/9 and C-207/10), which stated that it is acceptable for the parallel importer to put only its own name on the packaging, even if the repackaging has been carried out by another company on instruction of the parallel importer. The parallel importer is then responsible for any damages caused by the company that actually carried out the repackaging. Due to the strict control of marketing of pharmaceuticals within the European Union carried out by the EMA and national regulatory bodies, infringement claims against parallel importers are rarely based on inferior quality of the packaging and/or inappropriate relabelling.

Anti-counterfeiting and enforcement

Pharmaceutical companies can take measures in order to make their products easier to identify when compared to infringing products. Such measures include the use of certain markings on the package and/or on the products themselves, which makes it simpler to determine whether a product is genuine. Pharmaceutical companies can also seek assistance from the customs authorities to prevent infringing goods from entering the country. This kind of monitoring action can be taken for two or more member states within the European Union or on a national level. A national Swedish application for customs action against suspected counterfeit goods is available for rights holders when the requested border actions are limited to Sweden. Both national trademarks and Community trademarks may be included in an application for Sweden, whereas multinational applications can be made for Community trademarks only. Consequently, an unregistered trademark right cannot form the basis of an application for customs intervention.

When Swedish Customs seizes a delivery of suspected counterfeit goods, the rights holder is given the opportunity to confirm their legitimacy. Normally, Customs grants the rights holder two or three days in order to determine whether the goods are genuine. If no answer to the request is filed within this time, Customs will decide either to detain or to release the suspect goods. The

rights holder may examine the suspect goods via photos or by analysing samples. No additional information about the shipment or the importer is provided to the rights holder to assist in its determination. If Customs is informed that the goods are counterfeit, the rights holder has 10 days (limited to three days when the seizure involves perishable goods) either to file a claim with the district court or to settle the matter with the importer – this must include, where relevant, arrangements for the goods to be destroyed. This 10-day period may be extended by a further 10 days. If none of these courses is pursued, the goods will be released.

With regard to pharmaceutical preparations and drugs, it is difficult for the average consumer to determine whether the product is genuine. As the vast majority of pharmaceutical products in Sweden are available by prescription only, the risk of counterfeit products entering the market is, and has been, quite limited. However, since the deregulation of the state monopoly on operating pharmacies in Sweden, which took place in 2009, an increasing number of counterfeit pharmaceutical preparations are being sold in Sweden. Although some counterfeit pharmaceutical products have been found in newly launched pharmacies, the majority are being offered for sale online. Bearing in mind the injuries that can result if counterfeit medicinal products are sold in legitimate pharmacies, it is obviously an important task for the authorities to ensure that the available legal remedies and their enforcement are effective.

Advertising

The advertising of pharmaceutical products is regulated by the Medicinal Products Act (SFS 1982:859); the MPA is responsible for monitoring such activities in Sweden. Only non-prescription drugs may be advertised to the general public, the only exception being campaigns for vaccinations against infectious diseases. The advertising of pharmaceutical products must not be improper or encourage people to use products unnecessarily. All information and other promotion of pharmaceuticals must be truthful and not misleading. If the MPA discovers a violation, it can take immediate action and prohibit continued advertising. The MPA can also be alerted to improper advertising by a third party. Medicinal drug advertising must not include unsubstantiated health statements or be targeted at children; nor should it give an exaggerated or misleading picture of the efficiency of the drug. The distribution of samples of pharmaceutical preparations for promotional purposes is not permitted. Prescription drugs may be advertised only to doctors and other professionals – for example, in trade publications. There are very strict rules regarding pharmaceutical companies' marketing towards doctors, which basically forbid any kinds of gifts or sponsorship.

Generic substitution

Generic substitution by pharmacists is permitted in Sweden. It is also supported by the prevailing legislation and required for reimbursement purposes. In IP terms, this is more a matter of patent law, related to the active ingredient in a drug, than a trademark issue. Swedish pharmacists are obliged to offer to replace a prescribed pharmaceutical product with the cheapest equivalent medicine included in the lists provided by the MPA. However, the prescribing doctor may prevent a substitution for medicinal or therapeutic reasons. Of course, this legal framework can be disadvantageous to brand-name trademark holders, since the investment in the name of the product often results in a higher price. These products will often be exchanged for a cheaper, generically named product.

Online issues

Electronic prescriptions are common in Sweden and have resulted in improved safety regarding the correct delivery of drugs. A handwritten prescription can be misinterpreted and the electronic format minimises the risk of confusion.

No Swedish legislation prohibits pharmaceutical companies from selling their drugs online. However, the MPA has taken a restrictive and conservative position in discussions about the online sale of drugs, emphasising the safety aspects. Due to the deregulation of the state monopoly on the operation of pharmacies in Sweden in 2009, it is possible for anyone to run a pharmacy, provided that certain qualifications are met. Many of the new actors have decided to launch online shops for pharmaceutical products. The increasing number of online outlets where drugs are sold, including prescription pharmaceuticals, has without doubt created problems in Sweden due to the use of pharmaceutical trademarks that have not been licensed in Sweden by the MPA. WTR

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Ms Enström is a member of the International Trademark Association, MARQUES (the European Trademark Association) and the Pharmaceutical Trademark Group, as well as the Swedish Association for the Protection of Industrial Property.