Iceland

GH Sigurgeirsson IP

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Pharmaceutical Trademarks 2020/2021

A Global Guide

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Selection, clearance and registration

Like all trademarks, pharmaceutical trademarks must meet the requirements set out in the Icelandic Trademarks Act to be eligible for protection. Therefore, choosing a pharmaceutical trademark is complicated and requires vast knowledge and experience of trademark law and practice.

Iceland is a part of the European Economic Area (EEA) and thus the Trademarks Act is largely in line with EU trademark law. Both the Icelandic Intellectual Property Office (ISIPO) and the Appeals Committee frequently refer to the EU Intellectual Property Office and EU courts practice in their decisions.

When selecting a trademark, it is vital to keep in mind that, under the Trademarks Act, trademark rights can be established by either registration with the ISIPO or by use of a trademark in Iceland in relation to sales of goods or services. Performing an additional online clearance search before submitting an application for registration to the ISIPO will therefore minimise the risk of third-party oppositions on relative grounds. However, to be eligible for protection on grounds of use a trademark must meet the same criterion as for registration.

EU Directive 2015/2436 has not yet been transposed into the Trademarks Act. Under the act, a mark must therefore still be capable of graphical representation. In addition to traditional word and figurative marks, the requirement in principle allows for the protection of trademarks comprising shapes, colours and sounds, but excludes other non-traditional marks. However, no colour marks *per se* or sound marks have yet been registered in Iceland.

The Trademarks Act provides that the main criterion for registration is that a trademark be capable of distinguishing the goods and services of the rights holder from the goods and services of others. If a trademark is devoid of distinctive character or descriptive regarding kind, quality, quantity, intended use, value, geographical origin or time of production of the relevant goods and services, it is accordingly ineligible for registration. The same applies to marks that are misleading as regards kind, quality or origin of the relevant goods or services or contrary to public policy.

Moreover, a trademark must meet habitual relative requirements to be eligible for registration and, among other things, not be confusingly similar to a mark that has been registered or used in Iceland by another party.

The ISIPO examines all requirements set forth in the Trademarks Act and can refuse registration on either absolute or relative grounds.

Although applications for registration of pharmaceutical trademarks are subject to the same scrutiny as other applications, ISIPO practice demonstrates additional elements to be considered.

First, a trademark will be considered devoid of distinctive character if it is identical to or merely a slight deviation of an international non-proprietary name (INN), in particular if it includes the INN common stem. The aim of INNs is to facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognised and should as a result be free for use by others in the field. However, both the ISIPO and the Appeals Committee have highlighted that it must be individually examined on a case-by-case basis whether a trademark derived from an INN is sufficiently different from the INN in question to be considered distinctive.

Second, a slightly higher degree of similarity has been accepted in practice between trademarks for pharmaceuticals than other products or services. This is essentially due to the fact that many pharmaceutical trademarks contain elements that have weak distinctive character and are commonly used in trademarks in the field and thus discarded in the similarity assessment.

The similarity assessment is otherwise habitual and considers the visual, aural and conceptual similarity of the marks, as well as the similarity of the products and services in question. It is established practice by both the ISIPO and the Appeals Committee to take into specific account whether the first syllable in the marks in question is the same. If so, there is an increased likelihood of confusion as the emphasis is generally on the first syllable of words in the Icelandic language. In addition, it is standard practice that product similarity is found to exist between products in Class 5, even if the intended use differs.

The likelihood of confusion is considered from the point of view of the relevant public, which consists of both healthcare professionals and end consumers. Pharmaceutical products, whether issued by prescription or bought over the counter, are generally regarded as receiving a heightened degree of attentiveness by the reasonably well-informed, reasonably observant and circumspect member of the relevant public.

Finally, after five years from registration, a trademark may be subject to revocation for non-use. A revocation claim can be made by anyone with a legitimate interest. In practice, the ISIPO has considered there to exist a legitimate interest in all cases where an application for registration has been provisionally refused with reference to an existing registration. In such cases, the trademark owner must provide evidence of use for the designated goods and services in order to avoid revocation.

No prior regulatory authorisation is required for registration of a pharmaceutical trademark. However, there are some regulatory

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requirements regarding proprietary names of pharmaceutical products as further specified in the Icelandic Medicinal Products Act and secondary legislation. For example, the proprietary name must not create confusion with the INN of the pharmaceutical product in question.

Parallel imports and repackaging

The parallel import of pharmaceutical products is permitted under Icelandic trademark law, provided that the product has been put on the market in the EEA by or with the consent of the trademark owner. Should that be the case, the trademark rights are exhausted and the trademark owner cannot prevent further sales within the EEA unless it can demonstrate that it has a legitimate reason to do so. A legitimate reason can be, for example, that the condition of the goods or packaging has been changed or impaired.

Parallel import of pharmaceutical products is subject to a licence from the Icelandic Medicines Agency (IMA). The following conditions must be met in order to obtain a licence:

- The primary imported product must have a valid marketing authorisation in Iceland and the parallel imported product must contain the same active substance and have the same pharmaceutical form as the primary imported product.
- The parallel imported product must have a valid marketing authorisation in the exporting EEA member state.
- There must be no significant therapeutic difference between the primary imported product and the parallel imported product.
- The parallel importer must hold appropriate licences for import and wholesale distribution of medicinal products in Iceland.
- The distributor in the exporting EEA member state must hold appropriate licences for wholesale distribution of medicinal products in the relevant member state.

As Iceland is not a member of the European Union the same rules apply for products with central marketing authorisations. If a parallel import licence is granted for a pharmaceutical product with a central marketing authorisation it can, however, be imported from any of the EU member states subject to prior notification to the IMA. The holder of a parallel import licence is obliged to notify the holder of the product's marketing authorisation 15 working days before the parallel imported product is put on the market. Parallel import of pharmaceutical products under patent protection from certain EU member states is further subject to additional notification requirements.

It may be necessary to repackage a parallel imported product to ensure compliance with legal or regulatory requirements. Generally, such repackaging does not constitute trademark infringement if it is objectively necessary to ensure access to the Icelandic market. However, the holder of a parallel import licence must ensure that repackaging in no way impairs the quality of the product and that the labelling and information leaflet are in order.

Anti-counterfeiting and enforcement

To date no counterfeit pharmaceutical products have been circulated through legitimate distribution channels in Iceland. However, counterfeit pharmaceutical products have been offered for sale online and Customs has seized counterfeit products in quantities that give reason to believe that they were intended for distribution and sale on the Icelandic market. Accordingly, the relevant authorities as well as stakeholders are alert, and both preventive and enforcement measures are in place.

Prevention

In 2018 the EU Falsified Medicines Directive (2011/62) was implemented into Icelandic law by amendments to the Medicinal Products Act and secondary legislation. Among other provisions, the amendments require manufacturers, importers and wholesalers of pharmaceutical products to immediately inform the IMA and the marketing authorisation holder of pharmaceutical products that they purchase or are offered which are falsified or suspected to be falsified. In addition, to ensure that pharmaceutical anti-falsification strategies are more effective, particularly regarding sale of such products online, holders of pharmacy licences are now permitted to supply pharmaceutical products

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to the public online, subject to notification to the IMA.

The Icelandic Medicines Verification Organisation (ICEMVO) is a new organisation set up to protect Icelandic patients from the threat of falsified medicines being supplied through legitimate channels. ICEMVO is a not-for-profit organisation established by a range of stakeholders across the medicines supply chain (eg, pharmaceutical manufacturers, wholesalers and community pharmacists) to set up and manage the Icelandic medicines verification system. The system is designed to increase patient safety and prevent distribution of counterfeit pharmaceutical products being supplied through legitimate channels. Among other things, the system requires all pharmaceutical products released in Iceland to bear certain safety features as required (ie, a tamper-proof seal and two-dimensional barcode).

Enforcement

The general enforcement measures under the Customs Act apply to products infringing pharmaceutical trademark rights in the same manner as other IP rights. By request of an IP rights holder, Customs may suspend clearance if there is reasonable suspicion that the products infringe its rights. The following conditions must be met:

- The rights holder must submit a written request for deferment of clearance and commit to pay the cost of the operation.
- The rights holder must submit evidence that the IP rights are protected in Iceland, that it is in fact the holder of the rights and that import of the products in question will infringe its rights. Moreover, the rights holder must provide a sufficiently detailed description of the products for Customs to be able to identify them.
- The rights holder must submit monetary security, or another appropriate form of security, to cover damages or expenses incurred by an unjustified suspension of clearance.

Customs may also suspend clearance *ex officio* if there is sufficient evidence in place that the products in question infringe IP rights. Where this is the case, Customs will inform the relevant rights holder of its decision and afford it the opportunity to submit a request for suspension of clearance. If the rights holder does not act, Customs will however clear the products.

Even though infringement of IP rights constitutes a criminal offence under Icelandic law and can result in fines or imprisonment, such cases are rarely prosecuted. In principle, it is therefore in the hands of the relevant IP rights holder to protect its rights. Following suspension of clearance, the rights holder must accordingly file for an interim injunction with the relevant authorities and seek subsequent confirmation of the interim decision before the courts, unless an agreement is reached with the importer of the infringing products.

Advertising

Advertisements of pharmaceutical products are defined broadly under Icelandic law and constitute any type of advertising or promotional activity, whether written or oral, in the form of images, the supply of medicinal samples, promotional events and meetings, sponsored, directly or indirectly, by the holder

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of a marketing authorisation, for the purpose of promoting the prescription, supply, sale or consumption of pharmaceutical products.

Advertising of pharmaceutical products is governed by the Medicinal Products Act and secondary legislation. Under the act, the advertising of pharmaceuticals is in principle prohibited. However, the prohibition is subject to exhaustive derogations specified in the act and secondary legislation.

The derogations distinguish between advertisements directed towards the general public on one hand and healthcare professionals on the other. Advertisements and promotions directed towards the general public are limited to over-the-counter pharmaceutical products. Prescription-only pharmaceutical products may, however, be advertised and promoted to healthcare professionals that prescribe and distribute pharmaceutical products, provided that certain conditions are met. For example, the contents and manner of presentation of advertising should be such that it is unlikely that the advertisement will be seen by the general public.

Pharmaceutical product advertisements should in all instances give true and

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professional information about the product. All information in the advertisement should be clear and easy to read or hear. All information must be in accordance with the approved summary of product characteristics. The advertisement should encourage the sensible use of the product by advertising it in an impartial manner and without undue claims for its properties. Advertisements may not be misleading and all information should be set up or read in such a way that those in the target group for which the advertisement is intended can easily read or hear it, or understand the information in another manner.

The IMA monitors advertising of pharmaceutical products and may prohibit advertisements that provide misleading or inadequate information about a pharmaceutical product. The IMA may, moreover, direct an advertiser to publish a rectification or additional explanations in the same manner as the advertisement. Advertisers are obliged to keep a record of all advertisements for two years, showing where and when they were published. This record must be accessible to the IMA.

In addition, advertisements of pharmaceutical products must comply with the general rules set out in the Act on the Surveillance of Commercial Practices and Marketing governed by the Icelandic Consumer Agency.

Generic substitution

Substitution of an original prescription pharmaceutical product to a generic pharmaceutical product with the same qualitative and quantitative composition of active substances and the same pharmaceutical form is permitted in Iceland, if neither the prescriber nor the patient opposes. Healthcare professionals that prescribe pharmaceutical products are required to specifically state if it is prohibited to amend the prescription to a generic pharmaceutical product. Otherwise, a pharmacist may change the prescription to a cheaper generic if the patient approves. Further, the patient should always be informed of a cheaper generic alternative when available.

Online issues

The Falsified Medicines Directive was transposed into Icelandic law in 2018, permitting the online sale of pharmaceutical products to the public, subject to previous notification to the IMA by the pharmacy licence holder in question. The IMA keeps a register of licence holders that have notified the authority that they intend to sell products online. The register is accessible on the IMA website and consumers are encouraged to check it before purchasing pharmaceutical products online.

For verification purposes, the EU common logo with the Icelandic flag imbedded must be displayed on every website on which pharmaceutical products are offered for sale to the public. In general, both over-the-counter and prescription products may be sold online and the same restrictions largely apply to sale online as in-store. However, pharmacists that sell pharmaceutical products online must ensure that the products are delivered to the correct recipient (eg, by registered post).

A pharmaceutical trademark can, like other trademarks, be registered as a domain name. However, the rules on advertising

of pharmaceutical products apply equally to online activities and the corresponding websites must accordingly comply with the relevant provisions of the Medicinal Products Act and secondary legislation. WTR

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