Pharmaceutical Trademarks 2021

LEXOLOGY
Getting The Deal Through

Iceland

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OVERVIEW

Legislation

1 What is the primary law governing trademarks in your jurisdiction?

The primary law governing trademarks in Iceland is the Trademark Act No. 45/1997 (the Trademark Act). On 1 September 2020, amendments to the Trademark Act came into force. The amendments implement the European Union trademark directive 2015/2436 into Icelandic law. The Act contains various new provisions and harmonises the EU and European Economic Area (the EEA) trademark systems, not only regarding trademarks but also collective marks and guarantee and certification marks.

Iceland is a part of the EEA and therefore the Trademark Act is largely in line with EU trademark law and both the Icelandic Intellectual Property Office (the ISIPO) and the Appeals Committee frequently refer to the practice of the EUIPO and the EU courts in their decisions.

Agencies

2 Which agency is responsible for the grant and registration of pharmaceutical trademarks?

The ISIPO is responsible for the grant and registration of pharmaceutical trademarks in Iceland.

Regulators

3 What are the relevant national and international regulatory bodies and requirements that need to be considered when clearing a pharmaceutical trademark?

Like all trademarks, pharmaceutical trademarks must meet the requirements set forth in the Trademark Act to be eligible for protection. Choosing a pharmaceutical trademark is accordingly complex and requires vast knowledge and experience of trademark law and practice.

When selecting a trademark, it is vital to keep in mind that under the Trademark 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 applying for registration to the ISIPO will, therefore, minimise the risk of third-party oppositions on relative grounds. To be eligible for protection on grounds of use a trademark must however meet the same criterion as for registration.

Moreover, a trademark must meet habitual relative requirements to be eligible for registration and inter alia 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 Trademark 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, the practice of the ISIPO 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 because 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. Additionally, 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, it should be mentioned that after five years from the registration date, a trademark may be subject to revocation for non-use. A revocation claim can be made by anyone and claimant is not required to show legitimate interest. In such cases, the holder of the trademark must provide evidence of use for the designated goods and services to avoid revocation.

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

Non-traditional trademarks

4 | What non-traditional trademarks are available in your jurisdiction and how are they registered?

As of 1 September 2020, trademarks no longer have to be capable of graphical representation. This means that signs can be represented in any appropriate form using generally available technology, as long as the representation is clear, precise, self-contained, easily accessible, intelligible, durable and objective. Furthermore, the extent of the exclusive right must be clear from the specification in the trademark registry. This amendment offers the possibility for registration of various types of non-traditional trademarks in Iceland, such as sounds, colours, shapes, position marks, patterns, motion marks, multimedia marks and hologram marks. Traditional and non-traditional trademarks are registered in the Icelandic Trademark Registry and published in the Legal Gazette on the 15th of each month. The Icelandic supplementary Trademarks Regulation No. 850/2020 contains further provisions on the technical requirements for the representation of each type of non-traditional trademarks.

As at mid-October 2020, no non-traditional trademarks have yet been registered in Iceland.

Cannabis-derived products

5 | Does your jurisdiction allow the registration of cannabis-derived products?

There are no provisions in Icelandic law that explicitly forbid the registration of trademarks for cannabis-derived products. In Iceland, healthcare professionals may prescribe a pharmaceutical product containing cannabis, if the product in question has been granted a marketing authorisation by the Icelandic Medicinal Agency. At least one such pharmaceutical product has been granted a marketing authorisation in Iceland and the name of the pharmaceutical product has been registered as a trademark in the Icelandic Trademark Registry. However, the product specification of this particular trademark does not specify that the product is cannabis derived. For other cannabis-derived products, it is likely that any applications for trademarks will be refused on the grounds of a provision in the Trademarks Act prohibiting the registration of trademarks that are contrary to law, public order or public morality.

PARALLEL IMPORTS

Regulation

6 | What are the rules governing parallel imports of pharmaceutical goods?

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. If the trademark rights are exhausted, and the trademark owner cannot prevent further sales within the EEA unless he or she can demonstrate that he or she has a legitimate reason to do so. A legitimate reason can, for example, be 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 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; and
- 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 EU 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 obligated to notify the holder of the marketing authorisation for the product 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 furthermore 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 a trademark infringement if it is objectively necessary to ensure access to the Icelandic market. The holder of a parallel import licence must, however, ensure that repackaging does not in any way impair the quality of the product and that the labelling and information leaflet are in order.

Strategies against parallel imports

7 | What strategies are available to police and enforce against parallel imports?

As parallel import is permitted under Icelandic trademark law no specific strategies are available to police and enforce against parallel imports.

ANTI-COUNTERFEITING AND ENFORCEMENT

Types of proceedings

8 | What types of legal or administrative proceedings are available to enforce against infringing products?

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 have seized counterfeit products in quantities that give reason to believe they were intended for distribution and sale on the Icelandic market. Accordingly, the relevant authorities as well as stakeholders are alert and both preventative and enforcement measures are in place.

Remedies

9 | What are the available remedies for infringement?

In 2018, the EU Falsified Medicines Directive (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 Icelandic Medicines Agency (IMA) and the marketing authorisation holder of pharmaceutical products they purchase or are offered that are falsified or suspected to be falsified. Additionally, to ensure that pharmaceutical anti-falsification strategies are more effective, in particular as regards the sale of such products via the internet, holders of pharmacy licences are now permitted to supply pharmaceutical products to the public online, subject to notification to the IMA.

The Icelandic Medicines Verification Organisation (the ICEMVO) is a new organisation set up to protect Icelandic patients from the threat of falsified medicines being supplied through legitimate channels. The ICEMVO is a not-for-profit organisation established by a range of stakeholders across the medicines supply chain (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 tamperproof seal and 2D barcode).

Border enforcement

10 | What border enforcement measures are available to halt the import and export of infringing goods?

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 right holder, customs may suspend clearance if there is reasonable suspicion that the products infringe his rights. The following conditions must be met:

- the right holder must submit a written request for deferment of clearance and commit to pay the cost of the operation;
    - the rightholder must submit evidence that the IP rights are protected in Iceland, that he or she is the holder of the rights and that import of the products in question will infringe his or her rights. The rightholder must, moreover, provide a sufficiently detailed description of the products for customs to be able to identify them; and
    - the rightholder must submit a 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 sufficient evidence that the products in question infringe IP rights is in place. Be that the case customs shall inform the relevant rightholder of its decision and afford him or her the opportunity to submit a request for suspension of clearance. If the rightholder does not act customs shall, 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, and it is, therefore, in principle, in the hands of the relevant IP rightholder to protect his rights. Following suspension of clearance, the rightholder must accordingly file for 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.

Online pharmacy regulation

11 | What rules are in place to govern online pharmacies?

The Falsified Medicines Directive was transposed into Icelandic law in 2018 permitting the sale of pharmaceutical products to the public online 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's website and consumers are encouraged to check it before purchasing pharmaceutical products online.

For verification purposes the EU common logo with the Icelandic flag embedded 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. Pharmacists that sell pharmaceutical products online must, however, ensure that the products are delivered to the correct recipient (eg, by registered mail).

A pharmaceutical trademark, can like other trademarks, be registered as a domain main. 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.

Recent cases

12 | What are the most notable recent cases regarding the enforcement of pharmaceutical marks?

There are no recent cases regarding the enforcement of pharmaceutical trademarks in Iceland.

ADVERTISING

Regulatory bodies

13 | Which bodies are responsible for oversight of pharmaceutical advertising in your jurisdiction (and what are their powers)?

The Icelandic Medicines Agency (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 showing where and when they were published for two years. This record must be accessible to the IMA. The IMA is furthermore to be granted access to all relevant documents, data or information related to an infringement against the provisions on pharmaceutical advertisements and has the power to carry out necessary on-site inspections. Further, the IMA is authorised to purchase goods or services as test purchases, where necessary, under a cover identity, to detect infringements against the provisions on pharmaceutical advertising. In enforcing the provisions on pharmaceutical advertising, the IMA can adopt interim measures to avoid the risk of serious harm to the collective interests of consumers, obtain and accept commitments from the trader responsible for the infringement to cease that infringement and seek a preliminary injunction against the infringement to protect the collective interests of consumers.

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.

Advertising rules

14 | What specific rules are in place regarding the advertising of pharmaceutical products?

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 of a marketing authorisation, for the purpose of promoting 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, advertising of pharmaceuticals is, in principle, prohibited. The prohibition is however 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 shall be such that it is unlikely that the advertisement will be seen by the general public.

Pharmaceutical product advertisements shall, in all instances, give true and professional information about the product. All information in the advertisement shall be clear and easy to read or hear. All information shall furthermore be in accordance with the approved summary of product characteristics (SmPC, SPC). The advertisement shall 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 shall be set up or read in such a way that those in the target group for the advertisement are easily able to read or hear it, or understand the information in another manner.

GENERIC SUBSTITUTION

Legality

15 | Is generic substitution permitted in your jurisdiction?

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 shall always be informed of a cheaper generic alternative when available.

Regulations

16 | Which regulations govern generic substitution by pharmacists of brand-name drugs?

Article 16 of the Icelandic Regulation on Prescription and Delivery of Pharmaceutical Products No. 740/2020 governs generic substitution by pharmacists of brand-name drugs.

UPDATE AND TRENDS

Key developments and future prospects

17 | What were the key judicial, legislative, regulatory and policy developments of the past year in relation to the protection and enforcement of pharmaceutical trademarks? What are the prospects for future developments?

On 29 June 2020, the Icelandic parliament, Alþingi, approved a new Medicinal Products Act No. 100/2020. The new Act will enter into force on 1 January 2021, replacing the current Medicinal Products Act No. 93/1994. The main amendment relating to pharmaceutical trademarks is that once the new Act enters into force, the main rule will be that pharmaceutical advertisements will be authorised with certain restrictions, compared to the current regime, which forbids pharmaceutical advertisements as a general rule, unless specifically authorised.

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