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Pharmaceutical Trademarks 2018/2019

A Global Guide

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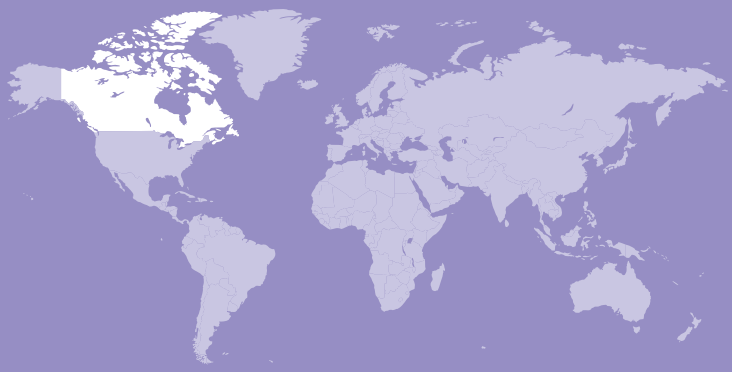

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Sweeping amendments to the Trademarks Act are expected to be implemented in 2019 which will bring Canada into line with international practices, allowing it to accede to the Madrid Protocol, the Nice Agreement and the Singapore Treaty. Canadian businesses will be better positioned to compete globally and it should also be easier for foreign companies to expand their operations into Canada. The legislative amendments will fundamentally affect the way in which all trademark owners will need to approach their selection, clearance and registration strategies, and the pharmaceutical industry is no exception.

Selection, clearance and registration

Drug name approval by Health Canada is distinct from the trademark registration process handled by the Canadian Intellectual Property Office (CIPO) and approval by one branch of government will not necessarily lead to approval by the other. Therefore, drug names must be selected and cleared having regard to both regulatory and trademark registration issues. While both processes deal with the potential for confusion between proposed brand names, the confusion analysis associated with each system differs. Health Canada assesses drug name confusion based on health and safety concerns, while CIPO examiners focus on the likelihood of confusion as to the source of origin of the trademarked products.

Drug names, confusion and regulatory approval

Under the Food and Drug Regulations, a drug's proposed brand name must be submitted to Health Canada for approval. Health Canada can refuse to issue a notice of compliance for new drugs or a drug identification number for new and existing drugs if confusion between a proposed drug name and an existing drug name is considered likely to result in health and safety issues.

Health Canada is not bound by drug name approvals in other jurisdictions and accordingly, a brand name approved and used internationally is not guaranteed to be allowed in the Canadian market.

> **The evaluation of risk through register searching will be rendered practically impossible under the new trademark regime and marketplace investigations will likely be necessary for clearance purposes**

The current Health Canada guidance document dealing with the drug name review process for lookalike, soundalike (LASA) drug names came into effect on June 13 2015. The guidance provides that a sponsor must first carry out an initial brand name review to determine whether the name is misleading with respect to the composition, effectiveness or safety, and then provide a LASA brand name assessment to determine the likelihood of confusion between the proposed name and authorised product names. The testing of LASA attributes involves a multi-step approach, including:

- searching relevant drug name and medication error databases and identifying drug names with a combined orthographic and phonetic similarity score of 50% or more;
- assessing the confusability of a proposed name using simulations; and
- synthesising the evidence obtained from the database search results and the simulations.

Non-prescription products and natural health products are excluded from the scope of the guidance.

Raw data to be submitted is limited to database search results (although Health Canada reserves the right to request additional material where necessary). Psycholinguistic tests are not required.

Drug names, confusion and trademark registration

Clearance searches for prior confusing marks will be fundamentally different once the new Canadian trademark legislation is implemented, although the analysis for assessing confusion will remain the same.

For a trademark to be registrable in Canada, it cannot cause a likelihood of confusion with a trademark previously used, applied for, registered or made known in Canada as to the origin of the goods or services with which the mark is associated. When assessing likelihood of confusion, several factors are examined, including the nature of the goods and services associated with the marks and the degree of resemblance between them.

When evaluating risk based on prior trademark rights, the Canadian Trademarks Register is of significant importance, since it reflects marks that have been commercially used. This is due to the fact that under the current trademark system in Canada, trademarks cannot issue to registration without use somewhere. An application filed on the basis of intent to use will issue to registration only on filing a declaration attesting to commercial use of the mark in Canada for those goods or services contained in the application. The declaration of use requirement is particularly onerous for pharmaceutical companies, since pharmaceutical products cannot be sold commercially in Canada until the drug is approved for sale by Health Canada. As such, applicants often need to file multiple extension requests for submitting the declaration of use and, in many cases, new filings are necessary once the maximum allowable extension period has expired.

Under the new regime, applications will issue to registration on expiry of the opposition period, regardless of whether

use has commenced anywhere. In the pharmaceutical field, this will mean that trademarks covering pharmaceutical products can issue to registration in Canada before the products are even approved for domestic sale. Moreover, the elimination of use as a prerequisite to registration will allow pharmaceutical companies to secure trademark registrations covering virtually all pharmaceutical products and services. The prospect of trademarks issuing to registration covering lengthy lists of goods and services, without use anywhere, is likely to result in a cluttered Trademarks Register. In addition, the Trademarks Register will no longer contain information on use. As such, the evaluation of risk through register searching will be rendered practically impossible under the new trademark regime and marketplace investigations will likely be necessary for clearance purposes.

The new trademark legislation will also affect the assessment of confusion during examination for trademark registration. Examination for confusion with previously filed applications and prior registrations considers, among other things, the degree of resemblance between the marks and the similarities between the goods or services with which they are associated. With the elimination of use as a prerequisite to registration, applicants are likely to overclaim, resulting in applications and registrations covering multiple – and often entirely unrelated – classes of goods and services. The corollary to this will likely be an increase in Trademarks Office citations based on confusion.

Moreover, while public health concerns, such as drug name mistakes, are not strictly relevant to the assessment of confusion between marks for trademark registration purposes (which deals essentially with the issue of confusion as to the source of origin), recent Canadian jurisprudence suggests that such mistakes may nevertheless be considered by Trademarks Office examiners as a surrounding circumstance. In *Sanofi-Aventis v GlaxoSmithKline Biologicals SA* ((2010) 89 CPR (4th) 378 (TMOB)) the Trademarks Opposition Board (TMOB) considered the issue of medication errors as a surrounding circumstance contributing to the likelihood of confusion between the trademarks PACIRIX and PLAVIX, finding the marks to be confusing even though they were associated with different pharmaceutical preparations. However, if a trademark contains a formative common to the industry, the likelihood of confusion will likely be deemed quite low. In *Ferring, Inc v Apotex Technologies, Inc* (2013 TMOB 225) the trademark FERRIPROX was held not to be confusing with the trademark FERRING, although both marks covered related preparations. The TMOB held that since the first portion of the marks consisted of 'fer' – which was highly suggestive of iron – consumers would focus on the suffix components of the marks 'prox' and 'ing', and these differences were considered sufficient to prevent a likelihood of confusion.

Cancellation for non-use

Under both the current trademark regime and the new legislation, trademark registrations are vulnerable to cancellation for non-use from three years after the registration date. Under the current system, trademarks can issue to registration only with use somewhere. Once the new legislation is implemented, situations may arise in the pharmaceutical field where a trademark registration (issued without use) could be challenged for non-use before the drug with which the mark is associated has been approved for sale in Canada. The inability to market a product due to a pending regulatory approval process may be considered a special circumstance permitting the registration to be maintained. However, even if the registration is cancelled for non-use, a fresh application can be filed and, under the new legislation, can issue to registration without use (subject to any intervening right). The new registration will therefore be immune from a non-use cancellation attack for a further three years following the new registration date.

Non-traditional marks

At present, registration of certain non-traditional marks (eg, colours, shapes and sounds) is permitted in Canada. The new

trademark legislation will permit registration of various other non-traditional marks, including scents, tastes and textures; however, applications to register such marks will be subject to examination for distinctiveness, which is not presently the case. If the registrar of trademarks holds that a mark is not inherently distinctive, the applicant will have to file evidence attesting to acquired distinctiveness across Canada as of the application filing date, failing which, the registration will be territorially restricted to the area in Canada where the mark is proven distinctive, or refused outright for lack of distinctiveness.

Examination for distinctiveness will be particularly relevant in the pharmaceutical field, where trademark protection is often sought for non-traditional marks such as colour and shape. Under the new regime, evidence of distinctiveness will be required to support these applications and the Trademarks Office will likely apply the high threshold currently required in opposition and litigation proceedings for establishing distinctiveness of such marks. Examination for distinctiveness will therefore add a further hurdle to securing registration of non-traditional marks in the pharmaceutical field.

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The recent decision in *Pfizer Products Inc v Canadian Generic Pharmaceutical Assoc* (2015 FC 493) highlights the high evidential burden on an applicant in establishing that a colour applied to a pharmaceutical tablet or capsule serves to distinguish the goods of the trademark owner from those of others. The case dealt with an application by Pfizer to register a trademark consisting of the colour blue applied to the visible surface of a diamond-shaped tablet (the Viagra tablet design). The Federal Court upheld the decision of the TMOB that the tablet design was not distinctive of Pfizer or any single source. The court agreed with Pfizer that distinctiveness need not be established in each consumer subgroup (ie, physicians, pharmacists and patients), but rather that a significant degree of recognition among the whole constituency of ordinary consumers was required. However, it nevertheless found that the limited use which physicians, pharmacists and patients made of the colour tablet design for identification purposes was not sufficient to establish the distinctiveness required for trademark registration.

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Parallel imports and repackaging

Pharmaceutical preparations cannot be sold in Canada without prior Health Canada approval. Further, such preparations must comply with the labelling requirements set out in the Food and Drug Regulations – including Section C.01.005, which requires the inner and outer label of a drug to display the drug identification number assigned to that product. Accordingly, the parallel import of pharmaceutical preparations that do not have Health Canada approval or the requisite drug identification number is illegal, even if the drug has been approved for sale in another country.

Bilingual language requirements further reduce the likelihood of a parallel import being legally sold in Canada.

Anti-counterfeiting and enforcement

The sale of counterfeit health products in Canada is governed primarily by the Customs Act, the Trademarks Act, the Copyright Act and the Criminal Code. However, rights holders have traditionally found it difficult to use the relevant legislation to effectively address counterfeiting in Canada. Over the past several years, the Canadian government has attempted to improve border protection measures to combat the import of counterfeit goods and on December 9 2014 Bill C-8, the Combating Counterfeit Products Act, received royal assent.

Key to the act is a request for assistance (RFA) procedure, which provides the Canada Border Services Agency (CBSA) with the power to detain alleged counterfeit products. The RFA process permits the owner of a registered trademark or copyright to record its rights, enabling customs personnel to

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then seize and detain suspected counterfeit goods and provide information about the detained goods to the registered trademark or copyright owner.

The RFA procedure is available only for owners of copyright and registered trademarks; accordingly, trademark owners would be well advised to register all marks that are potential counterfeiting targets in Canada and record their rights under the RFA process.

The provisions relating to the RFA procedure – including the required form for recording IP rights – came into force on January 1 2015, along with expanded definitions of 'infringement' and new criminal penalties.

In addition, on September 13 2017 the CBSA announced that it will accept information from rights holders regarding imminent shipments of dangerous counterfeit or pirated goods destined for Canada. This will be particularly useful to the pharmaceutical industry and supplements the RFA programme.

Advertising

Section C.01.044 of the Food and Drug Regulations restricts consumer-related advertising for prescription drugs to the mention of the name, price or quantity. Under this regulatory framework, Health Canada permits two types of prescription drug message directed to consumers: reminder ads and help-seeking messages.

Reminder ads, where only the name of a prescription drug is mentioned (not the disease), are interpreted as staying within the restrictions. However, depictions of easily recognisable product packages (eg, blister packs or inhalers) in reminder ads that lead to the identification of the therapeutic indication of a prescription drug are not permitted.

Help-seeking messages, where a disease is discussed without reference to a specific prescription drug product, are considered to be information and not advertising, provided that the criteria outlined in Health Canada's Distinction Between Advertising and Other Activities Policy are met.

Generic substitution

Both the federal and provincial governments regulate the pharmaceutical industry in Canada. The federal government has jurisdiction over IP rights, the approval of prescription drugs and labelling. The provincial governments oversee healthcare services funding. Each provincial drug plan sets specific price and other cost-containment guidelines (eg, drug product substitution laws and interchangeability designations) with respect to the pharmaceutical coverage provided.

Drug substitution regulations have been in place in most provinces for many years. These regulations typically focus on promoting the substitution of lower-priced generic drugs for brand-name drugs through implementation of product and price selection rules. Product selection involves

switching from a branded to a generic drug, whereas price selection involves choosing the least costly generic available.

In *Katz Group Canada Inc v Ontario (Health and Long-Term Care)* (2013 SCC 64), the Supreme Court upheld the validity of Ontario regulations prohibiting 'private label products' (ie, generic drugs sold under the brand name of a pharmacy, but manufactured by a third party) from obtaining an interchangeability designation in Ontario, which would have entitled the dispensing pharmacy to reimbursement from the government under the various provincial health plans.

Online issues

Online pharmacies

Canada does not prohibit the online sale of prescription drugs and, given the comparatively low cost of pharmaceuticals in Canada, there is a market for pharmaceuticals sold through Canadian online pharmacies. However, online consumers should be aware that the absence of personal contact between consumer and pharmacist may increase the risk of health and safety issues with such products.

Domain names

The Canadian Internet Registration Authority (CIRA) administrates '.ca' domain name registrations and restricts registrant eligibility through its Canadian Presence Requirements (CPRs) to certain qualifying parties, including those holding a Canadian trademark registration that corresponds to the domain name to be registered.

CPR-eligible parties, including trademark owners, may lodge complaints seeking the transfer of domain names registered in bad faith through the CIRA Domain Name Dispute Resolution Policy. Before it will order a domain name transfer, CIRA requires the complainant to demonstrate prior rights to the trademark, as well as the registrant's bad faith and lack of legitimate interest in the domain name. **WTR**

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