Canada

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There have been several notable developments in Canadian trademark law and practice during the past year, many of which are particularly relevant to the pharmaceutical trademark field.

Selection, clearance and registration
Drug names, confusion and regulatory approval
The selection of a brand name for a prescription drug in Canada must be assessed bearing in mind not only trademark registration issues pursuant to the Trademarks Act, but also regulatory issues handled by the Therapeutic Products Directorate of Health Canada. While both deal with brand-name approval and issues of confusion, their underlying focus is quite different. The selection of a trademark under the Trademarks Act focuses on the likelihood of confusion as to the source of manufacture of the products. By contrast, Health Canada considers the issue of drug name confusion from a health and safety perspective.

The Food and Drug Regulations require that a proposed drug name be submitted to Health Canada for approval. If confusion between the proposed drug name and an existing drug name is considered likely to result in safety concerns, Health Canada can refuse to issue a notice of compliance for new drugs, or a drug identification number (DIN) for new drugs and existing drugs, both of which are necessary in order to market a pharmaceutical product in Canada.

In an effort to reduce medication errors related to similar drug names, Health Canada drafted the Guidance for Industry - Drug Name Review: Lookalike Soundalike (LA/SA) Health Product Names, which came into force in 2006. Pursuant to this guidance, manufacturers are required to submit various materials, data and information to assist Health Canada in assessing the potential for confusion between a new drug name and products currently on the market. However, a review of new drug name submissions since the release of the guidance in 2006 revealed significant variations in the amount, type and quality of evidence submitted by manufacturers. This is in part due

to the absence of clear direction on the process to be followed by drug manufacturers and the risk assessment methods to employ.

With a view to addressing some of the deficiencies in the 2006 guidance, on February 19 2013 Health Canada released the Draft Revised Guidance Document - Review of Drug Names for Lookalike Soundalike (LA/SA) Attributes. The revised guidance is intended to provide more direction on the process to be followed and the information to be submitted to Health Canada regarding the issue of confusion between a proposed drug name and an existing product.

The revised guidance provides more specific procedures and risk assessment methods for manufacturers to follow when submitting a proposed drug name to Health Canada for approval, including use of a health product name search engine and simulation experiments to assess the confusability of a name.

The consultation on the revised guidance was open from February 19 to April 19 2013. At the time of writing, it is uncertain whether or when the revised guidance will take effect.

Drug names, confusion and trademark registration

As noted above, the drug name approval process in Canada is separate and distinct from trademark registration. If a product name is approved by Health Canada, it does not necessarily follow that the name will be registrable as a trademark; similarly, if a name is found to be registrable as a trademark, it does not ensure that the name will be accepted by Health Canada.

In the case of trademark registration, the Trademarks Office must determine whether the co-existence of two similar drug names is likely to cause confusion in the marketplace as to the source of origin of the products. Public health concerns (eg, medical risks associated with drug name mistakes) are not, strictly speaking, relevant to the issue of trademark registration. However, recent Canadian jurisprudence suggests that health and safety concerns may become increasingly relevant when assessing the issue of confusion between drug names for trademark registration purposes, particularly when assessing two relatively distinctive marks.

In *Sanofi-Aventis v GlaxoSmithKline Biologicals SA* ((2010) 89 CPR (4th) 378 (TMOB)) the Trademarks Opposition Board considered the issue of medication errors as a surrounding circumstance contributing to the likelihood of confusion between the trademarks PACIRIX and PLAVIX, and found the marks to be confusing even though they were associated with very different pharmaceutical preparations and end uses.

By contrast, however, if a trademark consists of elements common to the industry, the Trademarks Office will consider the likelihood of confusion to be quite low. In *Health4All Products Limited v Nutraceutical Medicine Company Inc* ((2012) 107 CPR (4th) 215 (TMOB)) the trademark FIBERLICIOUS was held not to be confusing with the trademark FIBERRIFIC, even though both marks covered dietary supplements containing fibre. Since the first portion of each mark consisted of the commonly used term 'fiber', even small differences between the marks were considered to be sufficient to distinguish between them and to avert any likelihood of confusion.

Colour and shape marks

In Canada, a trademark consisting of colour applied to the shape of a product is inherently registrable. In the pharmaceutical field, however, there is a high evidential burden on the applicant to establish that the mark serves to distinguish the wares and/or services of the trademark owner from those of others. Applicants must establish that the colour mark is distinctive in the entire pharmaceutical field, and not only with respect to the specific preparation(s) with which it is associated. Moreover, the applicant must establish that the relevant market (ie, physicians, pharmacists and patients) relate the trademark to a single source of manufacture and use the mark to make their prescribing, dispensing or purchasing choices. In the case of colour marks, this is an onerous burden of proof.

The recent Trademarks Opposition Board decision in *Canadian Generic Pharmaceutical Association v Pfizer Products Inc* (2013 TMOB 27) reinforces the difficulty of securing registered trademark protection for marks consisting of colour applied to a pharmaceutical tablet or capsule in Canada. The case involved an opposition by the Canadian Generic

Pharmaceutical Association (CGPA) to the registration by Pfizer Products Inc of its blue, shaped Viagra tablet. In this case, the CGPA was able to demonstrate that the colour and shape of the mark did not distinguish it from other pharmaceutical tablets and capsules, given the high number of blue and/or multi-sided pills actively marketed in Canada. Moreover, while the board was prepared to accept that Pfizer's mark was distinctive among patients, it held that the evidence was insufficient to demonstrate that the mark was distinctive among pharmacists and physicians, and the application was refused.

While the outcome of applications to register colour tablet or capsule marks is highly dependent on the nature and extent of evidence filed, the onus on the applicant is nevertheless significant, and invariably applications to register such marks are refused.

Sound marks

A recent decision of the Federal Court of Canada has reversed a longstanding policy of the Canadian Intellectual Property Office (CIPO) regarding the registrability of sound marks in Canada. After a two-decade legal battle in which Metro-Goldwyn-Mayer (MGM) sought to register the sound of a roaring lion as a trademark, the Federal Court set aside CIPO's refusal and MGM's sound mark application issued to registration on July 31 2012. Prompted by the Federal Court's decision, CIPO announced that it would accept applications to register sound marks.

Within the pharmaceutical industry, sound marks have and continue to be used by drug manufacturers. Among others, Bayer's well-known "PLOP PLOP FIZZ FIZZ OH WHAT A RELIEF IT IS" musical jingle, used in association with antacid preparations, is a notable example of the importance of sound marks in the marketing and sale of pharmaceutical products.

In the United States, Hisamitsu Pharmaceutical Co registered HISAMITSU, sung over the sound of four musical tones, for "medicated transdermal patches, plasters, pads, gels and sprays for the temporary relief of the aches of rheumatoid arthritis, and the aches and pains of muscles, joints and tendons". A corresponding Canadian application for the same sound mark was abandoned in 2011, shortly before Canadian practice changed to permit sound marks.

The MGM decision and the resulting change in Canadian practice have brought Canada into line with many other countries that have long since recognised the registrability of sound marks. No doubt pharmaceutical companies which use musical sounds and jingles in the branding of their products and services will welcome the shift in Canadian law and practice.

Parallel imports and repackaging

Pharmaceutical preparations that are to be sold in Canada must receive prior Health Canada approval to market, without which sales of the product will be prohibited. Moreover, all such preparations must comply with Canadian labelling requirements as set out in the Food and Drug Regulations, including Section C.01.005, which requires that the inner and outer label of a drug display the DIN assigned for that product. Accordingly, the parallel importation of pharmaceutical preparations into Canada that have not received Health Canada approval and that do not bear the requisite DIN is illegal, even though the drug has been approved for sale in another country.

Anti-counterfeiting and enforcement

The magnitude of counterfeit pharmaceuticals in Canada remains relatively small in comparison to other industrialised countries. There is no counterpart in Canada to the customs seizure regimes in the United States and many other countries worldwide. Moreover, Canada does not have a trademark recordal regime or any other recordal regime for IP rights. Equally problematic is that customs officials in Canada will not act directly to search and seize goods that violate a trademark owner's rights independently.

The sale of counterfeit health products is governed primarily by the Customs Act, the Trademarks Act and the Copyright Act. In addition, selling counterfeit health products is a violation of the Criminal Code. However, rights holders have found it difficult to use the relevant legislation effectively in the face of counterfeit activities in Canada.

On March 1 2013 the Canadian government introduced Bill C-56, An Act to Amend the Copyright Act and the Trademarks Act and to

Make Consequential Amendments to Other Acts. The short title of the proposed legislation is the Combating Counterfeit Products Act, and the bill introduces amendments to the Copyright Act and the Trademarks Act that would significantly improve border measures for counterfeit goods in Canada.

Presently available only with a court order, under the proposed legislation, the owner of a copyright and/or a registered trademark that is considered by the rights holder to be infringed by the import and sale of counterfeit products has access to an assistance procedure whereby the goods are detained by customs officials for a certain period of time. During this period, the owner is provided with a sample of the goods and can request information to assist in identifying the source of the counterfeit products. The proposed legislation also exposes offenders to fines of up to C$1 million and imprisonment.

However, the new assistance programme is available only with respect to registered trademarks and not common law trademark rights. Therefore, trademark owners would be well advised to register all marks that are potential counterfeit targets in Canada.

At the time of writing, Bill C-56 has passed its second reading and been referred to the Standing Committee on Industry, Science and Technology. It is expected to come into force before the end of the year.

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 has permitted 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 not going beyond the name, price and quantity restrictions of Section C.01.044. Help-seeking messages, where a disease state is discussed but there is no reference to a specific prescription drug product, are considered to be information and not advertising, provided that they meet the criteria outlined in Health Canada's policy entitled "The Distinction Between Advertising and Other Activities".

Depictions of easily recognisable product packages (eg, blister packs, inhalers) that lead to the identification of the therapeutic indication of a prescription drug in reminder ads are considered to exceed the consumer advertising limitations described in Section C.01.044 of the Food and Drug Regulations, and are therefore not permitted in Canada.

Canada's research-based pharmaceutical companies comply with a code of ethics as a requirement of their membership in their trade association, Rx & D. This code includes advertising guidelines. Recidivism or deliberate breach of the code may result in the expulsion of a member company from the trade association.

Generic substitution

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

Drug substitution regulations have been in place in most provinces for many years. These regulations have typically focused on promoting the substitution of lower-priced generic drugs for brand-name drugs, through the 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.

Online issues

Canada does not prohibit the online sale of prescription drugs and, given the comparatively low cost of pharmaceuticals in Canada as compared to many other countries (due in large part to substantial regulations), there is a growing market for pharmaceuticals sold through Canadian online pharmacies. However, ordering prescription

pharmaceuticals through the Internet is not without risk. The drug could have dangerous additives, stipulate the wrong dosage or contain no medicinal ingredients at all.

In 2012 the US Food and Drug Administration subpoenaed several doctors for information about a Canadian online pharmacy and one of its suppliers after counterfeit drugs were sold to 19 US medical practices. While the investigation did not implicate the online pharmacy in the direct handling of counterfeit drugs, the company was connected to drug wholesalers who distributed the drugs to US doctors, several of whom have had charges brought against them.

Recently, however, in Maine a bipartisan bill (LD 449) was introduced that would affirm the right of Maine consumers to buy prescription drugs through certain international mail-order companies, including a Canadian mail-order pharmacy. Advocates of the bill argue that permitting such sales from Canadian mail-order pharmacies would save the state millions of dollars annually. The bill has been forwarded to Maine's Committee on Labour, Commerce, Research and Economic Development for consideration.

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