Bereskin & Parr LLP

Applying the rules

Several notable developments in Canadian trademark law and practice during the past year are relevant to the pharmaceutical trademark field

In Canada, the selection of a brand name for a prescription drug must be assessed bearing in mind both regulatory issues handled by Health Canada and trademark registration issues pursuant to the Trademarks Act. If a product name is approved by Health Canada, it does not necessarily follow that the name will be registrable as a trademark; and similarly, if a name is found to be registrable as a trademark, this does not mean that the name will be accepted by Health Canada. Health Canada considers the issue of drug name confusion from a health and safety perspective. By contrast, the selection of a trademark under the Trademarks Act focuses on the likelihood of confusion as to the source of manufacture of the products.

Drug names and Health Canada regulatory approval

The Food and Drug Regulations require a manufacturer to file a new drug submission containing sufficient information and material to enable Health Canada to assess the safety and effectiveness of the drug, including a statement of the brand name. If there are safety concerns, Health Canada may refuse to issue a notice of compliance for new drugs, or a drug identification number for new and existing drugs, both of which are necessary in order to market a pharmaceutical product in Canada.

In an effort to provide clarification regarding the brand-name submission process for proposed drug names, and to reduce the risk of medication errors related to similar drug names, Health Canada drafted a guidance for industry – Drug Name Review: Look-alike Sound-alike (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 that of an existing product. However, a review of new drug name submissions since the release of the 2006 guidance revealed significant variations in the amount, type and quality of evidence submitted by manufacturers, largely due to the absence of a clear direction on the process to be followed and the risk assessment methods to employ.

With a view to addressing some of the deficiencies in the 2006 guidance, Health Canada released a draft revised guidance document – Review of Drug Names for Look-alike Sound-alike (LA/SA) Attributes – on February 19 2013. 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 two simulation tests: psycholinguistic testing and medication use testing.

Consultation on the revised guidance was open from February 19 2013 to April 19 2013. During this time, Health Canada met with individual stakeholders to hear their concerns. Most industry comments focused on the requirement for psycholinguistic testing, which was considered to be too stringent and exacting – particularly when compared to regulations of other countries – with no significant benefits.

In response to industry concerns, Health Canada stated that it would revise the guidance document. Regarding the issue of psycholinguistic testing, it indicated that it may be moved to an appendix to the guidance as an 'optional' test.

The final version of the guidance is expected to take effect in late 2013 or early 2014. Health Canada has proposed at least a one-year transition period during which it will not enforce the new guidance requirements.

Drug names and trademark registration

As noted above, the drug name approval process in Canada is separate and distinct from trademark registration.

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, such as 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. 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, and found the marks to be confusing, even though they were associated with different pharmaceutical preparations and end uses.

Non-traditional marks

Colour and shape

In Canada, a trademark consisting of colour applied to the shape of a product is inherently registrable. However, in

the pharmaceutical field, there is a high evidential burden on the applicant to establish that the mark serves to distinguish the wares or services of the trademark owner from those of others. An applicant 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 – namely, physicians, pharmacists and patients – relates the trademark to a single source of manufacture and uses it to make their prescribing, dispensing or purchasing choices. In the case of colour marks, this is an onerous burden of proof.

The recent TMOB 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 to the registration by Pfizer Products Inc of its blue shaped tablet (VIAGRA).

In this case, the association 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 pills that were actively marketed in Canada. Moreover, while the TMOB 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. Thus, the application was refused.

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

Sound

The Federal Court of Canada recently reversed the long-standing 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 decision, CIPO announced that it would accept applications to register sound marks.

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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. Pharmaceutical companies which use musical sounds and jingles in the branding of their products and services will no doubt welcome the shift in Canadian law and practice.

Anti-counterfeiting and enforcement

The magnitude of counterfeit pharmaceuticals in Canada remains relatively small in comparison to other industrialised countries, and there is no counterpart in Canada to the customs seizure regimes in the United States and many 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 independently that violate a trademark owner's rights.

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, the relevant legislation has proved difficult for rights holders to use effectively in the face of counterfeiting activities in Canada.

On October 16 2013 the Canadian government introduced Bill C-8, the Combating Counterfeit Products Act, to amend the Copyright Act and the Trademarks Act and make consequential amendments to other acts. It introduces amendments to the Copyright Act and Trademarks Act that will significantly improve border measures for counterfeit goods in Canada. (Bill C-8 was originally introduced as Bill C-56 earlier in 2013 and contains the same content).

Under Bill C-8, both the Trademarks Act and Copyright Act will be amended to include provisions that will grant the Canada Border Services Agency (CBSA) increased powers to prevent counterfeit goods from entering Canada. In addition, a copyright or registered trademark owner can file for a standing two-year request for assistance from the CBSA. During this period, the owner is provided with a sample of the goods and can request information to assist it in identifying the source of the counterfeit products. The proposed legislation also exposes offenders to fines of up to C$1 million and/or imprisonment.

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 counterfeiting targets in Canada. WTR