Bereskin & Parr LLP

Walking the tightrope

Pharmaceutical companies need to create a branding strategy that meets both trademark and regulatory requirements

In Canada, the brand name for a prescription drug must be selected bearing in mind not only trademark registration issues pursuant to the Trademarks Act and within the domain of the Canadian Trademarks Office, but also regulatory matters 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. Under the Trademarks Act, the registrability of a mark is assessed, in part, based on the likelihood of confusion with another mark as to the source of manufacture. By contrast, Health Canada's primary focus when assessing drug name confusion is the health and safety risks associated with similar drug names.

Pursuant to the Canadian Food and Drug Regulations (Sections C.08.002 and C.01.014.1), the name of a proposed drug must be submitted to the Therapeutic Products Directorate of Health Canada as part of the drug approval process and before the product will be officially approved for sale in Canada. In the case of different drug products that have orthographic similarities and/or similar phonetics, the name will be assessed for potential safety risks, with the aim of reducing the risk of errors in prescribing or dispensing medications, or in the administration of a product by a patient. If the proposed name is considered to look and/or sound similar to another drug name, it may be disallowed. However, the drug name approval process 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 registrable as a mark, this 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 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 confusion between drug names for trademark registration purposes.

In *Sanofi-Aventis v GlaxoSmithKline Biologicals SA* (2010 TMOB 200) the Trademarks Opposition Board did, in fact, consider the issue of medication error as a surrounding circumstance in assessing the likelihood of confusion as to source. In this case an application for PACIRIX for vaccines was successfully opposed by the owner of the PLAVIX mark for cardiovascular medications, despite the fact that the products associated with the respective marks were notably different. In support of its decision, the board noted that both products were "human pharmaceutical preparations", and that since the applicant's application was not restricted to a specific type of vaccine, the likelihood of confusion must be assessed bearing in mind that the applicant could conceivably develop vaccines overlapping in the field related to the opponent's cardiovascular product (although there was no evidence of any such product development). The hearing officer's position was perhaps best summarised by his comment on the connection between medication errors and the test of confusion for trademark application purposes:

"Although the possibility of errors in prescribing, dispensing or administering drugs is not directly related to the likelihood of confusion as to the source of the product, which is the issue for decision in this case,... mistake and confusion are not mutually exclusive... mistaking one trade-mark for another necessarily implies that there is a high degree of resemblance between the marks, which is one of the factors to be considered in the test for confusion pursuant to s. 6(5)(e) of the Act. (at p 9)."

However, where a pharmaceutical trademark consists of elements common in the industry, the Trademarks Office considers the likelihood of confusion to be much lower. In *Novartis Pharmaceuticals Canada Inc v Graceway Pharmaceuticals LLC* ((2010), 88 CPR (4th) 116 (TMOB)) an application for the trademark ESTRASORB for topical hormone preparations was allowed, despite an opposition on the basis of the trademarks ESTRADERM, ESTRADERM TTS and ESTRACOMB covering various hormonal preparations. The Trademarks Opposition Board noted that the first or dominant portion of the marks was the "ESTRA" component, and that it would readily be perceived as a shortened form of the chemical 'estrogen'. As such, the relevant consuming public would tend to discount the importance of the ESTRA prefix and focus more on the suffix components of the marks, which the board found to be sufficiently distinguishable.

Non-traditional marks – colour and shape

In Canada, a trademark consisting of a combination of product shape and colour is inherently registrable. However, there is a high evidential burden on the applicant to establish that the mark serves to distinguish its wares or services from those of others.

The recent case of *Apotex v Registrar of Trademarks* ((2010), 81 CPR (4th) 459 (FC); aff'd (2010), 91 CPR (4th) 320 (FCA); leave to

appeal refused), involved a successful attack on a trademark registration consisting of the colours dark purple and light purple applied to the visible surface of portions of a plastic spherical inhaler device containing medication for the treatment of asthma and chronic obstructive pulmonary disease. The trademarks ADVAIR and DISKUS also appeared on the product.

The court reinforced the principle that the relevant consumers – namely, physicians, pharmacists and patients – must relate the trademark to a single source of manufacture and thereby use the mark to make their prescribing, dispensing or purchasing choices. Moreover, the court noted that the distinctiveness of a mark consisting of colour and shape may be diminished when the pharmaceutical product is also used in association with a well-known word mark. To support a finding of distinctiveness, the trademark must be capable of being recognised on its own. In this case the court found that the essential problem with GlaxoSmithKline's evidence was that the inhaler device was never marketed without the brand-name label, and that therefore the evidence showing that the colour and shape mark was the primary distinguishing feature of the product was purely hypothetical – witnesses were opining on a situation that never presented itself.

GlaxoSmithKline's position was further weakened by virtue of the fact that, unlike the word marks ADVAIR and DISKUS, no trademark notice was given of the colour and shape mark on the product packaging or the device itself to reinforce the commercial association in the mind of the purchaser at the time of sale.

The *Apotex* decision was recently upheld on appeal to the Federal Court of Appeal and leave to appeal to the Supreme Court of Canada was refused.

Canadian trademark law will also protect the shape of a pharmaceutical tablet, capsule or device; however, such protection can be obtained only by way of a distinguishing guise registration. This requires the filing of evidence establishing that the mark or 'guise' has been so used in Canada as to have become distinctive as of the filing date, and that the exclusive use of the mark or guise by the applicant is unlikely to limit the development of the industry – a very difficult burden to discharge.

Counterfeit pharmaceuticals

The magnitude of counterfeit pharmaceuticals in Canada remains relatively small in comparison to other industrialised countries, but nevertheless the problem exists.

The applicable legislation dealing with the sale of counterfeit health products and the procedures and remedies available to prevent their importation and sale in Canada is the Customs Act, the Trademarks Act, the Copyright Act, the Criminal Code and, in some cases, the Patent Act.

The Royal Canadian Mounted Police may act on information provided by a rights holder about suspected counterfeit goods and pursue action. For instance, on May 5 2011 its investigators intercepted a package containing approximately 15,000 suspected counterfeit VIAGRA brand pills destined for a warehouse leased by the accused. At the warehouse, investigators subsequently seized approximately 100,000 suspected counterfeit VIAGRA and CIALIS brand pills in blister packs, as well as boxes used to prepare the pills for resale. The estimated total value of the seized counterfeit drugs exceeded C$1 million. The accused was charged with possession of property obtained by crime, contrary to Section 384(1) of the Criminal Code and in breach of Section 31 of the Food and Drugs Act.

In the wake of this seizure, Health Canada issued a warning to Canadians regarding the potentially serious health problems associated with counterfeit drug products. In this case the counterfeit CIALIS tablets contained sildenafil, whereas the authorised version of CIALIS tablets, manufactured by Eli Lilly, contained tadalafil.

In May 2010 Health Canada released a document entitled "Policy on Counterfeit Health Products". The document is intended to facilitate compliance by the regulated parties with the Food and Drugs Act and associated regulations, with the aim of mitigating the health and safety risks posed by counterfeit health products.

E-pharmacies

The sale of prescription drugs through the Internet is not prohibited in Canada. However, in recent years the sale of innovator drugs by Canadian online pharmacies has largely been shut down by innovator companies refusing to supply them. Any innovator drug offered for sale by a Canadian online pharmacy may well be counterfeit. Prescription drugs made by generics, which are not under patent, are generally available online. In Autumn 2010 the Royal Canadian Mounted Police was part of a global effort to combat the sale of counterfeit drugs through online pharmacies. Codenamed "Operation Pangea", the programme warned consumers that many of the websites claiming to be online Canadian pharmacies were, in fact, run from other countries around the world. The campaign resulted in suspects being arrested across the globe and the seizure of thousands of doses of counterfeit drugs. WTR

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