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Canada

Many trademark challenges are specific to the pharmaceutical industry. Issues include whether clinical trials can be considered trademark use in Canada – a prerequisite to trademark registration – and the limited extent to which pharmaceutical trademarks can be used in advertising

A host of trademark-related issues are unique to the pharmaceutical industry. This article discusses some of these issues, as well as some recent developments in pharmaceutical trademark law.

Clinical trials and trademark use

Pharmaceutical companies often select drug names long before the drug is approved for sale in Canada and intent to use trademark applications are filed with a view to securing trademark protection. However, to obtain trademark registration, the mark must be put into use in Canada. An issue that is often debated in the pharmaceutical trademark field is whether clinical trials constitute trademark use in Canada.

Under Section 4(1) of the Trademarks Act, a trademark is deemed to have been used in association with goods if, at the time of the transfer of the property, in the normal course of trade, it is marked on the products or their packaging or is somehow associated with the products.

The inquiry into this issue must, therefore, focus on whether use of the mark in the context of a clinical trial constitutes use "in the normal course of trade", within the meaning of Section 4(1).

A number of Canadian cases have held that if a mark is used on products in Canada purely for market testing, this does not constitute trademark use in the normal course of trade (*Grants of St James's v Andres Wines Ltd* (1969) 58 CPR 281; *San Tomo Partners v Compania Industrial de Conservas Alimenticias/Cica* (1994) 53 CPR (3d) 560; *Fisons Pharmaceuticals Ltd v Sales Affiliates Inc* (1973) 10 CPR (2d) 123). However, the case law also suggests that if product or market testing is routine in that type of business, and if the testing is subsequently followed by actual commercial sales, then use of the mark in product or market testing may, in fact, constitute use in the normal course of trade (*BFE Inc v Broadcast Designs Ltd* (1993)(TMOB); *ConAgra Foods Inc v Fetherstonhaugh & Co* (2002) 23 CPR (4th))

In *BFE Inc v Broadcast Designs Ltd*, the opponent was able to support its claim of a first use date prior to that of the applicant by arguing that shipments of speakers for evaluation purposes and to obtain Canadian Standards Association approval was a common practice in the industry and hence were made "in the normal course of trade". However, it is worth noting that in this case the test shipments were also followed closely by commercial sales.

The importance of sales closely following a trial shipment was further supported in *Canadian Olympic Assn v Pioneer Kabushiki Kaisha* ((1992) 42 CPR (3d) 470 (TMOB)), wherein it was held that the sample shipments will represent part of a dealing in the goods and support trademark use if:

- shipments of sample goods bearing the mark, in advance of a regular shipment, for marketing or promotional purposes is a regular practice in that field; and
- such sample shipments are followed by regular shipments of goods that are sold through normal commercial trade channels.

In *Immuno AG v Immuno Concepts Inc* ((1996) 69 CPR (3d) 374 (TMOB)), the Opposition Board held that distribution of samples of the applicant's immuno-assay diagnostic test kits did not constitute use in the normal course of trade because they were not immediately followed by regular shipments. The applicant argued that significant time was required to assess the marketability of its products and, for this reason, commercial shipments would not typically follow the sample test shipment. The board found that the applicant failed to provide evidence to support its submission. However, the case may well have been decided differently if the applicant had filed evidence to support the fact that in its normal course of trade, there can be significant lapses of time between testing and regular commercial use.

A recent decision of the Opposition Board went even further to lend support to the position that use of a mark in clinical trials is trademark use in the normal course of trade. In *Pharmacyclics Inc v McKesson Canada Corp* ([2008] TMOB 163), the opponent alleged that its trade name Pharmacyclics was being used through association with the XCYTRIN trademark and product, still in the clinical trial stage. The board found that the trade name was not sufficiently associated with the drug in question during the trials. However, in *obiter*, the board noted that "the only evidence that could be associated with the category of pharmaceutical products... does not concern the trademark PHARMACYCLICS but rather, the trademark XCYTRIN". This suggests that if the issue in the opposition had been the use of the XCYTRIN trademark appearing on the drug in the course of clinical trials, the board may have found there to be trademark use in the normal course of trade.

Depending on the specific facts in any given case, use of a mark in the context of a clinical trial may well constitute trademark use in the normal course of trade, within the meaning of the Trademarks Act. However, as there has not been any definitive ruling on the issue, relying on such use is not without risk.

Direct-to-consumer advertising of prescription drugs

Schedule F drugs

'Advertising' is broadly defined in the Canadian Food and Drugs Act as "any representation by any means whatever for the purpose of promoting directly or indirectly the sale of any food, drug or cosmetic device".

The direct-to-consumer advertising of Schedule F drugs (ie, drugs available only on prescription) is largely prohibited in Canada, save the limited exception described in Section C.01.044(1) of the Food and Drug Regulations. That provision states that "where a person advertises to the general public a Schedule F drug, the person shall not make any representation *other than* with respect to the brand name, proper name, common name, price and quantity of the drug" (emphasis added).

The exception to the general prohibition against direct-to-consumer advertising of prescription drugs was added to the Food and Drug Regulations in 1978, with the intention of allowing pharmacists to display their prices so that consumers could benefit from

competitive pricing. However, even if that was the original intent, in the late 1990s drug companies began publishing so-called reminder ads that displayed information permitted by the wording of the section, such as "CIALIS (tadalafil). Talk to your doctor".

In 2000 Health Canada confirmed that since these reminder ads display only the brand name (or trademark) for the Schedule F drug, they are legal under Section C.01.044.

Advertising v information

Apart from advertising, Health Canada acknowledges that drug companies must be permitted to distribute information to the general public. To this end, Health Canada issued a policy entitled "The Distinction Between Advertising and Other Activities".

The policy also sets out a non-exhaustive list of examples of different types of message that drug companies distribute, as well as the factors that Health Canada will consider in determining whether the primary purpose for each type of message is to promote a Schedule F drug or provide information.

A common vehicle for distributing information directly to consumers is the help-seeking announcement. The policy defines 'help seeking announcements' as announcements that ask patients among the general public who have a particular medical disorder, or who experience a given set of symptoms, to consult a physician for discussion of treatment options or to call a 1-800 telephone number for further information. According to the policy, such an announcement may be a promotional activity if, for example, a drug manufacturer's name or logo is displayed. (Health Canada prefers a statement such as "Sponsored by a research-based pharmaceutical company".)

Opposition Board – confusion and drug names

Recent Opposition Board decisions have dealt with confusing drug names. However, they do not provide much guidance on the extent to which the board will focus on differences between the purpose of the medications when analyzing the issue of confusion. The cases are fact-specific and largely depend on the evidence. Thus, in *ICN Pharmaceuticals Inc v Unger* (February 3 2006), the board found that the marks VIRAZOST for the treatment of skin conditions and VIRAZOLE for anti-viral agents were confusing. In *Bristol-Myers Squibb Co v International Wex Technologies Inc* (June 7 2007), the board found that TECTIN for opiate withdrawal treatment and cancer/neuropathic pain management and TEQUIN for antibiotics were confusing. In *Pfizer Products Inc v AstraZeneca AB* (August 8 2008), the board also found that ZELOXZAR for treatment of cancer and ZELDOX for treatment of neurological conditions were confusing.

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In all of these cases, the application at issue was refused. However, in *Genzyme v Merz Pharma* (October 272008), the board found that REJUGEL for hyaluronic acid filler for wrinkle and lip augmentation and RENAGEL for phosphate finders for treatment of hyperphosphatemia were not confusing and the opposition was rejected.

Lookalike/soundalike drug names

To clear brand names for drugs for human use in Canada, pharmaceutical companies must not only consider whether the names are available from a trademark perspective, but also have regard to Health Canada's guidance document entitled "Drug Name Review: Lookalike Soundalike (LA/SA) Health Product Names". Health Canada released the guidance document in October 2005 in an effort to reduce the risk of medication errors arising from lookalike/soundalike health product names, which are defined in the guidance document as "health products that have a similar written name or similar phonetics to those of another health product".

According to the guidance document, when filing a submission for drug approval, manufacturers should submit the proposed drug name and a prioritized list of alternative names (to a maximum of two), as well as a risk assessment and evaluation of the proposed name, supported with data and analysis.

In determining whether a similarity in names is likely to present a health and safety risk, Health Canada will consider a number of factors, including:

- the marketing status (ie, prescription or over-the-counter drugs);
- the therapeutic category;
- the indication(s) and directions for use; and
- the clinical setting for dispensing or use (inpatient or outpatient hospital or clinic versus retail pharmacy for use in home).

The guidance document acknowledges that since the science for the assessment of drug names is developing, it is not yet clear which assessment technique is the best for predicting the risk of medication errors with lookalike/soundalike drugs. At present, the guidance document recommends that a risk assessment include, but not be limited to, a search for similar proprietary and non-proprietary names using:

- medical reference searches;
- computer analysis (orthographic/phonetic);
- oral and handwritten prescription testing studies; and
- a process flow. WTR