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Trade-marks in the Canadian Pharmaceutical Industry

By Marie Lafleur

The development of a new drug, from discovery to marketing, is a long, costly and risky process. It can take 10 to 12 years to develop and test a drug. And for every drug that reaches the market, the average research and development costs exceed US$800 million. The risk of failure is high. On average, only one out of every 10,000 drugs submitted for evaluation will be approved by Health Canada.[1]

The R&D company (the "innovator") will obviously want to have the exclusive right to market the drug to recuperate its development costs and to set aside the funds necessary to pursue research and development. Long before a drug is marketed, it will therefore ensure that all intellectual property rights are protected. It will have obtained patents, not only on the molecule itself, but also on formulations, processes and uses so that it can enjoy a monopoly for as long as possible.

Once all patents have expired, the innovator will be flooded by one or many generic versions of its new drug. However, it can continue to enjoy a certain degree of protection. A smart innovator will have, throughout the existence of its patents, deployed marketing and advertising efforts to develop trade-marks in association with its product. It will have educated consumers to distinguish between its product and those of its competitors. Of course, generic competitors will want to copy the brand name or the appearance of the new drug in an attempt to obtain a bigger share of the market. The battle then becomes one against the risk of confusion between the trade-marks of the innovator and those of the infringer.

a) Trade-marks

A trade-mark is a mark used by a person for the purpose of distinguishing or so as to distinguish his wares or services from those of his competitors. Traditionally, a mark can be a word, logo or both. It can also be a distinguishing guise, which is the shaping of wares or their containers, or the mode of their wrapping or packaging, to the extent that these are distinctive. It can even be a colour, shape, slogan or sound.

The owner of a registered trade-mark is entitled to the exclusive use thereof in Canada. An exclusive right is deemed to have been infringed by any individual who uses a trade-mark or trade name that is confusing with the registered trade-mark. The criteria for determining whether confusion exists between a registered trade-mark and an infringing trade-mark or trade name goes beyond the mere question of whether there is a resemblance between the two. Essentially, the question consists in determining whether the average consumer, who is not on his guard, would conclude that there is an association between the owner and the infringer.

Pharmaceutical companies tend to avail themselves of two types of trade-marks: nominal trade-marks, such as a drug's trade name, and distinguishing guises, such as a drug's appearance including its shape and colour.

b) Prescription Drugs: Identifying the Consumer

In the case of drugs, the average consumer who is likely to be confused must be identified. For over-the-counter medication, the average consumer is obviously the patient who chooses, purchases and uses the medication. But in the case of prescription drugs, the answer is not quite so simple: is the average consumer the doctor who prescribes the drug, the pharmacist who dispenses it to the patient or the patient who uses it? In 1992, the Supreme Court of Canada[2] has held that, in the case of prescription drugs, patients, doctors and pharmacists must all be taken into consideration when determining the existence of confusion.

c) Prescription Drugs: Shape and Colour

Trade-mark law recognizes the rights that result from the appearance of a product. The innovator, however, must prove that the appearance of its product, whether it be the packaging, the tablet shape or its colour, has earned such a reputation that the consumer associates the innovator with these characteristics. As the Supreme Court of Canada ruled in *Ciba Geigy*, it is very difficult for a product to attain such a level of reputation:

> […] *pharmaceutical companies are limited in the choice of ways to distinguish the get-up of their products. As pharmacists buy such products in bulk and dispense them to the public in standard containers which are transparent and anonymous, the only way of drawing the attention of patients to the origin of the product is the capsule or tablet itself. There are not many possibilities: what is written on tablets is often too small to be legible, at least not readily so, and that leaves only the shape, size and colour of the products as a means of distinguishing them. Here again pharmaceutical laboratories have little room for manoeuvre. The size and shape of drugs cannot depend solely on imagination, since they must meet certain functional requirements resulting from physiological necessities such as ingestion and digestion. As to colour, owing partly to the small size of the products, combinations which might be original or characteristic are also relatively limited.* [3]

Ciba-Geigy was cited in several other cases involving a product's appearance. The major obstacle in finding that the appearance of a product constitutes a trade-mark is demonstrating that the appearance of the product has attained a secondary meaning within the relevant population. The facts specific to each case are crucial factors to the outcome of any given dispute. Among the more recent cases, *Eli Lilly & Co*. v. *Novopharm Ltd*. [4] illustrates the hesitation of the Courts in recognizing that the appearance of a product has attained such a degree of reputation.

In that case, the dispute was over Prozac, a medication that contains the drug fluoxetine. The capsule manufactured by Eli Lilly was half green, half cream. The generic version manufactured by Novopharm was half green, half light green. Both capsules were cylindrical, rounded at both ends and of a size standard to the industry. The Court held that the use of two colours did not succeed in distinguishing Eli Lilly's capsules from other capsules marketed in the industry. It based its conclusion on the fact that Eli Lilly failed to prove, by way of survey or otherwise, that consumers associated capsules of two colours with a specific manufacturer. The Court explained that patients usually associate the colour of a product with its therapeutic effect rather than with its source.

In *AstraZeneca AB* v. *Novopharm Ltd*.,[5] Astra tried to register the trade-mark "yellow tablet design" for a medication containing felodipine used in the treatment of hypertension. These round, 2.5-mg yellow tablets were available only on prescription. Novopharm opposed the application, alleging the lack of distinctiveness of the proposed trade-mark in that it did not distinguish, and was not adapted to distinguish, the wares of Astra from those of other manufacturers.

On March 9, 2000, the Registrar rejected Astra's registration application. He concluded that Astra's mark was not distinctive, as there were many other yellow tablets on the market used to treat hypertension. The Registrar dismissed Astra's argument to the effect that only tablets for the treatment of hypertension containing felodipine

could be considered. In the appeal from the Registrar's decision, the Federal Court held that the Registrar had not erred and added that the drug owed its distinctiveness to its packaging since that is what was first consulted by pharmacists to determine the tablets' source or origin. In a unanimous decision dated February 4, 2003, the Federal Court of Appeal confirmed the Trial Court's decision. The Court of Appeal held that it was incumbent on the applicant to demonstrate that its tablets were distinctive from those of other manufacturers because of their shape and colour. In this case, the Court decided, Astra had failed to do so.

d) Prescription Drugs: Trade-mark

In *Pierre Fabre Médicament* v. *SmithKline Beecham Corporation*,[6] the issue was whether or not there was any confusion between the trade-mark of Pierre Fabre Médicament, IXEL, and that of SmithKline Beecham Corporation, PAXIL. Both trade-marks were used in association with a prescription drug for the treatment of depression. It was admitted that there was no risk of confusion in French. In this regard, it should be noted that in Canada, it is sufficient if the risk of confusion exists in either official language.

This case is noteworthy because, while it applies *Ciba-Geigy*,[7] it places the emphasis on doctors, pharmacists and the manner in which prescriptions are transmitted. Indeed, the Court identified the patient as a sophisticated consumer since he consults a physician. The Court then took into account the entire prescription process – from the consultation of the doctor to the dispensation of the drug by the pharmacist. The Court concluded that the slight resemblance between the trade-marks, and the fact that the drug was available only on prescription, made the risk of confusion highly unlikely.

e) Over-the-Counter Drugs: Trade Names

In *Alticor Inc*. v. *Nutravite Pharmaceuticals Inc*.,[8] the Federal Court of Canada confirmed a decision of the Registrar of Trade-Marks allowing an application for the registration of the trade-mark NUTRATIVA in association with vitamins, minerals and herbs. Nutravite Pharmaceuticals opposed the registration, alleging that the requested trade-mark would lead to confusion with its own registered trade-mark, NUTRILITE, used in association with similar products. In this case, as opposed to the *Pierre Fabre Médicament* case, the products were sold over-the-counter. The Court noted that the prefix NUTR was widely used in the market in combination with various suffixes and that thus, consumers were used to distinguishing between various trade-marks with this same prefix. The Court consequently decided that the trade-mark NUTRAVITA could be registered.

f) Conclusion

A trade-mark can be an important asset for businesses. Whether it consists of a name or of a distinguishing guise, a trade-mark can help protect a product from competition. Moreover, innovators must try to give a secondary meaning to the appearance of their products. Generic companies who attempt to copy this appearance will then have to show that there is no confusion before attempting to acquire a share of the market.

Marie Lafleur *is a member of Fasken Martineau's* ***Litigation*** *Practice Group and specializes in intellectual property. She regularly appears before the Federal Court of Canada and the provincial courts of the Province of Quebec in matters involving the infringement and the validity of patents, trade-marks, copyrights and industrial designs, as well as in matters concerning trade secrets and unfair competition. She often deals with high technology issues. In the pharmaceutical field, Ms Lafleur has represented companies in numerous proceedings seeking to prohibit the Minister of Health Canada from issuing notices of compliance which would allow the sale of generic versions of patented drugs. She has also been involved in judicial review applications dealing with the addition or the removal of patents from the patent register as well as in actions concerning the infringement and the validity of pharmaceutical patents.*

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1) http://www.canadapharma.org

2) *Ciba Geigy Canada Ltd*. v. *Apotex Inc*., [1992] 3 S.C.R. 120; (1992) 44 C.P.R. (3d) 289

3) *Ciba Geigy Canada Ltd.* v. *Apotex Inc.*, *supra* page 304

4) (1997) 73 C.P.R. (3d) 371, upheld in appeal (2000) 10 C.P.R. (4th) 10, authorization to appeal before the Supreme Court of Canada refused in 2001

5) (2003), 24 C.P.R. (4th) 326 (F.C.A.)

6) (2004) FC 811

7) *Supra* note 4

8) (2003) 27 C.P.R. (4th) 99