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THE CANADIAN REGIME FOR PROTECTING AGAINST PHARMACEUTICAL TRADEMARK CONFUSION AND MISTAKES*

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I. INTRODUCTION

Mahatma Gandhi once said, "It is health that is real wealth and not pieces of gold and silver." Indeed, there are few things in life more important to one's quality of life than good health, and increasingly we have an arsenal of pharmaceutical products available to ensure its continuation. However, just as pharmaceuticals can be one of the keys to fight disease and ensure good health, they can also cause damage and even death if misused. Thus, with the proliferation of life enhancing and life prolonging drugs, it is also increasingly important that everyone involved in the health field, from the diagnosing and drug dispensing professionals to the patient who is actually using the drug, be able to easily and clearly distinguish between pharmaceutical products.

Like other products and services, pharmaceuticals are normally identified by trademarks, such as FLOVENT and NEO CITRAN, and also often slogans, such as, IT TASTES AWFUL. AND IT WORKS. In addition, tablets, capsules, solutions for injection, and creams are just some of the forms in which pharmaceutical products may be distributed. Color, shape and size are some of the characteristics that may help to distinguish between pharmaceuticals along with traditional word trademarks.

The involvement of various levels of health professionals, in addition to the ultimate consumer of pharmaceutical products, the various means by which pharmaceuticals can be identified, and the critical nature of the products, all give rise to a myriad of special considerations when contemplating how best to safeguard patient safety and well-being. This article will address two critical concepts that come into play, namely pharmaceutical product confusion and mistake. The meaning and fundamentals of these

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concepts will be discussed against the backdrop of the Canadian pharmaceutical trade. The article will then canvas and discuss the development of Canadian pharmaceutical trademark jurisprudence, and the role of the Canadian government in minimizing the risk of confusion and mistake in this important field.

II. POLICY CONSIDERATIONS IN PHARMACEUTICAL CASES

The 2007 Report of the World Health Organization on Look-Alike, Sound-Alike Medication Names began with the statement, "The existence of confusing drug names is one of the most common causes of medication error and is of concern worldwide."[1] With an estimated 24,000 therapeutic healthcare products currently on the Canadian market,[2] there are likely numerous drug name similarities. Studies have found that errors in drug use are common, costly and often result in injury to patients.[3]

The policy considerations relating to mistake of pharmaceutical products are clear. The elderly and most vulnerable members of society are particularly at risk. The use of the correct product can be life-enhancing and even life-saving for a patient. Conversely, in the event of an error, the use of the incorrect pharmaceutical product can have serious and even deadly consequences. There are few other products for which the consequences of a mistake can be so serious.

It is important that purveyors of healthcare, including pharmacy technicians, nurses, doctors and pharmacists, be able to easily and accurately determine whether they have selected and are dispensing and administering the correct pharmaceutical product. It is equally important that patients be confident in the system and not be subjected to the stress of uncertainty as to whether they are using the correct pharmaceutical product, particularly when they are seriously ill. While these concerns have sometimes been considered in likelihood of confusion cases in Canada, most decision makers agree that Canadian trademark law is not to be used to determine whether the co-existence of two pharmaceutical trademarks is likely to lead to a "mistake."

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1. World Health Organization, *Patient Safety Solutions*, Volume 1, Solution 1 (May 2007).

2. A. David Morrow, Opening Remarks at the Look-Alike, Sound-Alike (LA/SA) Health Product Names: Consultative Workshop (Oct. 20, 2003).

3. Lucian Leape et al., *Systems Analysis of Adverse Drug Events*, 274 (1) JAMA 35 (1995).

Guarding against trademark confusion between pharmaceutical trademarks is also important from a financial perspective. Pharmaceutical companies spend large amounts of money and expend significant efforts in marketing a particular brand, and therefore it is important that all of the traditional trademark protections be available to pharmaceutical manufacturers.

III. TYPES OF PHARMACEUTICAL PRODUCTS AND THE NATURE OF THE PHARMACEUTICAL TRADE IN CANADA

Given the specialized nature of the pharmaceutical trade in Canada, it is important at the outset to become familiar with the types of pharmaceutical products that are sold in Canada, their associated sale procedures, and the individuals who are involved in the marketing and sale of pharmaceutical products in Canada.

A. Types of Canadian Pharmaceutical Products

In the human pharmaceutical field, three main types of pharmaceutical products exist: prescription products, behind-the-counter products, and over-the-counter products. A brief discussion of each follows.

Prescription products require a licensed professional's prescription, and they are dispensed by a pharmacist. Typically doctors, psychiatrists, and dentists prescribe a medication, although in Canada nurse practitioners (registered nurses with advanced education) also have authority to write prescriptions for common illnesses and injuries.[4] In addition, as of April 2007, pharmacists in one province in Canada who have completed a requisite training program are authorized to write refill prescriptions for selected medications.[5]

Behind-the-counter products are products that are dispensed by a pharmacist (hence "behind" the counter) but are available without a prescription. Examples of behind-the-counter products include iron supplements and specialized multi-vitamins. Typically, products are designated as behind-the-counter because they include risks not associated with products available on the shelves of stores, and they therefore require a pharmacist's intervention.

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4. CBC News, *1st Nurse Practitioner-governed Clinic Opens in Sudbury*, (Aug. 31, 2007), http://www.cbc.ca.

5. CBC News, *Alberta Pharmacists Get a New Prescription*, (March 30, 2007), http://www.cbc.ca. (The authorization to prescribe is limited to prescribing refills).

Finally, an over-the-counter product, also referred to as an "OTC" product, is simply a product that is sold without a prescription and includes products such as TYLENOL pain reliever as well as cold and flu remedies. These products are typically sold in pharmacies but can also be sold in other stores, including supermarkets.

The classification of a product as either over-the-counter, behind-the-counter, or prescription, as discussed in greater detail below, can be an important factor in determining the likelihood of confusion or mistake.

B. Routes of Patient Administration of Pharmaceutical Products

The route of administration of a pharmaceutical product is also sometimes considered in the likelihood of confusion or mistake context. There are, in fact, many ways to administer pharmaceutical products to patients, including orally, by inhalation (an inhalant for asthma), or by injection (insulin). Many injectable pharmaceutical products are administered to a patient by a nurse in a hospital or similar setting.

C. Marketing of Pharmaceutical Products in Canada

The marketing of pharmaceutical products in Canada is monitored by Health Canada.[6] Unlike the United States, for example, direct-to-consumer advertising (DTCA) in Canada is prohibited under the *Food and Drugs Act* and the *Food and Drug Regulations* that were promulgated thereunder.[7] The *Food and Drug Regulations* include a broad prohibition on the advertising of prescription-only drugs to the public, although the name, price and quantity of the pharmaceutical product can be advertised.[8] In addition, the *Food and Drugs Act* also sets out a list of diseases for which preventatives, treatments or cures may not be advertised to the public.[9] The latter restriction applies not only to prescription

6. Health Canada is a department of the government of Canada and is responsible for national public health. Health Canada comprises of several functional and administrative branches operating in such areas as consumer safety, health care cost management and drug approval. In addition, Health Canada is the federal regulator of drug advertisements. Health Canada, About Health Canada, http://www.hc-sc.gc.ca/ahc-asc/index_e.html (last visited April 22, 2008); Health Canada, Regulatory Requirements for Advertisements, http://www.hc-sc.gc.ca/dhp-mps/legislation/advert-publicit_e.html (last visited April 22, 2008).

7. *Food and Drugs Act*, R.S.C. 1985, c. F-27, *Food and Drug Regulations*, C.R.C., c. 870.

8. *Food and Drug Regulations*, s. C.01.044.

9. *Food and Drugs Act*, s. 3.

drugs but also to any pharmaceutical that references the prohibited preventatives,[10] treatment or cures.

Despite the prohibition against marketing pharmaceuticals directly to consumers, limited advertising to the ultimate consumer is permissible in Canada in the following two forms:

1. *Reminder ads*: advertisements that include only the pharmaceutical's brand name and no health claims or hints about the product's use; and
2. *Disease-oriented or help-seeking ads*: these advertisements do not mention a specific pharmaceutical brand but rather discuss a condition and ask consumers to talk to their doctors about treatment.[11]

In addition, given Canada's proximity to the United States, Canadians are often exposed to spillover DTCA through United States television and magazine advertising.

It has been said that the ban on DTCA of some pharmaceutical products originated from a concern that DTCA may lead to an avoidable harm through its stimulation of unnecessary and inappropriate medicine use, and that DTCA fails to provide patients with a balanced understanding of the range of available treatments.[12] On the other hand, proponents claim that DTCA may save lives by leading the public to recognize symptoms and seek care at an earlier stage.[13]

Pharmaceutical manufacturers are, however, able to advertise pharmaceutical products directly to health professionals because health professionals are considered learned intermediaries. Pharmaceutical manufacturers advertise directly to health professionals, including through mail advertising, journal advertisements, sample hand-outs, and visits from a representative of the pharmaceutical company. Healthcare professionals also become aware of pharmaceuticals through journal articles and peers. The advertising of material for all healthcare products directed to healthcare professionals is reviewed and pre-cleared by an independent agency recognized by

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10. As of June 1, 2008, however, natural health products, nonprescription drugs (apart from drugs regulated as Class A precursors under the Precursor Control Regulations), and prescription drugs that are veterinary drugs listed in Part II to Schedule F (so long as the drug is in a form not suitable for human use or is labelled for veterinary use only) are exempt from the prohibition on preventative claims for the diseases listed in Schedule A to the *Food and Drug Regulations*. *See Regulations Amending Certain Regulations Made under the Food and Drugs Act (Project 1539)*, S.O.R./2007-288.

11. Barbara Mintzes, *Health Council of Canada, What are the Public Health Implications?* Direct-to consumer Advertising of Prescription Drugs in Canada, 1 (2006).

12. *Id.* at 6.

13. *Id.*

Health Canada that is called the Pharmaceutical Advertising Advisory Board, although pre-clearance is technically not mandatory.[14]

The prohibition against advertising some pharmaceutical products directly to patients was one of the reasons patients were historically (until a landmark Supreme Court of Canada decision[15]) not considered "customers" for the purpose of considering confusion under the Canadian *Trade-marks Act*.[16]

D. The Pharmaceutical Prescription

An important consideration in understanding the trade of prescription pharmaceutical products is the manner in which a prescription is provided. A doctor typically writes a prescription for the product of choice and provides the prescription to a patient to be brought to a pharmacist. Although less common, the doctor may alternatively provide a verbal prescription over the phone directly to a pharmacist. Whether written or verbal, a prescription normally contains the following:

1. the name of the patient;
2. either the brand name or the generic name of the pharmaceutical (the common name by which the medicinal ingredient is known, more formally referred to as the International Nonproprietary Name (INN));
3 the dose;
4. the frequency;
5. how many tablets (or other dosage form) to dispense;
6. the name of the doctor prescribing the medication; and
7. the route of administration.

Of particular importance in the likelihood of confusion context is the ability to prescribe a pharmaceutical product according to either the brand name or a generic name, given that similarities between trademarks both visually and phonetically is a critical factor in establishing confusion. For any given prescription pharmaceutical product already in use, doctors typically have a preference to prescribe by either a brand or by a generic name,

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14. Health Canada, Regulatory Requirements for Advertising, http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/index_e.html (last visited April 21, 2008); Health Canada, Overview of Health Product Advertising, http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/fs-fi/advert-publi_fs-fi_e.html (last visited April 21, 2008).

15. Ciba-Geigy Canada Ltd. v. Apotex Inc., [1992] 3 S.C.R. 120.

16. R.S.C. 1985, c. T-13.

which may also have an impact on the distinctiveness of the trademark.

E. The Role of the Pharmacist

The profession of pharmacy in Canada is regulated at the provincial level. In Ontario, for example, the regulating body is the Ontario College of Pharmacists. Various acts, by-laws, regulations and standards of practice apply to practicing pharmacists in Canada, and strictly govern the conduct of pharmacists.

As indicated above, pharmacists often become aware of pharmaceutical products through journal articles, advertising, and peers. In addition, and most importantly, pharmaceutical manufacturers sell products directly to pharmacies (or to wholesalers who sell to pharmacies). In Canada, two general types of pharmacies exist: the community pharmacy and the hospital pharmacy.

In a community pharmacy, the pharmacist typically receives a copy of a written prescription from a patient who has been to a doctor, or receives a phone call from a doctor with a verbal prescription. The pharmacist in some cases may call a doctor's office for clarification. The information is then typically entered into a computer where a label is generated. The pharmaceutical product is then dispensed from the shelf of the pharmacy. Some pharmaceutical products exist in a form that is ready to be provided to patients while other products are in bulk and require a pharmacy technician to count or measure out the specified amount of product and place the product into a vial or other container. For new prescriptions, pharmacists in Canada are required to take reasonable steps to counsel patients regarding the pharmaceutical product's properties, including side effects and therapeutic use.[17]

Hospital pharmacies are located on the hospital grounds, and are of two types: inpatient pharmacies and outpatient pharmacies. The dispensing procedure in an outpatient hospital pharmacy is almost equivalent to a community pharmacy. The dispensing practice in an inpatient pharmacy differs, however, as the patient neither brings the prescription to the pharmacist nor picks up the dispensed product. Rather, the pharmacist typically receives the prescription directly from the physician (whether in written form

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17. *See*, *e.g.*, Ontario College of Pharmacists, Standards of Practice (2003), Standard 4, Operational Component 4.3:

> The pharmacist takes reasonable steps to enter into dialogue with the patient or agent on all initial prescriptions in a community setting, in established programs in an institutional setting, or when made necessary by professional judgment of the pharmacist, the need of the patient or agent, or upon their request.

or as a result of direct order entry by the physician) and provides the dispensed product to a nurse for administration to the patient.

Whether a pharmaceutical product is dispensed only in an inpatient hospital pharmacy or in both a hospital and a community pharmacy could have potential relevance to the nature of the wares or the trade in cases dealing with likelihood of confusion.

IV. CONFUSION VERSUS MISTAKE

A. Confusion

Under the *Trade-Marks Act*, a trademark is considered to be likely to be confused with another trademark if the use of the two marks in the same area would be likely to lead to the inference that the wares or services associated with the two marks are manufactured, sold, leased, hired or performed by the same person.[18] In other words, the likelihood of confusion relates directly to the source of the wares or services. See, for example, the following quote from the Canadian Federal Court of Appeal:

> To decide whether the use of a trade mark or of a trade name causes confusion with another trade mark or another trade name, the court must ask itself whether, as a matter of first impression on the minds of an ordinary person having a vague recollection of that other mark or name, the use of both marks or names in the same area in the same manner is likely to lead to the inference that the services [or wares] associated with those marks or names are performed by the same person, whether or not the services [or wares] are of the same general class.[19]

In determining whether two marks are confusing, the *Trade-Marks Act* provides that the Registrar or the Court "shall have regard to all the surrounding circumstances," including the following:

1. the inherent distinctiveness of the trade-marks or trade-names and the extent to which they have become known;
2. the length of time the trade-marks or trade-names have been in use;
3. the nature of the wares, services or business;
4. the nature of the trade; and

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18. R.S.C. 1985, c. T-13, s. 6(1).
19. Miss Universe, Inc. v. Bohna (1994), 58 C.P.R. (3d) 381 at 387 (F.C.A.).

5. the degree of resemblance between the trade-marks or trade-names in appearance or sound or in the ideas suggested by them.[20]

This issue will come before the Registrar of Trade-marks during the prosecution of an application for registration, as well as through proceedings brought before the Opposition Board. The issue also arises before the Canadian Courts on appeal from a decision of the Registrar, or by an action for trade-mark infringement. While the *Trade-Marks Act* indicates that the Registrar or Court is supposed to consider all the surrounding circumstances of a case, the jurisprudence has shown that the Opposition Board, which hears these matters and renders decisions on behalf of the Registrar, is more likely to take a technical approach restricting the review and consideration of the issue to the factors enumerated in the list above. Canadian courts, on the other hand, are more likely to factor all of the surrounding circumstances of a case into its decision.[21] Nonetheless, both levels of review have long recognized that the field of pharmaceuticals gives rise to unique considerations.

B. Mistake

Alexander Pope, the famous English poet and satirist, said, "to err is human, to forgive divine."[22] Human error is, indeed, part of the human condition, and will arise in all fields of endeavour to some extent. The Concise Oxford Dictionary of Current English defines the word "mistake" as a "misunderstanding of a thing's meaning" or a "thing incorrectly done or thought through ignorance or inadvertence."[23] A mistake can, therefore, be distinguished from confusion by being a broader concept that is not necessarily related to the source of a pharmaceutical product.

A mistake in the pharmaceutical field can arise in the same almost infinite variety of ways that mistakes are made in any other field. For example, overworked, overtired and/or distracted healthcare professionals can misread labelling on a pharmaceutical product or administer a pharmaceutical product in an incorrect dosage. A doctor may provide a prescription in

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20. *Trade-Marks Act*, R.S.C. 1985, c. T-13, s. 6(5)(a) - (e).

21. *See*, *e.g.*, Interwood Mktg. Ltd. v. K-TEL Int'l Ltd. (1997), 76 C.P.R. (3d) 553 at 559 and Tele-Direct (Publ'ns) Inc. v. Telcor Canada Directories Inc. (1986), 11 C.P.R. (3d) 102 at 106-07 (F.C.T.D.).

22. Alexander Pope, *An Essay on Criticism* (1711).

23. The Concise Oxford Dictionary of Current English 648 (J.B. Sykes, ed., 1982).

illegible handwriting,[24] or a pharmacist may misunderstand instructions that are relayed by telephone. Mistakes can occur at any point during the course of treatment of a patient from the initial diagnosis to the selection of a proper form of treatment, to the administration of the treatment, to the correct dosage, and to the correct timing. Patients may similarly make mistakes at any point during the treatment process when selecting and self-administering pharmaceutical preparations.

Investigations of major accidents, such as Three Mile Island and the Challenger disaster, have shown that an accident is often the end result of a chain of events set in motion by faulty system design that either induces errors or makes them difficult to detect.[25] Preventive efforts that focus solely on individuals or rely upon inspecting the work performed by individuals have been shown to have little impact in a variety of settings. An analysis and correction of underlying system faults has been shown to be more likely to result in enduring changes and significant error reduction.[26] Regarding mistakes as primarily resulting from system failures has been suggested to be a more useful view than the attribution of fault to professionals working in the medical field.[27]

In Canada, there are many rules and systems in place that are designed to reduce mistakes in the process of prescribing and dispensing pharmaceuticals to patients. Healthcare professionals at all levels and in all settings are subject to a variety of procedural rules and protocols that guard against the possibility of mistakes in hospital and clinical settings.[28] Pharmacists are also subject to a variety of rules and procedural requirements when dispensing pharmaceuticals directly to patients.[29]

The balance of this paper discusses two systems through which confusion and mistake are assessed in the pharmaceutical field. The first is the protection of trade-marks under the Canadian

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24. A study from 1996 was designed to determine whether doctors have worse handwriting than other professionals. The authors concluded that the handwriting of doctors was no less legible than that of non-doctors. (Donald Berwick and David Winickoff, *Words, Words, Words, The Truth About Doctors' Handwriting: a Prospective Study*, 313 BMJ 1657 (1996)).

25. James Reason, Human Error 180-91 (1990); Donald Norman, The Psychology of Everyday Things (1988); Lucian L. Leape, *Error in Medicine*, 272 (23) JAMA 1851, (1994).

26. Leape, *supra* note 25 at 43.

27. Leape et al., *Systems Analysis of Adverse Drug Events*, 274 (1) JAMA 35-43 (1995).

28. For example, Regulations made under the *Medicine Act*, 1991, such as Ontario Regulations 856/93 and 241/94 as amended. Also see the College of Physicians & Surgeons of Ontario: Drugs and Prescribing – Preventing Medication Errors (Policy #1-02), http://www.cpso.on.ca/Policies/drug_error.htm.

29. *See*, *e.g.*, Regulations made under the *Pharmacy Act*, S.N.S. 2001, C. 36.

Trade-marks Act, and the enforcement of that legislation through the Trade-marks Opposition Board and the courts, and the second is the "Look Alike/Sound Alike" review that is undertaken by Health Canada.

V. ASSESSMENT OF THE LIKELIHOOD OF CONFUSION BY THE CANADIAN TRADE-MARKS OPPOSITION BOARD AND COURTS

A. Pharmaceutical Word Trademarks

Because word marks are generally protected in Canada without the requirement to prove acquired distinctiveness or secondary meaning, the analysis of whether a mark is likely to cause confusion has long been relatively straightforward. However, it is clear that unique considerations apply to pharmaceutical word marks, and the application of these considerations to the test for the likelihood of confusion has not been consistent.

One of the earliest known Canadian cases in which the issue of confusion among pharmaceutical word marks arose was *Battle Pharmaceuticals v. British Drug Houses*,[30] in which the Supreme Court of Canada considered an appeal from a decision of the Exchequer Court[31] relating to confusion of the trademarks MULTIVITE and MULTIVIMS. In dismissing the appeal, the Court considered an argument advanced by the appellant that the marks were not confusing because the products were both intended for medicinal purposes and users would be more careful than usual when making their purchases. Mr. Justice Kerwin, for the Court, indicated that the sounds of the two trademarks were similar, and because the products were vitamins and not sold by prescription,

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30. Battle Pharms. v. British Drug Houses, [1946] S.C.R. 50.

31. The Exchequer Court was the predecessor court of Canada's Federal Court and Federal Court of Appeal. The Exchequer Court was created in 1875, pursuant to the *Supreme and Exchequer Court Act* (R.S.C. 1900, c. 154). Initially, the Exchequer Court's jurisdiction was limited to revenue cases against the federal government. However, over its 95 years of existence, the jurisdiction of the Exchequer grew to include other types of litigation against the federal government as well as admiralty, tax, citizenship and some criminal matters. In addition, the Exchequer Court handled intellectual property cases, including patent and trademark matters. Decisions from the Exchequer Court were subject to appeal to the Supreme Court. In 1971, pursuant to the *Federal Court Act* (R.S.C. 1970, c. 10 (2d Supp.)), the jurisdiction of the Exchequer Court was inherited by its predecessor the Federal Court of Canada (appeal and trial divisions). This was, in turn, succeeded in 2003 by the Federal Court and Federal Court of Appeal (*Courts Administration Service Act*, S.C. 2002, c. 8). [Ian Bushnell, The Federal Court of Canada, A History, 1875-1992, 18, 27 (1997); Federal Court of Appeal (Canada), History, http://www.fca-caf.gc.ca/about/history/history_e.shtml (last visited April 22, 2008)].

users of the products were likely to be confused.[32] The implication, although not expressly stated, is that the decision on this particular point might have been different if the products were prescription pharmaceuticals.

The second seminal Canadian case on the topic of confusion between pharmaceutical word marks was *G.D. Searle & Co. v. Mead Johnson.*[33] The Court in Mead Johnson embarked on an extended discussion of the special significance of pharmaceutical trademarks and quoted extensively, and with approval, from a decision of the Third Circuit of the United States Court of Appeals.[34] This case, oft quoted thereafter,[35] held that it was important in the field of medicinal products to take great care to prevent any possibility of confusion. Specifically, the Court noted, "In the field of medical products, it is particularly important that great care be taken to prevent any possibility of confusion in the use of trade-marks. . . . Confusion in such products can have serious consequences for the patient. Confusion in medicines must be avoided."[36]

Since the *Battle* and *Mead Johnson* decisions, the issue of giving special consideration to pharmaceuticals has commonly arisen in the Canadian jurisprudence, although the specific nature of consideration that is warranted is not always clear. In addition, the relevant factors and even the implications of the factors have varied. Several examples of the factors are detailed below.

1. The Similarity in the Particular Disease or Disorder That Is Treated by the Pharmaceutical

In *Mead Johnson*, the Court introduced the concept of "great care" in analyzing trademark confusion in the pharmaceutical field. Following *Mead Johnson*, a number of decisions have held that where the pharmaceutical preparations in question are for the treatment of different diseases or disorders, confusion between the trademarks can have more serious consequences and therefore *more* caution is required in determining confusion. It is clear however that the "caution" required does not alter the test for

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32. Battle Pharms. v. British Drug Houses, [1946] S.C.R. 50 at 75.

33. (1967), 53 C.P.R. 1 (Exchq. Ct.).

34. *Id*. at 9 (quoting Morgenstern Chem. Co., Inc. v. G.D. Searle Co., 253 F.2d 390, 393 (3rd Cir. 1958).

35. *See*, *e.g.*, Schering Canada v. Thompson Med. Co. Inc. (1983), 81 C.P.R. (2d) 270 (Hearing Officer, Trade Marks; Lovens Kemiske Fabrik Produktionsaktieselskab v. Teijin Kabushiki Kaisha/Teijin Ltd. (1987), 17 C.P.R. (3d) 144 (T.M.O.B.); Nordic Labs. Inc. v. Novo-Nordisk A/S (1993), 50 C.P.R. (3d) 572 (T.M.O.B.)).

36. *Morgenstern Chem. Co.*, 253 F.2d 390 at 393 (quoting Cole Chem. Co. v. Cole Labs., 118 F. Supp. 612, 616 (1954)).

confusion under the *Trade-marks Act*, but rather suggests that the decision maker must be more careful in analyzing confusion. In addition, it is at least questionable as to whether the decision maker in these cases was in fact concerned with mistake, and not confusion.

This extra caution was referred to in *Schering Canada Inc. v. Thomson Medical Co., Inc.*,[37] where D.J. Martin, on behalf of the Opposition Board, considered the trademarks PROLAMINE for weight reduction or control, and POLARAMINE for an anti-histamine preparation. Mr. Martin recognized the significant difference between the products and stated that "the public interest is of even more importance in the present case in view of the fact that the products in question are pharmaceutical preparations having different compositions, one essentially being a depressant and the other being essentially a stimulant."[38]

Similarly, in a number of cases where the two drugs in question are for the treatment of the same, or very similar, diseases or disorders, the finding has been that less caution is required in conducting a confusion analysis.

For example, in an opposition case relating to the likelihood of confusion between the trademarks RETIVAN, RETIFAC and RETIN-A, for acne preparations, while the Opposition Board acknowledged previous jurisprudence indicating that particular care should be exercised in determining confusion in the pharmaceutical field, the Board also stated that "caution is probably of less significance where, as here, the descriptions of the wares are essentially the same."[39]

In *Syntex (U.S.A) Inc. v. E.R. Squibb & Sons, Inc.*,[40] D. Savard on behalf of the Opposition Board, again acknowledged the importance of the application of a high standard of care in the pharmaceutical field, and indicated that "in cases where the products are identical, as in the present case, such a standard might not apply as there would not be any health hazard to the patient."[41] D. Savard went on to consider the likelihood of confusion between the marks TOPRIN and TOPSYN, both for topical corticosteroid pharmaceutical preparations, and found a likelihood of confusion based on the application of the standard test without special consideration of the nature of the products.

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37. (1983), 81 C.P.R. (2d) 270 (Hearing Officer, Trade Marks).

38. *Id.* at 275.

39. Johnson & Johnson v. William R. Rorer (Canada) Ltd. (1978), 44 C.P.R. (2d) 90 at 97 (Hearing Officer, Trade Marks), *rev'd on other grounds* (1980), 48 C.P.R. (2d) 58.

40. (1991), 39 C.P.R. (3d) (T.M.O.B.).

41. *Id.* at 566.

Another case, *Endo Laboratories Inc. v. Dow Chemicals Co.*,[42] considered confusion between pharmaceutical preparations that were both for the relief of pain, and both, at least arguably, could be used in the field of dentistry. DILONE was an analgesic preparation and DYCLONE was for a topical anaesthetic. There was, however, considerable difference in the exact nature of the product—DILONE being for home use taken in the form of a tablet and DYCLONE, an anaesthetic, for injection by a healthcare professional. The Court stated, "[A]ny confusion between these entirely different forms of medication, if at all possible, would, in any event, not be dangerous but merely inconvenient."[43] After considering submissions that one must be particularly careful in the pharmaceutical field and that the overriding consideration must always be the protection of the public, Mr. Justice Noel stated, "I can, however, see no possible danger in allowing both of these marks to be registered."[44]

The interesting result of this case law is that pharmaceutical trademarks for similar products will apparently be subject to a reduced level of scrutiny by the Courts and the Opposition Board. Although this principle appears to be in contrast with the established principle that similarity in products tends toward a finding that the marks are likely to be confused, as suggested above, the scrutiny likely only relates to the degree of care in conducting the analysis of confusion and not the actual test for confusion itself.

Another line of cases relates to the assessment of the similarity in the uses of the drug, as part of the confusion test relating to the "nature of the wares." The issue in these cases is whether distinctions in the specific uses of the pharmaceutical products are a relevant consideration in determining the likelihood of confusion.

A number of decision makers have held that specific distinctions in the uses of pharmaceuticals are not important, but rather whether the pharmaceutical is for "human use" is the critical factor. For example, in *Servier Canada Inc. v. American Home Products*,[45] Mr. Partington, on behalf of the Opposition Board, considered confusion among products that were intended to treat different disorders. While not going so far as to say that the distinction made the possibility of confusion to be of even greater concern, the Opposition Board did indicate that the difference

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42. (1972), 8 C.P.R. (2d) 149 (F.C.T.D.).

43. *Id.* at 154.

44. *Id.*

45. (1997), 79 C.P.R. (3d) 539 (T.M.O.B.).

between the products was of limited assistance to the applicant in making an argument that the marks were unlikely to cause confusion. Mr. Partington indicated that the fact that the pharmaceutical preparations were both intended for the medical treatment of humans was of more importance than the specific differences between the particular preparations.

It was similarly held in *Mead Johnson* that the test as to whether there is "confusing similarity" with pharmaceutical trademarks "does not hinge on whether or not the medicines are designed for similar ailments."[46] The same view was expressed by the Opposition Board in *Lederle Piperacillin Inc. v. Zeneca Ltd.*[47] H.O. Vandenakker for the Opposition Board stated, "In my view, the fact that the parties' products are used for different purposes does not assist the applicant when I am determining the issue of confusion between the parties' mark. . . . The crucial factor is that both parties' wares are comprised of pharmaceutical preparations for human use."[48]

The *Servier* and *Lederle* cases should be contrasted with a line of cases holding that despite the fact that both parties' products are related to pharmaceutical preparations for human use, differences in the specific uses of the products makes confusion unlikely.[49] For example, in *Novartis AG v. Arachnova Ltd.*,[50] the Opposition Board was required to determine whether the applicant's mark ARADERM, for use in association with pharmaceutical and veterinary preparations for the treatment of dermatitis and related dermatoses, was confusing with the opponent's mark ESTRADERM, registered for use in association with estradiol administered by means of a patch or bandage attached to the skin of humans. The Opposition Board ultimately held that the marks were not confusing, in part because a hormonal preparation in the form of a patch was "quite different from the ARADERM product. . . ."[51]

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46. Mead Johnson & Co. v. G.D. Searle & Co (1967), 53 C.P.R. 1 at 9 (Exchq. Ct.) (quoting Morgenstern Chem. Co., Inc. v. G.D. Searle Co., 253 F.2d 390, 393 (3d Cir. 1958)).

47. (1996), 74 C.P.R. (3d) 532 (T.M.O.B.).

48. *Id.* at 537-38. *See also* American Home Prods. Corp. v. Abbott Labs. (1997) 77 C.P.R. (3d) 72 at 79 (T.M.O.B.).

49. Endo Labs. Inc. v. Dow Chem. Co. (1972) 8 C.P.R. (2d) 149 (F.C.T.D.); American Home Prods. Corp. and Wyeth Ltd. v. William H. Rorer (Canada) Ltd. (1978), 42 C.P.R. (2d) 225 (Hearing Officer, Trade Marks); Novartis AG v. Arachnova Ltd., 2007 CarswellNat 4018.

50. 2007 CarswellNat 4018.

51. *Id.* at paras. 18, 27.

2. Whether the Pharmaceutical Preparations in Issue Are Made Available to the Ultimate Consumer by "Over the Counter" Sale or by Doctor's Prescription

As described above, in the *Battle Pharmaceuticals* case,[52] the products in question were available without the requirement of a doctor's prescription, and the Supreme Court found that confusion was likely to occur. The implication seemed to be that if the products in question were prescription pharmaceuticals, confusion was unlikely, or less likely, to occur.

The likelihood of confusion between NOVETETRA and NOVOPHARM, both for use in association with prescription pharmaceuticals, was at issue in *Novopharm Ltd. v. Nu-Pharm Inc.*[53] Mr. Justice Pinard stated, as follows:

> Indeed, likelihood of confusion, in the prescriptive drug field, is not easy to establish. The nature of the trade is such that great skill and care is exercised in prescribing and dispensing the drug products. Here, the parties produce prescription drugs and supply pharmacies across the country. Pharmacists are careful professionals who are accustomed to making fine distinction in names. They can distinguish similarly named chemicals from one another, so I would expect them to be able to distinguish two trade names or two trade-marks. . . .[54]

This principle was subsequently adopted[55] and suggests that a finding of confusion is more difficult to establish if the products require the intervention of a healthcare professional. This reasoning is similar to the principle that customers of large and expensive items are likely to be more careful when making purchases, and therefore the likelihood of confusion is decreased.[56] In fact, the normal standard of a purchaser in a hurry has been held, at least in one case, not to apply when the purchaser is a doctor or pharmacist.[57]

Despite the views expressed by Mr. Justice Pinard, above, other adjudicators have not always taken the same view. In 1992, Mr. Herzig, on behalf of the Trade-marks Opposition Board in the

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52. Battle Pharms. v. British Drug Houses, [1946] S.C.R. 50.

53. Novopharm Ltd. v. Nu-Pharm Inc. (1990), 31 C.P.R. (3d) 99 (F.C.T.D.).

54. *Id.* at 101.

55. *See*, *e.g.*, Bristol-Myers Squibb Co. v. Int'l Wex Techs. Inc. (2007), 62 C.P.R. (4th) 380 (T.M.O.B.).

56. Gen. Motors Corp. v. Bellows, [1949] S.C.R. 678 at 692.

57. Ratiopharm Inc. v. Labs. Riva Inc. (2006), 51 C.P.R. (4th) 415 at 430, 431 (F.C.).

case of *Norwich Eaton Pharmaceutical, Inc. v. Cetus Corporation,*[58] held that whether the pharmaceutical preparations were prescription or non-prescription was immaterial. Mr. Herzig specifically stated, as follows:

> [N]othing turns on whether the wares are prescription or non-prescription items. The crucial factor is that both parties' wares are pharmaceutical preparations for human use. . . .[59]

Although prescription pharmaceutical products require the intervention of healthcare professionals, the landmark 1992 decision of the Supreme Court of Canada in *Ciba-Geigy Canada Ltd. v. Apotex Inc.*[60] found that in a passing-off action relating to the appearance of pharmaceuticals, the likelihood of confusion by the final consumer of pharmaceutical products, namely the patients, must also be taken into account. It is arguable, however, that consideration of patient confusion is limited to circumstances where the underlying products have the identical medicinal ingredients and are interchangeable because it is only in those cases at the level of the pharmacy that patients have a choice among different products.

However, despite what extra skill and care might be attributed to the physicians, dentists and/or pharmacists involved in the distribution of the products, the risk of confusion among patients remains a consideration. This principle has been incorporated into the cases that follow.

For example, in the *Servier Canada* case, Mr. Partington, on behalf of the Opposition Board, stated, as follows:

> It would appear that the opponent's anti-hypertensive diuretic preparation is sold under prescription and that the applicant's anti-inflammatory preparation will likely be sold under prescription. As a result, medical doctors and pharmacists will be involved in the prescribing and dispensing of the wares of the parties. However, in addition to doctors and pharmacists, patients must also be considered as part of the relevant public in assessing the issue of confusion where medication is dispensed under prescription. . . .[61]

Despite the Supreme Court of Canada's finding, the fact that a drug is sold under prescription remains a factor that may be used to argue that confusion, even on behalf of the patient, is unlikely.

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58. (1992), 45 C.P.R. (3d) 444 (T.M.O.B.).

59. *Id.* at 448.

60. [1992] 3 S.C.R. 120.

61. Servier Canada Inc. v. Am. Home Prods. Corp. (1997), 79 C.P.R. (3d) 539 at 546 (T.M.O.B.); *see also* Roberts Labs. Inc. v. Centrapharm Ltd./Cantrapharm Ltée (1997), 82 C.P.R. (3d) 409 (T.M.O.B.).

For example, in the 2004 decision of *Pierre Fabre Médicament v. SmithKline Beecham Corp.*,[62] the Court held that the likelihood of confusion in the prescriptive drug field is not easy to establish given that the nature of the trade is such that great skill and care is exercised in prescribing and dispensing the drug products. The Court also indicated that pharmacists are careful professionals who are accustomed to making fine distinctions in names and chemicals, by saying, "The patient for his part, will have the benefit of advice given freely by the pharmacist. The risk of confusion will then be less likely than in the cases of impulse buying."[63]

One can therefore conclude that while patients are likely part of the relevant group who must be considered when assessing the likelihood of confusion, the Canadian adjudicators may nonetheless find a reduced likelihood of confusion when the case involves a pharmaceutical supplied to the patient by way of prescription.

3. Whether the Products Are Self-Administered or Administered by Healthcare Professionals

In a 1989 case,[64] the Opposition Board considered whether MONOCID for cephalosporin preparations was likely to be confused with MINOCIN for antibiotic preparations. Both products were for administration to patients in hospitals rather than for out-patient self medication. Mr. Partington, on behalf of the Opposition Board, indicated that "it is apparent that considerable care is taken in the administration of medication to patients within hospitals and would, as a consequence, tend to minimize the likelihood of confusion between the trade-marks of the parties."[65]

Similarly, in *Neorx Corp. v. Cytogen Corp.*,[66] the Opposition Board distinguished the case before it from the case in *Ciba-Geigy*[67] on the basis that the "end user" of the products was not the general public, but highly trained, skilled persons, such as pharmacists, physicians, radiologists and technicians working in the specialized field of nuclear medicine. He stated, "In other words, the reference clientele for determining the issue of

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62. Pierre Fabre Médicament v. SmithKline Beecham Corp. (2004), 35 C.P.R. (4th) 23 at 29.

63. *Id.* at para. 16.

64. Cyanamid Canada Inc. v. Smith Kline & French Canada Ltd. (1989), 23 C.P.R. (3d) 189 (T.M.O.B.).

65. *Id.* at 196.

66. Neorx Corp. v. Cytogen Corp. (1995), 61 C.P.R. (3d) 559 (T.M.O.B.).

67. Ciba-Geigy Canada Ltd. v. Apotex Inc. [1992] 3 S.C.R. 120.

confusion does not include the patient since the patient does not purchase or self-administer the subject wares."[68]

B. Color, Shape and Size Trademarks

The appearance of a pharmaceutical capsule or tablet is an important means by which pharmaceutical manufacturers have sought to distinguish their products from those of others. Capsules and tablets vary primarily in terms of their color, shape and size. The registrability of the get-up of pharmaceutical preparations and the manner in which issues of confusion have been handled by the Canadian courts has recently and comprehensively been examined by Janet M. Fuhrer in her article, *Trade-mark Protection in Canada for the Appearance of Pharmaceutical Products: Get-up and Go*.[69] Ms. Fuhrer has discussed the availability of registration for marks, such as three-dimensional trademarks and distinguishing guises, and she has summarized recent cases and trends in the field. To date, cases regarding the color, shape and size for pharmaceutical preparations have centered largely upon the issue of whether the trade dress was sufficiently distinctive in order to be entitled to protection. In most cases, the Canadian courts have not been prepared to conclude that the get-up of pharmaceutical preparations is distinctive, in large part because of their finding that while the consumers may recognize a product by those indicia, they do not normally indicate the source of the product to the patient, but rather the therapeutic effect.[70]

As a consequence, Canadian decisions regarding the get-up of pharmaceutical preparations have most often resulted in the conclusion that there is no protection available in the circumstances, and there has been little discussion of the likelihood of confusion with other products.[71]

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68. *Neorx Corp.*, C.P.R. (3d) at 564-65.

69. Janet M. Fuhrer, *Trade-mark Protection in Canada for the Appearance of Pharmaceutical Products: Get-up and Go*, 23(1) Canadian Intellectual Property Review 77 (2006).

70. Eli Lilly & Co. et al. v. Novopharm et al. (1997), 73 C.P.R. (3d) 371 at 421 (F.C.T.D.), *aff'd* (2000), 10 C.P.R. (4th) 10 (F.C.A.).

71. *See*, *e.g.*, Hoffman-LaRoche Ltd. v. Apotex Inc. (1983), 72 C.P.R. (2d) 183 (Ont. H.C.J.); Novopharm Ltd. v. Searle Canada Inc. (1995), 60 C.P.R. (3d) 400 (T.M.O.B.); Novopharm Ltd. v. Burroughs Wellcome Inc., 1999 CarswellNat 3398 (T.M.O.B.); Novopharm Ltd. v. Astra AB (2003), 28 C.P.R. (4th) 129 (F.C.); Apotex Inc. v. Searle (2000), 6 C.P.R. (4th) 26 (F.C.); Novopharm Ltd. v. Astra Aktiebolag (2000), 6 C.P.R. (4th) 101 (T.M.O.B.), *aff'd* (2001) 15 C.P.R. (4th) 476 (F.C.), *aff'd* (2003), 24 C.P.R. (4th) 326 (F.C.A.); Novopharm Ltd. v. Pfizer Canada Inc. (2001), 18 C.P.R. (4th) 395 (T.M.O.B); Novopharm Ltd. v. Astra Aktiebolag (2004), 36 C.P.R. (4th) 158 (T.M.O.B.); Novopharm Ltd. v. Astra Aktiebolag 2004 WL 243636 (T.M.O.B.); Novopharm Ltd. v. Purdue Pharma, 2005 WL 2090609 (T.M.O.B.); Canadian Generic Pharm. Assn. v. Sanofi-Synthelabo Inc. (2006), 60 C.P.R. (4th) 74 (T.M.O.B.).

C. The Evolution from Mistakes to Confusion

As described earlier, mistake and trademark confusion are technically two separate, although overlapping, concepts. However, at least in the past, Canadian cases have sometimes held that confusion exists when a "mistake" is made. The first pharmaceutical confusion case to discuss mistake was the *Mead Johnson* case.[72] In *Mead Johnson*, the Court accepted the following statement from a U.S. case:

> [P]hysicians are not immune from confusion or mistake. Furthermore, it is common knowledge that many prescriptions are telephoned to the pharmacist and others are handwritten, and frequently the handwriting is not unmistakably legible. Those facts enhance the chances of confusion or mistake by the pharmacist in filling the prescription. . . .[73]

As a result of the finding in the *Mead Johnson* case, uncertainty surrounding the test for confusion among pharmaceutical products existed. In particular, it was not clear whether it was only necessary to demonstrate that a handwriting mistake or dispensing mistake could occur in order to obtain a finding of confusion.

Subsequent to *Mead Johnson*, Canadian adjudicators gradually recognized the inappropriate blurring of the concepts of mistake and confusion and clarified the distinction. For example, in *Servier Canada Inc. v. American Home Products Corp.*,[74] the Opposition Board considered the likelihood of confusion between the marks LODINE & Design for pharmaceutical preparations and LOZIDE for a diuretic anti-hypertensive drug. The opponent argued pharmacists could make errors given the similarity of the names and also relied on evidence to support the argument that elderly patients might mistake the medications associated with the trademarks at issue. However, the Opposition Board held, as follows:

> [T]he possibility of errors in the prescribing and dispensing of pharmaceutical products is not directly related to the likelihood of confusion as to the source of the products, which is the issue for determination under Section 6 of the *Trademarks Act*.[75]

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72. Mead Johnson & Co. v. G.D. Searle & Co (1967), 53 C.P.R. 1 (Exchq. Ct.).

73. Morgenstern Chem. Co., Inc. v. G.D. Searle Co., 253 F.2d 390, 393 (3d Cir. 1958) (quoting R.J. Strasenburgh Co. v. Kenwood Labs., Inc., 106 U.S.P.Q. 379, 380 (1955) (Patent Office, Assistant Commissioner)).

74. (1997), 79 C.P.R. (3d) 539 (T.M.O.B.).

75. *Id.* at 547.

Other cases have recognized that although special care must be taken with cases in the pharmaceutical field, "there is only one statutory standard fixed by subsection (2) of Section 6 of the Trade Marks Act and the essential question to be determined is expressly related to the source of the product."[76]

Although the difference between confusion and mistake appears to be well understood by most decision makers, the concepts are sometimes confused even today.[77]

VI. THE ROLE OF HEALTH CANADA—LOOK ALIKE/SOUND ALIKE POLICY

Health Canada began formally reviewing look-alike, sound-alike health product names on January 1, 2006. Such review was initiated as a result of a number of factors, including pressure from stakeholders, such as the Canadian Medical Association and the Canadian Pharmacists Association. In addition, a study from 1999 indicated that in the United States one in every four medication errors reported to the Medication Error Reporting Program was a name confusion error.[78] An earlier study in the Journal of American Medicine also suggested that a significant cause of identity errors was look-alike packaging and sound-alike names for drugs.[79]

As discussed above, more recent Canadian cases have held that mistakes in prescribing and dispensing pharmaceutical products are not directly related to likelihood of confusion as to source, and therefore such mistakes should not be considered when determining confusion under the *Trade-marks Act*. It is not clear whether judicial reluctance to consider mistake as an element of

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76. Johnson & Johnson v. William R. Rorer (Canada) Ltd. (1978), 44 C.P.R. (2d) 90 at 97 (Hearing Officer, Trade Marks).

77. *See* Bristol-Myers Squibb Co. v. Int'l Wex Techs. Inc. (2007), 62 C.P.R. (4th) 380 at para. 26 (T.M.O.B.) where the Board held:

> Given the many steps taken by pharmacists in dispensing drugs, it would seem unlikely that they would confuse one medication for another even where the names are similar. On the other hand, doctors or nurses may be presented with patients requiring both types of medications and may therefore be more susceptible to mistake.

See also Ratiopharm Inc. v. Labs. Riva Inc. (2006), 51 C.P.R. (4th) 415 at 432 (F.C.): "[E]ven taking into account a noisy background, there is little likelihood of confusion between the distinctive consonants 'C' and 'D.' "

78. Bruce L. Lambert et al., *Similarity As a Risk Factor in Drug-Name Confusion Errors*, 37(12) Medical Care 1214, 1214 (1999).

79. Leape, *supra* note 3, at 38. (Both the Bruce L. Lambert and Lucian Leape, JAMA articles were cited in Health Canada's document entitled, *Look-alike Sound-alike (LA/SA) Health Product Names*, August 14, 2003, http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/lasa-pspcs_factsheet-faitsaillant_e.pdf.).

confusion was also a factor in Health Canada's decision to formalize the procedure by which drug names are approved. In any event, it is clear that there are a number of reasons why the *Trade-marks Act* is not an appropriate vehicle for addressing safety concerns among similar drug product names. First, under trademark law, not all names are reviewed, including names that are used but never registered or litigated. Second, similar names owned by the same company are associated and are therefore allowed to co-exist.[80] Third, in the application phase, factors such as packaging and labeling are not typically considered when assessing confusion.[81]

Prior to January 1, 2006, the drug name review process followed by Health Canada was informal and inconsistent. Drug names were reviewed only if the reviewer anticipated that there could be confusion between drug names. On October 31, 2005, a Guidance document entitled, "Drug Name Review: Look-alike Sound-alike (LA/SA) Health Product Names"[82] (hereinafter the "Guidelines") was released by the Health Products and Food Branch of Health Canada (HPFB) and was designed to provide clarification regarding the way the HPFB assessed information and material relating to proposed drug names.[83] The Guidance document took effect on January 1, 2006, and since then the HPFB has been reviewing all proposed drug names submitted with all drug submissions and all applications for drug identification numbers, for similar drug product names. The Guidance document applies only to drug names in the pre-market stage and therefore does not apply to drugs that are already marketed.

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80. Johanne Auger and Marie-Josée Lapointe, *Grin and Bear it! The Proposed Health Canada Guidelines—What Impact Might They Have on Clearance?* 23(1) Canadian Intellectual Property Review 29, 42 (2006).

81. *See* Interwood Mktg. Ltd. v. K-TEL Int'l Ltd. (1997), 76 C.P.R. (3d) 553 at 559 (T.M.O.B.):

> The applicant also submits, as an additional surrounding circumstance, that I should consider how the applicant's mark is actually being used in advertising, packaging and labeling. However, I do not agree that this is an appropriate consideration. It is the information contained in the application itself which should be considered since this is the form in which the mark would be registered and the actual design or associated packaging that the applicant may currently be using is irrelevant as it could change at any time.

82. Health Canada, Guidance Document: Drug Name Review: Look-alike Sound-alike (LA/SA) Health Product Names (2005), http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/lasa_premkt-noms_semblables_precomm_e.pdf [hereinafter *Guidelines*]. Although the Guidelines also apply to natural health products and medical devices, for the purposes of this paper a discussion of the Guidelines only as they apply to drugs will be discussed.

83. *Id.* at 1.

Procedurally, according to the Guidelines, proposed drug names are submitted with drug submissions or drug identification number applications, and Health Canada completes an initial review of the name within a 90-day target and provides feedback. A second abbreviated review of the name takes place within 90 days of the anticipated day of approval. To facilitate the review, sponsors are asked to submit a list of alternate names and a risk assessment and evaluation of the proposed brand name.[84] If confusion is considered likely, HPFB can refuse to issue a drug identification number and/or a notice of compliance.[85]

The review of health product names by the HPFB includes the review of brand names, and therefore includes the review of trademarks. The Guidelines define Look-alike Sound-alike Health Product Names as: "Health products that have a similar written name or similar phonetics to those of another health product."[86] The test for confusion under Section 6(5)(e), as enumerated above, includes "the degree of resemblance between the trademarks or trade-names in appearance or sound or in the ideas suggested by them,"[87] and therefore it follows that there is at least some overlap in the considerations of the HPFB and the Trade-marks Office in determining whether two marks can co-exist.

The Guidelines set out a number of factors used by the HPFB in determining whether the degree of similarity in names is problematic, including:

1. the marketing status (prescription or over the counter);
2. therapeutic category;
3. indication(s) and directions for use;
4. the clinical setting for dispensing or use (inpatient or outpatient hospital or clinic versus retail pharmacy for use in home);
5. the packaging and labeling;
6. the strength;
7. the dosage form or routes of administration;
8. the proposed dose and dosing interval;
9. similar patient populations; and
10. storage.[88]

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84. *Guidelines*, *supra* note 82 at 7-8.
85. *Guidelines*, *supra* note 82 at 6.
86. *Guidelines*, *supra* note 82 at 4.
87. *Trade-marks Act*, R.S.C. 1985, c. T-13, s. 6(5)(e).
88. *Guidelines*, *supra* note 82 at 8.

The Guidelines further state, "[I]f one or more of the factors listed above are different enough that the potential for confusion can be minimized there may be less of a concern. . . ."[89] Interestingly, the use of the words "confusion" or "confusing" appear throughout the Guidelines, and, as discussed above, many of the same factors are reviewed in determining whether confusion exists between two pharmaceutical trademarks under the *Trademarks Act*.

Given the variety of mistakes that can occur in a pharmacy setting as a result of two similar pharmaceutical names, it is presumably difficult for the HPFB to reach a conclusion regarding a potential safety concern. For example, while differences in areas of use (indications) will in some instances lessen the likelihood of a mistake, the difference in use may not always prevent a mistake (for example, if the pharmacist does not counsel the patient) and in fact, the greater the difference in use, the greater the health concern if a mistake occurs. By way of example, suppose a pharmacist (or technician as is often the case) receives a handwritten prescription for a pharmaceutical product named NEMEX, and as a result of bad handwriting, mistakenly reads and dispenses NEMEZ, a product with a different area of use. Clearly in this situation the area of use is not a factor in the mistake made, but the different areas of use create a safety concern. However, in another example, a pharmacist looking for the pharmaceutical product VALIX might see a product named VALYX in a similar location in the pharmacy that contains a similar label and area of use, and based on these factors the pharmacist may confuse the two drugs. The variety of factors considered by the HPFB, as well as the stated flexibility of the Guidelines,[90] is necessary given the unique nature of mistakes with pharmaceutical product names. Unfortunately, the flexible approach may also result in inconsistent decisions.

With respect to pharmaceuticals that are already on the market, the HPFB on November 10, 2005, released a draft guidance document entitled, "Marketed Health Product Name Assessment: Look-alike Sound-alike (LA/SA) Health Product Names." The guidance document is in draft form only and is not yet in force, and the HPFB continues to investigate how post-

89. *Guidelines*, *supra* note 82 at 10.

90. *Guidelines*, *supra* note 82 at 3. The Foreword of the *Guidelines* indicates: "Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach" and "Health Canada reserves the right to request information or material, or define conditions not specifically described in this guidance, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product."

market safety issues can best be addressed. However, the guidance document notes that in the interim, when a marketed health product name is assessed to pose a safety risk due to its confusion with another marketed health product name, the company marketing the product will be contacted and asked to suggest possible interventions to mitigate risks.

It is not surprising that Health Canada has finalized a procedure relating to the review of pharmaceutical product names in the pre-market stage while the post-market review of similar pharmaceutical product names remains in the research phase. A post-market review of pharmaceutical names that results in a finding by Health Canada of confusion would likely require the pharmaceutical owner to change the name of a product already on the market, presumably at a great cost to the pharmaceutical owner. Also, if a pharmaceutical product name was previously screened under the pre-market Guidelines and was determined to be acceptable, and a safety issue later arises, it is unclear how the previous decision will be treated by Health Canada at the post-market stage. Therefore, given the complexity of the post-market review, the procedure to be adopted by Health Canada requires careful consideration.

Given the relatively recent adoption of a formal procedure for reviewing pharmaceutical product names in the pre-market stage, it is not known how a decision of the HPFB will affect a decision of the Canadian Trade-marks Office (and vice versa) in determining whether two pharmaceutical product trademarks can co-exist. The cases will no doubt be of interest given the overlap of at least some of the factors considered by the Trade-marks Office and the HPFB.

VII. CONCLUSION

Canadian law relating to the issue of confusion in pharmaceutical cases has, as evidenced herein, developed over time to focus on specific issues that are unique to the pharmaceutical field. At the same time, it has been recognized that the basic meaning of confusion is no different for pharmaceutical cases than for cases that relate to other products and services, and the essential question to be determined is whether the healthcare professional or patient is confused as to the source of the product. In recognition of the gap that is created when confusion and mistakes occur that are not related to the source of the product, Health Canada has stepped in to fill the void with its look-alike/sound-alike regime. This complementary method of protection has created a sound system for the avoidance of confusion and mistake among pharmaceutical products in Canada.