HIGH COURT ISSUE

Two Pesos v. Taco Cabana: Still More Interesting for What It Did Not Decide
Joan L. Dillon & Michael Landau

Even More Parodic Than the Real Thing: Parody Lawsuits Revisited
Bruce P. Keller and Rebecca Tushnet

Qualitex Revisited
Christopher C. Larkin

Wal-Mart v. Samara Brothers and Its Progeny
S. Lloyd Smith

TraffFix Revisited: Exposing the Design Flaw in the Functionality Doctrine
Clifford W. Browning

Federal Dilution Claims After Moseley v. V Secret Catalogue
Howard J. Shire and Michelle Mancino Marsh

Brand Name and “Look-Alike” Drugs in Canada After Ciba-Geigy v. Apotex: A Proposal for Relief From Slavish Imitation
Daniel R. Bereskin, Q.C.

A Sign of the Times? A Review of Key Trade Mark Decisions of the European Court of Justice and Their Impact Upon National Trade Mark Jurisprudence in the EU
Seiko Hidaka, Nicola Tatchell, Mark Daniels, Bonita Trimmer and Adam Cooke

Significant Trademark Developments in the Asia-Pacific Region
Joseph S. Yang
BRAND NAME AND “LOOK-ALIKE” DRUGS
IN CANADA AFTER CIBA-GEIGY v. APOTEX:
A PROPOSAL FOR RELIEF FROM
SLAVISH IMITATION

By Daniel R. Bereskin, Q.C.*

I. INTRODUCTION

In Ciba-Geigy Canada Ltd. v. Apotex Inc.,¹ the Supreme Court of Canada declared that competing laboratories must avoid manufacturing and marketing drugs with such a similar get-up to existing drugs “that it sows confusion in the customer’s mind.”² Despite this strong statement and others like it in the same case, slavish imitation of drug trade dress remains the rule, rather than the exception in Canada, and this has been the case for decades. The purpose of this article is to show why this is so and to propose an alternative to costly litigation.

The trade dress of a medicine, in principle, is subject to the basic legal rules that apply to any other trade dress.³ To be entitled to protection, it is necessary to show that the trade dress has acquired secondary meaning, and that the unauthorized use of a similar trade dress has caused or is likely to cause confusion. In addition, it may be necessary to defend against an attack that the trade dress is functional.⁴ To further complicate the situation, social issues may intrude into the legal analysis.⁵

The main variables in any drug trade dress are color, shape and size. Manufacturing and biological considerations limit these variables, so it is not surprising that most medicines are dispensed in cylindrical capsules with rounded ends, i.e., bi-convex circular or oval tablets. Such common shapes may be the cheapest to

* Partner, Bereskin & Parr, Toronto; Associate Member of International Trademark Association (INTA); Member of the Editorial Board of The Trademark Reporter; former legal counsel, INTA. The author gratefully acknowledges the research assistance of Sharyn Costin and Catherine Lovrics, students-at-law.

² Id. at 304.
manufacture, but the most difficult for establishing trade mark rights because they possess little or no inherent distinctiveness. Also, as will be seen, it is difficult to prove that a drug trade dress is distinctive by reason of its color alone, even if the color is relatively unique in relation to a particular molecule. Conversely, a tablet of a truly distinctive shape, or having an unusual color scheme or combination of colors, facilitates the establishment of trade mark rights, especially if the source significance of the trade dress is enhanced by advertising or promotion.6

In the case of pharmaceutical get-ups, usually there is no utilitarian, cost or quality reason sufficient to justify making a generic product look like the brand name product.7 However, generic companies take the position that irrespective of whether the get-up is functional in any normal respect,8 psychological factors make the trade dress functional or generic. They cite the following reasons, among others: using the same trade dress for the generic product reduces patient anxiety because patients primarily associate the trade dress with the medicine and, therefore, would be upset if they were confronted with medicine of a different appearance; it is easier for patients to distinguish among several different medications when they are intermingled in the same container; doctor or pharmacist communication with the patient is made easier; and it is quicker to identify drugs in emergency situations, such as in the case of an overdose.

These arguments do not respond to the issue that the trade dress of a medicine is an important aspect enabling the patient’s right to choose the source of their medicine. Some patients are on the same medication for a long time, and for both physical and psychological reasons, they become accustomed to the same medication and insist on the same brand, which is their right. Generic imitation of the trade dress of an innovative drug is likely to lead to confusion in the mind of the public, the very thing that trade mark law is intended to prevent. Lastly, patients may be reassured by their doctors or pharmacists that the generic drug is functionally equivalent to the brand name drug, and this should prevent anxiety even if the trade dress is different. Likewise, labels attached to the caps of the medicine containers, warning the patient about the change of shape or color, would significantly

---

6. Health Canada publishes guidance documents, which are available online, on how to advertise pharmaceuticals legally in Canada.
8. For example, if a tablet is scored with lines to make it easier to break into two or more pieces, those lines ordinarily would be functional, and therefore incapable of protection, even if the lines had acquired distinctiveness. Or, if a particular color is the natural color of the active ingredient, that color would be considered to be functional, irrespective of its distinctiveness.
reduce anxiety. It is submitted that the primary reason why generic companies slavishly imitate trade dress is because it is in their economic interest to do so.

Although the following discussion will largely be confined to the legal issues involved in drug trade dress disputes, the starting point in the analysis must be the political and social issues with which the protectability of drug trade dress is inextricably intermixed in Canada. The article concludes with a proposal for possible action by Health Canada.

II. POLITICAL AND ECONOMIC BACKGROUND

In recent years, there has been an epidemic of drug trade dress litigation in Canada. To understand why, it is necessary to consider some background facts concerning the Canadian generic drug industry.

The generic drug industry is big business in Canada, at least in relative terms. The prescription drug market in Canada in 2003 was 5.8 billion Canadian dollars. Of that amount, 12.93% or about $750 million dollars was made up of generic drugs. Most Canadian generic drugs come from two Canadian generic companies, Apotex Inc. and Novopharm Ltd., whose combined worldwide sales in 2003 totaled over 1.3 billion Canadian dollars. Apotex and Novopharm rank first and second in total number of all prescriptions dispensed from retail pharmacies in Canada. They are both well-financed, well-run companies and formidable competitors.

Generics account for slightly more than 40% of all prescriptions filled. Half of the business of Apotex and Novopharm is done outside Canada, in over 115 countries. In some countries, like Germany, Apotex has made significant inroads, and it accounts for a large share of the market in certain drugs.

There are two main reasons for the emergence and dominance of Apotex and Novopharm in the Canadian generic field. The first is that in 1969 Canadian patent law was amended to permit the issuance of compulsory drug patent licenses covering importations of patented drugs. This meant that Canadian companies did not have to be able to make the drugs themselves to secure cheap compulsory patent licenses. The motivation of the Canadian government was to keep drug prices down, but this policy resulted

---

9. See discussion of results of recent CDMA survey, infra Section V.
10. Id.
in a number of brand name companies stopping or reducing their research in Canada, with the resulting loss of important jobs, especially in Québec.

A second important fact is that, in Canada, prescribed drugs are available free of charge to senior citizens under provincial medical care plans. The cost is borne by the provincial governments, whose regulations require pharmacists to substitute lower-priced generic drugs to medical care patients when an equivalent generic drug is available, unless the prescription is marked “no substitution,” and this designation can be justified on medical grounds.

In addition to the fact that there was no effective patent protection for medicines in Canada, Apotex and Novopharm usually were able to imitate slavishly the trade dress of the drugs for which they had obtained compulsory licenses, for reasons that are explained in detail below.\textsuperscript{13}

The lobby arm of the generic industry, The Canadian Generic Pharmaceutical Association (CGPA) (previously known as Canadian Drug Manufacturers Association (CDMA)), has campaigned against drug trade dress protection, and has lobbied the Canadian government to regulate drug trade dress. Their objective is to require, by regulation, a specified trade dress to denote each particular molecule.\textsuperscript{14} The evidence upon which they rely in support of their position is dealt with in Section V below. Needless to say, innovative manufacturers urge exactly the opposite, that the trade dress of an innovative drug carries source significance and, therefore, slavish imitation is deceptive. The starting point is a discussion of unfair competition at common law and under the Trade-marks Act,\textsuperscript{15} because the \textit{Ciba-Geigy}\textsuperscript{16} case was based on the tort of passing off, as codified by Section 7(b) of the Trade-marks Act.

\textsuperscript{13} Patent Act Amendment Act, c. 2, 1993, Bill C-91, amending Canadian patent law, was passed shortly before Canada and the United States entered into the North American Free Trade Agreement (NAFTA). The resulting changes to the law have given more effective patent protection to new drugs and, since the passage of Bill C-91, Apotex and Novopharm have waged an unrelenting political campaign attacking it.

\textsuperscript{14} In the United States, a similar initiative appears to have unsuccessfully been launched before the FDA, which took the position that “the appearance of drug products is [not] closely enough related to their safety and effectiveness that the Agency can, on the basis of its present experience, require that generic drug products duplicate the appearance of their innovator drug counterparts” \textit{quoted in Ciba-Geigy Corp. v. Bolar Pharmaceutical Co. Inc.}, 747 F.2d 844 (3d Cir. 1984).


III. UNFAIR COMPETITION AT COMMON LAW AND UNDER THE TRADE-MARKS ACT

Features of color and shape are entitled to protection under the common law action of passing off, and under Section 7 of the Trade-marks Act, which essentially codifies the common law action for passing off. In order to succeed in such an action, the plaintiff must prove that the distinguishing features of the goods have acquired a secondary meaning, i.e., that by reason of the distinguishing features, doctors, pharmacists or patients have come to associate the goods with a particular source of the goods. The foundation of such a case is that the goods are known in the market, and have acquired a reputation in the market by reason of their distinguishing features.

In order to succeed in an action for passing off at common law or unfair competition under Section 7 of the Trade-marks Act, it is necessary for the plaintiff to prove that the distinguishing features signify a particular source. Even if the plaintiff has been the only entity using the distinguishing features for many years, and such use has been very extensive, it is not easy to prove that the distinguishing features are relied upon by physicians, pharmacists or patients as signifying the source of the drug. This is especially the case given the current judicial climate, where it is assumed that drug trade dress is a weak trade mark at best, and that the plaintiff has a high burden of proof in satisfying the court that the trade dress has acquired secondary meaning.

For many years, the prevailing judicial view was that the relevant universe for determining secondary meaning and likelihood of confusion in drug trade dress cases consisted of doctors, dentists and pharmacists. Patients were excluded on the basis that drug manufacturers at that time could not advertise a

17. Supra note 15, § 7.
20. Hoffman-La Roche Ltd. v. Apotex Inc., [1983] 72 C.P.R. (2d) 183 (Ont. H.C.J.), where it was held that the colors of the plaintiff’s capsules would not indicate the trade source but instead the characteristics of the medication.
21. Typically, secondary meaning or acquired distinctiveness is shown by sales and advertising, but it is thought that sheer volume of sales alone does not necessarily prove the perception of the public as to whether the trade dress signifies source, or whether it merely signifies the medicine. Market research may be necessary to prove this. In the United States, the deliberate copying of the brand name trade dress is a factor some courts take into consideration in determining the existence of secondary meaning. See Ciba-Geigy Corp. v. Bolar Pharmaceutical Co. Inc., 747 F.2d 844 (3d Cir. 1984).
prescription drug to the general public, only physicians and dentists can prescribe, and only physicians, dentists and pharmacists can dispense prescription drugs.

This reasoning was rejected by the Supreme Court of Canada in Ciba-Geigy.\textsuperscript{23} The Court concluded that the final consumer must be taken into account, so that the relevant universe must include patients as well as doctors, pharmacists and dentists. Further, the Court repeatedly expressed in strong terms that it did not approve of the imitation of drug trade dress.\textsuperscript{24}

The fact remains, though, that trade dress cases are won or lost on the evidence, and not on the basis of social or moral grounds alone. As will be seen, the Supreme Court’s apparent disapproval of slavish imitation of drug trade dress has not benefited innovative manufacturers in their battles with generic manufacturers. The situation remains that generic manufacturers routinely imitate the trade dress of innovative drugs as soon as the generic manufacturer has received approval to market a generic equivalent drug.

Since Ciba-Geigy, there has been only one adjudicated passing off action involving drug trade dress, and that case failed. In Eli Lilly & Co. v. Novopharm Ltd.,\textsuperscript{25} the plaintiff marketed fluoxetine under the trade mark PROZAC, a hugely successful antidepressant. The drug was sold in two dosages, 10 mg and 20 mg capsules. The 10 mg capsule was half green and half pale grey. The 20 mg capsule was half green and half cream. One end of each capsule was bullet shaped, the opposite end was the more common spherical shape. Prior to the trial, the plaintiff had sold more than $400 million worth of PROZAC tablets in this trade dress, and spent more than $22 million promoting the product. The appearance of PROZAC tablets had been depicted on the covers of national magazines. Evidence was received at the trial in the form of 51 expert reports and the testimony of 62 witnesses, including doctors, pharmacists and patients. The trial required 42 hearing days over 5 months. In the decision, the trial judge found that the


\textsuperscript{24} The following examples indicate the view the Supreme Court took of slavish imitation of drug trade dress: “... competing laboratories must avoid manufacturing and marketing drugs with such a similar get-up that it sows confusion in the customer's mind.” Id. at 304; “As the patient has no direct access to the product, it is all the more necessary for him to be able to exercise some kind of control over what he is being given.” Id. at 308; “In the field of prescription drugs the first information the patient receives when the product is given to him comes from its appearance.” Id. at 308; “Patients taking a drug for some time can become accustomed to it and insist on a particular brand.” Id. at 310; “... patients are not very willing to experiment and perhaps still less so when they are suffering from conditions such as hypertension.” Id. at 310.

action failed because she was not persuaded that the capsule appearance had acquired secondary meaning, or that confusion had occurred or was likely. She found that if the market attached any meaning to the capsule appearance, it was to the therapeutic effect of the medicine, and not its trade source or provenance. The Federal Court of Appeal affirmed these findings of the trial judge. The decision of the Supreme Court in Ciba-Geigy was referred to extensively in the reasons of the trial judge and the court of appeal, but on the evidence, all of the judges unanimously agreed that the plaintiff had failed to prove secondary meaning and likelihood of confusion.26

Although the trial judge was very critical of the plaintiff’s evidence of secondary meaning, and of the plaintiff’s principal survey expert, it is notoriously difficult to measure the perception of the public in relation to drug get-up. Doctors and pharmacists will seldom admit that they rely on get-up to identify a source. Patients and prospective patients, to the extent they can be identified (which is not easy, given the confidentiality of the physician/patient relationship) likely associate the drug get-up with the medication and the dosage to some extent at least.27 That said, it surely must also be the case that patients who have relied upon a medication for many months or years, including patients who associate the get-up with a particular medicine, believe that the medicine comes from a particular source and they have learned to trust that source.28 Therefore, it is submitted, evidence that the public associates the get-up with the medicine or its dosage should not be fatal to a plaintiff’s case if it can also be shown that the public, including perhaps the very same people, also associate the get-up with a particular source. Of course, it would be desirable to be able to show that the predominant significance is secondary meaning, but people to whom the trade dress means both source and the medicine do not tend to rank one meaning over the other. To put this another way, if there is convincing proof of confusion or of a likelihood of confusion among at least 10 to 15 percent (net of control) of the relevant universe, and at least some credible proof that the get-up communicates source significance, the plaintiff should not be disentitled to relief merely because the public also associates the get-up with the medicine or its dosage.29 To do so

26. Leave to appeal to the Supreme Court of Canada was denied.
27. Eli Lilly used different colors to denote different dosages.
28. In Eli Lilly, the trial judge acknowledged that 19% of the “Prozac Knowledgeable” respondents were able to identify the PROZAC color combinations.
29. Note that Article 16 (1) of the “Dunkel Text” Document MTN.TNC/W/FA of December 20, 1991, on Trade Related Aspects of Intellectual Property Rights (TRIPs), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed Marrakesh, Morocco, April 15, 1994, provides that “in case of the use of an identical sign for
would, in effect, give the generic manufacturers a license to deceive the public.

The trial judge found that many of the consumers who have taken the plaintiff’s product will associate the capsule appearance with the character of the medicine and not its trade source or provenance. That may be so, but it also seems likely to be the case that many consumers will likewise associate the brand name with the medicine and, obviously, this fact should not give a competitor the right to use the same brand name. Although some of the criticisms of the trial judge concerning the plaintiff’s survey evidence were justified, it is not clear that another survey would have fared better. This is because it appears to be assumed that color and shape are not inherently distinctive, there is a high level of proof required to prove acquired distinctiveness, and it is difficult to obtain convincing evidence, especially from patients, in relation to a prescription pharmaceutical. In any case, Eli Lilly was an enormous setback for innovative manufacturers given that PROZAC was a breakthrough drug, the trade dress of the PROZAC capsules is inherently more distinctive than many other drug get-ups, and PROZAC had very substantial sales and notoriety.

So why do generic manufacturers insist on engaging in slavish imitation in Canada? One reason may be to impede competition from U.S. generic manufacturers. In the United States, generic manufacturers generally use different trade dress from that of innovative manufacturers of the same drug. U.S. generic manufacturers are entitled to sell their products in Canada upon issuance of a Notice of Compliance by Health Canada. For marketing reasons, U.S. generic manufacturers would likely need to use the identical trade dress for bioequivalent drugs in Canada, given that for decades both innovative and generic manufacturers have marketed drugs in this manner on the Canadian market. This would mean creating a different trade dress for the Canadian and United States markets. Given that the Canadian market is already occupied by powerful generic companies, the additional cost of modifying the trade dress for the Canadian market may impede competition from U.S. generic manufacturers.

In addition, in many provinces patients have the right to require that their pharmacist dispense a particular interchangeable drug product of their choice. Therefore, if

30. Eli Lilly, 73 C.P.R. (3d) at 423.

31. See, e.g., The Drug Interchangeability and Dispensing Fee Act, R.S.O. 1990, c. P.23 (Ontario).
requested by the patient, the pharmacist must dispense the product of the innovative manufacturer even if a generic substitute is available at lower cost, although the patient is responsible for the higher cost. Also, a physician can prescribe the drug by its brand name and mark “No Substitution.” If this is justifiable for medical reasons, as on occasion it is, the pharmacist is not entitled to substitute. Therefore, it is to the commercial advantage of generic companies to communicate to the public that their product is interchangeable with the innovative manufacturer, even if it means that some members of the public are deceived into thinking that the source is one and the same, or that the innovative manufacturer controls the manufacture of the generic substitute. In short, it is submitted that the fight is primarily about market share, not public health, and the generic industry cannot justify their conduct by pretending to be custodians of the public good.

_Eli Lilly_ shows that despite the clear statements of the Supreme Court in _Ciba-Geigy_ with respect to slavish imitation in drug trade dress cases, and despite the fact that lower courts accept the “vital importance”₃² of the _Ciba-Geigy_ case, it is hard to imagine how a passing off trade dress case could be won in any but extraordinary circumstances. It is, therefore, understandable that innovative manufacturers have shifted their attention away from expensive and difficult passing off cases, and have focused instead on registration of the trade dress. Unfortunately, their efforts to date have had little success, as the following discussion will indicate.

**IV. REGISTRATION OF COLOR/SHAPE AS A TRADE MARK**

The basic premise is that possession of a valid registration for a particular trade dress entitles the owner to the exclusive right to use the trade dress.₃³ Although the validity of a trade mark registration may be attacked on several grounds, including non-distinctiveness,₃₄ in an infringement action the onus is on the party attacking the registration to prove non-distinctiveness. In contrast, in a passing off action, the onus is on the plaintiff to

---

₃². _Eli Lilly_, 73 C.P.R. (3d) at 379.

₃₃. Although this appears to be a common interpretation, in the author’s view § 19 and § 20 of the Trade-marks Act, _supra_ note 15, must be read together, with the result that likelihood of confusion must be proved even if the defendant has used a mark identical to the registered mark on goods covered by the registration. If the author’s view is correct, proof of likelihood of confusion would still be required even if the defendant had used a get-up identical to that covered by a trade mark registration.

prove that the trade dress has acquired distinctiveness or secondary meaning. At least, that's the theory.

There are two basic ways for securing registration of color and/or shape as a trade mark. The first is by registering the color, or color scheme of the capsule or tablet. The second is by registering the shape of the capsule or tablet as a distinguishing guise. In relation to drugs, neither is without problems, but this has not impeded many innovative companies in seeking registration.

A. Color

In Smith, Kline & French Canada Ltd. v. Registrar of Trade-marks (SKF No. 1)\textsuperscript{35} and Smith Kline & French Canada Ltd. v. Registrar of Trade-marks (SKF No. 2),\textsuperscript{36} SKF filed two separate trade mark applications intended to protect the trade dress of a drug called cimetidine sold under the trade mark TAGAMET. The drug was produced in the form of circular bi-convex green tablets. The first application (SKF No. 1) claimed that the trade mark was a distinguishing guise consisting of a green film applied to the outside of the tablet. The second application (SKF No. 2) described the trade mark as “the color green applied to a tablet and shown in the attached drawing lined for the color green the precise shade of which is shown on the attached color patch.” The trade mark drawing showed a circular device with green lines. Each application was refused by the Registrar of Trade-marks,\textsuperscript{37} the first on the ground that a green film applied to the surface of a tablet is not a mode of wrapping or packaging of wares as required by the definition of “distinguishing guise,” and the second, on the ground that color alone cannot function as a trade mark. The drawing was said to be merely a depiction of the wares, and not a depiction of a mode of wrapping or packaging the wares.

On appeal to the Federal Court,\textsuperscript{38} Mr. Justice Strayer agreed with the Registrar in SKF No. 1 that a green film applied to a tablet cannot comprise a distinguishing guise, but he reversed the Registrar in SKF No. 2 on the ground that it was conceivable that a color of a particular shape could constitute a trade mark. SKF No. 2, thus, went back to the Registrar for further examination, following which it was advertised for opposition, opposed and eventually abandoned for reasons that do not appear in the record.

Although Mr. Justice Strayer undoubtedly was correct in his view that a color of a particular shape can function as a trade mark.

\textsuperscript{35} 1987] 14 C.P.R. (3d) 432, 12 C.I.P.R. 199 (FCTD) [hereinafter “SKF No. 1”].
\textsuperscript{36} 1987] 12 C.I.P.R. 204 (FCTD) [hereinafter “SKF No. 2”].
\textsuperscript{37} See supra notes 35 and 36.
\textsuperscript{38} Id.
mark, it appears that he assumed that the mark would have to be distinct in order to be registrable, or at least capable of distinguishing the owner’s goods from those of others.\(^{39}\) He may not have appreciated, though, that the Registrar has no authority to require an applicant to prove distinctiveness of a mark consisting of a color of a particular shape.\(^{40}\) That issue can only be raised before the Registrar in an opposition.\(^{41}\) If an opposition is filed, the opponent will plead non-distinctiveness, and the Registrar must then determine whether the trade mark is distinctive or at least is adapted to distinguish.\(^{42}\)

**SKF No. 2** spawned numerous cases involving applications for registration of trade marks said to consist of a specific color or colors, as applied to a tablet or capsule of a specific shape. The shape is typically shown in the drawing in dotted outline. A typical description of the trade mark is as follows: “The tablet shown in dotted outline does not form part of the mark. Color is claimed as a feature of the trade mark. The trade mark is illustrated by the specimen tablets filed with the application and consists of the color (identify color) applied to substantially the entire surface of a (describe shape) pharmaceutical tablet of the illustrated shape and size.” The wares typically are also described narrowly, such as “pharmaceutical tablets containing (name of drug) for use in the treatment of (name of disease or diseases).”

The foregoing description clearly identifies the color, the shape of the color, and identifies the pharmaceutical in specific terms. To avoid the objection that the color or shape is not clear, a specimen may be filed, although the Trade-mark Rules do not specifically require this to be done. The reason for stating that the shape does not form part of the mark is that product shapes as such are registrable only as distinguishing guises, which require proof of secondary meaning as of the filing date. Color of a particular

---


41. Id. at § 38(1).

42. Three recent opposition cases have been decided against the brand name company, namely:

1. *Novopharm Ltd. v. Searle Canada Inc.*, [1995] 60 C.P.R. (3d) 400 (TMOB) where the “mark” was the color yellow applied to a circular biconvex tablet: refused because the color yellow was not shown to be distinctive of the goods;

2. *Novopharm Ltd. v. Burroughs Wellcome Inc.*, [1993] 52 C.P.R. (3d) 263 (TMOB) where the “mark” was the color blue applied to a shield-shaped tablet: refused because the shape was not precisely enough defined; and

3. *Burroughs Wellcome Inc. v. Novopharm Ltd.*, [1994] 58 C.P.R. (3d) 513 (FCTD) where the mark was the same color blue applied to a shield shaped tablet, but the shape was precisely defined: refused because specimens filed by the opponent showed that the mark as used was associated with the word ZOVIRAX, i.e., the design mark was not used simply.
shape, however, does not require proof of secondary meaning and, therefore, applications for registration of color of a particular shape can in theory be filed on the basis of proposed use.

In view of SKF No. 2, an application conforming to the foregoing conditions would likely be accepted for advertisement. With the exception of a few that seem to have escaped the scrutiny of Apotex or Novopharm, all have been opposed, and each reported case has ultimately resulted in a decision refusing registration. This is so despite the strong pronouncement of the Supreme Court of Canada in Ciba-Geigy.43 The reasons are as follows.

First, it has been held that the burden of establishing distinctiveness of a mark rests on the applicant, both in the opposition proceeding and on appeal to the Federal Court from a decision of the Registrar in the opposition proceeding.44 The correctness of this view is open to doubt. A trade mark is distinctive if it actually distinguishes the goods of the owner of the mark from those of others, or is adapted to do so.45 Distinctiveness is determined at the date when distinctiveness is called into question, which in the case of an opposition, is the filing date of the statement of opposition.46 There is nothing in the Trade-marks Act or Rules that indicates that the onus for proving distinctiveness in the case of a mark that is “adapted to distinguish” is on the applicant. Therefore, if the mark for which registration is sought appears to be “adapted to distinguish,” it must be advertised for opposition. As the burden for proving the grounds of opposition initially falls on the opponent, the opponent must lead at least some evidence of non-distinctiveness to shift the burden to the applicant.47 This is what usually occurs in fact, so the issue of who has the initial burden of proof usually is not a decisive factor.

Second, although the Trade-marks Act does not require proof of secondary meaning as a condition for registration of a mark consisting of color, the Federal Court of Appeal has held that color alone is not inherently distinctive.48 This conclusion is not based on the Trade-marks Act or Canadian case law, but instead on a

45. Trade-marks Act, supra note 15, § 2, definition of “distinctive.”
47. See John Labatt Ltd. v. The Molson Companies Ltd., [1990] 30 C.P.R. (3d) 293, 298 (FCTD), aff’d, 42 C.P.R. (3d) 495 (FCA).
48. AstraZeneca AB v. Novopharm Ltd., [2003] 24 C.P.R. (4th) 326, 336 (FCA); application for leave to appeal to the Supreme Court was filed by AstraZeneca AB on April 7, 2003 (Court File No. 29691).
U.S. unfair competition case\textsuperscript{49} and a U.K. registration case\textsuperscript{50} under a statute containing a different definition of "distinctive" than that of the Canadian Trade-marks Act.

Third, regardless whether the application specifies the drug in the narrowest possible terms, the Federal Court of Appeal has held that the relevant universe for establishing distinctiveness is the entire field of pharmaceuticals.\textsuperscript{51} In the case of monochrome biconvex tablets, it is difficult to imagine how any practical color of any normal shape could possibly meet such a test.

Fourth, the applicant must show that physicians, pharmacists or patients can and do use the proposed trade mark in choosing whether to prescribe, dispense or request the product.\textsuperscript{52} Patients typically receive their drugs in a package that itself is placed in an outer bag, and the drug is prescribed by the physician and is dispensed by the pharmacist. Given this, if this test were valid, it is hard to imagine how any applicant could ever prove that color/shape had anything to do with the selection process by patients.

If one strips away the reasons given in the court decisions from the basic facts before the court, the decisions are easier to understand. For example, if the "trade mark" under consideration is a pink, circular, biconvex tablet, one of perhaps a hundred tablets of similar color and shape, in the absence of extremely compelling proof it is reasonable to say that merely specifying the goods in narrow terms does not make something that inherently is not a trade mark into a trade mark. Proof of secondary meaning is hard to come by in many pharmaceutical get-up cases, let alone one where the color/shape under consideration is trite.

The conclusion, therefore, is that despite the strong statements of the Supreme Court of Canada in \textit{Ciba-Geigy},\textsuperscript{53} and despite the promise of \textit{SKF No. 2}, the likelihood of an innovative manufacturer proving distinctiveness of the color/shape combination of a monochrome tablet of conventional shape is limited. This difficulty is exacerbated when the same drug is sold in tablets of similar shape but different color, to denote different


\textsuperscript{51} AstraZeneca AB v. Novopharm Ltd., 24 C.P.R. (4th) at 338 where Stone, JA appears to have decided that as the active ingredient in the pharmaceutical itself was not claimed as part of the trade mark, the applicant had the burden of showing that the color of a particular shape distinguished the goods from those of all other manufacturers.


dosages. Given that this is done to promote patient safety, the innovative manufacturer can hardly be faulted for this, but it does make it harder to prove secondary meaning.

More promising than monochrome tablets are capsules in which each half is of a different color. In general, this should substantially reduce the number of other drugs of a similar trade dress, but even in this case, variations in hue may not be sufficient. For example, the trial judge in *Eli Lilly* 54 found that other drugs used for treating depression had been marketed in green and yellow capsules, albeit with different shades than that of PROZAC capsules. As a result, she found that the PROZAC trade dress was not inherently distinctive.

The conclusions that can be drawn from the foregoing discussion are that if the trade dress is applied to a color or color combination that is not unique in relation to pharmaceuticals generally, and the shape likewise is not unique, the chances of the applicant succeeding in an opposition are slim. The chances of success would be improved markedly if the trade dress is relatively unique and is promoted as a trade mark, for example, “The Purple Pill” of AstraZeneca. 55 Although AstraZeneca strongly stresses the color purple in advertising, the capsules themselves are marked with three distinctive parallel yellow bands to further distinguish the product. The resulting trade dress appears to be inherently highly distinctive. Presumably, though, the additional cost of producing capsules with relatively complex trade dress, and promoting the trade dress can be justified only in the case of a few highly successful products. Still, in the case of any “breakthrough” drug, innovative manufacturers should carefully consider adopting a distinctive trade dress at the outset, and taking reasonable precautions to ensure that the trade dress is depicted in a two-dimensional form in packaging and advertising (where permissible) with a message that reinforces the trade mark significance of the trade dress.

### B. Shape

If color of a particular shape is problematic, what then are the chances of successfully registering a shape as a distinguishing guise? A distinguishing guise is a shaping of wares or their containers or a mode of wrapping or packaging the wares or their containers. 56 The appearance of the wares, containers or wrapping must serve to distinguish the wares or services of the applicant from the wares or services of others. In the case of a

pharmaceutical, the distinguishing guise is the shaping of the wares. Unlike color of a particular pharmaceutical product, in the case of a distinguishing guise, the applicant must be able to prove acquired secondary meaning as of the filing date of the application.\textsuperscript{57} The distinctiveness of the distinguishing guise must stem from the shape alone; color is not part of the distinguishing guise,\textsuperscript{58} even though it is obvious that color can be an important quality that distinguishes the product as a whole.\textsuperscript{59} Therefore, a circular biconvex tablet, or a cylindrical capsule with spherical ends, among many other common shapes, would not be good candidates for registration as distinguishing guises, even if they have unique color schemes or patterns. Given the foregoing, it is to be expected that few drug get-ups will qualify for protection. Even if in theory they do, the innovative manufacturer still faces formidable problems of proof of secondary meaning, not unlike the problems faced by Eli Lilly in the PROZAC case.

\textit{Glaxo Wellcome Inc. v. Novopharm Ltd.}\textsuperscript{60} is illustrative. Glaxo Wellcome applied to register the shape of a tablet in the shape of a shield with six sides as a distinguishing guise for a product containing acyclovir as an active ingredient. The product was sold under the trade mark ZOVIRAX, which is used for treating herpes simplex and other conditions. Prior to the filing date of the application, the evidence showed that 56 million tablets had been sold. As this was a distinguishing guise application, it was necessary for the applicant to satisfy the Examiner that the distinguishing guise trade mark had acquired secondary meaning. In this regard, the applicant filed affidavits from individuals as well as medical practitioners showing that they were able to connect the shape of the tablets with the ZOVIRAX trade mark, from a single source. The application was advertised for opposition, and then opposed by Novopharm who submitted evidence that pharmacists could not identify the tablets without the word ZOVIRAX on it. The Registrar refused the application on a number of grounds, including the ground that the “vast majority” of Canadians are not aware of the shape of the applicant’s tablets much less whether the shape functions as a distinguishing guise.\textsuperscript{61} On appeal, O’Keefe, J. held that the Registrar was wrong in apparently requiring proof that the distinguishing guise was recognized as such by “most adult Canadians,” but agreed with the

\textsuperscript{57} Id., § 13 (1)(a).

\textsuperscript{58} See SKF No. 1, 14 C.P.R. (3d) at 432, comment of Strayer JA at 434.


\textsuperscript{60} [2000] 8 C.P.R. (4th) 448 (FCTD).

\textsuperscript{61} It may be inferred from this that the “vast majority” of Canadians are privileged not to suffer from herpes.
Registrar that Glaxo Wellcome had not met the burden of proving that its ZOVIRAX product had become distinctive by reason of its shape. The health care professionals who gave evidence in support of Glaxo Wellcome were found to have relied, not merely on the shape of the tablet, but also the markings on it, specifically the word ZOVIRAX and a triangular device impressed on one side of the tablets. No evidence from patients was tendered, which was held against Glaxo Wellcome in light of the fact that its professional witnesses appeared to be uncertain about the distinctiveness of the shape of the tablets.

It is possible that a case will come forward involving a truly distinctive shape, and that credible evidence will be adduced proving that the shape does in fact function as a trade mark and hence is registrable. The Glaxo Wellcome case shows, like the many other registration cases before and after it, that the Registrar and the courts impose a high burden of proof on a party seeking to prove that a drug trade dress has acquired distinctiveness. This is not to say that it is impossible to succeed, only that it is very difficult, and very expensive. Therefore, it may be timely to consider a radical alternative, as discussed below.

V. PROPOSAL FOR REGULATION OF DRUG TRADE DRESS

Pharmaceutical drugs may be sold in Canada only after having been approved by Health Canada’s Therapeutic Products Directorate, the authority that regulates pharmaceutical drugs and medical devices for human use. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product’s safety, efficacy and quality as required by the Food and Drug Act62 and Regulations.63

Section 9 (1) of the Food & Drug Act states:

No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

The author’s argument is that if it can be proved that slavish imitation of the trade dress of an approved drug is “false, misleading or deceptive,” Health Canada can and should intervene to prevent such conduct. Health Canada has the authority to do so, and can, if it wishes, issue a Notice of Compliance requiring an applicant to indicate the trade mark under which the product is

62. See supra note 6, § 8, § 10 and § 30.

63. Available online, see http://www.hc-sc.qc.ca/food-ailment/friia-raaifood_drugs-ailments_drogues/act-law/e_index.html.
intended to be sold, so that it can satisfy itself that the trade mark would not tend to deceive or cause mistake. Considering the history of failed trade mark litigation, and the fact that generic manufacturers may be expected to fiercely contest any change in the status quo, the question then, is how to prove that slavish imitation of trade dress is deceptive.

What is needed is compelling, neutral, scientific survey evidence. It is also clear that, in view of the substantial public interest at stake, an adversarial proceeding, such as a passing off action, is not the best way to determine the public perception of drug trade dress. Therefore, it is suggested that Health Canada undertake a study to determine patients' perceptions of drug trade dress. Innovative and generic manufacturers could be invited to fund the cost of such a survey, and should be entitled to be heard in relation to the proposed survey methodology, but it would be up to Health Canada, assisted by the Department of Justice, to determine what the survey should measure, and how. There is some precedent for such a survey, albeit from an unlikely source.

In late 1995, the Canadian Drug Manufacturers Association (CDMA) (now known as Canadian Generic Pharmaceutical Association (CGPA)) conducted a survey intended to show that patient safety is at risk if the color, shape and size of medications are not consistent among generic drugs and their brand name equivalents. The CGPA has recently advised the author that they are not aware of a more recent survey. Although the 1995 survey was intended to support a particular point of view, it is nevertheless instructive to examine the methodology and the results.

The survey interviewed seniors (persons aged 65 and over) chosen at random in the cities of Toronto and Montreal. All the respondents were people living at home who said they were taking one or more medications regularly.

Included below are a few of the questions contained in the CDMA survey relating to trade dress, and the responses thereto:

1. “Tell me the names of all the drugs you take on a regular basis.” 39% were able to identify the drugs by name, unaided. Considering that the universe was made up of people over 65 years of age and presumably included many quite elderly people, this seems to be a very substantial percentage. The figure went up to 72% when the respondent was taking only one drug.

2. After naming the medications they were taking, the respondents were asked to describe, from memory, everything they could remember about what the pill(s) looked like. 77% of the medications mentioned were linked by the respondents to size, shape or color. This result appears to be more helpful to brand name owners than to the CDMA because many people
seem to have unaided recall of their medication by brand name and are able to link that brand name with the trade dress.64 Furthermore, as the following question appears to show, and contrary to the survey relied upon by the generic manufacturers in the Eli Lilly case,65 many respondents were well aware of source significance of the brand name.

3. The respondents were asked if the name they gave for the medication was a brand name, or the name of the medicine. 55% said that they did not know, but a strong 41% correctly indicated that it was a brand name and not a generic name.

4. The next question asked respondents to “describe the method or system you use to keep track of all the different pills you take.” Interestingly, only 12% mentioned that they made use of the color, shape or size to keep track of the different pills. This ties in as well with another question, namely “how do you check to make sure that a repeat prescription has been dispensed properly?” 59% said that they checked the name, and only 19% said they checked the appearance of the pills.

5. “Would you ever insist on getting a specific brand name pill that your doctor had written on a prescription, if it meant paying an extra cost compared to the equivalent generic pill?” 40% of the respondents claimed that they would insist on getting a brand name drug even if it meant paying an extra cost. This tends to support the author’s argument that the main motive of generic manufacturers in engaging in slavish imitation of trade dress is their economic self-interest.

It is not possible to predict with precision the outcome of a truly neutral survey. That said, it is hard to imagine that the results would be any worse, from the point of view of innovative manufacturers, than the CDMA’s own survey commissioned for the purpose of proving a position opposite to that of innovative manufacturers. If such a neutral survey is performed, and the results demonstrate that people do in fact care about the sources of their medication, it is submitted that Health Canada has an obligation to require generic manufacturers to use a different trade

64. It is interesting to compare this survey with the Liefeld-Fenwick survey that was conducted on behalf of the defendants in the Eli Lilly case, where the survey purported to show that only 10% of the PROZAC Aware respondents identified a “half-green and half-whitish yellow capsule” with PROZAC, and that of these only a little more than one-quarter (i.e., 2.7% thought the PROZAC product was made by one company). That same survey, according to the trial judge, found that 55% of the respondents attribute no meaning to the color of capsules being the same: Eli Lilly & Co. v. Novopharm Ltd., [1997] 73 C.P.R. (3d) 371, 397-99 (FCTD).

65. Id.
dress than that of innovative manufacturers, just as they require different trade marks to be used.

VI. CONCLUSION

It is hard to imagine that the Supreme Court would have made the strong pronouncements it did in *Ciba-Geigy*,\(^{66}\) if they intended that only rare cases would merit such reprobation. However, to be fair, many of the post-*Ciba-Geigy* cases have involved standard colors applied to common shapes. What is needed is a neutral scientific survey that tests the public’s perception in relation to drug trade dress. If such a survey shows that a significant number of people who consume pharmaceutical drugs do rely on color and shape to indicate a source they have come to trust, then it surely must follow that allowing slavish imitation of the trade dress allows deception. As Health Canada is charged with preventing deceptive marketing of the drugs it regulates, it should act decisively to prevent slavish imitation in such circumstances.