

COLOUR AND SHAPE: A DIFFICULT PILL TO SWALLOW

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Over the years, it has become commonplace for pharmaceutical companies to apply for and defend trade-mark registrations for the colour and shape of pills. This has resulted in an abundance of jurisprudence which, on the one hand, has held that the colour and shape of a product is, in law, capable of constituting a trade-mark, but on the other hand, has set a high threshold for establishing the distinctiveness¹ of such trade-marks.

The present article does not purport to be an exhaustive review of Canadian case law on the subject. However, it will canvass some of the more recent decisions rendered by the Federal Court of Canada and address the requirements for obtaining the registration of a trade-mark for the colour and shape of pills and defending it successfully.

The notion of distinctiveness constitutes the very foundation of trade-mark law, for without distinctiveness, there is no indication of source, hence no protectable trade-mark right. It is with this legal principle in mind that the Courts have rendered their decisions. Indeed, Section 2 of the *Trade-marks Act*² defines "distinctive" as follows:

"distinctive", in relation to a trade-mark, means a trade-mark that actually distinguishes the wares or services in association with which it is used by its owner from the wares or services of others or is adapted so to distinguish them;

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¹ On the issue of establishing distinctiveness, see also *Oxford Pendaflex Canada Ltd. v. Korr Marketing Ltd.*, (1982) 1 S.C.R. 494 (S.C.C.); *Parke, Davis & Co. v. Empire Laboratories Ltd.*, (1964) S.C.R. 351 (S.C.C.); *Novopharm Ltd. c. Bayer Inc.*, (1999), 3 C.P.R. (4th) 305 (F.C.T.D.), affirmed (2000) 9 C.P.R. (4th) 304 (F.C.A.).

² R.S.C., 1985, c. T-13.

In *Novopharm Ltd. v. Bayer Inc.*³, (hereinafter “Novopharm” and “Bayer”) Bayer had applied for the registration of the trade-mark CIRCLE DESIGN (TMO 657,397), namely a dusty rose colour applied to the whole visible surface of its nifedipine tablets. Novopharm opposed Bayer’s application based on, amongst others, the ground that Bayer’s trade-mark lacked the distinctiveness required to constitute a trade-mark. The Registrar rejected Novopharm’s opposition on the issue of distinctiveness because it was inferred from Bayer’s evidence that, although there were dozens of pink tablets of different sizes on the pharmaceutical market, none had a reputation in Canada. The Registrar further concluded that since there were no other interchangeable products for Bayer’s nifedipine pills, it would be likely for pharmacists and patients to associate the colour and shape of the pills with Bayer’s nifedipine product.

On appeal before the Trial Division of the Federal Court, Novopharm submitted significant additional evidence relating to the crucial issue of the distinctiveness of Bayer’s trade-mark.

Based on all of the evidence, the Trial Judge considered that pink round small tablets were commonplace in the pharmaceutical market. Consequently, Bayer had a heavy burden to discharge in order to prove, on a balance of probabilities, that at the date of Novopharm’s opposition, the appearance of its tablets was associated by “ordinary consumers”, namely patients⁴, physicians and pharmacists, with one source.

The Court found that pharmacists rely on the colour and shape of pills as a “secondary check”, their primary source of identification being the label on the package in which the product is supplied. Furthermore, other evidence also indicated that pharmacists and physicians also identified Bayer’s tablets by appearance, to a very minimal degree, if at all.

It was also inferred from the evidence that patients tended to associate the colour and shape of their pills with their therapeutic effect⁵, rather than with a single source. The Court opined that the evidence suggested that patients were more likely to identify Bayer’s product by its brand name, or manufacturer, rather than by its appearance.

Consequently, the Court reversed the Registrar’s decision, ruling that Bayer had not discharged its onus of proving that its mark was distinctive of its wares.

³ (1999), 3 C.P.R. (4th) 305 (F.C.T.D.), affirmed (2000), 9 C.P.R. (4th) 304 (F.C.A.).

⁴ *Ciba-Geigy Canada Ltd. c. Apotex Inc.*, (1992) 3 S.C.R. 120 (S.C.C.).

⁵ *Eli Lilly & Co. v. Novopharm Ltd.*, (1997), 73 C.P.R. (3d) 371 (F.C.T.D.), affirmed on appeal (2000), 10 C.P.R. (4th) 10 (F.C.A.).

Three subsequent cases also dealt with the question of the distinctiveness of colour and shape of pills as a trade-mark.

In, *Novopharm Ltd. v. Ciba-Geigy Canada Ltd.*⁶ (hereinafter "Ciba"), the Trial Division of the Federal Court was seized with an appeal from a decision of the Registrar accepting Ciba's application pink TABLET DESIGN (TMO 630,536) for a triangular shaped tablet composed of diclofenac sodium

In another case, *Novopharm Ltd. v. Ciba-Geigy Canada Ltd.*⁷, the Trial Division of the Federal Court was also seized with an appeal from a decision of the Registrar accepting Ciba's application pink TABLET DESIGN (TMO 630,537) for a circular shaped tablet composed of diclofenac sodium

In both instances, the issue of distinctiveness was raised before the Registrar as one of the grounds of opposition. The Registrar ruled that, based on the evidence before it, Ciba's trade-marks were distinctive both in respect of their colour⁸ and their shape⁹.

These two cases were simultaneously heard on appeal by the Trial Division of the Federal Court which found that there was no evidence establishing, on a balance of probabilities, that a significant number of consumers, if any at all, associated the appearance of Ciba's pills with a single source. In rendering its decisions, the Court reiterated that it is settled in law that impressive sales figures alone cannot satisfy the burden of proving distinctiveness.

In the third case, *Novopharm v. Astra Aktiebolag*¹⁰, (hereinafter "Astra") Novopharm appealed the Registrar's decision allowing the registration of Astra's trade-mark CAPSULE DESIGN BROWN-PINK (TMO 692,410).

The Federal Court ruled that that Astra's trade-mark was not distinctive in light of evidence that there were a number of well-known, two-toned capsules sold in the pharmaceutical industry, including several capsules with a brown/pink combination of colours. Once again, the Court held that Astra had failed to adduce evidence proving the distinctiveness of its trade-mark.

⁶ (2000) CarswellNat 726 (F.C.T.D.).

⁷ (2000) 6 C.P.R. (4th) 224 (F.C.T.D.).

⁸ (TMO 630,537), *Novopharm Ltd. c. Ciba-Geigy Canada Ltd*, (2000), 6 C.P.R. (4th) 224 (F.C.T.D.), affirmed on appeal (2001), 15 C.P.R. (4th) 327 (F.C.A.). Application for to appeal to the Supreme Court of Canada is pending, having been filed on December 17, 200 (No. 28972).

⁹(TMO 630,536), *Novopharm Ltd. v. Ciba-Geigy Canada Ltd*, (2000) CarswellNat 726 (F.C.T.D.), affirmed on appeal (2001), 15 C.P.R. (4th) 327 (F.C.A.). Application for leave to appeal to the Supreme Court of Canada is pending, having been filed on December 17, 2001 (No. 28972).

¹⁰ (2000), 6 C.P.R. (4th) 16 (F.C.T.D.).

It is worth noting that in all three of these Federal Court rulings, which were upheld by the Federal Court of Appeal¹¹, the Trial Judge reserved harsh words regarding the Registrar's conclusions that the trade-marks in question were distinctive:

In my view, the Registrar failed to apply the established principles of law with respect to the issue of distinctiveness. Indeed, he appears to have had virtually little regard for the legal tenets established by the jurisprudence. In the same manner, his findings of fact can only be considered perverse, given that there was simply no evidence before him to substantiate a finding that the respondent's product has obtained recognition or a reputation in the mind of the consuming public as a result of its appearance of get-up¹².

More recently, in *Astrazeneca AB v. Novopharm Ltd.*¹³, Astra applied to register the trade-mark YELLOW TABLET DESIGN (TMO 783,267) for a tablet containing felodipine, a drug used in the treatment of persons suffering from hypertension. Novopharm opposed the trade-mark application alleging, amongst other grounds, that Astra's trade-mark was not distinctive.

The evidence submitted to the Registrar showed that Astra was the only manufacturer of felodipine. The tablets were packaged in a "blister bubble" sleeve which was inserted in a box marked under the trade-mark PLENDIL. The evidence submitted by Novopharm demonstrated that there were approximately twenty yellow round tablets available on the Canadian market for the treatment of hypertension.

The Federal Court confirmed the Registrar's findings that Astra's mark was not distinctive. The additional evidence adduced before the Federal Court showed that pharmacists primarily checked the markings on the outer and inner packaging which contained Astra's pills. As such, the Court held that it was the packaging which made the wares distinctive, rather than the colour and shape of the pills. Moreover, there was no evidence that pharmacists, physicians or patients identified Astra's pills solely by their appearance¹⁴.

Generally, from the body of case law related to the colour and shape of pills as a trade-mark, there are certain elements which have been deemed by the Courts to be in and of themselves insufficient to substantiate a finding of distinctiveness, namely:

¹¹ *Novopharm Ltd. c. AstraZeneca AB*, (2001), 15 C.P.R. (4th) 327 (F.C.A.). Application for to appeal to the Supreme Court of Canada is pending, having been filed on December 17, 2001 (No. 28972).

¹² See for example: *Novopharm v. Astra Aktiebolag*, (2000), 6 C.P.R. (4th) 16, at 26 (F.C.T.D.).

¹³ (2001) CarswellNat 2420 (F.C.T.D.).

¹⁴ *Apotex Inc. v. Searle Canada Inc.*, (2000), 6 C.P.R. (4th) 26 (F.C.T.D.).

- Showing use of the colour and shape of tablets on the market¹⁵
- Showing that pharmacists recognise the colour and shape of tablets inside their packaging¹⁶
- Showing that the pharmaceutical company is the sole manufacturer of the drug in question in Canada¹⁷
- Showing that there is no interchangeable product for the drug in question¹⁸
- Showing impressive sales figures¹⁹

Case law has consistently held that a pharmaceutical company must clearly establish, on a balance of probabilities, that the colour and shape of its pills have been used to the extent that pharmacists, physicians or patients associate the colour and shape with a single source.

However, from a practical standpoint, it may be quite difficult to meet this heaven burden. The reason is best reflected in the following passage from the Supreme Court of Canada's ruling in *Ciba-Geigy Canada Ltd. c. Apotex Inc.*²⁰:

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

In light of these inherent restrictions faced by the pharmaceutical industry and the requirements of proof set by the Courts on the issue of the colour and shape of pharmaceutical pills as trade-marks, practitioners may have to

¹⁵ *Astrazeneca AB v. Novopharm Ltd.*, (2001) CarswellNat 2420 (F.C.T.D.).

¹⁶ *Id.*

¹⁷ *Novopharm Ltd. v. Bayer Inc.*, (1999), 3 C.P.R. (4th) 305 (F.C.T.D.), affirmed (2000), 9 C.P.R. (4th) 304 (F.C.A.).

¹⁸ *Id.*

¹⁹ *Novopharm v. Astra Aktiebolag*, (2000), 6 C.P.R. (4th) 16 (F.C.T.D.), affirmed on appeal in *Novopharm Ltd. v. AstraZeneca AB*, (2001), 15 C.P.R. (4th) 327 (F.C.A.). See also *Novopharm Ltd. c. Ciba-Geigy Canada Ltd.*, (2000) CarswellNat 726 (F.C.T.D.) and *Novopharm Ltd. v. Ciba-Geigy Canada Ltd.*, (2000), 6 C.P.R. (4th) 224 (F.C.T.D.), affirmed on appeal (2001), 15 C.P.R. (4th) 327 (F.C.A.). An application for leave to appeal to the Supreme Court of Canada is pending, having been filed on December 17, 2001 (No. 28972).

²⁰ (1992) 3 S.C.R. 120 (S.C.C.), (1992), 44 C.P.R. (3d) 289 at 304.

readily caution clients: the high threshold established by the Courts for proving the distinctiveness of such trade-marks could be a difficult pill for them to swallow...

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