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IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Court of Appeal Raises the Bar for Registrability of Trade-marks for Pharmaceutical Appearance

In a seminal 1992 decision (*Ciba-Geigy Canada Ltd. v. Apotex Inc.,* [1992] 3 S.C.R. 120), the Supreme Court of Canada examined the prescription pharmaceutical marketplace in Canada, including the possibility that pharmacists could substitute brands of pharmaceuticals without advising patients, and concluded that "competing laboratories must avoid manufacturing and marketing drugs with such a similar get-up that it sows confusion in the customer's mind."

Despite this decision, the Federal Court of Appeal has since released a series of decisions that have frustrated pharmaceutical companies' attempts to obtain trade-mark registrations for the appearance of their products. On February 4, 2003, the Federal Court of Appeal rendered another such decision in a trade-mark opposition proceeding relating to the appearance of AstraZeneca's PLENDIL (felodipine) 2.5 mg yellow tablets (*AstraZeneca AB v. Novopharm Limited and The Registrar of Trade-marks*, Neutral citation: 2003 FCA 57). The Court affirmed the decision of the trial judge, which in turn affirmed the Trade-marks Opposition Board's decision, refusing AstraZeneca's trade-mark application. In doing so, the Court made findings that will make it very difficult to obtain registration for the appearance of pharmaceutical trade-marks in Canada.

In 1995, AstraZeneca applied for registration of the trade-mark, "a yellow colour applied to the whole of the visible surface of a tablet [shown to be round and biconvex in shape]," in association with "pharmaceutical preparations, namely, felodipine [PLENDIL]."

The only substantive issue for the Court of Appeal was whether AstraZeneca's trade-mark was distinctive. "Distinctive" is defined in the *Trade-marks Act* as: "in relation to a trade-mark, ... 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."

The Court rejected AstraZeneca's argument that the trade-mark was "adapted to distinguish," despite evidence that the appearance of the tablets is "arbitrary," that it is not dependent upon the active ingredient and that it was chosen "for marketing reasons and to be distinctive." The Court found that "there is no showing that the arbitrariness of colour and shape had the effect of distinguishing the appellant's wares from those of others" as "colour alone does not normally possess that quality. Nor would it seem that the combination of colour and shape in this case had that effect in the pharmaceutical products market in Canada."

The Court also rejected AstraZeneca's argument that the trade-mark "actually distinguishes" its wares from the wares of others. The issue here was "whether tablets other than the appellant's 2.5 mg tablets, marketed in an appearance similar to the appellant's tablets on the relevant date, precludes registration of the claimed trade-mark on the basis that those tablets render the appellant's trade-mark non-distinctive."

For the first time, the Court of Appeal squarely considered the issue of relevant wares, i.e. whether tablets relevant to distinctiveness are limited to other tablets that contain the same active ingredient or extend to all other tablets in the pharmaceutical marketplace.

In support of its position that relevant wares are limited to other tablets containing the same active ingredient, AstraZeneca submitted evidence that there was no possibility that some other drug could be substituted for PLENDIL 2.5 mg tablets. AstraZeneca also submitted evidence that "a pharmacist would not be considering any of such yellow tablets [which do not contain felodipine] as none of them could be dispensed pursuant to [sic] prescription which directs 'felodipine'." The Court, however, held that "this evidence suffers from the fact that [the witness] conceded that the pharmacist would not rely solely on colour and shape, but will ensure that other indicators of brand are what they should be for the PLENDIL brand."

The Court concluded that all other tablets are relevant, stating:

> "...it is to be noted that the active ingredient as such is not claimed by the appellant as the trade-mark. The trade-mark sought to be registered is the colour and shape, or appearance of the 2.5mg tablets that happens to contain the active ingredient. Thus, the appellant had to show that through use over time the colour and shape of its tablets actually distinguishes them from tablets of other manufacturers."

The Court's finding can be seen as a departure from the decision of the Supreme Court of Canada: the mere fact of the availability of other yellow tablets in the marketplace does not prevent a patient from using the appearance of AstraZeneca's PLENDIL to confirm that he or she has received the AstraZeneca brand of felodipine, rather than a generic substitute.

The Court's finding is also significant for another reason: given the limited number of choices available for colour and shape combinations for pharmaceuticals, it will be difficult for pharmaceutical manufacturers to adopt appearances that will distinguish their products from those of all other manufacturers.

Nancy P. Pei

Supreme Court of Canada Leave Applications

Apotex Inc. v. Parke-Davis (**atorvastatin calcium** (**LIPITOR**)), January 17, 2003

On January 17, 2003, Apotex filed an application seeking leave to appeal from a decision of the Federal Court of Appeal. The Court had allowed Parke-Davis' appeal of the motions judge's decision, which dismissed the Parke-Davis' application for an Order of prohibition. Warner-Lambert had dedicated Patent No. 1,268,768 (the 768 patent) to the public and Apotex relied on this dedication in its Notice of Allegation (NOA). The Court of Appeal accepted Parke-Davis' arguments that Apotex' NOA was of no legal effect because there was no evidence that Apotex had filed a New Drug Submission (NDS) by the date of the hearing and that the dedication of the patent to the public was a mistake.

Appeal decision (*For a printer friendly version, please scroll down to the end of the Judgment)

Trial Division decision

Apotex v. Merck (**enalapril maleate** (**VASOTEC**)), February 13, 2003

Supreme Court of Canada dismisses Apotex' leave application from decision of Federal Court of Appeal, dismissing appeal from decision of motions judge, granting Merck's motion for summary judgment in patent infringement action relating to enalapril. Motions judge had based his decision on doctrine of *res judicata.*

Appeal decision (*For a printer friendly version, please scroll down to the end of the Judgment)

Trial Division decision (*For a printer friendly version, please scroll down to the end of the Judgment)

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Apotex v. AstraZeneca (**omeprazole capsules** and **omeprazole magnesium tablets** (**LOSEC**)), February 12, 2003

Judge dismisses Apotex' appeal from Order of Prothonotary, which stayed the proceeding until the final disposition of a proceeding currently before the Ontario Superior Court of Justice. Both cases deal with copyright in drug product monographs.

Motions judge's decision (*For a printer friendly version, please scroll down to the end of the Judgment)

Prothonotary's decision

Apotex v. AstraZeneca (**omeprazole magnesium tablets** (**LOSEC**)), February 18, 2003

Court of Appeal dismisses Apotex' motion for leave to file new evidence in appeal from decision of motions judge, granting Order of prohibition. The new evidence consisted of a patent, accompanied by the affidavit of a lawyer. Court was not persuaded that existence of the patent could not have been ascertained by reasonable diligence. Court also finds that the patent, merely as explained by a lawyer, in absence of expert evidence, would not be very helpful to the Court on appeal.

Full Judgment (*For a printer friendly version, please scroll down to the end of the Judgment)

New Court Proceedings

New NOC Proceedings

Medicine:	**levofloxacin (LEVAQUIN)**
Applicants:	Janssen-Ortho Inc and Daiichi Pharmaceutical Co Ltd
Respondents:	Novopharm Limited and The Minister of Health
Date Commenced:	February 7, 2003
Comment:	Application for Order of prohibition until expiry of Patent No. 1,304,080. Novopharm alleges non-infringement and invalidity.

Medicine:	**paroxetine (PAXIL)**
Applicants:	GlaxoSmithKline Inc and SmithKline Beecham PLC
Respondents:	Novopharm Limited and The Minister of Health
Date Commenced:	February 11, 2003
Comment:	Application for Order of prohibition until expiry of Patents Nos. 1,287,060; 2,178,637; 2,214,575; 2,168,829; 2,210,023; and 2,211,522. Novopharm alleges invalidity and non-infringement.

Other New Proceedings

Medicine:	**medroxyprogesterone acetate tablets (APO-MEDROXY)**
Applicant:	Apotex Inc
Respondent:	The Minister of Health
Date Commenced:	February 7, 2003
Comment:	Application for Order setting aside the decision of the Minister to deny Apotex' second level appeal against the issuance of a notice of non-compliance withdrawal in respect of its Abbreviated New Drug Submission (ANDS) for Apo-Medroxy tablets.

Health Canada News

Health Canada has published a Draft Policy entitled "Interpretation of 'Identical Medicinal Ingredient'," whose purpose is as follows:

> to delineate the guiding principles that will be used to determine if two medicinal ingredients with the same active moiety are considered "identical" or "non-identical." This is used in establishing the pharmaceutical equivalence of dosage forms within the meaning of the term "identical medicinal ingredient" as mentioned in Section C.08.001 of the *Food and Drug Regulations*.

We will track the progress of this policy and report on developments in future issues of *Rx IP Update.*

Draft Policy

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