



IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Registrability of Trade-marks for Appearance of Pharmaceuticals: Where are we now?

Test for distinctiveness in opposition proceedings requires clarification.

Canadian law concerning the distinctiveness of the appearance of pharmaceuticals remains unsettled as demonstrated by two recent decisions by the Trade-marks Opposition Board relating to the appearance of Pfizer's **ZOLOFT** (yellow and white capsules) and **NORVASC** (white octagonal tablets) (see links on pages 3 and 4 of this issue). Pfizer successfully resisted the first opposition, but failed in the second.

In the ZOLOFT opposition, the Board found that Novopharm had failed to establish that yellow and white capsules were common to the trade as of the relevant date, so as to render the appearance of ZOLOFT non-distinctive.

In the NORVASC opposition, the application was rejected as the drawing did not provide an accurate representation of the trade-mark. Furthermore, with respect to distinctiveness, the Board found that the evidence failed to establish that the trade-mark is distinctive because Pfizer had not clearly established that a significant number of physicians, pharmacists or patients use the trade-mark in choosing whether to prescribe, dispense, or request Pfizer's amlodipine.

The Board made several surprising findings. First, there was no debate as to whether or not the opponent had met its evidential burden, although very few of the white tablets relied upon were octagonal in shape. Second, the Board concluded that the relevant market was the *general* pharmaceutical marketplace, rather than the narrower markets of therapeutic class or interchangeable medications. Finally, the Board suggested that only evidence that pharmacists use colour and shape as a *primary* check when dispensing would be relevant evidence of distinctiveness.

The Board also considered that since the packaging indicated that the *parent* company owned the NORVASC trade-mark, the NORVASC product was considered to be a third party tablet over which the applicant's wares could not be distinguished.

Despite these findings, the test for distinctiveness remains to be settled by the courts. As reported in the September issue of *RxIP Update*, AstraZeneca was recently successful in the Federal Court Trial Division in affirming the Opposition Board's dismissal of two oppositions. The Court, however, did not address the issue of distinctiveness. As well, in the NORVASC opposition, the Board relied upon another Trial Division decision involving Ciba-Geigy (now Novartis) in which the application was successfully opposed. However, appeals of this decision and two companion decisions involving AstraZeneca were heard on June 12, 2001. The Court of Appeal's decisions should clarify the law in this area. In the meantime, while the law of distinctiveness in the pharmaceuticals field continues to evolve, it is clear that there are significant benefits to obtaining trade-mark registrations for the appearance of pharmaceutical products.

Nancy P. Pei

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Patented Medicines (Notice of Compliance) Regulations

Parke-Davis v. Apotex (atorvastatin calcium (LIPITOR)), August 22, 2001

Judge dismisses application for prohibition order. Allegation of invalidity not invalid for failure of Apotex to have filed new drug submission. Notice of allegation also not invalid for failure to make allegation with respect to all patents on patent register; other patent may be subject of separate NOA. Dedication of a patent to the public is proper ground of allegation. Evidence insufficient to establish that dedication was not intentional. Judge not satisfied that dedication could be revoked.

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

Nu-Pharm Inc v. Minister of Health (enalapril maleate (VASOTEC)), August 31, 2001

Merck added as a party to Nu-Pharm's application for order declaring that Minister had no authority to declare that its sale or advertisement of Nu-Enalapril is unlawful. Nu-Pharm is arguing that Nu-Enalapril was not a New Drug and hence an NOC was not required for lawful sale. Merck has a direct, pressing and legitimate interest in these proceedings as they relate specifically to Merck's patent and its Canadian sales of Vasotec. Nu-Pharm has appealed.

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

Bayer v. Apotex (ciprofloxacin (CIPRO)), September 13, 2001

Court of Appeal affirms Trial Judge's prohibition order. Trial Judge had rejected Apotex' allegation that Bayer's patents were invalid by virtue of the statutory foreign patent bar (patented more than two years before Canadian filing date). Court finds no basis to interfere with Trial Judge's finding that the invention in the Canadian patent was not the same as that in the Chilean patent.

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

Pfizer Canada Inc and Pfizer Corporation v. Apotex Inc and The Minister of National Health and Welfare; Pfizer Canada Inc and Pfizer Corporation v. Nu-Pharm Inc and The Minister of National Health and Welfare (fluconazole (DIFLUCAN)), September 27, 2001

Supreme Court of Canada denies Pfizer leave to appeal decisions of the Federal Court of Appeal. Trial Judges had dismissed separate applications for prohibition orders and subsequently, Minister issued NOCs to Apotex and to Nu-Pharm. Court of Appeal dismissed Pfizer's appeals on the basis that the appeals were moot because of issuance of NOCs and, possibly, expiry of 30-month statutory stay.

Other Decisions

Baker Petrolite v. Canwell Enviro-Industries, August 15, 2001

Non-pharmaceutical subject-matter, but of interest to pharmaceutical patentees. First decision relating to a "new-Act" patent. Patent valid and infringed. Trial Judge affirms Mr. Justice Lederman's test for obviousness in *Bayer v. Apotex*, that to be obvious, "it must be something that would occur directly [to the notional skilled worker] ...without the necessity of his having to do any experimenting or serious thought, or research" [paras. 94-98]. First case to consider reasonable compensation for damages from date of laying open of patent to date of issue - as plaintiffs had not proven damages by way of evidence, Trial Judge awards nominal compensation only [paras. 168-171]. Canwell has appealed.

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

Novartis v. Novopharm (diclofenac sodium slow-release tablets (VOLTAREN SR)), August 28, 2001

Court of Appeal dismisses Novartis' appeal of Order permitting a reference on damages pursuant to an undertaking, as a result of an interlocutory injunction dissolved for delay. Novartis subsequently discontinued action. Eleven months later, Novopharm brought motion for reference. Court finds that Motions Judge had given sufficient weight to all relevant circumstances.

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

Novartis v. Novopharm (diclofenac sodium slow-release tablets (VOLTAREN SR)), August 30, 2001

Trial Judge affirms decision of Prothonotary, refusing to grant a restricted access confidentiality order in a reference to determine the nature and quantum of damages pursuant to an undertaking where an interlocutory injunction was dissolved for delay. Novopharm has appealed.

[Full Judgment](#)

Opposition by Novopharm to application for trade-mark Zoloft Capsule Design filed by Pfizer Canada (sertraline capsules (ZOLOFT)), September 3, 2001

Trade-marks Opposition Board rejects opposition to registration of trade-mark relating to appearance of Zoloft capsules. For more information, please refer to the article on page one of this newsletter.

[Full Decision](#)

Opposition by Novopharm to application for trade-mark Norvasc Tablet Design filed by Pfizer Canada (amlodipine tablets (NORVASC)), September 3, 2001

Trade-marks Opposition Board refuses application for registration of trade-mark relating to appearance of Norvasc tablets. For more information, please refer to the article on page one of this newsletter.

[Full Decision](#)

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	Diltiazem hydrochloride extended release capsules (CARDIZEM CD)
Applicants:	Biovail Corporation and Galephar PR Inc
Respondents:	The Minister of National Health and Welfare and RhoxalPharma Inc
Date Commenced:	September 12, 2001
Comment:	Application for an Order of prohibition until expiry of Patent No 2,111,085.

Medicine:	Domperidone maleate (MOTILIUM)
Plaintiff:	Apotex Inc
Defendants:	The Minister of Health and The Attorney General of Canada
Date Commenced:	September 21, 2001
Comment:	Action for damages suffered by reason of Minister's refusal to issue NOC for Apo-Domperidone. Although 45-day period with respect to second notice of allegation had expired, Minister refused to issue NOC in view of previous order of prohibition.

Medicine:	Acyclovir (ZOVIRAX)
Plaintiff:	Apotex Inc
Defendants:	The Wellcome Foundation Limited and GlaxoSmithKline Inc
Date Commenced:	September 21, 2001
Comment:	Action for damages suffered by reason of commencement of prohibition proceedings or profits, including claim for damages for unjust enrichment.

Other New Proceedings

Medicine: **Etanercept (ENBREL)**
Applicant: Immunex Corporation
Respondent: Canada (Minister of Health, Health Protection Branch)
Date Commenced: September 4, 2001
Comment: Application for review of Access to Information Act decision to disclose information pertaining to the approval of Enbrel.

Medicine: **Vitamins**
Plaintiffs: Novopharm Ltd and 34071 BC Ltd
Defendants: F Hoffmann-LaRoche Ltd, et al
Date Commenced: September 4, 2001
Comment: Ontario Court action for damages arising from alleged price-fixing of bulk vitamins against a number of suppliers.

Medicine: **Nizatidine (AXID)**
Plaintiffs: Eli Lilly and Company, Eli Lilly Canada Inc
Defendants: Apotex Inc and Novopharm Limited
Date Commenced: September 25, 2001
Comment: Action for infringement of Patent Nos 1,217,486 and 2,069,055.

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