



Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

1

Patent for
Controlled-Release
Tablet Found
Ineligible for
Listing on Patent
Register

Patent for Controlled-Release Tablet Found Ineligible for Listing on Patent Register

On August 22, 2005, a Judge dismissed Biovail's application for judicial review of the Minister's decision that Biovail's patent was ineligible for listing on the Patent Register (*Biovail v. Minister of Health (2005 FC 1135)*). The patent contained claims for a controlled release composition, one of which made specific mention of the medicines at issue, bupropion (active ingredient in **WELLBUTRIN SR**) and diltiazem hydrochloride (active ingredient in **TIAZAC XC**). The Judge found that the patent related to a drug delivery system, and not to a particular medicine or use of a medicine, and therefore held that the Minister was correct to not list the patent on the Patent Register:

As I see it, Biovail has patented a formulation for a delivery system that can be used for many different medicines [indicating earlier in the decision that there are 41 different potential active substances named within the patent's claims]. True, the tablet it has designed is unlike those in Glaxo [*GlaxoSmithKline v. The Minister of Health (2005 FCA 197)*] or Pfizer [*Pfizer v. The Minister of Health (2004 FC 370)*], above. Biovail's tablet involves mixing an active ingredient with other substances, not inserting an active ingredient into a mechanical capsule or shielding it within inactive layers and walls. Still, the patent's paramount purpose clearly is to protect the delivery system, not the payload.

This decision represents yet a further tightening of eligibility requirements for formulation patents. Biovail has not appealed the decision to date, but may do so as of right.

2

Patented
Medicines Prices
Review Board
(PMPRB) Matters

4

Trade-mark
Opposition Board
Decisions

Supreme Court of Canada Leave Applications

Pharmascience v. Option Consommateurs; Apotex v. Option Consommateurs; Genpharm v. Option Consommateurs, August 25, 2005

Leave has been denied. Pharmascience, Apotex and Genpharm had filed applications for leave to appeal decisions of the Quebec Court of Appeal in a class action. The claimants sought damages representing the value of reductions the claimants would have obtained in their premiums, deductibles and co-insurance if the prices of medicines had excluded the benefits given to pharmacists. The Court of Appeal had declared that articles 1002 and 1003 of the Quebec Civil Code relating to authorization of class actions were constitutionally valid and that the Superior Court had jurisdiction to hear the class action.

Court of Appeal Decisions:

(2005 QCCA 437) (English only)

(2005 QCCA 438) (French only)

(2005 QCCA 439) (French only)

Patented Medicines Prices Review Board (PMPRB) Matters

The PMPRB has issued an Advisory Note relating to adefovir dipivoxil (HEPSERA), manufactured by Gilead. The Note provides information on the price review process.

Advisory Note

The PMPRB has accepted a Voluntary Compliance Undertaking (VCU) from Novartis for nateglinide (STARLIX).

VCU Notice

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Apotex v. Eli Lilly (nizatidine (AXID, APO-NIZATIDINE)), June 17, 2005

Judge allows Lilly's appeal and dismisses Apotex's appeal. In an action for damages pursuant to the *Regulations*, a Prothonotary had required Eli Lilly and Company (patentee) and Eli Lilly Canada Inc. (the Canadian company) to produce further and better affidavits of documents relating to, among other things, Apotex's allegations of control over the Canadian company by the patentee.

Judge sets aside the Prothonotary's Order requiring the defendants to list documents relating to the scope and intention of the *Regulations*. Judge also finds that the Prothonotary was not clearly wrong in denying Apotex's motion requiring the defendants to list documents detailing the day-to-day operations of the defendants, including relating to whether a particular drug product will be formulated in Canada, and the source and defendants' inter-company price. Apotex has appealed.

Prothonotary's Decision

Applications Judge's Decisions: [Apotex Appeal](#) [Lilly Appeal](#)

Abbott v. Canada (Minister of Health) (lansoprazole (PREVACID)), July 15, 2005

Judge dismisses appeals by Abbott and Novopharm. A Prothonotary had granted a protective Order regarding some portions of Novopharm's abbreviated new drug submission (ANDS), which Novopharm had been required to produce pursuant to section 6(7) of the *Regulations*. While section 6(8) provides that any documents produced pursuant to section 6(7) shall be treated confidentially, Judge finds that the test for the grant of a protective Order must still be met.

Full Judgment (2005 FC 989)

Novopharm v. Pfizer (azithromycin (ZITHROMAX)), August 9, 2005

Court of Appeal allows Novopharm's appeal and sets aside a prohibition Order. The Judge had granted an Order prohibiting the Minister from issuing a notice of compliance (NOC) to Novopharm on the basis that its notice of allegation (NOA) was deficient. The NOA had not put into play all aspects of the non-infringement issue, specifically whether the dihydrate (the claimed hydrate form) would be present as an intermediate in the manufacture of Novopharm's product. The Court of Appeal reversed the decision, finding "[t]he legal test of adequacy does not require Novopharm to anticipate all possible grounds of infringement", and that Pfizer had not proven that the NOA was unjustified with respect to non-infringement.

Court of Appeal Decision (2005 FCA 270)

Applications Judge's Decision (2004 FC 1633)

Abbott v. Canada (Minister of Health) (clarithromycin (BIAXIN)), August 10, 2005

In separate decisions, a Judge dismisses two applications by Abbott for Orders prohibiting the Minister from issuing an NOC to Ratiopharm. In 2005 FC 1095, the allegation of non-infringement was successful. In 2005 FC 1093, the allegation of invalidity was successful with respect to one of the patents, and allegations of non-infringement were successful with respect to two other patents. Judge finds that use of a claimed product during production as an intermediate is not infringement for the purpose of the *Regulations*.

Full Judgment (2005 FC 1093)

Full Judgment (2005 FC 1095)

Other Decisions

Alticor v. Nutravite Pharmaceuticals (NUTRILITE and NUTRAVITE vitamins), August 9, 2005

Court of Appeal dismisses Alticor's appeal. A Trial Judge had dismissed Alticor's claim for infringement of its NUTRILITE trade-mark.

Court of Appeal Decision (2005 FCA 269)

Motions Judge's Decision (2004 FC 235)

Trade-mark Opposition Board Decisions

Novopharm v. Purdue Pharma (RED COLOURED ELONGATE SHAPED TABLET DESIGN, application no. 804,384) (morphine sustained release tablet (MS CONTIN)), May 6, 2005

Novopharm v. Purdue Pharma (GREY COLOURED CIRCULAR SHAPED TABLET DESIGN, application no. 804,385) (morphine sustained release tablet (MS CONTIN)), May 6, 2005

Novopharm v. Purdue Pharma (PURPLE COLOURED CIRCULAR SHAPED TABLET DESIGN, application no. 804,387) (morphine sustained release tablet (MS CONTIN)), May 6, 2005

Novopharm v. Purdue Pharma (GREEN COLOURED CIRCULAR SHAPED TABLET DESIGN, application no. 804,388) (morphine sustained release tablet (MS CONTIN)), May 6, 2005

Novopharm and Apotex v. Purdue Pharma (ORANGE COLOURED CIRCULAR SHAPED TABLET DESIGN, application no. 889,075) (morphine sustained release tablet (MS CONTIN)), May 13, 2005

Board refuses Purdue's applications to register trade-marks consisting of the colour red, grey, purple, green or orange applied to the whole of the visible surface of the tablet, in association with sustained release morphine. In each decision, the Board held the oppositions successful on the ground of non-distinctiveness. In the grey, purple and green cases, the Board further found that the applicant had not shown that the marks had been used in association with the wares since the date claimed. Novopharm had argued that the evidence did not indicate that the tablets were shown to consumers at the time of transfer.

Due to the large file size of the PDF versions of these decisions, please email us at rxip.update@smart-biggar.ca if you wish to obtain a copy.

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	risperidone oral solution (RISPERDAL)
Applicants:	Janssen-Ortho Inc and Janssen Pharmaceutica NV
Respondents:	Pharmascience Inc and The Minister of Health
Date Commenced:	July 21, 2005
Comment:	Application for Order of prohibition until expiry of Patents Nos 1,256,867 and 2,194,564. Pharmascience alleges non-infringement.

Medicine: **diltiazem hydrochloride (TIAZAC)**
Applicants: Biovail Corporation (dba Biovail Pharmaceuticals Canada), Laboratoires des Produits Ethiques Ethypharm; and Galephar PR Inc
Respondents: Apotex Inc and The Minister of Health
Date Commenced: July 21, 2005
Comment: Application for Order of prohibition until expiry of Patents Nos 2,111,085 and 2,242,224. Apotex alleges non-infringement and invalidity with respect to the '085 patent, and non-infringement with respect to the '224 patent.

Medicine: **omeprazole (LOSEC)**
Applicants: AstraZeneca AB and AstraZeneca Canada Inc
Respondents: Apotex Inc and The Minister of Health
Date Commenced: July 25, 2005
Comment: Application for Order of prohibition until expiry of Patent No 2,284,470. Apotex alleges non-infringement and invalidity.

Medicine: **omeprazole (LOSEC)**
Applicant: AstraZeneca AB and AstraZeneca Canada Inc
Respondents: Apotex Inc and The Minister of Health
Date Commenced: July 26, 2005
Comment: Application for Order of prohibition until expiry of Patent No 2,186,037. Apotex alleges non-infringement and invalidity.

Medicine: **sildenafil citrate (VIAGRA)**
Applicant: Pfizer Canada Inc and Pfizer Ireland Pharmaceuticals
Respondents: Apotex Inc and The Minister of Health
Date Commenced: July 28, 2005
Comment: Application for Order of prohibition until expiry of Patent No 2,163,446. Apotex alleges invalidity.

Medicine: **raloxifene hydrochloride (EVISTA)**
Applicant: Eli Lilly Canada Inc
Respondents: Eli Lilly and Company, Apotex Inc and The Minister of Health
Date Commenced: August 5, 2005
Comment: Application for Order of prohibition until expiry of Patent No 2,101,356. Apotex alleges non-infringement and invalidity.

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Other New Proceedings

Medicine: omeprazole (APO-OMEPRAZOLE, LOSEC)
Applicant: Apotex Inc
Respondents: The Minister of Health, The Attorney General of Canada, and AstraZeneca Canada Inc
Date Commenced: August 19, 2005
Comment: Application for Order compelling the Minister to reissue an NOC in respect of Apo-Omeprazole 20 mg capsules, originally issued on January 27, 2004. Apotex pleads that Patents Nos 2,186,037; 2,284,470; and 2,180,535 were not listed on the Patent Register in a manner requiring Apotex to deliver an NOA under the *Regulations*, including for the reason that the patents were listed in connection with a supplementary new drug submission (SNDS).

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