



Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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Apotex's Motion for Stay of Lisinopril Decision Dismissed

As reported in our [May 2006](#) issue of *Rx IP Update*, a Federal Court Judge held that the patent covering lisinopril was valid and infringed (*Merck and AstraZeneca v. Apotex*, [2006 FC 524](#)). On May 25, 2005, a Judge of the Federal Court of Appeal dismissed Apotex's motion for a stay of this decision, finding that "Apotex' evidence on the question of irreparable harm is too flimsy and speculative to warrant granting a stay". Merck and AstraZeneca had also offered an undertaking as to damages, should Apotex's appeal be allowed (*Apotex v. Merck and AstraZeneca*, [2006 FCA 198](#)).

Supreme Court of Canada Matters

AstraZeneca v. Apotex and Manitoba (Apo-Omeprazole; LOSEC), April 13, 2006

AstraZeneca has filed an application for leave to appeal a decision of the Manitoba Court of Appeal. The Manitoba decision reversed a Judge's decision declaring a *Manitoba Drug Interchangeability Formulary Regulation* invalid. That Regulation had listed Apo-Omeprazole on the formulary as fully interchangeable with LOSEC. The Court of Appeal decision was reported in our [February 2006](#) issue of *Rx IP Update*.

Sanofi-Aventis Canada Inc. v. Apotex Inc. (ramipril (ALTACE)), April 18, 2006

Sanofi-Aventis has filed an application for leave to appeal a decision of the Federal Court of Appeal, which dismissed its appeal of an Applications Judge's decision dismissing its prohibition application. The Court of Appeal decision was reported in our [February 2006](#) issue of *Rx IP Update*.

Jocelyn Binet v. Pharmascience Inc., May 9, 2006

As reported in the [November 2005](#) issue of *Rx IP Update*, the Supreme Court of Canada granted leave to Jocelyn Binet to appeal a judgment of the Quebec Court of Appeal. The syndic of pharmacists began an inquiry into allegations that financial benefits were being accepted from manufacturers of generic drugs, contrary to the professional ethics of pharmacists. The issue related to whether Pharmascience and its co-founder and chairman should be required to provide all documents necessary for the inquiry. The Court of Appeal held that the application of the syndic's power was limited to professionals themselves, whereas the two persons were third parties and therefore reversed the lower Court's Order for production.

The appeal was heard on May 9, 2006 and was taken under reserve by the Court.

Patented Medicine Prices Review Board (PMPRB) Matters

Discussion Guide for the Consultations on the Board's Excessive Price Guidelines

The PMPRB has released a Discussion Guide for the Consultations on the Board's Excessive Price Guidelines ("Guidelines") and invites comments to be submitted by **August 25, 2006**. The purpose of the Discussion Guide is to "obtain written feedback on specific elements of the Guidelines used to determine whether the prices of patented medicines are excessive, including ideas on possible options for change." Three specific Guideline issues have been identified:

- whether the current approach to the categorization of new patented medicines is appropriate;
- whether the current approach used to review the introductory prices of new patented medicines is appropriate; and
- whether the Board's Guidelines should address the direction in the Patent Act to consider "any market".

Discussion Guide

PMPRB to Strictly Enforce Filing Deadlines

In its April 2006 newsletter, the PMPRB advised that it will now more strictly enforce filing deadlines and states:

Starting with the regulatory filing period January to June 2006, the failure to file procedure will further change for patentees who completely fail to file any of the Form 2 (Block 4) information or any of the Form 2 (Block 5) information. In 2007, this change will also apply to a complete failure to file Form 3 information by March 31. These patentees will no longer be provided a further opportunity to provide the required information; instead Board Staff will immediately request that the Board issue an Order requiring the patentee to file the specified information.

Article on Filing Requirements (from April 2006 PMPRB newsletter)

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Abbott Laboratories v. Apotex (clarithromycin (BIAXIN BID)), March 15, 2006

Judge disqualifies expert, Dr. Jack Dunitz, from appearing as a witness in a proceeding and strikes his evidence from the record which had been filed on behalf of Apotex. Judge finds that the expert had knowingly received confidential information from Abbott with the expectation that it would be maintained in confidence and that there was a risk that the confidential information would be disclosed. Apotex has appealed.

Full Judgment ([2006 FC 340](#))

Aventis v. Novopharm (ramipril (ALTACE)), May 8, 2006

Prothonotary dismisses Novopharm's motion to dismiss Aventis' prohibition application. Novopharm had argued that the proceeding should be dismissed because the issue of whether there was a sound prediction had already been decided (*Aventis v. Apotex*, a case involving a different second person, 2005 FC 1283, affirmed 2006 FCA 64). Prothonotary dismisses the appeal on the basis that the prior decision is the subject of a Supreme Court leave application. Novopharm has appealed.

Order

Abbott Laboratories v. Ratiopharm and Minister of Health (clarithromycin (BIAXIN BID)), May 18, 2006

Court of Appeal dismisses Abbott's appeal of the dismissal by a Judge of its prohibition application. The Court, however, disagreed with the Judge that infringement by production of an intermediate product is not infringement under the *Patented Medicines (Notice of Compliance) Regulations* ("Regulations"), finding "making, constructing, using or selling" in the *Regulations* is broad enough to include the use of the patented substance as an intermediate, regardless of whether it is actually found in the finished product.

Court of Appeal Decision (2006 FCA 187)

Applications Judge's Decision (2005 FC 1093)

Other Decisions

Apotex v. Alberta (Minister of Health and Wellness) (Apo-Gabapentin, NEURONTIN), April 26, 2006

Apotex sued the Crown for damages arising out of conduct of the Minister and an expert committee which makes recommendations to the Minister as to the addition of drugs on the provincial drug benefit list. The Alberta Court of Appeal upholds the Judge's decision to order members of the expert committee to be produced for discovery, but allows the Minister's appeal with respect to notes of individual members and orders such notes need not be produced.

Full Judgment (2006 ABCA 0133)

Johnson & Johnson v. Boston Scientific; Johnson & Johnson v. Arterial Vascular Engineering (stent), May 23, 2006

Court of Appeal allows Johnson & Johnson's appeals and sets aside summary judgments in the infringement actions. The Defendants' motions for summary judgment were granted by the Judge on the basis that the patents were invalid for deficient fee payments. The Court of Appeal did not deal with the Dutch Industries decision on which the motions were granted; rather, the Court found that section 78.6(1) of the *Patent Act* (which came into force on February 1, 2006) effectively meant that there was no deficiency in the payment of the application fees. The Court held that the legal effect of section 78.6(1) is that top-up payments made for the patents in issue in this case must be treated for the purposes of the *Patent Act* as though they had been made on the date of the original deficient payments.

Court of Appeal Decision (2006 FCA 195)

Motions Judge's Decision (2004 FC 1672)

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: lansoprazole (PREVACID)
Applicants: Abbott Laboratories Limited and TAP Pharmaceuticals Inc
Respondents: Takeda Pharmaceutical Company Limited, Apotex Inc, and The Minister of Health
Date Commenced: April 25, 2006
Court File No: T-724-06
Comment: Application for Order of prohibition until expiry of Takeda's Patent No 1,312,548. Apotex alleges non-infringement, that the patent is not eligible for listing on the Patent Register, and that the statement made pursuant to section 4(2)(c) is false.

Medicine: Product "X"
Applicant: Apotex Inc
Respondent: The Minister of Health
Date Commenced: April 27, 2006
Court File No: T-737-06
Comment: Application for a declaration that the *Regulations* do not apply to Apotex's ANDS for Product "X".

Medicine: lansoprazole (PREVACID)
Applicants: Abbott Laboratories Limited and TAP Pharmaceuticals Inc
Respondents: Takeda Pharmaceutical Company Limited, Apotex Inc and The Minister of Health
Date Commenced: April 27, 2006
Court File No: T-738-06
Comment: Application for Order of prohibition until expiry of Takeda's Patent No 2,286,753. Apotex alleges non-infringement, invalidity, that the patent is not eligible for listing on the Patent Register, and that the statement made pursuant to section 4(2)(c) is false.

Medicine: Product "Y"
Applicant: Apotex Inc
Respondent: The Minister of Health
Date Commenced: May 2, 2006
Court File No: T-750-06
Comment: Application for a declaration that the *Regulations* do not apply to Apotex's ANDS for Product "Y".

Medicine: **modafinil (ALERTEC)**
Applicants: Shire Biochem Inc and Cephalon Inc
Respondents: Apotex Inc and The Minister of Health
Date Commenced: May 3, 2006
Court File No: T-756-06
Comment: Application for Order of prohibition until expiry of Patent No 2,201,967. Apotex alleges invalidity.

Medicine: **amlodipine (NORVASC)**
Applicants: Pfizer Canada Inc and Pfizer Inc
Respondents: Cobalt Pharmaceuticals Inc and The Minister of Health
Date Commenced: May 4, 2006
Court File No: T-768-06
Comment: Application for Order of prohibition until expiry of Patents Nos 1,321,393 and 2,355,493. Cobalt alleges invalidity ('393 and '493 patents), that the '493 patent is ineligible for listing on the Patent Register, and non-infringement ('493 patent).

Medicine: **lansoprazole (PREVACID)**
Applicants: Abbott Laboratories Limited and TAP Pharmaceuticals Inc
Respondents: Takeda Pharmaceutical Company Limited, Novopharm Limited and The Minister of Health
Date Commenced: May 5, 2006
Court File No: T-773-06
Comment: Application for Order of prohibition until expiry of Takeda's Patent No 2,286,753. Novopharm alleges non-infringement, invalidity, and that the patent is not properly listed on the Patent Register.

Medicine: **galantamine (REMINYL)**
Applicants: Janssen-Ortho Inc and Janssen Pharmaceutica NV
Respondents: Cobalt Pharmaceuticals Inc and The Minister of Health
Date Commenced: May 5, 2006
Court File No: T-774-06
Comment: Application for an Order of prohibition until expiry of Patent No 2,310,950. Cobalt alleges non-infringement, invalidity and that the patent is not eligible for listing on the Patent Register.

Medicine: **ciprofloxacin intravenous (CIPRO IV)**
Applicants: Bayer Healthcare AG and Bayer Inc
Respondents: Sandoz Canada Incorporated and The Minister of Health
Date Commenced: May 5, 2006
Court File No: T-775-06
Comment: Application for an Order quashing the notice of compliance (NOC) granted to Sandoz on April 18, 2006 and a declaration that the Minister failed to require Sandoz to comply with section 5 of the *Regulations*.

Medicine: **azithromycin (ZITHROMAX)**
Plaintiff: Apotex Inc
Defendant: Pfizer Canada Inc
Date Commenced: May 12, 2006
Court File No: T-825-06
Comment: Action brought pursuant to section 8 of the *Regulations* for damages allegedly suffered by Apotex by reason of initiation of a prohibition proceeding by Pfizer or, in the alternative, an accounting of profits.

Medicine: **fenofibrate (LIPIDIL SUPRA)**
Applicant: Apotex Inc
Respondent: Fournier Pharma Inc
Date Commenced: May 12, 2006
Court File No: T-826-06
Comment: Action brought pursuant to section 8 of the *Regulations* for damages allegedly suffered by Apotex by reason of initiation of a prohibition proceeding by Fournier or, in the alternative, an accounting of profits.

Medicine: **amlodipine (NORVASC)**
Applicants: Pfizer Canada Inc and Pfizer Inc
Respondents: Novopharm Limited and The Minister of Health
Date Commenced: May 12, 2006
Court File No: T-828-06
Comment: Application for Order of prohibition until expiry of Patent No 2,355,493. Novopharm alleges non-infringement, invalidity, that the patent is not eligible for listing on the Patent Register.

Medicine: **valacyclovir (VALTREX)**
Applicants: GlaxoSmithKline Inc and The Wellcome Foundation Limited
Respondents: Pharmascience and The Minister of Health
Date Commenced: May 15, 2006
Court File No: T-833-06
Comment: Application for Order of prohibition until expiry of Patents Nos 1,258,149 and 1,340,083. Pharmascience accepts that its NOC will not issue until the '149 patent expires and alleges non-infringement, invalidity, and that the patent is not properly listed on the Patent Register with respect to the '083 patent.

Other Proceedings

Medicine: **mixed salts amphetamines (ADDERALL XR)**
Applicant: Shire Biochem Inc
Respondents: Patented Medicine Prices Review Board and Attorney General of Canada
Date Commenced: April 19, 2006
Court File No: T-678-06
Comment: Application for a declaration that sections 83-86 and the words "in any proceedings under s. 83" in section 87(1) of the *Patent Act* are *ultra vires* the Parliament of Canada and that the PMPRB be prohibited from proceeding with a hearing concerning the price of ADDERALL XR.

Medicine: **ciprofloxacin intravenous (CIPRO IV)**
Plaintiffs: Bayer Healthcare AG and Bayer Inc
Defendant: Sandox Canada Incorporated
Date Commenced: May 4, 2006
Court File No: T-762-06
Comment: Patent infringement action regarding Patent No 1,282,006.

Medicine: **SANTASAPINA BONBONS ET ECHINACEA PASTILLES**
Applicant: Bioforce Canada Inc
Respondents: Madame Francine Ménard et Monsieur Stéphane Gélinas, Ministre de la Santé, Le Procureur Général du Canada
Date Commenced: May 12, 2006
Court File No: T-827-06
Comment: Application for judicial review of the Minister of Health's decision, ordering the quarantine of certain products because of lack of approval.

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Medicine: calcipotriol (DOVONEX)/betamethasone dipropionate (DIPROSONE) (DOVOBET)
Applicant: Leo Pharma Inc
Respondent: Attorney General of Canada
Date Commenced: May 19, 2006
Court File No: T-863-06
Comment: Application for an Order setting aside the decision of the PMPRB which ordered Leo Pharma to pay to the Crown the excessive revenues from the sale of DOBOVET in Canada.

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