



Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

June 2007

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Court has jurisdiction to grant prohibition Order after expiry of statutory stay if NOC has not issued

Abbott's application for a prohibition Order relating to clarithromycin (Abbott's BIAXIN) was dismissed on the basis that the claim at issue was not eligible under the *Patented Medicines (Notice of Compliance) Regulations* ("Regulations") (*Abbott Laboratories v. Apotex and Minister of Health*, 2006 FC 1558).

The Court of Appeal (2007 FCA 187) agreed with the lower Court Judge that the claim, "the use of [clarithromycin] Form O-ethanolate in the preparation of [clarithromycin] Form II for use as an antibiotic", was not a "claim for the use of the medicine" under the *Regulations* and therefore was ineligible for listing.

On the appeal, Apotex raised a novel jurisdictional argument, namely that the Court of Appeal lacked jurisdiction to issue a prohibition Order as the statutory stay had expired (as a result of the dismissal of the proceeding and expiry of the 24-month stay).

The notice of compliance (NOC) had not yet issued as another prohibition proceeding was pending.

The majority rejected the argument (with a third Judge dissenting on this issue), holding that if at the end of the statutory stay period:

- (i) there is no Order of prohibition, the Minister may issue an NOC, and if he does then the matter before the Court will become moot; however,
- (ii) if the Minister has not issued an NOC, the Federal Court and the Court of Appeal may still make an Order of prohibition.

Accordingly, the Court of Appeal found that there is no timeframe within which the Federal Court and the Court of Appeal must make a prohibition Order other than the possibility that the matter may become moot if no Order is made prior to the issuance of an NOC.

Welcome to the new *Rx IP Update*. This month we are pleased to introduce a new layout which we hope that you will find attractive and user-friendly. Although our format is updated, the contents have not changed: timely reports and commentary on

developments in Canadian intellectual property law of interest to the pharmaceutical industry. We strive to make *Rx IP Update* as valuable as possible to our readers, and all comments and suggestions are welcome. Please feel free to contact us at rxip.update@smart-biggar.ca.

Supreme Court of Canada matters

Supreme Court declines to hear lisinopril appeal. On May 10, 2007, the Supreme Court dismissed Apotex's application for leave to appeal a Court of Appeal decision (*Apotex v. AstraZeneca and Merck*, [2006 FCA 323](#)) affirming a Trial Judge's decision ([2006 FC 524](#)) that found the patent covering lisinopril (AstraZeneca's ZESTRIL and Merck's PRINIVIL) to be valid and infringed.

Apotex v. Sanofi-Synthelabo (clopidogrel bisulfate tablets (PLAVIX)), February 20, 2007. Apotex is seeking leave to appeal a Court of Appeal Order dismissing its appeal of a judgment granting Sanofi-Synthelabo an Order of prohibition ([2006 FCA 421](#)). The Court of Appeal found that the Applications Judge ([2005 FC 390](#)) did not err in concluding that

Apotex's allegations of anticipation, obviousness and double patenting were not justified.

sanofi-aventis v. Apotex (ramipril (ALTACE)), April 19, 2007. sanofi-aventis is seeking leave to appeal an Order of the Court of Appeal which allowed Apotex's appeal from an Order staying the Minister's decision to issue an NOC to Apotex for APO-RAMIPRIL ([2007 FCA 71](#)). The Court of Appeal held that the Motions Judge ([2006 FC 1559](#)) erred in issuing the stay when sanofi-aventis had failed to show irreparable harm. sanofi-aventis' leave application from the Court of Appeal's stay of the same lower Court Order was dismissed on May 3, 2007 ([2007 FCA 7](#)).

Patented Medicine Prices Review Board (PMPRB) matters

Following further consultation regarding amendments to the *Patented Medicines Regulations, 1994*, a revised regulatory package is being prepared for forwarding to the Treasury Board Cabinet Committee for publication in the *Canada Gazette*, Part II. ([Excerpt from April 2007 newsletter.](#))

The PMPRB has accepted a Voluntary Compliance Undertaking (VCU) from 3M

Canada Company for salbutamol sulphate (AIROMIR). Accordingly, the proceeding is concluded. ([Order VCU.](#))

The PMPRB has released a Communiqué to Stakeholders regarding its review of the Board's Excessive Price Guidelines, which provides the Board's preliminary response to the issues and views expressed regarding the Guidelines. ([Stakeholder Communiqué.](#))

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Pfizer v. Ratiopharm and the Minister of Health (amlodipine besylate (NORVASC)), April 26, 2007. Judge grants Ratiopharm's motion and strikes out Pfizer's application for a prohibition Order, finding the patent ineligible for listing on the Patent Register against NORVASC. The Judge found that the principle of judicial comity applies in view of recent decisions involving Cobalt ([2007 FC 187](#)) and Pharmascience ([2007 FC 188](#)), which turned solely on claim construction without reliance on expert evidence. However, the Judge rejected Ratiopharm's argument that bringing the prohibition application constituted an abuse of process by Pfizer. (Full judgment – [2007 FC 446.](#))

Abbott Laboratories v. AG Canada and the Minister of Health (clarithromycin (BIAXIN)), April 26, 2007. Judge upholds Minister's decision that a patent is ineligible for listing on the Patent Register. The patent relates to compounds that are produced during the synthesis of clarithromycin, including an oxime that Abbott alleged to be a medicine as it is an active ingredient made in the process of synthesizing clarithromycin. The Judge held that the patent in question must contain a claim for "the medicine" or for the use of "the medicine" for which the particular NOC was granted. The Judge found that the oxime is not the medicine clarithromycin, for which NOCs have been

issued, and thus the patent is ineligible for listing. (Full judgment – [2007 FC 444](#).)

Pfizer and Warner-Lambert v. Ranbaxy and Minister of Health (atorvastatin calcium (LIPITOR)), May 2, 2007. Prothonotary dismisses Ranbaxy's motion for summary dismissal of a prohibition proceeding. The Prothonotary rejected Ranbaxy's position that a prohibition application is limited to the submission filed with Health Canada. Citing evidence on record of a second process developed by Ranbaxy but not filed with Health Canada, the Prothonotary found that it is not plain and obvious that the application is frivolous, vexatious or an abuse of process. As a preliminary issue, the

Prothonotary rejected the argument by Pfizer and Warner-Lambert that the Prothonotary was without jurisdiction to hear and determine the motion. Ranbaxy has appealed. (Full judgment – [2007 FC 452](#).)

Pfizer v. Apotex (sildenafil (VIAGRA)), May 16, 2007. Court of Appeal dismisses Pfizer's appeal from an Order dismissing its prohibition application. The Applications Judge found that the patent at issue was invalid due to lack of sound prediction. The Court of Appeal held that the doctrine of sound prediction applies to a claim for a new compound. (Court of Appeal decision – [2007 FCA 195](#). Applications Judge's decision – [2007 FC 26](#).)

Other decisions

Bayer v. Sandoz Canada Inc. (intravenous ciprofloxacin (CIPRO I.V.)), April 26, 2007. Judge dismisses Bayer's motion for a *quia timet* injunction in a patent infringement action

against Sandoz. The Judge found that Bayer failed to demonstrate irreparable harm. (Full judgment – [2007 FC 352](#).)

Trade-mark decisions

Pharmawest Pharmacy Ltd. v. Thorkelson (CANADA DRUGS, CANADADRUGS.COM), April 19, 2007. Judge allows an application to expunge Thorkelson's trade-marks CANADA DRUGS and CANADADRUGS.COM for use in association with "operation of a drugstore, dispensary and pharmacy; online operation of a drugstore, dispensary and pharmacy". The Judge found that the marks are invalid as they are clearly descriptive, deceptively misdescriptive and had not acquired distinctiveness as of the filing dates of the trade-mark applications. (Full judgment – [2007 FC 411](#).)

Baxter International v. P.T. Kalbe Farma (RENAMIN), April 30, 2007. Judge allows Baxter's appeal and sets aside the Registrar's decision to expunge Baxter's trade-mark RENAMIN, registered in association with "nutritional, enteral and parenteral amino acid solutions for human use" pursuant to section 45 of the Trade-marks Act. The Judge found that Baxter's new evidence established the required use of the trade-mark. (Full judgment – [2007 FC 439](#).)

New proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	omeprazole capsules (LOSEC)
Applicants:	AstraZeneca Canada Inc, Aktiebolaget Hässle and AstraZeneca AB
Respondents:	The Minister of Health and Sandoz Canada Inc
Date Commenced:	April 26, 2007
Court File No:	T-705-07
Comment:	Application for Order of prohibition until expiry of Patents Nos. 1,292,693; 1,302,891 and 2,186,037. Sandoz alleges non-infringement and invalidity. Sandoz also asserts that the patents are not eligible for listing on the Patent Register and that it does not have to address the '037 patent in view of <i>AstraZeneca v. Minister of Health</i> (2006 SCC 49).

Medicine:	omeprazole capsules (LOSEC)
Applicants:	AstraZeneca Canada Inc and AstraZeneca AB
Respondents:	The Minister of Health and Sandoz Canada Inc
Date Commenced:	April 26, 2007
Court File No:	T-706-07
Comment:	Application for Order of prohibition until expiry of Patent No. 2,284,470. Sandoz alleges non-infringement and invalidity. Sandoz also asserts that the patent is not eligible for listing on the Patent Register and that it does not have to address the patent in view of <i>AstraZeneca v. Minister of Health</i> (2006 SCC 49).
Medicine:	atorvastatin calcium tablets (LIPITOR)
Applicants:	Pfizer Canada Inc and Warner-Lambert Company, LLC
Respondents:	The Minister of Health and Sandoz Canada Inc
Date Commenced:	April 30, 2007
Court File No:	T-739-07
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,220,455; 2,220,018; 2,220,458; 2,521,891; 2,522,899; 2,450,111; 2,521,908; 2,521,980; 2,521,933; 2,521,953; 2,521,956; 2,521,828; 2,521,833; 2,521,792; 2,521,776; 2,521,887 and 2,521,958. Sandoz alleges non-infringement and invalidity. Sandoz also asserts that the patents are not eligible for listing on the Patent Register and that it does not have to address the patents in view of <i>AstraZeneca v. Minister of Health</i> (2006 SCC 49).
Medicine:	ramipril capsules (ALTACE)
Applicant:	sanofi-aventis Canada Inc
Respondents:	The Minister of Health, the Attorney General of Canada and Pharmascience Inc
Date Commenced:	May 11, 2007
Court File No:	T-812-07
Comment:	Application for an Order quashing the decision of the Minister of Health that Pharmascience does not have to address Patents Nos. 2,382,387 and 2,382,549 in respect of its 2.5, 5.0 and 10 mg capsules. The Minister so decided on the basis of his interpretation of <i>AstraZeneca v. Minister of Health</i> (2006 SCC 49).
Medicine:	pantoprazole sodium IV (PANTO IV)
Applicants:	Altana Pharma Inc and Altana Pharma AG
Respondents:	The Minister of Health and Sandoz Canada Inc
Date Commenced:	May 14, 2007
Court File No:	T-828-07
Comment:	Application for Order of prohibition until expiry of Patent No. 2,428,870. Sandoz alleges non-infringement. Sandoz also asserts that the patent is not eligible for listing on the Patent Register and that it need not address the patent.

Medicine: ramipril capsules (ALTACE)
Applicant: Pharmascience Inc
Respondents: The Minister of Health and the Attorney General of Canada
Date Commenced: May 14, 2007
Court File No: T-837-07
Comment: Application for an Order quashing the decision of the Minister of Health that Pharmascience does have to address Patents Nos. 2,382,387 and 2,382,549 in respect of its 1.25 mg capsules. The Minister so decided on the basis of his interpretation of *AstraZeneca v. Minister of Health* (2006 SCC 49).

Medicine: celecoxib (CELEBREX)
Applicants: G.D. Searle & Co. and Pfizer Canada Inc
Respondent: The Minister of Health
Date Commenced: May 23, 2007
Court File No: T-884-07
Comment: Judicial review of Minister's decision to remove Patent No. 2,319,201 from Patent Register (originally listed July 27, 2006).

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