



Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

September 2007

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Federal Court of Appeal dismisses appeals relating to Minister's interpretation of Apotex Supreme Court decision

As reported in the [February](#) and [April](#) 2007 issues of *Rx IP Update*, the Minister had interpreted the November 3, 2006 Supreme Court decision in *Apotex Inc. v. AstraZeneca Canada Inc. et al* (2006 SCC 49) to mean that Apotex and Novopharm need not address certain patents on the Patent Register listed in connection with DDAVP tablets (desmopressin) and ALTACE (ramipril). Judicial review applications had been commenced (including one by Novopharm, as the Minister also decided that Novopharm was required to address two patents listed on the Register for ALTACE). On March 20, 2007, the Federal Court dismissed all judicial review applications (*Ferring Inc. v. Canada (Minister of Health)*, 2007 FC 300).

On September 6, 2007, the Federal Court of Appeal upheld the Applications Judge's decisions (apart from the Novopharm/ramipril appeal, which had been dismissed as moot): *Ferring Inc. v. Canada (Minister of Health)*, 2007 FCA 276. The Court issued short reasons.

First, the Court indicated that the *Patented Medicines (Notice of Compliance) Regulations* ("Regulations") "introduce a new regime", which appears to indicate that the Court was of the view that the test considered in the appeals is not applicable under the amended *Regulations*.

Second, the Court held that it did not consider it necessary to discuss the arguments in detail "because we are in substantial agreement with the decision of Justice Hughes and with his reasons". The Court concluded that the analytical approach adopted by the Minister was adequate for the factual circumstances of these cases, but also noted that whether it is adequate for all possible circumstances, including the Novopharm moot appeal, is a question upon which it expresses no opinion.

Third, the Court disagreed with the Applications Judge's finding that Ferring did not have standing to bring an application for judicial review. The Court found that Ferring

did have such standing because the decision was made by the Minister in the course of his administration of the *Regulations*.

Finally, the Court commented on the standard of review in such circumstances: correctness for questions of law, patent unreasonableness for questions of fact, and patent

unreasonableness for mixed questions of fact and law unless the question of law is extricable in which case the standard of review is correctness.

Any further appeal will require leave from the Supreme Court of Canada.

Supreme Court of Canada matters

Searle and Pfizer v. Novopharm (celecoxib (CELEBREX)), June 28, 2007. Novopharm is seeking leave to appeal the decision of the Court of Appeal to issue a prohibition Order. The Court of Appeal allowed the appeal by Searle and Pfizer and set aside the Applications Judge's decision which had denied a prohibition

Order. The Applications Judge had found that Novopharm's allegations of invalidity based on obviousness and on "abandonment" during prosecution were justified. (Court of Appeal decision – [2007 FCA 173](#). Applications Judge's decision – [2007 FC 81](#).)

Patented Medicine Prices Review Board (PMPRB) matters

The PMPRB will hold a hearing to determine whether Abbott is selling or has sold ZEMPLAR (paricalcitol) in Canada at prices that are or were excessive and if so, what order, if any, should

be made. The hearing will commence on December 10, 2007. A pre-hearing conference has been scheduled for November 13, 2007. ([Notice](#).)

Health Canada to post product monographs

Health Canada will commence publishing product monographs on its website in the winter of 2007/2008, starting with those

product monographs authorized after January 2004. Only the most recent authorized version will be published. ([Notice](#).)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Abbott v. Apotex (clarithromycin (BIAXIN)), July 17, 2007. Judge dismisses Abbott's application for a prohibition Order, finding that Apotex's allegations of invalidity regarding two patents relating to Forms I and II clarithromycin are justified. (Application Judge's decision – [2007 FC 753](#).)

Abbott v. Apotex (lansoprazole (PREVACID)), August 3, 2007. Judge dismisses Abbott's appeal from the Order of a prothonotary refusing Abbott's motion to file an affidavit in reply. (Full judgment – [2007 FC 817](#).)

sanofi-aventis Canada v. Riva (ramipril (ALTACE)), August 10, 2007. Prothonotary grants Riva's summary dismissal motion in part, striking portions of sanofi-aventis' notice of application (including that the notice of allegation was insufficient). The Prothonotary refused to strike the portion of the notice of application relating to infringement of the patents in issue (new use patents) as sanofi-aventis had led specific evidence relating to the use of price and exclusive supply contracts by Riva to compel the use of Riva's ramipril

product. sanofi-aventis has appealed.
(Full judgment – [2007 FC 832](#).)

Abbott and TAP v. Novopharm and the Minister of Health (lansoprazole (PREVACID)), August 29, 2007. Judge upholds Prothonotary's dismissal of a prohibition proceeding on the basis that the patent at issue is not eligible for listing on the Patent Register. The patent had

been listed under the pre-amended Regulations. The Prothonotary decided that the patent protects a delivery system and thus does not contain a claim for the medicine itself or for the use of the medicine.
(Applications Judge's decision – [2007 FC 865](#).
Prothonotary's decision – [2007 FC 622](#).)

Other decisions

GlaxoSmithKline Biologicals v. Novartis Vaccines and Diagnostics (vaccine adjuvant), August 10, 2007. Prothonotary strikes out Novartis's counterclaim for a declaration that its patent "will be infringed" by GSK and similar pleadings in its defence to GSK's impeachment action. The Prothonotary found Novartis's allegation that GSK is "proposing" and "intending" to sell the adjuvants failed to support a quia timet action for infringement.
(Full judgment – [2007 FC 833](#).)

Apotex v. Ontario (Office of the Lieutenant Governor) (flavoxate (APO-FLAVOXATE, URISPAS)), August 20, 2007. Ontario Court of Appeal upholds the Lieutenant Governor in Council's regulation, delisting Apo-Flavoxate as an interchangeable product under the *Drug Interchangeability and Dispensing Fee Act* ("DIDFA"). The regulation had been passed under the pre-amended DIDFA. The Court found that there was no Ministerial decision to

attack, as the de-listing was made by regulation. Applying the strict test for challenging the validity of a regulation, the Court concluded that the Divisional Court had erred in quashing the regulation.
(Court of Appeal's decision – [2007 ONCA 570](#).
Divisional Court's decision – [2006 ONSC 14338](#).)

Novopharm v. Janssen-Ortho and Daiichi Pharmaceutical (levofloxacin (LEVAQUIN)), August 23, 2007. Court of Appeal dismisses Novopharm's motion for reconsideration. The Court of Appeal had dismissed Novopharm's appeal from the Trial Judge's decision that the patent at issue is valid. In this motion, the Court found that what Novopharm was truly seeking was reconsideration of the arguments on the merits.
(Full judgment – [2007 FCA 269](#).
Court of Appeal decision – [2007 FCA 217](#).
Trial Judge's decision – [2006 FC 1234](#).)

New proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	olanzapine tablets (ZYPREXA)
Applicant:	Eli Lilly Canada Inc
Respondents:	The Minister of Health and Sandoz Canada Inc
Respondents/Patentees:	Lilly Industries Limited and Eli Lilly and Company
Date Commenced:	July 27, 2007
Court File No:	T-1389-07
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,214,005. Sandoz alleges non-infringement.

Medicine: olanzapine tablets (ZYPREXA)
Applicant: Eli Lilly Canada Inc
Respondents: The Minister of Health and Sandoz Canada Inc
Respondent/Patentee: Eli Lilly and Company Limited
Date Commenced: July 27, 2007
Court File No: T-1391-07
Comment: Application for an Order of prohibition until expiry of Patent No. 2,041,113. Sandoz alleges invalidity.

Medicine: escitalopram (oxalate) tablets (CIPRALEX)
Applicant: Lundbeck Canada Inc
Respondents: The Minister of Health and Cobalt Pharmaceuticals Inc
Respondent/Patentee: H. Lundbeck A/S
Date Commenced: July 30, 2007
Court File No: T-1395-07
Comment: Application for an Order of prohibition until expiry of Patent No. 1,339,452. Cobalt alleges non-infringement and invalidity.

Medicine: pantoprazole sodium (PANTO IV)
Applicants: Nycomed Canada Inc and Nycomed GmbH
Respondents: The Minister of Health and PharMel Inc
Date Commenced: August 2, 2007
Court File No: T-1432-07
Comment: Application for an Order of prohibition until expiry of Patent No. 2,428,870. PharMel alleges non-infringement and invalidity.

Medicine: pantoprazole sodium (PANTO IV)
Applicants: Nycomed Canada Inc and Nycomed GmbH
Respondents: The Minister of Health and Dominion Pharmacal
Date Commenced: August 2, 2007
Court File No: T-1433-07
Comment: Application for an Order of prohibition until expiry of Patent No. 2,428,870. Dominion Pharmacal alleges non-infringement and invalidity.

Medicine: ramipril capsules (ALTACE)
Applicants: sanofi-aventis Canada Inc and sanofi-aventis Deutschland GmbH
Respondents: The Minister of Health and Genpharm Inc
Respondent/Patentee: Schering Corporation
Date Commenced: August 3, 2007
Court File No: T-1446-07
Comment: Application for an Order of prohibition until expiry of Patents Nos. 1,341,206; 2,023,089; 2,382,387; 2,055,948; 2,382,549. Genpharm alleges non-infringement of the '089, '387, '948 and '549 patents. Genpharm alleges invalidity of the '206, '387 and '549 patents. Genpharm also asserts that the '089, '948, '387 and '549 patents are not eligible for listing on the Patent Register and that it does not have to address the patents in view of *AstraZeneca v. The Minister of Health*, 2006 SCC 49.

Medicine: olanzapine tablets and orally disintegrating tablets (ZYPREXA)
Applicant: Eli Lilly Canada Inc
Respondents: The Minister of Health and Pharmascience Inc
Respondents/Patentees: Eli Lilly and Company Limited and Eli Lilly and Company
Date Commenced: August 3, 2007
Court File No: T-1447-07
Comment: Application for an Order of prohibition until expiry of Patents Nos. 2,041,113 and 2,214,005. Pharmascience alleges non-infringement and invalidity of the patents. Pharmascience also asserts that the patents are not eligible for listing on the Patent Register.

Medicine: estradiol-17 β transdermal system (CLIMARA)
Applicant: Bayer Inc
Respondents: The Minister of Health and the Attorney General of Canada
Date Commenced: August 16, 2007
Court File No: T-1517-07
Comment: Judicial review of Minister's Decision not to list Patent No. 2,167,970. The patent list was submitted pursuant to the amended *Regulations*. The Minister stated the claims in the patent are not directed to a changed dosage form.

Medicine: estradiol-17 β transdermal system (MENOSTAR)
Applicant: Bayer Inc
Respondents: The Minister of Health and the Attorney General of Canada
Date Commenced: August 16, 2007
Court File No: T-1518-07
Comment: Judicial review of Minister's Decision not to list Patent No. 2,167,970. The patent list was submitted pursuant to the amended *Regulations*. The Minister stated the claims in the patent are not directed to a change in dosage form.

Medicine: sildenafil (citrate) tablets (VIAGRA)
Applicants: Pfizer Canada Inc, Pfizer Inc, Pfizer Ireland Pharmaceuticals, and Pfizer Research and Development Company N.V./S.A.
Respondents: The Minister of Health and Novopharm Limited
Date Commenced: August 24, 2007
Court File No: T-1566-07
Comment: Application for an Order of prohibition until expiry of Patents Nos. 2,044,748; 2,163,446; 2,277,017; 2,285,733; 2,290,766 and 2,324,324. Novopharm alleges non-infringement and invalidity of the patents. Novopharm also asserts that that the patents are not eligible for listing on the Patent Register.

Other new proceedings

Medicine: clarithromycin tablets (BIAXIN)
Plaintiff: Apotex Inc
Defendant: Abbott Laboratories, Limited
Date Commenced: July 30, 2007
Court File No: T-1396-07
Comment: Action for damages pursuant to section 8 of the *Regulations*.

Product: ciprofloxacin (CIPRO I.V.)
Plaintiffs: Bayer Healthcare AG and Bayer Inc
Defendant: Thunder Bay Regional Health Sciences Centre
Date Commenced: August 3, 2007
Court File No: T-1450-07
Comment: Patent infringement action relating to Patent No. 1,282,006.

Product: disulfiram capsules (ABSTAYNE)
Applicant: Wellesley Therapeutics Inc
Respondents: The Minister of Health (Health Canada), Director General Therapeutic Products Directorate (Health Canada) and the Attorney General of Canada
Date Commenced: August 21, 2007
Court File No: T-1537-07
Comment: Judicial review of Minister's decision to refuse to reconsider the screening rejection of the new drug submission for ABSTAYNE.

To check the status of Federal Court cases, [please click here](#).

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