



Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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PMPRB Decides It Has Jurisdiction During Laid-open Period

On December 15, 2006, the Patented Medicine Prices Review Board (PMPRB) decided that “for the time being” in the phrase “the person for the time being entitled to the benefit of the patent for that invention” in the definition of “patentee” under section 79 of the *Patent Act* includes the laid-open period (the period between the date the patent application is laid open for public inspection and the patent issuance date). It therefore concluded that once the patent issues, the Board has jurisdiction to prevent excessive pricing during the laid-open period. The Board relied on section 55(2) of the *Patent Act* which provides for liability for reasonable compensation during the laid-open period. The decision arose from a motion brought by Shire, supported by Rx&D, in the course of a hearing to determine whether **ADDERALL XR** was or is being sold at excessive prices. The Board distinguished the facts from the Federal Court decision *Hoechst Marion Roussel Canada Inc. v. Canada (Attorney General)* (“*HMRC*”, [2005 FC 1552](#), relating to the pricing of **NICODERM**), on the basis that in *HMRC*, the patent applications had not yet issued to patent as of the date of the decision. *Rx IP Update* will report further if Shire files an application in the Federal Court to review this decision.

PMPRB's Decision

Ontario Flat 50 Pricing Rule Upheld

As reported in our [November 2006](#) issue of *Rx IP Update*, Apotex brought an application for judicial review, seeking an Order declaring unlawful all or part of the amended regulations under the Ontario Drug Benefit Act (O Reg 459/06) and the Drug Interchangeability and Dispensing Fee Act (O Reg 458/06), focussing on the lowering of the permissible price of generic products from 70% of the drug benefit price of the original product to 50%. On December 15, 2006, the Ontario Divisional Court (*Apotex v. Minister of Health and Long Term Care*, [2006 CanLII 41810](#)) dismissed Apotex's application, rejecting Apotex's submission that the government failed to consult as required by Bill 102 and that the Lieutenant Governor in Council exceeded its jurisdiction in changing the method by which a reduction of 50% of the fee charged by the brand-name products was to be achieved.

Patented Medicines Prices Review Board (PMPRB) Matters

The PMPRB will hold a public hearing commencing on April 11, 2007, to determine whether Eli Lilly is selling or has sold **STRATTERA (atomoxetine hydrochloride)** in any market in Canada at a price that is or was excessive in the Board's opinion, and if so, what order (if any) should be made. A pre-hearing conference has been scheduled for February 22, 2007. Persons wishing to intervene are required to apply to the PMPRB for leave to intervene on or before January 19, 2007.

Notice of Hearing

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Pfizer and Warner-Lambert v. Minister of Health and Novopharm (atorvastatin calcium (LIPITOR)), December 7, 2006

Judge grants Pfizer's application for an Order of prohibition, finding that Novopharm's allegations that the patent is invalid on the basis of anticipation, obviousness and double patenting were not justified. Novopharm had sought to attack the patent on the basis of allegedly flawed data supporting the ten-fold activity claimed in the patent (the basis for the patent being a selection patent). However, the Judge did not permit Novopharm to so argue, as the allegations were not made in its notice of allegation (NOA). The Judge in any event, considering the evidence, would have rejected the argument.

Full Judgment ([2006 FC 1471](#))

Sanofi-Aventis v. Novopharm and Minister of Health (ramipril (ALTACE)), December 21, 2006

Judge dismisses Novopharm's motion to summarily dismiss Sanofi-Aventis' application for an Order of prohibition, in whole or in respect of one or more of the patents at issue, on the ground that the proceeding is redundant, scandalous, frivolous or vexatious, or otherwise an abuse or process. Novopharm argued that the decision of the Supreme Court in *Apotex v. AstraZeneca* ([2006 SCC 49](#)) results in the patents being irrelevant. The Minister had disagreed and advised Novopharm that these patents must be addressed; Novopharm has challenged that decision in a separate proceeding. Novopharm also argued that the evidence as to infringement by Novopharm is inadequate. The Judge held that "[a] motion to dismiss should not be used as a vehicle to resolve important, controversial points of law... particularly ... in an area where the law is currently evolving", and that the sufficiency of evidence on the infringement issue should be left to the hearing at trial. Novopharm has appealed.

Full Judgment ([2006 FC 1547](#))

Other Decisions

Novopharm v. Janssen-Ortho and Daiichi Pharmaceutical (levofloxacin (LEVAQUIN)), December 13, 2006

Court of Appeal denies Novopharm's motion for a stay of the trial judgment, which declared a claim of the levofloxacin patent valid and infringed by Novopharm and granted remedies, including an injunction (as reported in the [November 2006](#) issue of *Rx IP Update*). The Court found that Novopharm had not established irreparable harm, provided Janssen and Daiichi give an undertaking concerning compensation for damages if Novopharm's appeal of the judgment is allowed.

Court of Appeal Decision (2006 FCA 406)

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: **lansoprazole (PREVACID)**
Applicants: Abbott Laboratories Limited and Tap Pharmaceuticals Inc
Respondents: The Minister of Health, Novopharm Limited and Takeda Pharmaceutical Company Limited
Date Commenced: November 23, 2006
Court File No: T-2052-06
Comment: Application for Order of prohibition until expiry of Patent No. 2,269,053. Novopharm alleges non-infringement, invalidity and that the patent is not properly listed on the Patent Register.

Medicine: **atorvastatin calcium (LIPITOR)**
Applicants: Pfizer Canada Inc and Warner-Lambert Company, LLC
Respondents: The Minister of Health and Apotex Inc
Date Commenced: December 5, 2006
Court File No: T-2145-06
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,220,018, 2,220,458, 2,450,111, 2,521,776, 2,521,792, 2,521,828, 2,521,833, 2,521,887, 2,521,891, 2,521,908, 2,521,933, 2,522,899, 2,521,953, 2,521,956 and 2,220,455. Apotex alleges non-infringement.

Medicine: **ramipril (ALTACE)**
Applicant: Sanofi-Aventis Canada Inc
Respondents: Minister of Health, The Attorney General of Canada and Novopharm Limited
Date Commenced: December 12, 2006
Court File No: T-2188-06
Comment: Application for an Order quashing the decision of the Minister of Health that Novopharm does not have to address Patents Nos. 2,382,387 and 2,382,549. The Minister so decided on the basis of his interpretation of *AstraZeneca Canada Inc. v. Canada (Minister of Health)* (2006 SCC 49).

Medicine: **ramipril (ALTACE)**
Applicant: Sanofi-Aventis Canada Inc
Respondents: Minister of Health, The Attorney General of Canada and Apotex Inc
Date Commenced: December 12, 2006
Court File No: T-2189-06
Comment: Application for an Order quashing the decision of the Minister of Health that Apotex does not have to address Patents Nos. 2,382,387 and 2,382,549. The Minister so decided on the basis of his interpretation of *AstraZeneca Canada Inc. v. Canada (Minister of Health)* (2006 SCC 49).

Medicine: **ramipril (ALTACE)**
Applicant: Sanofi-Aventis Canada Inc
Respondents: Minister of Health, The Attorney General of Canada and Apotex Inc
Date Commenced: December 13, 2006
Court File No: T-2196-06
Comment: Application for an Order quashing the decision of the Minister of Health to issue a notice of compliance (NOC) to Apotex. The Minister so decided on the basis of his interpretation of *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, (2006 SCC 49).

Medicine: **ramipril (ALTACE)**
Applicant: Novopharm Limited
Respondents: The Minister of Health and The Attorney General of Canada
Date Commenced: December 15, 2006
Court File No: T-2220-06
Comment: Application for an Order quashing the decision of the Minister of Health that Novopharm is required to address Patents Nos. 2,055,948 and 2,023,089.

Medicine: **ramipril (ALTACE)**
Applicants: Sanofi-Aventis Canada Ltd and Sanofi-Aventis Deutschland GmbH
Respondents: Pharmascience Inc and The Minister of Health
Date Commenced: December 22, 2006
Court File No: T-2256-06
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,382,387 and 2,382,549. Pharmascience alleges non-infringement and invalidity.

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Other Proceedings

Medicine: unspecified
Plaintiff: GlaxoSmithKline Biologicals SA
Defendant: Chiron Corporation
Date Commenced: November 29, 2006
Court File No: T-1976-06
Comment: Motion for an Order directing GSK to post security for costs in connection with an action to be commenced to impeach a patent owned by Chiron Corporation.

Medicine: fexofenadine hydrochloride (ALLEGRA)
Plaintiff: AMR Technology, Inc
Defendants: Novopharm Limited, Teva Pharmaceutical Industries Ltd, Teva Pharmaceuticals USA, Inc, Dipharma SpA and Dipharma Francis Srl
Date Commenced: December 22, 2006
Court File No: T-2273-06
Comment: Patent infringement action relating to Patent No. 2,181,089. AMR pleads that Novopharm has manufactured an infringing formulation for Teva USA, for distribution and sale in the USA.

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