



Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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Federal Court Upholds Minister's Interpretation of Apotex Supreme Court Decision

As reported in the [February 2007](#) issue 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, rendering one set of reasons (*Ferring Inc. v. Canada (Minister of Health)*, [2007 FC 300](#)).

The Court interpreted the Minister to have made his decisions by applying the following test:

1. First, the date on which the generic has purchased the comparator drug is used to determine which notices of compliance have been issued in respect of that comparator drug. The position of the Minister is that all patents listed in respect of the relevant [notice of compliance] NOC as of that date must be addressed by the generic.
2. Second, where further NOC's have been issued to the innovator after the date of the purchase of the comparator drug, the Minister makes a determination as to whether the generic has made use of changes made to the comparator drug since the original date of purchase. If the generic has made use of such changes, then all patents added to the patent list subsequent to the date of purchase as are pertinent to the changes of which the generic has taken advantage must be addressed.

The Court found that the policy adopted by the Minister is consistent with the reasoning of the Supreme Court in *AstraZeneca* and the applicable provisions of the *Patented Medicines (Notice of Compliance) Regulations* ("*NOC Regulations*") and the *Food and Drug Regulations*. However, if the Court were to have modified the policy, it would have done so in two respects. First, a better date would be the filing date of the ANDS by the generic. Second, with respect to the second criteria, the changes made by the generic must be those as specified in section 5(1) of the *NOC Regulations*, namely for purposes of bioequivalence. However, the Court held that even if these changes had been applied by the Minister, it would not have changed the results of his decisions.

The Court also accepted Novopharm's argument in the *Ferring* case that *Ferring* had no status to seek judicial review. The Court rejected arguments that: (i) the Minister was *functus officio* and therefore could not revisit the issue as to whether the generics were required to address the patents (despite prohibition proceedings having been commenced in respect of some of the patents); (ii) the amended *Regulations* were applicable; and (iii) the Minister breached his duty of fairness.

Sanofi-Aventis has appealed. *Ferring* and Novopharm may also appeal, as of right.

The decision has potentially far-reaching implications. Unless reversed on appeal, the Minister could (if his test from *AstraZeneca* is met) decide that any generic with a pending ANDS as of October 5, 2006 need not address patents on the Register, and could issue an NOC, even if a prohibition proceeding is pending.

Nancy P. Pei, Toronto

* erratum corrected on April 2, 2007

Apotex's Data Protection Challenge Struck

On March 5, 2007, the Federal Court granted the Attorney General's motion to strike Apotex's application for judicial review of the data protection provision of the *Food and Drug Regulations* (*Apotex Inc. v. The Governor in Council, The Minister of Health and Canada (Attorney General)*, 2007 FC 232). The Judge found that Apotex had no standing to make this challenge as it is not a person directly affected: there was no evidence that the data protection rule had been applied to impose any actual limitation on Apotex (or on any other drug manufacturer seeking an NOC). The Judge noted that at some future time, the appropriate case will arise when the Minister makes a decision under the data protection rule and either the generic drug manufacturer or the innovator commences a judicial review application. The Judge also found that Apotex has no public interest standing. Apotex has appealed. As previously reported, the Attorney General's motion to strike the Canadian Generic Pharmaceutical Association's challenge was dismissed on February 9, 2007 (2007 FC 154). The Attorney General has appealed that decision.

Health Canada Releases Draft Post-Notice of Compliance Changes Guidance Documents

On March 16, 2007, Health Canada released draft Post-Notice of Compliance (NOC) Changes Guidance Documents for stakeholder consultation. The purpose of the documents is to provide guidance to sponsors intending to make changes to drugs that have received an NOC. Comments on the draft guidance documents should be provided to Health Canada within 90 days of the notice (June 14, 2007).

[March 16, 2007 Notice](#)

[Framework Document](#)

[Safety and Efficacy Document](#)

[Quality Document](#)

PMPRB Excessive Pricing Ruling Upheld

As reported in the [May 2006](#) issue of *Rx IP Update*, the PMPRB had held that the price of DOVOBET in Canada was excessive. On March 21, 2007, the Federal Court substantially upheld this decision (*Leo Pharma v. Canada (Attorney General)*, **calcipotriol (DOVONEX)/betamethasone dipropionate (DIPROSONE) (DOVOBET)**, 2007 FC 306). The Court declined to disturb the Board's finding that the price of DOVOBET should be compared to the combined prices of its two components, DOVONEX and DIPROSONE and in its application of the testing for international pricing comparison. The Court also rejected Leo Pharma's argument, namely that the Board lacks jurisdiction as it does not have sufficient institutional independence and impartiality to provide the applicant with a fair hearing in accordance with the principles of fundamental justice. The Court, however, reversed the PMPRB's finding that free goods should not be taken into account in assessing the average price of DOVOBET, holding that the free goods need not be distributed for 'compassionate reasons' in order to be taken into account.

Orders to Answer Discovery Questions in Section 8 Damage Cases Upheld

In separate decisions, the Federal Court has upheld decisions of prothonotaries (*Apotex v. Wellcome Foundation*, **acyclovir (ZOVIRAX)**, 2007 FC 236, and *Apotex v. Merck (norfloxacin (NOROXIN; APO-NORFLOXACIN))*, 2007 FC 250) requiring parties to provide answers to questions posed on discovery in section 8 damage actions under the *Regulations*. Apotex has appealed the decision in the acyclovir case.

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	lansoprazole delayed-release capsules (PREVACID)
Applicants:	Abbott Laboratories Limited, Tap Pharmaceuticals Inc and Tap Pharmaceutical Products Inc
Respondents:	The Minister of Health and The Attorney General of Canada
Date Commenced:	February 7, 2007
Court File No:	T-252-07
Comment:	Application for Order prohibiting the Minister from issuing an NOC to any person who has filed a submission for an NOC comparing that person's drug to PREVACID unless such person has complied with the <i>Regulations</i> in relation to Patents Nos. 1,327,010 and 1,338,377. Abbott refers to the Minister's interpretation of old section 5 with regard to <i>AstraZeneca v. Minister of Health</i> (2006 SCC 49).

Medicine:	escitalopram (oxalate) tablets (CIPRALEX)
Applicant:	Lundbeck Canada Inc
Respondents:	The Minister of Health and Genpharm Inc.
Respondent/Patentee:	H. Lundbeck A/S
Date Commenced:	March 5, 2007
Court File No:	T-372-07
Comment:	Application for Order of prohibition until expiry of Patent No. 1,339,452. Genpharm alleges non-infringement and invalidity.

Medicine: **perindopril tablets (COVERSYL)**
Applicants: Servier Canada Inc and ADIR
Respondents: The Minister of Health and Apotex Inc
Date Commenced: March 8, 2007
Court File No: T-393-07
Comment: Application for an Order quashing NOC issued for APO-PERINDOPRIL and a declaration that the *Regulations* apply to Apotex's ANDS.

Medicine: **gliclazide sustained release tablets (DIAMICRON MR)**
Applicants: Servier Canada Inc and Les Laboratoires Servier
Respondents: The Minister of Health and Apotex Inc
Date Commenced: March 8, 2007
Court File No: T-397-07
Comment: Application for Order of prohibition until expiry of Patent No. 2,273,420. Apotex alleges non-infringement.

Medicine: **ramipril tablets (ALTACE)**
Applicants: Sanofi-Aventis Canada Inc and Sanofi-Aventis Deutschland GmbH
Respondents: Sandoz Canada Inc and The Minister of Health
Date Commenced: March 14, 2007
Court File No: T-435-07
Comment: Application for Order of prohibition until expiry of Patent No. 2,382,549. Sandoz alleges non-infringement and invalidity. Sandoz also asserts that the patent is not eligible for listing on the Patent Register and that it need not address the patent in view of *AstraZeneca v. Minister of Health* (2006 SCC 49).

Medicine: **ramipril tablets (ALTACE)**
Applicants: Sanofi-Aventis Canada Inc and Sanofi-Aventis Deutschland GmbH
Respondents: The Minister of Health and Sandoz Canada Inc
Date Commenced: March 14, 2007
Court File No: T-436-07
Comment: Application for Order of prohibition until expiry of Patent No. 2,055,948. Sandoz alleges non-infringement and invalidity. Sandoz also asserts that the patent is not eligible for listing on the Patent Register and that it need not address the patent in view of *AstraZeneca v. Minister of Health* (2006 SCC 49).

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Medicine: ramipril tablets (ALTACE)
Applicants: Sanofi-Aventis Canada Inc and Sanofi-Aventis Deutschland GmbH
Respondents: The Minister of Health and Sandoz Canada Inc
Date Commenced: March 14, 2007
Court File No: T-437-07
Comment: Application for Order of prohibition until expiry of Patent No. 2,023,089. Sandoz alleges non-infringement and invalidity. Sandoz also asserts that the patent is not eligible for listing on the Patent Register and that it need not address the patent in view of *AstraZeneca v. Minister of Health* (2006 SCC 49).

Medicine: ramipril tablets (ALTACE)
Applicants: Sanofi-Aventis Canada Inc and Sanofi-Aventis Deutschland GmbH
Respondents: The Minister of Health and Sandoz Canada Inc
Date Commenced: March 14, 2007
Court File No: T-438-07
Comment: Application for Order of prohibition until expiry of Patent No. 2,382,387. Sandoz alleges non-infringement and invalidity. Sandoz also asserts that the patent is not eligible for listing on the Patent Register and that it need not address the patent in view of *AstraZeneca v. Minister of Health* (2006 SCC 49).

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