



# Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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## Amendments to Regulations Under Ontario Formulary Legislation Approved

Amendments to the regulations under the *Drug Interchangeability and Dispensing Fee Act* ("DIDFA") and the *Ontario Drug Benefit Act* ("ODBA") as a result of the amendments to the two Acts by the *Transparent Drug System for Patients Act, 2006* (Bill 102) were approved on September 28, 2006. Most of the amendments came into force on October 1, 2006 and the balance will come into force on April 1, 2007. As reported in our [August 2006](#) issue of *Rx IP Update*, the Ontario Government had published proposed amendments on July 24, 2006. The Government also announced the appointment of Ron Sapsford, Deputy Minister, Ministry of Health and Long-Term Care as the Executive Officer for the Ontario public drug programs.

[Notice of Regulation Amendments under the ODBA and the DIDFA](#)

[Notice to Pharmacies](#)

[Announcement of Executive Officer](#)

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## Supreme Court of Canada Leave Applications

*Abbott Laboratories v. Ratiopharm and Minister of Health* (**clarithromycin (BIAXIN BID)**), August 17, 2006

Abbott has filed an application for leave to appeal the Court of Appeal decision that upheld a dismissal of Abbott's application for a prohibition Order.

[Court of Appeal Decision \(2006 FCA 187\)](#)

[Applications Judge's Decision \(2005 FC 1093\)](#)

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*Ratiopharm v. Pfizer* (**amlopidine besylate (NORVASC)**), September 8, 2006

Ratiopharm has filed an application for leave to appeal the Court of Appeal decision that granted a prohibition Order, reversing a decision of an Applications Judge.

[Court of Appeal Decision \(2006 FCA 214\)](#)

[Applications Judge's Decision \(2006 FC 220\)](#)

## Recent Court Decisions

### *Patented Medicines (Notice of Compliance) Regulations*

*Abbott Laboratories v. Apotex and Minister of Health (clarithromycin (BIAXIN BID))*, September 5, 2006

Court of Appeal dismisses Apotex's appeals from two decisions: one disqualifying Apotex's expert and striking his evidence; and the other denying Apotex leave to replace the affidavit with that of another expert.

*Court of Appeal Decision (2006 FCA 294)*

*Motions Judge's Decision (2006 FC 340)*

*Motions Judge's Decision (2006 FC 823)*

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*Solvay and Altana v. Apotex and Minister of Health (pantoprazole (PANTOLOC))*, September 15, 2006

Judge dismisses an application by Solvay and Altana for an Order pursuant to the inherent jurisdiction of the Court to compel Apotex to produce samples of its tablets. The Judge held that Orders for production of samples should be permitted in only two instances: (i) under section 6(7) of the *Regulations* when a sample was submitted to the Minister as part of the ANDS, or (ii) where affidavits which discuss testing have been filed. Neither was applicable in this motion. The Judge also dismissed the motion on the grounds of issue estoppel in view of a prior motion for production made pursuant to section 6(7).

*Full Judgment (2006 FC 1101)*

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### *Other Decisions*

*Eli Lilly; Shionogi (Defendant by Counterclaim) v. Apotex (cefaclor (APO-CEFACTOR, CECLOR))*, September 1, 2006

Judge dismisses Apotex's motion to set aside the case management Prothonotary's Order requiring Apotex to provide Shionogi with an affidavit of documents restricted to the counterclaim. Shionogi is a party only to Apotex's counterclaim pursuant to the *Competition Act*, not the counterclaim for patent invalidity or Lilly's claim for patent infringement.

*Full Judgment (2006 FC 1050)*

## New Court Proceedings

### *Patented Medicines (Notice of Compliance) Regulations*

**Medicine:** **pantoprazole (PANTOLOC)**  
**Applicants:** Altana Pharma Inc and Altana Pharma AG  
**Respondents:** Cobalt Pharmaceuticals Inc and The Minister of Health  
**Date Commenced:** September 14, 2006  
**Court File No:** T-1662-06  
**Comment:** Application for Order of prohibition until expiry of Patents Nos. 2,089,748, 2,092,694 and 2,109,697. Cobalt alleges non-infringement, invalidity, and that the '748 and '694 Patents are not properly listed on the Patent Register.

**Medicine:** **venlafaxine hydrochloride (EFFEXOR XR)**  
**Applicants:** Wyeth Canada and Wyeth  
**Respondents:** Cobalt Pharmaceuticals Inc and The Minister of Health  
**Date Commenced:** September 14, 2006  
**Court File No:** T-1663-06  
**Comment:** Application for Order of prohibition until expiry of Patent No. 2,199,778. Cobalt alleges non-infringement, invalidity, and that the patent is not properly listed on the Patent Register.

**Medicine:** **clarithromycin (BIAXIN BID)**  
**Applicants:** Abbott Laboratories and Abbott Laboratories Limited  
**Respondents:** Sandoz Canada Inc and The Minister of Health  
**Date Commenced:** September 14, 2006  
**Court File No:** T-1671-06  
**Comment:** Application for Order of prohibition until expiry of Patent No. 2,393,614. Sandoz alleges non-infringement and invalidity.

**Medicine:** **clarithromycin (BIAXIN BID)**  
**Applicants:** Abbott Laboratories and Abbott Laboratories Limited  
**Respondents:** Sandoz Canada Inc and The Minister of Health  
**Date Commenced:** September 14, 2006  
**Court File No:** T-1672-06  
**Comment:** Application for Order of prohibition until expiry of Patents Nos. 2,261,732, 2,258,606, 2,277,274, 2,387,361, 2,386,534, 2,386,527, 2,387,356, 2,471,102, and 2,419,729. Sandoz alleges non-infringement and invalidity.

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*Other New Proceedings*

**Medicine:** **perindopril (COVERSYL)**  
**Plaintiffs:** Les Laboratoires Servier and Adir and Oril Industries  
**Defendants:** Apotex Inc and Apotex Pharmachem Inc  
**Date Commenced:** August 25, 2006  
**Court File No:** T-1548-06  
**Comment:** Patent infringement action relating to Patent No. 1,341,196. Servier alleges that Apotex Pharmachem Inc, under the control, authority and direction of Apotex Inc, has used and manufactured in Canada perindopril and perindopril tert-butyl amine, as well as exported and sold from Canada perindopril tert-butyl amine.

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