



# Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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Ontario Government Proposes Amendments to Regulations Under Formulary Legislation

## Ontario Government Proposes Amendments to Regulations Under Formulary Legislation

On July 24, 2006, the Ontario Government published proposed amendments to the regulations under the *Drug Interchangeability and Dispensing Fee Act* ("DIDFA") and the *Ontario Drug Benefit Act* ("ODBA"). This comes as a result of the amendments to the two Acts by the *Transparent Drug System for Patients Act, 2006* (Bill 102), which received Royal Assent on June 20, 2006. Interested parties are invited to provide written comments on the proposed amendments by **August 23, 2006**.

[Notice of Proposed Amendments and Proposed Amendments](#)

[Ontario Drug Benefit Act: Present Regulations under ODBA \(Ontario Regulation 201/96\)](#)

[Drug Interchangeability and Dispensing Fee Act: Present Regulations under DIDFA \(Regulation 935\)](#)

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## New Website on Access to Medicines for Developing Nations

On July 28, 2006, the Government launched a new website (<http://camr-rcam.hc-sc.gc.ca>) providing information on Canada's Access to Medicines Regime (CAMR), which allows lower-cost versions of patent-protected drugs to be exported to eligible countries that have little or no pharmaceutical manufacturing capacity. The website provides information on: eligibility, requirements and procedures for importing countries; requirements, application process and forms for companies; the role of non-governmental organizations; and key documents.

[News Release](#)

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## Government Proposes to Add Oseltamivir (TAMIFLU) to Schedule 1 of the Patent Act

On July 1, 2006, the Government published a proposed amendment to Schedule 1 of the *Patent Act* to add oseltamivir phosphate (75 mg capsules and 12 mg/mL powder for oral suspension), which is used in the treatment and prophylaxis of Type A and Type B influenza. It is presently sold by Roche under the brand name TAMIFLU. Schedule 1 is a list of patented pharmaceutical products that are eligible to be exported under compulsory license in accordance with the amendments to the Act brought into effect by the *Jean Chrétien Pledge to Africa Act*. In February 2006, Biolyse requested that the Government add oseltamivir to Schedule 1 so that it can eventually apply for a compulsory licence under CAMR. The consultation period expired on July 31, 2006.

[Proposed Amendment and Regulatory Impact Analysis Statement](#)

On August 31, 2005, Schedule 1 of the *Patent Act* was amended to add lamivudine (150 mg) + nevirapine (200 mg) + zidovudine (300 mg) tablets.

[Order](#)

New Website on Access to Medicines for Developing Nations

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## Supreme Court of Canada Leave Applications

*Sanofi-Aventis v. Apotex (ramipril (ALTACE))*, August 3, 2006

Leave has been denied. The Federal Court of Appeal decision dismissed Sanofi-Aventis' appeal from an Applications Judge's decision which dismissed its prohibition application. The Court of Appeal decision was reported in our [February 2006](#) issue of *Rx IP Update*.

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*Apotex v. Alberta (Minister of Health and Wellness) (gabapentin (APO-GABAPENTIN, NEURONTIN))*, June 26, 2006

The Crown has filed an application for leave to appeal a decision of the Alberta Court of Appeal. The Court of Appeal decision upheld a Judge's decision ordering members of the expert committee, which makes recommendations to the Minister as to addition of drugs on the provincial drug benefit list, to be produced for discovery. Apotex sued the Crown for damages arising out of conduct of the Minister.

[Alberta Court of Appeal Decision](#)

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## Patented Medicines Prices Review Board (PMPRB) Matters

The PMPRB has recently accepted three Voluntary Compliance Undertakings for:

- [etonogestrel/ethinyl estradiol slow release \(NUVARING\)](#);
  - [hetastarch \(HEXTEND\)](#); and
  - [oxaliplatin \(ELOXATIN\)](#).
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## Recent Court Decisions

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

*Biovail v. Sandoz (bupropion (WELLBUTRIN SR))*, June 21, 2006

Judge dismisses application for a prohibition Order for two patents, finding that Biovail had not established that the allegations of non-infringement were justified. However, Judge rejects Sandoz's argument that a previous decision involving Novopharm, Biovail, and the question of whether hydroxypropyl cellulose as a sustained release agent would infringe the same patent should be followed as a matter of judicial comity.

[Full Judgment \(2006 FC 784\)](#)

*Apotex v. Pfizer* (**fluconazole (APO-FLUCONAZOLE, DIFLUCAN)**), June 28, 2006

Court of Appeal allows Apotex's appeal of a Judge's Order not requiring Pfizer to answer certain discovery questions in the context of a section 8 damages action. Court of Appeal finds that the disputed questions are "relevant to claims made in the pleadings, either to the allegation of common enterprise or to the computation of damages, assuming that damages may be measured by reference to the respondents' profits".

*Court of Appeal Decision* ([2006 FCA 246](#))

*Motions Judge's Decision* ([2006 FC 262](#))

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*Apotex v. Bristol-Myers Squibb* (**pravastatin, APO-PRAVASTATIN, PRAVACHOL**), July 5, 2006

In a section 8 damages action, Judge dismisses Apotex's appeal from an Order of a Prothonotary granting leave to the Defendants to serve and file amended pleadings as a consequence of the Prothonotary allowing Apotex to withdraw assertions of non-infringement from its statement of claim. Apotex has appealed.

*Full Judgment* ([2006 FC 850](#))

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*Aventis v. Pharmascience* (**ramipril (ALTACE)**), July 10, 2006 and July 18, 2006

In separate decisions, Judge dismisses Aventis' applications for Orders of prohibition relating to two use patents (use of ramipril for the treatment of cardiac and vascular hypertrophy and hyperplasia, and use of compounds including ramipril in combination with a calcium antagonist to prevent and treat proteinuria). Pharmascience had alleged non-infringement. Judge finds that Aventis had not established that Pharmascience would induce infringement by patients.

*Full Judgment* ([2006 FC 861](#))

*Full Judgment* ([2006 FC 898](#))

### Other Decisions

*AstraZeneca v. Health Canada (esomeprazole magnesium trihydrate (NEXIUM)); AstraZeneca v. Health Canada (omeprazole, omeprazole magnesium (LOSEC, LOSEC MUPS))*, June 27, 2006

Court of Appeal dismisses AstraZeneca's consolidated appeals from Orders which dismissed AstraZeneca's applications for review of the Minister's decision to release certain information pursuant to the *Access to Information Act* relating to AstraZeneca's drug submission for NEXIUM tablets.

*Court of Appeal Decision (2006 FCA 241)*

*Applications Judge's Reasons for Order (2005 FC 189)*

*Applications Judge's Supplemental Reasons for Order (2005 FC 648)*

In three related decisions, Court of Appeal dismisses AstraZeneca's appeals of Orders which dismissed AstraZeneca's applications for review of the Minister's decisions to release certain information pursuant to the *Access to Information Act* relating to AstraZeneca's drug submissions for LOSEC tablets and capsules and LOSEC MUPS tablets.

*Court of Appeal Decisions (2006 FCA 242, 2006 FCA 243, 2006 FCA 244)*

*Applications Judge's Decision re: LOSEC Tablets (2005 FC 645)*

*Applications Judge's Decision re: LOSEC MUPS Tablets (2005 FC 646)*

*Applications Judge's Decision re: LOSEC Capsules (2005 FC 647)*

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## Trade-mark Decisions

*ICN v. Martin G. Unger (VIRAZOST)*, February 3, 2006

Opposition Board refuses application for registration of the trade-mark VIRAZOST for use in association with "pharmaceutical preparations for human and veterinary use namely, for the treatment of insect and parasitic irritations; bacterial, fungal, and viral skin conditions; summer itch and girth itch". The Board found a reasonable likelihood of confusion with ICN's VIRAZOLE (ribavirin), registered for use in association with "pharmaceutical preparations, namely a broad spectrum anti-viral agent".

*Full Decision*

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*Novopharm and Apotex v. Hoffmann-La Roche (XENICAL Capsule Design (orlistat))*, May 5, 2006

Opposition Board refuses Roche's application for registration XENICAL Capsule Design (the colour blue applied to the whole visible surface of the capsule), for use in association with a "pharmaceutical preparation, namely, an anti-obesity and lipid lowering agent containing 120 mg of orlistat". The Board refused the application on technical grounds, but noted that the opponents would also likely have succeeded on the ground of lack of distinctiveness.

*Full Decision*

*Eli Lilly and Company v. Novopharm Ltd. (fluoxetine (PROZAC CAPSULE DESIGN))*, June 30, 2006

Judge dismisses Eli Lilly's appeal from a decision of the Registrar of Trade-Marks, refusing Eli Lilly's application for the trade-mark PROZAC CAPSULE DESIGN (20MG) (which includes the colours pale green and whitish yellow) for use in association with "pharmaceutical preparations, namely, an antidepressant, antiobsessional and antidiabetic preparation containing fluoxetine hydrochloride", on the basis of non-distinctiveness. The Judge held that the Registrar's decision is reasonable on the basis of the evidence.

*Full Judgment (2006 FC 843)*

*TMOB Decision for 20mg Capsule*

*Ratiopharm v. Riva (cough syrups (CALMYLIN, DAMYLIN))*, July 18, 2006

Ratiopharm, owner of the registered trade-mark CALMYLIN for use in association with its codeine based syrup, instituted a trade-mark infringement and passing-off action against Riva for its use of the mark DAMYLIN also in association with a codeine based syrup. Judge finds that there is no likelihood of confusion between the marks.

*Full Judgment (2006 FC 889)*

## New Court Proceedings

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

**Medicine:** **risedronate sodium (ACTONEL)**  
**Applicants:** Procter & Gamble Pharmaceuticals Canada Inc and The Procter & Gamble Company  
**Respondents:** Merck & Co, Inc, Novopharm Limited and The Minister of Health  
**Date Commenced:** June 23, 2006  
**Court File No:** T-1053-06  
**Comment:** Application for Order of prohibition until expiry of Patent No 1,320,727 and Merck's Patent No 2,294,595. Novopharm alleges that the '727 Patent is invalid and that the '595 Patent is not eligible for listing on the Patent Register, is not infringed and is invalid.

**Medicine:** **omeprazole magnesium (LOSEC)**  
**Applicants:** AstraZeneca Canada Inc  
**Respondents:** Novopharm Limited, Takeda Pharmaceutical Company Limited, and The Minister of Health  
**Date Commenced:** July 10, 2006  
**Court File No:** T-1160-06  
**Comment:** Application for Order of prohibition until expiry of Takeda's Patent No 1,338,377. Novopharm alleges that the patent is not eligible for listing on the Patent Register, non-infringement and invalidity.

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**Medicine:** **atorvastatin calcium (LIPITOR)**  
**Applicant:** Pfizer Canada Inc and Warner-Lambert Company, LLC  
**Respondent:** Ranbaxy Laboratories Limited, Ranbaxy Inc and The Minister of Health  
**Date Commenced:** July 12, 2006  
**Court File No:** T-1171-06  
**Comment:** Application for Order of prohibition until expiry of Patents Nos 2,450,111; 2,521,953; and 2,521,933. Ranbaxy alleges non-infringement.

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**Medicine:** **omeprazole magnesium (LOSEC)**  
**Applicant:** AstraZeneca Canada Inc and AstraZeneca AB  
**Respondent:** Novopharm Limited and The Minister of Health  
**Date Commenced:** July 14, 2006  
**Court File No:** T-1186-06  
**Comment:** Application for Order of prohibition until expiry of Patent No 2,186,037. Novopharm alleges that the patent is not eligible for listing on the Patent Register, non-infringement and invalidity.

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**Medicine:** **diltiazem hydrochloride (TIAZAC, RHOXAL-DILTIAZEM T)**  
**Applicant:** Sandoz Canada Inc  
**Respondent:** Biovail Corporation  
**Date Commenced:** July 18, 2006  
**Court File No:** T-1245-06  
**Comment:** Action brought pursuant to section 8 of the *Regulations* for damages allegedly suffered by Sandoz by reason of initiation of the prohibition proceeding by Biovail and an accounting of Biovail's profits in respect of Sandoz's lost market share.

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**Medicine:** **moxifloxacin (AVELOX)**  
**Plaintiffs:** Bayer Inc and Bayer Healthcare AG  
**Defendant:** Novopharm Limited and The Minister of Health  
**Date Commenced:** July 20, 2006  
**Court File No:** T-1256-06  
**Comment:** Application for Order of prohibition until expiry of Patents Nos 1,340,114; 2,086,914 and 2,192,418. Novopharm alleges that the '114 and '418 Patents are not properly listed on the Patent Register; non-infringement of the '418 Patent and invalidity of the '114 and '914 Patents.

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*Other New Proceedings*

**Medicine:** **paroxetine (PAXIL)**  
**Plaintiffs:** Deanna Yuzicapi, John Doe Provincial Prescription Drug Program I, et al.  
**Defendants:** GlaxoSmithKline Inc, GlaxoSmithKline plc, et al  
**Date Commenced:** February 7, 2005 (recently transferred to Toronto)  
**Court File No:** 06-CV-313378PD3  
**Comment:** Action under the *Class Proceedings Act* for damages. The plaintiffs plead, "The Defendants, through evergreening, have artificially and inappropriately extended the monopoly over the drug Paxil. The result is that the drug purchaser has been prevented from receiving access to more affordable, safe, and effective generic drugs".

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