



Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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Supreme Court of Canada Leave Applications

Apotex v. AstraZeneca (omeprazole (LOSEC)), June 13, 2005

Apotex has filed an application for leave to appeal the Federal Court of Appeal's May 18, 2005 decision ([2005 FCA 189](#)), quashing Apotex's NOC for omeprazole capsules. The appeal turned on the Court's interpretation of the "marketed" requirement in section 5(1) of the *Patented Medicines (Notice of Compliance) Regulations* ("Regulations"). The Court of Appeal's decision has been stayed pending disposition of the leave application. A motion brought by the Canadian Generic Pharmaceutical Association for leave to intervene in the leave application was dismissed on July 21, 2005.

Patented Medicines Prices Review Board (PMPRB) Matters

The PMPRB has accepted a Voluntary Compliance Undertaking (VCU) from Amersham Health Inc., GE Healthcare for technetium TC-99M exametazine (CERETEC).

[VCU Notice](#)

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Hoffmann-La Roche v. Mayne Pharma (ceftriaxone disodium (ROCEPHIN)), June 7, 2005

Judge grants Roche's application for an Order of prohibition, finding that Mayne's allegation of non-infringement is not justified. Mayne has appealed.

[Full Judgment \(2005 FC 814\)](#)

Pharmascience v. Canada (Minister of Health) (clarithromycin (BIAXIN BID)), June 29, 2005

Court of Appeal dismisses Pharmascience's appeal of an Order of prohibition. The Applications Judge had found that Pharmascience's notice of allegation (NOA) was deficient, and that Pharmascience had failed to discharge its evidentiary burden to justify the allegations of non-infringement and invalidity.

[Court of Appeal Decision \(2005 FCA 250\)](#)

[Applications Judge's Decision \(2004 FC 1349\)](#)

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: **clopidogrel (PLAVIX)**
Applicants: Sanofi-Synthelabo Canada Inc and Sanofi-Aventis
Respondents: Apotex Inc and The Minister of Health
Date Commenced: June 21, 2005
Comment: Application for Order of prohibition until expiry of Patent No. 2,334,870. Apotex alleges non-infringement and invalidity.

Medicine: **atorvastatin (LIPITOR)**
Applicants: Pfizer Canada Inc and Warner-Lambert Company LLC
Respondents: Ratiopharm Inc and The Minister of Health
Date Commenced: June 30, 2005
Comment: Application for Order of prohibition until expiry of Patents Nos. 1,268,768; 2,021,546; 2,150,372; 2,220,018; 2,220,455; and 2,220,458. Ratiopharm alleges non-infringement and invalidity with respect to the 546, 372, 018, 455 and 458 Patents and accepts that an NOC will not issue until after expiry of the 768 Patent.

Medicine: **irinotecan (CAMPTOSAR)**
Applicants: Pfizer Canada Inc and Pharmacia & Upjohn
Respondents: Mayne Pharma (Canada) Inc and The Minister of Health
Date Commenced: July 7, 2005
Comment: Application for Order of prohibition until expiry of Patent No. 2,202,531. Mayne alleges non-infringement and that the patent is not eligible for listing.

Medicine: **quinapril (ACCUPRIL)**
Applicant: Pfizer Canada Inc
Respondents: Aventis Pharma Deutschland GmbH, Apotex Inc and The Minister of Health
Date Commenced: July 18, 2005
Comment: Application for Order of prohibition until expiry of Aventis' Patent No. 2,023,089. Apotex alleges non-infringement and invalidity.

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Other New Proceedings

Medicine: **alendronate (FOSAMAX)**
Plaintiff: Apotex Inc
Defendants: Merck & Co, Inc and Merck Frosst Canada & Co
Date Commenced: July 5, 2005
Comment: Action brought pursuant to the *Regulations* for damages allegedly suffered by Apotex by reason of initiation of a prohibition proceeding by Merck or, in the alternative, an accounting of profits.

Medicine: **health supplement**
Plaintiffs: Novogen Research Pty Ltd and Novogen (Canada) Limited
Defendants: WN Pharmaceuticals Ltd and Holista Health (Canada) Inc
Date Commenced: July 13, 2005
Comment: Patent infringement action relating to Patent No. 2,136,233 relating to the Defendants' sales of WEBBER NATURALS HRT MENO FORMULA, LONDON NATURALS HRT FORMULA ALTERNATIVE, LIFE BRAND PREMIUM HRT FORMULA, HOLISTA NATURAL HRT ALTERNATIVE, HOLISTA NATURAL HRT ALTERNATIVE. Novogen pleads that it markets its health supplement product based on red clover isoflavones in Canada under the trade-mark PROMENSIL.

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