



# Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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## Mixed Results for Ramipril Use Patents

Two recent decisions of the Federal Court have considered the test of infringement of a new use patent under the *Patented Medicines (Notice of Compliance) Regulations* ("Regulations"), with mixed results.

On October 11, 2005, a Judge granted Aventis' application to prohibit the Minister from issuing a notice of compliance (NOC) to Apotex for its ramipril product until after the expiry of Patent No. 1,246,457 (*Aventis v. Apotex*, 2005 FC 1381). The '457 patent covers the use of ramipril in the treatment of heart failure. Aventis sells ramipril under the brand name ALTACE which is widely prescribed in the treatment of heart failure.

Referring to two Court of Appeal decisions that considered the test for infringement of a new use patent under the *Regulations* (*Procter & Gamble v. Canada (Minister of Health)*, 2002 FCA 290 and *AB Hassle v. Canada (Minister of Health)*, 2002 FCA 421), the Judge found that proof on a balance of probabilities that third parties will infringe would satisfy the test of infringement. The Judge accepted Aventis' evidence that Apotex's ramipril product will inevitably be dispensed for heart failure, and found that Aventis has demonstrated that infringement will occur.

The Judge also determined that Apotex's product monograph enclosed with the notice of allegation (NOA) is the relevant product monograph. The Court rejected Apotex's argument that the product monograph revised to address Aventis' concerns about certain passages should be considered. In rejecting this argument, the Judge found that a party filing an NOA is obliged to put its full and best case forward, and an NOA is not an offer to open negotiations. The Judge agreed that the relevant product monograph indicates that Apo-Ramipril can be used to treat heart failure, and found that Apotex's non-infringement allegations are not credible. Apotex has appealed.

On October 27, 2005, another Judge dismissed Aventis' application to prohibit the Minister from issuing an NOC to Apotex for its ramipril product until the expiry of Patent No. 2,023,089 (*Aventis v. Apotex*, 2005 FC 1461). The '089 patent covers the use of ramipril for the treatment of cardiac and vascular hypertrophy and hyperplasia ("Hypertrophy").

ALTACE is prescribed for the treatment of Hypertrophy, although it is not formally approved for such use. Apotex conceded that "off-label" prescribing of its ramipril product will occur once the NOC is issued, with the result that patients will consume it to treat Hypertrophy. However, the Judge found that infringement by patients is not enough; there must be "something more", be it inducement, procurement, marketing or some other nexus. The Court found that Aventis did not establish the required nexus, and so dismissed the application.

It remains for the Court of Appeal to clarify whether a second person's allegation of non-infringement of a new use patent is justified where it is established that patients will infringe the new use patent once an NOC is issued to the second person.

Yoon Kang

## Supreme Court of Canada Leave Applications

*AstraZeneca v. Apotex (omeprazole magnesium (LOSEC))*, September 6, 2005

AstraZeneca has filed an application for leave to appeal a decision of the Court of Appeal, which dismissed AstraZeneca's appeal of the dismissal of its application for a prohibition Order. AstraZeneca had argued that the Judge erred in law in concluding that the NOA was not deficient, and that the Judge should have concluded that the allegation of non-infringement was not justified.

*Court of Appeal Decision (2005 FCA 216)*

*Applications Judge's Decision (discussed in the July 2004 issue of Rx IP Update) (2004 FC 647)*

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*Apotex v. AstraZeneca (omeprazole (LOSEC))*, October 20, 2005

As reported in our [October 2005 special edition](#) of *Rx IP Update*, leave was granted to Apotex to appeal a decision of the Federal Court of Appeal which quashed Apotex's NOC for omeprazole.

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*Pharmascience v. Régie de l'assurance-maladie du Québec; Apotex v. Régie de l'assurance-maladie du Québec*, October 20, 2005

Leave has been denied to appeal two judgments of the Quebec Court of Appeal. Régie de l'assurance maladie du Québec (the organization responsible for Quebec's health insurance plan) brought actions against Pharmascience, Apotex, and Ratiopharm, alleging that by giving certain discounts, promotions and gratuities to pharmacists, the Defendants had violated the pricing rules imposed by the *Act Respecting Prescription Drug Insurance* and regulations, and claimed damages. The Quebec Superior Court dismissed the Defendants' motions to dismiss, and the Court of Appeal denied leave to appeal.

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*Jocelyn Binet v. Pharmascience, Goodman, et Procureur general du Quebec*, October 20, 2005

Leave has been granted from a judgment of the Quebec Court of Appeal. The syndic of pharmacists began an inquiry into allegations that financial benefits were being accepted from manufacturers of generic drugs, contrary to the professional ethics of pharmacists. The issue related to whether Pharmascience and its co-founder and chairman should be required to provide all documents necessary for the inquiry. The Court of Appeal held that the application of the syndic's power was limited to professionals themselves, whereas the two persons were third parties and therefore reversed the lower Court's Order for production.

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## Recent Court Decisions

*Patented Medicines (Notice of Compliance) Regulations*

*Pfizer v. Novopharm (azithromycin (ZITHROMAX))*, October 3, 2005

Judges grants Pfizer's application for an Order of prohibition. The Judge found in favour of Novopharm on its allegation of invalidity on the basis of overbreadth of one claim, but found Novopharm's allegation of non-infringement of other claims not justified. Novopharm has appealed.

*Full Judgment (2005 FC 1299)*

*Fournier v. Cipher (fenofibrate (LIPIDIL SUPRA))*, October 12, 2005

Court of Appeal dismisses Fournier's appeal of a Judge's dismissal of its application for a prohibition Order. Cipher had alleged non-infringement.

*Court of Appeal's Decision (2005 FCA 326)*

*Applications Judge's Decision (2004 FC 1718)*

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*Apotex v. Canada (Minister of Health) (Apo-X)*, October 14, 2005

Judge dismisses Apotex's appeal of a Prothonotary's refusal to grant Apotex leave to file supplementary evidence. Apotex has appealed.

*Full Judgment (2005 FC 1401)*

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*Hoffmann-LaRoche v. Canada (Minister of Health) (ibandronate sodium (BONDRONAT))*, October 17, 2005

Judge dismisses Roche's application for judicial review of the Minister's decision to not list Roche's patent on the Patent Register. Roche had filed a first patent list mistakenly citing only its supplemental new drug submission (SNDS) for a name change as the basis for requesting such listing. Roche then filed a corrected second patent list outside the 30-day time limit, including the new drug submission (NDS) as a basis. The Judge found that the Minister was correct in refusing the first filing since: such an SNDS is not a proper basis for listing; the obligation is on the applicant to identify the submission on which the filing is based; and the Minister does not have discretion to accept an out-of-time filing.

*Full Judgment (2005 FC 1415)*

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*Pfizer v. Apotex (azithromycin (ZITHROMAX))*, October 17, 2005

Judge dismisses Pfizer's application for an Order of prohibition, finding that Pfizer had not established that Apotex's allegations of invalidity and non-infringement were not justified. Judge also finds that the patent was not properly listed on the Patent Register against ZITHROMAX 250 mg tablets in view of a timing issue.

*Full Judgment (2005 FC 1421)*

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*GlaxoSmithKline v. Canada (Attorney General) (salmeterol xinafoate/fluticasone propionate (ADVAIR, ADVAIR DISKUS), fluticasone propionate (FLOVENT HFA), salbutamol sulphate (VENTOLIN HFA))*, October 25, 2005

Judge dismisses GSK's application for judicial review of the Minister's refusal to list its patent on the Patent Register, finding the invention is not the "medicine" but rather the design of a system, including particularly a special valve, for the delivery or administration of medicaments.

*Full Judgment (2005 FC 1444)*

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*Apotex v. Merck (lovastatin (MEVACOR; APO-LOVASTATIN))*, October 25, 2005

Judge dismisses Apotex's appeal of a Prothonotary's decision, dismissing its motion for a preliminary determination of a question of law. Apotex had requested determination of whether a Defendant to a proceeding brought pursuant to section 8 of the *Regulations* (the damages provision) is entitled to defend on the basis that infringement would have occurred by the Plaintiff had the prohibition proceeding not been commenced by the Defendant. The Judge found the question to be a difficult legal question not well suited for preliminary determination, and one which could not be easily extricated from the other issues in the action.

*Full Judgment (2005 FC 1452)*

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*Bristol-Myers Squibb v. Novopharm (gatifloxacin (TEQUIN))*, October 28, 2005

Judge grants BMS's application for a prohibition Order. Novopharm had alleged invalidity on the basis of obviousness.

*Full Judgment (2005 FC 1458)*

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### *Other Decisions*

*Aventis v. Novopharm (enoxaparin sodium (LOVENOX))*, October 12, 2005

Judge affirms Prothonotary's decision to strike out certain paragraphs from Aventis' notice of application in which Aventis sought to have the Minister's decision to issue an NOC to Novopharm declared invalid. The paragraphs related to a request for a declaration that the Minister erred in concluding that Novo-enoxaparin is the "pharmaceutical equivalent" of Aventis' LOVENOX. The Judge found that Aventis had no status to challenge the Minister's decision since a commercial interest alone is insufficient to permit a person to seek judicial review who is not a party to the application before the Minister for an NOC. Aventis has appealed.

*Full Judgment (2005 FC 1396)*

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## Patent Appeal Board Decisions

*Re Sherman Patent Application No. 2,166,001 (enalapril sodium)* (Patent Appeal Board and Commissioner of Patents), July 13, 2005

Dr. Sherman had filed a patent application entitled, "Stable Solid Formulation of Enalapril Salt and Process for Preparation Thereof", for which a Final Action had issued. Board finds the invention was novel and unobvious and the Examiner's rejection should be reversed. The Commissioner of Patents returned the application to the Examiner for further prosecution.

*Full Decision*

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# New Court Proceedings

## Patented Medicines (Notice of Compliance) Regulations

**Medicine:** **clopidogrel (PLAVIX)**  
**Applicants:** Sanofi-Synthelabo Canada Inc and Sanofi-Aventis  
**Respondents:** Cobalt Pharmaceuticals Inc and The Minister of Health  
**Date Commenced:** September 22, 2005  
**Comment:** Application for Order of prohibition until expiry of Patents Nos 1,336,777 and 2,334,870. Cobalt alleges non-infringement and invalidity ('777 patent) and non-infringement ('870 patent).

**Medicine:** **pantoprazole sodium (PANTOLOC)**  
**Applicants:** Solvay Pharma Inc and Altana Pharma AG  
**Respondents:** Apotex Inc and the Minister Health  
**Date Commenced:** October 4, 2005  
**Comment:** Application for Order of prohibition until expiry of Altana's Patents Nos 2,092,694 and 2,089,748. Apotex alleges non-infringement.

**Medicine:** **pioglitazone hydrochloride (ACTOS)**  
**Applicants:** Eli Lilly Canada Inc  
**Respondents:** Novopharm Limited, the Minister of Health, Takeda Pharmaceutical Company Ltd  
**Date Commenced:** October 12, 2005  
**Comment:** Application for Order of prohibition until expiry of Takeda's Patent No 1,277,323. Novopharm alleges invalidity.

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