



# Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

## December 2007

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## Apotex's challenge to data protection to proceed

Apotex had brought an application for judicial review, challenging the validity of the data protection provision of the *Food and Drug Regulations*. On March 5, 2007, a Federal Court judge struck the application, finding that Apotex had no standing to make this challenge as it was not a person directly affected (*Apotex Inc. v. The Governor in Council, The Minister of Health and Canada (Attorney General)*, [2007 FC 232](#)). However, on November 27, 2007, the Federal Court of Appeal allowed Apotex's appeal and permitted Apotex's application to proceed ([2007 FCA 374](#)). The Court of Appeal noted that "...Apotex is currently subject to a direct legislative prohibition" and concluded that it was not plain and obvious that Apotex

was not directly affected by the new data protection provision. The matter of standing was left to be determined by the Judge ultimately hearing the application on the merits.

Apotex's appeal was heard together with the Attorney General's appeal of a separate decision, dismissing its motion to strike the Canadian Generic Pharmaceutical Association (CGPA)'s similar challenge to the data protection provision (*Canadian Generic Pharmaceutical Association v. Canada (Governor in Council)*, [2007 FC 154](#)). That appeal was dismissed: [2007 FCA 375](#). Accordingly, CGPA's challenge will also proceed.

## Health Canada reviewing Special Access Programme

The Special Access Programme (SAP) allows practitioners to gain access to drugs or medical devices that have not yet been authorized for sale in Canada through a regulatory exemption. In response to comments from stakeholders and users of the SAP, Health Canada has undertaken a comprehensive review to modernize the policy and regulatory

frameworks supporting the Programme. Health Canada began consultations at the beginning of 2007, and the issues identified by stakeholders have been included in an Issue Identification Paper. Health Canada will accept comments on the Paper until December 17, 2007. ([SAP Comprehensive Review](#), [SAP Issue Identification Paper](#).)

## Health Canada considering proposal re: Extraordinary Use New Drugs

An Extraordinary Use New Drug (EUND) is a drug that would be used to treat, mitigate or prevent a life-threatening or serious health condition in humans which results from exposure to a chemical, biological, radiological or nuclear substance in an emergency situation (e.g. an outbreak of pandemic influenza). Health Canada has identified the need to amend the *Food and Drug Regulations* to allow for market

authorization of EUNDS. On October 31, 2007, Health Canada sent a letter to stakeholders seeking comments/feedback regarding such an amendment, which is proposed to enable market authorization of EUNDS based on *in vitro* and animal studies and clinical data for safety. ([Letter to stakeholders](#).)

## Health Canada releases draft Guidance Document – risk communications under CAMR

Health Canada has released a draft Guidance Document to clarify responsibilities and procedures for risk communications relating to health products exported under *Canada's*

*Access to Medicines Regime (CAMR)*. Any comments should be submitted before January 21, 2008. ([Notice and draft Guidance Document](#).)

## Supreme Court of Canada matters

*Ranbaxy v. Pfizer* (atorvastatin calcium (LIPITOR)), September 19, 2007. Ranbaxy is seeking leave to appeal a Court of Appeal Order affirming the Motions Judge's Order granting leave to Pfizer to serve and file an amended notice of application (NOA) and extending the 24-month stay under the *Patented Medicines (Notice of Compliance) Regulations* ("Regulations"). Pfizer had discontinued its application regarding two patents in view of assurances and documents received from Ranbaxy's counsel. After learning that the assurances were not correct, Pfizer sought to bring the two patents back into the proceeding.  
(Court of Appeal decision – [2007 FCA 244](#).  
Motions Judge's decision – [2007 FC 205](#).)

*Apotex v. Pfizer* (quinapril (ACCUPRIL)), November 15, 2007. Apotex was denied leave to appeal a Court of Appeal decision allowing Pfizer's appeal and granting an Order of prohibition. The Court of Appeal concluded that Apotex's non-infringement allegation regarding one patent was not justified, and that Apotex's invalidity allegations of another patent on the grounds of overbreadth, obviousness, anticipation, double patenting and lack of utility were also not justified.  
(Court of Appeal decision – [2007 FCA 209](#).  
Applications Judge's decision – [2005 FC 1205](#).)

## Recent Court decisions

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

*AstraZeneca v. Apotex* (omeprazole (LOSEC)), October 16, 2007. Court of Appeal dismisses AstraZeneca's appeal from a judgment dismissing AstraZeneca's application for an Order of prohibition. The Judge found that AstraZeneca did not establish that Apotex's allegation of non-infringement was not justified.  
(Court of Appeal decision – [2007 FCA 327](#).  
Applications Judge's Decision – [2006 FC 7](#).)

*Eli Lilly v. Novopharm* (olanzapine (ZYPREXA)), November 6, 2007. Court of Appeal dismisses Eli Lilly's appeal for mootness. The Applications Judge had found that Eli Lilly did not establish that the allegation of invalidity on grounds of insufficient disclosure was not justified and dismissed Eli Lilly's prohibition application. A notice of compliance (NOC) was granted to Novopharm the next day. The Court of Appeal held that the appeal is moot and declined to exercise its discretion to hear the appeal.  
(Court of Appeal decision – [2007 FCA 359](#).  
Applications Judge's decision – [2007 FC 596](#).)

*sanofi-aventis v. Riva and The Minister of Health* (ramipril (ALTACE)), November 7, 2007. Prothonotary grants Riva's motion to dismiss sanofi-aventis's application for judicial review

of a decision of the Minister of Health contained in a letter addressed to counsel for Riva. The Prothonotary found that the letter does not contain a decision of the Minister and that sanofi-aventis lacks standing as it is not directly affected by the position of the Minister as set out in the letter. sanofi-aventis has appealed. (Full judgment – [2007 FC 1156](#).)

*Abbott v. Apotex and the Minister of Health* (clarithromycin (BIAXIN)), November 19, 2007. Court of Appeal grants Apotex's motion and dismisses Abbott's appeal on the basis of mootness. The Applications Judge had found that Apotex's allegation of invalidity was justified and an NOC then issued to Apotex. The Court of Appeal declined to exercise its discretion to hear the appeal despite mootness, rejecting Abbott's argument that the appeal may have a collateral consequence on a separate prohibition proceeding involving another generic.  
(Court of Appeal decision – [2007 FCA 368](#).  
Applications Judge's decision – [2007 FC 753](#).)

## Other decisions

*Bayer v. Sandoz* (ciprofloxacin intravenous (CIPRO IV)), October 17, 2007. Judge allows Sandoz's appeal and sets aside the Order of a Prothonotary which struck out, without leave to amend, portions of Sandoz's amended defence to Bayer's infringement action. The Judge found that Sandoz's amended "claims broader" pleading was not the same as that initially struck out in an earlier motion. The Judge also found that a new pleading of "bad faith" could be relevant to the issue of Sandoz's invalidity defence based on section 53 of the *Patent Act* and to Bayer's entitlement to an accounting of profits and aggravated, punitive and exemplary damages. Bayer has appealed. (Full judgment – [2007 FC 1068](#).)

*Eli Lilly v. Novopharm* (olanzapine (ZYPREXA)), October 31, 2007. Judge dismisses Novopharm's appeal from a case management Prothonotary's bifurcation Order. The Judge found that the Prothonotary did not err as argued by applying or assuming a presumption in favour of bifurcation in patent infringement actions or by failing to apply the evidentiary requirements. (Full judgment – [2007 FC 1126](#).)

*Apotex v. Servier* (perindopril (COVERSYL)), November 1, 2007. Court of Appeal allows Apotex's appeal from an Order of a Motions Judge granting the plaintiffs' motion to strike certain provisions of the defence and counterclaim dealing with the issue of "inventorship", which requires a statutory interpretation of the phrase "on which conflict proceedings should have been directed" in section 61(1)(b) of the pre-1989 *Patent Act*. The Court of Appeal finds that the Judge was clearly wrong in concluding that the defendants' inventorship allegations amount to an abuse of process. The Court of Appeal also finds that the Judge erred in finding that the defendants' statutory interpretation of section 61(1)(b) is either tenuous or devoid of any merit. (Court of Appeal decision – [2007 FCA 350](#). Motions Judge's decision – [2007 FC 837](#).)

*Pharmascience, ratiopharm, Cobalt, Ranbaxy, Sandoz, Genpharm and Novopharm v. Ontario (Health and Long-Term Care) and Apotex (intervenor)* (lisinopril (Apo-LISINOPRIL)), November 11, 2007. Judge grants generic group of applicants leave to bring an urgent application for judicial review of the Minister's decision to designate apo-lisinopril as a benefit

in the October Formulary Update; however, Judge dismisses the application. The generics argued that Apotex could not have met the supply condition under section 12(1)(e) of the *Ontario Drug Benefit Act* as of the date of its application (*i.e.* October 3, 2007) in view of an injunction issued by the Federal Court until the expiry of Merck's patents (*i.e.* October 16, 2007). The Judge agreed with the Minister and Apotex that the words of the subsection "...is able to supply the product..." "...to meet the anticipated demand for the product..." mean that a manufacturer must supply satisfactory evidence that it has the capability to supply product that will fill the anticipated demand for the product as at the effective date of designation (*i.e.* November 16, 2007), not that it has sufficient inventory on hand at the time of application. The Judge also rejected the argument that the decision was made unfairly to the prejudice of the applicants. The Judge denied the alternative relief of listing the applicants' comparable products together with Apotex's product. (First decision: [2007 CANLII 50601](#). Second decision: [2007 CANLII 50602](#).)

*Eli Lilly v. Novopharm* (olanzapine (ZYPREXA)), November 15, 2007. Prothonotary grants, in part, Novopharm's motion for a further and better affidavit of documents in a patent infringement action. (Full judgment – [2007 FC 1195](#).)

*Servier v. Apotex* (perindopril (COVERSYL)), November 19, 2007. Judge dismisses sanofi-aventis deutschland and Schering's motion to be added as a defendant to the Counterclaim in a patent infringement action. Although it alleged in the Counterclaim that sanofi-aventis deutschland and Schering entered into an agreement or conspiracy in contravention to section 45 of the *Competition Act*, Apotex did not name them as defendants to the Counterclaim. Judge found that sanofi-aventis deutschland and Schering have not satisfied the Court that they ought to be joined as parties to the counterclaim, or that such is necessary in the sense that they should be bound by the result of this action or that the issue of the conspiracy by Servier cannot be effectually and completely settled unless they are joined as parties. (Motions Judge's decision – [2007 FC 1210](#).)

## New proceedings

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

**Medicine:** tazobactam sodium/piperacillin sodium (TAZOCIN)  
**Applicant:** Wyeth Canada  
**Respondent:** The Minister of Health  
**Date Commenced:** October 24, 2007  
**Court File No:** T-1864-07  
**Comment:** Application for judicial review of the Minister's decision to grant an NOC to Sandoz. Wyeth alleges that the Minister has erred by using an "old" version of TAZOCIN as the Canadian Reference Product and by determining that the Sandoz product is safe and efficacious.

**Medicine:** testosterone gel (ANDROGEL)  
**Applicant:** Solvay Pharma Inc  
**Respondents:** The Attorney General of Canada and The Minister of Health  
**Date Commenced:** November 8, 2007  
**Court File No:** T-1934-07  
**Comment:** Judicial review of the Minister's decision not to list Patent No. 2,420,895 on the Patent Register. The Minister alleges the relevant supplemental new drug submission (SNDS) did not result in a change in use.

**Medicine:** pantoprazole sodium tablets (PANTOLOC)  
**Applicants:** Nycomed Canada Inc and Nycomed GmbH  
**Respondents:** The Minister of Health and Sandoz Canada Inc  
**Date Commenced:** November 9, 2007  
**Court File No:** T-1941-07  
**Comment:** Application for an Order of prohibition until expiry of Patent No. 2,089,748. Sandoz alleges non-infringement and invalidity. Sandoz further asserts that the '748 patent is not properly listed on the Patent Register.

**Medicine:** pantoprazole sodium tablets (PANTOLOC)  
**Applicants:** Nycomed Canada Inc and Nycomed GmbH  
**Respondents:** The Minister of Health and Sandoz Canada Inc  
**Date Commenced:** November 9, 2007  
**Court File No:** T-1942-07  
**Comment:** Application for an Order of prohibition until expiry of Patent No. 2,092,694. Sandoz alleges non-infringement and invalidity. Sandoz further asserts that the '694 patent is not properly listed on the Patent Register.

**Medicine:** pantoprazole sodium tablets (PANTOLOC)  
**Applicants:** Nycomed Canada Inc and Nycomed GmbH  
**Respondents:** The Minister of Health and Sandoz Canada Inc  
**Date Commenced:** November 9, 2007  
**Court File No:** T-1943-07  
**Comment:** Application for an Order of prohibition until expiry of Patent No. 2,109,697. Sandoz alleges invalidity and non-infringement. Sandoz further asserts that the '694 patent is not properly listed on the Patent Register, but that if it is, it is not required to address it.

## Other new proceedings

**Medicine:** Enalapril sodium tablets (Apo-Enalapril, Taro-Enalapril)  
**Plaintiffs:** Bernard Charles Sherman and Apotex Inc  
**Defendant:** Taro Pharmaceuticals Inc  
**Date Commenced:** November 13, 2007  
**Court File No:** T-1962-07  
**Comment:** Patent infringement action relating to Patent No. 2,166,001.

**Medicine:** Enalapril sodium tablets (Apo-Enalapril, PMS-Enalapril)  
**Plaintiffs:** Bernard Charles Sherman and Apotex Inc  
**Defendant:** Pharmascience Inc  
**Date Commenced:** November 13, 2007  
**Court File No:** T-1963-07  
**Comment:** Patent infringement action relating to Patent No. 2,166,001.

**Medicine:** Enalapril sodium tablets (Apo-Enalapril, Gen-Enalapril)  
**Plaintiffs:** Bernard Charles Sherman and Apotex Inc  
**Defendant:** Genpharm Inc  
**Date Commenced:** November 13, 2007  
**Court File No:** T-1964-07  
**Comment:** Patent infringement action relating to Patent No. 2,166,001.

**Medicine:** Enalapril sodium tablets (Apo-Enalapril, Sandoz-Enalapril)  
**Plaintiffs:** Bernard Charles Sherman and Apotex Inc  
**Defendant:** Sandoz Canada Inc  
**Date Commenced:** November 13, 2007  
**Court File No:** T-1965-07  
**Comment:** Patent infringement action relating to Patent No. 2,166,001.

**Medicine:** Enalapril sodium tablets (Apo-Enalapril, Ratio-Enalapril)  
**Plaintiffs:** Bernard Charles Sherman and Apotex Inc  
**Defendant:** ratiopharm Inc  
**Date Commenced:** November 13, 2007  
**Court File No:** T-1966-07  
**Comment:** Patent infringement action relating to Patent No. 2,166,001.

**Medicine:** Enalapril sodium tablets (Apo-Enalapril, Novo-Enalapril, Novo-Enalapril/HCTZ)  
**Plaintiffs:** Bernard Charles Sherman and Apotex Inc  
**Defendant:** Novopharm Limited  
**Date Commenced:** November 13, 2007  
**Court File No:** T-1967-07  
**Comment:** Patent infringement action relating to Patent No. 2,166,001.

**Medicine:** olanzapine tablets (ZYPREXA)  
**Plaintiff:** Apotex Inc  
**Defendants:** Eli Lilly and Company Limited, Eli Lilly and Company, Eli Lilly SA and Eli Lilly Canada Inc  
**Date Commenced:** November 13, 2007  
**Court File No:** T-1971-07  
**Comment:** Patent impeachment action relating to Patent No. 2,041,113.

**Medicine:** perindopril tablets (Apo-Perindopril, COVERSYL)  
**Applicant:** Servier Canada Inc  
**Respondent:** Minister of Health  
**Date Commenced:** November 23, 2007  
**Court File No:** T-2051-07  
**Comment:** Application for judicial review relating to a trade complaint by Servier. Servier seeks an Order requiring the Minister to investigate and render a decision. Servier alleges that Apo-Perindopril tablets are being manufactured and commercialized in Canada in an unapproved form.

To check the status of Federal Court cases, [please click here](#).

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