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# Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

## October 2007

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## First authorization granted under CAMR

The Commissioner of Patents has granted the first authorization to a generic drug company under Canada's Access to Medicines Regime (CAMR). On September 19, 2007, the Commissioner granted Apotex authorization to make, construct and use certain patented inventions, solely for purposes of manufacture of an HIV/AIDS drug (fixed dose combination tablet of lamivudine (150 mg) + nevirapine (200

mg) + zidovudine (300mg)), and to sell it for export to Rwanda. The nine patents identified in the authorization are owned by: Glaxo Group Limited, Wellcome Foundation Limited, Shire Biochem Inc. and Boehringer Ingelheim Pharmaceuticals, Inc.; and Dr. Karl Thomae GmbH.  
([Authorization](#). [Apotex's Application](#). [CIPO News](#).)

## Supreme Court of Canada matters

*Apotex v. Pfizer* (quinapril hydrochloride (ACCUPRIL)), July 30, 2007. Apotex is seeking 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](#).)

*Pfizer v. Apotex* (sildenafil (VIAGRA)), August 15, 2007. Pfizer is seeking leave to appeal the Court of Appeal's dismissal of its appeal from a judgment denying its prohibition application. The Applications Judge found that Pfizer failed to prove that Apotex's allegations of invalidity were unjustified. (Court of Appeal decision – [2007 FCA 195](#). Applications Judge's decision – [2007 FC 26](#).)

## Health Canada publishes new patent list forms

On September 24, 2007, Health Canada released new forms for submitting patent lists

to Health Canada ("Form IV Patent List"). ([Notice](#))

## Patented Medicine Prices Review Board (PMPRB) matters

On September 17, 2007, the PMPRB issued an Order in the matter of Leo Pharma Inc. and the medicine DOVOBET (calcipotriol (DOVONEX)/betamethasone dipropionate (DIPROSONE)). The Order establishes maximum non-excessive prices of the medicine and orders payment of the sum representing excess revenues. The Order follows the decision of the Federal Court in *Leo Pharma v. Canada (Attorney General)*, [2007 FC 306](#) (reported in

the [April 2007](#) issue of *Rx IP Update*), upholding the PMPRB ruling that the price at which the medicine was being sold was excessive. In accordance with the Court's decision, the PMPRB ordered that for the periods under review, the distribution of free DOVOBET by Leo Pharma is to be included in the average transaction price calculation and excess revenues shall be calculated on that basis. ([Order](#))

## Recent Court decisions

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

*Solvay and Altana v. Apotex and Minister of Health* (pantoprazole (PANTOLOC)), September 14, 2007. Judge dismisses applicants' appeal of a Prothonotary's decision refusing to

allow certain reply evidence. Solvay and Altana had sought to file 10 affidavits in reply to Apotex's expert affidavits. (Full judgment – [2007 FC 913](#).)

### Other decisions

*Servier, Adir and Oril Industries v. Apotex* (perindopril (COVERSYL)), August 10, 2007. In a patent infringement action, Motions Judge grants 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 Judge finds that validity claims relating to inventorship of the patent are precluded from being raised by section 61(1)(b) if there is no "missed conflict". The Judge holds that the defendants cannot meet the requirements of section 61(1)(b) and thus it is plain and obvious that the impugned provisions of the defence and counterclaim disclose no reasonable cause of action and should be struck. The Judge also finds that the defendants' inventorship allegations amount to

an abuse of process and should be struck. Apotex has appealed. (Full judgment – [2007 FC 837](#).)

*sanofi-aventis and Schering v. Apotex* (ramipril (ALTACE)), September 12, 2007. In a patent infringement action, Motions Judge dismisses Apotex's appeal from a Prothonotary's Order staying certain paragraphs of the counterclaim against ratiopharm under section 50(1) of the *Competition Act*, as Apotex is seeking essentially the same relief against ratiopharm in an Ontario action. Similarly, the Judge stays paragraphs from the counterclaim against the sanofi-aventis plaintiffs. The Judge also struck out Apotex's allegations under the *Competition Act* in the defence as against sanofi-aventis Canada. (Full judgment – [2007 FC 907](#).)

*sanofi-aventis and Schering v. Apotex* (ramipril (ALTACE)), September 12, 2007. Motions Judge dismisses Apotex's appeal of a Prothonotary's Order setting a trial date for a patent infringement action.  
(Full judgment – [2007 FC 906](#).)

*Eli Lilly v. Apotex; Eli Lilly v. Apotex and Novopharm* (nizatidine (AXID)), September 18, 2007. Judge dismisses appeals by Eli Lilly from

three Orders of a Prothonotary relating to examinations for discovery. The Judge found that the Prothonotary had not erred in her interpretation of her previous scheduling Orders, and that Apotex and Novopharm were therefore not out of time to examine the inventors or Lilly USA. In the alternative, an extension of time ought to be granted.  
(Full judgment – [2007 FC 929](#).)

## New proceedings

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

**Medicine:** raloxifene (HCl) tablets (EVISTA)  
**Applicant:** Eli Lilly Canada Inc  
**Respondents:** The Minister of Health and Novopharm Limited  
**Respondent/Patentee:** Eli Lilly and Company  
**Date Commenced:** August 24, 2007  
**Court File No:** T-1561-07  
**Comment:** Application for an Order of prohibition until expiry of Patent No. 2,158,399. Novopharm alleges invalidity.

**Medicine:** raloxifene (HCl) tablets (EVISTA)  
**Applicant:** Eli Lilly Canada Inc  
**Respondents:** The Minister of Health and Novopharm Limited  
**Respondent/Patentee:** Eli Lilly and Company  
**Date Commenced:** August 24, 2007  
**Court File No:** T-1562-07  
**Comment:** Application for an Order of prohibition until expiry of Patents Nos. 2,143,263 and 2,250,191. Novopharm alleges non-infringement and invalidity of both patents. Novopharm further asserts that it need not address the '191 patent as it is not a "second person" and the use claim in the patent is not an approved use nor a use for which Novopharm is seeking approval.

**Medicine:** raloxifene (HCl) tablets (EVISTA)  
**Applicant:** Eli Lilly Canada Inc  
**Respondents:** The Minister of Health and Novopharm Limited  
**Respondent/Patentee:** Eli Lilly and Company  
**Date Commenced:** August 24, 2007  
**Court File No:** T-1563-07  
**Comment:** Application for an Order of prohibition until expiry of Patent No. 2,101,356. Novopharm alleges invalidity of the patent and non-infringement of claim 6. In addition, Novopharm asserts that the patent is not eligible for listing on the Patent Register.

**Medicine:** sibutramine (HCl monohydrate) capsules (MERIDIA)  
**Applicant:** Abbott Laboratories Limited  
**Respondents:** The Minister of Health and The Attorney General of Canada  
**Date Commenced:** August 24, 2007  
**Court File No:** T-1564-07  
**Comment:** Judicial review of the Minister's decision not to list Patent No. 2,182,620 on the Patent Register. The patent list was submitted pursuant to the amended *Regulations*.

**Medicine:** raloxifene (HCl) tablets (EVISTA)  
**Applicant:** Eli Lilly Canada Inc  
**Respondents:** The Minister of Health and Apotex Inc  
**Respondent/Patentee:** Eli Lilly and Company  
**Date Commenced:** September 5, 2007  
**Court File No:** T-1617-07  
**Comment:** Application for an Order of prohibition until expiry of Patent No. 2,158,399. Apotex alleges non-infringement and invalidity.

### Other new proceedings

**Medicine:** clarithromycin tablets (Apo-clarithromycin, BIAxin)  
**Applicant:** Apotex Inc  
**Respondents:** Executive Officer for the Ontario Public Drug Programs and Attorney General of Ontario  
**Date Commenced:** August 20, 2007  
**Court File No:** 07-CV-338667-PD1  
**Comment:** Urgent application for judicial review of the Decision of the Executive Officer refusing to add Apotex's 250 mg Apo-clarithromycin tablets to the next monthly update of the Ontario Drug Benefit Formulary/Comparative Drug Index as an interchangeable drug product under the *Drug Interchangeability and Dispensing Fee Act* and as a listed product under the *Ontario Drug Benefit Act* and refusing to add Apotex's 500 mg Apo-clarithromycin tablets to the next monthly update of the Formulary/CDI as an interchangeable drug product.

**Medicine:** ciprofloxacin (CIPRO I.V.)  
**Plaintiffs:** Bayer Healthcare AG and Bayer Inc  
**Defendant:** Sunnybrook Health Sciences Centre  
**Date Commenced:** September 5, 2007  
**Court File No:** T-1616-07  
**Comment:** Patent infringement action related to Patent No. 1,282,006.

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

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## Disclaimer

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