



# Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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## Update: Amendments to Linkage Regulations

On February 6, 2007, Health Canada released a guidance document in response to the amendments to the *Patented Medicines (Notice of Compliance) Regulations*, which came into force on October 5, 2006. The guidance document outlines the roles and responsibilities of first persons, second persons and the Therapeutic Products Directorate (TPD) under the amended *Regulations*. Any comments on the document should be submitted no later than March 27, 2007. Health Canada has also released new Forms IV and V.

*Draft Guidance Document*

*Form IV*

*Form V*

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## Motion to Strike CGPA Data Protection Challenge Dismissed

As reported in the [February 2007](#) issue of *Rx IP Update*, the Attorney General brought a motion to strike the Canadian Generic Pharmaceutical Association (CGPA)'s challenge to the amended data protection provisions that came into force on October 5, 2006. The motion was dismissed on February 9, 2007 (*Canadian Generic Pharmaceutical Association v. Canada*, [2007 FC 154](#)). The Judge found that it is not plain and obvious that CGPA lacks standing in its own right, or as informally representing a class of litigants, or that public interest mitigates against giving it standing. The Attorney General has appealed. However, Canada's Research-Based Pharmaceutical Companies (Rx&D) was granted intervener status in the proceeding.

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## Supreme Court of Canada Matters

*Abbott Laboratories v. Ratiopharm and Minister of Health (clarithromycin (BIAXIN BID))*, February 8, 2007

Leave denied. Abbott had sought leave to appeal a decision of the Court of Appeal, which upheld a dismissal of a prohibition application.

*Court of Appeal Decision* ([2006 FCA 187](#))

*Applications Judge's Decision* ([2005 FC 1093](#))

## Patented Medicines Prices Review Board (PMPRB) Matters

The PMPRB has released its January 2007 newsletter. It reports that the amendments to the *Patented Medicines Regulations, 1994* continue to be “in the final stages of moving forward to Treasury Board Cabinet Committee for publication in the *Canada Gazette Part II*”.

*PMPRB Newsletter – January 2007*

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The PMPRB has updated Form 3 – Revenues and Research and Development Expenditures to be filed by March 1, 2007.

*Updated Form 3*

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## Recent Court Decisions

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

*Procter & Gamble v. Minister of Health (risedronate sodium (ACTONEL))*, February 1, 2007

Court of Appeal dismisses Procter & Gamble’s appeal from a decision of the Federal Court which dismissed its application seeking to list a patent on the Patent Register under the pre-amended *Regulations*. The Court agrees with the applications Judge that the invention claimed was a delivery system for the medicine and not the medicine itself. The applications Judge had noted that the essence of the patent is a film coated tablet dosage which avoids irritation to the oesophagus and other upper passages, delivering the active ingredient to the stomach where it is dissipated.

*Court of Appeal Decision (2007 FCA 31)*

*Applications Judge’s Decision (2006 FC 411)*

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*Sanofi-Aventis v. Apotex and Minister of Health (ramipril (ALTACE; APO-RAMIPRIL))*, February 12, 2007

Court of Appeal allows Apotex’s appeal from an Order staying the Minister’s decision to issue Apotex a notice of compliance (NOC) for APO-RAMIPRIL, as reported in the February 2007 issue of *Rx IP Update*. The Court held that the motions Judge erred in issuing the stay when Sanofi-Aventis had failed to show irreparable harm.

*Court of Appeal Decision (2007 FCA 71)*

*Motion Judge’s Decision (2006 FC 1559)*

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*Pfizer v. Pharmascience and Minister of Health; Pfizer v. Cobalt and Minister of Health (amlodipine (NORVASC))*, February 14, 2007

Judge permits applicants to add Pfizer Limited, patentee of one of the patents at issue, as a party to two proceedings under the *Regulations*.

*First Decision (2007 FC 167)*

*Second Decision (2007 FC 169)*

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*Abbott v. Pharmascience and Minister of Health (clarithromycin (BIAXIN BID))*, February 16, 2007

Court of Appeal allows Abbott's appeal and grants an Order of prohibition. The Judge had found that Abbott had not established that Pharmascience's allegation of non-infringement was not justified, finding use of a claimed product during production as an intermediate is not infringement for the purpose of the *Regulations*. The Court of Appeal relied on its decision in *Abbott v. Ratiopharm* (2006 FCA 187 – leave to SCC denied, see above) involving the same patent. In the *Ratiopharm* decision, the Court held that production of an intermediate (Form 0 clarithromycin) is caught within the *Regulations*, notwithstanding that the finished product only contains Form II clarithromycin.

*Court of Appeal Decision* (2007 FCA 73)

*Applications Judge's Decision* (2006 FC 120)

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*Pfizer v. Pharmascience and Minister of Health; Pfizer v. Cobalt and Minister of Health (amlodipine (NORVASC))*, February 19, 2007

Judge dismisses applications pursuant to section 6(5)(a) as they relate to one patent. The Judge finds that the patent should not have been listed on the Patent Register (it had been listed under the pre-amended *Regulations*), as the "medicine" of the NOC is the racemate (amlodipine besylate), not the R(+) enantiomer claimed in the patent.

*Pfizer v. Pharmascience and Minister of Health* (2007 FC 187)

*Pfizer v. Cobalt and Minister of Health* (2007 FC 188)

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*Pfizer v. Ranbaxy Laboratories and Minister of Health (atorvastatin calcium (LIPITOR))*, February 22, 2007

Judge affirms the Prothonatary's order granting leave to Pfizer to serve and file an amended notice of application and extending the 24-month stay under the *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.

*Full Judgment* (2007 FC 205)

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*Ratiopharm v. Abbott (clarithromycin (BIAXIN))*, February 23, 2007

Court of Appeal dismisses Ratiopharm's appeal from an Order of prohibition. Ratiopharm had alleged obviousness.

*Court of Appeal Decision* (2007 FCA 83)

*Applications Judge's Decision* (2006 FC 69)

## New Court Proceedings

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

**Medicine:** **clarithromycin extended-release tablets (BIAXIN XL)**  
**Applicants:** Abbott Laboratories and Abbott Laboratories Limited  
**Respondents:** The Minister of Health and Sandoz Canada Inc  
**Date Commenced:** January 22, 2007  
**Court File No:** T-135-07  
**Comment:** Application for Order of prohibition until expiry of Patents Nos. 2,261,732, 2,258,606, 2,277,274, 2,387,361, 2,386,534, 2,386,527, 2,387,356, 2,471,102 and 2,419,729. Sandoz alleges non-infringement, invalidity and that the patents are not properly listed on the Patent Register.

**Medicine:** **desmopressin (DDAVP)**  
**Applicant:** Ferring Inc  
**Respondents:** The Minister of Health, Apotex Inc and Novopharm Limited  
**Date Commenced:** January 29, 2007  
**Court File No:** T-165-07  
**Comment:** Application for an Order quashing decisions of the Minister of Health that Apotex and Novopharm need not address Patents Nos. 2,486,833 and 1,232,839. The Minister so decided on the basis of his interpretation of *AstraZeneca Canada Inc. v. Canada* (Minister of Health) (2006 SCC 49). The application was heard on March 1 and 2, 2007. The Judge has reserved his decision.

**Medicine:** **gliclazide sustained release tablets (DIAMICRON MR)**  
**Applicants:** Servier Canada Inc and Les Laboratoires Servier  
**Respondents:** The Minister of Health and Apotex Inc  
**Date Commenced:** January 31, 2007  
**Court File No:** T-218-07  
**Comment:** Application for Order of prohibition until expiry of Patent No. 2,273,420. Apotex alleges non-infringement.

**Medicine:** **ramipril (ALTACE)**  
**Applicant:** Sanofi-Aventis Canada Inc  
**Respondents:** Sandoz Canada Inc and The Minister of Health  
**Respondent/Patentee:** Schering Corporation  
**Date Commenced:** February 2, 2007  
**Court File No:** T-233-07  
**Comment:** Application for Order of prohibition until expiry of Schering's Patent No. 1,341,206. Sandoz alleges invalidity.

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**Medicine:** omeprazole (LOSEC)  
**Applicant:** AstraZeneca Canada Inc  
**Respondents:** Sandoz Canada Inc and The Minister of Health  
**Respondent/Patentee:** Takeda Pharmaceutical Company Limited  
**Date Commenced:** February 16, 2007  
**Court File No:** T-310-07  
**Comment:** Application for Order of prohibition until expiry of Takeda's Patent No. 1,338,377. Sandoz alleges non-infringement, invalidity and that the patent is ineligible for listing on the Patent Register.

*Other Proceedings*

**Medicine:** ramipril (ALTACE, APO-RAMIPRIL)  
**Plaintiffs:** Sanofi-Aventis Canada Inc and Schering Corporation  
**Defendant:** Apotex Inc  
**Date Commenced:** January 26, 2007  
**Court File No:** T-161-07  
**Comment:** Patent infringement action relating to Schering's Patent No. 1,341,206.

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