



# Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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## Supreme Court Finds Apo-Omeprazole NOC Valid

On November 3, 2006, the Supreme Court of Canada issued its decision, *Apotex Inc. v. AstraZeneca Canada Inc. et al* ([2006 SCC 49](#)), allowing Apotex's appeal of a Federal Court of Appeal decision that had quashed its notice of compliance (NOC) for **Apo-Omeprazole** (*AstraZeneca v. Minister of Health* ([2005 FCA 189](#))).

The case turned on the interpretation of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") and specifically, section 5(1). The issue was whether Apotex was required to address two patents listed on the Patent Register in connection with AstraZeneca's omeprazole capsules, **LOSEC**, which had been added to the Register after AstraZeneca had ceased marketing LOSEC in 1996 (while the Court indicated that there is no dispute that LOSEC was not marketed throughout the period from 1996 to the present, that fact was disputed by AstraZeneca). The Minister decided that Apotex need not address the patents and the applications judge agreed (*AstraZeneca v. Minister of Health* ([2004 FC 1277](#))). While the Court of Appeal reversed and quashed Apotex's NOC, the Supreme Court agreed with the Minister.

The Court, focussing on the specific LOSEC product that was the subject of Apotex's bioequivalence studies, stated as follows:

39. ...In my view, s. 5(1) of the NOC Regulations requires a patent-specific analysis, *i.e.* the generic manufacturer is only required to address the cluster of patents listed against submissions relevant to the NOC that gave rise to the comparator drug, in this case the 1989 version of Losec 20.

40. If AstraZeneca had brought to market a Losec 20 product pursuant to the later NOCs and if Apotex had made reference to that modified product for the purpose of demonstrating bioequivalence, Apotex would have been required to file a notice of allegation with respect to the 037 and 470 patents.

41. However, it is clear that AstraZeneca did not market any product pursuant to the subsequent NOCs and that the preconditions to any obligations of Apotex under s. 5(1) were therefore not triggered.

Whether this decision will be interpreted by the Federal Courts as being limited to the unusual facts of this case or as having broader implications remains to be seen.

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## Court of Appeal Affirms Validity of Lisinopril Patent

As reported in our [May 2006](#) issue of *Rx IP Update*, a Federal Court Judge held that the patent covering **lisinopril** (AstraZeneca's **ZESTRIL** and Merck's **PRINIVIL**) was valid and infringed (*Merck and AstraZeneca v. Apotex*, [2006 FC 524](#)). On October 10, 2006, the Court of Appeal affirmed that decision ([2006 FCA 323](#)).

The main validity attack was based on the propriety of the filing of a voluntary divisional application claiming compounds including lisinopril. The Court of Appeal agreed with the Trial Judge that the divisional was not improper, and that in any event, an improper divisional of a patent does not, in the absence of double patenting, give rise to a loss of patent rights.

However, the Court of Appeal reversed the Trial Judge's finding that Apotex was precluded from raising certain validity attacks in view of previous litigation involving Apotex, Merck, and another patent directed to **enalapril** (which arose from the same parent application as the lisinopril patent). The Court held that issue estoppel should not have been applied, as AstraZeneca did not have a participatory interest in the enalapril litigation so as to be considered a privy of Merck.

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## Validity of Levaquin Patent Upheld

On October 17, 2006, a Trial Judge decided that a claim of the patent covering **levofloxacin** (Janssen-Ortho's **LEVAQUIN**) was valid (*Janssen-Ortho and Daiichi Pharmaceutical v. Novopharm* ([2006 FC 1234](#))). Novopharm had obtained its notice of compliance (NOC) for Novo-Levofloxacin following litigation under the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") in which the Applications Judge found that Janssen-Ortho had not established that Novopharm's allegation of invalidity based on obviousness was not justified ([2004 FC 1631](#)). The Trial Judge, following established jurisprudence, held that the decision under the *Regulations* was not binding, and indeed found that the claim was not invalid despite Novopharm's assertion of obviousness. Novopharm also argued anticipation, ambiguity and insufficiency, but admitted infringement.

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## Proceeding Against Different Generic Under Linkage Regulations Found Abusive

A Judge has dismissed a proceeding under the *Regulations* as an abuse of process. Sanofi-Aventis' application against one generic, Apotex, relating to the drug **ramipril** (Sanofi-Aventis' **ALTACE**) had been dismissed on the merits on the basis of Apotex's allegation of invalidity based on lack of sound prediction. That decision was upheld on appeal, and a leave application was dismissed. Sanofi-Aventis commenced a proceeding against Novopharm relating to the same drug and the same patent. Novopharm also alleged invalidity on the basis of lack of sound prediction. Novopharm brought a motion for summary dismissal on the basis that the application was an abuse of process having regard to the earlier Apotex decision. A Judge dismissed the proceeding (*Sanofi-Aventis v. Novopharm* ([2006 FC 1135](#))), finding that it is "plain and obvious" that Sanofi-Aventis has no chance of success with respect to the current application "as the Federal Court is bound to follow the decision of the Federal Court of Appeal in the First Aventis ...Application". Sanofi-Aventis has appealed.

## Update: Amendments to Linkage Regulations and to Data Protection

As reported in our [October 2006 Special Edition](#) of *Rx IP Update*, sweeping amendments to the *Regulations* and to the data protection provision of the *Food and Drug Regulations* came into force on October 5, 2006. On October 18, 2006, the Government formally published the amendments in Part II of the *Canada Gazette*, along with a press release.

*Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*  
(HTML) (Bilingual PDF/official)

*Regulations Amending the Food and Drug Regulations (Data Protection)*  
(HTML) (Bilingual PDF/official)

*Press Release: Government of Canada Amends Intellectual Property Rules for Pharmaceuticals and Bio-Pharmaceuticals*

Following the registration of the amendments to the *Regulations*, Health Canada has released a revised [Form IV: Patent List](#) and [Form V: Declaration re: Patent List Documents](#) and has requested immediate use of the forms. Any comments on the new forms should be submitted to the Therapeutic Products Directorate before November 30, 2006. Health Canada will also be producing a guidance document in the near future.

[Notice](#)

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## Apotex Seeks Declaration that New Ontario Formulary Regulations are Unlawful

As reported in our [October 2006](#) issue of *Rx IP Update*, amended regulations under the *Ontario Drug Benefit Act* (O Reg 459/06) and the *Drug Interchangeability and Dispensing Fee Act* (O Reg 458/06) were approved on September 28, 2006. Among the changes to the regulations was a lowering of the permissible price of generic products from 70% of the drug benefit price of the original product to 50%. A formulary update which reflects this new pricing rule has been published and became effective on October 23, 2006 (see [Edition 39: Update 13 Bulletin](#)). Apotex has brought an application for judicial review, seeking an Order declaring all or part of the regulations unlawful, quashing them and suspending their operation, pleading that the publication requirements regarding these specific amendments had not been complied with. Apotex was denied interim relief on October 13, 2006 and its application on the merits will be heard on November 7, 2006.

*Motions Judge's Endorsement* ([2006 Can LII 34411](#))

Consolidated regulations have now been published:

[REGULATION 201/96](#) (amended to O. Reg. 459/06) (Regulations under *Ontario Drug Benefit Act*)

[REGULATION 935](#) (amended to O. Reg. 458/06) (Regulations under *Drug Interchangeability and Dispensing Fee Act*)

## TAMIFLU Now Part of CAMR Regime

In the [August 2006](#) issue of *Rx IP Update*, we reported that the Government proposed to add **oseltamivir phosphate (TAMIFLU)** to Schedule 1 of the *Patent Act* under Canada's Access to Medicines Regime. On September 21, 2006, an Order so amending the *Act* came into force.

[\*Order\*](#)

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## Supreme Court of Canada Matters

*Sanofi-Aventis v. Pharmascience (ramipril (ALTACE))*, September 20, 2006

Pharmascience has filed an application for leave to appeal a decision of the Federal Court of Appeal which held that a patent covering ramipril was not invalid for double patenting. Sanofi-Aventis has also filed an application for leave to appeal the same decision insofar as it relates to Pharmascience's allegation of non-infringement of a use patent. The Court of Appeal Decision was reported in our [July 2006](#) issue of *Rx IP Update*.

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*Alberta (Minister of Health and Wellness) v. Apotex (Apo-Gabapentin)*, October 12, 2006

Leave has been denied. The Alberta Court of Appeal upheld a Judge's decision ordering members of the expert committee, which makes recommendations to the Minister as to addition of drugs on the provincial drug benefit list, to be produced for discovery. Apotex sued the Crown for damages arising out of the conduct of the Minister. The Court of Appeal Decision was reported in our [August 2006](#) issue of *Rx IP Update*.

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*AstraZeneca v. Apotex and Manitoba (Apo-Omeprazole, LOSEC)*, October 12, 2006

Leave has been denied. The Manitoba Court of Appeal reversed a Judge's decision declaring a Manitoba *Drug Interchangeability Formulary Regulation* invalid. That *Regulation* had listed Apo-Omeprazole on the formulary as fully interchangeable with LOSEC. The Court of Appeal decision was reported in our [February 2006](#) issue of *Rx IP Update*.

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*Jocelyn Binet v. Pharmascience Inc.*, October 26, 2006

The Supreme Court of Canada allows Binet's appeal and restores an injunction order made by the Quebec Superior Court. The Order had directed Pharmascience to provide Binet, syndic of the *Ordre des pharmaciens du Québec*, with information requested regarding allegations of unlawful rebates and benefits provided to pharmacy owners.

[\*Full Judgment\*](#)

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## Recent Court Decisions

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

*Pfizer Canada Inc. v. Canada (Minister of Health) (amlodipine besylate (NORVASC), amlodipine besylate/atorvastatin calcium (CADUET))*, September 28, 2006

Court of Appeal dismisses Pfizer's appeal of a decision refusing to Order the Minister to add Pfizer's patent to the Patent Register. The Court agrees with the Minister and the Court below that the patent cannot be listed against Norvasc because it does not contain a claim for amlodipine besylate or for the use of amlodipine besylate.

*Court of Appeal Decision (2006 FCA 310)*

*Applications Judge's Decision (2006 FC 210)*

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*Sanofi-Aventis Canada Inc. v. Apotex Inc. (ramipril (ALTACE))*, October 11, 2006

Court of Appeal allows a motion brought by Apotex seeking to dismiss, on the ground of mootness, Sanofi-Aventis' appeal of an Order dismissing its application for a prohibition Order related to a use patent. The Court finds that the appeal became moot as a result of the expiration of the patent in issue.

*Court of Appeal Decision (2006 FCA 328)*

*Applications Judge's Decision (2005 FC 1504)*

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*Hoffmann-La Roche Limited v. Canada (The Minister of Health) (ibandronate sodium (BONDRONAT))*, October 18, 2006

Court of Appeal upholds a Judge's decision dismissing 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 citing only one submission, characterized by the Court of Appeal as falling under the category of a supplemental new drug submission ("SNDS") for a change in manufacturer's name. Roche then filed a corrected second patent listing application outside the 30-day time limit, including the new drug submission ("NDS") as a basis. The Court of Appeal held that an SNDS for a change in the name of the drug manufacturer is not a submission that can support the filing of a new or amended patent list, and that Roche's second patent list was correctly rejected by the Minister for being filed outside of the time limit.

*Court of Appeal Decision (2006 FCA 335)*

*Applications Judge's Decision (2005 FC 1415)*

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# Canadian Internet Registration Authority's Domain Name Dispute Resolution Policy Decisions

*Mead Johnson v. Turvill Consultants - NARD ([www.buspar.ca](http://www.buspar.ca)), September 22, 2006*

The domain name buspar.ca is ordered transferred to complainant Mead. The Panellist finds: the trademark BUSPAR is widely used and known in Canada and was registered by Mead; the domain name is confusingly similar to BUSPAR; the respondent registrant had no legitimate interest in the domain name; and the respondent had registered the domain name in bad faith.

[Full Decision](#)

## New Court Proceedings

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

**Medicine:** **ramipril (ALTACE)**  
**Applicants:** Sanofi-Aventis Canada Inc and Sanofi-Aventis Deutschland GmbH  
**Respondents:** Cobalt Pharmaceuticals Inc and The Minister of Health  
**Date Commenced:** September 22, 2006  
**Court File No:** T-1710-06  
**Comment:** Application for Order of prohibition until expiry of Patents Nos. 1,341,206, 2,023,089, 2,382,387, 2,055,948 and 2,382,549. Cobalt alleges non-infringement ('089, '387, '948, and '549 patents), invalidity ('206 patent) and that the '948 and '549 patents are not eligible for listing on the Patent Register.

**Medicine:** **clarithromycin (BIAXIN oral suspension, BIAXIN BID tablets and BIAXIN XL extended release tablets)**  
**Applicants:** Abbott Laboratories Limited and Abbott Laboratories  
**Respondents:** Attorney General of Canada and The Minister of Health  
**Date Commenced:** September 22, 2006  
**Court File No:** T-1711-06  
**Comment:** Application for a declaration that Patent No. 2,250,736 is eligible for listing on the Patent Register.

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**Medicine:** **omeprazole magnesium (LOSEC)**  
**Applicants:** AstraZeneca Canada Inc, AstraZeneca AB and Aktiebolaget Hässle  
**Respondents:** Novopharm Limited and The Minister of Health  
**Date Commenced:** October 5, 2006  
**Court File No:** T-1778-06  
**Comment:** Application for Order of prohibition until expiry of Patents Nos. 2,025,668 and 2,133,762. Novopharm alleges non-infringement, invalidity, and that the patents are not eligible for listing on the Patent Register.

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**Medicine:** **pantoprazole (PANTALOC)**  
**Applicants:** Altana Pharma Inc and Altana Pharma AG  
**Respondents:** Novopharm Limited and The Minister of Health  
**Date Commenced:** October 11, 2006  
**Court File No:** T-1799-06  
**Comment:** Application for Order of prohibition until expiry of Patent No. 2,109,697. Novopharm alleges non-infringement, invalidity, and that the patent is not properly listed on the Patent Register.

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**Medicine:** **pantoprazole (PANTALOC)**  
**Applicants:** Altana Pharma Inc and Altana Pharma AG  
**Respondents:** Novopharm Limited and The Minister of Health  
**Date Commenced:** October 19, 2006  
**Court File No:** T-1836-06  
**Comment:** Application for Order of prohibition until expiry of Patents Nos. 2,089,748 and 2,092,694. Novopharm alleges non-infringement, invalidity, and that the patents are not eligible for listing on the Patent Register.

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### *Other New Proceedings*

**Medicine:** **unidentified (a delayed release tablet containing two ingredients, component X and component Y)**  
**Applicant:** Pharmascience Inc  
**Respondent:** Attorney General of Canada  
**Date Commenced:** September 20, 2006  
**Court File No:** T-1693-06  
**Comment:** Application for an Order setting aside the decision of the Minister of Health whereby Pharmascience's application for a NOC was considered withdrawn without prejudice to refiling and remitting the matter back to the Minister for redetermination.

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**Medicine:** **ONE TOUCH, BASIC, and PROFILE (for blood glucose meters and blood glucose monitoring test strips)**

**Plaintiffs:** Johnson & Johnson and Lifescan, Inc

**Defendants:** Medical Plastic Devices MPD Inc/Les Appareils Médicaux de Plastique MPD Inc

**Date Commenced:** October 5, 2006

**Court File No:** T-1779-06

**Comment:** Trade-infringement and passing-off action. Plaintiffs plead that the blood glucose test strips sold by the defendant bearing the trade-marks are counterfeit.

**Applicant:** Apotex Inc

**Respondents:** The Minister of Health and Long Term Care, Executive Officer, Lieutenant Governor in Council and Attorney General of Ontario

**Date Commenced:** October 10, 2006

**Court File No:** 491/06

**Comment:** Application for an Order quashing Ontario Regulations 458/06 and 459/06 (see article, above).

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