



# Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

1

Federal Court  
Addresses Timing  
Issues Regarding  
Motions for  
Production of  
Samples in  
*Patented  
Medicines (Notice  
of Compliance)*  
Proceedings

2

Supreme Court of  
Canada Leave  
Applications

2

Recent Court  
Decisions

3

New Court  
Proceedings

## Federal Court Addresses Timing Issues Regarding Motions for Production of Samples in *Patented Medicines (Notice of Compliance)* Proceedings

Recently, in *AB Hassle v. Apotex Inc.* ("AB Hassle") ([2004 FCA 255](#)), the Federal Court of Appeal confirmed that, in proceedings under the *Patented Medicines (Notice of Compliance) Regulations* (the "*Regulations*"), when a generic manufacturer tests samples of its proposed product and files evidence regarding the results of the testing, an innovator has the right to immediately bring a motion for production of samples with which to conduct its own testing.

The issue arose as a result of a motion brought by AstraZeneca to file an expert affidavit analyzing samples of omeprazole magnesium tablets produced by Apotex. Earlier in the proceedings, Apotex filed an affidavit relating to the testing of samples of its proposed product. AstraZeneca requested the samples during the cross-examination of one of Apotex' affiants, and was provided with the samples following that cross-examination.

The Prothonotary denied AstraZeneca's motion to file an expert affidavit, finding that AstraZeneca had failed to bring the motion for the production of samples in a timely manner ([2004 FC 694](#)). A motions judge allowed AstraZeneca's appeal, finding that evidence based on testing is vital and that both parties were responsible for the delay, and allowed the expert affidavit to be filed ([2004 FC 762](#)). Apotex appealed this decision to the Federal Court of Appeal.

The Court of Appeal dismissed Apotex' appeal, finding that the motions judge was correct in allowing the expert affidavit, and stated:

[6]...Subsection 6(7) of the Regulations allows a party to compel the production of samples where such samples have been filed with the Minister as part of an applicant's regulatory submissions (NDS). Since the appellant did not submit samples of its product to the Minister, Astra could not exercise the right conferred by subsection 6(7) and compel production.

Further, the Court indicated, "The Prothonotary has cited no authority, and I know of none, to support the conclusion that Astra could and should have sought production of the samples at an earlier stage than it did and, therefore, should be blamed for the delay which resulted from its failure to do so... At best, the law is unclear and uncertain on the issue. At worst, Astra had no right to compel the production of the samples prior to cross-examination". The Court continued:

[11]...In my view, in circumstances where the disclosure process envisaged in subsection 6(7) of the Regulations cannot be resorted to because the samples have not been provided to the minister and where the second person proceeds to their testing and file affidavit evidence of the results of these tests in the prohibition proceedings, expediency, fairness and the overall interest of justice give the first person the right to, immediately after such filing, seek by motion the production of these samples for a testing of its own. This should remedy the unfortunate

delay encountered in the present proceedings. The first person can then be held accountable for its failure to proceed promptly.

The Court's decision confirms that:

- an innovator cannot obtain production of samples pursuant to section 6(7) of the *Regulations* unless the samples have been filed with the Minister; and
- an innovator has the right to bring a motion for production of samples immediately after a generic manufacturer files an affidavit regarding testing of its proposed product.

This decision is significant because in certain cases under the *Regulations* the issue of infringement may turn on the evidence of testing conducted on samples of the generic manufacturer's proposed product.

*Heather E. Tonner*

---

## Supreme Court of Canada Leave Applications

*Janssen-Ortho v. The Minister of Health (fentanyl transdermal patch (DURAGESIC))*, August 26, 2004

Leave has been denied. Janssen-Ortho had sought leave to appeal a decision of the Federal Court of Appeal, which dismissed an applications judge's decision. The judge had dismissed its application for judicial review of a Minister's decision to remove a patent from the Patent Register, finding that the DURAGESIC patch (in particular the release membrane, the drug reservoir, and the backing) does not fall within the definition of "medicine" for the purposes of the *Regulations*. The Federal Court judgments were reported in the [March 2004](#) issue of *Rx IP Update*.

---

## Recent Court Decisions

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

*Apotex v. GlaxoSmithKline (paroxetine (PAXIL, APO-PAROXETINE))*, July 23, 2004

Prothonotary dismisses GlaxoSmithKline PLC (Glaxo UK) and SmithKline Beecham Corporation (Glaxo US)'s motion for an order striking these defendants as parties to the action, on the basis that the *Apotex v. Eli Lilly* decision ([2004 FC 502](#)) upon which GSK relies is under appeal and the *Eli Lilly* decision resulted from a summary judgment motion whereas the present motion is tantamount to a motion to strike, which is a stringent test.

*Full Judgment* ([2004 FC 1035](#))

---

*Abbott v. Pharmascience (clarithromycin (BIAXIN BID))*, July 29, 2004

Judge dismisses Pharmascience's appeal of a Prothonotary's Order, extending the twenty-four month period specified in section 7(1)(e) of the *Regulations*.

*Full Judgment* ([2004 FC 1049](#))

---

---

## New Court Proceedings

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

**Medicine:** **ramipril (ALTACE)**  
**Applicants:** Aventis Pharma Inc and Aventis Pharma Deutschland GmbH  
**Respondents:** Laboratoire Riva Inc, The Minister of Health and Schering Corporation  
**Date Commenced:** July 23, 2004  
**Comment:** Application for Order of prohibition until expiry of Schering's Patent No. 1,341,206 and Aventis' Patents Nos. 1,246,457 and 2,023,089. Riva alleges non-infringement and invalidity.

---

**Medicine:** **ibandronate sodium (BONDRONAT)**  
**Applicant:** Hoffmann-La Roche Limited  
**Respondents:** The Minister of Health and The Attorney General of Canada  
**Date Commenced:** August 11, 2004  
**Comment:** Application for declaration that Patent No. 2,141,964 is eligible for listing on the Patent Register.

---

### *Other Proceedings*

**Medicine:** **etidronate disodium (DIDROCAL)**  
**Applicants:** The Procter & Gamble Company and Procter & Gamble Pharmaceuticals Canada Inc  
**Respondent:** The Commissioner of Patents  
**Date Commenced:** July 23, 2004  
**Comment:** Application for judicial review of a decision of the Commissioner, refusing to correct a clerical error, and seeking an Order requiring the Commissioner to correct the re-issue date of Patent No. 1,338,376 to read June 18, 1996 (rather than June 11, 1996). Procter & Gamble pleads that the patent has been the subject of legal proceedings under the *Regulations* in which respondents have alleged that the patent was not properly listed on the Patent Register on the basis that the listing was not done within 30 days after June 11, 1996, the erroneous re-issue date.

---

**Medicine:** **omeprazole (LOSEC)**  
**Plaintiffs:** AstraZeneca Canada Inc and Aktiebolaget Hässle  
**Defendant:** Apotex Inc  
**Date Commenced:** July 30, 2004  
**Comment:** Infringement action relating to Patents Nos. 1,292,693 and 1,302,891.

**OTTAWA**

55 Metcalfe Street, Suite 900  
 P.O. Box 2999, Station D  
 Ottawa, Ontario Canada  
 K1P 5Y6  
 t. 613.232.2486  
 f. 613.232.8440

ottawa@smart-biggar.ca

**TORONTO**

438 University Avenue  
 Suite 1500, Box 111  
 Toronto, Ontario Canada  
 M5G 2K8  
 t. 416.593.5514  
 f. 416.591.1690

toronto@smart-biggar.ca

**MONTREAL**

1000 de La Gauchetière St. W.  
 Suite 3300  
 Montreal, Québec Canada  
 H3B 4W5  
 t. 514.954.1500  
 f. 514.954.1396

montreal@smart-biggar.ca

**VANCOUVER**

650 West Georgia Street  
 Suite 2200  
 Box 11560, Vancouver Centre  
 Vancouver, B.C. Canada  
 V6B 4N8  
 t. 604.682.7780  
 f. 604.682.0274

vancouver@smart-biggar.ca

**EDMONTON**

10060 Jasper Avenue, Suite 1501  
 Scotia Place, Tower Two  
 Edmonton, Alberta Canada  
 T5J 3R8  
 t. 780.428.2960  
 f. 780.423.6975

edmonton@smart-biggar.ca

[www.smart-biggar.ca](http://www.smart-biggar.ca)

**Trade-mark:**

**IXEL**

**Applicants:**

SmithKline Beecham Corporation

**Respondents:**

The Registrar of Trade-marks and Pierre Fabre Médicament

**Date Commenced:**

August 9, 2004

**Comment:**

Application for an Order quashing the Registrar's Notice of Allowance regarding the trade-mark IXEL. The Registrar had issued the Notice of Allowance following a judge's decision, rejecting SmithKline Beecham's opposition to registration of the trade-mark IXEL. The Registrar had issued the Notice of Allowance prior to the expiration of time for the filing by SmithKline Beecham of a Notice of Appeal of the judge's decision.

**Contact Info**

For more information, or to request a copy of any decision, pleading or legislation, please contact:

**Gunars A. Gaikis**  
 ggaikis@smart-biggar.ca

**J. Sheldon Hamilton**  
 jshamilton@smart-biggar.ca

**Nancy P. Pei (Editor)**  
 nppei@smart-biggar.ca

**Pharmaceutical Practice Group**

James D. Kokonis, Q.C.  
 John Bochnovic  
 Keltie R. Sim  
 J. Christopher Robinson  
 J. Sheldon Hamilton  
 Yoon Kang  
 Daphne C. Ripley  
 May Ming Lee  
 Scott A. Beeser

A. David Morrow  
 Joy D. Morrow  
 Michael D. Manson  
 Solomon M.W. Gold  
 David E. Schwartz  
 Nancy P. Pei  
 Denise L. Lacombe  
 James Jun Pan

John R. Morrissey  
 Gunars A. Gaikis  
 Tokuo Hirama  
 Steven B. Garland  
 Brian G. Kingwell  
 Thuy H. Nguyen  
 Sally A. Hemming  
 Kavita Ramamoorthy

**Disclaimer**

The preceding is intended as a timely update on Canadian intellectual property and regulatory law of interest to the pharmaceutical industry. The contents of our newsletter are informational only, and do not constitute legal or professional advice. To obtain such advice, please communicate with our offices directly. To join the *Rx IP Update* mailing list, or to amend address information, please send an e-mail to [rxip.update@smart-biggar.ca](mailto:rxip.update@smart-biggar.ca).