



Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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Supreme Court of Canada Declines to Consider "Mootness" Decisions

After a notice of compliance (NOC) was issued to Apotex for ciprofloxacin following patent expiry, Bayer brought a motion to dismiss Apotex's appeal of a prohibition Order on the grounds of mootness. While the Court of Appeal ([2004 FCA 242](#)) found that the appeal was moot as the patent had expired and an NOC had issued to Apotex, it exercised its discretion to hear and decide the moot appeal, finding that there may be "collateral consequences" from the outcome of the appeal as the *Patented Medicines (Notice of Compliance) Regulations* ("Regulations") provide that a patentee may be liable to a generic manufacturer for loss suffered by the generic if an Order of prohibition is reversed on appeal.

In another decision, the Federal Court of Appeal ([2004 FCA 224](#)) dismissed AstraZeneca's appeal of a dismissal of its application for a prohibition Order relating to Apotex and omeprazole capsules, on the basis of mootness as an NOC had issued to Apotex.

Despite the apparent inconsistency in the decisions, the Supreme Court of Canada dismissed Bayer's and AstraZeneca's applications for leave to appeal on January 21, 2005 and January 27, 2005, respectively.

Supreme Court of Canada Leave Applications

Pharmascience v. Régie de l'assurance maladie du Québec, Apotex v. Régie de l'assurance maladie du Québec, December 14, 2004

Régie de l'assurance maladie du Québec (the organization responsible for Quebec's health insurance plan) brought actions for damages against Pharmascience, Apotex, and Ratiopharm, alleging that by giving certain discounts, promotions and gratuities to pharmacists, the Defendants had violated the pricing rules imposed by the *Act respecting Prescription Drug Insurance*. The Quebec Superior Court dismissed the defendants' motions to dismiss and the Court of Appeal denied leave to appeal. Pharmascience and Apotex have sought leave to appeal.

Eli Lilly v. Apotex (**nizatidine (AXID, APO-NIZATIDINE)**), December 24, 2004

Eli Lilly has filed an application for leave to appeal the Federal Court of Appeal's dismissal ([2004 FCA 358](#)) of Lilly U.S.'s motion for summary judgment in Apotex' action for damages under section 8 of the *Regulations*. Lilly U.S., the patentee, had argued that it was not properly joined as a defendant as it is not a "first person" for the purposes of section 8.

Genpharm v. Procter & Gamble (**etidronate disodium (DIDROCAL)**), January 12, 2005

Genpharm has filed an application for leave to appeal a decision of the Federal Court of Appeal ([2004 FCA 393](#)) which dismissed its appeal of a prohibition Order.

Genpharm v. AB Hassle (**omeprazole (LOSEC)**), January 12, 2005

Genpharm has filed an application for leave to appeal a decision of the Federal Court of Appeal ([2004 FCA 413](#)) which dismissed its appeal of a prohibition Order.

Apotex v. AB Hassle (**omeprazole magnesium (LOSEC)**), January 14, 2005

Apotex has filed an application for leave to appeal a decision of the Federal Court of Appeal ([2004 FCA 369](#)) which dismissed its appeal of a prohibition Order.

Apotex v. Ontario (Minister of Health) (**perphenazine (APO-PERPHENAZINE), lisinopril (APO-LISINOPRIL)**), January 21, 2005

Apotex has filed an application for leave to appeal a decision of the Ontario Court of Appeal which dismissed its challenge of two policies of the Ontario government with respect to drug benefit pricing: the 75/90 rule (the maximum price for the first listed interchangeable drug is 75 per cent of the price of the brand name drug; the maximum price for the second listed generic drug is 90 per cent of the first generic drug), and the price freeze policy that only allows the price of one product to rise if it is offset by a price reduction of another product.

Patented Medicines Prices Review Board (PMPRB) Matters

The PMPRB will hold a public hearing on May 11, 2005 to determine whether Janssen-Ortho is selling or has sold **EVRA (norelgestromin/ethinyl estradiol patch)** in any market in Canada at a price that is or was excessive and if so, what Order if any should be made. A pre-hearing conference will be held on February 24, 2005.

[Notice of Hearing](#)

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Biovail v. Novopharm (**bupropion hydrochloride (WELLBUTRIN SR)**), January 6, 2005

Judge dismisses Biovail's application for an Order of prohibition. Novopharm had alleged non-infringement and invalidity of the patents. Biovail has appealed.

Full Judgment ([2005 FC 9](#))

Apotex v. Syntex and Roche; Canada (Attorney General), Third Party (naproxen slow-release tablets (NAPROSYN SR)), January 27, 2005

Prothonotary dismisses the Crown's motion to strike the defendants' third party claim against the Crown in the event that Syntex/Roche is found liable to Apotex for damages under section 8 of the *Regulations*. The Prothonotary found that it is not plain and obvious that the defendants' claim based on negligent conduct of the Minister cannot possibly succeed.

Full Judgment ([2005 FC 121](#))

Other Proceedings

Apotex v. Minister of Health (APO-OMEPRAZOLE), January 25, 2005

Apotex has a pending application for an Order requiring the Minister of Health to state a Canadian Reference Product on the NOC that issued for Apo-Omeprazole. AstraZeneca brought a motion to vary the protective order to allow AstraZeneca, a non-party, to access certain documents, arguing that it required access in order to determine whether its interests are affected by the proceedings relating to its drug LOSEC, so that it may consider participating in the application. AstraZeneca's motion was dismissed by a Prothonotary and by a Judge on appeal. AstraZeneca has appealed.

Full Judgment ([2005 FC 97](#))

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: clarithromycin (BIAXIN BID)
Applicants: Abbott Laboratories and Abbott Laboratories Limited
Respondents: Pharmascience Inc and The Minister of Health
Date Commenced: December 23, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 2,393,614. Pharmascience alleges invalidity.

Medicine: bupropion hydrochloride (WELLBUTRIN SR)
Applicants: Biovail Corporation (dba Biovail Pharmaceuticals Canada), Biovail Laboratories Inc and GlaxoSmithKline Inc
Respondents: RhoxalPharma Inc and The Minister of Health
Date Commenced: January 6, 2005
Comment: Application for Order of prohibition until expiry of Patents Nos. 1,321,754; 2,142,320 and 2,168,364. RhoxalPharma alleges non-infringement and invalidity with respect to the 320 patent and non-infringement with respect to the 364 patent.

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Medicine: **clopidogrel bisulfate (PLAVIX)**
Applicants: Sanofi-Synthelabo Canada Inc and Sanofi-Aventis
Respondents: Novopharm Limited and The Minister of Health
Date Commenced: January 14, 2005
Comment: Application for Order of prohibition until expiry of Patent No. 1,336,777. Novopharm alleges non-infringement and invalidity.

Medicine: **risedronate sodium (ACTONEL)**
Applicant: Procter & Gamble Pharmaceuticals Canada Inc
Respondents: The Minister of Health and The Attorney General of Canada
Date Commenced: January 21, 2005
Comment: Application for Order requiring the Minister to list Patents Nos. 2,122,479 and 2,293,815 on the Patent Register. The Minister decided that the patents are ineligible for listing as the dosage form described in the 479 patent is "not relevant" to that of ACTONEL and the 815 patent covers a drug delivery system and not a pharmaceutical formulation and thus contains no claim for the medicine risedronate sodium.

Medicine: **carvedilol (COREG)**
Plaintiff: Pharmascience Inc
Defendants: GlaxoSmithKline Inc, GlaxoSmithKline PLC, SmithKline Beecham Corporation, The Wellcome Foundation Limited and Doe Co and all other entities unknown to the Plaintiff which are part of the GlaxoSmithKline group of companies
Date Commenced: January 21, 2005
Comment: Action brought pursuant to section 9 of the *Regulations* for damages allegedly suffered by Pharmascience by reason of initiation of prohibition proceedings by GlaxoSmithKline and SmithKline Beecham and an accounting of profits.

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