



IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Court of Appeal Confirms that an SNDS will Support a Patent Listing Except in Limited Circumstances

The Federal Court of Appeal, in *Abbott Laboratories v. Canada (Minister of Health)* (“*Abbott*”) (2004 FCA 154), has confirmed that a Supplemental New Drug Submission (SNDS) will support the listing of a patent on the Patent Register maintained pursuant to the *Patented Medicines (Notice of Compliance) Regulations* (“*Regulations*”), except in limited circumstances.

The *Abbott* decision resulted from a motion brought by Apotex, Ratiopharm and Pharmascience to dismiss *Abbott*’s applications for Orders of prohibition, on the basis that the patent was not eligible for listing on the Patent Register. The patent was filed with an SNDS for a revision to the product monograph for BIAXIN to include a cross-reference to another monograph for BIAXIN in triple therapy. The *Regulations* permit a first person to submit a patent list within 30 days after the issuance of a patent, provided the application for patent has a filing date that precedes the filing date of the submission for a notice of compliance. The generics argued that the SNDS was trivial because it did not relate to a change in the drug, or to a new use or indication for the drug, and related to a mere labelling revision; therefore it could not support the filing of a patent list. However, the generics agreed that if the SNDS was eligible to support the filing of the patent list, *Abbott* had met the timing requirements of the *Regulations*. The motions judge (2004 FC 465) agreed with the generics and concluded that the SNDS “lacked substance” and was therefore not eligible to support the filing of the patent and ordered the patent removed from the Patent Register.

On appeal, the Court concluded that, in the circumstances of this case, the motions judge’s inquiry should have gone no further after she found that (i) an SNDS was required; (ii) the SNDS was not filed in an effort to circumvent the time limitations under section 4 of the *Regulations*; and (iii) the filing of the patent in connection with the SNDS was *bona fide*. The Court also stated, “The SNDS in the current appeal was necessary in order for *Abbott* to comply with the *Food and Drug Regulations*, and *Abbott* was entitled to file the... patent for listing. It is not for this Court to alter the patent benefits to which a manufacturer is entitled after validly complying with the various requirements set out in the regulations.”

Furthermore, the Court found that the case fell outside the scope of *Bristol Myers Squibb v. Attorney General of Canada* (“*BMS*”) (aff’d 2002 FCA 32) and *Apotex v. Ferring* (“*Ferring*”) (2003 FCA 274). The Court stated that *BMS* and *Ferring* “offer examples of manifest attempts to list patents after the time limitations set out in section 4 of the *PM(NOC) Regulations* had expired” and “this was not an attempt by *Abbott* to circumvent the time limitations set out in the *PM(NOC) Regulations*.”

This decision is significant in confirming that all required SNDSs afford an opportunity to file a patent list except in the limited circumstances where the SNDS was filed for strategic reasons, *i.e.* to circumvent the timing requirements of the *Regulations*. The Court also confirmed that, once it is determined that an SNDS is required and that the SNDS was not filed to circumvent the timing requirements, the Court should not go behind the SNDS and assess the “substance” of the submission.

Should the respondents wish to appeal the decision, leave must first be granted by the Supreme Court of Canada.

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House of Commons Set to Vote on Proposed Legislation to Facilitate Exports of Generic Pharmaceuticals to Developing Countries

On April 23, 2004, the Standing Committee on Industry, Science and Technology reported proposed amendments to Bill C-9, *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)* to the House of Commons. The Report was debated by the House on April 28, 2004, with further amendments proposed. A vote by the House to pass the Bill is expected on May 4, 2004. If passed, the Bill will then be sent to the Senate for final approval.

[Report by the Standing Committee](#)

[Press Release \(April 20, 2004\) - Rx & D \(Canada's Research-Based Pharmaceutical Companies\)](#)

[Letter to the National Post Editor \(April 26, 2004\) - Rx & D \(Canada's Research-Based Pharmaceutical Companies\)](#)

[Press Release \(April 28, 2004\) - Canadian HIV/AIDS Legal Network](#)

[Press Release \(April 20, 2004\) - CGPA \(Canada's Generic Pharmaceutical Industry\)](#)

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Biobail v. RhoxalPharma (diltiazem extended-release (TIAZEC, CARDIZEM CD)), February 20, 2004

Judge dismisses application for an Order of prohibition. RhoxalPharma had alleged non-infringement.

[Full Judgment](#) (2004 FC 257)

Apotex v. Eli Lilly (nizatidine (AXID)), March 31, 2004

In an action for damages brought pursuant to section 8 of the *Regulations*, Judge grants partial summary judgment, dismissing the claim against Eli Lilly and Company, the patentee of the relevant patent. Judge finds that Eli Lilly and Company is not a proper party as section 8 provides a right of action against a "first person" and Eli Lilly and Company is not a "first person." Judge dismisses Eli Lilly Canada's motion for dismissal of the unjust enrichment claim on the basis of previous jurisprudence. Apotex has appealed.

[Full Judgment](#) (2004 FC 502)

Aventis v. Apotex and Schering (ramipril (ALTACE)), April 15, 2004

Judge affirms Prothonotary's Order, refusing to strike Schering's evidence. Pursuant to a scheduling Order issued on consent, Schering (unrelated to Aventis and represented by its own counsel) filed evidence after the filing of Aventis' evidence. Apotex sought to strike Schering's evidence on the basis that the evidence constituted an abuse of process because Schering, as patentee, had no right to file separate evidence to support Aventis' application for an Order of prohibition. Judge confirms Schering's right to file evidence regarding validity of its patent.

[Full Judgment](#) (2004 FC 570)

Pfizer v. Apotex (**quinapril (ACCUPRIL)**), April 16, 2004

Pfizer had commenced one application for an Order of prohibition in respect of four Notices of Allegation (NOA). On motion by Apotex, Judge orders two of the notices of allegation severed and made the subject of separate proceedings, in part on the basis that separate proceedings may be amenable to summary disposition, which would not be available if they remained in a single proceeding.

[Full Judgment](#) (2004 FC 572)

Abbott v. Pharmascience, Apotex, and Ratiopharm (**clarithromycin (BIAXIN)**), April 19, 2004

Court of Appeal allows Abbott's appeal of a motions judge's decision, granting summary dismissal of applications for Orders of prohibition on the basis that the patent is ineligible for listing on the Patent Register. For further information, please see the article on page one of this issue of *Rx IP Update*.

[Court of Appeal Decision](#) (2004 FCA 154)

[Motions Judge's Decision](#) (2004 FC 465)

Other Decisions

Hoechst Marion Roussel v. Patented Medicine Prices Review Board (**nicotine transdermal patch (NICODERM)**), March 31, 2004

Judge dismisses Hoechst's appeal of a prothonotary's decision, dismissing its request for an Order compelling the production of certain documents. The motion was brought in the context of a judicial review application of a decision of the PMPRB, declining to terminate its proceeding and rescind the Notice of Hearing to determine whether Hoechst has engaged in excessive pricing of NICODERM.

[Full Judgment](#) (2004 FC 489)

Merck v. Brantford Chemicals (**sodium enalapril-sodium iodide and sodium enalapril**), April 2, 2004

Judge dismisses Merck's appeal of a decision of the Patent Appeal Board. In January 1999, the Commissioner of Patents refused Brantford's first application for a compulsory licence for the manufacture and sale of sodium enalapril-sodium iodide and sodium enalapril. Prior to the hearing before the Board in connection with Brantford's second application, Merck sought a declaration that Brantford was barred from proceeding. The Board dismissed Merck's motion. Judge finds that *res judicata* does not apply. Merck has appealed.

[Full Judgment](#) (2004 FC 516)

Trade-mark Opposition Board Decisions

Wyeth v. Fempro (**FEMPRO & Design**), March 4, 2004

Board rejects Wyeth's opposition to application for trade-mark FEMPRO & Design for use in association with feminine hygienic products. Wyeth had alleged confusion with its previously filed application for PREMPRO in association with pharmaceutical preparations for use in hormonal replacement therapy.

[Full Decision](#)

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: **diltiazem extended-release (CARDIZEM CD, TIAZEC)**
Applicants: Biovail Corporation and Laboratoires Des Produits Ethiques Ethypharm
Respondents: RhoxalPharma Inc and The Minister of Health
Date Commenced: April 1, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 2,242,224 and an Order requiring RhoxalPharma to deliver to Biovail, in respect of Patent No. 2,111,085, a notice of allegation and detailed statement. RhoxalPharma alleges non-infringement, invalidity, and that the patent is not properly listed on the Patent Register.

Medicine: **ciprofloxacin IV (CIPRO)**
Applicants: Bayer AG, Bayer Healthcare AG and Bayer Inc
Respondents: Novopharm Limited and the Minister of Health
Date Commenced: April 2, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 1,282,006. Novopharm alleges non-infringement and invalidity.

Medicine: **omeprazole (LOSEC)**
Applicant: AstraZeneca Canada Inc
Respondents: Nu-Pharm Inc, Takeda Chemical Industries, Ltd, and The Minister of Health
Date Commenced: April 13, 2004
Comment: Application for Order of prohibition until expiry of Takeda's Patent No. 1,338,377. Nu-Pharm alleges non-infringement.

Medicine: **omeprazole (LOSEC)**
Applicants: AstraZeneca Canada Inc and AstraZeneca AB
Respondents: Nu-Pharm Inc and The Minister of Health
Date Commenced: April 15, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 2,133,762. Nu-Pharm alleges non-infringement.

Medicine: **omeprazole (LOSEC)**
Applicants: AstraZeneca Canada Inc and AB Hässle
Respondents: Nu-Pharm Inc and The Minister of Health
Date Commenced: April 16, 2004
Comment: Application for Order of prohibition until expiry of Patents Nos. 1,292,693 and 1,302,891. Nu-Pharm alleges non-infringement and invalidity.

Medicine: **omeprazole (LOSEC)**
Applicants: AstraZeneca Canada Inc and AB Hässle
Respondents: Nu-Pharm Inc and The Minister of Health
Date Commenced: April 17, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 2,025,668. Nu-Pharm alleges non-infringement.

Other New Proceedings

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Medicine: **simvastatin (APO-SIMVASTATIN, ZOCOR)**
Applicant: Apotex Inc
Respondent: The Minister of Health
Date Commenced: April 5, 2004
Comment: Application for Order compelling the Minister to forthwith process the Apotex Supplemental Abbreviated NDS (SANDS) for Apo-Simvastatin.

Medicine: **Apo-X**
Applicant: Apotex Inc
Respondent: The Minister of Health
Date Commenced: April 14, 2004
Comment: Application for Order compelling the Minister to forthwith issue Apotex a DIN for each dosage strength of its Apo-X drug product.

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