



IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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Court of Appeal Further Addresses Patent Listing Issues

In two recent decisions, the Federal Court of Appeal has further clarified the thresholds for listing patents on the Patent Register maintained by the Minister of Health pursuant to the *Patented Medicines (Notice of Compliance) Regulations* (“Regulations”). In both cases, the Court of Appeal found the patents to be ineligible for listing.

The first decision, *Apotex v. Ferring* (“*Ferring*” 2003 FCA 274) relates to the medicine desmopressin acetate (DDAVP, MINIRIN). As reported in the lead article of the [May 2003 Issue](#) of *Rx IP Update*, the applications judge found that a Supplementary New Drug Submission (SNDS) for a change of brand name qualifies to support the listing of a patent where there is no existing patent list. As a result, the Minister was ordered to revoke the NOC for Apo-Desmopressin and to re-list the patent on the Patent Register. However, the Court of Appeal granted a stay of that portion of the Order, revoking the NOC, pending the disposition of the appeal upon Apotex’ undertaking to pay damages to Ferring resulting from the grant of the stay.

On appeal, the Federal Court of Appeal reversed the decision, holding that the judge below should have followed the *Bristol Myers Squibb v. Attorney General of Canada* (2001), 10 C.P.R. (4th) 318 (F.C.T.D.) (“*BMS*”) decision wherein the Court, affirmed on appeal, held that the change in brand name at issue could not be used to circumvent the timing requirements of the *Regulations*. While the applications judge had distinguished the *BMS* case on the basis that it involved an attempt to amend an existing list, the Court of Appeal found that in *BMS*, the patent list had ceased to exist at the relevant date and therefore, there was no basis for the distinction made. The Court of Appeal echoed the comment made in *BMS* that if Ferring’s strategy of changing its brand name to overcome the time limitation within which a first person must file its patent list is sanctioned, it would render the time requirements meaningless.

The second decision, *Novartis v. Minister of Health* (2003 FCA 299) relates to ESTRACOMB patches. The Federal Court of Appeal upheld the applications judge’s finding that the patent covering a transdermal patch did not include a claim to the medicine or the use of a medicine as defined under the *Regulations* and therefore, was properly removed by the Minister from the Patent Register.

The patent included a claim for “a therapeutic system for the transdermal combined administration of oestrogens and gestagens,” consisting of four discrete layers including a drug reservoir. The applications judge concluded that the claims were analogous to the claims found in *Glaxo v. Novopharm* (1999), 87 C.P.R. (3d) 525 (which patent was found to relate to a “device for administering medicaments”) and therefore did not contain a claim for the medicine itself or the use of the medicine. The judge also found that the subject matter of the patent was not analogous to the subject matter of the patent considered in *Hoffmann-La Roche v. Minister of Health* (1995), 67 C.P.R. (3d) 25 (F.C.A.) (“*Hoffmann*”) to be within the *Regulations* (which patent was found to relate to a “composition of substances in a container”).

In upholding the applications judge’s finding, the Court of Appeal held that the proper test to determine if the patches are “medicine” under the *Regulations* is “whether they are administered to the patient or whether they administer substances to the patient.” As the Court concluded that the patches claimed in the patent are used to administer estradiol or estradiol and norethindrone acetate to patients, it concluded that the patent was not eligible for inclusion on the Register.

While the Court of Appeal appears to have articulated a straightforward test for assessing whether claims are claims for a medicine under the *Regulations*, the assessment may not be an easy one to make. For example, in *Hoffmann*, at least one of the claims included the limitation that the composition is “*in a container adapted for nasal administration*.” While the composition itself is clearly administered, the container is clearly not.

If Ferring and Novartis wish to appeal these decisions further, they must first obtain leave from the Supreme Court of Canada. Given the critical importance of listing patents on the Patent Register, we will continue to report developments on patent listing issues in upcoming issues of *Rx IP Update*.

Nancy P. Pei

Supreme Court of Canada Leave Applications

Biolyse v. Bristol-Myers Squibb (paclitaxel for injection (TAXOL)), June 20, 2003

On June 20, 2003, Biolyse filed an application seeking leave to appeal a decision of the Federal Court of Appeal, which dismissed its appeal of an applications judge’s decision, quashing Biolyse’s NOC. Biolyse had submitted a New Drug Submission (NDS) for its paclitaxel, which contained many references to and comparisons with TAXOL, but not for the purpose of establishing bioequivalence. The Court of Appeal affirmed the applications judge’s finding that the Minister should have required Biolyse to serve a Notice of Allegation (NOA) on BMS, since subsection 5(1.1) of the *Regulations* applied. The Court of Appeal judgment was reported in the [May 2003 issue](#) of *Rx IP Update*.

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Abbott v. Genpharm (clarithromycin (BIAXIN BID)), June 26, 2003

Motions judge rejects Abbott’s request for an order extending the twenty-four month statutory stay period for ten months beyond the date of May 2, 2004, without prejudice to a future request for an extension of time. Judge finds that Abbott did not produce evidence to show that Genpharm had failed to reasonably expedite the conclusion of the proceeding and finds that the motion is premature. Abbott has appealed.

[Full Judgment](#) (2003 FCT 790)

(*For a printer friendly version, please scroll down to the end of the Judgment)

Abbott v. Novopharm (**clarithromycin (BIAXIN BID)**), July 2, 2003

Judge strikes portions of evidence filed by Novopharm as being hearsay evidence.

[Full Judgment](#) (2003 FC 821)

(*For a printer friendly version, please scroll down to the end of the Judgment)

Novartis v. The Minister (**estradiol-17B/norethindrone acetate patches (ESTRACOMB)**), July 7, 2003

Court of Appeal dismisses Novartis' appeal from applications judge's decision, upholding the Minister's decision to remove a patent relating to a transdermal patch from the Patent Register. For further information, please see the lead article on page one of this issue.

[Appeal Decision](#) (2003 FCA 299)

(*For a printer friendly version, please scroll down to the end of the Judgment)

[Trial Division Decision](#) (2003 FCT 1042)

(*For a printer friendly version, please scroll down to the end of the

GlaxoSmithKline v. Pharmascience (**carvedilol (COREG)**), July 18, 2003

Judge dismisses application for order of prohibition, on the basis of obviousness.

[Full Judgment](#) (2003 FC 899)

(*For a printer friendly version, please scroll down to the end of the Judgment)

Other Decisions

Apotex v. Merck (**enalapril maleate (VASOTEC)**), June 30, 2003

Court of Appeal allows Apotex' appeal, in part, of an Order issued following disposition of a summary judgment motion in Merck's favour, finding infringement by Apotex relating to its acquisition of 772.9 kg of enalapril maleate subsequent to trial of first action, but before judgment. Court of Appeal finds that Apotex should be permitted to discover Merck so that it may make submissions relating to Merck's entitlement to Apotex' profits and that punitive damages should not be considered until after all other remedies are determined.

[Appeal Decision](#) (2003 FCA 291)

(*For a printer friendly version, please scroll down to the end of the Judgment)

[Trial Division Decision](#) (2002 FCT 626)

(*For a printer friendly version, please scroll down to the end of the Judgment)

New Court Proceedings

New NOC Proceedings

Medicine: **calcitonin nasal spray (MIACALCIN)**
Applicants: Novartis AG and Novartis Pharmaceuticals Canada Inc
Respondents: Apotex Inc and The Minister of Health
Date Commenced: June 24, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 1,220,138. Apotex alleges non-infringement, invalidity and that certain claims are not claims to the medicine itself.

Medicine: **alendronate monosodium trihydrate (FOSAMAX)**
Applicants: Merck & Co, Inc and Merck Frosst Canada & Co
Respondents: Apotex Inc and The Minister of Health
Date Commenced: June 30, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,149,052. Apotex alleges non-infringement and invalidity.

Medicine: **etidronate disodium tablets (GEN-ETIDRONATE, DIDROCAL)**
Applicants: Procter & Gamble Pharmaceuticals Canada, Inc and The Procter & Gamble Company
Respondents: Genpharm Inc and The Minister of Health
Date Commenced: July 3, 2003
Comment: Application for Order, quashing the decision of the Minister of Health to issue an NOC to Genpharm for Gen-Etidronate, in the event that the Order dated June 3, 2003, in Court File No. T-1970-99 does not preclude the issuance of the NOC, and an interim injunction preventing Genpharm from selling Gen-Etidronate and taking any steps to list Gen-Etidronate with any provincial formulary, pending the outcome of the application for judicial review.

Medicine: **antihaemophilic factor (ANTIHAEMOPHILIC FACTOR (RECOMBINANT), PLASMA/ALBUMIN FREE METHOD))**
Applicants: Bayer Corporation and Bayer Inc
Respondents: Baxter Healthcare Corporation and The Minister of Health
Date Commenced: July 14, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 1,339,477. Baxter alleges non-infringement.

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Medicine: **ceftriaxone disodium (ROCEPHIN)**
Applicant: Hoffmann-LaRoche Limited
Respondents: Mayne Pharma (Canada) Inc, Aventis Pharma Deutschland GMBH, and The Minister of Health
Date Commenced: July 17, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 1,259,606. Mayne alleges non-infringement and invalidity.

Other New Proceedings

Medicine: **Product X**
Applicant: Apotex Inc
Respondents: The Minister of Health and The Attorney General of Canada
Date Commenced: July 17, 2003
Comment: Application for Order, quashing a Notice of Non-Compliance – Withdrawal Letter in respect of Apotex’ Abbreviated New Drug Submission (ANDS) for Product X and requiring the Minister to process and deal with the ANDS in accordance with its Published Policy on Management of Drug Submissions.

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