



IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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New Court Proceedings

Generic Estopped From Relying on Patent Listing Issue Not Determined in Previous *Patented Medicines (Notice of Compliance)* Proceeding

On December 3, 2003 the Federal Court of Appeal released *Genpharm v. Procter & Gamble Pharmaceuticals* (2003 FCA 467) [<http://decisions.fct-cf.gc.ca/fct/2003/2003fca467.html>] which is a significant decision relating to issue estoppel in the context of multiple proceedings under the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*").

Procter & Gamble ("P&G") commenced a proceeding under the *Regulations* against Genpharm Inc. ("Genpharm") relating to the medicine etidronate disodium and involving a use patent. Genpharm brought a motion to have the application dismissed on the basis that the patent was not eligible for inclusion on the Patent Register, as the amendment to the patent list was filed more than 30 days after the patent issued (based on the date shown on the face of the patent). The motions judge refused to dismiss P&G's application, in view of the particular circumstances surrounding the issuance of the patent.

On appeal, the Court of Appeal also declined to dismiss the application, but on the basis of issue estoppel. The Court was unanimous in its finding that the date of issuance of a patent is that which is noted on the face of a patent. Therefore, given the facts, P&G was out of time to list the patent on the Patent Register.

Nonetheless, the majority of the Court found that Genpharm was estopped from raising the patent eligibility question in view of prior litigation between the same parties wherein an order of prohibition issued. Notably, the patent eligibility issue had not been adjudicated in the previous proceeding. However, the Court found that "[g]iven that a prohibition order issued in the previous litigation, for purposes of issue estoppel in these proceedings, that decision must be taken to have implicitly determined that the ... patent was eligible for inclusion on the Patent Register."

The Court was divided by whether the Court should refuse to apply issue estoppel as a matter of discretion. The majority declined to do so. The dissenting judge, however, referred to estoppel in these circumstances as "unduly harsh" and found that the Court should exercise its discretion not to apply the doctrine for reasons including the public law nature of litigation under the *Regulations*.

This decision may have potentially far-reaching consequences regarding the ability of generic producers to raise patent listing issues, or indeed, possibly other issues, that were raised or could have been raised in previous proceedings under the *Regulations*. However, given the fact-specific nature of issue estoppel, the full impact of the Court of Appeal's decision on future cases under the *Regulations* remains to be seen.

Should Genpharm wish to appeal the decision, it must obtain leave from the Supreme Court of Canada. The application for an order of prohibition has been heard on its merits and a decision is under reserve. We will report on any developments in future issues of *Rx IP Update*.

Kavita Ramamoorthy

Supreme Court of Canada Proceedings

Percy Schmeiser v. Monsanto Canada (**glyphosate-resistant canola (ROUNDUP READY CANOLA)**)

On January 20, 2004, the Supreme Court heard Mr. Schmeiser and Schmeiser Enterprises' appeal of the decision of the Federal Court of Appeal, dismissing their appeal from a decision of a trial judge. The trial judge had found that the appellants had infringed Monsanto's patent by planting a crop of glyphosate-resistant canola having a gene or cell that is the subject of the patent and granted Monsanto an injunction and damages. The Supreme Court reserved its decision.

Court of Appeal Decision (2002 FCA 309) [<http://decisions.fct-cf.gc.ca/fct/2002/2002fca309.html>]

Recent Court Decisions

Copyright Infringement

Apotex v. AstraZeneca (**omeprazole and omeprazole magnesium tablets (LOSEC)**), January 16, 2004

In a copyright infringement action brought by AstraZeneca, Judge dismisses AstraZeneca's motion for summary judgment or, in the alternative, an interlocutory injunction restraining Apotex from reproducing its product monograph. While the judge proceeded on the basis that there was a serious issue to be tried, he found that there was no irreparable harm and that a "very much greater inconvenience" would be imposed on Apotex if the injunction was granted. AstraZeneca has appealed??? [ask JRM]

[Full Judgment](#)

Trade-mark Opposition Board Decisions

*Opposition by Trovan and EID Electronic Identification Devices to applications nos. 826,729 and 846,400 for the trade-marks **TOVAN I.V.** and **TOVADYN** in the name of Pfizer, Date???*

Board rejects oppositions to applications for trade-marks TROVAN I.V. and TROVADYN for "pharmaceutical preparation, namely an antibiotic." The opponents alleged, among other grounds, confusion with the trade-mark TROVAN for "electrical apparatus and instruments, etc." EID has appealed??

[Full Decision](#)

New Court Proceedings

New NOC Proceedings

Medicine: **clarithromycin (BIAXIN BID)**
Applicants: Abbott Laboratories and Abbott Laboratories Limited
Respondents: Pharmascience Inc and The Minister of Health
Date Commenced: January 2, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 2,393,614. Pharmascience alleges non-infringement and that the patent is not properly listed on the Patent Register.

Medicine: **ramipril (ALTACE)**
Applicants: Aventis Pharma Inc and Aventis Pharma Deutschland GmbH
Respondents: Apotex Inc and The Minister of Health
Date Commenced: January 5, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 2,023,089. Apotex alleges non-infringement and invalidity.

Medicine: **citalopram hydrobromide (CELEXA)**
Applicants: H Lundbeck A/S and Lundbeck Canada Inc
Respondents: Dominion Pharmacal Inc, Pharmascience Inc and The Minister of Health
Date Commenced: January 5, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 2,353,693. Lundbeck pleads that the Abbreviated New Drug Submission (ANDS) is said to have been filed by Dominion; however, it appears tablets for which approval is sought are those of Pharmascience. Non-infringement is alleged.

Other New Proceedings

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Plaintiff:

Defendants:

Date Commenced:

Comment:

Kirin-Amgen, Inc

Genetics Institute, Inc and The Board of Regents of the University of Washington

December 10, 2003

An appeal of a decision of the Commissioner of Patents in a conflict proceeding relating to Kirin-Amgen's patent application No. 469,938, "Production of Erythropoietin," Genetics Institute's [unidentified], 740 application, "Method for the Production of Erythropoietin," and the University of Washington's patent application No. 540,234, "Human Erythropoietin Gene: High Level Expression in Stably Transfected Mammalian Cells."

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