



Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

June 2010

- 1 Merck denied Order of prohibition against Pharmascience concerning finasteride (PROPECIA)
- 2 Patented Medicine Prices Review Board news

Recent Court decisions

AstraZeneca denied leave to file video recordings of cross-examinations

Novopharm granted confidentiality Order in judicial review proceeding regarding requirement to address patents

- 3 New Court proceedings

Merck denied Order of prohibition against Pharmascience concerning finasteride (PROPECIA)

On May 11, 2010, Justice Hughes of the Federal Court dismissed Merck's application for an Order of prohibition against Pharmascience regarding **finasteride** (Merck's **PROPECIA**): *Merck & Co., Inc. v. Pharmascience Inc.*, 2010 FC 510.

The claim at issue claimed the use of finasteride "for the preparation of a medicament adapted for oral administration useful for the treatment of male pattern baldness in a person and wherein the dosage amount is about 1.0 mg."

As the claim was drafted as a "Swiss" type claim, Justice Hughes provided a detailed discussion of the construction of such claims in U.K., European and Canadian decisions. However, Justice Hughes ultimately dealt with construction by following the characterization by Pharmascience in its notice of allegation (NOA), namely that the claim is directed to the use of finasteride at a particular dosage in oral form to treat male pattern baldness rather than being directed to the manufacture of a tablet.

Justice Hughes rejected Pharmascience's submission that the claim was invalid as being a method of medical treatment, stating that:

"[A] distinction must be made between claims that rely upon the skill and judgment of a medical practitioner and those that deal with a vendible product, be it a scalpel, X-ray machine or 1 mg tablet that are to be used or prescribed for use by such practitioner. In the present case, we have a 1.0 mg tablet taken as a daily dose. No skill or judgment is brought to bear. It is a vendible product and not a method of medical treatment."

Justice Hughes found the claim invalid on the basis of double patenting ("identical or co-terminus") with the claims of a prior patent. The claims of the prior patent did not refer to a dosage range, and Justice Hughes declined to limit the scope of the claims to a higher range of 5 to 2,000 mg including as the disclosure of the prior patent said that this was the range that "exemplifies" the dosage but did not state that it was so limited or restricted. The claim was also found invalid for obviousness.

Justice Hughes also found the claim invalid as lacking novelty in light of two separate

references: the use of finasteride in an oral composition to treat male pattern baldness had been disclosed, and the selection of a dosage range was within the skill of an ordinary person skilled in the art. However, the claim was found not to be obvious as prior art references would have discouraged researchers from pursuing research in that

area; in other words, “motivation” would be lost.

Pharmascience’s sound prediction/overbreadth attack was rejected as not being properly raised in the notice of allegation.

The application was therefore dismissed.

Patented Medicine Prices Review Board news

New NEWSletter released. The PMPRB has released its April 2010 NEWSletter, which reports on voluntary compliance undertakings

(VCUs) regarding FSME-IMMUN and PAXIL CR. ([NEWSletter](#).)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

AstraZeneca denied leave to file video recordings of cross-examinations. The applicants requested an order to file video recordings of the cross-examinations of expert witnesses as a supplemental volume of the application record. The applicants asserted that watching the video recording would assist the Court to understand the scientific evidence and assign weight to it. The Judge dismissed the motion, stating that neither reason warranted deviation from the existing practices in notice of compliance (NOC) proceedings. (*AstraZeneca Canada Inc. v. Novopharm Limited*, March 11, 2010. Full judgment – [2010 FC 276](#).)

Novopharm granted confidentiality Order in judicial review proceeding regarding requirement to address patents. Novopharm sought judicial review of the Minister’s decision that it must address a specific patent listed on the Register before it can obtain an NOC. Novopharm moved for the matter to proceed under a confidentiality Order, in particular to identify the patents and drugs at issue as Patents X and Y and Drugs A and B, to maintain the confidentiality of its dealings with the Minister and of its abbreviated new drug submission (ANDS). It argued that disclosure of details about its ANDS will entail disclosure of its legal and business strategy, resulting in prejudice to its commercial interests. The Minister disagreed and argued that an innovator has the right to participate as a party to the

hearing. The Prothonotary framed the issues as two-fold: first, are the rights of the innovator affected such that the innovator should be a party to the proceeding; and second, if not, is a confidentiality Order appropriate that names neither the patent, the drug, nor the innovator?

The Prothonotary agreed with Novopharm and granted the Order. He stated that a generic’s drug submission is confidential as between the Minister and the drug sponsor, and the public has little interest in the contents of such submissions. He noted that commercial interests are a legitimate risk to protect. He further stated that it was for the Minister alone to decide whether Novopharm was required to address patents on the Register and distinguished the proceeding from cases in which an NOC had been issued. In this proceeding, the decision only affects the rights of Novopharm, and the patent holder was therefore not a necessary party. The innovator has no interest if Novopharm is not required to address the patent, and alternatively, if Novopharm is required to address the patents, the innovator’s legal rights are protected. Finally, the Prothonotary pointed to the fact that the decision should be directed primarily to the integrity of the Minister’s internal decision-making process and not to protecting the innovator’s interests. (*Novopharm v. Canada (Health)*, May 26, 2010. Full judgment – [2010 FC 566](#).)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	galantamine hydrobromide (REMINYL)
Applicants:	Janssen-Ortho Inc and Janssen Pharmaceutica NV
Respondents:	Teva Canada Limited (formerly Novopharm Limited) and The Minister of Health
Date Commenced:	April 16, 2010
Court File No.:	T-603-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,310,950. Teva alleges non-infringement and invalidity and asserts ineligibility.
Medicine:	clarithromycin (BIAXIN)
Applicants:	Abbott Laboratories and Abbott Laboratories Limited
Respondents:	Ranbaxy Pharmaceuticals Canada Inc and The Minister of Health
Date Commenced:	April 20, 2010
Court File No.:	T-613-10
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,386,527, 2,387,356, 2,471,102, 2,419,729, 2,386,534, 2,277,274, 1,328,609 and 2,235,607. Ranbaxy alleges invalidity and non-infringement of the patents.
Medicine:	losartan potassium / hydrochlorothiazide (HYZAAR & HYZAAR DS)
Applicants:	Merck Frosst Canada Ltd and El DuPont De Nemours and Company
Respondents:	Teva Canada Limited and The Minister of Health
Date Commenced:	April 23, 2010
Court File No.:	T-637-10
Comment:	Application for Order of prohibition until expiry of Patent No. 1,338,238. Teva alleges non-infringement and invalidity. Teva acknowledges that an NOC for its tablets will not issue until expiry of Patent No. 1,334,092 on January 24, 2012.
Medicine:	atomoxetine hydrochloride (STRATTERA)
Applicant:	Eli Lilly Canada Inc
Respondents:	Pharmascience Inc and The Minister of Health
Respondent/Patentee:	Eli Lilly and Company
Date Commenced:	April 30, 2010
Court File No.:	T-669-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,209,735. Pharmascience alleges invalidity.

Medicine: donepezil hydrochloride (ARICEPT)
Applicants: Pfizer Canada Inc and Eisai Co, Ltd
Respondents: ratiopharm Inc. and The Minister of Health
Date Commenced: May 7, 2010
Court File No.: T-713-10
Comment: Application for Order of prohibition until expiry of Patents Nos. 1,338,808 and 2,252,806. ratiopharm alleges invalidity (both patents), non-infringement ('808 Patent only) and asserts ineligibility ('806 Patent).

Medicine: repaglinide (GLUCONORM)
Applicant: Novo Nordisk Canada Inc
Respondents: Pharmascience Inc, The Minister of Health and Dr. Karl Thomae GmbH
Date Commenced: May 12, 2010
Court File No.: T-733-10
Comment: Application for an Order of prohibition until expiry of Dr. Thomae's Patent No. 2,111,851. Pharmascience alleges non-infringement and invalidity and asserts ineligibility.

Other proceedings

Medicine: raloxifene hydrochloride (EVISTA)
Plaintiffs: Eli Lilly Canada Inc, Eli Lilly and Company, Eli Lilly SA and Lilly, SA
Defendant: Teva Canada Limited (formerly known as Novopharm Limited)
Date Commenced: April 19, 2010
Court File No.: T-607-10
Comment: Action for infringement of Patent No. 2,250,191.

Medicine: valacyclovir hydrochloride (VALTREX)
Plaintiff: Pharmascience Inc
Defendant: GlaxoSmithKline Inc
Date Commenced: April 23, 2010
Court File No.: T-643-10
Comment: Action for section 8 damages.

To check the status of Federal Court cases, [please click here](#).

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