SMART & BIGGAR | FETHERSTONHAUGH DECEMBER 2005

Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Federal Court Finds PMPRB Does Not Have Jurisdiction Over Patent Applications

The *Patent Act* grants the Patented Medicine Prices Review Board ("PMPRB" or the "Board") jurisdiction to reduce the price of a medicine where it finds that "a patentee of an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board's opinion is excessive."

In 1996, in *ICN Pharmaceuticals and ICN Canada Limited v. Canada (PMPRB)*, the Federal Court of Appeal held that the connection between the patent in question and the medicine needs only to be of the "merest slender thread".

On November 17, 2005, in *Hoechst Marion Roussel Canada Inc. v. Canada (Attorney General)* ("*Nicoderm*") (2005 FC 1552), the Federal Court further clarified the Board's jurisdiction. In this case, the Court held that the Board cannot assert jurisdiction over patent applications.

The *Nicoderm* decision resulted from two applications for judicial review of the Board's decisions brought by Hoechst Marion Roussel Canada ("HMRC"), challenging the Board's jurisdiction to inquire into HMRC's pricing of NICODERM (a nicotine transdermal patch).

The Court dismissed HMRC's first application for judicial review involving issues of procedural fairness and bias. In its second application, HMRC challenged the Board's statutory jurisdiction.

With reference to one of the patents at issue, the Court, noting the *ICN* decision, found that "the fact that the '689 Patent is for a nicotine transdermal patch system, capable of being used in the drug product Nicoderm, is a sufficient connection to support the conclusion that the '689 Patent pertains to Nicoderm. It is irrelevant whether the '689 Patent is actually being used in connection with the medicine Nicoderm."

As for the PMPRB's jurisdiction over patent applications, the government had argued that the PMPRB had such jurisdiction on the basis that patentees are accorded a benefit after the application is laid open (reasonable compensation) creating significant *de facto* protection. The Court rejected this argument, finding that a patent application gives rise only to the potential for the grant of a patent and found that the Board erred in law in purporting to exercise jurisdiction over two laid-open patent applications.

HMRC and the government may appeal to the Federal Court of Appeal, as of right.

Junyi Chen

Health Canada Launches NOC Database

On November 17, 2005, the Health Minister announced the launch of a notice of compliance database that will allow searches on all drugs approved in Canada since 1994. The database provides information such as a drug's full name, the date it was authorized, the active/medicinal ingredient, the manufacturer, the therapeutic class of the drug, and the Drug Identification Number. The database will be updated daily.

News Release

Notice of Compliance Database

Supreme Court of Canada Leave Applications

GlaxoSmithKline v. Canada (Attorney General) (**paroxetine hydrochloride (PAXIL CR)**), August 23, 2005

GSK has filed an application for leave to appeal a decision of the Federal Court of Appeal. The Court of Appeal dismissed GSK's appeal of a Judge's decision, thus upholding the Minister's refusal to list two of GSK's patents on the Patent Register. The patents' claims do not explicitly claim the medicine at issue, paroxetine hydrochloride. The majority found that the claims in the patents for controlled release of "active substances" gave no guidance "for the medicine itself" and were too imprecise. The minority found that if the patent protected the delivery system, then it did not contain a claim for the medicine itself or the use of the medicine, even if it refers to a medicine.

Court of Appeal Decision (2005 FCA 197)

Applications Judge's Decision (2004 FC 1725)

Pharmascience v. Abbott (**clarithromycin (BIAXIN BID)**), September 28, 2005

Pharmascience has filed an application for leave to appeal a decision of the Court of Appeal, which dismissed Pharmascience's appeal of an Order of prohibition. The applications Judge had found that Pharmascience's notice of allegation (NOA) was deficient, and that Pharmascience had failed to discharge its evidentiary burden to justify the allegations of non-infringement and invalidity.

Court of Appeal Decision (2005 FCA 250)

Applications Judge's Decision (2004 FC 1349)

Bayer v. Jean Pardy, Bruce McCullough and John Ryan (**cerivastatin (BAYCOL)**), November 10, 2005

Leave has been denied. Bayer had sought leave to appeal a judgment of the Court of Appeal of Newfoundland and Labrador. Patients alleged to have experienced serious side effects from BAYCOL sought to have a class action certified with the named Respondents as representative Plaintiffs. The case management Judge granted the Order for certification, but stayed its effect pending the outcome of a settlement motion in the Ontario Court. Leave to appeal this decision was refused by the Court of Appeal.

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Biovail v. RhoxalPharma (**diltiazem hydrochloride (TIAZAC)**), October 19, 2005

Judge dismisses Biovail's application for a prohibition Order, finding that Biovail has not met its burden of establishing that RhoxalPharma's allegation of non-infringement is not justified. Biovail has appealed.

Full Judgment (2005 FC 1424)

Pfizer v. Ranbaxy (**atorvastatin calcium (LIPITOR)**), November 1, 2005

Judge dismisses Pfizer's appeal from an Order of a Prothonotary, dismissing Pfizer's motion for an Order directing both the Applicants and the Respondents (Ranbaxy) to refrain from relying on, leading, or otherwise filing evidence in relation to statements in Ranbaxy's NOA on the grounds that the statements in the NOA are irrelevant, have no reasonable chance of success or are vague or overly broad. Pfizer has appealed.

Motions Judge's Decision (2005 FC 1482)

Aventis v. Apotex (**ramipril (ALTACE)**), November 4, 2005

Judge dismisses Aventis' application for a prohibition Order related to a use patent. The Judge holds that Apotex is not precluded from bringing its second NOA relating to invalidity because it is "factually and legally distinct" from its first NOA relating to non-infringement. The Judge found in Apotex's favour on the allegation of obviousness. Aventis has appealed.

Full Judgment (2005 FC 1504)

Other Decisions

Apotex v. Eli Lilly and Shionogi (**APO-CEFACLOR, CECLOR**), November 2, 2005

Court of Appeal allows Apotex's appeal from a Judge's decision granting summary judgment, striking Apotex' defence and counterclaim that rested on the *Competition Act*. Apotex pleaded that Eli Lilly "conspired" with Shionogi to acquire patents from Shionogi for the purpose of preventing others from producing or acquiring cefaclor. Apotex therefore alleged violation of the *Competition Act* and sought damages from Eli Lilly and Shionogi. The Court of Appeal found that an assignment of patents is not exempt from section 45 of the *Competition Act* when, by reason of the assignee's existing ownership of other patents, the assignment transfers more market power than that inherent in the patents assigned. The Court also suggests that the motions Judge was incorrect in his view that there must be agreement as to something more than a mere exercise of patents rights (in this case the assignment) in order for there to be a finding of conspiracy.

Court of Appeal's Decision (2005 FCA 361)

Motions Judge's Decision (2004 FC 1445)

Trade-mark Opposition Board Decisions

Canadian Medical Association v. Eclectic Echinacea Inc. (**PRAIRIE DOCTOR BRAND, application no. 1,060,581**), September 21, 2005

Board rejects Canadian Medical Association's (CMA) opposition to application for the trade-mark PRAIRIE DOCTOR BRAND for use in association with a number of herbal products. CMA, owner of the advertised official mark DOCTOR, opposed registration of the application on the basis, among other grounds, that the mark is deceptively misdescriptive, that the mark resembles the official mark and that it is not distinctive.

Full Decision

Canadian Internet Registration Authority's Domain Name Dispute Resolution Policy Decisions

Glaxo v. Turvill Consultants - NARD (**www.advair.ca**), November 10, 2005

Panel orders the registration of the domain name to be transferred to the complainant, Glaxo. Panel finds the registrant's domain name to be confusingly similar to Glaxo's registered trade-mark ADVAIR, in which GLAXO had rights prior to the date of registration of the domain name, and that the registrant has no legitimate interest in it.

Full Decision

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	**ramipril (ALTACE)**
Applicant:	Aventis Pharma Inc
Respondents:	Schering Corporation, Novopharm Limited and The Minister of Health
Date Commenced:	October 31, 2005
Comment:	Application for Order of prohibition until expiry of Schering's Patent No 1,341,206. Novopharm alleges non-infringement and invalidity.

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Medicine:	**ramipril (ALTACE)**
Applicants:	Aventis Pharma Inc and Sanofi-Aventis Deutschland GmbH
Respondents:	Novopharm Limited and The Minister of Health
Date Commenced:	November 2, 2005
Comment:	Application for Order of prohibition until expiry of Patents Nos 2,023,089; 2,055,948; 2,382,549 and 2,382,387. Novopharm alleges non-infringement and invalidity with respect to the 089, 549 and 387 patents and non-infringement with respect to the 948 patent.

Medicine:	**fenofibrate (LIPIDIL SUPRA)**
Applicants:	Fournier Pharma Inc and Laboratoires Fournier SA
Respondents:	Novopharm Limited and The Minister of Health
Date Commenced:	November 7, 2005
Comment:	Application for Order of prohibition until expiry of Patents Nos 2,219,475 and 2,372,576. Novopharm alleges non-infringement and invalidity.

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