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IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Minister Seeks Court's Assistance in Interpreting *Notice of Compliance Regulations*

Reference may answer significant question relating to listing of patents on patent register.

The listing of a patent by way of a patent list on the patent register is required to trigger the various protective rights afforded to a first person (usually a patentee or a licensee) under the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*").

Section 4 of the *Regulations* governs when a patent may be added to a patent list. Subject to subsection 4(4), a first person must file a patent list at the time the person files a submission for a notice of compliance. Subsection 4(4) allows a first person to submit a patent list or an amendment to a patent list *after* the filing date of a submission, provided it is within 30 days after the issuance of a patent that has a filing date preceding the filing date of the submission. Section 4(6) prohibits a person from adding a patent to an existing patent list except in accordance with section 4(4).

As reported in the February issue of *Rx IP Update*, The Minister of Health filed a notice of application on January 28, 2002, referring the following question relating to the listing of a patent on the patent register, to the Federal Court, Trial Division,

> Does a patent list submitted with a supplemental new drug submission meet the requirements of section 4 of the *Regulations* where:
> (a) the patent has not been applied for at the time of the original new drug submission;
> (b) the timing requirements of subsection 4(4) are not met in respect of the original new drug submission; and,
> (c) the patent is not directed to the subject matter of the supplemental new drug submission?

In the Record of Decision to apply for the reference, the Minister *alleges* that the factual underpinning of the reference is as follows. A patent list was submitted by Eli Lilly Canada on July 27, 2001 for the drug, **ZYPREXA** (**olanzapine**). Eli Lilly filed a new drug submission ("NDS") for ZYPREXA in 1995. Eli Lilly has another patent listed in respect of this submission. In 1996, Eli Lilly filed a patent application for the patent at issue. In 1997 and 1999, Eli Lilly filed two supplemental new drug submissions ("SNDS"), for two new strengths and for a new dosage form, respectively. Within 30 days following grant of the patent in 2001, patent lists were filed to list the patent against all three drug submissions. The patent claims a polymorphic form of olanzapine.

The Minister's version of the key issue, as set out in the Record of Decision, is as follows:

> [The] patent is relevant to the subject matter of the NDS for which a NOC was originally issued for ZYPREXA on October 3, 1995, but is out of time to list against that submission, since the patent was applied for after the submission was filed. In attempting to list the patent against a [SNDS] to which the patent is not relevant, Eli Lilly would appear to have avoided the original timing requirements under section 4. Although it has been clarified that first persons can list a patent against a [SNDS] in *Apotex Inc v. Canada (Attorney General)* [which was affirmed on appeal] where relevance is not required, other developing jurisprudence may suggest there must be relevance between the claims of the patent and the subject matter of the [SNDS], where the patent is out of time for listing against the original [NDS].

The only "other developing jurisprudence" referred to by the Minister in the Record of Decision is the *Bristol-Myers Squibb v. Canada (Attorney General)* decision. In this case, the first person was prevented from maintaining a patent on the patent register on the basis of an SNDS for a change to the brand name of the product, on the basis that the brand name change does not change the drug and thus the patent was effectively added to the *existing* patent list, outside of the strict time limits permitted by the *Regulations*. The patent had issued for well over 30 days before an attempt was made to submit it on the patent list. As reported in the February issue, this decision was recently affirmed on appeal. The Court of Appeal distinguished the *Apotex Inc v. Canada (Attorney General)* decision on the basis that it was decided prior to the introduction of subsection 4(6) of the *Regulations* and involved an SNDS based on a new indication or use.

Pending the decision on the reference, the Minister has "conditionally" listed the patent on the patent register.

On January 31, 2002, the Court issued a Direction setting a schedule for the reference, such that the reference may be heard by the Trial Division as early as this summer. Pursuant to the Direction, the Minister of Health, Eli Lilly Canada Inc, Canada's Research-Based Pharmaceutical Companies (Rx & D), and the Canadian Drug Manufacturers Association (CDMA) are now parties to the reference.

The decision on this issue will have significant implications for the ability of innovator companies to use the *Regulations* to assist in preventing patent infringement. The Minister indicates that there are at least five other drugs for which patents are being sought to be listed on the patent register in similar circumstances. However, it is likely that there are many other drugs, for which patents have not yet issued, that may also be affected by this decision. The Minister may also use the decision to decide whether to maintain or de-list patents from the patent register. We will report on the progress of this reference in future issues of *Rx IP Update*.

Nancy P. Pei

Supreme Court of Canada Hearings

Novopharm Ltd et al v. The Wellcome Foundation Limited et al (**zidovudine**, **AZT** (**RETROVIR**))

This is an appeal arising from a Federal Court of Appeal decision, dismissing in large part, Novopharm and Apotex' appeal of the Trial Judge's decision, which held that some of the claims of the AZT patent were valid and infringed. The Supreme Court heard this appeal on February 14, 2002 and reserved its decision.

SCC Press Release

The Commissioner of Patents v. The President and Fellows of Harvard College (Harvard mouse)

As reported in the September issue of *Rx IP Update*, the Supreme Court of Canada granted the Commissioner of Patents leave to appeal the decision of the Federal Court of Appeal, which ruled that higher life forms are patentable subject matter under the Canadian *Patent Act*. The "Harvard mouse" appeal will be heard on May 16, 2002.

We will report on the decisions of the Court, once released.

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Pfizer v. Apotex (**sertraline** (**ZOLOFT**)), February 11, 2002

During cross-examination, Apotex challenged the applicants' experts' evidence by referring to and producing prior art references not included in the notice of allegation. Trial Judge dismisses appeal of Prothonotary's decision, finding that the prior art references may be relied upon for the purpose of cross-examination, but not for the purpose of arguing in the application that the patent is invalid.

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

Apotex v. Merck (**norfloxacin** (**NOROXIN**)), February 18, 2002

In action for damages brought under *Regulations*, Judge dismisses Merck's motion to strike Apotex' statement of claim.

Full Judgment

Other Decisions

Merck v. The Minister of Health (**alendronate sodium** (**FOSAMAX**)), January 24, 2002

Court of Appeal dismisses appeal of Trial Judge's decision, dismissing Merck's application for review of *Access to Information Act* decisions to release certain records from Merck's FOSAMAX new drug submission. Court of Appeal finds that there was ample evidence before the Judge to support a finding that Merck had not proven that the information was "confidential information".

Full Judgment (Court of Appeal)

Full Judgment (Trial Division)

Wyeth-Ayerst v. Attorney General of Canada (**conjugated estrogens** (**PREMARIN**)), February 5, 2002

Judge dismisses application to review Minister of Health's decision to release information pursuant to an *Access to Information Act* request. Judge finds that there is no evidence to show that irrelevant or improper factors entered into the consideration of the eligibility of the requester made by the officer handling the request. With respect to applicant's assertion of confidentiality, the affidavit based on belief is not proper evidence, and is otherwise insufficient to support such a finding.

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

Apotex v. Minister of Health; *Pfizer v. Minister of Health* (**sertraline** (**ZOLOFT**)), February 13, 2002

Pfizer's NOC for Zoloft extended to use for treatment of three disorders, including depression. Apotex' NOC was restricted to use for treatment of depression. Ontario Court of Appeal dismisses Apotex' appeal of Trial Judge's decision, finding that the Ontario Ministry of Health had jurisdiction to place Apo-Sertraline on the Formulary as interchangeable with Zoloft but with an asterisk limiting its use to treatment for depression. Court of Appeal finds that it is well within the purpose and ambit of the *Drug Interchangeability and Dispensing Fee Act* to assure that the Formulary lists only those drugs that are "legal to sell" and identifies those drugs of "limited legality", as indicated by the relevant NOC.

Full Judgment

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	**Carvedilol** (**COREG**)
Applicants:	GlaxoSmthKline Inc and SmithKline Beecham Corporation
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	January 31, 2002
Comment:	Application for Order of prohibition until expiry of Patent No. 1,259,071. Apotex alleges non-infringement and invalidity.

Medicine:	**Etidronate disodium/calcium carbonate tablets** (**DIDROCAL**)
Applicants:	Procter & Gamble Pharmaceuticals Canada, Inc and The Procter & Gamble Company
Respondents:	Genpharm Inc and The Minister of Health
Date Commenced:	February 1, 2002
Comment:	Application for Order of prohibition until expiry of Patent No. 1,338,376. Genpharm alleges non-infringement and invalidity.

Medicine:	**Fosinopril** (**MONOPRIL**)
Applicants:	Bristol-Myers Squibb Canada Inc and Bristol-Myers Squibb Company
Respondents:	Novopharm Limited and The Minister of Health
Date Commenced:	February 4, 2002
Comment:	Application for Order of prohibition until expiry of Patent No. 2,019,324. Novopharm alleges non-infringement.

Medicine:	**Levodopa/carbidopa controlled-release tablets** (**SINEMET CR**)
Applicants:	Merck Frosst Canada & Co and Merck & Co, Inc
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	February 6, 2002
Comment:	Application for Order of prohibition until expiry of Patent No. 1,318,602. Apotex alleges non-infringement, invalidity and that the patent was not eligible for inclusion on patent register in relation to Sinemet CR.

Other New Proceedings

Medicine: **Enalapril maleate** (**VASOTEC**)
Plaintiff: Nu-Pharm Inc
Defendants: Her Majesty The Queen in Right of Canada, The Attorney General of Canada, The Minister of Health and The Director-General, Therapeutic Products Directorate of Health Canada
Date commenced: February 12, 2002
Comment: Action for an Order prohibiting Health Canada from publishing statements that the sale of Nu-Enalapril is unlawful and to retract any such statements; and damages for abuse of authority and illegal interference with Nu-Pharm's economic interest in unlawfully advising provincial regulatory authorities, third party pharmacists, distributors of pharmaceutical products, public and private insurers and other persons that the sale of Nu-Enalapril is unlawful.

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