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IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

"Product-Specific Patent List" Does Not Require That Commercial Formulation Embody Patented Invention

In a significant decision released on January 22, 2003, *Eli Lilly Canada v. The Minister of Health*, Neutral Citation: 2003 FCA 24, the Federal Court of Appeal has determined that a patent can be listed on the Patent Register maintained pursuant to the *Patented Medicines (Notice of Compliance) Regulations ("Regulations")*, even if the patentee's commercial formulation does not make use of the patented invention. In doing so, the Court of Appeal has overruled previous jurisprudence of the Federal Court, Trial Division (*Warner-Lambert Canada Inc. v. Canada (Minister of Health)*, [2001] F.C.J. No. 801 (T.D.))(*"Warner-Lambert"*).

In April of 1993, Eli Lilly submitted patent lists for its TAZIDIME products (TAZIDIME and TAZIDIME ADD-VANTAGE), each of which listed Patent No. 1,249,969 (the 969 patent). The claims of the 969 patent are directed to ceftazidime pentahydrate in combination with amorphous lactose. The amorphous lactose solved a toxicity problem relating to ceftazidime pentahydtrate. In its TAZIDIME marketed formulations, Eli Lilly did not use amorphous lactose.

On July 6, 2000, the Minister removed the 969 patent from the Patent Register as he concluded that, as there is no amorphous lactose in the TAZIDIME formulations and as the claims of the 969 patent are directed to pharmaceutical formulations including amorphous lactose, the patent was not relevant to the drug outlined in the submission for a Notice of Compliance (NOC).

Eli Lilly sought judicial review of this decision. The Federal Court, Trial Division judge dismissed Eli Lilly's application (*Eli Lilly Canada v. The Minister of Health*, Neutral Citation: 2002 FCT 28).

The Court of Appeal, in a 2-1 decision, allowed the appeal and rejected the Minister's argument that the required "relevance" between the drug named in the NOC and the patent sought to be included in the patent register does not exist if the invention disclosed in the patent is not somehow included or embodied in the drug.

The majority found that the interpretation suggested by the Minister was not supported by the wording of the *Regulations* and, in particular, was not supported by the following words of section 4 of the *Regulations* relied upon by the Minister:

> 4(1) A person who files or has filed a submission for, or has been issued, a notice of compliance in respect of a drug that contains a medicine may submit to the Minister **a patent list** certified in accordance with subsection (7) **in respect of the drug**.
>
> 4(7) A person who submits a patent list ... must certify that...the patents set out on the patent register... are eligible for inclusion on the register and are relevant to the dosage, form, strength and route of administration **of the drug in respect of which the submission for a notice of compliance has been filed**.

The majority held that the words in section 4(7)(b) do not describe any relationship between the drug named in the NOC and the patents that may be included on the patent list. Rather, the "drug in respect of which the submission for a notice of compliance has been filed" was found to be, simply, TAZIDIME.

In addition to finding support in the words of the *Regulations*, the majority also found it significant that this interpretation had at least the potential of preventing infringement of the 969 patent, while the Minister's interpretation did not. The majority accepted that it was possible that a generic producer could produce a drug consisting of a formulation of ceftazidime and amorphous lactose that was bioequivalent to TAZIDIME and which could thus infringe the 969 patent.

In allowing the appeal, the majority disagreed with the previous *Warner-Lambert* decision, wherein the judge, on an indistinguishable fact pattern, found that the patents at issue were ineligible for inclusion on the patent register. The judge in that case found support in his interpretation from the Regulatory Impact Analysis Statement that accompanied the 1998 amendments to the *Regulations*, which referred to the amendments as "ensuring a product-specific patent list".

As the remedies provided by the *Regulations* are not available to a patentee unless its patent is listed on the Patent Regiser, this decision is a significant one to both patentees and generic producers alike (as reported previously, Apotex had sought and was denied intervener status (*Eli Lilly Canada v. The Minister of Health*, Neutral Citation 2001 FCT 56, aff'd, Neutral citation 2001 FCA 108). It is open to the Minister to seek leave to appeal this decision to the Supreme Court of Canada. We will report on developments in this area in a future issue of *Rx IP Update*.

Nancy P. Pei

Supreme Court of Canada Leave Applications

AB Hassle v. The Minister of Health (**omeprazole capsules** (**LOSEC**)), December 31, 2002

On December 31, 2002, AB Hassle and AstraZeneca Canada filed an application seeking leave to appeal from a decision of the Federal Court of Appeal, which dismissed their appeal of a Federal Court, Trial Division decision. The motions judge had dismissed the applicants' application for an order of prohibition with respect to a "use" patent.

Appeal Decision

Trial Division Decision

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Apotex v. Bayer (**ciprofloxacin** (**CIPRO**)), December 18, 2002.

Court of Appeal dismisses appeal of Order of motions judge, granting Bayer leave to file reply evidence.

Appeal Decision

Trial Division Decision

Apotex v. Bayer (**ciprofloxacin** (**CIPRO**)), December 18, 2002

Court of Appeal dismisses appeal of Order of motions judge, granting Bayer leave to file reply evidence.

Appeal Decision

Trial Division Decision

Pfizer v. Apotex (**azithromycin** (**ZITHROMAX**)), January 17, 2003

Court dismisses Apotex' motion, seeking to set aside a Prothonotary's Order. The Prothonotary had dismissed Apotex' motion for production of certain documents and materials by Pfizer, which Apotex alleged were required to prepare its responding affidavit evidence.

Full Judgment

Eli Lilly v. The Minister of Health (**ceftazidime** (**TAZIDIME, TAZIDIME ADD-VANTAGE**)), January 22, 2003

Court of Appeal allows Eli Lilly's appeal of motions judge's decision. Motions judge had dismissed Eli Lilly's application for judicial review of Minister's decision to remove Eli Lilly's Patent No. 1,249,969 from Patent Register. For further information and links to the decisions, please see the article on page 1 of this issue.

Trade-mark Opposition Board Decisions

Schering Canada v. Biomune Systems (**OPTIMUNE**), December 9, 2002

Registrar refuses application to register trade-mark OPTIMUNE for "nutraceutical products derived from whey". Board finds that the applicant failed to show that there was not a reasonable likelihood of confusion between its trade-mark and OPTIMINE for "anti-histamine preparations".

Full Judgment

New Court Proceedings

New NOC Proceedings

Medicine: **alendronate sodium (FOSAMAX)**
Applicants: Merck & Co, Inc and Merck Frosst Canada & Co
Respondents: Novopharm Limited and The Minister of Health
Date Commenced: January 13, 2003
Comment: Application for Order of prohibition until expiry of Patent Nos. 2,018,477 and 2,221,417. Novopharm alleges non-infringement.

Medicine: **estradiol transdermal patch (VIVELLE)**
Applicants: Novartis Pharmaceuticals Canada Inc and Noven Pharmaceuticals, Inc
Respondents: RhoxalPharma Inc and The Minister of Health
Date Commenced: January 17, 2003
Comment: Application for Order of prohibition until expiry of Patent Nos. 2,110,914; 1,338,660; and 2,044,132. RhoxalPharma alleges invalidity, non-infringement, and improper listing of the 914 patent on the Patent Register.

Medicine: **azithromycin (ZITHROMAX)**
Applicants: Pfizer Canada Inc and Pfizer Inc
Respondents: Novopharm Limited and The Minister of Health
Date Commenced: January 17, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 1,314,876. Novopharm alleges non-infringement.

Other New Proceedings

Medicine:	**TORONTO SPV**
Plaintiffs:	Edwards Lifesciences Corp, Edwards Lifesciences LLC and Edwards Lifesciences (Canada) Inc
Defendants:	St Jude Medical Inc and St Jude Medical Canada Inc
Date Commenced:	January 6, 2003
Comment:	Patent infringement action regarding Patent No. 1,177,602, entitled "Low Pressure Fixation of Valvular Tissue Intended for Implantation".

Medicine:	**simvastatin (ZOCOR, Apo-Simvastatin)**
Applicant:	Apotex Inc
Respondent:	The Minister of Health
Date Commenced:	January 17, 2003
Comment:	Application for Order compelling the Minister to honour the undertaking given by the Director General to reconsider the refusal to approve the Apo-Simvastatin submission.

Medicine:	**QUICKTABS, EXCEDRIN QUICK TABS**
Plaintiff:	Bristol-Myers Squibb Company
Defendant:	Mepha AG
Date Commenced:	January 22, 2003
Comment:	Action for declaration that Trade-mark Registration No. TMA347,573 for QUIKTABS-MEPHA is invalid. BMS has applied for registration of trade-marks QUICKTABS and EXCEDRIN QUICK TABS.

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