SMART & BIGGAR | FETHERSTONHAUGH April 2006

Rx IP Update

Canadian Pharmaceutical Intellectual Property Law Newsletter

Ontario Government Tables Bill to Amend Formulary Legislation

On April 13, 2006, the Ontario Government introduced Bill 102, the *Transparent Drug System for Patients Act, 2006*. The legislation, if passed, will result in far-reaching changes to the *Drug Interchangeability and Dispensing Fee Act* and the *Ontario Drug Benefit Act*.

Proposed amendments include:

- Most of the functions and powers under the *Acts* that previously rested with the Minister of Health and Long-Term Care (Minister) and the Lieutenant Governor in Council would be transferred to the executive officer of the Ontario public drug programs.
- Products may be designated as interchangeable not only where they have the same active ingredients in a same dosage form, but also where they have **similar** active ingredients in a **similar** dosage form.
- Interchangeability designation would no longer require regulations.
- Manufacturers would be prohibited from providing rebates to pharmacies.

Most of the amendments, if passed, would come into force on October 1, 2006. Notably, however, the Minister would be enabled to make a regulation to designate products as interchangeable where they have similar active ingredients and are in a similar dosage form, as soon as the Bill receives Royal Assent.

News Release

Overview

Bill 102

Compendium to the Legislation

Two Further Decisions Reject Listing of "Dosage Form" Patents on Patent Register

In two recent Court decisions, the question for determination was whether the patents at issue contained "a claim for the medicine itself" and were therefore eligible for listing on the Patent Register pursuant to the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*").

In a March 13, 2006 decision (*Biovail v. The Minister of Health*, 2006 FCA 105), the Federal Court of Appeal considered a claim for a controlled-release composition which listed the relevant active ingredients dilitiazem hydrochloride (the active ingredient in TIAZAC XC) and bupropion (the active ingredient in WELLBUTRIN SR). Biovail had argued that since the active ingredients were uniformly and

intimately mixed with the polymers and were not separated by any structure, the tablets were not a "delivery system", but the medicine itself.

The Court of Appeal held that whether a patent claims a composition, which can be "the medicine itself", or a delivery system for medicine, is a question of construing the patent. The Court decided that the claim should be construed as a claim for the use of the polymers to achieve the slow release of six of the 49 or so active ingredients mentioned in the patent and therefore, the claimed invention is not the medicine itself. The Applications Judge's decision (reported in the September 2005 issue of *Rx IP Update*) finding that the Minister was correct not to list the patent was therefore affirmed.

The second decision was a March 30, 2006 decision of the Federal Court (*Procter & Gamble v. The Minister of Health*, 2006 FC 411) relating to the medicine risedronate sodium (ACTONEL). This case appears to have been decided without consideration of the *Biovail* Court of Appeal decision.

In considering the issue, the Judge chose to follow the approach suggested in the minority reasons in *GlaxoSmithKline v. The Minister of Health*, 2005 FCA 197, namely, a consideration of whether the patents claimed a "delivery system" or "payload". The Judge decided that, while both patents specifically referred to the active ingredient in the claims, both patents claimed a delivery system. The Judge noted that the essence of the '815 patent is a film coated tablet dosage which avoids irritation to the oesophagus and other upper passages, delivering the active ingredient to the stomach where it is dissipated. The '479 patent's purpose was found to protect a system of delivery of that payload, risedronate, to the lower intestinal tract.

A further issue was whether the '479 patent was relevant to the "dosage form" of the innovator's drug as required by section 4(7)(b) of the *Regulations*. The Judge agreed with the Minister's finding that the patent was not relevant because it was directed to an enteric coating for delayed-release which was a different dosage form from ACTONEL which did not have such a coating.

Should Biovail wish to appeal further, leave must be obtained from the Supreme Court of Canada. Procter & Gamble may appeal as of right.

Nancy P. Pei, Toronto

Patented Medicines Prices Review Board (PMPRB) Matters

The Patented Medicines Prices Review Board will hold a public hearing on July 10, 2006, to determine whether 3M Canada Company is selling or has sold AIROMIR (salbutamol sulphate) in any market in Canada at a price that is or was excessive and, if so, what order (if any) should be made. A pre-hearing conference will be held on May 19, 2006.

Notice of Hearing

On February 22, 2006, the Board ordered Novartis Consumer Health Canada Inc to provide Board Staff with price and sales information for:

HABITROL 7
HABITROL 14
HABITROL 21
TRANSDERMAL NICOTINE PATCH 14
TRANSDERMAL NICOTINE PATCH 7
TRANSDERMAL NICOTINE PATCH 21
TRIAMINIC SOFTCHEWS COLD & COUGH
TRIAMINIC SOFTCHEWS COLD & ALLERGY
TRIAMINIC SOFTCHEWS THROAT PAIN & COUGH

Order

On February 22, 2006, the Board ordered Gilead Sciences Inc to provide Board Staff with price and sales information for VIREAD (tenofovir disoproxil fumarate).

Order

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Apotex v. Pfizer (**fluconazole (DIFLUCAN, APO-FLUCONAZOLE)**), February 28, 2006

Apotex had alleged, in a claim for damages pursuant to section 8 of the *Regulations*, that the nature of the relationship between Pfizer Corporation (the patentee) and Pfizer Canada was such that Pfizer Corporation should be considered a "first person" and thus liable to Apotex. The Judge set aside portions of a Prothonotary's Order requiring Pfizer to answer discovery questions which aimed to elucidate the role that an entity of the Pfizer group (other than Pfizer Corporation) played in the underlying proceeding. In reviewing the questions, the Judge found that they amounted to a fishing expedition attempting to add other potential defendants not pleaded. Apotex has appealed.

Full Judgment (2006 FC 262)

Biovail Corporation v. Canada (Minister of National Health and Welfare) (**diltiazem hydrochloride (TIAZAC)**), March 1, 2006

Court of Appeal dismisses Biovail's appeal from an Order dismissing its application for an Order of prohibition on the ground of mootness, as the Minister had issued a notice of compliance (NOC) to RhoxalPharma.

Full Judgment (2006 FCA 92)

Abbott v. Pharmascience (**clarithromycin (BIAXIN)**), March 16, 2006

Judge grants Order of prohibition, finding that issue estoppel applies to Pharmascience's allegation of invalidity in view of a previous Order of prohibition with respect to the same patent.

Full Judgment (2006 FC 341)

Bayer v. Novopharm (**ciprofloxacin iv minibags (CIPRO IV)**), March 24, 2006

Judge grants Order of prohibition, rejecting Novopharm's allegations of: obviousness type double patenting; Gillette defence; and that the patent does not meet the criteria for a selection patent.

Full Judgment (2006 FC 379)

Other Decisions

Eli Lilly v. Apotex (**nizatidine (AXID)**), March 3, 2006

Apotex and Novopharm moved to compel production of laboratory notebooks of the inventors of the patent at issue, in order to facilitate examination of the inventors. Prothonotary finds that the lab notebooks are not compellable merely by virtue of the right of discovery of the assignor, but on the basis of their relevance to one or more of the pleaded defences. They were ordered to be produced as relevant to issues relating to inventorship and assignment of the patents at issue.

Full Judgment (2006 FC 282)

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	**amlodipine (NORVASC)**
Applicant:	Ratiopharm Inc
Respondent:	The Minister of Health
Date Commenced:	February 20, 2006
Court File No:	T-314-06
Comment:	Application for an Order requiring the Minister to delete Patent No 2,355,493 from the Patent Register.

Medicine: **pantoprazole (PANTOLOC)**
Applicants: Solvay Pharma Inc and Altana Pharma AG
Respondents: Apotex Inc and The Minister of Health
Date Commenced: March 9, 2006
Court File No: T-427-06
Comment: Application for Order of prohibition until expiry of Altana's Patents Nos 2,092,694 and 2,089,748. Apotex alleges non-infringement and invalidity.

Medicine: **pantoprazole (PANTO IV)**
Applicants: Altana Pharma Inc and Altana Pharma AG
Respondents: Pharmascience and The Minister of Health
Date Commenced: March 10, 2006
Court File No: T-443-06
Comment: Application for Order of prohibition until expiry of Patents Nos 1,254,215 and 2,089,748. Pharmascience alleges non-infringement and invalidity ('748 patent) and accepts that the NOC will not issue until after expiry of the '215 patent.

Other Proceedings

Medicine: **"pms-X" (unidentified)**
Applicant: Pharmascience Inc
Respondent: Attorney General of Canada
Date Commenced: February 27, 2006
Court File No: T-49-06
Comment: Application for an Order setting aside the decision of Health Canada whereby Pharmascience's submission for an NOC was considered withdrawn without prejudice to re-filing.

Trade-mark: **CANADA DRUGS and CANADADRUGS.COM**
Applicant: Pharmawest Pharmacy Ltd
Respondent: Kris Thorkelson
Date Commenced: February 21, 2006
Court File No: T-318-06
Comment: Application for a declaration that Trade-mark Registrations Nos TMA581,915 (CANADA DRUGS) and TMA581,899 (CANADADRUGS.COM), both in the name of Kris Thorkelson, be struck out on the grounds that they do not accurately express or define the existing rights of the person appearing to be the registered owner of the marks.

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Trade-mark:	**CANAMERICA DRUGS and CAN AMERICAN DRUG MART**
Plaintiff:	CanAmerica Drugs Inc
Defendants:	4784881 Manitoba Ltd, carrying on business as PharmaZeem Pharmacy and the said PharmaZeem Pharmacy
Date Commenced:	March 14, 2006
Court File No:	T-470-06
Comment:	Trade-mark infringement action.

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