SMART & BIGGAR / FETHERSTONHAUGH

AUGUST 2004

IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Federal Court Finds that Portions of New Drug Submission are Exempt from Disclosure Under the *Access to Information Act*

The Federal Court of Canada has determined that the Comprehensive Summary of a New Drug Submission (NDS), the associated reviewer's notes and the correspondence between Health Canada and the manufacturer ("disputed record") for a marketed drug, SINGULAIR, are exempt from disclosure under the federal *Access to Information Act* ("*AIA*"). (*Merck Frosst Canada & Co. v. Canada (Minister of Health)* (2004 FC 959))

The *AIA* allows a member of the public to request information in the hands of the federal government. The government compiles "relevant" information, reviews it and, if third party information is found, gives notice to the third party (in this case Merck Frosst Canada & Co. ("Merck"), the party who filed the NDS) that it is contemplating the release of the information, subject to certain statutory exemptions for third party information and to the third party's submissions. The *AIA* provides a mandatory exemption for "financial, commercial, scientific or technical information that is confidential information supplied to a government institution by a third party and is treated consistently in a confidential manner by the third party."

In this case, a requester sought information related to the Comprehensive Summary, reviewer's notes, and correspondence between Merck and Health Canada for the drug SINGULAIR (montelukast sodium). Merck objected to disclosure of the entire disputed record and brought an application for judicial review.

The Federal Court accepted that the disputed record was third party information since the information would not exist but for Merck's submission.

The judge found that the disputed record is confidential, recognizing that confidentiality is a cornerstone of the regulatory scheme in the *Food and Drug Regulations*. In considering whether the information, in whole or in part, had lost its confidentiality, the Court found that some of the information appeared to be in the public domain. However, the Court agreed with Merck that confidentiality would only be lost if the information as presented by Merck was in the public domain.

Finally, the Court found that information within the disputed record that was already in the public domain could not reasonably be severed from the portions of the record that remained confidential. The Judge found that the "disconnected snippets" of releasable information were incomprehensible on their own, and if competitors found it comprehensible it was because they could gain insight from what had been deleted. Therefore, the entire disputed record was determined to be exempt from disclosure under the *AIA*.

This decision is significant as the Court has recognized the "confidential" nature of an NDS and has confirmed that the context in which information is found is a relevant consideration. The decision should be of considerable benefit to innovators seeking to prevent the disclosure of confidential commercial information to requesting parties under the *AIA*. It is not yet known whether the Minister of Health will appeal the decision.

Denise L. Lacombe

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Apotex v. Bayer (**ciprofloxacin (CIPRO)**), June 23, 2004

Court of Appeal dismisses Bayer's motion to dismiss Apotex' appeal of an Order of prohibition, on the grounds of mootness. While Court finds that the appeal is moot as the patent had expired and a Notice of Compliance (NOC) had been issued to Apotex, Court also finds that it should exercise its discretion to hear and decide the moot appeal. Court finds that there may be "collateral consequences" from the outcome of the appeal as the *Regulations* provide that a patentee may be liable to a generic manufacturer for loss suffered by the generic if an Order of prohibition is reversed on appeal.

Full Judgment (2004 FCA 242)

Aventis v. Mayne (**cefotaxime (CLAFORAN)**), July 5, 2004

Judge orders that Mayne shall not rely on certain paragraphs of its expert's affidavit since the evidence is directed to factual issues not supported by the Notice of Allegation (NOA). Mayne has appealed.

Full Judgment

Apotex v. AstraZeneca (**omeprazole magnesium (LOSEC)**), July 7, 2004

AstraZeneca sought production of Apotex' omeprazole product after cross-examination of Apotex' witness who analyzed this product. After receipt of the samples, AstraZeneca sought leave to file an affidavit which described the results of testing of Apotex' product. The Prothonotary had dismissed AstraZeneca's motion on the basis that AstraZeneca had delayed in seeking production of the samples. Court of Appeal finds that the Prothonotary was in error: because Apotex did not submit samples to the Minister, AstraZeneca could not compel production pursuant to section 6(7) of the *Regulations*. Court of Appeal states:

> "In my view, in circumstances where the disclosure process envisaged in subsection 6(7) of the Regulations cannot be resorted to because the samples have not been provided to the minister and where the second person proceeds to their testing and file affidavit evidence of the results of these tests in the prohibition proceedings, expediency, fairness and the overall interest of justice give the first person the right to, immediately after such filing, seek by motion the production of these samples for a testing of its own."

The Order, confirming the motions judge's decision to permit the filing of AstraZeneca's further evidence, was made without prejudice to Apotex to bring a motion seeking leave to file responding evidence.

Full Judgment (2004 FCA 255)

Other Decisions

Merck v. The Minister of Health (**montelukast sodium (SINGULAIR)**), July 6, 2004

Judge allows Merck's application for judicial review of Health Canada's decision that certain portions of documents relating to the review of the NDS for SINGULAIR would be disclosed pursuant to an *Access to Information Act* request. For further information relating to this decision, please see the article on page one of this newsletter.

Full Judgment (2004 FC 959)

Patented Medicines Prices Review Board (PMPRB) Matters

On July 6, 2004, the PMPRB filed an Order approving the terms of a Voluntary Compliance Undertaking (VCU) from Sanofi-Synthelabo for rasburicase (FASTURTEC).

VCU Notice

On July 9, 2004, the PMPRB accepted a VCU from Bayer Inc for alpha 1-proteinase inhibitor and alpha 1-antitrypsin replenisher (PROLASTIN).

VCU Notice

On July 15, 2004, the PMPRB accepted a VCU from Servier Canada Inc for zaleplon (STARNOC).

VCU Notice

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	**botulinum toxin Type A (BOTOX)**
Applicants:	Allergan Inc, Allergan Sales, Inc and Allergan, Inc
Respondents:	Ipsen Limited and The Minister of Health
Date Commenced:	June 23, 2004
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,310,845; 2,300,703; and 2,180,011. Ipsen alleges non-infringement.

Medicine:	**amlodipine (NORVASC)**
Applicants:	Pfizer Canada Inc and Pfizer Limited
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	July 2, 2004
Comment:	Application for Order of prohibition until expiry of Patent No. 1,321,393. Apotex alleges non-infringement and invalidity.

Medicine:	**ciprofloxacin injection (CIPRO)**
Applicants:	Bayer AG, Bayer Healthcare AG and Bayer Inc
Respondents:	Pharmaceutical Partners of Canada Inc and The Minister of Health
Date Commenced:	July 15, 2004
Comment:	Application for Order of prohibition until expiry of Patent No. 1,282,006. Pharmaceutical Partners of Canada alleges non-infringement and invalidity.

Medicine:	**amlodipine (NORVASC)**
Applicants:	Pfizer Canada Inc and Pfizer Limited
Respondents:	Ratiopharm Limited and The Minister of Health
Date Commenced:	July 19, 2004
Comment:	Application for Order of prohibition until expiry of Patent No. 1,321,393. Ratiopharm alleges non-infringement and invalidity.

OTTAWA

55 Metcalfe Street, Suite 900
P.O. Box 2999, Station D
Ottawa, Ontario Canada
K1P 5Y6
t. 613.232.2486
f. 613.232.8440

ottawa@smart-biggar.ca

TORONTO

438 University Avenue
Suite 1500, Box 111
Toronto, Ontario Canada
M5G 2K8
t. 416.593.5514
f. 416.591.1690

toronto@smart-biggar.ca

MONTREAL

1000 de La Gauchetière St. W.
Suite 3300
Montreal, Québec Canada
H3B 4W5
t. 514.954.1500
f. 514.954.1396

montreal@smart-biggar.ca

VANCOUVER

650 West Georgia Street
Suite 2200
Box 11560, Vancouver Centre
Vancouver, B.C. Canada
V6B 4N8
t. 604.682.7780
f. 604.682.0274

vancouver@smart-biggar.ca

EDMONTON

10060 Jasper Avenue, Suite 1501
Scotia Place, Tower Two
Edmonton, Alberta Canada
T5J 3R8
t. 780.428.2960
f. 780.423.6975

edmonton@smart-biggar.ca

www.smart-biggar.ca

Contact Info

For more information, or to request a copy of any decision, pleading or legislation, please contact:

Gunars A. Gaikis
ggaikis@smart-biggar.ca

J. Sheldon Hamilton
jshamilton@smart-biggar.ca

Nancy P. Pei (Editor)
nppei@smart-biggar.ca

Pharmaceutical Practice Group

James D. Kokonis, Q.C.
John Bochnovic
Keltie R. Sim
J. Christopher Robinson
J. Sheldon Hamilton
Yoon Kang
Daphne C. Ripley
May Ming Lee
Scott A. Beeser
A. David Morrow
Joy D. Morrow
Michael D. Manson
Solomon M.W. Gold
David E. Schwartz
Nancy P. Pei
Denise L. Lacombe
James Jun Pan
John R. Morrissey
Gunars A. Gaikis
Tokuo Hirama
Steven B. Garland
Brian G. Kingwell
Thuy H. Nguyen
Sally A. Hemming
Kavita Ramamoorthy

Disclaimer