SMART & BIGGAR / FETHERSTONHAUGH SEPTEMBER 2003

IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

1
Approval of Drug Names by Health Canada

2
Recent Court Decisions

3
New Court Proceedings

4
Health Canada News

Approval of Drug Names by Health Canada

Formalization of review process may be pending.

In reviewing a drug submission, in addition to the safety and efficacy of the drug, the Therapeutics Product Directorate ("TPD") of Health Canada also considers the acceptability of the drug name. The statutory basis for the TPD's review of drug names is section 9(1) of the *Food and Drugs Act*, which provides:

> 9(1) No person shall label, package, treat, process, sell or advertise any drug in any manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

At present, the drug name review by the TPD is completely informal. In addition to considering whether the drug name is misleading, the reviewer will check the TPD internal database for possible confusion with another approved or pending drug name, but only if the reviewer first suspects that there may be confusion. If a confusion objection is raised, the applicant will be provided an opportunity to submit arguments to attempt to overcome the objection. In view of the absence of formal guidelines, it is unclear whether the drug name which is first filed with the TPD or the name of the first approved drug that takes priority.

The review process in the US is far more rigorous and formal. Within the Center for Drug Evaluation and Research of the Food and Drug Administration ("FDA"), the Office of New Drugs works in consultation with the Office of Medical Policy/Division of Drug Marketing, Advertising, and Communications to review drug names for embedded false and misleading claims. It also consults the Office of Drug Safety/Division of Medication Error and Technical Support ("ODS/DMETS") to review drug names for potential confusion (sound-alike or look-alike) with approved or marketed names, as well as commonly used medical abbreviations, medical procedures, and lab tests. With respect to the confusion analysis, the ODS/DMETS conducts an expert panel review, verbal and handwritten prescription studies and computer-assisted analysis. The first party to have its drug *approved* by the FDA takes priority.

The significant gap between the review procedures in Canada as compared to those in the US may be narrowed in the near future. Consultations regarding proposed amendments to the review process in Canada may take place as early as this Fall. We will keep you advised of any developments in future issues of *Rx IP Update*.

Nancy P. Pei

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Procter & Gamble v. Genpharm (**etidronate disodium** (**GEN-ETIDRONATE**, **DIDRONEL**)), July 24, 2003

Judge dismisses Procter & Gamble ("P&G")'s application for an order varying an Order of prohibition to make it clear that the order includes a Notice of Compliance (NOC) subsequently granted for 200mg Gen-Etidronate and an order quashing the NOC. P&G had obtained the Order of prohibition in October 2001, preventing the Minister from issuing an NOC to Genpharm "in connection with its tablets containing 200mg and 400mg of the drug etidronate disodium until after the expiration of ... Patent number 1,338,376". The Order of prohibition arose in connection with a submission that named DIDROCAL as the reference product. The NOC at issue was granted in respect of Genpharm's further submission filed in August 2002 which named DIDRONEL as the reference product, for which there was no patent list.

Judge finds that P&G has failed to establish that if the new matter had initially been brought forward it would probably have resulted in a different original order and therefore the Order should not be varied. As reported in the August 2003 issue of *Rx IP Update*, P&G has filed a separate notice of application to quash the NOC.

Full Judgment (2003 FC 911)
(*For a printer friendly version, please scroll down to the end of the Judgment)

GlaxoSmithKline v. Apotex (**paroxetine hydrochloride** (**PAXIL**)), July 25, 2003

Judge strikes two affidavits filed by the applicants as being irrelevant. GlaxoSmithKline had argued that the affidavits demonstrate that the prior art cited by Apotex in the notice of allegation was insufficient to establish the safety and efficacy of the drug to the satisfaction of Health Canada and therefore, by analogy, could not be used to render the patent obvious.

Full Judgment (2003 FC 920)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Other Decisions

Genpharm v. Legault (**simvastatin** (**ZOCOR**, **GEN-SIMVASTATIN**)), July 9, 2003

Quebec Court of Appeal dismisses Genpharm's appeal from a judgment of the Superior Court, District of Montreal, which dismissed Genpharm's application to require the Conseil consultatif de pharmacologie du Québec to include Gen-Simvastatin in the list of medications insured by the Ministry of Health and Social Services. In order to have its product included in the June 1, 2003 list, Genpharm was required to file its application, accompanied by its NOC (pursuant to a Ministerial directive), by January 8, 2003. As Merck's patent expired on January 14, 2003, Genpharm could not obtain its NOC until January 15, 2003, and therefore, on December 19, 2002, Genpharm filed a patent hold letter and explained why it could not immediately transmit the NOC. Genpharm subsequently filed its NOC on January 15, 2003. The Conseil rejected the application as being incomplete. The Court of Appeal finds that the Conseil's insistence on enforcing the deadlines was in no way unreasonable: if the Conseil treated Genpharm's application differently, it would give it an advantage over its competitors.

Appeal Decision (French)

Trial Decision (French)

New Court Proceedings

New NOC Proceedings

Medicine:	**ramipril (ALTACE)**
Applicants:	Aventis Pharma Inc and Aventis Pharma Deutschland GmbH
Respondents:	Pharmascience Inc, The Minister of Health and Schering Corporation
Date Commenced:	March 27, 2003
Comment:	Application for Order of prohibition until expiry of Schering's Patent No. 1,341,206 and Aventis' Patent No. 1,246,457. Pharmascience alleges non-infringement and invalidity.

Medicine:	**sumatriptan succinate tablets (IMITREX)**
Applicants:	GlaxoSmithKline Inc and Glaxo Group Limited
Respondents:	Novopharm Limited and The Minister of Health
Date Commenced:	August 11, 2003
Comment:	Application for Order of prohibition until expiry of Patent No. 2,105,180. Novopharm alleges invalidity.

Medicine:	**ramipril (RAMACE)**
Applicant:	AstraZeneca Canada Inc
Respondents:	Apotex Inc, The Minister of Health and Schering Corporation
Date Commenced:	August 13, 2003
Comment:	Application for Order of prohibition until expiry of Schering's Patent No. 1,341,206. Apotex alleges invalidity.

Health Canada News

Health Canada has announced the finalization of its policy, "Interpretation of 'Identical Medicinal Ingredient'," effective July 9, 2003. The purpose of this policy is:

> to delineate the guiding principles that will be used to determine if two medicinal ingredients with the same active moiety are considered "identical" or "non-identical". This is used in establishing the pharmaceutical equivalence of dosage forms within the meaning of the term "identical medicinal ingredient" as mentioned in Section C.08.001 of the *Food and Drug Regulations*.

A draft of this policy was reported in our March 2003 issue of *Rx IP Update.*

Policy

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 3400
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
Michael D. Manson
Solomon M.W. Gold
David E. Schwartz
Nancy P. Pei
Denise L. Lacombe
James Jun Pan
A. David Morrow
Joy D. Morrow
Tokuo Hirama
Steven B. Garland
Brian G. Kingwell
Thuy H. Nguyen
Sally A. Hemming
Kavita Ramamoorthy
John R. Morrissey
Gunars A. Gaikis
J. Christopher Robinson
J. Sheldon Hamilton
Yoon Kang
Daphne C. Ripley
May Ming Lee