SMART & BIGGAR | FETHERSTONHAUGH JANUARY 2006

Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Guidance Document for Health Canada Review of Look-alike Sound-alike Health Product Names Now in Force

In our November 2004 edition of *Rx IP Update*, we reported on draft Health Canada guidance documents for Look-alike Sound-alike ("LA/SA") health product names.

Pre-market Guidelines

On October 31, 2005, the Health Products and Food Branch ("HPFB") of Health Canada released a revised guidance document, entitled *Drug Name Review: Look-alike Sound-alike (LA/SA) Health Product Names*. The revised guidance document, which came into effect on January 1, 2006, applies to all drug submission types received after this date.

The revised guidance document is generally similar to the draft document published in September 2004. The HPFB will review all proposed drug names submitted with all new drug submission types, applications for a drug identification number, or administrative submissions that involve a change to the name. All submissions will be reviewed within a 90 day period and a name may be disallowed if it is identified as potentially confusing. If the brand/proprietary name is a submission's only outstanding issue, a notice of compliance (NOC) will be issued without the brand name. The sponsor may follow up with an administrative submission in order to obtain approval for a proposed brand name. If the only outstanding issue is the proper name or common name of the product, a notice of non-compliance (NON) will issue, as an NOC cannot be issued without a proper or common name.

To facilitate the name review process, sponsors should submit:

- a proposed proprietary name and, if desired, a prioritized list of up to two alternate name choices; and
- a risk assessment and evaluation of the product's proposed brand name, supported with studies, data and analysis.

One change from the draft guidelines is a new requirement for sponsors in respect of product line extensions (defined as when a drug is named by using the brand name of another drug with the addition of a modifying prefix or suffix that is intended to distinguish the product from the original). Where a sponsor seeks to proceed with a product line extension, the sponsor must now provide a rationale stating why it is unlikely the proposed name will give rise to safety and/or efficacy concerns. Health Canada may reject the proposed name if it considers that the name may cause confusion, or may be misleading or unsafe.

Post-market Draft Guidelines

On November 10, 2005, the HPFB released a revised further draft guidance document for marketed LA/SA health product names, entitled *Marketed Health Product Name Assessment: Look-alike Sound-alike (LA/SA) Health Product Names*. Specific details of the post-marketing procedures remain to be defined, and HPFB intends to investigate how it can work with members of the pharmaceutical industry, health care professionals and related organizations to respond to post-market safety issues arising from medication errors.

Scott A. Beeser

Supreme Court of Canada Leave Applications

AstraZeneca v. Apotex (**omeprazole (LOSEC)**), December 15, 2005

Leave has been denied. AstraZeneca had applied for leave to appeal a judgment of the Court of Appeal, which dismissed AstraZeneca's appeal of the dismissal of its application for a prohibition Order. AstraZeneca argued before the Court of Appeal that the Judge erred in law in concluding that the notice of allegation (NOA) was not deficient, and that the Judge should have concluded that the allegation of non-infringement was not justified.

Court of Appeal Decision (2005 FCA 216)

Applications Judge's Decision (2004 FC 647)

GlaxoSmithKline v. Canada (Minister of Health) (**paroxetine hydrochloride (PAXIL CR)**), December 15, 2005

Leave has been denied. GSK had filed an application for leave to appeal a decision of the Federal Court of Appeal, which dismissed GSK's appeal of a Judge's decision upholding the Minister's refusal to list two of GSK's patents on the Patent Register. The claims of the patents do not explicitly claim the medicine at issue, paroxetine hydrochloride. The majority found that the claims in the patents for controlled release of "active substances" gave no guidance "for the medicine itself" and were too imprecise. The minority found that if the patent protected the delivery system, then it did not contain a claim for the medicine itself or the use of the medicine, even if it refers to a medicine.

Court of Appeal Decision (2005 FCA 197)

Applications Judge's Decision (2004 FC 1725)

Patented Medicines Prices Review Board (PMPRB) Matters

Proposed *Regulations Amending the Patented Medicines Regulations, 1994* were published on December 31, 2005. The *Patented Medicines Regulations, 1994* set out patentees' filing requirements with respect to the PMPRB, specifying the information that patentees must file with the PMPRB and the timeframes for doing so. The deadline for filing representations regarding the proposed *Regulations* is **January 30, 2006**.

The PMPRB has accepted a Voluntary Compliance Undertaking (VCU) from Janssen-Ortho for risperidone (RISPERDAL).

VCU Notice

The PMPRB has accepted a VCU from Sanofi Pasteur for DUKORAL.

VCU Notice

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Pfizer v. Mayne (**irinotecan (CAMPTOSAR)**), November 24, 2005

Court of Appeal dismisses an appeal by Pfizer from a Judge's decision denying Pfizer's motion for the production of information by Mayne Pharma pursuant to section 6(7) of the *Regulations*.

Full Judgment (2005 FCA 396)

Janssen-Ortho v. Novopharm (**levofloxacin solution for i.v. administration (LEVAQUIN)**), November 28, 2005

Judge grants Novopharm's motion to dismiss Janssen-Ortho's application for an Order of prohibition pursuant to section 6(5)(b) of the *Regulations*. In a previous case, *Janssen-Ortho v. Novopharm* (2004 FC 1631), a judge dismissed Janssen-Ortho's application for an Order of prohibition in connection with levofloxacin tablets, finding the same patent at issue invalid for obviousness. The Judge held that issue estoppel applied.

Full Judgment (2005 FC 1603)

Syntex and Roche v. Canada (Attorney General) (**naproxen slow-release (NAPROSYN SR)**), December 12, 2005

Court of Appeal allows Roche's appeal of a Judge's decision, striking the Defendants' third party claim against the Minister, in the event that Syntex/Roche is found liable to Apotex for damages under section 8 of the *Regulations*. Court of Appeal upholds the Judge's finding that section 8 does not provide for any claim over against the Crown and that it is a complete code for the recovery of damages by a second person against a first person. However, the Court finds that there can be a claim in negligence against the Crown and proof of a statutory breach that causes damages may be evidence of such negligence, and therefore grants leave to file a third party claim, alleging a valid cause of action in negligence.

Full Judgment (2005 FCA 424)

Pfizer v. Mayne (**epirubicin injectable ready-to-use solution (PHARMORUBICIN PFS)**), December 20, 2005

Judge grants Order of prohibition, finding that Pfizer's construction of the claims is the correct one and that on that construction, the Mayne product is an infringement of at least claim 1.

Full Judgment (2005 FC 1725)

Other Decisions

Aventis v. Novopharm (**enoxaparin sodium (NOVO-ENOXAPARIN, LOVENOX)**), November 21, 2005

Court of Appeal dismisses Aventis' appeal from a judgment dismissing Aventis' motion for an interlocutory injunction to restrain Novopharm from, among other things, selling Novo-enoxaparin pending trial of its patent infringement action.

Court of Appeal Decision (2005 FCA 390)

Motions Judge's Decision (2005 FC 815)

Zambon v. Teva; Teva v. Zambon, Apotex, and Torpharm (**gabapentin (APO-GABAPENTIN)**), November 23, 2005 and January 18, 2005

Zambon brought a patent impeachment action regarding a Teva patent. In a counterclaim, Teva alleges that Zambon and Apotex/Torpharm infringed its patent.

Apotex pleaded that the patent at issue was invalid pursuant to section 53(1) of the *Patent Act* because Teva's petition for the patent contained an untrue material allegation, namely, that the persons named in the petition were the inventors and that there was an invention was misleading because the purported invention was, to the knowledge of the petitioners, disclosed in the prior art and was offered for sale by Teva prior to the relevant date at issue. Teva brought a motion to strike arguing that the impugned paragraphs failed to disclose the essential element of willfulness required under section 53(1). The motions judge dismissed Teva's motion, finding that it was not settled law that willfulness is essential.

Full Judgment (2005 FC 1585)

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	**galantamine hydrobromide (REMINYL)**
Applicants:	Janssen-Ortho Inc and Janssen Pharmaceutica NV
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	December 5, 2005
Comment:	Application for Order of prohibition until expiry of Patent No 2,310,926. Apotex 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

Medicine:	**tolterodine L-tartrate (DETROL)**
Applicant:	Pfizer Canada Inc
Respondents:	Minister of Health and The Attorney General of Canada
Date Commenced:	December 9, 2005
Comment:	Application for Order requiring Minister to list Patent No 2,350,061 on the Patent Register.

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., B.A.Sc. (Metallurgy), LL.B.
John R. Morrissey, B.Eng. (Elec.Eng.), S.M., LL.B.
Joy D. Morrow, B.Sc., M.Sc. (Cell Bio.), LL.B.
Michael D. Manson, B.Sc. (Bio.), Dipl.Ed., LL.B.
Tokuo Hirama, B.Sc., M.Sc. (Chem.)
J. Christopher Robinson, B.Sc., M.Sc. (Genetics), LL.B.
Steven B. Garland, B.Eng. (Chem.-Biochem.Eng.), LL.B.
David E. Schwartz, B.Sc. (Genetics), LL.B.
Yoon Kang, B.Sc., M.Sc. (Molec.Bio. & Genetics), LL.B.
Geneviève M. Prévost, B.Sc. (Chem.), LL.B.
Jeremy E. Want, B.Sc. (Chem.), LL.B.
Daphne C. Ripley, B.Sc., M.Sc. (Chem.), LL.B.
Denise L. Lacombe, B.Sc. (Chem.), M.Sc. (Chem.Phys.), LL.B.
James Jun Pan, B.Eng. (Eng.Phys.), Ph.D. (Chem.), LL.B.
Jennifer L. Ledwell, B.Sc. (Biochem.), Ph.D. (Molec. & Cell Physio.)
T. Nessim Abu-Zahra, B.Sc. (Life Sci.), M.Sc. (Pharmacology), J.D.
Daniel M. Anthony, B.Sc. (Cell Bio. & Genetics), J.D.
A. David Morrow, B.Sc. (Physics), LL.B.
John Bochnovic, B.Eng. (Elec.Eng.), S.M., LL.B.
Gunars A. Gaikis, B.Sc.Phm., LL.B.
Keltie R. Sim, B.Sc. (Mycology), LL.B.
Mark K. Evans, B.Sc., LL.B.
Solomon M.W. Gold, B.Sc., M.Sc. (Bio.), LL.B.
J. Sheldon Hamilton, B.A.Sc. (Chem.Eng.), LL.B.
Brian G. Kingwell, B.Sc. (Biochem.), M.Sc. (Molec. Cell Bio.), LL.B.
Nancy P. Pei, B.Sc.Phm., LL.B.
Thuy H. Nguyen, B.Sc., Ph.D. (Biochem.)
Colin B. Ingram, B.A.Sc. (Elec.Eng.), LL.B.
Sally A. Hemming, B.Sc., Ph.D. (Biochem.), J.D.
May Ming Lee, B.Sc.Phm., LL.B.
Scott A. Beeser, B.Sc. (Biochem.) Ph.D. (Bio.), LL.B.
Kavita Ramamoorthy, B.Sc. (Pharma.), Ph.D. (Toxic.), LL.B.
Y. Lynn Ing, B.Sc. (Biochem.), Ph.D. (Molec.Bio.), J.D.
Junyi Chen, B.A. (Chem.), M.Sc. (Chem.), Ph.D. (Chem.), J.D.

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