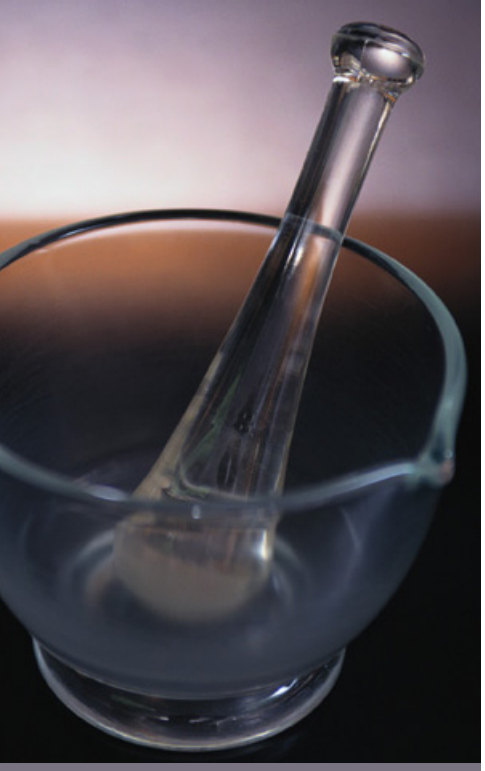

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

November 2007

Proposed amendments to PMPRB Regulations published

Proposed amendments to the *Patented Medicines Regulations, 1994* were published on October 5, 2007. The proposed amendments set out patentees' filing requirements with respect to the Patented Medicine Prices Review Board (PMPRB), specifying the information that patentees must file with the PMPRB and the timeframes for doing so. The deadline for filing representations regarding the amendments was October 22, 2007. The current amendments follow consultations following publication of previous proposed amendments on December 31, 2005. According to the Board's October 2007 newsletter, the Board intends to forward a regulatory package to the Minister of Health for submission to the Treasury Board Cabinet Committee recommending publication of the amendments prior to year end. (Proposed amendments.)

Separately, on October 18, 2007, the PMPRB released a Board Communiqué stating that it is continuing its work with stakeholders on resolving the issues arising from the decision of the Federal Court in *Leo Pharma v. Canada (Attorney General)*, 2007 FC 306, as reported in the April 2007 issue of *Rx IP Update*. In the meantime, for the periods of July 2007 to December 2008, patentees may elect to include or exclude all benefits and reductions in the calculations of average transaction prices, as long as consistency with previous reporting periods is maintained.

Finally, the PMPRB has accepted a Voluntary Compliance Undertaking (VCU) from Abbott for the medicine ZEMPLAR (paricalcitol). (VCU.)

Competition Bureau of Canada publishes Generic Drug Sector Study

In October, 2007, the Competition Bureau published its report, "Canadian Generic Drug Sector Study". The study was prompted by several studies that found the price of prescription generics to be high in Canada compared to other countries. Key findings include:

- Generic drugs are supplied through a unique and complex framework.
- Generic manufacturing has become more competitive over the past 15 years. It appears that strong competition exists in the supply of many generic drugs in Canada.
- In most provinces, an important way in which manufacturers compete to have their product stocked by pharmacies is to offer them rebates off invoice prices.
- Rebates and allowances are not typically reflected in amounts paid for drugs by public or private drug plans, or out-of-pocket by consumers.
- Plans incorporate various policies to reduce their generic drug costs. However, they provide limited incentive for manufacturers to offer competitive prices to end payers.

(Backgrounder. Report.)

Supreme Court of Canada matters

Novopharm v. Janssen-Ortho (levofloxacin (LEVAQUIN)), August 29, 2007. Novopharm is seeking leave to appeal an Order of the Court of Appeal which affirmed the Trial Judge's decision that the patent at issue is valid. The Court of Appeal also later denied a motion for reconsideration.
(Court of Appeal decision – 2007 FCA 217. Trial Judge's decision – 2006 FC 1234.)

sanofi-aventis v. Novopharm (ramipril (ALTACE)), October 25, 2007. sanofi-aventis' application for leave to appeal a Court of Appeal decision, which affirmed a decision to dismiss sanofi-aventis' application for a prohibition Order as an abuse of process, was denied. The Motions Judge had dismissed the application in view of an Order dismissing a previous proceeding relating to the same drug, the same patent, and the same allegation of invalidity, but against a different generic.
(Court of Appeal decision – 2007 FCA 163. Motions Judge's decision – 2006 FC 1135.)

Pfizer v. Apotex (sildenafil (VIAGRA)), November 1, 2007. Pfizer's leave application to appeal a Court of Appeal decision, which dismissed its appeal of the dismissal of its prohibition application, was denied. Apotex had succeeded in its allegation of invalidity based on lack of sound prediction.
(Court of Appeal decision – 2007 FCA 195. Applications Judge's decision – 2007 FC 26.)

Searle and Pfizer v. Novopharm (celecoxib (CELEBREX)), November 1, 2007. Novopharm's leave application was denied. Novopharm had sought to appeal the Court of Appeal's decision reversing the Applications Judge on his conclusion that Novopharm's allegation of invalidity was justified, including due to lack of good faith during the prosecution of the patent application.
(Court of Appeal decision – 2007 FCA 173. Applications Judge's decision – 2007 FC 81.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Pfizer Canada Inc. v. Apotex Inc. (sildenafil (VIAGRA)), September 27, 2007. Judge grants Pfizer's application for a prohibition Order. The Judge finds that Apotex's allegation of invalidity on the grounds of obviousness, anticipation and overbreadth is not justified. The Judge also dismisses Apotex's motion to dismiss the application on the ground that the claims at issue are not eligible for inclusion on the Patent Register. Apotex has appealed.
(Full judgment – 2007 FC 971.)

Pfizer and Warner-Lambert v. Ranbaxy and Minister of Health (atorvastatin calcium (LIPITOR)), October 5, 2007. Judge grants Pfizer's application for a prohibition Order for one patent and dismisses the application regarding another. The Judge found Ranbaxy's allegation of non-infringement with respect to Pfizer's patent claiming Form I atorvastatin was not justified, rejecting Ranbaxy's argument that use of Form I as an intermediate in the production of its product in India did not constitute infringement. The Judge was satisfied that the "Saccharin doctrine" was not limited to process claims. With respect to Pfizer's process patent, the Judge found that Ranbaxy's allegation of non-infringement was inadequate. However, Pfizer failed to show that Ranbaxy's allegation of invalidity due to insufficiency was unjustified. The Judge found that while the teachings of the patent could be followed with access to the Form I patent, that patent was not part of the common general knowledge. Ranbaxy has appealed.
(Full judgment – 2007 FC 898.)

sanofi-aventis Canada Inc. v. Pharmascience Inc. (ramipril (ALTACE)), October 17, 2007. Judge finds that the doctrine of issue estoppel operates to preclude Pharmascience from making further allegations of invalidity on different grounds, given that its initial allegation of invalidity was finally determined in a previous proceeding.
(Full judgment – 2007 FC 1057.)

Altana Pharma v. Novopharm and the Minister of Health (pantoprazole sodium (PANTOLOC)), October 23, 2007. Judge sets aside the decision of the Prothonotary which limited the number of expert witnesses that could be relied upon by Altana. Both Altana and Novopharm appealed. The Judge reviewed the law under section 7 of the *Canada Evidence Act* and found that the Prothonotary erred in concluding that the law limits a party or side to five experts per *issue*, unless leave of the Court is obtained. Rather, the limit is five experts in the *case* without leave. This is consistent with the Eli Lilly decision (2007 FC 1041) referenced below.
(Prothonotary's decision – 2007 FC 637. Motions Judge's decision – 2007 FC 1095.)

Eli Lilly Canada Inc. v. Novopharm Limited (olanzapine (ZYPREXA)), October 23, 2007. Court of Appeal dismisses applications by the Canadian Chamber of Commerce, BIOTECanada, Canada's Research-Based Pharmaceutical Companies (Rx&D) and the Canadian Generic Pharmaceutical Association (CGPA) for leave to intervene in Eli Lilly's appeal from a decision relating to disclosure requirements for a selection patent and on the motion to dismiss the appeal as moot.
(Court of Appeal decision – 2007 FCA 329. Application Judge's decision – 2007 FC 596.)

Other decisions

Zhan v. Pfizer (www."Pfizer".com), June 28, 2007. Judge grants Pfizer's motion for a stay of proceedings and sets aside service of the statement of claim. After being unsuccessful before a WIPO panel in a domain name dispute commenced by Pfizer regarding its trade-mark registrations in China for a Chinese transliteration of "Pfizer", Zhan commenced an action in Ontario for a declaration that the domain name should stay with him and for damages and costs arising from the WIPO proceeding. The Judge found that Ontario is a *forum non conveniens* since Mr. Zhan had agreed to be bound by the Uniform Domain Name Dispute Resolution Policy and Rules, which provides a jurisdiction clause, namely the location of the registrar of the domain (in this case, Colorado). (Full judgment – 2007 CanLII 24109.)

Nu-Pharm Inc. v. Canada (enalapril (NU-ENALAPRIL, VASOTEC)), September 28, 2007. Judge grants Crown's summary judgment motion, dismissing Nu-Pharm's action for damages against the Crown. Nu-Pharm alleged that the Crown unlawfully advised provincial regulatory authorities, pharmacists, distributors, and public and private insurers that the sale of

Nu-Enalapril is unlawful following the quashing of Nu-Pharm's NOC. The Judge finds that obtaining damages is entirely dependent upon Nu-Pharm's showing of the unlawful character of the Government's decisions, which must be determined by way of judicial review. While Nu-Pharm had previously brought such an application, it was discontinued. Nu-Pharm has appealed.
(Full judgment – 2007 FC 977.)

Eli Lilly; Shionogi (Defendant by Counterclaim) v. Apotex (cefaclor (APO-CEFACLOR, CECLOR)), October 10, 2007. Judge grants Apotex leave to adduce the evidence of up to 15 expert witnesses, subject to the discretion of the Trial Judge to disallow evidence which is duplicative or unnecessary. The Judge considered that the proper test is whether, taken as a whole, the case that a party has to present or meet fairly requires more than five experts (the number permitted under the *Canada Evidence Act* without leave of the Court). It is not necessary to determine the number of "issues" in the case. The Judge found that Apotex had shown at least a *prima facie* case that it requires the additional experts.
(Full judgment – 2007 FC 1041.)

Trade-mark decisions

Novartis AG v. Arachnova Ltd. (ARADERM, ESTRADERM), July 26, 2007. Opposition Board rejects Novartis's opposition to Arachnova's application to register the trade-mark ARADERM based upon proposed use in association with "pharmaceutical and veterinary preparations for the treatment of dermatitis and related dermatoses". The board rejected Novartis's argument that the mark is confusing with ESTRADERM for use in association with "estradiol administered by means of a patch or bandage attached to the skin of humans". (Full decision.)

New proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	pioglitazone (HCl) tablets (ACTOS)
Applicant:	Eli Lilly Canada Inc
Respondents:	The Minister of Health and Apotex Inc
Respondent/Patentee:	Takeda Pharmaceutical Company Limited
Date Commenced:	September 21, 2007
Court File No:	T-1715-07
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,531,834. Apotex alleges non-infringement and invalidity. Apotex further asserts that the patent is not eligible for listing on the Patent Register.

Medicine:	lansoprazole capsules (PREVACID)
Applicants:	Abbott Laboratories Limited and Tap Pharmaceuticals Inc
Respondents:	The Minister of Health, Novopharm Limited and Takeda Pharmaceutical Company Limited
Date Commenced:	September 21, 2007
Court File No:	T-1718-07
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,009,741. Novopharm alleges non-infringement and invalidity.

Medicine:	salmeterol xinafoate/fluticasone propionate inhalation aerosol (ADVAIR) and fluticasone propionate inhalation aerosol (FLOVENT HFA)
Applicant:	GlaxoSmithKline Inc
Respondents:	The Attorney General of Canada and The Minister of Health
Date Commenced:	September 28, 2007
Court File No:	T-1755-07
Comment:	Judicial review of the Minister's Decision not to list Patent No. 2,447,517. The patent list was submitted pursuant to the amended *Regulations*. The Minister stated claims in the patent are not directed to a dosage form.

Medicine:	sumatriptan hemisulphate nasal spray (IMITREX)
Applicant:	GlaxoSmithKline Inc and Glaxo Group Limited
Respondents:	The Minister of Health and Apotex Inc
Date Commenced:	October 5, 2007
Court File No:	T-1780-07
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,098,302. Apotex alleges invalidity.

Medicine:	oxycodone (HCl) tablets (OXYCONTIN)
Applicant:	Purdue Pharma
Respondents:	The Minister of Health and Pharmascience Inc
Date Commenced:	October 19, 2007
Court File No:	T-1836-07
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,296,633. Pharmascience alleges non-infringement. Pharmascience further asserts that the '633 patent is not properly listed on the Patent Register.

Medicine:	oxycodone (HCl) tablets (OXYCONTIN)
Applicant:	Purdue Pharma
Respondents:	The Minister of Health and Pharmascience Inc
Date Commenced:	October 19, 2007
Court File No:	T-1837-07
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,098,738. Pharmascience alleges non-infringement and invalidity and relies on allegations in Novopharm's NOA dated January 13, 2005. Pharmascience further asserts that the '738 patent is not properly listed on the Patent Register.

Other new proceedings

Medicine:	amlodipine besylate tablets (NORVASC)
Plaintiff:	ratiopharm Inc
Defendant:	Pfizer Limited
Date Commenced:	September 21, 2007
Court File No:	T-1712-07
Comment:	Action for a declaration of invalidity of Patent No. 1,321,393.

Medicine:	gemcitabine (HCl) (GEMZAR)
Plaintiffs:	Eli Lilly Canada Inc and Eli Lilly and Company
Defendant:	Hospira Healthcare Corporation
Date Commenced:	October 4, 2007
Court File No:	T-1773-07
Comment:	Patent infringement action relating to Patent No. 2,098,881.

Medicine:	venlafaxine (HCl) capsules (EFFEXOR XR)
Plaintiff:	ratiopharm Inc
Defendants:	Wyeth and Wyeth Canada
Date Commenced:	October 22, 2007
Court File No:	T-1844-07
Comment:	Action for damages pursuant to section 8 of the *Regulations*.

To check the status of Federal Court cases, please click here.

SMART & BIGGAR
FETHERSTONHAUGH

Barristers & Solicitors • Patent & Trade-mark Agents

OTTAWA
55 Metcalfe Street Suite 900
P.O. Box 2999 Station D
Ottawa ON K1P 5Y6
Canada
t. 613.232.2486
f. 613.232.8440
ottawa@smart-biggar.ca

TORONTO
Box 111 Suite 1500
438 University Avenue
Toronto ON M5G 2K8
Canada
t. 416.593.5514
f. 416.591.1690
toronto@smart-biggar.ca

MONTREAL
Suite 3300
1000 De La Gauchetière Street West
Montreal QC H3B 4W5
Canada
t. 514.954.1500
f. 514.954.1396
montreal@smart-biggar.ca

VANCOUVER
Box 11560 Vancouver Centre
2200-650 West Georgia Street
Vancouver BC V6B 4N8
Canada
t. 604.682.7780
f. 604.682.0274
vancouver@smart-biggar.ca

www.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. Lainson, 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.
Christian Bérubé, B.Sc. (Chem.), M.Sc. (Inorganic Chem.)
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.
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. (Mol. 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.
T. Nessim Abu-Zahra, B.Sc. (Life Sci.), M.Sc. (Pharmacol.), J.D.
Daniel M. Anthony, B.Sc. (Cell Bio. & Genetics), J.D.
Elizabeth A. Hayes, B.Sc. (Biochem.), M.Eng. (Biomed. Eng.)

Contact Information

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

Yoon Kang
ykang@smart-biggar.ca

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

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