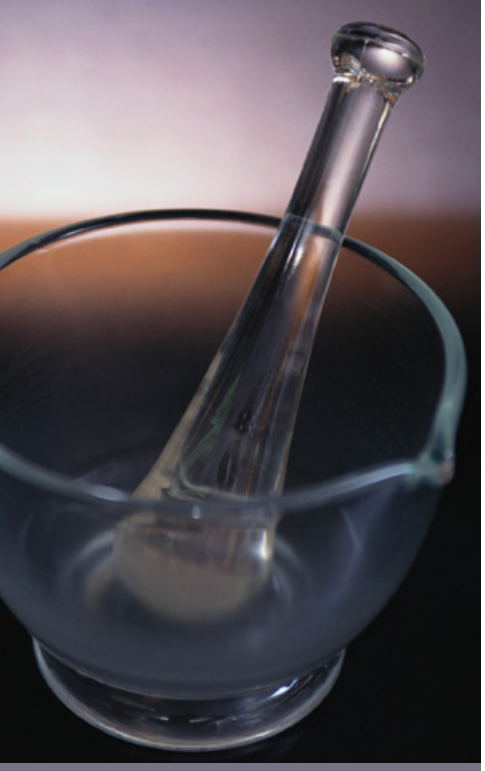

SMART & BIGGAR
FETHERSTONHAUGH
Barristers & Solicitors • Patent & Trade-mark Agents

Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

February 2009

Federal Court of Appeal considers Supreme Court obviousness test

On January 16, 2009, the Federal Court of Appeal considered for the first time the obviousness test set out by the Supreme Court of Canada in *Apotex v. Sanofi-Synthelabo* (2008 SCC 61). In *Apotex Inc v. Pfizer Canada Inc.*, the Court noted that the Supreme Court distinguished between "worth a try" and "obvious to try" tests and recognized the latter. The Court held that according to the "obvious to try" test, an invention is not made obvious because the prior art would have alerted the person skilled in the art to the possibility that something might be worth trying; the invention must be more or less self-evident. The Court found that the Applications Judge did not fail to apply the "obvious to try" test and upheld his decision that Apotex had failed to establish that the patent at issue claiming the oral use of **sildenafil** (Pfizer's **VIAGRA**) to treat erectile dysfunction was obvious. Specifically, the Court noted that the Applications Judge drew the line precisely where the Supreme Court drew it in *Sanofi-Synthelabo* when it held that "the mere possibility that something might turn up is not enough." The Court found that the Applications Judge correctly rejected the contention that the invention was obvious based on mere possibilities or speculation and looked for evidence that the invention was more or less self-evident. (*Apotex Inc v. Pfizer Canada Inc.*, January 16, 2009.
Full judgment – 2009 FCA 8.
Applications Judge's decision – 2007 FC 971.)

CIPO releases revised Biotechnology chapter of MOPOP

The Canadian Intellectual Property Office (CIPO) released the revised version of Chapter 17 of the Manual of Patent Office Practice (MOPOP), on the subject of biotechnology, with an in-effect date of January 14, 2009. Although the subject of Chapter 17 is biotechnology, CIPO has stated that "[t]he revised chapter will be of interest to practitioners from all disciplines." The MOPOP provides CIPO's examination practice arising from the Office's interpretation of the *Patent Act*, *Patent Rules* and jurisprudence. (News Release. MOPOP.)

Patented Medicine Prices Review Board news

New NEWSletter released. The Patented Medicine Prices Review Board (PMPRB) has released the January 2009 NEWSletter. In this issue, the Board indicates that it is looking to release a new version of the draft Revised Excessive Price Guidelines for final Notice and Comment in March, and that following review and consideration of stakeholder feedback, the final text is planned for release around the end of May, with implementation expected on July 1, 2009. With reference to its August 2008 Communiqué on the plans to enforce mandatory reporting by patentees of all benefits, the Board notes that as two judicial review applications are scheduled for June 16 and 17, mandatory reporting of benefits will be suspended until January 1, 2010. (NEWSletter. August 2008 Communiqué.)

STRATTERA hearing postponed. The PMPRB hearing to determine whether Eli Lilly is selling or has sold **STRATTERA (atomoxetine hydrochloride)** in any market in Canada at a price that is or was excessive has been postponed to February 11, 2009. (Update.)

Appeals of first section 8 decision will be heard in April 2009

As reported in the January 2009 issue of *Rx IP Update*, Merck and Apotex both appealed the Federal Court's decision finding Merck liable for Apotex's damages (lost profits) pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*"). The two separate appeals have been consolidated and have been set down for a hearing on April 21 and 22, 2009.
(Federal Court judgment – 2008 FC 1185.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Lundbeck's judicial review applications relating to EBIXA struck. Lundbeck was issued a notice of compliance with conditions (NOC/c) for **memantine (EBIXA)** in 2004. The Minister accepted abbreviated new drug submissions (ANDSs) by ratiopharm and Cobalt in 2007 and 2008 respectively that used EBIXA as their Canadian Reference Product (CRP). Lundbeck sought to quash this decision and to prohibit issuance of an NOC (or NOC/c) to the generics until EBIXA was issued a full NOC. Lundbeck also sought a declaration that EBIXA was an "innovative drug" under the amended data protection provision and an Order prohibiting the Minister from accepting an ANDS identifying EBIXA as a CRP until six years after issuance of an NOC. The Motions Judge struck Lundbeck's judicial review applications on three grounds: (1) lack of standing (as the matters related to the Minister's administration of the *Food and Drug Regulations*); (2) that the applications were premature (as NOCs had not issued to the generics); and (3) Lundbeck's applications are bereft of any chance of success. With respect to the last ground, the Judge rejected Lundbeck's argument that an NOC/c is not an NOC for all purposes of the *Food and Drugs Act*. The Judge also rejected Lundbeck's argument that the new data protection provision applied as the NOC issued before June 17, 2006 (the cut-off in the transitional provision). Lundbeck has appealed. (*Lundbeck Canada Inc. v. Canada (Health)*, December 16, 2008. Full judgment – 2008 FC 1379.)

Federal Court of Appeal declines to set aside prohibition orders against Apotex. Apotex appealed from a decision of the Motions Judge dismissing its motions to set aside two prohibition Orders (granted in 2002 and 2005) on the basis of a third Order in a subsequent prohibition proceeding relating to a different patent. Apotex argued that the previous Orders should be set aside because they cannot stand with certain conclusions reached by the Judge in the third case. The Judge rejected Apotex's argument that the Court could re-open the prohibition Orders relating to AstraZeneca's **LOSEC** (**omeprazole** and **omeprazole magnesium**) on the basis of continuing jurisdiction if there are changed circumstances. The Judge also rejected Apotex's argument that the determinations in the subsequent proceeding constituted new "matter" such that the Court should set aside

or vary the earlier judgments. The Federal Court of Appeal dismissed Apotex's appeal, finding:

> [28] Justice Hughes declined to exercise his discretion to set aside the orders in Case 1 or Case 2 because he understood that Apotex was attempting to reverse the effects of its unsuccessful litigation strategies in Case 1 and Case 2 by arguing that those cases might have been decided differently if Apotex had conducted itself differently. In these circumstances, I find no error of law or any other basis upon which this Court should intervene in the decision of Justice Hughes to dismiss the motions.

(*Apotex Inc. v. AB Hassle*, December 22, 2008. Court of Appeal decision – 2008 FCA 416. Motions Judge's Decision – 2008 FC 184.)

Federal Court releases second decision considering "dosage form" eligibility. GlaxoSmithKline sought judicial review of the Minister's decision that a patent was not eligible for listing against **ADVAIR (salmeterol xinafoate/fluticasone propionate)** and FLOVENT HFA (fluticasone propionate). The Judge held that the decision to list involves a three-step determination:

1. What does the '517 Patent claim?
2. What is the approved dosage form?
3. Do the claims of the '517 Patent correspond to the approved dosage form?

Regarding the first question, the Judge agreed with the Minister that the patent at issue "contains claims directed towards an aluminum can with coated internal surfaces in the form of a metered dose inhaler."

On the second question, the Judge held that the question to be addressed is: "What is the content of the underlying NOCs?" The Minister held that "The approved dosage form as indicated on the notices of compliance issued for the above-noted submissions [for ADVAIR and FLOVENT HFA] that support the listing of a patent ... is not for a device, namely a 'metered dose inhaler' as specified in Claim 1 of the 517 patent, but for an aerosol for metered dose inhalation." The Judge, reviewing the drug submissions and the product monographs, agreed that the approved dosage form is an inhalation aerosol.

The Judge concluded that the patent is directed to a device, that being a metered-dose inhaler (MDI) with the properties described in the claims of the patent, and the approved dosage form is an inhalation aerosol. The Judge concluded that as there was no correspondence, the requirements for listing were not met, and the application was therefore dismissed.
(*GlaxoSmithKline Inc. v. Canada (Attorney General)*, December 29, 2008.
Full judgment – 2008 FC 1415.)

Motion to strike claim against the Crown for damages dismissed. Apotex had brought a section 8 claim against AstraZeneca Canada for damages and/or profits arising from alleged delayed market entry of its omeprazole capsule product. In its counterclaim, AstraZeneca sought contribution and indemnity and damages from the Crown on the basis that the Minister of Health was negligent in requiring an allegation from Apotex. A Prothonotary had dismissed the Crown's motion to strike. A Judge has dismissed the Crown's appeal, finding that the Crown has not established that the Prothonotary's decision was clearly wrong.
(Applications Judge's decision – 2009 FC 120. Prothonotary's decision.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	irbesartan/hydrochlorothiazide (AVALIDE)
Applicant:	sanofi-aventis Canada Inc
Respondents:	ratiopharm Inc and The Minister of Health
Respondent/Patentee:	sanofi-aventis
Date Commenced:	November 27, 2008
Court File No:	T-1857-08
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 2,057,913 and 2,177,772. ratiopharm alleges non-infringement and invalidity with respect to the '772 patent and accepts that an NOC will not issue until expiry of the '913 patent.

Medicine:	rosuvastatin calcium tablets (CRESTOR)
Applicants:	AstraZeneca Canada Inc, AstraZeneca AB and Shionogi Seiyaku Kabushiki Kaisha
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	December 22, 2008
Court File No:	T-1972-08
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 2,072,945 and 2,313,783. Apotex alleges non-infringement and invalidity.

Medicine:	methylphenidate hydrochloride extended release tablets (CONCERTA)
Applicants:	Janssen-Ortho Inc and Alza Corporation
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	December 23, 2008
Court File No:	T-1983-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,264,852. Apotex alleges non-infringement, invalidity and ineligibility.

Medicine:	risedronate sodium/calcium tablets (ACTONEL PLUS CALCIUM)
Applicants:	Procter & Gamble Pharmaceuticals Canada Inc and The Procter & Gamble Company
Respondents:	Minister of Health and Cobalt Pharmaceuticals Inc
Date Commenced:	December 23, 2008
Court File No:	T-1988-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,399,976. Cobalt alleges non-infringement and invalidity.

Medicine:	sildenafil citrate (VIAGRA)
Applicants:	Pfizer Canada Inc and Pfizer Ireland Pharmaceuticals
Respondents:	Sandoz Canada Inc and The Minister of Health
Date Commenced:	December 24, 2008
Court File No:	T-1989-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,163,446. Sandoz alleges non-infringement, invalidity and ineligibility.

Other new proceedings

Medicine:	valcyclovir hydrochloride (VALTREX, APO-VALCYCLOVIR)
Plaintiff:	Apotex Inc
Defendant:	GlaxoSmithKline Inc
Date Commenced:	January 6, 2009
Court File No:	T-14-09
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
PO 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.
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.
James Jun Pan, B.Eng. (Eng.Phys.), Ph.D. (Chem.), 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
Elizabeth A. Hayes, B.Sc. (Biochem.), M.Eng. (Biomed. Eng.)
Urszula Wojtyra, B.Sc. (Applied Biochem.), M.Sc. (Biochem.) 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.
Mark G. Biernacki, B.A.Sc. (Mech. Eng.), LL.B.
Jeremy E. Want, B.Sc. (Chem.), LL.B.
Daphne C. Lainson, B.Sc., M.Sc. (Chem.), LL.B.
May Ming Wu, B.Sc.Phm., LL.B.
Christian Bérubé, B.Sc. (Chem.), M.Sc. (Inorganic Chem.)
Daniel M. Anthony, B.Sc. (Cell Bio. & Genetics), J.D.
Andrew Mandlsohn, B.Sc. (Pharm.), J.D.
David J. Suchon, B.Sc. (Biochem.), LL.B.

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

Disclaimer