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

Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

March 2009

Federal courts uphold two further patent listing decisions of the Minister of Health

Two further patent listing decisions relating to listing patents against supplementary new drug submissions (SNDSs) have recently issued.

In the first, *Solvay Pharma Inc. v. Canada (Attorney General)*, 2009 FC 102, the Federal Court agreed with the two bases for the Minister's rejection of a proposed listing. First, the SNDS was for an update to the product monograph regarding safety of long-term usage and therefore was not a submission for a change in use of the medicinal ingredient (testosterone). The Federal Court agreed with the Minister's decision that the SNDS was not for a change in use, holding that the change in use is measured by the approved use in the Indications and Clinical Use Section of the product monograph; this section was unchanged by the SNDS. Second, the Minister had decided that even if the SNDS was understood to be related to a change in use, the patent at issue did not contain a claim for the changed use in the SNDS. The Federal Court agreed with the Minister that the patent at issue did not address the issue of the duration of the testosterone therapy. (*Solvay Pharma v. Minister of Health*, January 20, 2009. Full judgment – 2009 FC 102.)

The second decision related to the relevance requirement as between an SNDS for a change in use and a formulation patent that includes claims for the use of the formulation. As reported in the May 2008 edition of *Rx IP Update*, in *G.D. Searle and Pfizer v. Minister of Health*, the Court considered whether "claim for the use of the medicinal ingredient" under the amended *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") includes a claim for the use of a formulation containing the medicinal ingredient. The Court concluded that such a claim could fall within the definition, but to make that determination, the jurisprudence under the pre-amended *Regulations* considering "whether it is in fact the use of the medicinal ingredient that is claimed, or simply the use of the formulation or dosage form" must be applied. Analyzing the issue, the Court agreed with the Minister that the claims were not for the use of **celecoxib** (Pfizer's **CELEBREX**) and were therefore not

claims for the use of the medicinal ingredient. As a result, the Court found that the patent was ineligible for listing against an SNDS for a new indication. On appeal, the Court did not point to the Federal Court's finding that the patent did not include claims for the use of the medicinal ingredient but instead upheld the Minister's decision on the basis that, following the decision in *Abbott Laboratories Ltd. v. Canada (Attorney General)*, 2008 FCA 244, the patent did not claim the **very use** that was approved by the SNDS against which the patent was sought to be listed: the claimed use ("for pain") was found to be too general for listing against an SNDS for the short-term management of moderate to severe acute pain in adults in conditions such as musculoskeletal and/or soft-tissue trauma, including sprains, post-operative orthopedic and pain following dental extraction. (*G.D. Searle and Pfizer v. Minister of Health*, February 9, 2009. Court of Appeal decision – 2009 FCA 35. Applications Judge's decision – 2008 FC 437.)

Patented Medicine Prices Review Board news

The Board has approved a Voluntary Compliance Undertaking (VCU) for Eli Lilly's **STRATTERA**. (Update.)

The Board has also approved a VCU for Bristol-Myers Squibb's **VEPESID**. (Update.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Court of Appeal dismisses CGPA's motion to intervene in Novopharm's appeal challenging 2008 amendments relating to pre-October 2006 relevance requirement. As reported in the December 2008 issue of *Rx IP Update*, the Federal Court dismissed Novopharm's motion for a declaration that the 2008 amendments relating to the pre-October 2006 relevance requirement are *ultra vires* (*Eli Lilly Canada Inc. v. Novopharm Limited*, 2008 FC 1221). The Motions Judge held that the requested declaration is not available on a summary dismissal motion, and Novopharm appealed. The Court of Appeal dismissed the Canadian Generic Pharmaceutical Association ("CGPA")'s motion for leave to intervene, as it was not persuaded that the interests of justice would be advanced by granting leave. The Court of Appeal found that even if it agreed that the Federal Court has and should have exercised jurisdiction to make the declaration, it is unlikely that the Court would proceed to determine the validity of the impugned provisions in the appeal. (*Novopharm v. Eli Lilly and Minister of Health*, January 29, 2009. Full judgment – 2009 FCA 24.)

Court finds Apotex's allegation of invalidity relating to cefepime dihydrochloride monohydrate (BMS's MAXIPIME) justified; considers pre-disclaimer claims only. The Court dismissed BMS's application for an Order prohibiting the Minister from issuing an NOC to Apotex for its generic version of BMS's **MAXIPIME**. Apotex was successful in its allegation of invalidity on the grounds of obviousness and double patenting. The day before the notice of application was filed, the patentee filed a disclaimer directed to two claims of the patent at issue. Justice Hughes held that because the disclaimer was filed after service of the notice of allegation (NOA) and before the commencement of the proceeding, Apotex cannot amend the NOA to raise new grounds of invalidity nor allege non-infringement of the reformulated claims. Hence, the Court held that for this particular proceeding, the claims were to be construed as of the date the NOA was served. Justice Hughes also gave little weight to testing conducted by Apotex, as Apotex had conducted the tests months before serving its NOA and only hinted at the results in its NOA. Furthermore, the results were controversial and inconclusive. (*BMS v. Apotex*, February 10, 2009. Full judgment – 2009 FC 137.)

Other decisions

GSK permitted to amend pleading in AZT reference. In the AZT reference to quantify the damages sustained by the Wellcome Foundation Limited and Glaxo Wellcome ("GSK") as a result of the infringement by Apotex and Novopharm of a patent claiming the use of AZT for the treatment and prophylaxis of HIV, the Prothonotary granted GSK leave to file a Further Fresh as Amended Statement of Issues. GSK's amendments consist of (i) an allegation that GSK would have increased the price of **RETROVIR (zidovudine)** but for the infringement and (ii) a claim against Novopharm for a reasonable royalty on export sales. Apotex has appealed. (*Apotex and Novopharm v. Wellcome Foundation*, February 3, 2009. Full judgment – 2009 FC 117.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	orally disintegrating olanzapine tablets (ZYPREXA ZYDIS)
Applicant:	Eli Lilly Canada Inc
Respondents:	Cobalt Pharmaceuticals Inc and The Minister of Health
Respondent/Patentee:	Eli Lilly and Company Limited
Date Commenced:	January 15, 2009
Court File No:	T-73-09
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 2,041,113, 2,214,005 and 2,265,712. Cobalt alleges invalidity with respect to all three patents, non-infringement ('005 and '712 patents) and ineligibility ('712 patent).

Medicine:	irbesartan (AVAPRO)
Applicant:	sanofi-aventis Canada Inc
Respondents:	Cobalt Pharmaceuticals Inc and The Minister of Health
Respondent/Patentee:	sanofi-aventis
Date Commenced:	January 19, 2009
Court File No:	T-84-09
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 2,057,913 and 2,177,772. Cobalt alleges non-infringement and invalidity ('772 patent) and accepts that an NOC will not issue until expiry of the '913 patent.

Medicine:	escitalopram (CIPRALEX)
Applicant:	Lundbeck Canada Inc
Respondents:	The Minister of Health and Sandoz Canada Inc
Respondent/Patentee:	H. Lundbeck A/S
Date Commenced:	January 26, 2009
Court File No:	T-122-09
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,339,452. Sandoz alleges non-infringement, invalidity and ineligibility.

Medicine:	olanzapine tablets (ZYPREXA)
Applicant:	Eli Lilly Canada Inc
Respondents:	Sandoz Canada Inc and The Minister of Health
Respondent/Patentee:	Eli Lilly and Company Limited
Date Commenced:	January 30, 2009
Court File No:	T-147-09
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,214,005. Sandoz alleges non-infringement, invalidity and ineligibility.

Medicine:	olanzapine tablets (ZYPREXA)
Applicant:	Eli Lilly Canada Inc
Respondents:	Sandoz Canada Inc and The Minister of Health
Respondent/Patentee:	Eli Lilly and Company Limited
Date Commenced:	January 30, 2009
Court File No:	T-148-09
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,041,113. Sandoz alleges non-infringement and invalidity.

Medicine:	oxycodone hydrochloride tablets (OXYCONTIN)
Applicant:	Purdue Pharma
Respondents:	Sandoz Canada Inc and The Minister of Health
Date Commenced:	February 5, 2009
Court File No:	T-169-09
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,098,738. Sandoz alleges non-infringement, invalidity and ineligibility.

Medicine:	dorzolamide hydrochloride ophthalmic solutions (TRUSOPT)
Applicants:	Merck & Co, Inc and Merck Frosst Canada Ltd
Respondents:	The Minister of Health and Sandoz Canada Inc
Date Commenced:	February 5, 2009
Court File No:	T-170-09
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,329,211. Sandoz alleges non-infringement and invalidity.

Medicine:	dorzolamide hydrochloride/timolol maleate ophthalmic solutions (COSOPT)
Applicants:	Merck & Co, Inc and Merck Frosst Canada Ltd
Respondents:	The Minister of Health and Sandoz Canada Inc
Date Commenced:	February 5, 2009
Court File No:	T-171-09
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,329,211. Sandoz alleges non-infringement, invalidity and ineligibility.

Medicine:	dorzolamide hydrochloride/timolol maleate ophthalmic solution (COSOPT)
Applicants:	Merck & Co, Inc and Merck Frosst Canada Ltd
Respondents:	The Minister of Health and Sandoz Canada Inc
Date Commenced:	February 5, 2009
Court File No:	T-172-09
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,065,965. Sandoz alleges non-infringement and invalidity.

Medicine:	galantamine hydrobromide extended release capsules (REMINYL ER)
Applicants:	Janssen-Ortho Inc and Janssen Pharmaceutica NV
Respondents:	Genpharm ULC and The Minister of Health
Date Commenced:	February 6, 2009
Court File No:	T-175-09
Comment:	Application for an Order of prohibition until the expiry of Patent No. 2,310,950. Genpharm alleges non-infringement, invalidity and ineligibility.

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