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

Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

April 2010

Health Canada releases finalized guidance document on SEBs

Health Canada has released the finalized Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs). The document is meant to provide guidance to sponsors to enable them to satisfy the requirements under the *Food and Drugs Act* and *Regulations*. Updated Guidance Documents pertaining to data protection and the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") that reflect the finalized SEB Guidance were released on the same date. The guidance will be effective on the date of publication, March 5, 2010. (Health Canada news release. Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs). Updates to Guidance Document: Data Protection. Updates to Guidance Document: *Patented Medicines (Notice of Compliance) Regulations*.)

Merck liable to Apotex for damages regarding norfloxacin under amended section 8

On March 12, 2010, the Federal Court issued its third decision on the merits pursuant to section 8 of the *Regulations*: *Apotex v. Merck Frosst Canada & Co.*, 2010 FC 287. Justice O'Reilly allowed Apotex's action for damages pursuant to section 8 of the March 1998 version of the *Regulations* for the period from June 10, 1994 to July 9, 1998; determination of the quantum of damages was bifurcated.

The first issue for determination was whether the 1993 or the 1998 version of section 8 applied. The 1998 version applied to an "application pending" on March 12, 1998. An Order of prohibition had been granted and upheld on appeal prior to March 12, 1998; however, that Order was set aside by the Supreme Court on July 9, 1998. The Court held that Merck's application was "pending" on the relevant date "in the sense that its legal foundation was very much a live issue before the Supreme Court of Canada when the 1998 *Regulations* came into effect." The Court did

not interpret the 1998 *Regulations* as interfering with Merck's vested rights.

The second issue was whether, if Merck had not sought an Order prohibiting Apotex from obtaining an NOC, Apotex would have been able to get onto the market and, if so, when. The Court held that Apotex must show, on a balance of probabilities, that it was prevented from getting onto the norfloxacin market because of Merck's prohibition application and that, in the circumstances, Apotex must show at a minimum that it had access to a supply of norfloxacin. The Court considered whether Apotex could have entered the market with material obtained from Novopharm under Novopharm's compulsory licence with Merck; Apotex and Merck had entered into a supply agreement in 1992 that was alleged to entitle Apotex to purchase bulk norfloxacin from Novopharm. The Court held that Apotex was not in a position to enter the market in June 1993 (the apparent approvable date) as Apotex did not have a willing supplier and Apotex did not have a willing partner in Novopharm and concluded that it would have taken Apotex up to a year to establish an arrangement with Novopharm.

Merck may appeal as of right to the Federal Court of Appeal.

Health Canada news

Regulatory amendments proposed for Extraordinary Use New Drugs. The current practice of using the Special Access Programme to authorize sale of Extraordinary Use New Drugs (EUNDs) for broad distribution has been determined to be inappropriate by the Office of the Auditor General of Canada. Possible EUNDs include military medical countermeasures and pandemic influenza vaccines. On April 3, 2010, proposed regulatory amendments were published to create a new type of new drug submission (NDS) in Division 8, Part C of the *Food and Drug Regulations for EUNDs: Regulations Amending the Food and Drug Regulations (1319 — New Drugs for Extraordinary Use)* (HTML/PDF.) The proposed regulations detail the criteria that a new drug would have to meet before a manufacturer can file an EUND submission and submission requirements. The regulations would allow manufacturers to use results of animal studies, in conjunction with results from limited human safety studies, in support of their drug submission. Existing regulations that apply to other drugs, including data protection and protection under the *Patented Medicines (Notice of Compliance) Regulations*, would apply to EUNDs. The deadline for representations on the proposal is June 17, 2010.

2008 statistical report for *Regulations* and data protection released

The Therapeutic Products Directorate has released its 2008 statistical report relating to the administration of the *Regulations* and data protection. The report provides a number of statistics relating to the maintenance of the Patent Register (including the number of patent lists filed by first persons, the number of patent lists accepted and rejected, and related litigation) and statistics relating to the number of notices of allegation (NOAs) served, the resulting initiation of prohibition applications and outcomes of the applications. The report also provides statistics on products added to the Register of Innovative Drugs, broken down according to product type. (Therapeutic Products Directorate Statistical Report 2008, *Patented Medicines (Notice of Compliance) Regulations* and Data Protection.)

Patented Medicine Prices Review Board news

Board orders repayment of excess revenue from sale of PENTACEL and QUADRACEL. As reported in the February 2010 issue of *Rx IP Update*, on December 21, 2009, the Board found that sanofi pasteur's **QUADRACEL** and **PENTACEL** medicines were priced excessively, and it ordered sanofi pasteur to reduce the price at which it sells the medicines by the excess amount during the term of its contract with the Government of Canada. On March 16, 2010, the Board ordered sanofi pasteur to repay the excess revenues resulting from the sale of PENTACEL and QUADRACEL. (Order.)

Notice of hearing in the matter of Sandoz Canada Inc. (status as patentee). The Board announced that it will hold a hearing, on a date to be set by the Board, to receive evidence and argument regarding Sandoz's status as a patentee within the meaning of the *Patent Act* and to file all statutory information required of a patentee pursuant to the *Patent Act* and *Regulations*. Applications for leave to intervene must be submitted to the Board on or before April 6, 2010. (Notice.)

Supreme Court of Canada news

Leave to appeal denied in *Apotex Inc. and Apotex Pharmachem Inc. v. ADIR and Servier Canada Inc.* (COVERSYL). As reported in the July 2009 issue of *Rx IP Update*, the Federal Court of Appeal dismissed Apotex's appeal from the Trial Judge's decision that Apotex had infringed the patent covering **perinodopril** (Servier's **COVERSYL**) and that the patent was valid. The Supreme Court denied Apotex leave to appeal on March 25, 2010.
(Supreme Court summary – 33357.
Court of Appeal decision – 2009 FCA 222.
Trial Judge's decision – 2008 FC 825.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

sanofi-aventis denied Order of prohibition against ratiopharm concerning irbesartan. The Federal Court dismissed sanofi-aventis's application for an Order of prohibition against ratiopharm regarding a formulation patent relating to **irbesartan** (sanofi-aventis's **AVAPRO**). The Court concluded that ratiopharm's allegations of non-infringement and lack of sound prediction (obviousness or alternatively anticipation regarding claim 36 only) were justified. (*sanofi-aventis Canada Inc. v. ratiopharm Inc.*, March 5, 2010.
Full judgment – 2010 FC 230.)

Other decisions

Colour mark applied to ADVAIR DISKUS inhaler struck as non-distinctive. In a decision released March 12, 2010, the Federal Court struck GSK's registration consisting of dark and light purple applied to its **ADVAIR DISKUS** inhaler from the Register of Trade-marks. The Court first found that the applicants, generic pharmaceutical companies, were interested parties and entitled to bring the proceeding. The Court then went on to decide the issue of distinctiveness, stating that although colour and shape can help to distinguish products of one manufacturer from another and can be a powerful influence on consumer behavior, distinctiveness requires that physicians, pharmacists and patients relate the trade-mark to a single source and use the mark in prescribing, dispensing and purchasing choices. Regarding the GSK inhaler, the Court found that the colour and shape are not the primary characteristic by which GSK distinguishes its product from the wares of its competitors or, more significantly, by which its purchasers make their choices. The Court also found that the evidence was insufficient to support GSK's contention that a substantial body of patients would make an

association between the appearance of the GSK mark and a single source and did not find that any physicians or pharmacists would draw such an association in the exercise of their professional judgment. GSK has appealed. (*Apotex Inc. v. Registrar of Trademarks*, March 12, 2010. Full judgment – 2010 FC 291.)

Novopharm's motion for Mareva injunction or posting of security denied. The Federal Court dismissed Novopharm's motion for an Order in the nature of a Mareva injunction enjoining Lilly Canada from transferring revenues to its parent company (Lilly U.S.) or, in the alternative, an Order requiring Lilly Canada to post security for liability under section 8 of the *Regulations* and requiring Lilly Canada to disclose financial information to Novopharm on a quarterly basis. The Court found that it was not a certainty that Novopharm would be awarded damages pursuant to section 8 of the *Regulations* regarding **olanzapine** (Lilly's **ZYPREXA**) and that the injunction would therefore not be post-judgment as asserted by Novopharm. The Court also found, among other things, that Novopharm did not establish any amount as the likely award it would receive, that Novopharm ought to have provided an undertaking as to damages, that Novopharm failed to prove irreparable harm, and that Novopharm failed to show that there is a real risk that Lilly Canada is removing or is about to remove its assets from Canada to avoid the possibility of a judgment or that it is otherwise dissipating or disposing of its assets in a manner clearly distinct from its usual or ordinary course of business so as to render the possibility of future tracing of the assets remote or impossible. (*Eli Lilly Canada Inc. v. Novopharm Limited*, March 2, 2010. Full judgment – 2010 FC 241.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	mycophenolate mofetil (CELLCEPT)
Applicant:	Hoffmann-La Roche Limited
Respondents:	Novopharm Limited and The Minister of Health
Respondent/Patentee:	Roche Palo Alto LLC
Date Commenced:	February 1, 2010
Court File No.:	T-137-10
Comment:	Application for Order of prohibition until expiry of Patent No. 1,333,285. Novopharm alleges non-infringement and invalidity.

Medicine:	repaglinide (GLUCONORM)
Applicant:	Novo Nordisk Canada Inc
Respondents:	Sandoz Canada Inc, the Minister of Health and Dr. Karl Thomae GmbH
Date Commenced:	February 18, 2010
Court File No.:	T-232-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,111,851. Sandoz alleges non-infringement, invalidity and improper listing.

Medicine:	repaglinide (GLUCONORM)
Applicant:	Novo Nordisk Canada Inc
Respondents:	Apotex Inc, the Minister of Health and Dr Karl Thomae GmbH
Date Commenced:	March 5, 2010
Court File No.:	T-307-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,111,851. Apotex alleges non-infringement and invalidity.

Medicine:	mycophenolate sodium (MYFORTIC)
Applicant:	Novartis Pharmaceuticals Canada Inc
Respondents:	Apotex Inc and the Minister of Health
Respondent/Patentee:	Novartis AG
Date Commenced:	March 5, 2010
Court File No.:	T-317-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,250,906. Apotex alleges non-infringement, invalidity and improper listing.

Medicine:	telmisartan (MICARDIS)
Applicants:	Boehringer Ingelheim (Canada) Ltd and Dr Karl Thomae GmbH
Respondents:	Sandoz Canada Inc and The Minister of Health
Date Commenced:	March 18, 2010
Court File No.:	T-399-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,060,624. Sandoz alleges non-infringement, invalidity and ineligibility.

Other proceedings

Medicine:	lansoprazole (PREVACID)
Plaintiff:	Apotex Inc
Defendants:	Abbott Laboratories, Limited, Takeda Pharmaceuticals America, Inc, and Takeda Pharmaceuticals Company Limited
Date Commenced:	November 25, 2009
Court File No.:	CV-09-391938
Comment:	Ontario Superior Court action for section 8 damages and/or disgorgement of the defendants' revenues, or alternatively profits. Apotex also asserts breach of contract.

Medicine:	methylphenidate (CONCERTA, Novo-Methylphenidate ER-C)
Plaintiff:	Janssen-Ortho Inc
Defendants:	Attorney General of Canada, the Minister of Health and Novopharm Limited
Date Commenced:	February 19, 2010
Court File No.:	T-240-10
Comment:	Application for a declaration that the declaration of equivalence between a new drug and the Canadian reference drug referred to in a notice of compliance issued pursuant to s. C.08.002.1 does not constitute a declaration of therapeutic or clinical equivalence in those cases where release from the dosage form or the profile in plasma is a significant factor in therapeutic or clinical effect.

Medicine:	oxycodone hydrochloride/naloxone hydrochloride (TARGIN)
Plaintiff:	Purdue Pharma
Defendants:	Attorney General of Canada and the Minister of Health
Date Commenced:	February 22, 2010
Court File No.:	T-248-10
Comment:	Application for a declaration that Patent No. 2,098,738 is eligible for listing on the Patent Register in respect of TARGIN.

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

smart-biggar.ca

Pharmaceutical Practice Group

John R. Morrissey, B.Eng. (Elec.Eng.), S.M., LL.B.
Joy D. Morrow, B.Sc., M.Sc. (Cell Bio.), LL.B.
Keltie R. Sim, B.Sc. (Mycology), 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.
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.
Vik Tenekjian, B.Sc. (Microbio./Immun.), J.D.
Ivan C. Fong, B.Sc. (Microbio./Immunology), Ph.D. (Mol. Bio.), LL.B.
Urszula Wojtyra, B.Sc. (Applied Biochem.), M.Sc. (Biochem.), J.D.
John Bochnovic, B.Eng. (Elec.Eng.), S.M., LL.B.
Gunars A. Gaikis, B.Sc.Phm., LL.B.
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.
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.
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.
Timothy O. Stevenson, B.Sc. (Biochem.), LL.B.
Elizabeth A. Hayes, B.Sc. (Biochem.), M.Eng. (Biomed. Eng.)
David J. Suchon, B.Sc. (Biochem.), LL.B.
Tracey L. Stott, B.Sc. (Chem.), Ph.D. (Chem.), 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