



Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

July 2008

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Regulations Amending the Patented Medicines (Notice of Compliance) Regulations published in Canada Gazette

As reported in the [June 2008 Special Edition](#) of *Rx IP Update*, the *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations* were registered and came into force on June 12, 2008. The *Regulations* were

published in Part II of the Canada Gazette on June 25, 2008. (*Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/2008-211 ([official version](#)))

Statistical Report for *Regulations* and Data Protection released

The Therapeutic Products Directorate has released a statistical report relating to the administration of the *Patented Medicines (Notice of Compliance) Regulations* ("*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 number of prohibition applications initiated per drug, and information on judicial review applications challenging the requirement to address patents. The report also provides statistics on products added to the Register of Innovative Drugs, broken down according to product type. As of June 26, 2008, fifty-one products have been added to the Register of Innovative Drugs and are therefore subject to data protection. (Therapeutic Products Directorate [Statistical Report 2007: Patented Medicines \(Notice of Compliance\) Regulations](#) and Data Protection.)

Patented Medicine Prices Review Board tables annual report

On June 18, 2008, the PMPRB tabled its 2007 Annual Report before Parliament. The report includes statistics, including that the sales of patented drugs in Canada increased by 3.0% to \$12,300,000,000 in 2007 and that the R&D expenditures reported by patentees in 2007 was \$1,325,000,000, an increase of 9.5% over

2006. The Board also reports that it approved nine Voluntary Compliance Undertakings (including one in May 2008), completed six hearings and issued two Notices of Hearing in 2007 and one at the beginning of 2008. ([Annual Report 2007.](#))

Competition Bureau publishes findings regarding acquisition of Organon Biosciences by Schering-Plough

On November 16, 2007, the Competition Bureau announced that it would not challenge Schering-Plough Corporation's acquisition of Organon BioSciences N.V. from Akzo Nobel N.V. On May 30, 2008, the Competition Bureau published a technical backgrounder summarizing its main findings of its review of this acquisition. The Competition Bureau

concluded that the proposed transaction was unlikely to result in a substantial lessening or prevention of competition in any relevant market, including the human health and animal health markets. (Acquisition of Organon BioSciences N.V. by Schering-Plough Corporation Technical Backgrounder ([Report](#)). [News Release.](#))

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Pharmascience precluded from alleging new invalidity grounds in view of its earlier unsuccessful validity challenge. On June 12, 2008, the Court of Appeal dismissed Pharmascience's appeal from an Order of the Applications Judge finding that Pharmascience was estopped from alleging new invalidity grounds regarding a patent relating to ramipril (sanofi-aventis's ALTACE), as Pharmascience's initial allegation of invalidity was finally determined in a previous proceeding. (*Pharmascience v. sanofi-aventis*, June 12, 2008, reasons – [2008 FCA 213](#), aff'g [2007 FC 1057](#).)

Subsequently, on June 20, 2008, the Applications Judge issued an Order prohibiting the Minister from issuing a notice of compliance (NOC) to Pharmascience until the expiry of the patent, given the earlier estoppel ruling. (*sanofi-aventis v. Pharmascience*, June 20, 2008, reasons – [2008 FC 782](#).)

Court grants Order of prohibition against Apotex regarding levofloxacin (LEVAQUIN). The Court granted Janssen-Ortho a prohibition Order against Apotex regarding the patent claiming levofloxacin (LEVAQUIN). The Judge

found that Apotex's allegations of non-infringement and invalidity were not justified. Apotex had alleged invalidity on the grounds of anticipation, obviousness, claims broader than the invention made, lack of sound prediction, and that the patent was void as the applicant's agent failed to provide complete particulars of the prior art cited in the corresponding United States and European Patent Office applications, resulting in abandonment of the application, and that by so doing the applicant breached its duty of candour with the Commissioner of Patents. The Judge held that while the current *Patent Act* obligates an applicant to reply in good faith to every requisition made by an examiner, the old *Act* (by which the patent is governed) merely requires an applicant to make a *bona fide* attempt to advance a patent application to allowance as a whole. The Judge also held that while a duty of candour and good faith exists during the prosecution of patent applications in the United States Patent Office, a similar duty apart from what the statute and rules require does not exist in Canada. In reaching his conclusions on all the issues, the

Judge considered a previous Federal Court decision in a patent infringement action regarding the same patent and medicine at issue (*Novopharm v. Janssen-Ortho and Daiichi Pharmaceutical*, [2007 FCA 217](#), aff'g [2006 FC 1234](#)), wherein the patent had been found valid and infringed. The Judge found that no better evidence or more appropriate legal argument had been submitted in the present proceeding and therefore concluded that it was an abuse of process for Apotex to commence the proceeding. (*Janssen-Ortho v. Apotex*, June 17, 2008, reasons – [2008 FC 744](#).)

Patent ineligible for listing under old Regulations for being irrelevant to the dosage form of the product. The Court dismissed an application from Abbott seeking judicial review of the Minister's decision that a patent submitted under the old *Regulations* was ineligible for listing on the Patent Register. The patent contains claims for an orally rapidly disintegrating solid preparation and Abbott sought to list the patent against lansoprazole (PREVACID) delayed-release capsules. The Minister concluded that as the capsules are not rapidly disintegrable in the oral cavity, the patent is not relevant to the dosage form of the PREVACID products. As noted in the article on page 1, the *Regulations* were amended on June 12, 2008, and as a result the Minister can no longer refuse to list a patent submitted under the old *Regulations* solely on the basis

that the patent is not relevant to the submission for an NOC to which the patent list relates. It remains to be seen whether this provision will be interpreted to extend to findings as those before the Court in this case. (*Abbott v. Canada (Attorney General)*, June 11, 2008, reasons – [2008 FC 730](#).)

Challenge of same allegation of invalidity against second generic found to be an abuse of process. A Judge dismissed Pfizer's appeal from an Order of a Prothonotary summarily dismissing Pfizer's application against Novopharm regarding a patent pertaining to sildenafil citrate (Pfizer's VIAGRA) in view of a previous decision, *Pfizer v. Apotex* ([2007 FCA 195](#), aff'g [2007 FC 26](#)). In the previous case, Pfizer's application against Apotex was dismissed as Pfizer failed to prove that Apotex's allegation of invalidity of the same patent was not justified. In this case, it was not contested that Novopharm's NOA contained all of the allegations of invalidity that were contained in Apotex's successful NOA. The Court rejected Pfizer's argument that the circumstances were distinguishable from those in *sanofi-aventis v. Novopharm*, [2007 FCA 163](#), as no evidence had been filed in the first case on the point at issue as Pfizer had not appreciated the need for that evidence. Pfizer has appealed. (*Pfizer v. Novopharm*, May 29, 2008, reasons – [2008 FC 674](#).)

Other decisions

Licensee may claim equitable relief in patent infringement action. In a patent infringement action relation to ramipril (sanofi-aventis's ALTACE), a Judge dismissed Apotex's appeal from an Order of a Prothonotary, finding that sanofi-aventis, a licensee of the patent in issue, can claim equitable relief, namely an injunction,

delivery-up Order and an accounting of profits and also a declaration of infringement. The Judge found that the recent decision of the Court of Appeal, *Apotex Inc. v. sanofi-aventis*, [2008 FCA 175](#), supported the decision of the Prothonotary. (*sanofi-aventis v. Apotex*, May 21, 2008, reasons – [2008 FC 628](#).)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	irbesartan tablets (AVAPRO)
Applicant:	sanofi-aventis Canada Inc
Respondents:	ratiopharm Inc and The Minister of Health
Respondent/Patentee:	sanofi-aventis
Date Commenced:	March 7, 2008
Court File No:	T-370-08
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 in respect of the '772 patent. ratiopharm accepts that its NOC will not issue until the expiry of the '913 patent on March 20, 2011.
Medicine:	memantine hydrochloride tablets (EBIXA)
Applicants:	Lundbeck Canada Inc, H. Lundbeck A/S and Merz Pharma GmbH & Co. KGaA
Respondents:	ratiopharm Inc and The Minister of Health
Date Commenced:	March 13, 2008
Court File No:	T-414-08
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 2,014,453 and 2,426,492. ratiopharm alleges non-infringement, invalidity and improper listing.
Medicine:	risedronate sodium tablets (ACTONEL)
Applicants:	Procter & Gamble Pharmaceuticals Canada Inc and The Procter & Gamble Company
Respondents:	Minister of Health and ratiopharm Inc
Date Commenced:	May 23, 2008
Court File No:	T-818-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,320,727. ratiopharm alleges abuse of process in light of T-1053-06, improper listing and invalidity.
Medicine:	amlodipine tablets (NORVASC)
Applicants:	Pfizer Canada Inc, Pfizer Limited and Pfizer Research and Development Company, NV/SA
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	June 4, 2008
Court File No:	T-876-08
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 1,321,393 and 2,170,278. Apotex alleges non-infringement and invalidity and, for the '278 patent only, improper listing.

Medicine: amlodipine tablets (NORVASC)
Applicants: Pfizer Canada Inc, Pfizer Limited and Pfizer Research and Development Company, NV/SA
Respondents: Apotex Inc and The Minister of Health
Date Commenced: June 5, 2008
Court File No: T-886-08
Comment: Application for an Order of prohibition until expiry of Patents Nos. 1,321,393 and 2,170,278. Apotex alleges non-infringement and invalidity and, for the '278 patent only, improper listing.

Medicine: omeprazole delayed release tablets (LOSEC)
Applicants: AstraZeneca Canada Inc, AstraZeneca AB, Aktiebolaget Hässle and Takeda Pharmaceutical Company Limited
Respondents: Apotex Inc and The Minister of Health
Date Commenced: June 13, 2008
Court File No: T-951-08
Comment: Application for an Order of prohibition until expiry of Patents Nos. 1,338,377, 2,166,483, 2,166,794, 1,292,693, 1,302,891 and 2,186,037. Apotex alleges non-infringement with respect to all the patents and further alleges invalidity with respect to the '891 and '037 patents.

Medicine: sildenafil citrate tablets (REVATIO)
Applicants: Pfizer Canada Inc and Pfizer Inc
Respondents: ratiopharm Inc and The Minister of Health
Date Commenced: June 16, 2008
Court File No: T-955-08
Comment: Application for an Order of prohibition until expiry of Patent No. 2,324,324. ratiopharm alleges non-infringement, invalidity and ineligibility for listing.

Medicine: olanzapine tablets (ZYPREXA)
Applicant: Eli Lilly Canada Inc
Respondents: Nu-Pharm Inc and The Minister of Health
Respondent/Patentee: Eli Lilly and Company Limited
Date Commenced: June 20, 2008
Court File No: T-986-08
Comment: Application for an Order of prohibition until expiry of Patent No. 2,216,372. Nu-Pharm alleges non-infringement.

Medicine: olanzapine tablets (ZYPREXA)
Applicant: Eli Lilly Canada Inc
Respondents: Nu-Pharm Inc and The Minister of Health
Respondent/Patentee: Eli Lilly and Company Limited
Date Commenced: June 20, 2008
Court File No: T-987-08
Comment: Application for an Order of prohibition until expiry of Patent No. 2,041,113. Nu-Pharm alleges invalidity.

Medicine: olanzapine tablets (ZYPREXA)
Applicant: Eli Lilly Canada Inc
Respondents: Nu-Pharm Inc and The Minister of Health
Respondent/Patentee: Eli Lilly and Company Limited
Date Commenced: June 20, 2008
Court File No: T-988-08
Comment: Application for an Order of prohibition until expiry of Patent No. 2,214,005. Nu-Pharm alleges non-infringement.

Medicine: olanzapine tablets (ZYPREXA)
Applicant: Eli Lilly Canada Inc
Respondents: Genpharm ULC and The Minister of Health
Respondent/Patentee: Eli Lilly and Company Limited
Date Commenced: June 20, 2008
Court File No: T-989-08
Comment: Application for an Order of prohibition until expiry of Patents Nos. 2,041,113, 2,214,005, and 2,216,372. Genpharm alleges non-infringement of all three patents, invalidity in respect of the '113 and '005 patents and improper listing of the '005 and '372 patents.

Medicine: pantoprazole sodium (PANTO IV)
Applicants: Nycomed Canada Inc and Nycomed GmbH
Respondents: Pharmaceutical Partners of Canada Inc and The Minister of Health
Date Commenced: June 24, 2008
Court File No: T-1007-08
Comment: Application for an Order of prohibition until expiry of Patent No. 2,428,870. PPC alleges non-infringement and that it is not required to address the patent.

Other new proceedings

Medicine: mixed salts amphetamines (ADDERALL XR)
Applicant: Shire Biochem Inc, now known as Shire Canada Inc
Respondent: Patented Medicine Prices Review Board and Attorney General of Canada
Date Commenced: May 12, 2008
Court File No: T-749-08
Comment: Application for judicial review of the Board's decision, in which the Board concluded that ADDERALL XR was not a substantial improvement over existing medications in the same therapeutic class and that the Board had jurisdiction to determine the appropriate pricing for ADDERALL XR while the product was sold under the Special Access Program.

Plaintiff: Novopharm Limited
Defendant: Company "X"
Date Commenced: May 22, 2008
Court File No: T-811-08
Comment: Pleadings marked confidential and sealed.

Medicine: magnesium citrate (PICO-SALAX)
Plaintiffs: Ferring BV and Ferring Inc
Defendant: Odan Laboratories Ltd
Date Commenced: June 2, 2008
Court File No: T-866-08
Comment: Trade-mark and copyright infringement action relating to Odan's use of the mark PICODAN in light of Ferring's registered trade-mark TMA 648,368 for PICO-SALAX and Odan's use of certain marketing materials in light of Ferring's registered copyright in five works used in connection with the marketing and sale of their PICO-SALAX product.

Medicine: glatiramer (COPAXONE)
Applicant: Teva Neuroscience GP-SENC
Respondent: Attorney General of Canada
Date Commenced: June 11, 2008
Court File No: T-939-08
Comment: Application for judicial review of the Board's decision ordering Teva to pay \$2,417,223.29 subsequent to an earlier decision in which the Board held that Teva had sold COPAXONE at an excessive price.

Device: mechanical auto-injector of epinephrine (TWINJECT)
Applicant: Paladin Labs Inc
Respondent: The Minister of Health
Date Commenced: June 20, 2008
Court File No: T-980-08
Comment: An order quashing the decision of the Minister to publish an article in the Canadian Adverse Reaction Newsletter entitled, "Twinject auto-injector and device malfunctions."

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 Hiram, 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.
T. Nessim Abu-Zahra, B.Sc. (Life Sci.), M.Sc. (Pharmacol.), J.D.
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.

A. David Morrow, B.Sc. (Physics), LL.B.
John Bochnovic, B.Eng. (Elec.Eng.), S.M., LL.B.
Gunars A. Gaikis, B.Sc.Pharm., 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.Pharm., 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.Pharm., 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.
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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