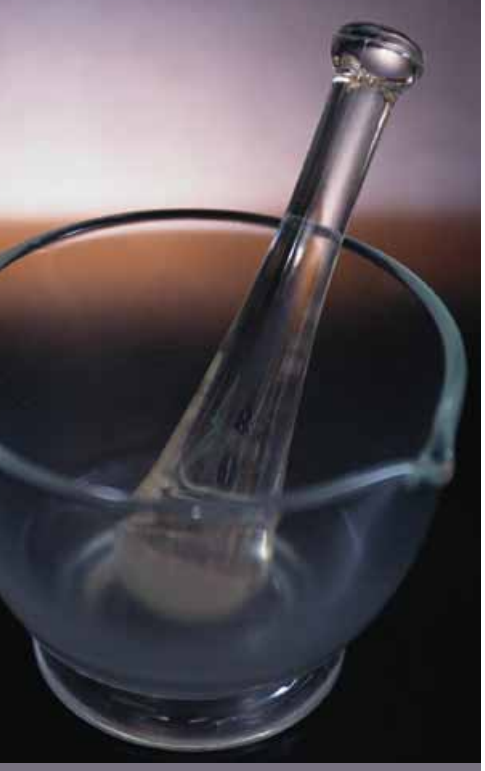

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Data protection upheld as valid

As reported in the January 2009 edition of *Rx IP Update*, Apotex's and the Canadian Generic Pharmaceutical Association (CGPA)'s applications for judicial review challenging the validity of the data protection provisions of the *Food and Drug Regulations* (section C.08.004.1) ("*Data Protection Regulation*") and *Food and Drugs Act* (section 30(3)) were heard by Justice Mandamin of the Federal Court in December 2008. Canada's Research-Based Pharmaceutical Companies (Rx&D) and Eli Lilly intervened. On July 17, 2009, the Court dismissed the applications, finding the data protection provisions valid.

Section 30(3) of the *Food and Drugs Act* permits the Governor in Council to make such regulations as it deems necessary for the purpose of implementing, in relation to drugs, Article 1711 of NAFTA or paragraph 3 of Article 39 of TRIPS. The data protection provision of the *Food and Drug Regulations* as amended on October 5, 2006 was described in the October 2006 Special Edition of *Rx IP Update*.

The Court held that:

(1) the *Data Protection Regulation* is *intra vires* the federal legislative powers pursuant to section 91(2) of the *Constitution Act, 1867*;

(2) section 30(3) of the *Act* and the *Data Protection Regulation* are *intra vires* the federal legislature powers as being enacted pursuant to NAFTA and TRIPS;

(3) the *Data Protection Regulation* is valid:

  (a) as rationally connected to the grant of authority in section 30(3) of the *Act*, and

  (b) because the enabling provision, section 30(3), is a "permissible sub-delegation by Parliament to the Governor in Council since the delegated regulatory power is constrained by the limitations in the NAFTA and TRIPS agreements."

Apotex and the CGPA may appeal as of right. (*Apotex Inc. v. Eli Lilly Canada Inc.*, July 17, 2009. Full judgment – 2009 FC 725.)

Supreme Court of Canada news

Merck Frosst Canada Ltd., et al. v. Benny Mignacca, et al. Merck Frosst has applied for leave to appeal a decision of the Ontario Court of Appeal denying Merck an extension of the time to seek leave to appeal an Order of the Superior Court of Justice. That Order denied Merck leave to appeal to the Divisional Court from an Order granting certification of the class proceeding relating to the drug **Vioxx**. (Court of Appeal decision – 2009 ONCA 393. Superior Court of Justice decision – 2008 CanLII 61238.)

Patented Medicine Prices Review Board news

PMPRB tables 2008 annual report. On July 22, 2009, the Minister of Health tabled the PMPRB's Annual Report 2008 before Parliament. The report contains compliance and enforcement statistics, including that 1,260 patented drug products for human use were under the PMPRB's jurisdiction in 2008 and that the Board approved nine Voluntary Compliance Undertakings (up to and including April 2009), completed four hearings and issued five new Notices of Hearing (including one in 2009). The Board also reports that the sales of patented drug products in Canada increased by 5% to $13 billion in 2008 and that the R&D expenditures reported by patentees were $1.3 billion in 2008, a decline of 1.1% over 2007. (Annual Report 2008.)

Federal Court finds PMPRB cannot require patentees to report payments to third parties. In two separate applications that were heard and decided together, patentees sought judicial review of the PMPRB's decision (as communicated in an August 2008 Stakeholder Communiqué) requiring patentees to report, among other things, rebates or payments to third parties (for example, provincial governments) for inclusion in the calculation of the average price for sales of patented medicines. The Court set aside the PMPRB's decision, concluding that the provisions at issue of the *Patented Medicines Regulations* do not authorize the Board to require the reporting of rebates or payments made to third parties by the manufacturers of patented medicines. The Court held that patentees did not "sell" patented medicines to the provinces and provinces are not "customers" of the patentees. The Court also held that this interpretation is consistent with the constitutional limitation on the PMPRB's ability to look beyond the factory-gate price of patented medicines and to consider contractual arrangements involving patentees and entities further down the distribution chain. (*Pfizer Canada Inc. v. Attorney General pf Canada*; *Canada's Research-Based Pharmaceutical Companies et al. v. Attorney General of Canada*, July 10, 2009. Full judgment – 2009 FC 719.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Abbott partially successful in its application for an Order of prohibition against Sandoz regarding BIAXIN. Abbott sought an Order prohibiting the Minister of Health ("Minister") from issuing a notice of compliance ("NOC") to Sandoz for a generic version of **clarithromycin extended release tablets** (Abbott's **BIAXIN XL**) until expiry of two patents. The Court granted an Order of prohibition regarding one of the patents (which claims an extended-release formulation of clarithromycin), finding that Sandoz's invalidity allegation on the ground of obviousness was not justified. The Court denied an Order of prohibition for the second patent (which also claims an extended-release formulation of clarithromycin with an improved taste profile) on the basis of double patenting. After the commencement of the proceeding, Abbott submitted to the Patent Office a notice of dedication regarding one of the patents that Sandoz relied on for its double-patenting attack. The Court rejected Abbott's argument that the effect of the notice of dedication was as if the patent had never been issued. (*Abbott Laboratories v. Sandoz Canada Inc.*, July 7, 2009. Full judgment – 2009 FC 648.)

Apotex's claim for unjust enrichment in section 8 action struck. Apotex commenced an action for damages pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") in relation to alleged delayed market entry for its **raloxifene** product (Eli Lilly's product is **EVISTA**). Eli Lilly sought an Order striking out paragraphs from Apotex's statement of claim seeking disgorgement of Eli Lilly's excess revenues on the basis of unjust enrichment. The Prothonotary applied the Federal Court ruling in *Apotex Inc. v. Merck & Co. Inc.*, 2008 FC 1185, aff'd 2009 FCA 187, that a generic's remedies under section 8 do not include disgorgement of a patentee's profits. Further, the Prothonotary rejected Apotex's argument based on an independent claim for unjust enrichment outside the scope of section 8 on the basis that such a claim would be outside the jurisdiction of the Federal Court. She found it was therefore plain and obvious that any claim made by Apotex seeking disgorgement of Eli Lilly's profits or excess revenues could not succeed and must therefore be struck. She also denied Eli Lilly's motion for a stay pending leave to appeal the dismissal of its application for a prohibition Order to the Supreme Court of Canada, citing any prejudice to Eli Lilly as "manageable and remote" as weighed against the prejudice caused to Apotex and the interest of justice in ensuring actions proceed expeditiously and without delay, particularly in the context of the recent policy initiatives of the Federal Court. Apotex has appealed. (*Apotex Inc. v. Eli Lilly Canada Inc.*, July 3, 2009. Full judgment – 2009 FC 693).

FCA dismisses Apotex's appeal of Order of prohibition for amlodipine tablets. The Federal Court of Appeal dismissed Apotex's appeal of an Order of prohibition regarding **amlodipine** (Pfizer's **NORVASC**). The Court reasoned that Apotex was effectively asking for a reconsideration of its decision in *Pfizer Canada Inc. v. ratiopharm Inc.*, 2006 FCA 214 ("*ratiopharm*") in light of the Supreme Court of Canada's decision in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 ("*Sanofi*"). The Court held that Apotex had failed to show that the *ratiopharm* decision was decided on a wrong principle and expressly held that the "principles enunciated by this Court in *ratiopharm* are consistent with the law of selection patents, including the approaches to anticipation and obviousness, as stated by the Supreme Court in *Sanofi*." (*Apotex Inc. v. Pfizer Canada Inc.*, June 24, 2009. Full judgment – 2009 FCA 216.)

Minister must perform patent-specific analysis of Apotex's SANDS seeking new indication. Apotex sought an Order requiring the Minister to process Apotex's supplementary abbreviated new drug submission ("SANDS") seeking to change the product monograph for its **Apo-Omeprazole** capsules to add an indication for the use of the capsules in combination with antibiotics for the eradication of *H. pylori*. Apotex successfully addressed two patents relating to this additional indication in connection with its SANDS. The Minister refused to issue the NOC on the basis that Apotex had not met the requirements of the *Regulations* because the remaining listed patents were not addressed, as required, in the Minister's opinion, under section 5(2) of the *Regulations*. Apotex argued that the requirements of the *Regulations* had been satisfied because it had previously addressed the remaining patents in connection with its ANDS and the subject matter of the patents is not the same as the subject matter of its SANDS. The Court held that in light of *Pharmascience Inc. v. Canada (Minister of Health)*, 2009 FCA 183, the Minister was required to perform a patent-specific analysis and remitted the matter back to the Minister to perform such analysis. (*Apotex Inc. v. Canada (Minister of Health)*, July 15, 2009. Full judgment – 2009 FC 721.)

Other decisions

Apotex and Novopharm succeed in defending ramipril infringement actions. On June 29, 2009, Justice Snider released judgments, following a 37-day trial, in the infringement actions against Apotex and Novopharm regarding a patent covering **ramipril** (sanofi-aventis's **ALTACE**). While Justice Snider rejected validity attacks on the grounds of obviousness double patenting, insufficiency, Gillette defence and first inventorship, she found the relevant claims invalid for lack of sound prediction and, in the alternative, as obvious. (*sanofi-aventis Canada Inc. v. Apotex Inc.*, June 29, 2009. Full judgment – 2009 FC 676.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	rosuvastatin (CRESTOR)
Applicants:	AstraZeneca Canada Inc, AstraZeneca AB and Shionogi Seiyaku Kabushiki Kaisha
Respondents:	Sandoz Canada Inc and The Minister of Health
Date Commenced:	July 2, 2009
Court File No.:	T-1074-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,072,945 and 2,313,783. Sandoz alleges invalidity with respect to both patents and non-infringement with respect to the '783 Patent.

Medicine:	donezepil hydrochloride (ARICEPT)
Applicants:	Pfizer Canada Inc and Eisai Co, Ltd
Respondents:	Genpharm ULC, Mylan Pharmaceuticals ULC and The Minister of Health
Date Commenced:	July 10, 2009
Court File No.:	T-1118-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 1,338,808 and 2,252,806. Genpharm alleges non-infringement, invalidity and ineligibility.

Medicine:	irbesartan/hydrochlorothiazide (AVALIDE)
Applicant:	sanofi-aventis Canada Inc
Respondents:	Sandoz Canada Inc and The Minister of Health
Date Commenced:	July 15, 2009
Court File No.:	T-1141-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,057,913 and 2,177,772. Sandoz alleges non-infringement, invalidity and ineligibility with respect to the '772 Patent and accepts that its NOC will not issue until the expiry of the '913 Patent.

Medicine:	mycophenolate mofetil (CELLCEPT)
Applicant:	Hoffmann-La Roche Limited
Respondents:	Apotex Inc and The Minister of Health
Respondent/Patentee:	Roche Palo Alto LLC
Date Commenced:	July 17, 2009
Court File No.:	T-1165-09
Comment:	Application for Order of prohibition until expiry of Patent No. 1,333,285. Apotex alleges non-infringement and invalidity.

Other proceedings

Trade-mark:	CLARITIN
Plaintiffs:	Schering-Plough Ltd and Schering-Plough Canada Inc
Defendant:	McMahon Distributor Pharmaceutique Inc c.o.b. as Brunet Pharmacies
Date Commenced:	June 29, 2009
Court File No.:	T-1056-09
Comment:	Trade-mark infringement and passing-off action.

Medicine:	Apo-Lansoprazole
Plaintiff:	Apotex Inc
Defendants:	Abbott Laboratories, Limited, Takeda Pharmaceuticals America, Inc and Takeda Pharmaceuticals Company Limited
Date Commenced:	June 29, 2009
Court File No.:	T-1058-09
Comment:	Action for damages pursuant to section 8 of the *Regulations*.

Trade-marks:	PFIZER, PFIZER & Design, PFIZER LABS and VIAGRA & Diamond Design
Plaintiffs:	Pfizer Canada Inc and Pfizer Products Inc
Defendant:	Vyser Inc
Date Commenced:	June 30, 2009
Court File No.:	T-1060-09
Comment:	Trade-mark infringement and passing-off action relating to Vyser's use of VYSER.

Medicine:	amlodipine besylate (NORVASC)
Plaintiff:	Apotex Inc
Defendant:	Pfizer Limited
Date Commenced:	June 30, 2009
Court File No.:	T-1072-09
Comment:	Action seeking declaration of invalidity and non-infringement of Patent No. 1,321,393.

Plaintiff:	Novartis AG
Defendant:	Research Corporation
Date Commenced:	July 21, 2009
Court File No.:	T-1180-09
Comment:	Action seeking issuance of a patent or patents in respect of conflict claims. The conflict proceedings related to Applications Nos. 486,372, 616,701, 617,041 and 495,255.

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 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.
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.
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.
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.
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

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