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

Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

July 2010

Court of Appeal affirms dismissal of section 8 action against Roche

As reported in the June 2009 issue of *Rx IP Update*, in May 2009, the Federal Court found that Roche was not liable to Apotex for damages under section 8 of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") in relation to **naproxen** sustained release tablets (Roche's **NAPROSYN SR**). In July, the Court of Appeal affirmed the Trial Judge's decision. This was the first Court of Appeal decision to interpret the original 1993 version of section 8 of the *Regulations* and the transitional provision of the 1998 amendments.

In March 1996, the Federal Court granted a prohibition Order preventing the Minister of Health from issuing a notice of compliance (NOC) to Apotex for naproxen sustained release tablets. The Court found that Apotex's allegation of non-infringement was not justified, and the Order was upheld on appeal. In 1999, following trial, the patent at issue was declared invalid, and the Apotex formulation of naproxen slow release tablet was held to be non-infringing. On motion, the prohibition Order was set aside, and the prior application under the NOC application was dismissed. Apotex's NOC issued shortly afterward.

Apotex's action for damages pursuant to section 8 (as amended in 1998) — or, in the alternative, pursuant to pre-amended section 8 — was dismissed. The Court of Appeal agreed with the Trial Judge's holding that, under the circumstances, the 1993 version (rather than the 1998 version) of section 8 was applicable: the transitional provisions in the 1998 amendments provide that the 1998 version of section 8 applies to applications "pending" as of March 11, 1998 (when the amendments came into force), and the word "pending" was interpreted to refer to legal proceedings in which there is no final judgment; the fact that a judgment is later varied or set aside does not mean that it was not "final" or pending as of March 11, 1998.

Interpreting the 1993 version of section 8, which provides for liability when "the Minister delays issuing a notice of compliance beyond expiration of all patents that are the subject of an order pursuant to subsection 6(1)," the Court of Appeal held that "section 8 was not intended to provide redress where the innovator prevailed in the prohibition proceeding, even if the generic was later successful in patent litigation." The Court of

Appeal therefore agreed that Apotex cannot "reach back and apply the finding of invalidity in the action so as to argue that the patent had 'expired' within the meaning of section 8" of the 1993 version of the *Regulations*. The Court of Appeal therefore upheld the Trial Judge's finding that the requirements of pre-amended section 8 were not met. (*Apotex Inc. v. Syntex Pharmaceuticals International Inc.*, June 10, 2010. Court of Appeal decision – 2010 FCA 155. Trial Judge's decision – 2009 FC 494.)

Patented Medicine Prices Review Board news

PMPRB tables 2009 annual report. On June 16, 2010, the Minister of Health tabled the PMPRB's Annual Report 2009 before Parliament. The report contains compliance and enforcement statistics, including that 1,177 patented drug products for human use were under the PMPRB's jurisdiction in 2009 and that the Board approved 17 Voluntary Compliance Undertakings (up to May 2010), completed five hearings and issued two new Notices of Hearing. The Board also reports that the sales of patented drug products in Canada increased by 2.8% to $13.3 billion in 2009 and that the R&D expenditures reported by patentees were $1.2 billion in 2008, a decline of 1.2% over 2008. (Annual Report 2009.)

VCU. The Board is proposing to approve a Voluntary Compliance Undertaking (VCU) for AstraZeneca's **FASLODEX (fulvestrant)**. (Notice.)

Amendments to Ontario prescription drug system in force

On June 7, 2010, the Ontario Ministry of Health and Long-Term Care announced that the provincial government is finalizing reforms that will lower generic drug prices. The measures, which started to take effect on July 1, 2010, and will be fully implemented by April 1, 2013, include lowering the price of most generic drugs to 25% of the corresponding innovator's drug (from the previous 50%) and eliminating "professional allowances." (Press release. Backgrounder. Fact sheet.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Pfizer denied Order of prohibition against ratiopharm regarding sildenafil citrate (REVATIO). On June 8, 2010, the Federal Court denied Pfizer's application for an Order of prohibition against ratiopharm regarding **sildenafil citrate** (Pfizer's **REVATIO**). The patent claims the use of sildenafil citrate for treating or preventing pulmonary hypertension. The Court found that Pfizer was entitled to the priority claim date asserted and that ratiopharm's allegation of lack of sound prediction was justified. The Court also found that the allegation of obviousness was justified, determining that the skilled person would consider that it was "obvious to try" sildenafil for the treatment of pulmonary hypertension and that the skilled person would have a "fair expectation of success." Finally, the Court found that the prior art would not have anticipated the patent. (*Pfizer Canada Inc. v. ratiopharm Inc.*, June 8, 2010. Full judgment – 2010 FC 612.)

Federal Court of Appeal upholds decision declining to dismiss successful prohibition applications in light of subsequent finding of invalidity. On June 8, 2010, the Federal Court of Appeal upheld a lower Court decision that, in light of a subsequent finding of invalidity, set aside the existing prohibition Orders but declined to dismiss the previous successful prohibition applications. The Federal Court of Appeal dismissed Pharmascience's appeal. Aventis's cross appeal on the setting

aside of the prohibition Orders was dismissed as moot. (*Pharmascience Inc. v. Aventis Pharma Inc.*, June 8, 2010. Full judgment – 2010 FCA 153.)

Applications judge recuses himself. On his own initiative, Justice Shore recused himself from determining an application. Justice Shore had granted an Order of prohibition against Apotex relating to Janssen-Ortho's **levofloxacin (LEVAQUIN)** in 2008. The Court of Appeal allowed Apotex's appeal and remitted back to Justice Shore for redetermination on the basis that there was no abuse of process on the part of Apotex in making the allegations found in its notice of allegation (NOA) and in contesting the application. The majority of the Court of Appeal had also made comments regarding adoption by the Judge of a substantial part of Janssen-Ortho's written submissions; however, the Court indicated that it was not prepared to conclude that the Judge did not perform his duty to examine the evidence. Justice Shore recused himself on the redetermination, finding that he could not sit on the matter without again reaching the same conclusion through the same reasons. (*Janssen-Ortho Inc. v. Apotex Inc.*, June 14, 2010. Reasons – 2010 FC 643. Court of Appeal decision – 2009 FCA 212. Initial Federal Court decision – 2008 FC 744.)

Genpharm successful in having allegations regarding its corporate and second person status struck. On June 22, 2010, the Federal Court granted Genpharm's motion to strike Pfizer's allegations that Genpharm was not a proper second person because it served its NOA in its pre-amalgamation name. The Court found that neither company entering into an amalgamation ceases to exist and that Genpharm therefore existed under its pre-amalgamation name at the time its NOA was served. Pfizer has appealed. (*Pfizer Canada Inc. v. Genpharm ULC*, June 22, 2010. Reasons – 2010 FC 684.)

Court of Appeal finds relevant date for assessing patent dedication is date of hearing. On June 22, 2010, the Federal Court of Appeal, having found no palpable and overriding error in the Judge's assessment of the obviousness allegation, dismissed Sandoz's appeal of a prohibition Order with respect to a patent related to **clarithromycin** extended release (Abbott's **BIAXIN XL**). However, the Court of Appeal did allow Abbott's cross-appeal and granted an Order of prohibition with respect to a separate patent. As reported in the August 2009 issue of *Rx IP Update*, the lower Court denied Abbott's request for an Order of prohibition finding Sandoz's allegations of invalidity justified on the basis of double patenting, despite Abbott's dedication of the earlier patent to the public after the service of the NOA. The Court of Appeal found that the Applications Judge erred by considering the status of the earlier patent as of the date that the NOA was issued rather than as of the date of the prohibition hearing. As a result, and as accepted by the Applications Judge, the dedication removed the evidentiary basis for the allegation of double patenting; the allegation was therefore found not justified. The Court of Appeal upheld the Applications Judge's conclusion that Sandoz failed to justify its allegation that this patent was obvious. (*Sandoz Canada Inc. v. Abbott Laboratories*, June 22, 2010. Court of Appeal decision – 2010 FCA 168. Applications Judge's decision – 2009 FC 648.)

AstraZeneca denied Order of prohibition against Apotex regarding esomeprazole magnesium (NEXIUM). On June 30, 2010, the Federal Court denied AstraZeneca's application for an Order of prohibition against Apotex regarding **esomeprazole magnesium (NEXIUM)**. The patent claim at issue claims a salt of esomeprazole having an optical purity of 99.8% or greater. The Court found that Apotex's allegations of sound prediction and obviousness were justified but that the allegation of anticipation was not justified. (*AstraZeneca Canada Inc. v. Apotex Inc.*, June 30, 2010. Full judgment – 2010 FC 714.)

Federal Court upholds denial of NOA designation as confidential. As reported in the May 2010 issue of *Rx IP Update*, the Federal Court denied Novopharm's motion to designate its NOA confidential in a proceeding regarding **pregabalin** (Pfizer's **LYRICA**). This decision was upheld on appeal. (*Pfizer Canada Inc. v. Novopharm Limited*, June 21, 2010. Motions Judge's decision – 2010 FC 668. Prothonotary's decision – 2010 FC 409.)

Other decisions

Federal Court refuses to strike pleadings alleging estoppel based on prior NOC proceedings. In an impeachment action by Apotex relating to **sildenafil citrate** (Pfizer's **VIAGRA**), Apotex moved to strike a portion of Pfizer's Statement of Defence, which pled that Apotex was estopped from contesting the validity of the patent at issue by reasons of *res judicata*, issue estoppel, collateral estoppel, comity and abuse of process. Pfizer asserted that the prior NOC proceedings between the parties on the same patent entitled it to raise the allegations. Apotex argued that NOC proceedings have no precedential effect and that Pfizer's pleading should therefore be struck. The Court acknowledged that NOC proceedings are summary proceedings but stated that this does not mean they are not extremely sophisticated and intensively litigated. In addition, the issues in NOC proceedings mirror the allegations in an impeachment or invalidity patent action. The Court found that although the doctrine of *res judicata* did not render the proceeding moot or previously decided, it will be relevant to those issues on which the evidence from the prior proceedings is identical to that in the present case as "parties ought not to be able to have endless "kicks at the can" and use up more and more judicial resources ... ." Apotex has appealed. (*Apotex Inc. v. Pfizer Ireland Pharmaceuticals*, June 11, 2010. Full judgment – 2010 FC 633.)

Federal Court of Appeal upholds lower Court decision dismissing judicial review of Minister's listing decision regarding formulation patent. The Court of Appeal upheld Bayer's appeal of an Applications Judge's decision to dismiss Bayer's application for judicial review of the Minister's decision not to list a patent with respect to Bayer's **YAZ**. The patent claims a formulation explicitly referring to one medicinal ingredient; YAZ is a combination product containing two medicinal ingredients. While there was no dispute that YAZ falls within the scope of the claims, the Minister found that the relevance requirement had not been met. (*Bayer Inc. v. Canada (Health)*, June 15, 2010. Court of Appeal decision – 2010 FCA 161. Applications Judge's decision – 2009 FC 1171.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	candesartan cilexetil hydrocholorothiazide (ATACAND PLUS)
Applicants:	AstraZeneca Canada Inc and Takeda Pharmaceutical Company Ltd
Respondents:	Cobalt Pharmaceuticals Inc and The Minister of Health
Date Commenced:	June 10, 2010
Court File No.:	T-908-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,083,305. Cobalt alleges non-infringement, invalidity and that the patent is improperly listed on the Patent Register.

Medicine:	candesartan cilexetil hydrocholorothiazide (ATACAND PLUS)
Applicants:	AstraZeneca Canada Inc and Takeda Pharmaceutical Company Ltd
Respondents:	Cobalt Pharmaceuticals Inc and The Minister of Health
Date Commenced:	June 10, 2010
Court File No.:	T-909-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,215,251. Cobalt alleges non-infringement and invalidity.

Medicine:	candesartan cilexetil hydrocholorothiazide (ATACAND PLUS)
Applicants:	AstraZeneca Canada Inc and Takeda Pharmaceutical Company Ltd
Respondents:	Pharmascience Inc and The Minister of Health
Date Commenced:	June 10, 2010
Court File No.:	T-949-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,083,305. Pharmascience alleges non-infringement.

Medicine:	fenofibrate (LIPIDIL EZ)
Applicants:	Fournier Pharma Inc and Laboratoires Fournier SA
Respondents:	The Minister of Health and Sandoz Canada Inc
Date Commenced:	June 24, 2010
Court File No.:	T-991-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,372,576. Sandoz alleges invalidity and non-infringement.

Medicine:	telmisartan (MICARDIS)
Applicants:	Boehringer Ingelheim (Canada) Ltd and Dr Karl Thomae GmbH
Respondents:	Mylan Pharmaceuticals ULC and The Minister of Health
Date Commenced:	June 24, 2010
Court File No.:	T-993-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,060,624. Mylan alleges invalidity and non-infringement.

Medicine:	telmisartan/hydrochlorothiazide (MICARDIS PLUS)
Applicants:	Boehringer Ingelheim (Canada) Ltd, Dr Karl Thomae GmbH and Boehringer Ingelheim Pharma GmbH & Co
Respondents:	Mylan Pharmaceuticals ULC and The Minister of Health
Date Commenced:	June 24, 2010
Court File No.:	T-994-10
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,060,624 and 2,472,392. Mylan alleges invalidity and non-infringement with respect to both patents.

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., J.D.
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