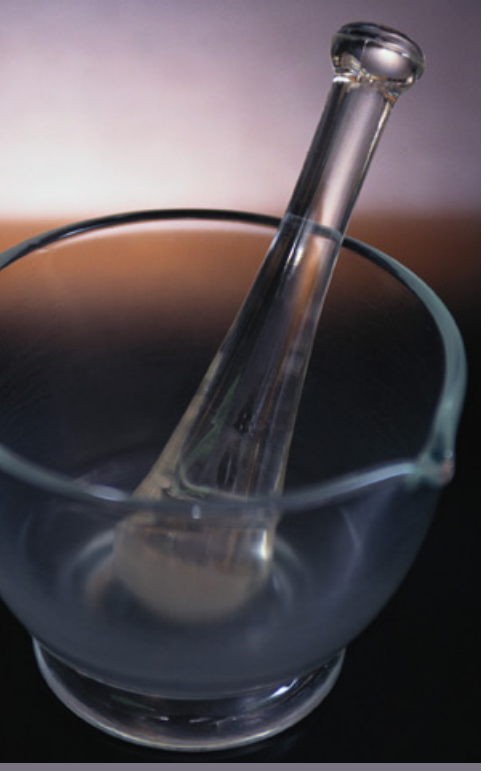

SMART & BIGGAR
FETHERSTONHAUGH
Barristers & Solicitors • Patent & Trade-mark Agents

# Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

**December 2008**



## Motion challenging 2008 amendments relating to pre–October 2006 "relevance" requirement dismissed

As reported in the June 2008 Special Edition of *Rx IP Update*, amendments made to the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") strictly limited the bases upon which patents submitted before June 17, 2006, may be delisted or refused to be listed. Those amendments were made in response to a 2007 Federal Court decision, upheld by the Federal Court of Appeal, finding that for patent lists submitted under the pre–2006 amended *Regulations*, "relevance" is required between a patent and the submission against which it is listed (*Wyeth Canada v. ratiopharm Inc.*, 2007 FC 340, rev'd 2007 FCA 264, leave denied).

Shortly before the amendments came into force, Novopharm brought a s. 6(5)(a) summary dismissal motion in a prohibition proceeding relating to orally disintegrating olanzapine tablets (Eli Lilly's **ZYPREXA ZYDIS**), submitting that the patent was ineligible for listing on the basis of the *Wyeth* test. However, because the motion was brought after April 26, 2008, the amendments precluded summary dismissal on the basis of ineligibility. Novopharm therefore submitted that s. 6(5)(a) should be applied as if the amendments had not been made and requested that the Court declare that sections 2, 3 and 4 of the amendments are *ultra vires* and of no force and effect on the basis that they are retroactive and/or not authorized by s. 55.2(4) of the *Patent Act*. Justice Martineau dismissed the motion (*Eli Lilly Canada Inc. v. Novopharm Limited*, 2008 FC 1221), holding that the requested declaration is not available on a summary dismissal motion. Justice Martineau held that, in any event, the Court had discretion to decline ruling upon the validity of the impugned regulatory provisions. He concluded, "considering the Court's limited jurisdiction and powers, the summary nature of this proceeding, the public interest, the complexity of the matters Novopharm wishes to raise preliminary [sic], the balance of convenience and the availability of another and better suited recourse [an application for judicial review], I am not satisfied that it is in the best interests of justice that a final ruling be made today by the Court with respect to Novopharm's motion to invalidate section 2, 3 and 4 of the *2008 Amending Regulations*. Accordingly, I decline to rule on their alleged illegality." Novopharm has appealed.

## Competition Bureau of Canada publishes report with recommendations for passing on the benefits of generic drug competition to end-payers

On November 25, 2008, the Competition Bureau published its report "Benefiting from Generic Drug Competition in Canada: The Way Forward." This is a follow-up to the Bureau's October 2007 report "Canadian Generic Drug Sector Study", which was reported in the November 2007 issue of *Rx IP Update*. The October 2007 study concluded that while there is strong competition for many generic drugs, the design of drug plans has not resulted in the benefits of this competition being passed along to Canadians in the form of lower prices. The current report is the second phase of work in the generic drug sector.

The report provides an update on the generic drug sector, in light of changes made by provincial governments to their public drug plans. It concludes that there is increasing use of competitive processes by plans to reduce generic drug prices.

The Report recommends strategies for cost savings of public plans, which account for 48% of drug expenditures in Canada. It concludes that obtaining the maximum benefits of competitive generic drug prices does not require the development of a national approach. Rather, the Bureau recommends putting the following four elements in place:

1. introducing measures for reimbursing pharmacies for the true competitive cost of their drugs,
2. reimbursing pharmacy services such as dispensing and patient counselling separately from drug costs,
3. removing unnecessary restrictions to pharmacy competition and
4. coordinating provincial generic pricing and reimbursement policies to ensure that they promote and sustain effective generic drug competition.

Further, the report examines ways for Canadians to obtain the full benefits of generic drug competition. The Bureau identified possible strategies for passing on competitive drug prices to private payers, such as businesses, employees and individuals. These strategies include developing preferred pharmacy networks, promoting greater use of mail-order pharmacies, and providing patients with incentives to seek lower prices. The Bureau estimated implementation of these recommendations would lead to savings of up to $600 million per year. (Backgrounder. Report.)

## European Pharmaceutical Sector Inquiry preliminary report released

The Pharmaceutical Sector Inquiry, under the European Commission competition rules, was launched in January 2008 with unannounced inspections in a number of pharmaceutical companies.

The purpose of the inquiry is described as follows:

> The inquiry is a response to indications that competition in Europe's pharmaceuticals markets may not be working well: fewer new medicines are being brought to market, and the entry of generic medicines sometimes seems to be delayed. The inquiry will therefore look at the reasons for this.
>
> In particular, the inquiry will examine whether agreements between pharmaceutical companies, such as settlements in patent disputes, have blocked or lead to delays in market entry. It will also look into whether companies may have created artificial barriers to entry (through the misuse of patent rights, vexatious litigation or other means). The sector inquiry does not aim to establish infringements of EC competition law by individual companies (Articles 81 and 82 EC).
>
> The inquiry's findings will, if necessary, allow the Commission or national competition authorities to focus any future action on the most serious competition concerns, and to identify remedies to resolve the specific competition problems in individual cases.

The Inquiry's preliminary report was released on November 28, 2008, along with an executive summary and fact sheets. (Report.)

# Patented Medicine Prices Review Board news

**Mandatory full reporting of benefits temporarily suspended.** The Board released a communiqué on November 25, 2008, indicating that the Board is temporarily suspending patentees' mandatory reporting of benefits for the reporting period of January 1 to June 30, 2009. The decision to suspend reporting was made in light of two separate Federal Court applications for judicial review of the Board's decision, released on August 18, 2008 (stakeholder communiqué), which required full mandatory reporting of benefits to start in January 2009. As reported in the October 2008 issue of *Rx IP Update*, the judicial review applications, launched by innovators, seek an order setting aside the Board's decision insofar as it directs patentees to report benefits granted to third parties. (Communiqué.)

**Submissions on draft Revised Excessive Price Guidelines posted.** As reported in the September 2008 issue of *Rx IP Update*, the PMPRB released a Notice and Comment package in respect of its Revised Excessive Price Guidelines on August 20, 2008. The deadline for submitting comments was October 6, 2008. The Board received a total of 44 submissions, which are now available on the PMPRB's website. (Submissions.)

**New NEWSletter released.** The PMPRB has released the October 2008 NEWSletter. (NEWSletter.)

**Decision released on preliminary motions in the matter of Apotex as a patentee under the jurisdiction of the PMPRB.** As reported in the April 2008 issue of *Rx IP Update*, the Board will be holding a hearing requiring Apotex to disclose certain information to determine its 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 the *Patented Medicines Regulations*. A decision on preliminary motions, heard on October 6, 2008, was released on October 27, 2008. The Panel granted the Board's request to add Apotex Pharmachem Inc. and Apotex Technologies Inc. as parties to the application on the basis that if the Board has jurisdiction in relation to medicines sold by Apotex, it should be Pharmachem or Technologies that are the patentees that should be required to report to the Board concerning those sales. The Panel denied Apotex's motion to consolidate the present application with the pricing hearing for Apo-Salvent, for which Apotex acknowledges being a patentee. (Decision.)

**ratiopharm in the PMPRB.** On October 27, 2008, the PMPRB Panel granted ratiopharm intervener status in the Apo-Salvent CFC Free matter on the issues of the interpretation of the *Patent Act* and the scope of the Board's jurisdiction as currently framed by the Board and Apotex. In granting ratiopharm's motion, the Panel made it clear that ratiopharm's participation was not to be duplicative of Apotex's participation, and was therefore required to coordinate with Apotex at each stage of the proceeding. Separately, the hearing relating to ratio-Salbutamol is scheduled for January 12, 2009. (Decision.)

# Supreme Court of Canada matters

***Nu-Pharm v. Canada.*** Nu-Pharm has sought leave to appeal the Court of Appeal's affirmation of the dismissal of its action for damages against the Crown. Nu-Pharm brought an action for damages against the Crown, alleging that it unlawfully advised provincial regulatory authorities, pharmacists, distributors, and public and private insurers that the sale of Nu-Enalapril is unlawful following the quashing of Nu-Pharm's NOC. The Motions Judge granted the Crown's motion for summary judgment and found that obtaining damages is entirely dependent upon Nu-Pharm's showing of the unlawful character of the government's decisions, which must be determined by way of judicial review. The Court of Appeal upheld the decision. (Court of Appeal reasons – 2008 FCA 227. Motions Judge's reasons – 2007 FC 977.)

***Abbott v. Attorney General of Canada.*** As reported in the August 2008 issue of *Rx IP Update*, the Court of Appeal imposed a strict matching requirement for listing a use patent against a supplemental new drug submission (SNDS) for a change in use. In doing so, the Court of Appeal affirmed that the Minister of Health properly delisted a patent listed against an SNDS relating to lansoprazole (PREVACID). Abbott has sought leave to appeal. (Court of Appeal reasons – 2008 FCA 244. Application Judge's reasons – 2007 FC 797.)

# Recent Court decisions

## *Patented Medicines (Notice of Compliance) Regulations*

**Court of Appeal affirms Minister's decision rejecting Abbott's patent listing for MERIDIA (sibutramine).** Abbott appealed an Applications Judge's dismissal of its application for judicial review of the Minister's decision that the patent at issue is not eligible for listing against MERIDIA, as the claimed use is not an approved use of MERIDIA. The claims were construed as claiming use of sibutramine for improving the glucose tolerance of humans, obese and otherwise, having pre-type 2 diabetes or type 2 diabetes, while the approved use is as adjunctive therapy within a weight management program for certain obese patients. The Court of Appeal rejected Abbott's argument that because claim 6 would necessarily be infringed by the use of sibutramine for improving the glucose tolerance of an obese person with pre-type 2 diabetes or type 2 diabetes, the patent should be listed against MERIDIA. The Court held that this is not the question to be determined under s. 4(2)(d), which instead is whether the claim is for a use of sibutramine that is an approved use of MERIDIA. The Court also stated that it did "not ignore" Abbott's argument that the patent is eligible if only one of the uses it claims is an approved use, noting that the Minister does not disagree with that proposition but found that the Minister reasonably concluded that MERIDIA is not approved for improving glucose tolerance in anyone. The Court also concluded that the record before the Federal Court should not include any documentary evidence not before the Minister. However, the Court has discretion to admit expert evidence on patent construction. (*Abbott Laboratories Limited v. Canada (Attorney General)*, November 17, 2008. Full judgment – 2008 FCA 354. Applications Judge's decision – 2008 FC 700.)

**Federal Court affirms refusal of the reversal of the order of filing evidence on validity.** As reported in the November 2008 issue of *Rx IP Update*, orders requiring the generic manufacturer to serve its evidence regarding validity first have been issued in a number of proceedings. In proceedings relating to esomeprazole (NEXIUM), the case management Prothonotary declined to order Apotex to provide its evidence first in those applications involving allegations of invalidity and AstraZeneca's appeal has recently been dismissed. (*AstraZeneca v. Apotex*. Motion Judge's decision – 2008 FC 1316. Prothonotary's decision – 2008 FC 537. )

## Other decisions

**Apotex denied leave to amend its statement of defence and counterclaim.** In a patent infringement action involving nefazodone (BMS's SERZONE), the Court dismissed Apotex's appeal of a Prothonotary's decision denying leave to amend its statement of defence and counterclaim to plead that the BMS plaintiffs are not entitled to damages based on the common law doctrine of *ex turpi causa*, and that Apotex is entitled to set off against damages the investments it made in developing a generic formulation of the plaintiffs' product. The Judge was not satisfied that Apotex's proposed amendments are in the interests of justice and that they can be made without injustice to the plaintiffs. The Judge also found that the proposed amendments would not withstand a motion to strike, as it is plain and obvious that they fail to disclose a reasonable cause of defence or counterclaim in the context of the present patent infringement proceeding. In particular, he found that the proposed amendments are too remote and do not have a sufficient relationship with the real issues: patent infringement and validity. (*Bristol-Myers Squibb Company v. Apotex Inc.*, October 24, 2008. Full judgment – 2008 FC 1196.)

**Apotex's appeal re: discovery questions dismissed.** In a patent infringement action relating to omeprazole (AstraZeneca's LOSEC), a Judge dismissed Apotex's appeals from two orders of a Prothonotary relating to questions refused on discovery. In doing so, the Judge reviewed in detail the jurisprudence governing the principles relating to discovery. (*AstraZeneca Canada Inc. v. Apotex Inc.*, November 21, 2008. Full judgment – 2008 FC 1301.)

**Court finds CADTH did not breach duty of fairness.** Boehringer Ingelheim's request for a judicial review of actions of the Canadian Agency for Drugs and Technologies in Health (CADTH) has been dismissed by the Ontario Divisional Court. Boehringer alleged that CADTH breached its duty of fairness to

Boehringer by failing to publish the draft rules of a pilot project. The pilot project, which began in 2006, permits the Health Canada drug submission and the CADTH procedures to occur concurrently with the right of experts to share information. Boehringer had its drug **PRADAX (dabigatran etexilate)** considered by the standard process of obtaining a notice of compliance (NOC) first, followed by consideration by CADTH. Bayer, an intervener in the case, volunteered and was approved by Health Canada to participate in the pilot project for its drug **XARELTO (rivaroxaban)**. Both drugs are indicated for venous thromboembolism prevention. As a result of the different approval procedures, both drugs were considered at the same meeting of the Canadian Expert Drug Advisory Committee (CEDAC) and if both are approved, they will be listed on drug plans at the same time. Had Bayer followed the usual course for CADTH consideration, its drug would not have been approved prior to February 2009. Boehringer alleged that the procedures and draft rules for the pilot project were not listed on the CADTH website in breach of their usual practice and that Bayer had an unfair advantage as Bayer received a copy of the draft rules in March 2008. The Court held that CADTH is subject to a duty of procedural fairness but found that it had not breached its duty in these circumstances, as there was ample evidence that CADTH made the pharmaceutical industry aware of the pilot project. The Court concluded that "there was no obligation for CADTH to publish the draft rules on their website. The Pilot Project was in a state of flux, and the rules were a draft only and were subject to change." Further, the Court found that "[t]he conduct of CADTH throughout has been transparent, even-handed, fair and reasonable." (*Boehringer Ingelheim (Canada) Ltd. v. Canadian Agency for Drugs and Technologies In Health*, October 29, 2008. Endorsement – 510/08.)

# New Court proceedings

## *Patented Medicines (Notice of Compliance) Regulations*

| | |
|---|---|
| **Medicine:** | amlodipine besylate (NORVASC) |
| **Applicants:** | Pfizer Canada Inc and Pfizer Ireland Pharmaceuticals |
| **Respondents:** | Dr. Reddy's Laboratories, Inc and The Minister of Health |
| **Date Commenced:** | October 30, 2008 |
| **Court File No:** | T-1684-08 |
| **Comment:** | Application for an Order of prohibition until expiry of Patent No. 2,170,278. Dr. Reddy's alleges improper listing, non-infringement and invalidity. |

| | |
|---|---|
| **Medicine:** | escitalopram (CIPRALEX) |
| **Applicant:** | Lundbeck Canada Inc |
| **Respondents:** | The Minister of Health and Pharmascience Inc |
| **Respondent/Patentee:** | H. Lundbeck A/S |
| **Date Commenced:** | November 6, 2008 |
| **Court File No:** | T-1708-08 |
| **Comment:** | Application for an Order of prohibition until expiry of Patent No. 1,339,452. Pharmascience alleges ineligibility, non-infringement and invalidity. |

## Other new proceedings

| | |
|---|---|
| **Medicine:** | bupropion hydrochloride tablets (WELLBUTRIN SR) |
| **Plaintiff:** | Novopharm Limited |
| **Defendants:** | Biovail Corporation (d.b.a. Biovail Pharmaceuticals Canada), GlaxoSmithKline Inc and The Wellcome Foundation Limited |
| **Date Commenced:** | November 7, 2008 |
| **Court File No:** | T-1717-08 |
| **Comment:** | Action for damages pursuant to section 8 of the *Regulations*. |

| | |
|---|---|
| **Medicine:** | gliclazide (DIAMICRON) |
| **Plaintiff:** | Apotex Inc |
| **Defendant:** | Servier Canada Inc |
| **Date Commenced:** | November 18, 2008 |
| **Court File No:** | T-1783-08 |
| **Comment:** | Action for damages pursuant to section 8 of the *Regulations*. |

| | |
|---|---|
| **Medicine:** | pantoprazole (PANTOLOC) |
| **Plaintiff:** | Apotex Inc |
| **Defendant:** | Nycomed Canada Inc |
| **Date Commenced:** | November 18, 2008 |
| **Court File No:** | T-1786-08 |
| **Comment:** | Action for damages pursuant to section 8 of the *Regulations*. |

| | |
|---|---|
| **Medicine:** | modafinil (ALERTEC) |
| **Plaintiff:** | Apotex Inc |
| **Defendant:** | Shire Canada Inc |
| **Date Commenced:** | November 18, 2008 |
| **Court File No:** | T-1787-08 |
| **Comment:** | Action for damages pursuant to section 8 of the *Regulations*. |

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