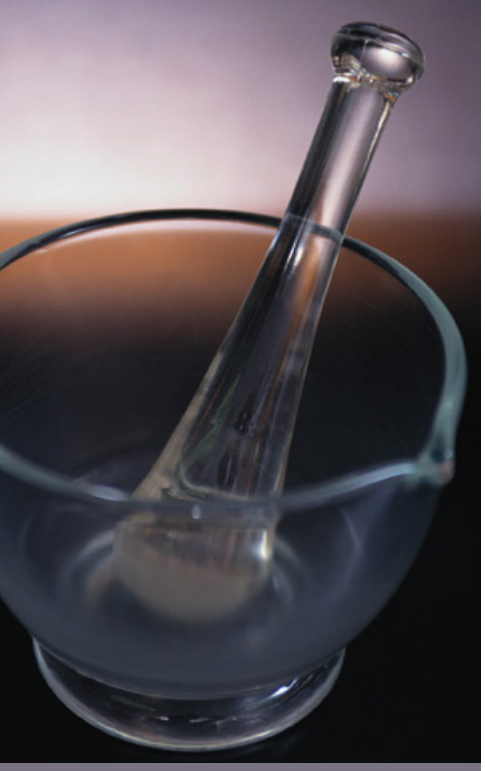

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

November 2008

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Federal Court releases first section 8 decision: Merck liable for damages, not profits

Section 8 of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") provides that if an application for an Order of prohibition is withdrawn or discontinued, dismissed, or if an Order of prohibition is reversed on appeal, the "first person" (the company that filed the original new drug submission (NDS) and the patent list) is liable to the "second person" (typically the generic manufacturer) for certain losses. The first section 8 decision on the merits was released on October 21, 2008. The action was brought by Apotex, seeking damages and/or profits from Merck for alleged delayed market entry relating to alendronate (Merck's FOSAMAX): *Apotex Inc. v. Merck Frosst Ltd. et al.*, 2008 FC 1185.

Justice Hughes held that Apotex is entitled to claim damages or its lost profits from the Merck Canadian entities for the period from February 3, 2004 (the date the Minister sent a letter to Apotex advising that its application was approved but would be placed on patent hold) to May 26, 2005 (the date of dismissal of the prohibition proceeding at issue) and certain damages beyond May 26, 2005. Quantification of damages had been previously bifurcated to be determined at a later trial.

Justice Hughes held that section 8 can be analogized to the undertaking usually required by a party seeking an interlocutory injunction from a Court. He stated:

> [55] Merck characterizes section 8 as providing a civil remedy without a wrong having been committed. Merck argues that the simple institution of a section 6 application and being subsequently unsuccessful cannot be said to be a "wrong" for which liability is created. This is a mischaracterization of the circumstances. Merck and others in its position have choices, a patent may be listed or not, an application may be instituted or not. Just like the institution of proceedings and seeking an interlocutory injunction, choices are made. Section 8 is a consequence of such choices. Merck and any other patentee has available to it all the remedies afforded to any patentee under the Patent Act, it is deprived of nothing in that regard. In seeking the advantage of section 6, it must be presumed to have done so mindfully of section 8.

Justice Hughes rejected Merck's defences to the section 8 claim, finding: (i) the Federal Court has jurisdiction to hear and determine actions instituted under section 8; (ii) section 8 is properly enabled by section 55.2(4) of the *Patent Act*; and (iii) section 8 is intra vires the constitutional authority of the federal Parliament.

Justice Hughes also rejected Merck's argument that Apotex delayed in serving its notice of allegation (NOA) for 66 days (rather than serving it once its regulatory submission was filed) and that the period of compensation should therefore be reduced accordingly. Section 8(1)(a) provides that the start date for the period of liability is "the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court concludes that ... (ii) a date other than the certified date is more appropriate". Justice Hughes held that he can only exercise his discretion under section 8(4)(a) if he is satisfied on the evidence that another date is more appropriate. He held that "there is absolutely no evidence before me that the Minister would have sent the letter of February 3, 2004 [the date of the patent hold letter, when Apotex's submission was otherwise approvable] at some earlier or later date having regard to some event or some conduct of some person or otherwise". Accordingly, he found that the relevant start date for the period of compensation was the date of the patent hold letter.

Perhaps the most significant finding is Justice Hughes's rejection of Apotex's claim for an election of Merck's profits. Specifically, Justice Hughes held that the proper interpretation of section 8(4) is that the words "damages or profits" are to be interpreted to include only "compensation" for the "loss", if any, suffered by a generic, and that those words do not provide for a right of a generic to elect for a disgorgement or account of a first person's profits. Section 8(4) as amended on October 5, 2006 no longer makes reference to "or profits", but applies only to actions commenced prior to October 5, 2006 and therefore did not apply.

Finally, Justice Hughes permitted Apotex's claim for "future losses", *i.e.*, damages for the following, provided it is shown in the evidence that such loss was not rectified and could not have been rectified before that date:

> (ii) lost sales and permanent market share due to the fact that launch by Apotex of its alendronate product was unjustly delayed with the result that two other generic manufacturers, Novopharm Limited ("Novopharm") and Cobalt Pharmaceuticals Inc. ("Cobalt"), launched their alendronate products essentially simultaneously, thus denying Apotex the opportunity to establish a permanent market share advantage in advance of any generic competitor.

Justice Hughes characterized this claim as follows:

> [120] As I understand Apotex's claim, it is saying that during the period from February 3, 2004 to May 26, 2005, the marketplace for this particular product became distorted because two other generics entered the marketplace in that period. Apotex claims that, were it not for Merck's NOC application against Apotex, Apotex could have been first in the marketplace or at least entered the marketplace at about the same time that the other generics did and that Apotex's market share would, thereby, have been larger that [sic] it now is. Apotex argues that such lesser market share is a matter that permanently endures and is a matter of permanent loss. The loss, says Apotex, may be quantified by experts at the later trial.

Apotex withdrew its unjust enrichment claim at trial and its claim against the patentee, Merck & Co., was dismissed on consent.

Merck and Apotex may appeal as of right to the Federal Court of Appeal. As the questions decided are legal questions, the issues, assuming an appeal is filed, will therefore be reviewed on a correctness standard.

Supreme Court of Canada to release PLAVIX decision on November 6

As reported in the August 2007 issue of *Rx IP Update*, the Supreme Court of Canada granted Apotex leave to appeal a decision of the Court of Appeal which had upheld a prohibition Order relating to clopidrogel (PLAVIX), a selection patent. The decision will be released on November 6 and *Rx IP Update* will report on the decision in a future issue. (News release.)

Update on reversal of order of evidence in NOC proceedings

Under the *Federal Courts Rules*, innovators, while responding to an allegation of invalidity, are required to put forward their evidence first in proceedings under the *Regulations*. The Federal Court implemented a Practice Direction regarding the conduct of proceedings under the *Regulations* effective January 7, 2008 which indicates that counsel are expected to address scheduling matters at an early case conference, including whether it is appropriate to reverse the order in which some or all of the evidence is submitted. Such orders, requiring the generic manufacturer to serve its evidence regarding validity first, have been issued in a number of proceedings, including in:

- *Lundbeck v. ratiopharm*, relating to memantine (Lundbeck's EBIXA); 2008 FC 579.
- *Schering-Plough v. Pharmascience*, relating to desloratadine (Schering-Plough's AERIUS); Court file number T-2102-07.
- *Eli Lilly v. Novopharm*, relating to olanzapine (Eli Lilly's ZYPREXA); 2008 FC 875.
- *Pfizer v. Apotex*, relating to latanoprost (Pfizer's XALATAN); Order.
- *sanofi-aventis v. ratiopharm*, relating to irbesartan (sanofi-aventis's AVAPRO); Order.
- *Procter & Gamble v. Pharmascience*, relating to risedronate sodium (P&G's ACTONEL); Order.
- *Eli Lilly v. Nu-Pharm*, relating to olanzapine (Eli Lilly's ZYPREXA); Order.
- *Novo Nordisk v. Cobalt*, relating to repaglinide (Novo Nordisk's GLUCONORM); Order.

A reversal Order was denied in proceedings relating to esomeprazole (NEXIUM): *AstraZeneca v. Apotex*, 2008 FC 537 (a decision from AstraZeneca's appeal is under reserve).

More recently, an order requiring the generic to serve its evidence on invalidity first was granted in *Biovail Corp. v. Apotex Inc.*, 2008 FC 1162. The Prothonotary determined that invalidity was the main issue in the proceeding and that requiring Apotex to serve its evidence first on invalidity would better define the grounds of alleged invalidity that would be pursued and avoid the need for Biovail to file evidence "in a vacuum" and address every possible point of alleged invalidity raised in the notice of allegation (NOA). The Prothonotary held that the dominant consideration for the reversal of evidence will be whether it will result in the streamlining of the proceeding or in delay and increased expense by further motions seeking to file reply evidence. The Prothonotary also distinguished the NEXIUM proceeding based upon the unique circumstances of that case.

The Canadian Regime for Protecting Against Pharmaceutical Trademark Confusion and Mistakes

The Canadian Regime for Protecting Against Pharmaceutical Trademark Confusion and Mistakes was written by Keltie Sim and Heather Robertson of our Toronto office and was published in the September-October issue of *The Trademark Reporter* (Vol. 98, No. 5).

The paper provides background on the nature of the pharmaceutical trade in Canada and discusses the concepts of confusion and mistake in the context of the distribution of pharmaceutical products. Trade-mark law, insofar as it relates to the assessment of the likelihood of confusion between pharmaceutical marks, is reviewed and the particular factors that the Canadian courts have reviewed in assessing confusion are canvassed, along with an analysis of the leading Canadian cases in the field. The role of Health Canada in guarding against mistakes is also discussed.

This article provides a useful resource for those seeking an understanding of the Canadian pharmaceutical trade-mark regime. The full content of the article can be found here.

New Federal Cabinet appointments

On October 30, 2008, Prime Minister Harper announced the new Cabinet appointments, including the appointment of Tony Clement, former Minister of Health, as Minister of Industry and the appointment of newly-elected Leona Aglukkaq as Minister of Health.

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	2% dorzolamide hydrochloride/0.5% timolol maleate ophthalmic solution (COSOPT)
Applicants:	Merck Frosst Canada Ltd and Merck & Co, Inc
Respondents:	The Minister of Health and Apotex Inc
Date Commenced:	October 7, 2008
Court File No:	T-1544-08
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 1,329,211 and 2,065,965. Apotex alleges invalidity. Apotex also alleges non-infringement of certain claims of the patents.

Medicine:	2% dorzolamide hydrochloride ophthalmic solution (TRUSOPT)
Applicants:	Merck & Co, Inc and Merck Frosst Canada Ltd
Respondents:	The Minister of Health and Apotex Inc
Date Commenced:	October 7, 2008
Court File No:	T-1545-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,329,211. Apotex alleges non-infringement of certain claims and invalidity.

Medicine:	atomoxetine hydrochloride (STRATTERA)
Applicant:	Eli Lilly Canada Inc
Respondents:	Apotex Inc and The Minister of Health
Respondent/Patentee:	Eli Lilly and Company
Date Commenced:	October 10, 2008
Court File No:	T-1565-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,209,735. Apotex alleges invalidity.

Medicine:	escitalopram (CIPRALEX)
Applicant:	Lundbeck Canada Inc
Respondents:	The Minister of Health and ratiopharm Inc Limited
Respondent/Patentee:	H. Lundbeck A/S
Date Commenced:	October 16, 2008
Court File No:	T-1599-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,339,452. ratiopharm alleges ineligibility, non-infringement of certain claims, and invalidity.

Medicine:	ezetimibe (EZETROL)
Applicants:	Merck Frosst – Schering Pharma GP and Schering Corporation
Respondents:	The Minister of Health and Novopharm Limited
Date Commenced:	October 20, 2008
Court File No:	T-1610-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,172,149. Novopharm alleges non-infringement and invalidity.

Medicine:	rosuvastatin calcium (CRESTOR)
Applicants:	AstraZeneca Canada Inc, AstraZeneca AB and Shionogi Seiyaku Kabushiki Kaisha
Respondents:	Novopharm Limited and The Minister of Health
Date Commenced:	October 23, 2008
Court File No:	T-1636-08
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 2,072,945 and 2,313,783. Novopharm alleges invalidity of the '945 patent and non-infringement of the '783 patent.

Medicine:	oxycodone hydrochloride (OXYCONTIN)
Applicant:	Purdue Pharma
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	October 23, 2008
Court File No:	T-1641-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,296,633. Apotex alleges non-infringement and invalidity.

Medicine:	oxycodone hydrochloride (OXYCONTIN)
Applicant:	Purdue Pharma
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	October 23, 2008
Court File No:	T-1642-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,098,738. Apotex alleges non-infringement and invalidity.

Other new proceedings

Medicine:	ramipril (ALTACE)
Plaintiffs:	sanofi-aventis Canada Inc, sanofi-aventis Deutschland GmbH and Schering Corporation
Defendant:	Ranbaxy Pharmaceuticals Canada Inc
Date Commenced:	October 20, 2008
Court File No:	T-1614-08
Comment:	Patent infringement action regarding Patent No. 1,341,206.

Medicine:	ramipril (ALTACE)
Plaintiffs:	sanofi-aventis Canada Inc, sanofi-aventis Deutschland GmbH and Schering Corporation
Defendant:	Cobalt Pharmaceuticals Inc
Date Commenced:	October 20, 2008
Court File No:	T-1615-08
Comment:	Patent infringement action regarding Patent No. 1,341,206.

Medicine:	ramipril (ALTACE)
Plaintiffs:	sanofi-aventis Canada Inc, sanofi-aventis Deutschland GmbH and Schering Corporation
Defendant:	Genpharm ULC
Date Commenced:	October 20, 2008
Court File No:	T-1616-08
Comment:	Patent infringement action regarding Patent No. 1,341,206.

Medicine:	ramipril (ALTACE)
Plaintiffs:	sanofi-aventis Canada Inc, sanofi-aventis Deutschland GmbH and Schering Corporation
Defendant:	Pro Doc Limitée
Date Commenced:	October 20, 2008
Court File No:	T-1617-08
Comment:	Patent infringement action regarding Patent No. 1,341,206.

Medicine:	ramipril (ALTACE)
Plaintiffs:	sanofi-aventis Canada Inc, sanofi-aventis Deutschland GmbH and Schering Corporation
Defendant:	Sandoz Canada Inc
Date Commenced:	October 20, 2008
Court File No:	T-1618-08
Comment:	Patent infringement action regarding Patent No. 1,341,206.

To check the status of Federal Court cases, please click here.

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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 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

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