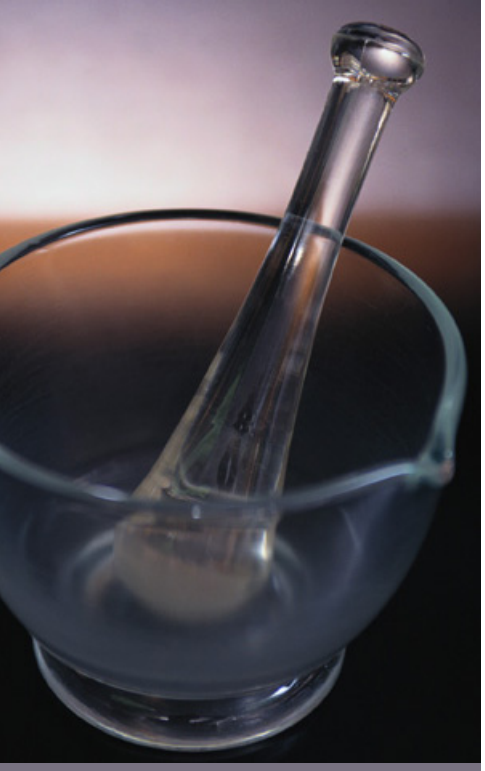

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# Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

**January 2009**



## Applications seeking to strike down data protection heard December 16–18, 2008

Apotex's (T-2047-06) and the Canadian Generic Pharmaceutical Association's (T-1976-06) applications for judicial review challenging the validity of the data protection provision of the *Food and Drug Regulations* were heard by Justice Mandamin of the Federal Court from December 16 to 18, 2008. A decision remains pending.

## Merck and Apotex both appeal first section 8 decision

As reported in the November 2008 issue of *Rx IP Update*, the Federal Court issued its first decision finding liability pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*"). The Court held that Merck was liable for Apotex's damages (lost profits) during the period from the date the Minister sent a letter to Apotex advising that its application for a notice of compliance ("NOC") for alendronate (Merck's FOSAMAX) was approvable to the date the prohibition proceeding was dismissed. The Court denied Apotex's claim for an election of Merck's profits but did hold that Apotex is entitled to claim certain "future losses", i.e., damages beyond the dismissal date Apotex alleges to have suffered and will continue to suffer by not being the first entrant on the generic market as a result of the prohibition proceedings, provided it is shown in evidence that such loss was not rectified and could not have been rectified before that date. The Court rejected Merck's defences to the section 8 claim, finding that: (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. Both Merck (Federal Court of Appeal File No. A-571-08) and Apotex (Federal Court of Appeal File No. A-580-08) have appealed. (Full judgment – 2008 FC 1185.)

# Federal Court interprets "carry-forward" provision for patent listing

One of the October 2006 amendments to the *Regulations* was a "carry-forward" provision, s. 4.1(2), which provides that:

> (2) A first person who submits a patent list in relation to a new drug submission referred to in subsection 4(2) may, if the list is added to the register, resubmit the same list in relation to a supplement to the new drug submission, but may not submit a new patent list in relation to a supplement except in accordance with subsection 4(3).

On December 23, 2008, the Federal Court issued its first decision interpreting this provision: *Immunex v. The Minister of Health*, 2008 FC 1409.

The patent had been listed against the new drug submission (NDS) for ENBREL (etanercept) in a lyophilized formulation that was approved in 2000, and Immunex sought to list the patent pursuant to s. 4.1(2) against a subsequent submission for a new manufacturing site against both the lyophilized formulation and a liquid formulation. The Minister refused to list the patent against the liquid formulation on the basis that the patent was not previously listed on the Patent Register with respect to a previous NOC that approved the liquid formulation in 2005. Snider J. dismissed Immunex's application for judicial review, finding that the Minister was correct in refusing to list the patent against the supplemental new drug submission (SNDS) for the additional manufacturing site for the liquid formulation, indicating that the better interpretation of s. 4.1(2) is that in which the words are read to prevent the listing of a patent that would circumvent the timing requirements. While Immunex argued, among other arguments, that the liquid formulation was filed by way of an update to the submission that resulted in the 2005 approval and there was therefore no opportunity to list the patent against that submission, Snider J. rejected this argument, indicating that there was evidence that Immunex could have submitted the patent with a new SNDS for a change in formulation and missed this opportunity. Snider J. concluded that the only time that the patent could be listed in respect of the new formulation would be at the time of the first submission related to that formulation.
(Full judgment – 2008 FC 1409.)

# Supreme Court of Canada matters

***Option Consommateurs v. Novopharm et al.*, December 5, 2008.** Leave has been denied. Option Consommateurs, a consumer rights group, had filed applications seeking leave to appeal the Quebec Court of Appeal's decision affirming the Superior Court's refusal to authorize a class action against a number of generic drug companies. The class action was commenced on the belief, based on a newspaper article, that as a result of illegal rebates provided to pharmacists by generic drug companies, Quebec residents paid more for drug insurance than they should have.
(QCCA decision (French only): 2008 QCCA 949; Superior Court decision (French only): 2006 QCCS 118.)

***Nu-Pharm v. Canada*, December 19, 2008.** Nu-Pharm was denied leave to appeal the Federal 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 the Crown 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 proving the unlawful character of the Government's decisions, which must be determined by way of judicial review. The Court of Appeal affirmed the decision.
(Court of Appeal reasons – 2008 FCA 227; Motions Judge's reasons – 2007 FC 977.)

***Abbott v. Canada*, December 19, 2008.** Abbott was denied leave to appeal a Court of Appeal decision that imposed a strict matching requirement for listing a use patent against an SNDS for a change in use. The Court of Appeal's decision affirmed that the Minister of Health properly delisted a patent listed against an SNDS in respect of lansoprazole (PREVACID).
(Court of Appeal reasons – 2008 FCA 244; Application Judge's reasons – 2007 FC 797.)

# Recent Court decisions

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

**Proceeding against Sandoz regarding clarithromycin (Abbott's BIAXIN XL) dismissed.** The Court dismissed Abbott's application for an Order prohibiting the Minister from issuing an NOC to Sandoz for its generic version of Abbott's BIAXIN XL until the expiry of Abbott's patent claiming a particular crystalline form of clarithromycin. The Court found that while Sandoz's allegations of non-infringement were not justified, Abbott had failed to satisfy the Court that Sandoz's allegations of anticipation and obviousness were not justified. This was the first consideration of challenges to a patent based on anticipation and obviousness since the Supreme Court's decision in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* (PLAVIX), reported in the November 2008 Special Edition of *Rx IP Update*. (*Abbott Laboratories v. Sandoz*, December 11, 2008. Full judgment – 2008 FC 1359.)

## Other decisions

**Federal Court of Appeal refuses defendant's motion for recusal of Trial Judge in pending patent infringement action.** In a patent infringement action relating to ramipril (sanofi-aventis's ALTACE), the defendant, Apotex, moved for the recusal of Justice Snider, the Judge designated to preside at the trial commencing January 12, 2008, on the basis of an apprehension of bias. Justice Snider refused to recuse herself, and her decision was upheld by the Federal Court of Appeal. Apotex alleged that there was an apprehension of bias because Justice Snider had previously rendered a decision in favour of the applicants (the plaintiffs in the present action) in an NOC application in respect of the same patent, and she had also held that Apotex had infringed a valid patent related to Servier's COVERSYL (perindopril). The Federal Court of Appeal held that Apotex had failed to rebut the "strong presumption of judicial impartiality", which is "particularly difficult to rebut when an allegation of a reasonable apprehension of bias is based on a judge's previous encounter with a party, a witness or an issue in his or her judicial capacity." (*Apotex v. sanofi-aventis*, December 10, 2008. Full Judgment – 2008 FCA 394; Federal Court Judgment.)

# New Court proceedings

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

| | |
|---|---|
| **Medicine:** | olanzapine tablets (ZYPREXA) |
| **Applicant:** | Eli Lilly Canada Inc |
| **Respondents:** | Cobalt Pharmaceuticals Inc and The Minister of Health |
| **Respondent/Patentee:** | Eli Lilly and Company Limited |
| **Date Commenced:** | November 10, 2008 |
| **Court File No:** | T-1731-08 |
| **Comment:** | Application for an Order of prohibition until expiry of Patents Nos. 2,041,113, 2,214,005 and 2,216,372. Cobalt alleges non-infringement and invalidity. |

| | |
|---|---|
| **Medicine:** | clopidogrel bisulfate (PLAVIX) |
| **Applicant:** | sanofi-aventis Canada Inc |
| **Respondents:** | Pharmascience Inc and The Minister of Health |
| **Respondent/Patentee:** | sanofi-aventis |
| **Date Commenced:** | November 10, 2008 |
| **Court File No:** | T-1732-08 |
| **Comment:** | Application for an Order of prohibition until expiry of Patents Nos. 1,336,777 and 2,334,870. Pharmascience alleges non-infringement, invalidity and ineligibility. |

| | |
|---|---|
| **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:** | November 14, 2008 |
| **Court File No:** | T-1745-08 |
| **Comment:** | Application for an Order of prohibition until expiry of Patent No. 2,041,113. Genpharm alleges invalidity. |

| | |
|---|---|
| **Medicine:** | sildenafil citrate (VIAGRA) |
| **Applicants:** | Pfizer Canada Inc and Pfizer Ireland Pharmaceuticals |
| **Respondents:** | ratiopharm Inc and The Minister of Health |
| **Date Commenced:** | December 15, 2008 |
| **Court File No:** | T-1935-08 |
| **Comment:** | Application for an Order of prohibition until expiry of Patent No. 2,163,446. ratiopharm alleges non-infringement and invalidity. |

| | |
|---|---|
| **Medicine:** | sildenafil citrate (VIAGRA) |
| **Applicants:** | Pfizer Canada Inc and Pfizer Ireland Pharmaceuticals |
| **Respondents:** | Pharmascience Inc and The Minister of Health |
| **Date Commenced:** | December 19, 2008 |
| **Court File No:** | T-1967-08 |
| **Comment:** | Application for an Order of prohibition until expiry of Patents Nos. 1,336,777 and 2,334,870. Pharmascience alleges non-infringement, invalidity and ineligibility in respect of both patents. |

| | |
|---|---|
| **Medicine:** | clopidogrel bisulfate (PLAVIX) |
| **Applicants:** | sanofi-aventis Canada Inc |
| **Respondents:** | Pharmascience Inc and The Minister of Health |
| **Respondent/Patentee:** | sanofi-aventis |
| **Date Commenced:** | November 10, 2008 |
| **Court File No:** | T-1732-08 |
| **Comment:** | Application for an Order of prohibition until expiry of Patent No. 2,163,446. Pharmascience alleges non-infringement and invalidity. |

## Other new proceedings

| | |
|---|---|
| **Medicine:** | desmopressin acetate tablets (DDAVP) |
| **Plaintiff:** | Apotex Inc |
| **Defendant:** | Ferring Inc |
| **Date Commenced:** | December 18, 2008 |
| **Court File No:** | T-1954-08 |
| **Comment:** | Action for damages pursuant to section 8 of the *Regulations*. |

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

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