



# Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

## May 2009

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## Federal Court implements Practice Direction to streamline complex litigation

As a result of a recent initiative taken by the Federal Court in intellectual property litigation, the Federal Court has implemented a Practice Direction, dated May 1, 2009, to streamline complex actions so that where possible, a trial will be scheduled within two years of the commencement of the proceedings. Pursuant to the Direction: (1) parties and their counsel may seek an order for directions regarding discovery from a case management judge;

(2) parties may seek an order for directions allowing service by electronic mail; and (3) parties may request that a trial date be assigned at any point in a case-managed proceeding; the Court will endeavour to have the action tried within two years of its commencement if the request is made early in the action. ([Notice to the Parties and the Profession.](#))

## Ontario takes legal action against pharmacies, generics and wholesalers regarding professional allowances

As a result of audits conducted by the Ministry of Health and Long-Term Care's Ontario Public Drug Programs, it was found that some pharmacies have been purchasing a greater amount of generic drugs than they require, collecting professional allowances on the full amount and then returning what they do not need to the wholesaler. The wholesaler was

then reselling the product, triggering a second professional allowance payment. According to the Ontario Ministry, this scheme enables professional allowances to be collected multiple times.

The Ontario government has therefore taken a number of enforcement actions, including:

issuing rebate penalty orders against seven generic drug companies, four wholesalers and one pharmacy in the amount of \$33.8 million; and laying 20 provincial offence charges for

providing false and/or misleading information or obstructing an inspection against a generic manufacturer, a wholesaler, a pharmacy and three individuals. ([News release](#).)

## Patented Medicine Prices Review Board news

The Board has approved two Voluntary Compliance Undertakings (VCUs) for sanofi-aventis: SUPRAX (cefixime) and ELIGARD (leuprolide acetate). ([Notice](#).)

The Board has also approved a VCU for Janssen-Ortho's CONCERTA (methylphenidate hydrochloride). ([Notice](#).)

As reported in the [April 2009](#) issue of *Rx IP Update*, the Board released a Notice and Comment package, including a further draft revised Compendium of Policies, Guidelines and Procedures. The Board has published comments from various sectors regarding the Draft Revised Excessive Price Guidelines. ([Comments](#).)

## Health Canada releases revised Guidance Document: *Patented Medicines (Notice of Compliance) Regulations*

On April 3, 2009, Health Canada published a revised Guidance Document for the *Patented Medicines (Notice of Compliance) Regulations* ("Regulations"). The revisions reflect the [amendments](#) to the *Regulations* that came into force on June 12, 2008. The 2008 amendments (as reported in the [June 2008 Special Edition](#) of *Rx IP Update*) prohibit the Minister from deleting grandfathered patents (patents on a

patent list submitted before June 17, 2006) from the Patent Register (subject to certain exceptions) and from refusing to add any grandfathered patent to the Patent Register solely on the ground that the patent is not "relevant" to the submission for which listing is sought. ([Notice and Revised Guidance Document](#).)

## Recent Court decisions

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

**Federal Court dismisses Eli Lilly's Application for Order of prohibition for raloxifene.** The Federal Court dismissed Eli Lilly's application for an Order of prohibition against Apotex relating to its raloxifene hydrochloride tablets (Eli Lilly's EVISTA). The patent at issue was the same as the one considered by the same Judge in *Eli Lilly Canada Inc. v. Novopharm Limited*, 2009 FC 301 (not yet reported). In that case, the Judge held that Novopharm's allegation of invalidity on the grounds of obviousness and anticipation was justified. In this case,

the Judge found no reason to arrive at a result any different from the Novopharm case with respect to Apotex's allegation of invalidity on the basis of anticipation and obviousness. The Judge also found that Apotex's overbreadth allegation is justified. While the Judge held that the claims would be infringed, the Gillette Defence was justified on the basis that as the claims are not valid, no valid claim would be infringed. (*Eli Lilly Canada v. Apotex and Minister of Health*, March 26, 2009. Full judgment – [2009 FC 320](#).)

## Other decisions

### **Court affirms Health Canada's classification of VANCOPAK as a drug in dosage form.**

Canadian Pharmaceutical Technologies (CPTI) sells **vancomycin hydrochloride powder** requiring reconstitution by pharmacists under the tradename **VANCOPAK** (formerly **VANCOMYSOL**). In 2005, Health Canada determined that CPTI's product should be classified as "a drug in dosage form" and thus subject to the provisions of the *Food and Drugs Act*. The Federal Court allowed CPTI's application for judicial review of Health Canada's decision and remitted the matter to Health Canada for reconsideration (2006 FC 708). Health Canada redetermined that VANCOPAK is a drug in

dosage form. CPTI sought judicial review of this decision. The Federal Court dismissed CPTI's application. The Court held that CPTI was not denied procedural fairness in the redetermination process and was satisfied that Health Canada did not discriminate against CPTI in the regulatory process. It concluded that Health Canada's classification of VANCOPAK as a drug in dosage form, requiring a Drug Identification Number before it could be sold in Canada, is an outcome that was reasonably open to Health Canada. (*Canadian Pharmaceutical Technologies v. The Attorney General of Canada*, April 7, 2009. Full judgment – 2009 FC 244.)

## New Court proceedings

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

<b>Medicine:</b>	atorvastatin calcium (LIPITOR)
<b>Applicants:</b>	Pfizer Canada Inc, Warner-Lambert Company and Warner-Lambert Company LLC
<b>Respondents:</b>	Pharmascience Inc and The Minister of Health
<b>Date Commenced:</b>	April 3, 2009
<b>Court File No.:</b>	T-531-09
<b>Comment:</b>	Application for an Order of prohibition until expiry of Patents Nos. 2,220,455, 2,220,458, 2,220,018, 2,521,891, 2,522,899, 2,450,111, 2,521,908, 2,521,933, 2,521,953, 2,521,956, 2,521,828, 2,521,833, 2,521,792, 2,521,776 and 2,521,887. Pharmascience alleges non-infringement.
<b>Medicine:</b>	atorvastatin calcium (LIPITOR)
<b>Applicants:</b>	Pfizer Canada Inc and Warner-Lambert Company, LLC
<b>Respondents:</b>	Pharmascience Inc and The Minister of Health
<b>Date Commenced:</b>	April 3, 2009
<b>Court File No.:</b>	T-532-09
<b>Comment:</b>	Application for an Order of prohibition until expiry of Patent No. 2,021,546. Pharmascience alleges non-infringement and invalidity.
<b>Medicine:</b>	atorvastatin calcium (LIPITOR)
<b>Applicants:</b>	Pfizer Canada Inc and Pfizer Products Inc
<b>Respondents:</b>	Pharmascience Inc and The Minister of Health
<b>Date Commenced:</b>	April 3, 2009
<b>Court File No.:</b>	T-533-09
<b>Comment:</b>	Application for an Order of prohibition until expiry of Patent No. 2,150,372. Pharmascience alleges non-infringement and invalidity.

**Medicine:** olanzapine (ZYPREXA, ZYPREXA ZYDIS and ZYPREXA INTRAMUSCULAR)  
**Applicants:** Eli Lilly Canada Inc  
**Respondents:** Cobalt Pharmaceuticals Inc and The Minister of Health  
**Respondent/Patentee:** Eli Lilly and Company Limited  
**Date Commenced:** April 6, 2009  
**Court File No.:** T-544-09  
**Comment:** Application for an Order of prohibition until expiry of Patent No. 2,041,113. Cobalt alleges non-infringement and invalidity.

**Medicine:** olanzapine (ZYPREXA, ZYPREXA ZYDIS and ZYPREXA INTRAMUSCULAR)  
**Applicants:** Eli Lilly Canada Inc  
**Respondents:** Cobalt Pharmaceuticals Inc and The Minister of Health  
**Respondent/Patentee:** Eli Lilly and Company Limited  
**Date Commenced:** April 6, 2009  
**Court File No.:** T-545-09  
**Comment:** Application for an Order of prohibition until expiry of Patent No. 2,041,113. Cobalt alleges non-infringement and invalidity.

**Medicine:** atorvastatin calcium (LIPITOR)  
**Applicants:** Pfizer Canada Inc and Warner-Lambert Company, LLC  
**Respondents:** Apotex Inc and The Minister of Health  
**Date Commenced:** April 14, 2009  
**Court File No.:** T-579-09  
**Comment:** Application for an Order of prohibition until expiry of Patent No. 2,021,546. Apotex alleges invalidity.

**Medicine:** atorvastatin calcium (LIPITOR)  
**Applicants:** Pfizer Canada Inc, Warner-Lambert Company and Warner-Lambert Company, LLC  
**Respondents:** Apotex Inc and The Minister of Health  
**Date Commenced:** April 14, 2009  
**Court File No.:** T-580-09  
**Comment:** Application for an Order of prohibition until expiry of Patents Nos. 2,220,018, 2,220,455, 2,220,458, 2,450,111, 2,521,776, 2,521,792, 2,521,828, 2,521,833, 2,521,887, 2,521,891, 2,521,908, 2,521,933, 2,522,899, 2,521,953 and 2,521,956. Apotex alleges non-infringement (all patents) and invalidity ('455 patent).

**Medicine:** drospirenone/ethinyl estradiol (YAZ)  
**Applicant:** Bayer Inc  
**Respondents:** The Minister of Health and The Attorney General of Canada  
**Date Commenced:** April 14, 2009  
**Court File No.:** T-582-09  
**Comment:** Application for judicial review of The Minister of Health's decision refusing to add Patent No. 2,194,979 to the Patent Register in respect of the NDS for YAZ. The OPML decided the patent was ineligible pursuant to section 4(2)(b) as it was directed towards pharmaceutical compositions comprising 17-*a* estradiol, none of which specify the medicinal ingredients drospirenone/ethinyl estradiol.

**Medicine:** tamsulosin hydrochloride (FLOMAX CR)  
**Applicants:** Boehringer Ingelheim (Canada) Limited and Astellas Pharma Inc  
**Respondents:** Sandoz Canada Inc and The Minister of Health  
**Date Commenced:** April 23, 2009  
**Court File No.:** T-651-09  
**Comment:** Application for an Order of prohibition until expiry of Patent No. 2,144,077. Sandoz alleges non-infringement and invalidity.

**Medicine:** tamsulosin hydrochloride (FLOMAX CR)  
**Applicants:** Boehringer Ingelheim (Canada) Limited and Astellas Pharma Inc  
**Respondents:** Sandoz Canada Inc and The Minister of Health  
**Date Commenced:** April 23, 2009  
**Court File No.:** T-652-09  
**Comment:** Application for an Order of prohibition until expiry of Patent No. 2,490,299. Sandoz alleges non-infringement and invalidity.

**Medicine:** tamsulosin hydrochloride (FLOMAX CR)  
**Applicants:** Boehringer Ingelheim (Canada) Limited and Astellas Pharma Inc  
**Respondents:** Sandoz Canada Inc and The Minister of Health  
**Date Commenced:** April 23, 2009  
**Court File No.:** T-652-09  
**Comment:** Application for an Order of prohibition until expiry of Patent No. 2,490,299. Sandoz alleges non-infringement and invalidity.

**Medicine:** olanzapine (ZYPREXA ZYDIS)  
**Applicant:** Eli Lilly Canada Inc  
**Respondents:** Sandoz Canada Inc and The Minister of Health  
**Respondent/Patentee:** Eli Lilly and Company  
**Date Commenced:** April 27, 2009  
**Court File No.:** T-667-09  
**Comment:** Application for an Order of prohibition until expiry of Patent No. 2,265,712. Sandoz alleges ineligibility, non-infringement and invalidity.

**Medicine:** olanzapine (ZYPREXA ZYDIS)  
**Applicant:** Eli Lilly Canada Inc  
**Respondents:** Sandoz Canada Inc and The Minister of Health  
**Respondent/Patentee:** Eli Lilly and Company Limited  
**Date Commenced:** April 27, 2009  
**Court File No.:** T-668-09  
**Comment:** Application for an Order of prohibition until expiry of Patent No. 2,041,113. Sandoz alleges non-infringement and invalidity.

**Medicine:** olanzapine (ZYPREXA, ZYPREXA ZYDIS and ZYPREXA INTRAMUSCULAR)  
**Applicant:** Eli Lilly Canada Inc  
**Respondents:** Sandoz Canada Inc and The Minister of Health  
**Respondent/Patentee:** Eli Lilly and Company Limited  
**Date Commenced:** April 27, 2009  
**Court File No.:** T-669-09  
**Comment:** Application for an Order of prohibition until expiry of Patent No. 2,214,005. Sandoz alleges non-infringement, invalidity and ineligibility.

## Other proceedings

**Medicine:** modafinil (ALERTEC)  
**Plaintiff:** Cephalon, Inc  
**Defendant:** Apotex Inc  
**Date Commenced:** April 17, 2009  
**Court File No.:** T-609-09  
**Comment:** Patent infringement action regarding Patents Nos. 2,201,967 and 2,382,275.

**Patent Title:** HIV Replication Inhibiting Pyrimidines  
**Applicant:** Janssen Pharmaceutica N.V.  
**Respondent:** Commissioner of Patents  
**Date Commenced:** April 20, 2009  
**Court File No.:** T-623-09  
**Comment:** Application pursuant to section 52 of the *Patent Act* to name an additional inventor in Patent No. 2,350,801.

**Medicine:** Apo-Memantine  
**Applicant:** Lundbeck Canada Inc.  
**Respondents:** The Minister of Health (Canada) and Apotex Inc  
**Date Commenced:** April 27, 2009  
**Court File No.:** T-672-09  
**Comment:** Application for judicial review of the Minister's decision to accept and proceed to review Apotex's ANDS for Apo-Memantine identifying Lundbeck's brand of memantine (EBIXA) as a Canadian Reference Product.

**Medicine:** clopidogrel bisulfate (PLAVIX)  
**Plaintiff:** Apotex Inc  
**Defendants:** sanofi-aventis and sanofi-aventis Canada Inc  
**Date Commenced:** April 22, 2009  
**Court File No.:** T-644-09  
**Comment:** Action for Orders declaring Patent No. 1,336,777 invalid, declaring the '777 Patent not infringed, setting aside the Order of Shore J. dated March 21, 2005 in Court File No. T-668-03 and dismissing the application for prohibition brought in Court File No. T-668-03.

**Medicine:** Apo-Raloxifene  
**Plaintiff:** Apotex Inc  
**Defendant:** Eli Lilly Canada Inc  
**Date Commenced:** April 24, 2009  
**Court File No.:** T-656-09  
**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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