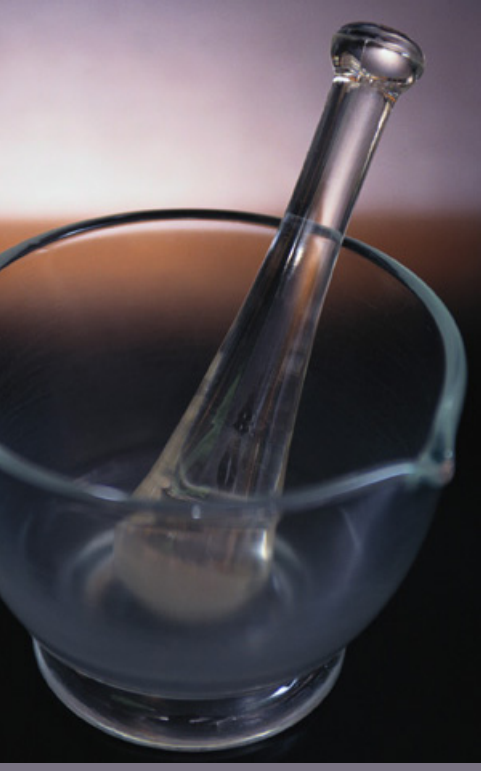

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# Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

**June 2008**



## Court finds allegation of invalidity re: selection patent justified

As previously reported, the disclosure requirements for selection patents were recently clarified by the Federal Court of Appeal in *Pfizer v. Ranbaxy*, 2008 FCA 108, and further jurisprudence will issue on the topic of selection patents as the **PLAVIX** appeal (appeal of *Apotex v. Sanofi-Synthelabo*, 2006 FCA 421) was heard by the Supreme Court on April 16, 2008 and a decision is under reserve.

The Federal Court has recently commented further on selection patents, again in the context of a proceeding under the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") (*GlaxoSmithKline v. Pharmascience*, 2008 FC 593). Pharmascience had alleged that a patent relating to **valacyclovir** (GlaxoSmithKline's **VALTREX**) does not contain or disclose a valid selection over an earlier patent covering a genus that included valacyclovir within its scope. The patent stated that valacyclovir "surprisingly has improved bioavailability after oral administration compared with alanine and glycine esters mentioned" in the prior patent. The Judge concluded that GSK had not met the burden of establishing a valid selection, at least in terms of utility, on the basis that neither the patent nor the evidence of GSK's expert witnesses support a prediction that valacyclovir had a better oral bioavailability profile than any of the other compounds of the genus, apart from two others. The Judge stated that while a patentee of a selection patent need not test every compound in the genus, sufficient representative testing is required so that a person skilled in the art could soundly predict that the surprising characteristic would not be expected to be found in a large number of the other members of the genus.

While the Judge did not make a finding regarding whether the section 27(3) disclosure requirements had been met, he stated that there may be an obligation to disclose **in the patent** the underlying facts and the line of reasoning which support the prediction and stated:

> Here, the disclosure of the 083 Patent completely fails to address the issue of whether and why the asserted bioavailability advantage of valacyclovir would be predicted to be substantially unique among the other esters of

acyclovir claimed by the 493 Patent. It seems to me that if a patentee is relying on sound prediction to establish that its selection has some unexpected advantage over the genus, it does have a heightened obligation to disclose in the patent its line of reasoning because that is part of the quid pro quo for the claimed monopoly over the selection.

# British Columbia Ministry of Health news

On May 21, 2008, the BC Government announced that it had accepted all of the recommendations from the Pharmaceutical Task Force. The task force was charged with advising the government on key areas of pharmaceutical policy within the health system. The report makes twelve recommendations in five areas: an improved drug review/listing process; improved procurement practices; building positive and productive relationships; improving the common drug review process; and replacing or reconstituting the therapeutics initiative. (News release. Report.)

# Patented Medicine Prices Review Board news

**PMPRB issues Order regarding COPAXONE.** As reported in the April 2008 edition of *Rx IP Update*, the Board concluded that while Teva Neuroscience sold **COPAXONE** syringes (**glatiramer**) at an excessive price, it found that the increases in prices were not to be strictly limited by the Consumer Price Index Methodology set out in the Board's Excessive Price Guidelines. Teva Neuroscience's application for judicial review of this decision is pending.

An issue that arose in settling the terms of the Order was whether, because Teva Neuroscience sold COPAXONE in 2006 and 2007 at prices below the maximum non-excessive (MNE) prices permitted by the Decision, this should offset its sales during 2004 and 2005 at prices above the MNE. The Board decided that Teva could not offset excessive revenue in this manner, finding that such revenues could only be offset by compliance with an Order of the Board. (Board Order. Decision/reasons regarding form of Order. Decision on the merits.)

# Recent Court decisions

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

**Apotex denied leave to intervene to comment on *Saccharin* doctrine in Ranbaxy's appeal.** Ranbaxy had appealed an Order of prohibition relating to **atorvastatin** (Pfizer's **LIPITOR**). Ranbaxy had alleged non-infringement, including on the basis that the intermediates purported to infringe the patent were used in India, not Canada. The Judge rejected this argument, applying the UK decision *Saccharin Corpo v. Anglo-Continental Chemical Works* (1900), 17 RPC 307 (Ch.). Apotex, presently in trial defending an unrelated patent infringement action brought by Eli Lilly, sought leave to intervene in the appeal to argued that the *Saccharin* doctrine ought to have no application in Canada at all and suggesting its position would not be represented by Ranbaxy. The Court of Appeal denied Apotex leave, finding that it was far from clear that a decision by the Court would resolve the issue in the Eli Lilly infringement action, relying on it its previous decision, wherein it stated, "[s]imilarly it is inappropriate to rely on NOC proceedings to set binding precedent on controversial questions in patent law": *Eli Lilly v. Novopharm*, 2007 FCA 359. The Court also stated that it was therefore preferable for the larger issue to be determined in the Eli Lilly litigation and that intervention would undoubtedly complicate and delay the appeal. Intervention was therefore not clearly warranted. (*Ranbaxy v. Pfizer*, April 15, 2008, reasons – 2008 FCA 138.)

**Sandoz's abuse of process motions re: pantoprazole dismissed.** Sandoz brought motions for summary dismissal in two proceedings relating to **pantoprazole** (Nycomed's **PANTOLOC**) arguing that the proceedings were redundant, frivolous or vexatious or otherwise an abuse of process. The Prothonotary dismissed both motions.

The first motion was brought on the basis of a decision relating to the same patent and Apotex (*Solvay v. Apotex*, 2008 FC 308). The Prothonotary rejected Sandoz's argument that there had been a prior determination that the patent was ineligible for listing, finding that the Judge's comments in *Apotex* regarding eligibility were *obiter* and in any event it was unclear whether the Judge had reached any definitive conclusion on eligibility. Furthermore, a subsequent motion in *Nycomed v. Genpharm*, 2008 FC 330, rejected a motion based on ineligibility. The Prothonotary also questioned whether an application could be dismissed as an abuse of process on an eligibility issue outside the context of a section 6(5)(a) motion. The Prothonotary also rejected Sandoz's argument that there had been a determination in Apotex that the patents do not contain claims for the use of the medicine. Finally, the Prothonotary rejected Sandoz's argument that as it has made the same allegation of non-infringement as Apotex and its product monograph is similar to that of Apotex, it must follow that Nycomed's application must be dismissed as an abuse of process. The Prothonotary distinguished *Nycomed v. Novopharm*, 2008 FC 454, in which the Court summarily dismissed a proceeding against Novopharm on the basis of *Apotex*, finding that while the evidence had been filed by Nycomed in *Novopharm*, it had not yet been filed by Nycomed in the present proceeding. In responding to the motion, Nycomed showed the type of evidence it would lead in the application and the Prothonotary noted that this type of evidence was discussed in neither the *Apotex* nor *Novopharm* cases.

Similar findings were made in dismissing the second motion, although on the question of infringement the Prothonotary found that the issue had not properly been raised in Sandoz's motion. Sandoz has appealed. (*Nycomed v. Canada (Health)*, April 28, 2008, reasons – 2008 FC 541. *Nycomed v. Canada (Health)*, April 29, 2008, reasons – 2008 FC 555.)

**Court orders reversal of evidence.** 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*. However, as reported in the January 2008 edition of *Rx IP Update*, the Court has implemented a Practice Direction regarding the conduct of proceedings under the *Regulations* which indicates that counsel will be 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. In *Lundbeck v. ratiopharm*, relating to **memantine** (Lundbeck's **EBIXA**), a Prothonotary issued the first decision granting such an Order, specifically a timetable that required the generic to deliver its evidence on invalidity before the applicants. The Prothonotary found that the substantial narrowing of the issues on invalidity, along with the likely commensurate limits on the number of experts, cannot but offer substantial economies including in respect of the likelihood of the need for reply evidence. The Prothonotary was therefore satisfied that full reversal on issues of invalidity will result in a trimmer and more expeditious proceeding. A reversal order was also granted in T-2102-07 (*Schering-Plough v. Pharmascience*, reasons have not issued), but denied in cases relating to **esomeprazole (NEXIUM)**: T-371-08, T-372-08, T-374-08 (appeal pending). (*Lundbeck v. Ratiopharm*, May 6, 2008, reasons – 2008 FC 579. *AstraZeneca v. Apotex*, April 24, 2008, reasons – 2008 FC 537.)

**Court of Appeal affirms *Abbott* decision regarding requirement to address patents under old *Regulations*.** Abbott had brought an application for an Order prohibiting the Minister from issuing a notice of compliance (NOC) to any person for a generic version of **PREVACID (pantoprazole)** without requiring that person to address two patents listed on the Register. The applications Judge had held that it would be inappropriate for the Court to grant such an Order in the circumstances as these matters are fact-specific and the jurisprudence is evolving. The Judge also held that it is equally inappropriate to grant such an Order respecting a specific fact situation in the absence of the party engaged in that situation. The Court of Appeal upheld that decision, finding that the requisite certainty was lacking in this case because it was not clear when the Minister would be required to decide whether to issue such an NOC, what the relevant facts will be at that time, or whether at that time the Minister will still be following the analytical framework that flowed from a previous decision under section 5 (*Ferring v. Minister of Health*, 2007 FC 300, aff'd 2007 FCA 276). The Court also noted that it remains an open question whether the Minister would be correct to apply his analytical framework in

every case, given that in the Ferring appeals the Court stated that it expressed no opinion on whether the analytical approach was adequate for all possible circumstances and that the Minister is aware of the need for a case-by-case determination. (*Abbott v. Attorney General of Canada*, May 20, 2008, reasons – 2008 FCA 186, 2007 FC 1318.)

## Other decisions

**Licensee may claim equitable relief in patent infringement action.** In a patent infringement action relating to **ramipril** (sanofi-aventis' **ALTACE**), sanofi-aventis had brought a motion to strike paragraphs from Apotex's statement of defence which denied the entitlement of the plaintiffs to an accounting of profits on the basis of inequitable and unlawful conduct on the part of plaintiffs in entering into arrangements and agreements with ratiopharm by way of alleged anti-competitive activity. The motions Judge had held that one of the sanofi-aventis plaintiffs, sanofi-aventis Canada, was not entitled to claim equitable relief because it was a mere licensee and therefore, because the impugned paragraphs were raised as a defence to a claim that sanofi-aventis Canada was not entitled to make, that portion of the claim was struck out against sanofi-aventis Canada. The Court of Appeal, however, confirmed that a licensee is entitled to equitable relief and also confirmed that a party claiming equitable relief will not be disentitled to that relief by virtue of inappropriate conduct on its part, unless that conduct relates directly to the subject matter of that party's claim and the equitable relief sought. As the Court concluded that there was no relationship between the alleged improper conduct and the equitable relief sought, it agreed with the motions Judge that the impugned paragraphs should be struck. (*Apotex v. sanofi-aventis*, May 13, 2008, reasons – 2008 FCA 175.)

# New Court proceedings

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

| | |
|---|---|
| **Medicine:** | orally disintegrating olanzapine tablets (ZYPREXA ZYDIS) |
| **Applicant:** | Eli Lilly Canada Inc |
| **Respondents:** | Pharmascience Inc and The Minister of Health |
| **Respondent/Patentee:** | Eli Lilly and Company Ltd |
| **Date Commenced:** | May 2, 2008 |
| **Court File No:** | T-701-08 |
| **Comment:** | Application for an Order of prohibition until expiry of Patent No. 2,041,113. Novopharm alleges non-infringement and invalidity. |

| | |
|---|---|
| **Medicine:** | orally disintegrating olanzapine tablets (ZYPREXA ZYDIS) |
| **Applicant:** | Eli Lilly Canada Inc |
| **Respondents:** | Pharmascience Inc and The Minister of Health |
| **Respondent/Patentee:** | Eli Lilly and Company Ltd |
| **Date Commenced:** | May 2, 2008 |
| **Court File No:** | T-703-08 |
| **Comment:** | Application for an Order of prohibition until expiry of Patent No. 2,214,005. Novopharm alleges non-infringement, invalidity, and that the patent is ineligible for listing on the Register. |

| | |
|---|---|
| **Medicine:** | valacyclovir (VALTREX) |
| **Applicants:** | GlaxoSmithKline Inc and The Wellcome Foundation Limited |
| **Respondents:** | Apotex Inc and The Minister of Health |
| **Date Commenced:** | May 6, 2008 |
| **Court File No:** | T-714-08 |
| **Comment:** | Application for an Order of prohibition until expiry of Patent No. 1,340,083. Apotex alleges non-infringement, invalidity, and that the patent is ineligible for listing on the Register. |

| | |
|---|---|
| **Medicine:** | risedronate sodium (ACTONEL) |
| **Applicants:** | Procter & Gamble Pharmaceuticals Canada Inc and The Procter & Gamble Company |
| **Respondents:** | The Minister of Health and Pharmascience Inc |
| **Date Commenced:** | May 16, 2008 |
| **Court File No:** | T-777-08 |
| **Comment:** | Application for an Order of prohibition until expiry of Patent No. 1,320,727. Pharmascience alleges non-infringement, invalidity, and that the patent is ineligible for listing on the Register. |

| | |
|---|---|
| **Medicine:** | methyphenidate hydrochloride (CONCERTA) |
| **Applicants:** | Janssen-Ortho Inc and Alza Corporation |
| **Respondents:** | The Minister of Health and Novopharm Limited |
| **Date Commenced:** | May 16, 2008 |
| **Court File No:** | T-780-08 |
| **Comment:** | Application for an Order of prohibition until expiry of Patent No. 2,264,852. Novopharm alleges non-infringement and that the patent is improperly listed on the Register. |

## Other new proceedings

| | |
|---|---|
| **Medicine:** | vancomycin hydrochloride powder (VANCOMYSOL) |
| **Applicant:** | Canadian Pharmaceutical Technologies International (C.P.T.) Inc |
| **Respondent:** | The Attorney General of Canada |
| **Date Commenced:** | May 5, 2008 |
| **Court File No:** | T-712-08 |
| **Comment:** | Application for judicial review of the Minster of Health's decision that VANCOPAK is a "drug in dosage form", is sold to hospitals and pharmacies in a form which is "ready for use by the consumer" and, as such, is subject to the requirements of the *Food and Drug Regulations*. |

| | |
|---|---|
| **Medicine:** | agents for treating fat deposits (RAPIDCUTS HARDCORE and RAZOR 8) |
| **Plaintiffs:** | Multi Formulations Ltd, IML Formulations Ltd, Pump Formulations Ltd and MTOR Formulations Ltd |
| **Defendants:** | Allmax Nutrition Inc, Healthy Body Services Inc, Ron Torch and Michael Kichuk |
| **Date Commenced:** | May 6, 2008 |
| **Court File No:** | T-724-08 |
| **Comment:** | Patent infringement action relating to Patent No. 2,028,581. |

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

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