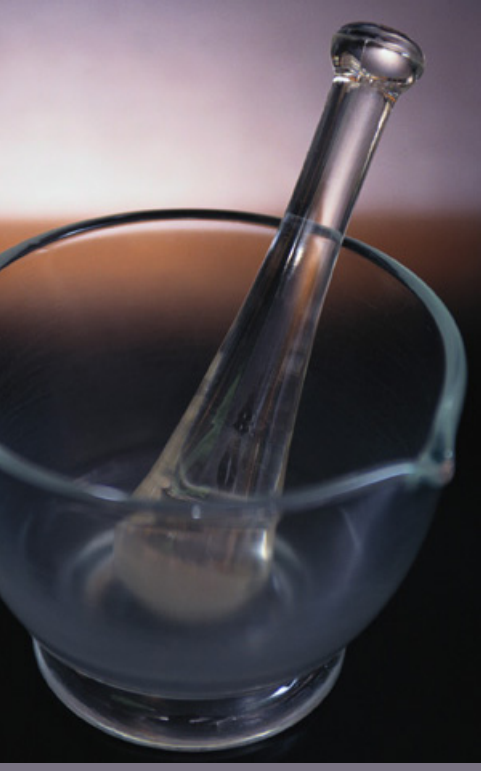

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

April 2008

Federal Court of Appeal clarifies sufficiency requirement for selection patents

As reported in the July 2007 issue of *Rx IP Update*, in *Eli Lilly v. Novopharm*, 2007 FC 596 (appeal dismissed as moot 2007 FCA 359, leave to appeal denied), relating to the medicine **olanzapine (ZYPREXA)**, the Court appeared to have created a new requirement for comparative data in a selection patent. In a March 20, 2008 decision, while not explicitly referring to the *Eli Lilly* decision, the Federal Court of Appeal stated that (i) the Federal Court of Appeal has not suggested that a higher level of disclosure is required for selection patents and (ii) that the Applications Judge was wrong in interpreting the disclosure requirement as requiring that a patentee back up his invention by data (*Pfizer v. Ranbaxy*, 2008 FCA 108).

The Applications Judge (2007 FC 91) had dismissed Pfizer's application for a prohibition Order relating to the patent that claimed the calcium salt of atorvastatin (LIPITOR).
A previous patent had claimed a class of compounds which included atorvastatin. The Judge dismissed the application on the basis of insufficiency, finding that the patent promised a ten-fold increase in activity for atorvastatin (an enantiomer) compared to the racemic mixture, but the data (including data not in the patent) did not substantiate this increase.

The Court of Appeal reversed the decision. It held that there "can be no doubt" that the patent is a selection patent. The Court held that the Judge had erred (i) in construing the patent as promising a ten-fold increase and (ii) focusing his analysis on whether the data substantiates the promise made by the patent. The Court held that the analysis of the data was irrelevant to disclosure requirements, but rather, was relevant to an analysis of the utility, novelty, and/or obviousness of a patent. The Court held as follows regarding the disclosure requirement:

> [59] Only two questions are relevant for the purpose of subsection 27(3) of the Act. What is the invention? How does it work?: see *Consolboard [v. MacMillan Bloedel*, [1981] 1 S.C.R. 504] at 520. In the case of selection patents, answering the question "What is the invention?" involves disclosing the advantages conferred by the selection. If the patent specification (disclosure

> and claims) answers these questions, the inventor has held his part of the bargain. In the case at bar, the 546 patent answers each of these questions.
>
> [60] *What is the invention?* The invention consists of having identified an enantiomer, and in particular the calcium salt of that enantiomer, that is better at inhibiting the biosynthesis of cholesterol than would be expected, given the common knowledge and prior art at the time of application for the patent.
>
> [61] *How does it work?* The 546 patent sets out the methods for producing the compounds covered by the patent.

The Court also concluded that the fact the patent does not provide a justification as to why the calcium salt is the preferred embodiment does not render the disclosure insufficient, as there is no requirement that a patentee explain why and how the invention is useful. The Court also found that the allegations of obviousness, double patenting and anticipation were not justified.

The case is significant as it confirms the disclosure requirements under the *Patent Act* generally and clarifies the disclosure requirements for selection patents, a matter which was in flux following the ZYPREXA decision, for which Eli Lilly did not have the opportunity to pursue its appeal as the appeal was dismissed as moot. As previously reported, further jurisprudence will issue on the topic of selection patents, as the PLAVIX decision will be heard by the Supreme Court on April 16, 2008 (appeal of *Apotex v. Sanofi-Synthelabo*, 2006 FCA 421). Furthermore, Eli Lilly's patent infringement action against Novopharm relating to the ZYPREXA patent is scheduled to be heard in November-December 2008.

Health Canada news

Deadline extended for commenting on draft Guidance for subsequent entry biologics. As reported in the February 2008 issue of *Rx IP Update*, Health Canada has released a draft Guidance for Sponsors regarding information and submission requirements for subsequent entry biologics. The deadline for submitting comments has been extended to April 16, 2008. Health Canada has also requested interested parties to express their interest in participating in a two-day consultation regarding the document in May 2008. (Consultation on Draft Guidance for Sponsors. Draft Guidance Document.)

Health Canada to revise notice of compliance with conditions Policy and Guidance. Health Canada will be revising the notice of compliance with conditions (NOC/c) Policy and Guidance to allow for the filing of abbreviated new drug submissions (ANDSs) relying on a Canadian Reference Product (CRP) that has been issued an NOC/c. Specifically, the revisions will address an ANDS filing when the CRP sponsor has not yet fulfilled the conditions outlined in the Qualifying Notice and Letter of Undertaking. Similar conditions as those imposed for the CRP may be necessary prior to the approval of any subsequent-market entry drug. Until revisions to the Policy and Guidance are finalized, post-marketing conditions requested of the ANDS sponsor will be determined on a case-by-case basis. Draft revisions will be made available for consultation when completed. Any feedback regarding the revisions should be provided by May 2, 2008. (Notice. Policy: notice of compliance with conditions. Guidance document: notice of compliance with conditions.)

Annual performance reports for drug submissions released. The Therapeutic Products Directorate (TPD) and the Biologics and Genetic Therapies Directorate (BGTD) have released their annual drug submission performance reports, which provide statistical information relating to drug submissions, including average approval times. (Therapeutic Products Directorate (TPD) - 2007 Annual Drug Submission Performance Report - Part I. Biologics and Genetic Therapies Directorate (BGTD) - 2007 Annual Drug Submission Report - Part II.)

TPD Spring Newsletter released. The TPD has released its Spring 2008 newsletter. (TPD News – Spring 2008.)

Patented Medicine Prices Review Board news

Amendments to *Patented Medicines Regulations* in force. The *Patented Medicines Regulations* specify the information that patentees must file with the PMPRB and the timeframes for doing so. Following pre-publication on October 5, 2007, the amendments were published on March 19, 2008. The amendments came into force on March 6, 2008, apart from section 7 (see below), which will come into force on July 1, 2008. The Regulatory Impact Analysis Statement provides the following summary of the most salient changes:

- Information identifying the medicine (*i.e.*, Form 1) shall now be accompanied by the product monograph for the medicine or, if a notice of compliance (NOC) has not been issued in respect of the medicine, by information similar to that contained in a product monograph.
- Information identifying the medicine (*i.e.*, Form 1) shall now be provided no later than the earlier of: seven days after the day on which the first NOC is issued in respect of the medicine, and seven days after the day on which the medicine is first offered for sale.
- Where a patented prescription medicine is for human use, information on the identity and prices of the medicine (*i.e.*, Form 2) shall now be provided for the day on which the medicine is first sold in within 30 days after that day.
- For veterinary and over-the-counter medicines, information on the identity and prices of the medicine (*i.e.*, Form 2) shall now be provided on a complaints-based approach, wherein a patentee shall provide to the Board the necessary information for each six-month period beginning on January 1 and July 1 of each year, within 30 days after the date on which the Board sends a request in response to a complaint respecting the price of a medicine, and during the two years following the request within 30 days after each six-month period.
- Patentees are now required to provide information to the Board using a specified electronic document in its original format and file type, bearing the electronic signature of an authorized individual, certifying that the information set out in the document is true and complete (section 7).

(*Regulations Amending the Patented Medicines Regulations, 1994* (SOR/2008-70). *Patented Medicines Regulations* (consolidated to SOR/2008-70). Revised Compendium of Guidelines, Policies and Procedures (2008). Revised Patentee's Guide to Reporting (2008) (including links to electronic Forms 1, 2, and 3.)

Board declines to strictly apply CPI-Adjustment Methodology. The Board conducted a hearing to consider whether Teva Neuroscience sold COPAXONE syringes (glatiramer) at an excessive price, in view of a 20% price increase in 2004. The Board was required to consider whether the increase was to be strictly limited by the Consumer Price Index (CPI) Methodology set out in the Board's Excessive Price Guidelines. The Methodology limits an annual percentage increase to the lesser of (a) the cumulative percentage change in CPI since the benchmark year to a maximum of three years back and (b) 1.5 times the current year forecast change in CPI. The Board decided that because after the price increase COPAXONE remained the lowest price in a group of medicines in its therapeutic class, the patentee may increase the price in excess of the guidelines. The Board also referred to the fact that there were four higher-priced products in the class and that there were costs associated with product improvements (the Board found that the improvement from a vial to a syringe significantly benefited users of COPAXONE). The permitted price increase was based on an amount equal to the CPI increase from the date of the first sale in 1997 (in vial form) until 2004 (approximately 15.9%), divided in three equal, yearly phases commencing in 2004. Teva has filed an application for judicial review. (Reasons.)

Board to determine whether Apotex is a "patentee" subject to the Board's jurisdiction. The Board will be holding a hearing on a date to be set regarding the Board Staff's application for an Order requiring Apotex to disclose whether it is entitled to the benefit of rights in relation to any patents for an invention intended or capable of being used for a medicine or for the preparation or production of a medicine where the medicine is being sold in Canada by Apotex or it has a notice of compliance. Board Staff is also seeking production of Form 1, Form 2 and Form 3 information regarding any such medicines, other than Apo-Salvent (for which Apotex does not dispute the jurisdiction of the Board). The notice of application refers to a number of patents owned by Apotex Pharmachem that pertain to some of Apotex's medicines sold in Canada. (Notice of hearing. Notice of application.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Order of prohibition reversed after patent delisted. sanofi-aventis had obtained an Order of prohibition relating to the medicine **cefotaxime (CLAFORAN)**, *Aventis Pharma v. Mayne*, 2005 FC 1183. After that decision, the Minister delisted the patent. sanofi-aventis challenged that decision by way of judicial review on the basis that the Minister was estopped, but was unsuccessful (*sanofi-aventis v. Mayne*, 2007 FC 545). Mayne therefore brought a motion in the Court of Appeal in the context of its appeal, seeking to set aside the Order of prohibition. The Court (2008 FCA 21) held that "if the prohibition order is allowed to stand, the respondent will have the benefit of a remedy which is not available outside the context of the PM(NOC) Regs in a case where no basis exists under those regulations for the remedy". The Court decided the matter went to the merits of the appeal and therefore set aside the prohibition Order as of the date of its decision and the application for a prohibition Order was dismissed as of that date.

Federal Court applies "Wyeth" relevance requirement. As previously reported, the Federal Court of Appeal in *Wyeth Canada v. ratiopharm Inc.*, 2007 FCA 264 (leave to appeal to SCC denied) had agreed with the Applications Judge that there must be relevance between the patent and the submission against which the patent is listed under the pre-amended *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*").

This decision was recently applied in four cases.

The first three cases related to the medicine, **pantoprazole**, Nycomed's **PANTOLOC**.

The first is *Solvay Pharma and Altana (now Nycomed) v. Apotex*, 2008 FC 308, which was a decision following a hearing on the merits. The Judge decided that absent a section 6(5)(a) motion, the Court has no jurisdiction to consider eligibility issues. However, the Court must consider whether the claims that are at issue regarding infringement are claims for the medicine itself or for the use of the medicine, because only claims of the former type can justify a prohibition Order. The Judge considered the eligibility issues in the alternative.

The Judge concluded that the first patented invention ('694) was the use of pantoprazole as an antimicrobial to treat H. pylori infection and gastrointestinal diseases arising therefrom and that the patent was not eligible for listing against NOCs for prevention of lesions induced by NSAIDs and eradication of H. pylori infection associated with an active ulcer (as the role of pantoprazole was as a proton-pump inhibitor, not an antimicrobial).

Regarding the second patent ('748, construed as a composition combining pantoprazole and a Helicobacter-inhibiting antimicrobial agent, such components being administered concurrently or non-concurrently), while the Judge made no explicit ruling, she did question Health Canada's view that "patents claiming the use of a medicine in combination with one or more other medicines are eligible for listing against that medicine where the use of said combination is found in the indication section of the drug approved Product Monograph and the patent allows for separate administration".

The second decision arose from a section 6(5)(a) motion: *Nycomed GmbH and Nycomed Canada Inc. v. The Minister of Health and Genpharm Inc.*, 2008 FC 330, and involved the same patents as the first. The Prothonotary decided that the '694 patent was ineligible, but that the '748 patent was eligible for listing. As a preliminary matter, the Prothonotary rejected Genpharm's argument that the application should be dismissed as Nycomed failed to lead evidence in the application that the patents were properly listed. The Prothonotary held that the '694 patent was ineligible for listing against a submission for the use of pantoprazole as a proton-pump inhibitor in combination with specific antibiotics as the patent relates to the use of pantoprazole as an antimicrobial. The Prothonotary found that the '748 patent, which related to the use of the pharmaceutical composition of pantoprazole and one or more HIAMAS which in combination have the desired effect of treating gastrointestinal diseases caused by H. pylori infection, was relevant to a submission for the use of pantoprazole in combination with clarithromycin and either amoxicillin or metronidazole. The Prothonotary held that as a result of the change in use, the use of pantoprazole had the potential to infringe the '748 patent. Genpharm has appealed.

The third decision, *Nycomed v. Novopharm*, 2008 FC 313, also arose from a section 6(5)(a) motion. The Prothonotary held that the

invention was in respect of the new formulations, not uses of pantoprazole, despite the existence of "use" claims (for example, "use of the medicament according to any one of Claims 1-30 to inhibit H+/K+-ATPase"), as she held that the use of pantoprazole as a proton pump inhibitor was known as of the priority date; adding the known use did not add anything to the invention claimed. The Prothonotary granted the motion, finding that each of the submissions relate only to new uses that are not disclosed or claimed in the patent and do not form part of the patented invention disclosed by the patent (treatment of H. pylori infections associated with active duodenal ulcers when used in combination with appropriate antibiotics; treatment of symptomatic GERD; prevention of gastrointestinal lesions induced by NSAIDs in patients requiring continuous NSAID therapy). Nycomed's appeal is scheduled for April 17, 2008.

The final decision, *Abbott v. Sandoz*, 2008 FC 352, relates to the medicine **clarithromycin (BIAXIN)**. One SNDS was for a new indication for use of clarithromycin in triple therapy to treat H. pylori. The Judge held that the patents at issue all contain claims for the use of medicinal crystal forms of clarithromycin in the treatment of bacterial infections such as H. pylori whether alone or in combination. The Judge, in assessing whether relevance had been met, considered whether the change made by the NOC "may be relevant to the potential infringement of the use claims contained in the Abbott Patents". The Judge concluded there was a sufficient linkage. The Judge however found that nothing in a second SNDS (new formulation of the tablet) could be relevant to the potential infringement of the patent claims and therefore dismissed the application relating to the listing of the patents against that NOC. Sandoz has appealed.

Court of Appeal dismisses impeachment action after patent expires. AstraZeneca had obtained a prohibition Order in 2003 against Apotex relating to the medicine **omeprazole** (AstraZeneca's **LOSEC**) and a patent claiming novel salts of omeprazole (*AstraZeneca v. Apotex*, 2003 FCT 771). Apotex then brought an impeachment action in 2003, which was set down for a ten-day trial in February 2009. Following expiry of the patent in January 2007, AstraZeneca brought a motion seeking dismissal of the action. While a Prothonotary and Judge on appeal declined to dismiss the action, the Court of Appeal dismissed the action as moot (2008 FCA 88), declining to exercise its discretion to hear the moot dispute. The Court rejected Apotex's argument based on a possible section 8 claim which would be commenced if the action (and another action relating to another patent) were successful and the corresponding prohibition Orders were overturned *ab initio*. The Court concluded that the concern for judicial economy strongly militated against allowing the action to proceed.

Two further allegations of non-infringement of "use" patents justified. In two further Federal Court cases, the Court has dismissed applications for Orders of prohibition relating to "use" patents.

In *sanofi-aventis v. Riva*, 2008 FC 291, relating to **ramipril** (sanofi-aventis' **ALTACE**), Riva alleged that it does not seek approval for any use other than the "old" use, hypertension, and in its product monograph, Riva will not include any statement encouraging any of the claimed uses (use of ramipril for the management of patients at increased risk of cardiovascular events). Among sanofi-aventis' arguments was that the focus of Riva's marketing efforts will be to provide financial inducements to pharmacists to encourage them to stock only Riva-Ramipril as the exclusive generic ramipril. In dismissing the application, the Judge held that the evidence does not establish that Riva will be providing financial incentives to pharmacists to compel them to dispense Riva-Ramipril for the patented use.

In *Solvay Pharma and Altana (now Nycomed) v. Apotex*, 2008 FC 308 (the first patent listing case referred to above), the Court considered Apotex's allegation of non-infringement relating to two claims of the '748 patent (construed as a composition combining pantoprazole and a Helicobacter-inhibiting antimicrobial agent, such components being administered concurrently or non-concurrently). The Court could not conclude that Apotex intends to market its tablets for use as part of the triple therapy regime and had not otherwise established a causal link between Apotex's actions and its proposed product monograph (the Judge found that the dosage could not be construed as referring to the standard triple therapy regimen) and the direct infringement it was asked to assume.

Notice of appearance by respondent-patentee struck. Sepracor, a patentee, had been named a respondent in a prohibition proceeding. Pharmascience brought a motion to strike Sepracor's notice of appearance, on the basis that it had replaced "oppose" with "participate" in the form (*Schering-Plough and Schering v. Pharmascience and Sepracor*, 2008 FC 359). The Judge struck the notice of appearance. While he determined that Sepracor was properly named as a respondent, he held that if Sepracor wishes to make representations that *support* the application, it must seek intervener status or apply to be joined as an applicant. Sepracor has appealed.

New proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	pantoprazole sodium tablets (PANTOLOC)
Plaintiff:	Novopharm Limited
Respondents:	Nycomed Canada Inc, Nycomed GmbH and Nycomed International Management GmbH
Date Commenced:	March 7, 2008
Court File No:	T-368-08
Comment:	Action for damages pursuant to section 8 of the *Regulations* and section 36 of the *Competition Act*.

Medicine:	esomeprazole magnesium tablets (NEXIUM)
Applicants:	AstraZeneca Canada Inc and AstraZeneca Aktiebolag
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	March 7, 2008
Court File No:	T-371-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,139,653. Apotex alleges non-infringement and invalidity.

Medicine:	esomeprazole magnesium tablets (NEXIUM)
Applicants:	AstraZeneca Canada Inc and AstraZeneca AB
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	March 7, 2008
Court File No:	T-372-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,290,963. Apotex alleges non-infringement and invalidity.

Medicine:	esomeprazole magnesium tablets (NEXIUM)
Applicants:	AstraZeneca Canada Inc and AstraZeneca AB
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	March 7, 2008
Court File No:	T-373-08
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 2,166,483 and 2,166,794. Apotex alleges non-infringement.

Medicine:	esomeprazole magnesium tablets (NEXIUM)
Applicants:	AstraZeneca Canada Inc and AstraZeneca AB and Aktiebolaget Hässle
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	March 7, 2008
Court File No:	T-374-08
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 1,292,693, 1,302,891 and 2,186,037. Apotex alleges non-infringement and invalidity ('891 and '037 patents only).

Medicine:	esomeprazole magnesium tablets (NEXIUM)
Applicants:	AstraZeneca Canada Inc and AstraZeneca AB
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	March 7, 2008
Court File No:	T-376-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,290,531. Apotex alleges non-infringement.

Medicine:	esomeprazole magnesium tablets (NEXIUM)
Applicants:	AstraZeneca Canada Inc
Respondents:	Apotex Inc and The Minister of Health
Respondent/Patentee:	Takeda Pharmaceutical Company Limited
Date Commenced:	March 7, 2008
Court File No:	T-377-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,338,377. Apotex alleges non-infringement.

Medicine:	esomeprazole magnesium tablets (NEXIUM)
Applicants:	AstraZeneca Canada Inc and AstraZeneca AB
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	March 7, 2008
Court File No:	T-378-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,170,647. Apotex alleges non-infringement.

Medicine:	olanzapine orally dispersing tablets (ZYPREXA ZYDIS)
Applicant:	Eli Lilly Canada Inc
Respondents:	Attorney General of Canada and The Minister of Health and Pharmascience Inc
Date Commenced:	March 7, 2008
Court File No:	T-382-08
Comment:	Application for a declaration that Patent No 2,265,712 is eligible for listing on the Patent Register as of the date the patent lists were submitted (November 27, 2006), rather than the date that notice was provided to Lilly Canada that the patent would be listed on the Patent Register (November 19, 2007), and an order in the nature of mandamus compelling the Minister to require all second entry manufacturers to address the '712 patent in compliance with section 5 of the *Regulations*.

Other new proceedings

Medicine:	venlafaxine hydrochloride extended release tablets (EFFEXOR XR)
Plaintiffs:	Wyeth and Wyeth-Whitehall Pharmaceuticals Inc
Defendant:	Pharmascience Inc
Date Commenced:	February 26, 2008
Court File No:	T-306-08
Comment:	Patent infringement action relating to Patent No. 2,199,778.

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

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