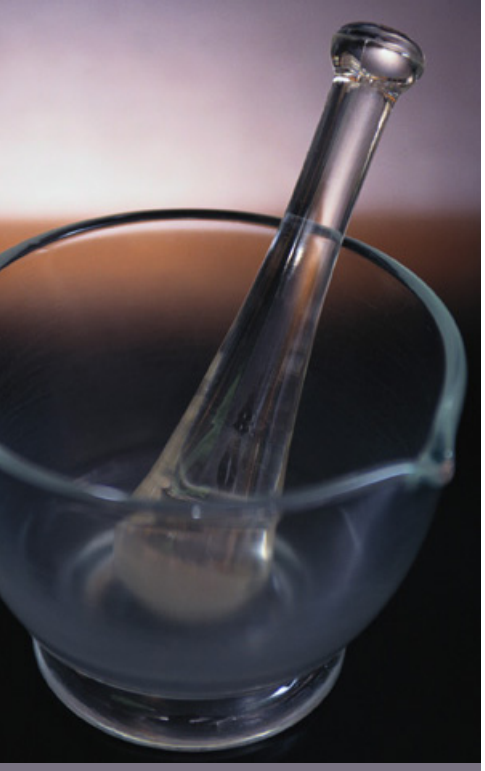

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

May 2008

Proposed amendments to linkage *Regulations* – May 11 deadline for comments

As reported in the April 2008 Special Edition of *Rx IP Update*, on April 26, 2008, the Government published proposed amendments to the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") that would undo a 2007 Federal Court decision, upheld by the Federal Court of Appeal, finding that for patent lists submitted under the pre-2006 amended *Regulations*, "relevance" is required between a patent and the submission against which it is listed (*Wyeth Canada v. ratiopharm Inc.*, 2007 FC 340, rev'd 2007 FCA 264, leave denied).

The 15-day comment period will expire on May 11, 2008. If the amendments to the *Regulations* are adopted as published, there will be a 30-day period after the coming into force date within which to request that the Minister of Health list patents on the Patent Register that were refused for listing or delisted, and to which the amendments apply.

Patented Medicine Prices Review Board news

Board departs from Excessive Price Guidelines in assessing pricing of ADDERALL XR. On April 10, 2008, the Board released a decision following a hearing to determine whether ADDERALL XR has been sold by Shire in Canada at excessive prices. While the Board decided that ADDERALL XR was sold by Shire at excessive prices, it agreed with Shire that ADDERALL XR is a medicine with benefits relative to existing medicines of the same class (medicines to treat attention deficit hyperactivity disorder (ADHD)) that entitle Shire to sell ADDERALL XR at a price exceeding that indicated by the Excessive Price Guidelines.

The Board held that the onus is on Board staff to satisfy the hearing panel on two points before a finding of excessive pricing is reached: (i) that the Guidelines represent an appropriate

implementation and particularization of section 85 of the *Act*; and (ii) that the pricing of the medicine exceeds the Guidelines. The hearing panel must be satisfied that the Guidelines provide for an appropriate application of the terms of section 85 of the *Act* in the circumstances of the case before it.

The Panel found that the distinction in the Guidelines between Category 1, Category 2 and Category 3 medicines, and the different pricing tests in the Guidelines for determining the maximum non-excessive prices of medicines in each category, are appropriate implementations of section 85 of the *Act*. However, it decided that neither Category 2 nor Category 3 adequately captured the relationship between ADDERALL XR and the multiple daily dose ADHD medicines: it provides more than a moderate improvement over multiple daily dose ADHD medicines, yet there is no reliable evidence that there is a material therapeutic advantage over the multiple daily dose medicines, or significant savings to the health care system. The Panel therefore set the maximum non-excessive price (MNE) at the mid-point between the MNEs that would be generated by the two tests. (Full decision.)

New newsletter released. The PMPRB has released the April 2008 NEWSletter, which includes a summary of the major proposals and options found in the discussion paper Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines, and stakeholder feedback and preliminary responses from the Board.

Government proposes amendments to *Food and Drugs Act* and new *Canada Consumer Product Safety Act*. On April 8, 2008, the federal Government tabled two bills: Bill C-51, *An Act to amend the Food and Drugs Act and to make consequential amendments to other Acts*, and Bill C-52, *An Act respecting the safety of consumer products*. Both bills are key components of Canada's new Food and Consumer Safety Action Plan.

Bill C-51. According to the Government, "proposed amendments to the Food and Drugs Act would modernize our regulation of health products and food; provide new tools that more quickly and effectively protect Canadians; and, provide better information that empowers Canadians to play a more active role in their own health and safety. The proposed amendments to the Food and Drugs Act are a key component of Canada's new Food and Consumer Safety Action Plan."

The Government describes the proposed amendments as focussing on three key areas:

(i) Active prevention (outline key elements of a product life cycle approach, which would permit continuing safety oversight during a product's full life cycle after it hits the market);

(ii) Targeted oversight (enable Health Canada to develop regulations requiring a mandatory adverse drug reaction reporting requirement for health care institutions); and

(iii) Rapid response (ensure that those contemplating actions that would jeopardize the health and safety of Canadians face effective deterrents).

(Modernizing the *Food and Drugs Act* - Fact Sheet. Product Life Cycle Approach – Clarification.)

Bill C-52. Bill C-52 would replace Part I of the *Hazardous Products Act*.

The Government describes these amendments as also focussing on three key areas:

(i) Active prevention (provide better safety information to consumers and guidance to industries on building or improving safety throughout their supply chains; introduce a general prohibition against the manufacture, importation, advertisement or sale of consumer products that are a danger to human health or safety);

(ii) Targeted oversight (require companies that produce consumer products to conduct safety tests and provide the results where there are indications of a problem; require suppliers to notify Health Canada of reports of adverse incidents/defects); and

(iii) Rapid response (provide Health Canada with the power to pull unsafe consumer products from store shelves and order mandatory recalls or other corrective measures, and require suppliers to notify Health Canada and their product source of reports of adverse incidents/defects).

(*Canada Consumer Product Safety Act* - Fact Sheet.)

Supreme Court of Canada matters

***Apotex v. Attorney General of Québec*, April 10, 2008.** The Court dismissed Apotex's leave application regarding the Quebec Court of Appeal's dismissal of its appeal from a Judge's decision to permit the intervenor, the Attorney General, to participate in examinations for discovery in this action by the Régie de l'assurance maladie du Québec (the organization responsible for Quebec's health insurance plan). The RAMQ claims damages against Apotex in relation to alleged violations of the *Act Respecting Prescription Drug Insurance* and regulations through discounts, promotions and gratuities to pharmacists. (Court of Appeal decision – 2007 QCCA 1426. Superior Court Judge's decision – 2006 QCCS 3662. Both decisions in French only.)

***Apotex v. Sanofi-Synthelabo* (clopidrogel (PLAVIX)), April 16, 2008.** 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 a selection patent. Apotex's appeal was heard on April 16, 2008 and a decision was taken under reserve.

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Federal Court considers listing requirements under new *Regulations*. The October 2006 amendments to the *Regulations* substantially amended the requirements for patent listing. One of the amendments was the addition of a "claim for the formulation" to the list of eligible claims. In *G.D. Searle and Pfizer v. Minister of Health*, the Court considered whether "claim for the use of the medicinal ingredient" under the amended *Regulations* includes a claim for the use of a formulation containing the medicinal ingredient. The Court concluded that such a claim could fall within the definition, but to make that determination, the jurisprudence under the pre-amended *Regulations* considering "whether it is in fact the use of the medicinal ingredient that is claimed, or simply the use of the formulation or dosage form" must be applied.

Analyzing the issue, the Court agreed with the Minister that the claims were not for the use of **celecoxib** (Pfizer's **CELEBREX**), and were therefore not claims for the use of the medicinal ingredient. As a result, the Court found that the patent was ineligible for listing against a supplementary new drug submission (SNDS) for a new indication.

The Court also considered whether the approved uses fell within the scope of the claims. The Court held that it would be entirely impractical to require that the indications in the SNDS read identically with the claims, and that requiring as such would lead to absurd results given the time difference and the varying concerns of the two audiences to whom the indications and the claims are directed. Thus, the Court was satisfied that the claims cover the changed use of the SNDS.

The appeal of a previous decision of the Court, which also rejected a strict matching requirement for relevance between the patent and submission against which it is listed (*Abbott Laboratories v. Canada (Attorney General)*, 2007 FC 797), is scheduled to be heard on June 11, 2008. (*G.D. Searle and Pfizer v. Minister of Health*, April 4, 2008. Full judgment – 2008 FC 437.)

Generic cannot avoid *Regulations* by conducting bioequivalence studies using different strength. Servier has a patent listed against **COVERSYL (perindopril)** 2 mg and 4 mg tablets, but not against the 8 mg tablets. Apotex filed an abbreviated new drug submission (ANDS) for perindopril and included comparative data only against COVERSYL 8 mg, including for the 2 mg and 4 mg tablets, requesting a waiver of the requirement to submit additional bioavailability data for its 2 mg and 4 mg strengths pursuant to a Health Canada policy. Health Canada decided that Apotex was required to address the patent as an ANDS, requiring inclusion of a comparison with a Canadian reference product (in this case, COVERSYL 2 mg and 4 mg strengths) for the purpose of demonstrating bioequivalence, was sufficient to trigger section 5(1) of the *Regulations*. Apotex sought judicial review. Although Apotex subsequently addressed the patent and a proceeding was commenced, the Judge permitted Apotex's judicial review to

proceed despite its mootness. The Judge dismissed Apotex's application, finding the Minister was correct in requiring Apotex to address the patent. (*Apotex v. Servier*, April 14, 2008. Full judgment – 2008 FC 475.)

Abuse of process doctrine considered in three further cases. Increasingly, parties have been raising abuse of process arguments in the context of prohibition proceedings. Three cases have considered this doctrine in different contexts.

Pursuing same allegation of infringement against second generic found to be abuse of process. A Prothonotary summarily dismissed a proceeding against Novopharm relating to **pantoprazole** (Nycomed's **PANTOLOC**) as an abuse of process. The patents generally relate to the new use of pantoprazole for the treatment of *H. pylori* bacterial infections. Novopharm had argued that Nycomed's prohibition application constituted an abuse of process because Nycomed was attempting to relitigate issues that had been decided in a proceeding against Apotex (*Solvay Pharma v. Apotex*, 2008 FC 308). The Prothonotary was satisfied that Novopharm made the same allegations of non-infringement based on the same factual nexus that was considered in the previous decision. The Prothonotary relied on *sanofi-aventis v. Novopharm*, 2007 FCA 163, wherein the Court of Appeal upheld a Judge's finding that it was abusive for a first person to pursue a prohibition proceeding against a second generic making the same allegation of invalidity. Nycomed has brought a motion for reconsideration. (*Nycomed Canada and Nycomed GmbH v. Novopharm*, April 8, 2008. Full judgment – 2008 FC 454.)

Pharmascience precluded from asserting obviousness challenge in view of earlier unsuccessful generic challenge by ratiopharm. In a prohibition proceeding relating to **amlodipine** (Pfizer's **NORVASC**), the Applications Judge, Justice Hughes, held that in assessing a generic's allegation, the Court must consider whether the matter has been previously determined even if the generic is different, and if so, whether the present generic has "better evidence or a more appropriate legal argument". This decision is consistent with Justice Hughes' previous decision, *Pfizer v. Novopharm*, 2008 FC 11. Applying this test, Justice Hughes concluded that Pharmascience is precluded by an earlier decision involving the same drug but a different generic, ratiopharm (*Pfizer v. ratiopharm*, 2006 FCA 214), from asserting obviousness of the patent at issue, which claimed the besylate salt of amlodipine. However, Justice Hughes held that if obviousness could be considered, he would find that Pfizer had failed to displace the burden of proof that Novopharm's allegation of obviousness is not justified. Justice Hughes held that while Pharmascience was not precluded from alleging lack of sufficiency and lack of utility, these attacks failed. Accordingly, a prohibition Order was granted. (*Pfizer v. Pharmascience*, April 17, 2008. Full judgment – 2008 FC 500.)

Not an abuse of process to pursue proceeding while pursuing appeal of prior unfavourable decision against another generic. The Court had dismissed Eli Lilly's application for a prohibition Order regarding **raloxifene** (Eli Lilly's **EVISTA**) and Apotex (*Eli Lilly v. Apotex*, 2008 FC 142), finding that Apotex's allegation of lack of sound prediction was justified. Novopharm, which had also filed a submission for raloxifene and had made an allegation of lack of sound prediction regarding the same patent, brought a motion for summary dismissal of the proceeding commenced by Eli Lilly, relying on *sanofi-aventis v. Novopharm*, 2007 FCA 163. As Eli Lilly's appeal of the Apotex decision was likely to be determined before the hearing of this application on its merits, and before either Apotex or Novopharm were in a position to receive a notice of compliance (NOC), the Prothonotary held that Eli Lilly's prosecution of the application was not an abuse of process. Novopharm has appealed. (*Eli Lilly v. Novopharm*, April 18, 2008. Full judgment – 2008 FC 513.)

Proceeding against Apotex regarding modafinil (ALLERTEC) dismissed. The Court dismissed an application for a prohibition Order regarding Apotex, **modafinil** (Shire's **ALLERTEC**), and a patent claiming a pharmaceutical composition comprising modafinil. The Judge found that Shire had failed to establish that Apotex's allegations of invalidity on the grounds of anticipation, obviousness, and utility are not justified. (*Shire v. Apotex*, April 25, 2008. Full judgment – 2008 FC 538.)

Other decisions

Court dismisses application to disqualify PMPRB counsel as premature. sanofi pasteur brought an application for judicial review of the decision by the PMPRB not to accept the recommendation by Blake Cassels & Graydon LLP that it step down as Board counsel. sanofi pasteur alleged that the fact that Blakes has a current relationship with an entity that advocated an interest clearly contrary to the applicant (GlaxoSmithKline) raises a reasonable apprehension of bias. The Order arose from a motion brought prior to the commencement of a hearing to determine whether **QUADRACEL** and **PENTACEL** vaccines were sold at excessive prices. The Judge found that there were no special circumstances which warranted the immediate judicial review of the interlocutory decision. (*sanofi pasteur v. Attorney General of Canada*, March 4, 2008. Full judgment – 2008 FC 286.)

CIRA orders zantac.ca transferred to Johnson & Johnson. On March 11, 2008, the Canadian Internet Registration Authority ordered the domain name **zantac.ca** to be transferred from Globe Media International Corporation to the complainant, Johnson & Johnson. The CIRA was satisfied that: the domain name is "confusingly similar" to Johnson & Johnson's registered trade-mark, ZANTAC; Johnson & Johnson had rights in the mark prior to the registration of the domain name, and Johnson & Johnson continues to have rights in ZANTAC; the Registrant had registered the domain name in bad faith; and, the Registrant has not proven that it has a legitimate interest in the domain name.
(Full decision.)

New proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	amlodipine besylate (NORVASC)
Applicants:	Pfizer Canada Inc, Pfizer Limited and Pfizer Research and Development Company, NV/SA
Respondents:	Pharmascience Inc and The Minister of Health
Date Commenced:	April 10, 2008
Court File No:	T-575-08
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 1,321,393 and 2,170,278. Pharmascience alleges non-infringement and invalidity ('393 patent) and non-infringement and ineligibility for listing ('278 patent).

Medicine:	valacyclovir (VALTREX)
Applicants:	GlaxoSmithKline Inc and The Welcome Foundation Limited
Respondents:	Cobalt Pharmaceuticals Inc and The Minister of Health
Date Commenced:	April 11, 2008
Court File No:	T-578-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,340,083. Cobalt alleges non-infringement, invalidity, and ineligibility for listing.

Medicine:	ramipril (ALTACE)
Applicant:	sanofi-aventis Canada Inc
Respondents:	The Minister of Health, The Attorney General of Canada and Laboratoire Riva Inc
Date Commenced:	April 11, 2008
Court File No:	T-584-08
Comment:	Application for an Order quashing the NOC issued to Riva. The NOC was issued in circumstances where Minister is prohibited from issuing an NOC to Pharmascience, and Riva's submission is cross-referenced to Pharmascience's submission.

Medicine:	pantoprazole (PANTOLOC)
Applicants:	Nycomed Canada Inc and Nycomed GmbH
Respondents:	The Minister of Health and Pharmascience Inc
Date Commenced:	April 18, 2008
Court File No:	T-608-08
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 2,089,748, 2,092,694 and 2,109,697. Pharmascience alleges non-infringement and invalidity in respect of all three patents. Pharmascience also alleges that all three patents are improperly listed on the Patent Register.

Other new proceedings

Medicine:	acetylsalicylic acid 81 mg tablet (Apo-ASA)
Applicant:	Apotex Inc
Respondent:	The Minister of Health and Attorney General of Canada
Date Commenced:	March 11, 2008
Court File No:	T-394-08
Comment:	Application for an Order compelling the Minister to issue an NOC to Apotex. Apotex alleges that the data submitted in its ANDS demonstrates that Apo-ASA is safe and effective, despite Apotex's failure to demonstrate bioequivalence with Bayer's ASA.

Medicine:	glatiramer (COPAXONE)
Applicant:	Teva Neuroscience GP-SENC
Respondent:	Attorney General of Canada
Date Commenced:	March 27, 2008
Court File No:	T-470-08
Comment:	Application for an Order quashing the decision of the PMPRB, finding that Teva had sold COPAXONE at an excessive price.

Trade-mark:	COBALT and COBALT PHARMACEUTICALS
Plaintiff:	Cobalt Pharmaceuticals Inc
Defendants:	Wm. Wrigley Jr. Company, Wrigley Canada Inc and Wrigley Canada Holding Inc
Date Commenced:	March 28, 2008
Court File No:	T-510-08
Comment:	Action for damages pursuant to the *Competition Act* and *Trade-marks Act* for trade-mark infringement, passing off, and the making of false and misleading representations. The claim is based on the alleged sale and advertising of "Cobalt" flavoured gum product.

Biologic:	Recombinant human erythropoetin (EPREX, MIRCERA)
Plaintiffs:	Kirin-Amgen Inc and Janssen-Ortho Inc
Defendant:	Hoffman-La Roche Limited
Date Commenced:	April 3, 2008
Court File No:	T-534-08
Comment:	Patent infringement action regarding Patent No 1,339,047.

Medicine:	tazobactam sodium/piperacillin sodium (TAZOCIN)
Applicant:	Wyeth Canada
Respondents:	The Minister of Health and Pharmaceutical Partners of Canada Inc
Date Commenced:	April 9, 2008
Court File No:	T-560-08
Comment:	Application for an Order quashing the NOC issued to PPC. Wyeth alleges that there will be serious health risks to patients and that it will have been treated unfairly should the PPC product, a generic version of the old formulation of TAZOCIN, be marketed alongside its reformulated version of TAZOCIN in view of their different compatibility profiles.

Medicine:	tazobactam sodium/piperacillin sodium (TAZOCIN)
Applicant:	Wyeth Canada
Respondents:	The Minister of Health and Strides Canada Inc
Date Commenced:	April 9, 2008
Court File No:	T-561-08
Comment:	Application for an Order quashing the NOC issued to Strides. Wyeth alleges that there will be serious health risks to patients and that it will have been treated unfairly should the Strides product, a generic version of the old formulation of TAZOCIN, be marketed alongside its reformulated version of TAZOCIN in view of their different compatibility profiles.

Biologic:	vancomycin (hydrochloride) powder (VANCOMYSOL/VANCOPAK)
Applicant:	Canadian Pharmaceutical Technologies International (CPT) Inc
Respondent:	Le Procureur Général du Canada (The Attorney General of Canada)
Date Commenced:	April 14, 2008
Court File No:	T-589-08
Comment:	Action for damages for alleged negligence by Health Canada in connection with its decision that VANCOPAK is a drug rather than an active pharmaceutical ingredient sold for compounding purposes and as such is subject to the *Food and Drug Regulations*.

Trade-mark:	PREOS
Applicant:	NPS Pharmaceuticals Inc
Respondents:	BioPharma, Société par Actions Simplifiée
Date Commenced:	April 14, 2008
Court File No:	T-593-08
Comment:	Application for an Order setting aside the decision of the Registrar of Trade-marks which had allowed an opposition to application for PREOS for use in association with "Pharmaceutical preparations for the prevention or treatment of osteoporosis; Pharmaceutical preparations for the prevention or treatment of bone metabolism-related disorders or diseases" and ordering the Registrar of Trade-marks to allow the application. The opposition was allowed on the basis of confusion with PROTOS for use in association with "Pharmaceutical preparation for the prevention or treatment of osteoporosis".

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

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