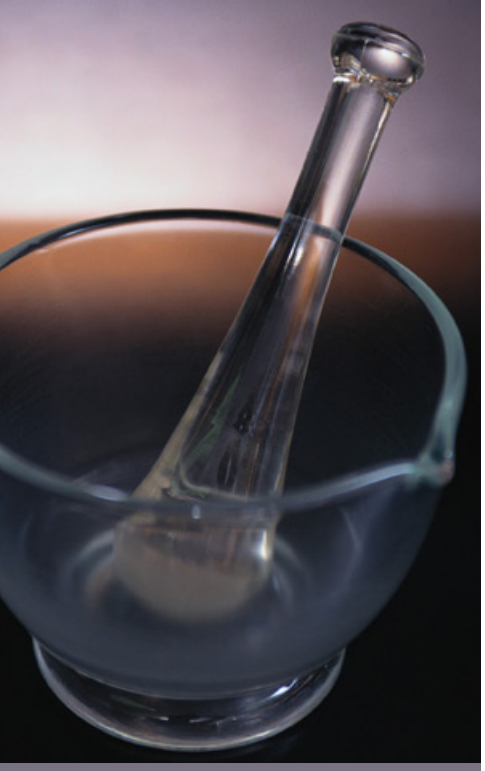

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

October 2008

Innovators challenge PMPRB Stakeholder Communiqué

As reported in the September 2008 issue of *Rx IP Update*, on August 18, 2008, the Patented Medicine Prices Review Board (PMPRB) released a Stakeholder Communiqué relating to the reporting of benefits which states that the Board will insist upon mandatory reporting of benefits beginning with the January to June 2009 reporting period. In particular, it states that "the calculation of the Average Price must include any and all benefits listed in sub-section 4(4) of the Regulations that are connected to sales transactions: rebates (including rebates/payments to third parties); discounts; free goods; free services; gifts; and other benefits of a like nature". (Stakeholder Communiqué.)

On September 17, 2008, separate applications for judicial review in the Federal Court were commenced by Pfizer Canada (T-1442-08) and Canada's Research-Based Pharmaceutical Companies (Rx&D) and seventeen innovative pharmaceuticals companies (T-1447-07). The applicants seek an Order setting aside the decision of the Board as communicated in the communiqué insofar as it directs patentees to include benefits granted to "third parties" in their reports to the Board. The applicants plead that the decision is outside the jurisdiction of the Board under the *Patent Act* and outside the jurisdiction of Parliament under the *Constitution Act, 1867*. Pfizer pleads that the pricing and sales information that is required to be reported relates only to the "actual" sales made by the patentee to its customer and that there is no requirement under the *Patented Medicines Regulations* for patentees to report any benefits to third parties or expenditures not directly related to the actual price or actual revenue for the sale. Similarly, the applicants in the Rx&D proceeding plead that there is no requirement under the *Regulations* for patentees to report benefits granted to anyone who is not a customer in such sales transactions.

Patented Medicine Prices Review Board news

The Patented Medicine Prices Review Board (PMPRB) has applied for an Order imposing reporting requirements on ratiopharm in relation to ratio-Fluticasone and ratio-Paroxetine, allegedly sold pursuant to agreements with GlaxoSmithKline, and all other patented medicines that ratiopharm sells in any market in Canada under licence from a patent holder. On August 28, 2008, the PMPRB issued a Notice of Hearing, on a date to be set. (Notice of Hearing. Application.)

The pre-hearing conference in the matter of Apotex's Apo-Salvent CFC Free, which had been scheduled for September 29, 2008, was postponed with a new date to be announced shortly. As reported in the August 2008 issue of *Rx IP Update*, the hearing has been scheduled for December 8, 2008. (Update.)

Recent Court decisions

Pfizer's motion for production of documents related to Pharmascience's drug submission dismissed. Pfizer brought a motion seeking production of a number of documents related to Pharmascience's drug submission in respect of amlodipine mesylate tablet (Pfizer's NORVASC contains amlodipine besylate). The Prothonotary dismissed the motion, finding that the information sought was not relevant, necessary or important to issues of infringement and validity set out in the notice of allegation ("NOA"). Pfizer appealed. The Court dismissed the appeal, finding that the Prothonotary's Order was not clearly wrong. Pfizer has appealed.
(Full judgment – 2008 FC 950.)

Court of Appeal affirms summary dismissal of Pfizer's prohibition application for abuse of process. The Court of Appeal found that Pfizer's failure to adduce relevant evidence in an earlier application against Apotex, which Pfizer sought to rely upon in its application against Novopharm, is an inadequate basis for distinguishing the jurisprudence precluding relitigation. Accordingly, it affirmed a summary dismissal of an application relating to sildenafil citrate (VIAGRA).
(Court of Appeal decision – 2008 FCA 263. Motion Judge's decision – 2008 FC 674.)

Apotex's evidence on testing tendered after the date of the NOA allowed. In an application regarding escitalopram oxalate (CIPRALEX), a Motions Judge allowed Lundbeck's appeal from a decision of the Prothonotary insofar as it relates to its motion to strike an affidavit regarding test results tendered by Apotex on the ground that the results did not exist at the date of the NOA. Apotex appealed and the Court of Appeal allowed the appeal. The Court found that the Prothonotary did not err for the following reasons: i) the affiant had produced relevant test results prior to the issue of the NOA; ii) the results subsequently obtained were simply confirmatory and could not be regarded as additional facts beyond those set out in the NOA; and iii) since Apotex was not required to include the affiant's report in the NOA, the fact that it was completed after the issuance of the NOA does not render it irrelevant to this proceeding. The Court also dismissed Lundbeck's cross-appeal from the Order, dismissing its appeal from the Prothonotary's decision to dismiss its motion to strike certain portions of the affidavits filed by Apotex and to file reply affidavits.
(Court of appeal decision – 2008 FCA 265. Motion Judge's decision – 2008 FC 787.)

Other decisions

Court of Appeal affirms Minister's decision rejecting Pharmascience's regulatory submission for combination product. Pharmascience appealed from an Applications Judge's dismissal of its application for judicial review of the Minister's decision rejecting its regulatory submission for a combination product. The Minister rejected the submission, as it did not include comparative bioavailability studies regarding one of the two components. Pharmascience appealed and the Court of Appeal dismissed the appeal, finding that the Minister's decision was well "within the range of acceptable and rational solutions".
(Court of Appeal decision – 2008 FCA 258. Applications Judge's decision – 2007 FC 1323.)

Applications Judge dismisses judicial review application relating to cross-referenced application. sanofi-aventis sought judicial review of a decision of the Minister of Health which permitted Riva to receive a notice of compliance (NOC) for its ramipril capsules, despite that the fact that its drug submission

was cross-referenced to that of Pharmascience, in respect of which prohibition Orders precluded issuance of an NOC. The Judge found that the mere fact of cross-referencing does not invoke the judicial preclusions held against the party that filed the original submission and that there must be more evidence such as would establish that one party is a privy of the other or that some other situation existed that would require that the Court intervene to prevent an abuse. sanofi-aventis has appealed.
(Full judgment – 2008 FC 1062.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	rivastigmine capsules (EXELON)
Applicant:	Novartis Pharmaceuticals Canada Inc
Respondents:	Zymcan Pharmaceuticals Inc and The Minister of Health
Respondent/Patentee:	Novartis AG
Date Commenced:	August 21, 2008
Court File No:	T-1312-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,307,003. Zymcan alleges non-infringement, invalidity and improper listing on the Patent Register.

Medicine:	mometasone furoate monohydrate (NASONEX)
Applicants:	Schering-Plough Canada Inc and Schering Corporation
Respondents:	Attorney General of Canada and The Minister of Health
Date Commenced:	September 4, 2008
Court File No:	T-1374-08
Comment:	Application for an Order requiring the Minister to add Patent No. 2,182,086 to the Patent Register.

Medicine:	desloratadine (AERIUS)
Applicants:	Schering-Plough Canada Inc and Schering Corporation
Respondents:	The Minister of Health, Apotex Inc and Sepracor Inc
Date Commenced:	September 4, 2008
Court File No:	T-1375-08
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 2,267,136 and 2,325,014. Apotex alleges non-infringement and invalidity.

Medicine:	latanoprost ophthalmic solution (XALATAN)
Applicants:	Pfizer Canada Inc and Pharmacia Atkiebolag
Respondents:	The Minister of Health and Cobalt Pharmaceuticals Inc
Date Commenced:	September 11, 2008
Court File No:	T-1412-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,339,132. Cobalt alleges non-infringement, invalidity and ineligibility for listing on the Patent Register.

Medicine:	finasteride (PROPECIA)
Applicants:	Merck & Co, Inc and Merck Frosst Canada Ltd
Respondents:	Pharmascience Inc and The Minister of Health
Date Commenced:	September 22, 2008
Court File No:	T-1476-08
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 1,331,601 and 2,173,457. Pharmascience alleges non-infringement, ineligibility for listing ('601 patent) and invalidity ('457 patent).

Other new proceedings

Medicine:	nicotine transdermal patch (NICODERM)
Applicant:	sanofi-aventis Canada Inc
Respondent:	Attorney General of Canada
Date Commenced:	August 29, 2008
Court File No:	T-1359-08
Comment:	Application for an Order setting aside the decision of the Patented Medicine Prices Review Board, dismissing the request of Board Staff and the Applicant that further proceedings be terminated and requiring a hearing on the merits of whether the Applicant had engaged in excessive pricing during the period 1995-2001.

Applicant:	Pfizer Canada Inc
Respondent:	Attorney General of Canada
Date Commenced:	September 17, 2008
Court File No:	T-1442-08
Comment:	Application for an Order setting aside the decision of the Patented Medicine Prices Review Board communicated in the Board's Stakeholder Communiqué dated August 18, 2008 advising that effective January 1, 2009, patentees are obliged to include: (a) reports of price or sales information to the Board; and (b) the calculation of the average price, any and all benefits connected to the sales transaction, including rebates and payments to third parties.

Applicants:	Canada's Research-Based Pharmaceutical Companies, Amgen Canada Inc, AstraZeneca Canada Inc, Bayer Inc, Bristol-Myers Squibb Canada Inc, Boehringer Ingelheim (Canada) Ltd, Eli Lilly Canada Inc, EMD Serono Canada Inc, GlaxoSmithKline Inc, Hoffmann-La Roche Limited, Janssen-Ortho Inc, Merck Frosst Canada Ltd, Merck Frosst-Schering Pharma Partnership, Novartis Pharmaceuticals Canada Inc, Procter & Gamble Pharmaceuticals Canada Inc, Schering-Plough Canada Inc, Shire Canada Inc and Solvay Pharma Inc
Respondent:	Attorney General of Canada
Date Commenced:	September 17, 2008
Court File No:	T-1447-08
Comment:	Application for an Order setting aside the decision of the Patented Medicine Prices Review Board provided in the Board's Stakeholder Communiqué dated August 18, 2008, directing patentees to include benefits to "third parties" in the reports mandated under the *Patented Medicines Regulations*.

Medicine:	olanzapine (ZYPREXA)
Plaintiffs:	Eli Lilly Canada Inc, Eli Lilly and Company, Eli Lilly and Company Limited and Eli Lilly SA
Defendant:	Pharmascience Inc
Date Commenced:	September 26, 2008
Court File No:	T-1497-08
Comment:	Patent infringement action regarding Patent No. 2,041,113.

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

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