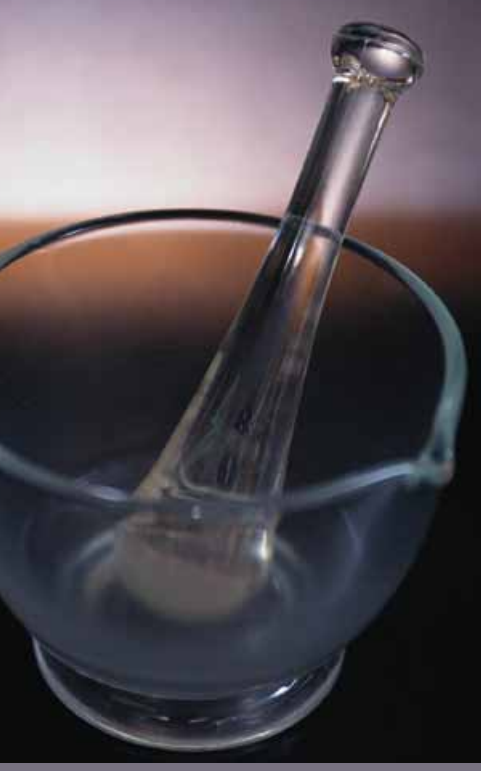

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

February 2010

Supreme Court of Canada denies Apotex leave to appeal regarding scope of remedies under section 8 of the *Regulations*

As reported in the September 2009 issue of *Rx IP Update*, Apotex filed an application for leave to appeal the Federal Court of Appeal's first decision on the merits relating to section 8 of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") (**alendronate**, Merck's **FOSAMAX**). The Court of Appeal affirmed the Trial Judge's holding that Apotex is not entitled to compensation by way of disgorgement of Merck's profits. The Court of Appeal also held that Apotex is confined to losses incurred during the section 8 period and is not entitled to claim certain "future losses," i.e., damages Apotex alleged it had suffered beyond the dismissal date of the prohibition proceeding.
(*Apotex Inc. v. Merck Frosst Canada Ltd.* Court of Appeal decision – 2009 FCA 187. Federal Court decision – 2008 FC 1185.)

Patented Medicine Prices Review Board news

Voluntary Compliance Undertaking for Xarelto. The Board recently approved a Voluntary Compliance Undertaking (VCU) for Bayer's **XARELTO (rivaroxaban)**. (Notice.)

Board finds that QUADRACEL and PENTACEL priced excessively. On December 21, 2009, the Board found that sanofi pasteur's QUADRACEL and PENTACEL medicines were priced excessively. The Board ordered sanofi pasteur to reduce the price at which it sells the medicines by the excess amount during the term of its contract with the Government of Canada. As exceptions to the Guidelines, the Board found that: the maximum non-excessive price (MNE) of QUADRACEL and PENTACEL should be

calculated without discounts provided to the Ontario government so as to encourage patentees to provide benefits to their purchasers; and PEDIACEL inherits the MNE of PENTACEL since the new medicine is identical in all material ways and most sales continue under contracts for the previous medicine. sanofi pasteur has sought judicial review. (Full decision – PMPRB-07-D5-QUADRACEL and PENTACEL.)

Supreme Court of Canada news

Supreme Court hears Nu-Pharm's appeal. As reported in the July 2009 issue of *Rx IP Update*, the Supreme Court granted Nu-Pharm leave to appeal the Federal Court of Appeal's Order dismissing its action for damages against the Crown. Nu-Pharm alleged that the Crown unlawfully advised provincial regulatory authorities, pharmacists, distributors, and public and private insurers that the sale of Nu-Enalapril is unlawful following the quashing of Nu-Pharm's notice of compliance (NOC). The Court of Appeal affirmed the Motions Judge's decision to grant the Crown's motion for summary judgment and finding that obtaining damages is entirely dependent upon Nu-Pharm proving the unlawful character of the government's decisions, which must be determined by way of judicial review. The appeal to the Supreme Court was heard January 20, and the Court reserved its decision.
(Supreme Court summary. Court of Appeal decision – 2008 FCA 227. Federal Court decision – 2007 FC 977.)

Leave to appeal granted in *Merck Frosst Canada Ltd. v. Minister of Health* (Access to Information). As reported in the July 2009 issue of *Rx IP Update*, the Federal Court of Appeal allowed the Minister's appeals from two Federal Court decisions finding that (i) Merck was entitled to a declaratory Order about the illegality of the process followed by the Minister in handling the access request (the Minister disclosed certain pages relating to Merck's drug submissions for SINGULAIR without consulting Merck), (ii) the disclosure of documents by the Minister without consultation was contrary to section 20(1) the *Access to Information Act*, and (iii) certain portions of the documents should not be disclosed. Merck was granted leave to appeal the decision to the Supreme Court on January 21.
(Supreme Court summaries – 33290 and 33320. Court of Appeal decision – 2009 CAF 166. Federal Court decisions – 2006 FC 1200, 2006 FC 1201.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Schering-Plough denied Order of prohibition against Pharmascience concerning desloratadine (DCL). On December 22, 2009, the Federal Court dismissed Schering-Plough's application for an Order of prohibition against Pharmascience regarding **desloratadine (DCL)** (Schering-Plough's **AERIUS**). The Court concluded that Pharmascience's allegations of non-infringement, anticipation, invalidity and overbreadth regarding one patent and non-infringement regarding a second patent were justified. (*Schering-Plough Canada Inc. v. Pharmascience Inc.*, December 22, 2009. Full judgment – 2009 FC 1128.)

Biovail denied Order of prohibition against Apotex concerning metformin. On January 20, 2010, the Federal Court dismissed Biovail's application for an Order of prohibition against Apotex regarding **metformin extended release** (Biovail's **GLUMETZA**). While the Court concluded that Biovail had established that Apotex's allegations on the bases of anticipation, double patenting and the Gillette defence were not justified, it found that Biovail did not meet its legal burden to establish that Apotex's allegation on the ground of obviousness was not justified as the evidence on the "obvious to try" test was evenly balanced and thus favoured Apotex. Biovail has appealed. (*Biovail v. Apotex*, January 20, 2010. Full judgment – 2010 FC 46.)

Janssen-Ortho moves to strike affidavit evidence. Janssen-Ortho brought a motion to strike certain paragraphs and exhibits from

Apotex's evidence or, in the alternative, to file reply evidence in an NOC proceeding regarding Janssen-Ortho's **CONCERTA (methylphenidate hydrochloride extended release tablets)**. There was a reversal of evidence in the proceeding such that Apotex was required to file its evidence on validity first. Janssen alleged that Apotex's infringement evidence contained evidence on invalidity and therefore violated the Court's scheduling Order. The Motions Judge found that much of Apotex's evidence was proper but did strike those portions he determined were directed at validity or irrelevant to infringement. Regarding Janssen's reply evidence, the Judge allowed only those portions relating to a study performed by Apotex. (*Janssen-Ortho Inc. v. Apotex Inc.*, January 25, 2010. Full judgment (identical reasons) – 2010 FC 82, 2010 FC 81.)

Other decisions

AstraZeneca's motion to enforce its Letter of Request granted with amendments. The Ontario Superior Court of Justice granted AstraZeneca's motion to enforce its Letter of Request issued by the U.S. District Court of Delaware for the oral examination of Dr. Stephen Wolman in connection with litigation in the U.S. regarding **budesonide** (AstraZeneca's **ENTOCORT**). The issuance of the Letter of Request was not opposed in the U.S. In enforcing the Letter of Request, the Court ordered several amendments narrowing the request and introduced undertakings similar to the implied undertaking rule. (*AstraZeneca LP v. Wolman*, December 14, 2009. Full judgment – CV-09-389581.)

Motions to compel further documents dismissed. In an action for patent impeachment for sanofi-aventis's **PLAVIX (clopidogrel bisulfate)** against Apotex, both parties brought motions to compel further and better affidavits of documents. The Prothonotary dismissed Apotex's motion entirely and also dismissed much of sanofi's motion. In doing so, the Prothonotary cited the Federal Court's initiative to streamline complex intellectual property litigation and noted that, given the sophistication of the parties and the level of preparation expected of them in the circumstances of a case moving to trial quickly, the presumption that the absence of a document from the affidavit of documents signals that, if it exists, a strategic and informed decision that it will not be relied on at trial is all the greater. (*Apotex Inc. v. sanofi-aventis*, January 22, 2010. Full judgment – 2010 FC 77.)

Trade-mark decisions

Federal Court of Appeal affirms rejection of NPS's application for PREOS. On January 12, 2010, the Federal Court of Appeal dismissed NPS's appeal from a decision of the Federal Court that upheld a decision of the Trade-marks Opposition Board. The Board had refused the application for registration of the mark PREOS on the basis of a likelihood of confusion with Biofarma's PROTOS; both were proposed to be used in relation to pharmaceutical preparations for the prevention of treatment of osteoporosis. The Court found that NPS essentially raised the same arguments that were submitted to both the Trade-marks Opposition Board and the lower Court and saw no error in the Judge's decision that would require its intervention.
(*NPS Pharmaceuticals, Inc. v. Biofarma, Société Par Actions Simplifiée*, January 12, 2010. Court of Appeal decision – 2010 FCA 8. Federal Court decision – 2009 FC 172.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	mycophenolate mofetil (CELLCEPT)
Applicant:	Hoffmann-La Roche Limited
Respondents:	Mylan Pharmaceuticals ULC and The Minister of Health
Respondent/Patentee:	Roche Palo Alto LLC
Date Commenced:	December 22, 2009
Court File No.:	T-2149-09
Comment:	Application for Order of prohibition until expiry of Patent No. 1,333,285. Mylan alleges non-infringement and invalidity and that certain claims are ineligible.

Medicine:	donezepil hydrochloride (ARICEPT)
Applicants:	Pfizer Canada Inc and Eisai Co, Ltd
Respondents:	Sandoz Canada Inc and The Minister of Health
Date Commenced:	January 22, 2010
Court File No.:	T-103-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,252,806. Sandoz alleges non-infringement and invalidity.

Other proceedings

Medicine:	oxycodone controlled release tablets (OXYCONTIN)
Plaintiff:	Pharmascience Inc
Defendant:	Purdue Pharma
Date Commenced:	December 7, 2009
Court File No.:	T-2050-09
Comment:	Action seeking declaration of invalidity and non-infringement of Patent No. 2,098,738.

Medicine:	QUADRACEL and PENTACEL
Applicant:	sanofi pasteur Limited
Respondent:	Attorney General of Canada
Date Commenced:	January 19, 2010
Court File No.:	T-83-10
Comment:	Application for judicial review of the PMPRB's decisions that sanofi pasteur charged excessive prices for **QUADRACEL** and **PENTACEL** and is not entitled to rely on the reduced prices charged starting in October 2007 to July 2008 to redress the excessive prices but, rather, must further reduce its prices going forward.

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

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