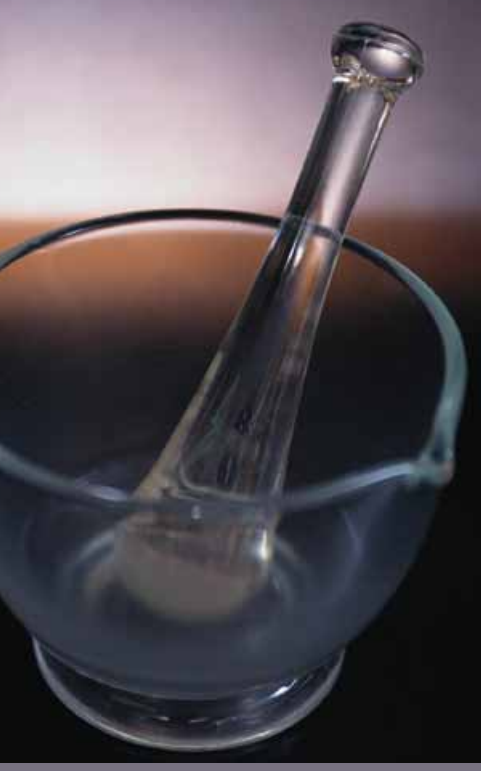

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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Apotex and CGPA appeal decision upholding data protection

As reported in the August 2009 edition of *Rx IP Update*, the Federal Court upheld the validity of the data protection provisions of the *Food and Drug Regulations* (section C.08.004.1) ("Data Protection Regulation") and *Food and Drugs Act* (section 30(3)). The challenge to the validity was brought by Apotex and the Canadian Generic Pharmaceutical Association ("CGPA"), and Canada's Research-Based Pharmaceutical Companies (Rx&D) and Eli Lilly intervened. Both Apotex and the CGPA have appealed the ruling to the Federal Court of Appeal. (*Apotex Inc. v. Eli Lilly Canada Inc.*, July 17, 2009. Full judgment – 2009 FC 725.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Court upholds Prothonotary's decision allowing Eli Lilly to amend notice of application and dismissing summary dismissal motion. A Motions Judge dismissed Novopharm's appeal of a Prothonotary's decision allowing Eli Lilly to amend its notice of application and dismissing Novopharm's motion to summarily dismiss Eli Lilly's application relating to **olanzapine** (Eli Lilly's **ZYPREXA ZYDIS**). Eli Lilly had successfully argued before the Prothonotary that it should be allowed to amend its notice of application to include a claim that Novopharm's notice of allegation (NOA) contained a deceptive and misleading allegation that its proposed olanzapine product would be made from a non-infringing form of olanzapine, Form 1. Novopharm asserted that the issue was not whether its product was made from that particular form but whether it contained the patented form of olanzapine. Novopharm also argued that Eli Lilly's evidence for the potential conversion of Novopharm's product to an infringing form of olanzapine was speculation and insufficient to establish infringement. The Judge agreed with the

Prothonotary that there has not yet been a judicial determination of whether a factual allegation in an NOA that is later shown to be untrue but which is not relevant to the issue of infringement will, in itself, provide a basis for an Order of prohibition and that it should not be resolved on such a motion without the benefit of a full evidentiary record. (*Eli Lilly Canada Inc. v. Novopharm Limited*, June 29, 2009. Prothonotary's decision. Motion Judge's decision – 2009 FC 675.)

Novopharm granted leave to file reply evidence in two separate proceedings. Two separate decisions were rendered by the Court regarding a request by a generic to file reply evidence in applications for an Order of prohibition. In both proceedings, the order regarding evidence on validity was reversed such that the generic served its evidence first followed by the evidence of the innovator company.

In *AstraZeneca Canada Inc. v. Novopharm Limited*, the Prothonotary granted Novopharm leave to file three further expert affidavits on the basis of his finding that AstraZeneca raised an issue or put forward evidence that was new or unanticipated. AstraZeneca's appeal was dismissed. (*AstraZeneca Canada Inc. v. Novopharm Limited*, September 11, 2009. Full judgment – 2009 FC 902.)

In *Merck-Frosst-Schering Pharma GP v. Novopharm Limited*, the Federal Court overturned a Prothonotary's decision denying leave to Novopharm to file a further expert affidavit. The Judge ruled that a two-step analysis is required to determine whether proposed reply evidence was not available and/or could not be anticipated as being relevant at an earlier date. The first step is to ask whether the proposed evidence is properly responsive to the other party's evidence. If responsive, the second step is to ask whether the proposed reply evidence could have been anticipated as being relevant at an earlier date. The Judge found that the Prothonotary had failed to make this second assessment and thus assessed the proposed reply evidence anew, finding that portions of the proposed evidence were proper reply. (*Merck-Frosst-Schering Pharma GP v. Novopharm Limited*, September 15, 2009. Full judgment – 2009 FC 914.)

Declaration of invalidity not a ground to dismiss prior successful applications. In light of the recent Federal Court's decision in *sanofi-aventis v. Apotex* (2009 FC 676) declaring that certain claims of a patent covering **ramipril** (sanofi-aventis's **ALTACE**) are invalid, Pharmascience brought a motion to set aside the Orders of prohibition previously granted by the Court and to dismiss sanofi-aventis's prior successful applications relating to the same patent. While the Court ordered that the Orders of prohibition be set aside so that the Minister may issue a notice of compliance (NOC) to Pharmascience without being in breach of the previous Orders of prohibition, it declined to dismiss the previous successful applications. Pharmascience has appealed and sanofi-aventis has cross-appealed. (*Aventis Pharma Inc. v. Pharmascience Inc.*, September 15, 2009. Full judgment – 2009 FC 915.)

Other decisions

Judge upholds decision permitting GSK to amend pleading in AZT reference. In the AZT reference to quantify the damages sustained by the Wellcome Foundation Limited and Glaxo Wellcome ("GSK") as a result of the infringement by Apotex and Novopharm of a patent claiming the use of AZT for the treatment and prophylaxis of HIV, the Prothonotary granted GSK leave to file a Further Fresh as Amended Statement of Issues. GSK's amendments consist of (i) an allegation that GSK would have increased the price of RETROVIR (zidovudine) but for the infringement and (ii) a claim against Novopharm for a reasonable royalty on export sales. A Judge upheld the Prothonotary's decision, varying the decision only in the fixing of costs which was left to be determined by the Trial Judge. (*Apotex and Novopharm v. Wellcome Foundation*, September 22, 2009. Prothonotary's decision – 2009 FC 117. Trial Judge's decision – 2009 FC 949.)

Federal Court dismisses review of interlocutory NICODERM PMPRB decision. The Federal Court has dismissed sanofi-aventis Canada's application for judicial review of an interlocutory decision in which the PMPRB dismissed sanofi-aventis's request, on joint submissions with the Board Staff, that further Board proceedings regarding the pricing of **NICODERM** be terminated. The Court held that the application should be dismissed as it calls for the review of an interlocutory decision and

the case did not raise any special circumstances that merit immediate review by the Court. The Court also found, in any event, that the Board had jurisdiction to continue the proceedings, the Board did not breach the principles of procedural fairness, and the Board's decision to continue the proceeding were not otherwise unreasonable. (*sanofi-aventis Canada Inc. v. Canada (Attorney General)*, September 24, 2009. Full judgment – 2009 FC 965.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	lansoprazole (PREVACID)
Applicants:	Takeda Pharmaceuticals America Inc, Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals North America Inc
Respondents:	The Minister of Health and Genpharm ULC
Date Commenced:	July 30, 2009
Court File No.:	T-1229-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,009,741, 1,327,010 and 1,338,377. Genpharm alleges non-infringement and invalidity with respect to all patents and improper listing with respect to the '741 patent.

Medicine:	pregabalin (LYRICA)
Applicants:	Pfizer Canada Inc, Warner-Lambert Company and Warner-Lambert Company LLC
Respondents:	ratiopharm Inc, The Minister of Health, Northwestern University and The Board of Regents for the University of Oklahoma
Date Commenced:	August 26, 2009
Court File No.:	T-1422-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,134,674, 2,255,652, 2,325,045, 2,327,285 and 2,297,163. ratiopharm alleges non-infringement, invalidity and improper listing.

Medicine:	atorvastatin calcium (LIPITOR)
Applicants:	Pfizer Canada Inc, Warner-Lambert Company and Warner-Lambert Company, LLC
Respondents:	Genpharm ULC, Mylan Pharmaceuticals ULC and The Minister of Health
Date Commenced:	August 27, 2009
Court File No.:	T-1437-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,021,546, 2,220,018, 2,220,458, 2,220,455, 2,521,891, 2,522,899, 2,450,111, 2,521,908, 2,521,933, 2,521,953, 2,521,956, 2,521,828, 2,521,833, 2,521,792, 2,521,776 and 2,521,887. Genpharm alleges non-infringement, invalidity and improper listing.

Medicine:	risedronate sodium (ACTONEL)
Applicants:	Procter & Gamble Pharmaceuticals Canada Inc and The Procter & Gamble Company
Respondents:	Mylan Pharmaceuticals ULC and The Minister of Health
Date Commenced:	August 28, 2009
Court File No.:	T-1438-09
Comment:	Application for Order of prohibition until expiry of Patent No. 1,320,727. Mylan alleges invalidity.

Medicine:	memantine hydrochloride (EBIXA)
Applicants:	Lundbeck Canada Inc and Merz Pharma GmbH & Co KGaA
Respondents:	Cobalt Pharmaceuticals Inc and The Minister of Health
Date Commenced:	September 2, 2009
Court File No.:	T-1462-09
Comment:	Application for Order of prohibition until expiry of Patent No. 2,014,453. Cobalt alleges non-infringement, invalidity and improper listing.

Medicine:	anastrozole (ARIMIDEX)
Applicants:	AstraZeneca Canada Inc and AstraZeneca UK Limited
Respondents:	Mylan Pharmaceuticals ULC and The Minister of Health
Date Commenced:	September 3, 2009
Court File No.:	T-1473-09
Comment:	Application for Order of prohibition until expiry of Patent No. 1,337,420. Mylan alleges non-infringement, invalidity and improper listing.

Medicine:	montelukast sodium (SINGULAIR)
Applicants:	Merck & Co Inc and Merck Frosst Canada Ltd
Respondents:	The Minister of Health and Mylan Pharmaceuticals ULC
Date Commenced:	September 11, 2009
Court File No.:	T-1524-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,053,209 and 2,179,407. Mylan alleges non-infringement with respect to the '407 patent and accepts that an NOC will not issue until after the expiry of the '209 patent.

Medicine:	candesartan cilexetil/HCT (ATACAND PLUS)
Applicants:	AstraZeneca Canada Inc and Takeda Pharmaceutical Company Limited
Respondents:	Sandoz Canada Inc and The Minister of Health
Date Commenced:	September 23, 2009
Court File No.:	T-1589-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,083,305 and 2,125,251. Sandoz alleges non-infringement and improper listing with respect to both patents, invalidity with respect to the '251 patent and accepts that an NOC will not issue until the expiry of the '955 patent.

Other proceedings

Medicine:	escitalopram oxalate (CIPRALEX)
Plaintiff:	Apotex Inc
Defendant:	H. Lundbeck A/S
Date Commenced:	August 21, 2009
Court File No.:	T-1407-09
Comment:	Action seeking declaration of invalidity and non-infringement of Patent No. 1,339,452.

Medicine:	rosuvastatin calcium (CRESTOR)
Plaintiffs:	AstraZeneca Canada Inc, IPR Pharmaceuticals Inc, AstraZeneca UK Limited and Shionogi Seiyaku Kabushiki Kaisha
Defendant:	Apotex Inc
Date Commenced:	September 18, 2009
Court File No.:	T-1562-09
Comment:	Patent infringement action regarding Patent No. 2,072,945.

Medicine:	rosuvastatin calcium (CRESTOR)
Plaintiffs:	AstraZeneca Canada Inc, IPR Pharmaceuticals Inc, AstraZeneca UK Limited and Shionogi Seiyaku Kabushiki Kaisha
Defendant:	Novopharm Limited
Date Commenced:	September 18, 2009
Court File No.:	T-1563-09
Comment:	Patent infringement action regarding Patent No. 2,072,945.

Medicine:	omeprazole (LOSEC)
Applicant:	AstraZeneca Canada Inc
Respondents:	The Minister of Health, The Attorney General of Canada and Apotex Inc
Date Commenced:	September 21, 2009
Court File No.:	T-1575-09
Comment:	Application for judicial review of the Minister's decision to issue an NOC to Apotex for the use of Apo-Omeprazole in combination with antibiotics for the eradication of *H. pylori*.

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

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