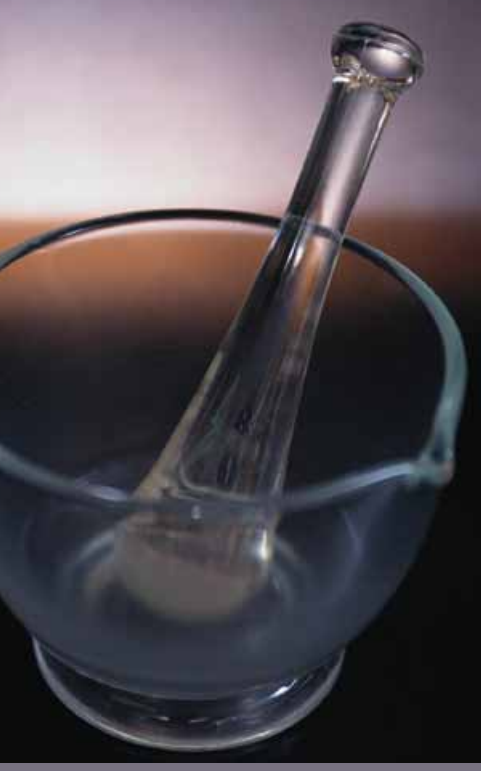

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Federal Court renders judgment in cefaclor litigation

Madam Justice Gauthier of the Federal Court has rendered judgment in the longstanding Canadian patent litigation between Eli Lilly and Apotex concerning the antibiotic **cefaclor** (sold by Eli Lilly in Canada as **CECLOR**): *Eli Lilly and Company v. Apotex Inc.*, 2009 FC 991. Apotex was found to have infringed at least one valid claim of each of the eight patents in issue by its importation, manufacture, export, sale and offers for sale of cefaclor in Canada (although it will be noted that infringement was not found in respect of all of the cefaclor in issue).

Apotex commenced sale of cefaclor in Canada in 1997 and was sued by Eli Lilly shortly thereafter. The action finally proceeded to trial in 2008, the hearing of which commenced in April and finally concluded in December (with various breaks in the proceeding in between). Justice Gauthier's lengthy and detailed reasons reflect the length and complexity of the proceedings leading up to and including trial.

In the action, Eli Lilly alleged infringement by Apotex of eight patents covering processes and intermediates useful in the manufacture of cefaclor. Four of the patents originally issued to Eli Lilly (the "Lilly Patents") and pertained to a first process for manufacturing cefaclor (the "Lilly Process"). The remaining patents issued to Shionogi, a Japanese company (the "Shionogi Patents") and pertained to a second process for manufacturing cefaclor (the "Shionogi Process"). The Shionogi Patents were assigned to Eli Lilly in 1995. Apotex was alleged to have infringed the patents by the sale in Canada of finished dosage form cefaclor manufactured from bulk cefaclor purchased from third parties in India and Korea who manufactured the bulk using either the Lilly or Shionogi Process.

Given the length of the proceedings and resultant judgment, it is not surprising that many infringement and validity issues are canvassed in the Reasons for Judgment.

Several issues addressed by the Court are worthy of note.

First, Apotex argued vigorously that its importation and use in Canada of cefaclor manufactured abroad using the patented processes was not infringement of the Canadian patents in issue. In this regard, Apotex argued that the Canadian courts had improperly accepted the "*Saccharin* doctrine"

as being applicable in Canada or that the *Saccharin* doctrine should be restricted in its application in Canada in a manner similar to restrictions imposed on infringement by importation in Europe and the United States as a result of legislation adopted in those jurisdictions.

The *Saccharin* doctrine (which derives its name from a UK decision involving the artificial sweetener) permits a finding of infringement of a Canadian patent pertaining to a process or intermediate which has been practiced abroad in the manufacture of a product which is imported for use and sale in Canada. Following a detailed review of the Canadian and UK authorities, Justice Gauthier concluded that it is too late to "turn back the clock" on the application of the principles concerning infringement by importation stated in the Canadian jurisprudence and that it would be inappropriate to re-write the Canadian law based on the statutes adopted in foreign jurisdictions. Justice Gauthier further accepted that the *Saccharin* doctrine applied to Apotex's conduct in this case.

Another notable aspect of this case is the Court's consideration of Apotex's allegations concerning violations of the *Competition Act*.

Apotex counterclaimed against Eli Lilly and Shionogi, alleging that the assignment of the Shionogi Patents to Eli Lilly (which occurred in 1995) was a conspiracy to unduly lessen competition contrary to section 45 of the *Competition Act* and that Apotex was entitled to recover its damages in accordance with section 36 of the *Competition Act*. The Court dismissed Apotex's counterclaim, finding that it was barred by the limitation period provided in section 36(4) and that Apotex had failed to establish that it had suffered any damage. Apotex also relied upon the violations of the *Competition Act* as a basis for the defences of disentitlement and equitable set-off in respect of Eli Lilly's patent infringement action. Apotex's defences were also dismissed.

Overall, the Court's affirmation of the *Saccharin* doctrine will be of significance to patentees in the pharmaceutical industry for whom process patents will frequently be practiced in foreign jurisdictions where generic bulk pharmaceuticals are most often manufactured. Moreover, the Court's rejection of Apotex's counterclaim and associated defences based on the *Competition Act* may constitute further evidence of the Court's reluctance to assess liability for conduct involving patents other than in cases where a party is able to clearly demonstrate it has been damaged by anti-competitive conduct. Eli Lilly has appealed.

Colin B. Ingram, Ottawa

Patented Medicine Prices Review Board news

The Board recently approved three Voluntary Compliance Undertakings (VCUs): Baxter's **BREVIBLOC (esmolol hydrochloride)** (Notice), Schering-Plough's **ANDRIOL (testosterone undecanoate)** (Notice) and Amgen's **NEULASTA (pegfilgrastim)** (Notice).

Supreme Court of Canada news

Leave denied in class actions relating to VIOXX. As reported in the August 2009 edition of *Rx IP Update*, Merck Frosst applied for leave to appeal a decision of the Ontario Court of Appeal denying Merck an extension of the time to seek leave to appeal an Order of the Superior Court of Justice. That Order denied Merck leave to appeal to the Divisional Court from an Order granting certification of the class proceeding relating to the drug **rofecoxib (VIOXX)**. The application for leave has been dismissed with costs. (Court of Appeal decision – 2009 ONCA 393. Superior Court of Justice decision – 2008 CanLII 61238.)

Leave to appeal was also denied in an application in another class action related to VIOXX. The plaintiffs in the action sought leave to appeal a decision of the Saskatchewan Court of Appeal in a class action certified in Saskatchewan for residents and non-residents. After certification, the plaintiffs obtained an order expanding the class to include a national opt-out non-resident class. However, after the Ontario action was certified, the Saskatchewan Court of Appeal quashed the order for certification. In the same application, Merck also sought leave to appeal another order in which the Court refused to allow Merck to amend its

notice of appeal to include a constitutional issue. Merck's application was also dismissed. (Court of Appeal decisions – 2009 SKCA 43, 2008 SKCA 125.)

Leave denied re: disclosure requirement for sound prediction (raloxifene). The Supreme Court of Canada has denied Eli Lilly's application for leave to appeal a Federal Court of Appeal decision relating to a patent for a new use of the medicine **raloxifene (HCl)** (Eli Lilly's **EVISTA**). The Court of Appeal dismissed Eli Lilly's appeal from a decision finding that Apotex's invalidity allegation is justified on the ground of lack of sound prediction. The Court of Appeal disagreed with Eli Lilly's argument that the patent was not based on a prediction as the utility of the invention was conclusively established by the Canadian filing date, and it held that the Applications Judge proceeded on a proper principle when he held that, where a patent is based on a sound prediction, the disclosure must include the prediction. (*Eli Lilly Canada Inc. v. Apotex Inc.* Federal Court of Appeal decision – 2009 FCA 97. Federal Court decision – 2008 FC 142.)

Apotex seeks leave re: perindopril. Apotex has sought leave to appeal the Federal Court of Appeal decision upholding the Trial Judge's decision that the patent claiming **perindopril** (Servier's **COVERSYL**) was valid and infringed. The Court of Appeal also upheld that ADIR was merely exercising its rights under the *Patent Act* to obtain its patent and therefore did not violate the *Competition Act*. (*Apotex Inc. v. Adir and Servier Canada Inc.*, September 29, 2009. Court of Appeal decision – 2009 FCA 222. Trial Judge's decision – 2008 FC 825.)

Competition Bureau reaches agreements re: Pfizer/Wyeth and Merck/Schering-Plough mergers

The Competition Bureau has announced that it has reached agreements with the parties involved in two pharmaceutical company mergers. In reaching an agreement with Pfizer and Wyeth in respect of their proposed merger, the Competition Bureau has required divestiture of a number of animal health products. Additionally, Pfizer will amend an arrangement regarding the distribution, marketing and sale of Pfizer's **ESTRING** to ensure continued competition in the supply of hormone replacement therapy products. Regarding the proposed merger between Merck and Schering-Plough, the Competition Bureau has required that the two companies divest a product in development for the treatment of chemotherapy-induced and post-operative side effects. As well, because of competition issues regarding animal health markets, Merck has divested its interest in an animal health business to its joint venture partner, sanofi-aventis. With these agreements, the competition concerns in both mergers have been resolved. (Competition Bureau news announcement re: Pfizer Inc. and Wyeth merger. Competition Bureau news announcement re: Merck and Schering-Plough merger.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Apotex precluded from pursuing notice of allegation regarding orally disintegrating olanzapine tablets. The Federal Court determined that Apotex is precluded by the doctrine of issue estoppel from pursuing its current notice of allegation (NOA) in relation to **orally disintegrating olanzapine tablets** (Eli Lilly's **ZYPREXA ZYDIS**). Apotex previously served an NOA in relation to the conventional **olanzapine tablets** (Eli Lilly's **ZYPREXA**). In that case, the Court granted Eli Lilly's prohibition application (2007 FC 455, affirmed 2008 FCA 44) and refused to consider the selection patent issue as it was not pleaded in Apotex's NOA. Apotex subsequently filed a supplemental abbreviated new drug submission (SANDS) for a notice of compliance (NOC) in relation

to orally disintegrating olanzapine tablets and served Eli Lilly the current NOA, which relied exclusively on Justice Hughes's decision in *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596, finding that Novopharm's allegation with respect to the sufficiency of the selection patent was justified, and the subsequent dismissal of Eli Lilly's appeal to the Court of Appeal, 2007 FCA 359. The Judge dismissed Apotex's preliminary objection that the Court cannot examine the issue estoppel argument made by Eli Lilly as it was not explicitly pleaded in the notice of application. He rejected Apotex's argument that issue estoppel was not applicable in the present circumstances because the product at issue in each proceeding was different, finding what really mattered was the validity of the same selection patent. He found that all three criteria required for issue estoppel were met:

(i) the issue to be determined in the current application is the same as that which was determined in the previous prohibition application, namely whether the selection patent was invalid;

(ii) the previous decision was final; and

(iii) the parties were the same.

He also did not find any special overriding circumstances that would warrant exercising his discretion not to apply the doctrine. (*Eli Lilly Canada Inc. v. Apotex Inc.*, October 19, 2009. Full judgment – 2009 FC 1053.)

Novopharm succeeds in defending olanzapine infringement action. On October 5, 2009, the Federal Court found Canadian Patent 2,041,113 ("'113") invalid (which specifically claims **olanzapine** (Eli Lilly's **ZYPREXA**)). Because Eli Lilly previously held a genus patent that encompassed and claimed 15 trillion compounds (the '687 patent), including olanzapine, the '113 patent was considered a selection patent. The Court found that the '113 patent asserted various advantages of olanzapine over compounds claimed by the '687 patent, as well as other antipsychotic compounds. On the evidence, the Court concluded that none of the alleged advantages were shown by the inventors prior to filing the patent, nor could they be soundly predicted. Furthermore, the Court held that the alleged advantages of olanzapine over two other compounds from the '687 patent were not substantial, which was necessary as "it is not enough for a selected compound merely to achieve what was promised in the genus patent." For these reasons, among others, the Court held that the '113 patent was an invalid selection patent. The Court briefly considered obviousness and held that olanzapine was an "almost invention": it was neither obvious nor a genuine invention. Eli Lilly may appeal as of right. The '113 patent was the subject of two previous proceedings under the *Patented Medicines (Notice of Compliance) Regulations* in which Eli Lilly was successful against Apotex (2007 FC 455, affirmed 2008 FCA 44; see also decision immediately above) but lost to Novopharm (2007 FC 596, appeal dismissed as moot 2007 FCA 359). (*Eli Lilly Canada Inc. v. Novopharm Limited*, October 5, 2009. Full judgment – 2009 FC 1018.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	irbesartan/hydrochlorothiazide (AVALIDE)
Applicant:	sanofi-aventis Canada Inc
Respondents:	Cobalt Pharmaceuticals Inc and The Minister of Health
Respondent/Patentee:	sanofi-aventis
Date Commenced:	September 25, 2009
Court File No.:	T-1579-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,057,913 and 2,177,772. Cobalt alleges non-infringement and invalidity with respect to the '772 patent and accepts that an NOC will not issue until after the expiry of the '913 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 after the expiry of Patent No. 2,040,955.

Medicine: atomoxetine hydrochloride (STRATTERA)
Applicant: Eli Lilly Canada Inc
Respondents: ratiopharm Inc and The Minister of Health
Respondent/Patentee: Eli Lilly and Company
Date Commenced: October 2, 2009
Court File No.: T-1639-09
Comment: Application for Order of prohibition until expiry of Patent No. 2,209,735. ratiopharm alleges invalidity.

Medicine: memantine hydrochloride (EBIXA)
Applicants: Lundbeck Canada Inc, H. Lundbeck A/S and Merz Pharma GmbH & Co KGaA
Respondents: Pharmascience Inc and The Minister of Health
Date Commenced: October 8, 2009
Court File No.: T-1668-09
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,014,453 and 2,426,492. Pharmascience alleges non-infringement, invalidity and improper listing with respect to both patents.

Medicine: rosiglitazone maleate (AVANDIA)
Applicants: GlaxoSmithKline Inc and Beecham Group plc
Respondents: Pharmascience Inc and The Minister of Health
Date Commenced: October 13, 2009
Court File No.: T-1687-09
Comment: Application for Order of prohibition until expiry of Patent No. 1,328,452. Pharmascience alleges invalidity.

Medicine: rosuvastatin calcium (CRESTOR)
Applicants: AstraZeneca Canada Inc, AstraZeneca AB and Shionogi Seiyaku Kabushiki Kaisha
Respondents: ratiopharm Inc and The Minister of Health
Date Commenced: October 14, 2009
Court File No.: T-1694-09
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,072,945 and 2,313,783. ratiopharm alleges invalidity and non-infringement.

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:	October 22, 2009
Court File No.:	T-1723-09
Comment:	Application for Order of prohibition until expiry of Patent No. 2,014,453. Cobalt alleges non-infringement, invalidity and improper listing.

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

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