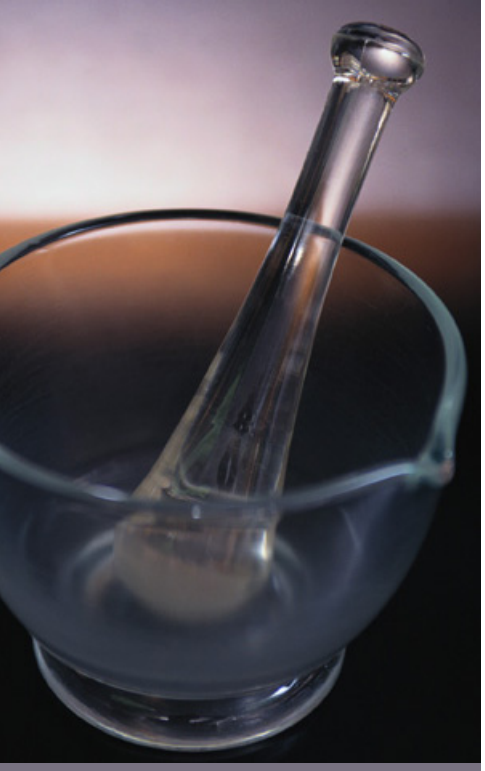

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

March 2008

Federal Court comments on "proper disclosure" requirement for sound prediction

In the AZT case (*Apotex v. Wellcome Foundation*, 2002 SCC 77), the Supreme Court articulated a three-part test for the doctrine of sound prediction:

(i) there must be a factual basis for the prediction;

(ii) the inventor must have, at the date of the patent application, an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis; and

(iii) there must be proper disclosure.

The Supreme Court commented as follows regarding the "proper disclosure" requirement:

> Normally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practised: H. G. Fox, The Canadian Law and Practice Relating to Letters Patent for Inventions (4th ed. 1969), at p. 167. It is generally not necessary for an inventor to provide a theory of why the invention works. Practical readers merely want to know that it does work and how to work it. In this sort of case, however, the sound prediction is to some extent the quid pro quo the applicant offers in exchange for the patent monopoly. Precise disclosure requirements in this regard do not arise for decision in this case because both the underlying facts (the test data) and the line of reasoning (the chain terminator effect) were in fact disclosed, and disclosure in this respect did not become an issue between the parties. I therefore say no more about it.

Recently, in a case decided under the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") (*Eli Lilly v. Apotex and the Minister of Health*, 2008 FC 142), relating to the medicine **raloxifene (HCl) tablets** (Eli Lilly's **EVISTA**), the Federal Court held that the "disclosure" must be in the patent, not elsewhere, stating that "[t]he public should not be left to scour the world's publications in the hope of finding something more to supplement or complete a patent disclosure". As the patent did not disclose the specific study which provided the

basis for the prediction and sound line of reasoning, the Judge concluded there was no sound prediction for lack of disclosure. Eli Lilly's application for an Order of prohibition was therefore dismissed. Eli Lilly may appeal as of right.

Product Monographs accessible through Health Canada website

Health Canada now posts Product Monographs authorized subsequent to January 2004 and that have been market notified on the Drug Product Database ("DPD"). Health Canada intends to publish Product Monographs at the time of authorization (*i.e.* notice of compliance (NOC) or No Objection Letter (NOL) issuance). For those Product Monographs not available on the website, Health Canada will continue to release them directly upon request. (Health Canada Notice. Drug Product Database.)

PMPRB asserts jurisdiction over U.S.-based sales

On January 21, 2008, the PMPRB issued an Order in the matter of Celgene and the medicine **THALOMID (thalidomide)**. No NOC has been issued for the sale of THALOMID in Canada, but sales have been made pursuant to Health Canada's Special Access Program ("SAP"). The Board found that the Board's jurisdiction extends to sales made pursuant to the SAP. The Board also found that although the applicable principles of commercial common law establish New Jersey as the *locus* of Thalomid sales to Canadian patients (Celgene pointed in part to invoices marked "FOB New Jersey"), this was not germane to, and certainly not determinative of, its jurisdiction. The Board therefore concluded that it has jurisdiction to make a remedial Order concerning the pricing of THALOMID from the laid-open date of the relevant patents. Celgene has commenced an application for judicial review of the Board's decision. (Decision.)

PMPRB releases discussion paper relating to Excessive Pricing Guidelines

The PMPRB has released a discussion paper titled "Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines". The discussion paper builds on consultations with stakeholders on the guidelines as well as the Court decision of *Leo Pharma v. Canada (Attorney General)*, 2007 FC 306 (reported in the April 2007 issue of *Rx IP Update*) relating to the inclusion of benefits in average price calculations. Written comments may be submitted by March 3, 2008. (Report.)

Supreme Court of Canada matters

Apotex v. Attorney General of Québec, December 17, 2007. Apotex seeks to appeal the Quebec Court of Appeal's dismissal of its appeal from a Judge's decision to permit the intervenor 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 against Apotex for damages 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.)

Eli Lilly Canada v. Novopharm (olanzapine (ZYPREXA)), January 4, 2008. Eli Lilly has sought leave to appeal a Court of Appeal Order which dismissed Eli Lilly's appeal from the Applications Judge's dismissal of its prohibition application. The appeal was dismissed as moot, as Eli Lilly had received its NOC. Novopharm had succeeded on its allegation of invalidity of a selection patent, as the Judge found that Eli Lilly had failed to demonstrate that the disclosure was not insufficient. (Court of Appeal decision – 2007 FCA 359. Applications Judge's decision – 2007 FC 596.)

Apotex v. Sanofi-Synthelabo (clopidrogel (PLAVIX)), January 28, 2008. As reported in the August 2007 issue of *Rx IP Update*, the Supreme Court of Canada has granted Apotex leave to appeal a decision of the Court of Appeal which had upheld a prohibition Order relating to a selection patent. On January 28, 2008, the Supreme Court granted BIOTECanada, the Canadian Generic Pharmaceutical Association ("CGPA") and Canada's Research-Based Pharmaceutical Companies ("Rx&D") leave to intervene. The appeal is presently scheduled to be heard on April 16, 2008. (Court of Appeal decision – 2006 FCA 421. Applications Judge's decision – 2005 FC 390.)

Wyeth Canada v. ratiopharm Inc. (venlafaxine (EFFEXOR XR)), February 7, 2008. Leave has been denied. Wyeth had sought leave to appeal the Court of Appeal's decision to grant ratiopharm's motion to dismiss the prohibition application on the basis of improper patent listing. The Court of Appeal had agreed with the Applications Judge that there must be relevance between the patent and the submission against which the patent is listed. (Court of Appeal decision – 2007 FCA 264. Motions Judge's decision – 2007 FC 340.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Bayer Healthcare AG v. Sandoz Canada (ciprofloxacin (CIPRO I.V. minibag)), January 23, 2008. Court of Appeal dismisses Bayer's appeal from the Applications Judge's dismissal of its application for judicial review of the Minister's decision that Sandoz was not required to address a patent listed against CIPRO I.V. minibag. Sandoz intended to market a more concentrated version in glass vials, comparing its drug to Bayer's U.S. CIPRO I.V. (in vials), as the product was no longer sold in Canada. Bayer had no patents listed against CIPRO I.V. at the time Sandoz's NOC was issued. The Court of Appeal held that the Applications Judge correctly concluded that section 5(1) was not triggered because Sandoz did not compare its product with Bayer's Minibag for purposes of showing bioequivalence, and that Sandoz's reference to Bayer's Minibag concerned only the establishment of a safety limit for a certain impurity and formed no part of any comparison for demonstrating bioequivalence. (Court of Appeal's decision – 2008 FCA 25. Applications Judge's decision – 2007 FC 590.)

Apotex Inc. v. Eli Lilly Canada Inc. (olanzapine (ZYPREXA)), February 4, 2008. Court of Appeal dismisses Apotex's appeal from an Order of prohibition. The Court held that the Applications Judge committed no error in holding that the sufficiency of disclosure ground was not properly raised by Apotex in its notice of allegation. (Court of Appeal decision – 2008 FCA 44. Applications Judge's decision – 2007 FC 455.)

AB Hassle v. Apotex and the Minister of Health (omeprazole and omeprazole magnesium (LOSEC)), February 13, 2008. Judge dismisses motions by Apotex to set aside two prohibition Orders on the basis of a third Order in a subsequent proceeding relating to a different patent. The Judge rejected Apotex's argument that the Court could re-open the prohibition Orders on the basis of continuing jurisdiction if there are changed circumstances, finding no jurisdiction when "evidence adjudicated in another case, in respect of another patent, even if closely related, appears to be more favourable to a party than the evidence that was or could have been adduced by that party in the earlier case, or could have been considered if the party had framed its Notice of Allegation more properly". The Judge also rejected Apotex's argument that the determinations in the subsequent proceeding constituted new "matter" such that the Court should set aside or vary the earlier judgments. Apotex has appealed. (Reasons – 2008 FC 184. First prohibition application decisions – 2002 FCT 931; 2003 FCA 409. Second prohibition application decisions – 2005 FC 234; 2006 FCA 51. Third prohibition application decisions – 2006 FC 7; 2007 FCA 327.)

Other decisions

Pharmascience Inc. v. Attorney General of Canada (unidentified combination product), December 14, 2007. Judge dismisses Pharmascience's application for judicial review of the Minister's decision rejecting its regulatory submission for a combination product. The Minister rejected the submission, as while it included comparative bioavailability studies regarding one component, it did not include such studies for the second component. The Court found that the Minister's decision was within his expertise and was not patently unreasonable. Pharmascience has appealed. (Full judgment – 2007 FC 1323.)

Novopharm Limited v. Minister of Health for the Province of British Columbia and Her Majesty the Queen in Right of the Province of British Columbia (olanzapine ((Novo-Olanzapine, ZYPREXA)), January 22, 2008. Novopharm brought an action against the defendants based on the tort of civil conspiracy and an allegation that the Minister of Health for British Columbia deliberately failed to discharge his statutory duty in relation to Novopharm's application for listing Novo-Olanzapine on the British Columbia Pharmacare Formulary. A Judge dismissed Novopharm's motion for an interlocutory injunction restraining the defendants from continuing with the tender process concerning Request for Proposals for the provision of olanzapine and an interlocutory declaration listing NOVO-OLANZAPINE on the Formulary. (Full judgment – 2008 BCSC 82.)

New proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	metformin extended-release tablets (GLUMETZA)
Applicants:	Biovail Corporation and Depomed Inc
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	January 23, 2008
Court File No:	T-118-08
Comment:	Application for an Order of prohibition until expiry of Canadian Patents Nos. 2,290,624 and 2,412,671. Apotex alleges non-infringement and invalidity.

Medicine:	esomeprazole magnesium trihydrate tablets (NEXIUM)
Applicants:	AstraZeneca Canada Inc and AstraZeneca Aktiebolag
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	January 25, 2008
Court File No:	T-138-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,139,653. Apotex alleges non-infringement and invalidity.

Medicine:	oxycodone hydrochloride tablets (OXYCONTIN)
Applicant:	Purdue Pharma
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	January 31, 2008
Court File No:	T-182-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,296,633. Apotex alleges non-infringement and invalidity.

Medicine:	oxycodone hydrochloride tablets (OXYCONTIN)
Applicant:	Purdue Pharma
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	January 31, 2008
Court File No:	T-183-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,098,738. Apotex alleges non-infringement and invalidity.

Other new proceedings

Medicine:	fenofibrate capsules (FENOMAX, LIPIDIL SUPRA)
Plaintiff:	Cipher Pharmaceuticals Inc
Defendants:	Fournier Pharma Inc., Laboratoires Fournier SA, Solvay SA
Date Commenced:	February 15, 2008
Court File No:	T-262-08
Comment:	Action for damages pursuant to section 8 of the *Regulations*.

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

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