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Rx IP Update

Canadian Pharmaceutical Intellectual Property Law Newsletter

Minister of Health Interprets *Apotex* Supreme Court Decision

As reported in the November 2006 issue of *Rx IP Update*, the Supreme Court released a decision on November 3, 2006 (*Apotex Inc. v. AstraZeneca Canada Inc. et al*, 2006 SCC 49), deciding that Apotex was not required to address two patents listed on the Patent Register in connection with AstraZeneca's **omeprazole capsules, LOSEC**. The patents at issue had been added to the Register after AstraZeneca had ceased marketing LOSEC in 1996 for a period of time.

Recently, the Minister has decided to interpret the decision as being applicable beyond the unusual facts that were before the Court. Specifically, in cases where a second person's abbreviated new drug submission (ANDS) was submitted pursuant to the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") as they read before the amendments came into force on October 5, 2006, the Minister will apply the following stepwise determination:

> First, the date on which the second person purchases the comparator drug will be used to determine the NOCs that have been issued in respect of that comparator drug. All patents added to the Patent Register in respect of submissions which have received an NOC as of the date of purchase of the comparator drug must be addressed under subsections 5(1) and 5(2).
>
> Second, the Minister will also consider any NOCs that have been issued to the first person after the date of purchase of the comparator drug by the second person. A determination will be made as to whether or not the second person has made use of the changes to the comparator drug as outlined in the relevant submissions. If the second person has made use of the changes to the comparator drug, all patents added to the Patent Register in respect of those submissions must be addressed.

The Minister has applied such an analysis in cases involving **ramipril (ALTACE)** and **desmopressin (DDAVP)**. Despite pending prohibition proceedings, the Minister has issued notices of compliance (NOCs) to Apotex for these products as a result of such analysis. The Minister also issued an NOC to Novopharm for desmopressin. Judicial review applications have been commenced in all cases, which will likely be heard this spring.

In the ramipril case, Sanofi-Aventis brought a motion for a stay which was granted by the Federal Court, where the Judge found that the issuance of the NOC in light of the prohibition proceeding showed "an utter disrespect" by the Minister for the Court and the proceedings before it to which the Minister is a party.

Full Judgment (2006 FC 1559)

Apotex appealed and brought its own motion for a stay which was granted by the Court of Appeal. The Judge hearing the motion held that Apotex had established that it will suffer irreparable harm if the stay Order was not stayed.

Court of Appeal Decision (2007 FCA 7)

A further stay was denied by the Supreme Court.

Court Accepts Allegation of Invalidity for Lack of "Good Faith" During Prosecution

In a proceeding under the *Regulations* relating to **celecoxib (CELEBREX)** (*Searle and Pfizer v. Novopharm and Minister of Health*, 2007 FC 81), Novopharm argued that a patent was invalid as it was "abandoned" during prosecution. Section 73 of the *Patent Act* provides that an application "shall be deemed abandoned" if the applicant does not reply in good faith to any requisition made by an Examiner. Novopharm argued that Searle had misled the Patent Office by remaining silent regarding certain details of one of the pieces of prior art cited by the Examiner in an Office Action.

The Judge agreed with Novopharm, finding that Searle failed to advise the Patent Office that it had not only already found that at least one of the compounds in a cited reference had similar properties to those claimed, but also that Searle had disclosed this fact to the public before the Canadian application was filed. The Judge stated, "the essential point is that all appropriate facts should have been stated in the patent application itself, and disclosed to the Patent Office so as to allow the examiner to make an appropriate assessment and, if necessary, require amendment or cancellation respecting the specification and proposed claims". He concluded that "good faith" was not shown in submitting the application as filed without fuller disclosure regarding the reference, nor in responses to the Patent Office dealing with the reference.

The Judge also found that Searle had not established that Novopharm's allegation of invalidity on the basis of obviousness was not justified.

Attorney General Seeks to Strike CGPA's Data Protection Challenge

As reported in the December 2006 issue of *Rx IP Update*, the amended data protection provision of the *Food and Drug Regulations* has been challenged by the Canadian Generic Pharmaceutical Association (CGPA), an industry association representing most generic drug manufacturers in Canada, and separately by Apotex. CGPA amended its notice of application on November 22, 2006, adding three new bases for its challenge (mirroring attacks in Apotex's complaint): (i) the protection of trade secrets and confidential information is within the exclusive legislative competence of the provinces; (ii) the regulation-making authority conferred under the *Act* is an impermissible sub-delegation of legislative function; and (iii) the *Regulations* are void for uncertainty or vagueness.

The Attorney General brought a motion to strike CGPA's claim as being frivolous, vexatious and an abuse of process, citing the CGPA's lack of standing to bring the application. The motion was heard on January 30, 2007 and taken under reserve.

PMPRB's Decision on Laid-open Jurisdiction Challenged in Federal Court

As reported in the January 2007 issue of *Rx IP Update*, the Patented Medicine Prices Review Board (PMPRB) decided, in connection with a hearing on pricing of **ADDERALL XR**, that once a patent issues, the Board has jurisdiction to prevent excessive pricing during the laid-open period. On January 16, 2007, Shire filed a judicial review application of that decision in the Federal Court. Janssen-Ortho filed a similar Court challenge on the same day, relating to the drug **CONCERTA**. Details of these Court filings are listed in the New Proceedings section, below.

Consolidated Version of Amended Linkage Regulations Published

As reported in the October 2006 Special Edition of *Rx IP Update*, sweeping amendments to the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") came into force on October 5, 2006. The Government has recently published a consolidated version of the *Regulations* that includes these amendments.

A consolidated version of the *Food and Drug Regulations*, including the amended data protection provision, has also recently been published.

Supreme Court of Canada Matters

Leave Applications Filed

Apotex v. Merck (**lisinopril (ZESTRIL, PRINIVIL)**), December 11, 2006

By Apotex. The Court of Appeal (as reported in the November 2006 issue of *Rx IP Update*) affirmed the Trial Judge's decision (reported in the May 2006 issue of *Rx IP Update*) holding the patent covering lisinopril valid and infringed.

Sanofi-Aventis v. Apotex (**ramipril (ALTACE)**), January 2, 2007

By Sanofi-Aventis. The Court of Appeal (as reported in the December 2006 issue of *Rx IP Update*) declined to grant an Order of prohibition for a "use" patent under the *Regulations*. The Court of Appeal found that the issue – whether Apotex would infringe the patent by mere sale of its drug product, where it was conceded that infringement by patients would occur – was squarely addressed and dealt with in *Pharmascience v. Sanofi-Aventis* (2006 FCA 229, reported in the July 2006 issue of *Rx IP Update*).

Sanofi-Aventis v. Apotex (**ramipril (ALTACE)**), January 16, 2007

By Sanofi-Aventis. The Court of Appeal granted Apotex's motion for a stay of an Order which stayed the operation of a notice of compliance issued on December 12, 2006 to Apotex in respect of its Apo-Ramipril capsules. The stay was granted until the earlier of: the disposition of a judicial review proceeding brought by Sanofi-Aventis; or the termination of the 24-month stay in a co-pending proceeding under the *Regulations* (see article, above). On January 29, 2007, the Supreme Court denied Sanofi-Aventis' motion for a stay and ordered the leave application expedited.

Leave Applications Dismissed

Johnson & Johnson v. Boston Scientific; Johnson & Johnson v. Arterial Vascular Engineering (**stent**), January 19, 2007

By Boston Scientific and Arterial Vascular Engineering. The Court of Appeal had allowed Johnson & Johnson's appeals from summary judgments which were granted to the Defendants based on the Dutch Industries decision on invalid patents for deficient fee payments. The Court of Appeal had reversed the decision based on section 78.6(1) of the *Patent Act*, which came into force on February 1, 2006.

Ratiopharm v. Pfizer (**amlopidine besylate (NORVASC)**), February 1, 2007

By Ratiopharm. The Court of Appeal granted a prohibition Order, reversing a decision of an Applications Judge. The Court of Appeal upheld the validity of a selection patent, relying on the uncontested facts and the findings of the Applications Judge that the selected salt had an advantage and quality of a special character in respect of certain pharmaceutical properties.

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Sanofi-Synthelabo v. Apotex (**clopidogrel bisulfate tablets (PLAVIX)**), December 22, 2006

Court of Appeal dismisses Apotex's appeal from a judgment granting Sanofi an Order of prohibition. The Court found that the Applications Judge did not err in concluding that Apotex's allegations of anticipation, obviousness and double patenting were not justified.

Court of Appeal Decision (2006 FCA 421)

Applications Judge's Decision (2005 FC 390)

Abbott Laboratories v. Pharmascience (**clarithromycin (BIAXIN BID)**), January 11, 2007

Judge dismisses Abbott's application for an Order of prohibition with respect to the '606 patent in light of the decision in *Abbott Laboratories v. Ratiopharm* (2005 FC 1093, affirmed 2006 FCA 187), which found that the same piece of prior art that was relied upon by Pharmascience also anticipated the patent. The Judge found that no extrinsic evidence, expert or otherwise, could change the plain language of the claims. Judge also dismisses Abbott's application for an Order of prohibition with respect to the '361 patent, finding that the relevant claims do not meet the eligibility requirements for listing.

Full Judgment (2006 FC 1558)

Pfizer v. Apotex (**sildenafil (VIAGRA)**), January 12, 2007

Judge dismisses Pfizer's application for an Order of prohibition. Apotex had alleged invalidity based on lack of sound prediction.

Full Judgment (2007 FC 26)

Pfizer and Warner-Lambert v. Ranbaxy and Minister of Health (**atorvastatin (LIPITOR)**), January 25, 2007

Judge grants, in part, Pfizer's application for an Order of prohibition. In respect of one of the patents at issue, the Judge found that Pfizer was successful in disproving Ranbaxy's allegation of non-infringement; in respect of a second patent, the Judge found that Pfizer had not disproven Ranbaxy's allegation of invalidity for insufficiency. The Judge found that the assertion of ten-fold increased activity of atorvastatin calcium over the racemic calcium salt was, from the evidence presented, incorrect. Notably, this result was different from that in a case involving Novopharm (2006 FC 1471).

Full Judgment (2007 FC 91)

Other Decisions

Servier, Adir and Oril Industries v. Apotex (**perindopril (COVERSYL)**), November 29, 2006; January 3, 2007

In a patent infringement action, Motions Judge grants in part the Plaintiffs' motion for an interim injunction preventing the exporting of perindopril products to Australia, as well as the sale, distribution, supply or shipment of any perindopril products already in Australia, by Apotex. However, Judge subsequently dismisses Servier's motion for an interlocutory injunction to restrain Apotex in relation to perindopril products in the UK, Australia or Canada, finding the plaintiffs failed to demonstrate they would suffer irreparable harm in any of the jurisdictions.

Motions Judge's Reasons (2006 FC 1443)

Motions Judge's Reasons (2006 FC 1493)

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	**ramipril (ALTACE)**
Applicant:	Sanofi-Aventis Canada Inc
Respondents:	Pharmascience Inc and The Minister of Health
Respondent/Patentee:	Schering Corporation
Date Commenced:	December 29, 2006
Court File No:	T-2300-06
Comment:	Application for Order of prohibition until expiry of Schering's Patent No. 1,341,206. Pharmascience alleges invalidity and asserts that Sanofi-Aventis is estopped from asserting the validity of the patent on the basis of two previous decisions of the Court.

Medicine: **atorvastatin calcium (LIPITOR)**
Applicants: Pfizer Canada Inc and Warner-Lambert Company, LLC
Respondents: The Minister of Health and Ratiopharm Inc
Date Commenced: January 18, 2007
Court File No: T-115-07
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,521,891, 2,522,899, 2,450,111, 2,521,908, 2,521,980, 2,521,933, 2,521,953, 2,521,956, 2,521,828, 2,521,833, 2,521,792, 2,521,776, 2,521,887 and 2,521,958. Ratiopharm alleges non-infringement, invalidity and that the '980 and '958 patents are not eligible for listing on the Patent Register.

Other Proceedings

Medicine: **omeprazole (APO-OMEPRAZOLE); medroxyprogesterone (APO-MEDROXY); levodopa and carbidopa (APO-LEVOCARB CR); simvastatin (APO-SIMVASTATIN); clarithromycin (APO- CLARITHROMYCIN); and digoxin (APO-DIGOXIN)**
Plaintiff: Apotex Inc
Defendants: Attorney General of Canada, Minister of Health, Mr. Eric Ormsby and Dr. Craig Simon
Date Commenced: January 3, 2007
Court File No: 07-CV-325077 PD3
Comment: Claim for damages, including punitive damages, "caused to Apotex by reason of persistent, and systematic refusal of the defendants to consider in good faith Apotex's submissions, and, in particular Apotex's appeals from refusals to approve submissions" for the above-noted medicines. Mr. Ormsby was Acting Manager in the Therapeutics Drugs Directorate's Office of Science. Mr. Simon was Acting Manager in the Therapeutics Drugs Directorate's Division of Biopharmaceutics Evaluation.

Medicine: **methylphenidate (CONCERTA)**
Applicant: Janssen-Ortho Inc
Respondent: Attorney General of Canada
Date Commenced: January 16, 2007
Court File No: T-100-07
Comment: Application for an Order setting aside an Order of the Board dated December 18, 2006 which rejected an objection by Janssen-Ortho to the Board's jurisdiction made during a hearing; and an Order declaring that the Board is without jurisdiction to make an Order pursuant to section 83 of the *Patent Act* in respect of any period during which a patentee has no issued patent (see article above).

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Medicine:	**mixed salts amphetamines (ADDERALL XR)**
Applicant:	Shire Biochem Inc
Respondent:	Attorney General of Canada
Date Commenced:	January 16, 2007
Court File No:	T-101-07
Comment:	Application for an Order quashing the December 18, 2006 decision of the Board (see article above).

Medicine:	unidentified
Applicant:	Mayne Pharma (Canada) Inc
Respondents:	Attorney General of Canada and The Minister of Health
Date Commenced:	January 18, 2007
Court File No:	T-116-07
Comment:	Application for an Order quashing and setting aside the decision of The Minister of Health, refusing to process Mayne's new drug submission for "Drug A" and an Order directing the Minister to issue a notice of compliance to Mayne for "Drug A".

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