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Rx IP Update

Canadian Pharmaceutical Intellectual Property Law Newsletter

Federal Court Finds "Relevance" Required for Listing Under Old Linkage Regulations

In a decision from March 29, 2007, a Judge found that, in view of two Supreme Court decisions (*Bristol-Myers Squibb Co. v. Biolyse*, 2005 SCC 26, and *AstraZeneca v. Apotex*, 2006 SCC 49), under the pre-amended *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*"), the Minister must look at the "patented invention" and determine if there is a "relationship" between that "patented invention" so as to make it "relevant" to the particular notice of compliance (NOC) against which it is sought to be listed on the Patent Register or, if listed, to be delisted (*Wyeth Canada v. Ratiopharm Inc.*, 2007 FC 340).

In effect, the Judge decided that the Supreme Court had overruled a Court of Appeal decision which had determined that the patented invention is not required to be embodied in an innovator's approved product in order for the patent to be listed on the Patent Register (*Eli Lilly Canada v. Canada (Minister of Health)*, 2003 FCA 24).

The decision arose from a motion brought by ratiopharm for summary dismissal of a prohibition proceeding in respect of a patent listed against Wyeth's drug, **EFFEXOR XR (venlafaxine)**. The Judge declined to find the patent was improperly listed in association with two NOCs, concluding:

> The Minister has, in law, created [the requisite] relationship by listing the '778 patents against those NOCs. While there is no record as to what factual deliberations, if any, the Minister undertook in establishing such relationship, one must presume that he did so deliberate and determined, factually, that such relationship existed. This presumption would not arise in all cases where for instance, it was clear no such relationship existed. However, where there is a reasonable dispute as to the facts and opinions necessary to establish such relationship, deference must be given to the Minister.

Based on the facts set out in the decision, the nature of "relevance" required to support listing a patent is unclear. Ratiopharm has appealed. The appeal is scheduled to be heard on June 25, 2007.

Proceeding Against Different Generic on Same Allegation of Invalidity Found Abusive

On April 23, 2007 in a 2:1 decision, the Court of Appeal affirmed a Motions Judge's dismissal of a proceeding under the *Regulations* as an abuse of process (*Sanofi-Aventis Canada Inc. v. Novopharm Limited*, 2007 FCA 163). Sanofi-Aventis' application against one generic (Apotex) relating to the drug **ramipril** (Sanofi-Aventis' **ALTACE**) had been dismissed on the merits, on the basis of Apotex's allegation of invalidity based on lack of sound prediction. That decision was upheld on appeal, and a leave application was dismissed. Sanofi-Aventis commenced a subsequent proceeding against Novopharm relating to the same drug and the same patent. Novopharm also alleged invalidity on the basis of lack of sound prediction. Novopharm brought a motion for summary dismissal, declaring the application an abuse of process due to the earlier Apotex decision. A Judge dismissed the second proceeding (*Sanofi-*

Aventis v. Novopharm (2006 FC 1135)), finding it "plain and obvious" that Sanofi-Aventis has no chance of success with the current application "as the Federal Court is bound to follow the decision of the Federal Court of Appeal in the First Aventis …Application". While the Court of Appeal disagreed with the finding that the previous Judge's decision would be binding in a subsequent proceeding and therefore that the application was not "clearly futile", the majority nevertheless found the proceeding an abuse of process and that it therefore should be dismissed.

Issue Estoppel Precludes Second Allegation of Invalidity

On April 5, 2007, the Court of Appeal concluded that generics should in most circumstances be precluded by issue estoppel from alleging for a second time that a patent is invalid, unless the basis relied upon for the subsequent allegation could not be determined with reasonable diligence at first instance, or some special overriding circumstance exists to warrant a Judge exercising his or her discretion not to apply issue estoppel on the facts of the particular case (*Pharmascience Inc. v. Canada (Minister of Health)*, 2007 FCA 140). As the Court of Appeal found that no extraordinary circumstances existed in the case at hand, it affirmed the Applications Judge's finding that issue estoppel applied (2006 FC 341), and therefore affirmed the Order of prohibition relating to **clarithromycin (BIAXIN)**.

Court of Appeal Reverses "Abandonment" Finding

In a proceeding under the *Regulations* relating to **celecoxib (CELEBREX)** (*Searle and Pfizer v. Novopharm and Minister of Health*, 2007 FC 81), the Judge found that Novopharm's allegations of invalidity based on obviousness and on "abandonment" during prosecution were justified. On April 30, 2007, the Court of Appeal reversed 2007 FCA 173. The Court found that both issues rested on the Judge's finding that Searle was not the applicant as of the claim date of the patent application. However, it found that the Judge was not free to determine that Searle was not the applicant, both as a matter of procedural fairness (the issue had not been raised in the notice of allegation (NOA)) and based on the record before him. The obviousness and abandonment allegations could therefore not succeed.

Court of Appeal Comments on Burden for Invalidity Allegations Under Linkage Regulations

In dismissing Abbott's appeal of an Order dismissing its application for a prohibition Order relating to **clarithromycin (BIAXIN)**, the Court of Appeal stated that the presumption of validity under the *Patent Act* "cannot determine the outcome of prohibition proceedings under the *NOC Regulations* if, as in this case, the record contains any evidence that, if accepted, is capable of rebutting the presumption".

Court of Appeal Decision (2007 FCA 153)

Federal Court Decision (2005 FC 1332)

Judge Grants Prohibition Order for Olanzapine

On April 27, 2007, a Judge granted a prohibition Order against Apotex relating to **olanzapine** (Eli Lilly's **ZYPREXA**), rejecting Apotex's allegation of invalidity on the grounds of anticipation, obviousness, double patenting and a violation of section 53 of the *Patent Act* (*Eli Lilly v. Apotex*, 2007 FC 455).

Supreme Court Denies Leave for "Use" Patent Cases

On April 20, 2007, the Supreme Court denied Sanofi-Aventis leave to appeal two Court of Appeal decisions which considered the test of infringement for "use" patents under the *Regulations* (*Sanofi-Aventis v. Pharmascience, Minister of Health and Schering,* 2006 FCA 229, and *Sanofi-Aventis v. Apotex and Minister of Health*, 2006 FCA 357 **(ramipril (ALTACE)**).

In *Pharmascience*, the Court of Appeal found the allegation of non-infringement justified as it had not been established that Pharmascience would infringe, induce or procure infringement. In the *Apotex* case, the Court of Appeal followed *Pharmascience* and found that mere sale of the drug product would not constitute indirect infringement.

In a subsequent decision (*Novopharm v. Sanofi-Aventis*, 2007 FCA 167 **(ramipril (ALTACE)**), the Court of Appeal reversed a Motions Judge's decision (2006 FC 1547) and summarily dismissed a prohibition proceeding relating to "use" patents. The Judge accepted Novopharm's argument that it is "inevitable" that its non-infringement allegation will be found to be justified because Novopharm was not seeking approval to market its product for any of the claimed uses, and because there was no evidence that Novopharm will induce others to use its product for any of those new uses.

Progressive Licensing Framework Update

As part of its plan to revise Canada's laws regarding health products and food in Canada, the Health Products and Food Branch (HPFB) has proposed a new progressive licensing framework to replace the current model. Presently, federal government drug licensing is point-in-time, such that Health Canada only becomes involved in a drug product's life at defined points. The progressive licensing project is proposing a shift to a life-cycle approach that would include a continuous monitoring of a drug product throughout its life.

Potential features of the new framework include pre-submission consultation, filing and review of a life-cycle management plan that would include pharmacovigilance and risk management strategies, and re-evaluation and updating of drug information after a period of initial marketing. HPFB is also proposing adding a benefit-risk analysis to its current market authorization review of safety, efficacy and quality. Benefit-risk factors that are currently being considered include availability and performance of other therapies, anticipated patterns of use and manageability of risks, the seriousness of the disease or condition that the drug is proposed to treat, the identity of the target population, and pre-market access to the drug. While the proposed changes will likely require greater interaction with Health Canada for most drug products, the changes might also provide earlier marketing approval for some drugs and pre-approval of some drug changes without the filing of a further submission. There is also the potential for any proposed changes to drug licensing to have an impact on the scope of protections afforded by Canada's amended regulations governing data protection or the recently amended *Regulations*. The protections afforded under both are linked to different stages in Canada's current point-in-time review process.

HPFB is currently involved in internal and external consultations on the Progressive Licensing Project, which are expected to continue through the summer of 2007. A number of discussion documents have been released and are available through the Blueprint for Renewal and Progressive Licensing Project web-sites, and a series of further discussion documents are planned for release this Spring. Following this latest round of consultations, the next step will likely be the publication of proposed new Regulations for public comment.

Developments on the Progressive Licensing Project can be monitored on its website, and the broader review of Canada's food and drug laws on the Blueprint for Renewal site. The broader review includes a review of the regulatory framework for clinical trials and a review of the medical devices program.

Progressive Licensing Project Website

Blueprint for Renewal Website

Health Canada Reviews Regulatory Framework for Clinical Trials

Health Canada has released a report on the results of public e-consultation to assess the impact of the 2001 amendments to Part C, Division 5 of the *Food and Drug Regulations* (Drugs for Clinical Trials Involving Human Subjects). It has also released a discussion document and presentation from the March 26, 2007 stakeholder workshop on ways to improve Canada's regulatory framework for clinical trials.

Review of Regulatory Framework for Clinical Trials

Summer 2006 E-consultation Report

March 2007 Workshop Discussion Document and Presentation

Update: Ontario Formulary Regulation Amendments

As reported in the October 2006 issue of *Rx IP Update*, the regulations under the *Ontario Drug Benefit Act* (*ODBA*) and *Drug Interchangeability and Dispensing Fee Act* (*DIDFA*) were amended as a result of the *Transparent Drug System for Patients Act*, 2006 (Bill 102). Further amending regulations were filed on December 14, 2006 as O. Reg. 558/06 (amending Reg. 935 under the *DIDFA*) and O. Reg. 559/06 (amending O. Reg. 201/96 under the *OBDA*), and came into force on that date. Certain sections are deemed to have come into force on October 1, 2006, and other sections came into force on March 1, 2007. The most significant amendment is the introduction of new exceptions to the 50% generic price rule: where the Executive Officer is satisfied that the generic drug would be the only product of its type proposed to be designated as interchangeable, the Executive Officer is permitted to negotiate agreements for any drug benefit price lower than the original product price.

Notice from the Executive Officer

DIDFA Amending Regulation O. Reg. 558/06

REGULATION 935 (amended to O. Reg. 558/06) (Regulations under DIDFA)

ODBA Amending Regulation O. Reg. 559/06

REGULATION 201/96 (amended to O. Reg. 559/06) (Regulations under ODBA)

On April 1, 2007, the amendments to *DIDFA* which permit off-formulary interchangeability – the application of interchangeability designations to drug products that are not listed as ODB benefits in the Formulary – came into force. The Ministry has released a notice with deadlines for OFI Submissions.

Notice: Implementation of Off-Formulary Interchangeability

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	**atorvastatin (LIPITOR)**
Applicants:	Pfizer Canada Inc and Warner-Lambert Company, LLC
Respondents:	The Minister of Health and Sandoz Canada Inc
Date Commenced:	March 22, 2007
Court File No:	T-488-07
Comment:	Application for Order of prohibition until expiry of Patent No. 2,021,546. Sandoz alleges non-infringement and invalidity.

Medicine: **clarithromycin (BIAXIN BID)**
Applicants: Abbott Laboratories and Abbott Laboratories Limited
Respondents: The Minister of Health and Pharmascience Inc
Date Commenced: March 26, 2007
Court File No: T-506-07
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,471,102 and 2,419,729. Pharmascience alleges non-infringement and invalidity. Pharmascience also asserts that the patents are not eligible for listing on the Patent Register.

Medicine: **lansoprazole capsules (PREVACID)**
Applicants: Abbott Laboratories Limited, Tap Pharmaceuticals Inc and Tap Pharmaceutical Products Inc
Respondents: The Attorney General of Canada and The Minister of Health
Date Commenced: March 26, 2007
Court File No: T-513-07
Comment: Judicial review of Minister's decision to remove Patent No 2,269,053 from the Patent Register. Applicants assert pre-amended *Regulations* apply to patent list submitted on July 20, 2006.

Medicine: **desmopressin (acetate) tablets (MINIRIN/DDAVP)**
Applicants: Ferring Inc and Ferring BV
Respondents: The Minister of Health and Pharmascience Inc
Date Commenced: April 2, 2007
Court File No: T-541-07
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,486,833 and 2,490,335. Genpharm alleges non-infringement and invalidity. Genpharm also asserts that the patents are not eligible for listing on the Patent Register.

Medicine: **pantoprazole (PANTOLOC)**
Applicants: Altana Pharma Inc and Altana Pharma AG
Respondents: The Minister of Health and Genpharm Inc
Date Commenced: April 5, 2007
Court File No: T-566-07
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,109,697, 2,089,748 and 2,092,694. Genpharm alleges non-infringement and invalidity. Genpharm also asserts that the '748 patent is not eligible for listing on the Patent Register.

Medicine: **gliclazide sustained release tablets (DIAMICRON MR)**
Applicants: Servier Canada Inc and Les Laboratoires Servier
Respondents: The Minister of Health and Apotex Inc
Date Commenced: April 25, 2007
Court File No: T-692-07
Comment: Application for Order of prohibition until the expiry of Patent No. 2,273,420. Apotex alleges non-infringement.

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Other Proceedings

Medicine: **vancomycin (hydrochloride) powder (VANCOMYSOL/VANCOPAK)**
Applicants: Canadian Pharmaceutical Technologies International (C.P.T.) Inc
Respondents: The Attorney General of Canada
Date Commenced: March 15, 2007
Court File No: T-459-07
Comment: Review of Health Canada decision that VANCOMYSOL is a drug rather than an active pharmaceutical ingredient sold for compounding purposes and as such is subject to the *Food and Drug Regulations*.

Applicant: IMS Health Consulting Inc
Respondents: Industry Canada and The Attorney General of Canada
Date Commenced: April 16, 2007
Court File No: T-626-07
Comment: Application for an Order prohibiting the Minister from disclosing contested information from a report entitled "Canadian Pharmaceutical Market Forecast, Modelling the impact of patent expiry on major brands."

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