SMART & BIGGAR | FETHERSTONHAUGH JULY 2006

Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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Test for Infringement of Use Patents Under Linkage Regulations Tightened

In *Pharmascience Inc. v. Sanofi-Aventis Canada Inc.* (2006 FCA 229), an appeal from an Order of prohibition (2005 FC 340) regarding ramipril (ALTACE), the Federal Court of Appeal considered the infringement of a use patent. The Court ruled that the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") are intended to prevent infringement by generic drug manufacturers, rather than infringement generally, such as by patients. Two previous Court of Appeal decisions provided arguably conflicting guidance on the issue: *AB Hassle v. Minister of Health* (2002 FCA 421) and *Procter & Gamble v. Minister of Health and Genpharm* (2002 FCA 290). Given that it was not established that Pharmascience would infringe or would induce or procure infringement, the allegation was found to be justified. The Court also overruled the Applications Judge's finding that the allegation was insufficient.

In the same ruling, the Court considered whether a patent covering ramipril, owned by Schering and listed on the Patent Register by Sanofi-Aventis, was invalid for double patenting. Pharmascience relied on two Sanofi-Aventis patents that were applied for after the Schering patent, but which issued earlier.

The Court found that there was not sufficient evidence on whether the Schering patent would have been obvious in view of the Sanofi-Aventis patents. While this finding was sufficient to uphold the Order of prohibition, the Court offered some guidance on double patenting, noting that double patenting is devised to prevent evergreening. The Court agreed that applying double patenting in this case would have been inconsistent with the provision of the relevant *Patent Act*, which granted a patent on the basis of first to invent rather than first to file. As the inventors of the later Sanofi-Aventis patents and the Schering patent worked independently, the filing of the Schering patent was not an attempt to unduly extend the terms of the other two patents. The application of double patenting would have unfairly deprived Schering of patent rights merely because of delay beyond its control in the issuance of the Schering patent.

The Court expressly declined to adopt the proposition that double patenting applies only where there is common inventorship, although it noted that it was difficult to envisage a case involving more than one inventor that is or should be vulnerable to double patenting.

J. Sheldon Hamilton

Court of Appeal Provides Guidance on Selection Patents and Empirical Testing

In *Pfizer v. Ratiopharm* (2006 FCA 214), the Court of Appeal reversed a lower Court decision (2006 FC 220) that an allegation of invalidity was justified in respect of a patent for amlopidine besylate (NORVASC).

The primary issue was the validity of a selection patent for the besylate salt of amlopidine in view of an earlier patent disclosing amlopidine and its pharmaceutically acceptable salts. The Court discussed the concept of selection patents, noting that they exist to encourage researchers to discover new

advantages for compounds within a known class. The Court rejected the proposition that empirical research for the purpose of making a selection from a class is verification, noting that "verification means confirming predicted or predictable qualities of known compounds, *i.e.* components that have already been discovered and made".

In allowing the appeal, the Court cited uncontested factual findings made by the Applications Judge, including that the skilled person would neither know nor predict certain properties of a salt and therefore could not know which particular salt will be best for a particular purpose until the salts are made and tested.

The Judge below had erroneously applied the principle of verification, causing him to conclude that the salt at issue had no advantage or quality of a special character capable of supporting a selection patent. The Court of Appeal upheld the validity of the patent, relying on the uncontested facts and the findings of the Judge below that the salt had an advantage and quality of a special character in respect of certain pharmaceutical properties.

The Court of Appeal also upheld a finding that the patent was not anticipated by an earlier European patent application, given the findings by the Applications Judge that a skilled person would not know: to select the besylate salt as one of the initial choices; whether it would form a salt of amlopidine in the solid state; particular properties of the salt; or the advantages for pharmaceutical formulation.

J. Sheldon Hamilton

Proposed Amendments to Linkage Regulations and Data Protection

As reported in our June 2006 Special Edition of *Rx IP Update*, proposed amendments to the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") and to the data protection provision of the *Food and Drugs Regulations* were published on June 17, 2006. The deadline for filing submissions on the proposed amendments is **July 17, 2006**.

Ontario Bill Amending Formulary Legislation Receives Royal Assent

Bill 102, the *Transparent Drug System for Patients Act, 2006,* which amends the *Drug Interchangeability and Dispensing Fee Act* and the *Ontario Drug Benefit Act*, received Royal Assent on June 20, 2006.

An Act to amend the Drug Interchangeability and Dispensing Fee Act and the Ontario Drug Benefit Act

News Release

Health Canada News

The Therapeutic Products Directorate has released a statistical report relating to the administration of the *Patented Medicines (Notice of Compliance) Regulations*. The report provides a number of statistics including relating to the maintenance of the Patent Register, the number of notices of allegation (NOAs) served, prohibition applications and outcomes of these applications.

Statistical Report 2005

Health Canada will now directly release product monographs to requesters, following issuance of the corresponding notice of compliance (NOC).

Notice

Practice Notice: Fertilized Eggs, Stem Cells, Organs and Tissues

The Canadian Patent Office has issued a practice notice stating its position regarding the patentability of higher life forms.

The Patent Office takes the position that animals at any stage of development, from fertilized eggs on, are higher life forms and are thus **not** patentable subject matter. Totipotent stem cells, which have the same potential as fertilized eggs to develop into an entire animal, are considered to be equivalents of fertilized eggs and are thus also **not** patentable subject matter. Embryonic, multipotent and pluripotent stem cells, which do not have the potential to develop into an entire animal, **are** patentable subject matter.

Further, the Office takes the position that organs and tissues are **not** patentable subject matter. Artificial organ-like or tissue-like structures, generated substantially through the hand-of-man by combining various cellular components and/or inert components, may be considered, on a case-by-case basis, to be compositions of matter and patentable subject matter.

A more detailed analysis of the CIPO practice notice is available in the June 2006 2nd Edition of our firms' *IP Update*.

CIPO Notice

Competition Bureau Concludes Review of Acquisition of ID Biomedical by GSK

In September 2005, GlaxoSmithKline (GSK) announced it had reached an agreement to acquire ID Biomedical Corporation, a biotechnology company dedicated to the development of innovative vaccine products. The Competition Bureau conducted an examination and concluded that the proposed transaction would not result in any substantial lessening of competition in the vaccine market in Canada.

News Release

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Pharmascience v. Sanofi-Aventis (**ramipril (ALTACE)**), June 7, 2006

Court of Appeal dismisses motion by Pharmascience for an Order that a patent is invalid and incapable of supporting a prohibition Order, or alternatively that it is an abuse of process for Sanofi-Aventis to argue that the patent is valid. Pharmascience had relied on a decision in a proceeding where a different second person's allegation of invalidity was found to be justified. Court of Appeal confirms that NOC proceedings do not determine the validity of a patent.

Full Judgment (2006 FCA 210)

Other Decisions

Apotex v. Minister of Health (**flavoxate (APO-FLAVOXATE, URISPAS)**), May 30, 2006

Ontario Superior Court quashes the Ontario Minister of Health's decision to delist Apo-Flavoxate as an interchangeable product under the *Drug Interchangeability and Dispensing Fee Act*.

Full Judgment

Canadian Pharmaceutical Technologies v. Canada (**vancomycin hydrochloride (VANCOPAK, formerly VANCOMYSOL)**), June 7, 2006

CPTI had offered to sell vancomycin hydrochloride powder requiring reconstitution to a purchasing group for hospitals. Judge allows CPTI's application for judicial review of a Health Canada decision to classify CPTI's drug as a "drug in dosage form" under the *Food and Drugs Regulations*, thus requiring a drug identification number (DIN), and not as an active pharmaceutical ingredient (API) for compounding. The Judge found that Health Canada had breached its duty of fairness by failing to provide CPTI with knowledge of the case it had to meet and an opportunity to respond, and therefore permitted CPTI to provide evidence in response to Health Canada's concerns. The Court also commented that there is an urgent need for Parliament to regulate active pharmaceutical ingredients not being marketed as "drugs in dosage form".

Full Judgment (2006 FC 708)

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: **amlodipine besylate (NORVASC)**
Applicants: Pfizer Canada Inc and Pfizer Inc
Respondents: Sandoz Canada Inc and The Minister of Health
Date Commenced: May 25, 2006
Court File No: T-885-06
Comment: Application for Order of prohibition until expiry of Patents Nos 1,321,393 and 2,355,493. Sandoz alleges non-infringement and invalidity ('393 and '493 patents) and that the patent is not eligible for listing on the Patent Register ('493 patent only).

Medicine: **amlodipine besylate (NORVASC)**
Applicants: Pfizer Canada Inc and Pfizer Inc
Respondents: Pharmascience Inc and The Minister of Health
Date Commenced: May 29, 2006
Court File No: T-899-06
Comment: Application for Order of prohibition until expiry of Patents Nos 1,321,393 and 2,355,493. Pharmascience alleges non-infringement and that the patents are not eligible for listing on the Patent Register ('393 and '493 patents) and invalidity ('393 patent only).

Medicine: **galantamine hydrobromide (REMINYL)**
Applicants: Janssen-Ortho Inc and Janssen Pharmaceutica NV
Respondents: Apotex Inc and The Minister of Health
Date Commenced: June 2, 2006
Court File No: T-922-06
Comment: Application for Order of prohibition until expiry of Patent No 2,310,950. Apotex alleges non-infringement, invalidity, and that the patent is not eligible for listing on the Patent Register.

Medicine: **felodipine (RENEDIL)**
Applicant: Sanofi-Aventis Canada Inc
Respondents: AB Hassle, Sandoz Canada Inc and The Minister of Health
Date Commenced: June 7, 2006
Court File No: T-940-06
Comment: Application for Order of prohibition until expiry of Hassle's Patent No 1,304,294. Sandoz alleges non-infringement and that the patent is not eligible for listing on the Patent Register.

Medicine: **cefepime hydrochloride (MAXIPIME)**
Applicants: Bristol-Myers Squibb Canada Co and Bristol-Myers Squibb Company
Respondents: Apotex Inc and The Minister of Health
Date Commenced: June 7, 2006
Court File No: T-941-06
Comment: Application for Order of prohibition until expiry of Patents Nos 1,307,464 and 2,011,116. Apotex alleges non-infringement.

Medicine: **felodipine (PLENDIL)**
Applicants: AstraZeneca Canada Inc and AB Hassle
Respondents: Sandoz Canada Inc and The Minister of Health
Date Commenced: June 8, 2006
Court File No: T-947-06
Comment: Application for Order of prohibition until expiry of Patent No 1,304,294. Sandoz alleges non-infringement and that the patent is not properly listed on the Patent Register.

Medicine: **cefotaxime (CLAFORAN)**
Applicant: Sanofi-Aventis Canada Inc
Respondent: The Minister of Health
Date Commenced: June 15, 2006
Court File No: T-979-06
Comment: Application for an Order directing the Minister to reinstate Patent No 1,319,682 on the Patent Register. Sanofi-Aventis pleads *res judicata* and/or issue estoppel as a judgment in a prior proceeding had issued prohibiting the Minister from issuing an NOC to a second person until after the expiration of the '682 Patent.

Medicine: **galantamine hydrobromide (REMINYL)**
Applicant: Janssen-Ortho Inc and Janssen Pharmaceutica NV
Respondent: Genpharm Inc and The Minister of Health
Date Commenced: June 16, 2006
Court File No: T-992-06
Comment: Application for Order of prohibition until expiry of Patents Nos 2,257,431, 2,310,926 and 2,310,950. Genpharm alleges non-infringement ('341 patent); non-infringement, invalidity, that the patent is not eligible for listing on the Patent Register ('926); and non-infringement and invalidity ('950 patent).

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Other Proceedings

Medicine: **sumatriptan succinate tablets (IMITREX and IMITREX DF)**
Plaintiffs: GlaxoSmithKline Inc and Glaxo Group Limited
Defendant: Pharmascience Inc
Date Commenced: June 14, 2006
Court File No: T-968-06
Comment: Action for a declaration that Pharmascience has directed public attention to its wares, services and business in such a way as to cause, or would be likely to cause confusion in Canada between Pharmascience's wares, services and business and the wares, services and business of GlaxoSmithKline, contrary to section 7(b) of the *Trade-marks Act* and the common law, specifically relating to the package design used by Pharmascience for its generic version of IMITREX DF.

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