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IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Recent Decisions under the *Patented Medicines (Notice of Compliance) Regulations* on Obviousness

In our July 2003 issue, we reviewed recent decisions under the *Patented Medicines (Notice of Compliance) Regulations ("Regulations")* considering the doctrine of anticipation. In this issue, we review the Courts' treatment of obviousness in proceedings under the *Regulations*. As a preface to the discussion, we note that decisions under the *Regulations* are not determinative of issues of patent validity, and parties may still litigate that issue in patent infringement/impeachment actions. Decisions under the *Regulations* simply determine whether the Minister may take the administrative step of issuing a notice of compliance.

In *Novartis v. Apotex* (2001 FCT 1129) the Court found that claims to a microemulsion formulation of cyclosporin were obvious in light of a prior patent describing an emulsion formulation. Since the Court found it was known (a) that a small droplet size was desirable to increase drug bioavailability, (b) how to make microemulsions and (c) that a microemulsion was one type of emulsion, the Court ruled that the claims would have been obvious based on the earlier patent disclosure pertaining to emulsions generally. The Court declined to find that the patent was non-obvious on the basis of secondary considerations such as commercial success and long-felt need. The fact of commercial success was discounted since Novartis held a monopoly due to the patent, and success was, in the Court's words "simply normal."

In *Pfizer v. Apotex* (2002 FCT 1138) the Court found that Pfizer's 065 patent for use of sertraline to treat or prevent certain anxiety disorders including panic disorder (PD) and obsessive-compulsive disorder (OCD) was obvious. The Court concluded that the prior art taught that "SSRIs, of which sertraline is one, were logical candidates for further investigation for both OCD and PD, that sertraline was in trials with respect to OCD, that sertraline was probably one of the SSRIs that would be a cornerstone of OCD treatment and that preliminary results suggested that drugs, including sertraline, should have anti-panic activity." The Court therefore concluded, "I see no inventive step or undue experimentation required in that circumstance for the notional skilled psychiatrist to prescribe sertraline for OCD or PD."

In *AstraZeneca v. Apotex* ("*AstraZeneca*", 2003 FCT 771) the Court rejected assertions that AstraZeneca's 751 patent for base addition salts of omeprazole was obvious. The Court concluded that there was no motivation to make a base addition salt of omeprazole since neutral omeprazole had sufficient stability and solubility for development and marketing. As a result, there was no need to make a salt to improve these characteristics. Moreover, the Court noted a teaching that pointed away from making an omeprazole base addition salt.

In *SmithKline Beecham Pharma v. Apotex* (2001 FCT 770), Apotex alleged that SmithKline's 637 patent for paroxetine tablets was obvious in light of SmithKline's earlier 060 patent. The 060 patent disclosed crystalline paroxetine hydrochloride hemihydrate, which could be prepared by "conventional methods of admixture." The Court found that there was no dispute that these methods would include wet granulation, dry granulation, and direct compression. The 637 patent related to paroxetine formulations prepared by a process where water was absent, thereby overcoming a "pink hue" discolouration that some paroxetine tablets had developed. The Court relied on expert testimony that the major challenge would have been to identify the cause of the pink hue problem and rejected the assertion of obviousness. (In the same case,

however, the Court upheld the allegation of invalidity on the basis of anticipation leading to the somewhat curious result of the patent being anticipated but not obvious). While the decision was upheld on appeal, the Court of Appeal did not discuss the obviousness analysis.

Similar facts were before the Court in a subsequent paroxetine decision. In *GlaxoSmithKline v. Apotex* (2003 FCT 687), the Court considered the 575 patent, which excluded both microcrystalline cellulose and water from the formulation (the 575 patent was a divisional of the 637 patent at issue in the earlier SmithKline case). The Court concluded that in light of the Court's previous finding that using a dry formulation process to solve the pink hue problem was not obvious, Apotex' allegation of obviousness must fail.

In *GlaxoSmithKline v. Pharmascience* (2003 FC 899), the Court upheld an assertion of obviousness in respect of SmithKline Beecham's 548 patent, which claimed the use of carvedilol, a beta-blocker, to treat congestive heart failure ("CHF"). The basis for this finding was that the association between the use of carvedilol and the prolongation of survival in the treatment of patients with CHF was known. While final Phase III results were required to eliminate uncertainty regarding carvedilol's effect on mortality, the Court concluded, "that element of creativity which is essential to an invention surely cannot be found in test results."

Given the fact specific scenarios before the Court in these decisions, it is difficult to draw any clear conclusions on the judicial approach to obviousness. However, the Courts have demonstrated a willingness to uphold assertions of obviousness, particularly where the patent relates to a new use for a known product. This willingness to find a patent obvious is noteworthy given the statutory presumption of validity enjoyed by patentees, which firmly places the burden on generics to demonstrate that a patent is invalid in proceedings under the *Regulations*.

J. Sheldon Hamilton

Supreme Court of Canada Leave Applications

Apotex v. AstraZeneca (**omeprazole and omeprazole magnesium tablets** (**LOSEC**)), August 25, 2003

On August 25, 2003, Apotex filed an application seeking leave to appeal a Federal Court of Appeal decision, which dismissed Apotex' appeal from an Order of a motions judge. The motions judge had affirmed the Order of a Prothonotary, staying the proceeding until final disposition of a proceeding currently before the Ontario Superior Court of Justice. Both cases deal with copyright in drug product monographs. On September 15, 2003, the Supreme Court ordered the leave application to be expedited. The Court of Appeal judgment was reported in our July 2003 issue of *Rx IP Update*.

Apotex and Dr. Sherman v. Merck (**enalapril** (**VASOTEC**)), August 25, 2003

On August 25, 2003, Apotex filed an application seeking leave to appeal a Federal Court of Appeal decision. The Court of Appeal had upheld decisions of a motions judge, finding Apotex and Dr. Sherman in contempt of court and imposing fines for selling enalapril, after Reasons finding infringement were released. The Court of Appeal judgment was reported in our July 2003 issue of *Rx IP Update.*

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

GlaxoSmithKline v. Apotex (**paroxetine hydrochloride** (**PAXIL**)), September 10, 2003

Judge dismisses Apotex' application for summary dismissal of GSK's application for an Order of prohibition. Apotex took the position that the application should be summarily dismissed because: (1) the patents were not listed in accordance with the strict timing requirements of section 4 of the *Regulations* and so were not properly included on the Patent Register; (2) the patents were not eligible for inclusion on the Patent Register because of their subject matter; (3) the patents were not eligible for inclusion on the Patent Register because they are not relevant to the medicine or the submission in respect of which they are listed; and (4) even if the patents were properly listed, they are not relevant to Apotex' NOC so that GSK's application is frivolous, vexatious, and an abuse of process. Judge finds that he is not convinced under any relevant standard that the patents were not properly listed and that Apotex clearly failed to meet the "plain and obvious" standard applicable to Apotex' fourth argument.

Full Judgment (2003 FC 1055)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Pharmascience v. Abbott (**clarithromycin** (**BIAXIN BID**)), September 15, 2003

Although Pharmascience's appeal is moot, Court of Appeal indicates that it agrees with motions judge that subsection 6(7) of the Regulations permits an order for disclosure of information from a drug master file that is cross-referenced or incorporated into an Abbreviated New Drug Submission (ANDS) because, as a matter of law, cross-referenced information is part of what the second person has "filed" as part of its ANDS. However, Court of Appeal also finds that "[I]f it is established by credible evidence that a generic manufacturer has filed an [ANDS] that includes cross-referenced third party information that the generic manufacturer does not have, that it has tried and failed to obtain, and that it has no legal right to obtain, it would be an error of law for a judge to order production of the cross-referenced information...However, even if there is such evidence, it would be open to a judge to order the generic manufacturer to use its best efforts to obtain the information, and to insist on a credible explanation if those best efforts fail."

Full Judgment (2003 FCA 333)
(*For a printer friendly version, please scroll down to the end of the Judgment)

New Court Proceedings

New NOC Proceedings

Medicine: **citalopram hydrobromide (CELEXA)**
Applicants: H Lundbeck AS and Lundbeck Canada Inc
Respondents: Ratiopharm Inc and The Minister of Health
Date Commenced: August 25, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,049,368. Ratiopharm alleges non-infringement and invalidity.

Medicine: **alendronate sodium (FOSAMAX)**
Applicants: Merck & Co Inc and Merck Frosst Canada & Co
Respondents: Novopharm Limited and The Minister of Health
Date Commenced: September 5, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,294,595. Novopharm alleges that certain claims are irrelevant to the drug in Novopharm's submission; that certain claims should not be considered as being included on the Patent Register in regard to this drug identification number; and invalidity.

Medicine: **quinapril (ACCUPRIL)**
Applicants: Pfizer Canada Inc, Warner-Lambert Company LLC and Parke, Davis & Company LLC
Respondents: Apotex Inc and The Minister of Health
Date Commenced: September 5, 2003
Comment: Application for Order of prohibition until expiry of Patents Nos. 1,291,999; 1,297,023; 1,297,024; 1,300,510; 1,331,615 and 1,341,330. Apotex alleges non-infringement and invalidity.

Medicine: **clarithromycin (BIAXIN BID)**
Applicants: Abbott Laboratories and Abbott Laboratories Limited
Respondents: Ratiopharm, a Division of Ratiopharm Inc and The Minister of Health
Date Commenced: September 10, 2003
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,258,606; 2,386,527; 2,386,534; 2,277,274; 2,387,361 and 2,387,356. Ratiopharm alleges non-infringement and invalidity. No. 2,105,180.

Medicine:	**ramipril (ALTACE)**
Applicant:	Aventis Pharma Inc
Respondents:	Apotex Inc, The Minister of Health and Schering Corporation
Date Commenced:	September 23, 2003
Comment:	Application for Order of prohibition until expiry of Schering's Patent No. 1,341,206. Apotex alleges invalidity.

Other New Proceedings

Medicine:	**tadalafil (CIALIS)**
Plaintiffs:	Pfizer Ireland Pharmaceuticals and Pfizer Canada Inc
Defendants:	Lilly Icos LLC and Eli Lilly Canada Inc
Date Commenced:	September 19, 2003
Comment:	Patent infringement action relating to Patent No. 2,163,446. Pfizer pleads that Lilly threatens to imminently sell tadalafil in Canada. As reported in the April 2002 issue of RxIP Update, by statement of claim dated March 1, 2002, Lilly has sought a declaration of invalidity of this patent.

Trade-marks Office News

The Trade-marks Office has recently published the attached practice notice, indicating that the Office requires the phrase "pharmaceutical preparations" in trade-mark applications to be specified in greater detail in order to comply with section 30(a) of the *Trade-marks Act*. In particular, the notice requires "pharmaceutical preparations" to be specified by (a) naming the disease, (b) specifying the disease group or type of disease, disorder or condition to be treated, or (c) by indicating the specific type of medication. A draft of this practice notice was published in our July 2003 issue of *Rx IP Update*.

Practice Notice

Canada's Patent Act may be Amended to Permit Generic Exports of AIDS Drugs

Canada may amend its *Patent Act* to allow Canadian generic pharmaceutical companies to export patented AIDS drugs to developing nations, following Canada's agreement to a World Trade Organization (WTO) Decision (Decision on implementation of paragraph 6 of the Doha Declaration on the TRIPS agreement and public health), made on August 30, 2003. The decision is intended to make it easier for poorer countries to import generic versions of patented drugs made under compulsory licences if they are unable to manufacture the medicines themselves. Canada's Research-Based Pharmaceutical Companies (Rx&D) has declared its support for the WTO Decision. The Canadian Generic Pharmaceutical Association (CGPA) has recently released a statement indicating that it is "very pleased" with the government's reponse to this issue.

We will report on developments on this issue in future issues of *Rx IP Update*.

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