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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

A Review of Decisions Addressing Allegations of Invalidity based on Anticipation under the *Patented Medicines (Notice of Compliance) Regulations*

The summary proceedings under the *Patented Medicines (Notice of Compliance) Regulations ("Regulations")* have generated a flurry of decisions in the Federal Court applying the doctrine of anticipation. This article reviews five such cases, including the latest decision, *AstraZeneca v. Apotex* (*"AstraZeneca"* 2003 FCT 771), which involved AstraZeneca's omeprazole magnesium product (LOSEC). Surprisingly, in four of these decisions, Apotex succeeded on allegations of invalidity on the basis of anticipation. In the interest of length, this discussion is limited to the Court's treatment of the anticipation issues. We will consider the Court's treatment of obviousness in a future issue of *Rx IP Update*.

As reported in the July 2002 issue of *Rx IP Update*, the Federal Court of Appeal, in *SmithKline Beecham Pharma v. Apotex* (*"SmithKline 1"* 2002 FCA 216, leave to S.C.C. dismissed on March 20, 2003), upheld a Trial Division decision (2001 FCT 770) ruling that an allegation of invalidity made by Apotex was justified on the basis of anticipation by an earlier SmithKline patent. The decision related to the medicine paroxetine (PAXIL).

In the second decision, *Novartis v. Apotex* (2001 FCT 1129), the Federal Court, Trial Division, ruled that Apotex' allegation of invalidity against Novartis' cyclosporin (NEORAL) formulation patent ("the 150 patent") was justified on, *inter alia*, the ground of anticipation. The patent at issue covered an improved cyclosporin formulation in the form of a microemulsion preconcentrate or a microemulsion.

Apotex alleged that certain claims of the 150 patent were anticipated by two earlier Novartis patents which allegedly disclosed cyclosporin emulsions. Despite the fact that microemulsions were apparently not specifically described in the two allegedly anticipatory patents, the judge agreed with one of Apotex' experts that "a microemulsion is merely an emulsion in which the droplet size is very small" and concluded that the impugned claims of the 150 patent were anticipated by the earlier patents. The judge also apparently accepted that a formulator would be aware of the well-known deficiencies in cyclosporin formulations and further that smaller droplet size would optimize drug release.

While Novartis appealed, Apotex succeeded in dismissing the appeal on grounds of mootness (2002 FCA 440) since the Minister of Health had issued the Notice of Compliance (NOC) before the appeal was considered.

In the third decision (*Pfizer v. Apotex* 2002 FCT 1138), the Federal Court Trial Division dismissed Pfizer's application for an Order of prohibition in connection with its sertraline product (ZOLOFT) since Pfizer failed to show that Apotex' allegation of invalidity on the basis of, *inter alia*, anticipation was not justified. The patent at issue ("the 065 patent") related to the use of sertraline to treat or prevent anxiety-related disorders including obsessive compulsive disorder (OCD) and panic disorder (PD). Apotex asserted that the claims regarding the treatment or prevention of OCD in the 065 patent were invalid on the basis of

anticipation. Apotex relied on a publication reporting that sertraline was undergoing Phase II clinical trials for the treatment of OCD and on an earlier Pfizer patent ("the 815 patent") disclosing the administration of sertraline for the treatment of depression.

Although the applications judge rejected Apotex' allegation that the 815 patent anticipated the 065 patent, she accepted the argument that the patent was anticipated by the Phase II clinical trial publication, finding that Pfizer failed to meet its burden of establishing that Apotex' allegation was not justified. Pfizer argued that the publication did not anticipate the 065 patent because the mere reference to sertraline in a Phase II trial for the treatment of OCD did not provide information that the drug worked for OCD. The judge noted that it was unnecessary for the publication to state that the drug was effective for the treatment of OCD in order for it to anticipate the 065 patent. Since it taught a skilled person to test sertraline for the treatment of OCD and the person could carry out the test without the aid of inventive genius, the publication anticipated the impugned claims of the 065 patent.

In the fourth decision, *GlaxoSmithKline v. Apotex* (*"SmithKline 2"* 2003 FCT 687), the Federal Court Trial Division held that Apotex' allegation of invalidity was justified on, *inter alia*, the basis of anticipation. The patent at issue ("the 575 patent") was a divisional application of SmithKline's 637 patent, which Apotex successfully alleged to be invalid in *SmithKline 1*. The 575 patent disclosed a dry formulation process for tableting paroxetine in the absence of microcrystalline cellulose to avoid the "pink hue" problem encountered during formulation. The applications judge essentially adopted the reasons in *SmithKline 1* and held that the 575 patent was anticipated by the 060 patent (the same patent was the basis for the finding of anticipation in *SmithKline 1* - see the July 2002 issue of *RxIP Update* for a discussion of *SmithKline 1*). The Court also accepted that the 575 patent was anticipated on the basis of two other patent documents, applying similar reasoning to that applied in respect of the 060 patent. The Court rejected anticipation by other publications (identified as the "Buxton articles") on the basis that there are "too many steps between the process outlined in the Buxton articles" and the production of commercial tablets.

In the recent *AstraZeneca* decision (2003 FCT 771), the Federal Court Trial Division held that Apotex failed to prove, on a balance of probabilities, that AstraZeneca's patent ("the 751 patent") was invalid on, *inter alia*, the basis of anticipation. The 751 patent covered certain base addition salts of omeprazole. Apotex alleged that the 751 patent was anticipated by AstraZeneca's European patent application 5129 ("the 5129 application"), which disclosed the neutral form and acid addition salts of omeprazole, and on the basis of anticipation by prior use.

The applications judge did not accept Apotex' argument that the 5129 application disclosed base addition salts of omeprazole and rejected the allegation of anticipation. The Court also rejected the assertion of anticipation on the basis of prior use.

This recent jurisprudence on anticipation under the *Regulations* is significant for several reasons:

- First, as mentioned in our July 2002 issue, the Court may have narrowed the scope of protection for formulations that employ known techniques to overcome development problems, at least where the cause of the problems can be readily identified.

- Second, these decisions suggest that the Court, in some instances, in applying the test for anticipation, may be prepared to read into the alleged anticipatory document words or formulation techniques that are not expressly disclosed.

- Third, the decisions highlight that anticipation is highly fact specific, turning on the particular circumstances before the Court.

- Finally, it remains uncertain how rulings of invalidity under the *Regulations* will affect future patent infringement actions initiated by pharmaceutical patentees. The Federal Court of Appeal, in *SmithKline 1*, cautioned that, since the issue of the validity of a patent arose only in the context of an NOC proceeding, the outcome from that proceeding does not necessarily determine the outcome of any future patent impeachment or infringement actions. Whether this is true in practice remains to be seen.

We will continue to report developments on these and other issues raised in NOC proceedings in future issues of *Rx IP Update*.

J. Sheldon Hamilton

Pharmaceutical IP conference to be held in Montreal this October

The Pharmaceutical Trade Marks Group (PTMG), an international organization devoted to advancing the trade-mark interests of innovative pharmaceutical companies, will be meeting for the first time in North America this October, in Montreal. The conference, entitled "The Increasing Value and Vulnerability of Trade Marks," will be held on October 8-10, 2003, starting with a short welcoming reception early on the evening of Wednesday October 8. Speakers include the Canadian Registrar of Trade-marks and the US Commissioner of Trademarks. Gunars Gaikis, head of our Pharmaceutical practice group, will be speaking on "Internet Pharmacy — Trade Mark Issues." Plenary sessions are held on Thursday and Friday with a social event organized by PTMG at the end of each of these days.

As this is the first time the PTMG will be holding a meeting in Canada, we are endeavouring to facilitate attendance by our North American pharmaceutical clients.

The sign up forms have recently become available and the meeting will likely be oversubscribed within weeks. If you are interested in attending the PTMG conference, please let us know by sending an email to rxip.update@smart-biggar.ca. We will promptly forward to you a copy of these forms.

Should you wish further information about PTMG generally or the October 2003 PTMG conference, please send your questions to rxip.update@smart-biggar.ca.

We look forward to hearing from you, and hope you will join us in Montreal this October.

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Eli Lilly v. The Attorney General of Canada (**sodium monensin** (**RUMENSIN**)), May 29, 2003

Judge dismisses application for judicial review of Minister of Health's decision, refusing to list patent on the Patent Register. Judge finds that the claims relate to a capsule adapted to be inserted into the rumen of a ruminant animal and the means for the retention of this capsule in the rumen and concludes that the patent does not claim protection for the medicine sodium monensin. Eli Lilly has appealed.

Full Judgment (2003 FCT 676)
(*For a printer friendly version, please scroll down to the end of the Judgment)

GlaxoSmithKline v. Apotex (**paroxetine** (**PAXIL**)), May 30, 2003

Judge dismisses application for Order of prohibition, concluding that the allegations of non-infringement and invalidity (based on anticipation, obviousness and double patenting) are justified. GlaxoSmithKline has appealed. For further information, please see the lead article on page one of this newsletter.

Full Judgment (2003 FCT 687)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Apotex v. Ferring (**desmopressin acetate nasal solution** (**DDAVP**, **MINIRIN**)), June 19, 2003

Court of Appeal sets aside decision of applications judge and reinstates decisions of the Minister to remove Ferring's patent from the patent list and to issue an NOC to Apotex for Apo-Desmopressin.

Minister had refused to add the patent to the Patent Register in respect of DDAVP as Ferring's patent application was not filed before the date of filing of the Supplemental New Drug Submission (SNDS) for DDAVP. Ferring therefore filed a second SNDS, solely on the basis of a name change to MINIRIN. The Minister listed the patent but later removed it. Applications judge had distinguished the facts from a previous decision of the Court of Appeal (*Bristol-Myers Squibb v. Apotex*) on the basis that, unlike the BMS case, there was no existing patent list for desmopressin acetate when Ferring filed its SNDS for MINIRIN. However, Court of Appeal finds that the BMS case did not involve an attempt to amend an existing patent list and therefore should have been followed by the applications judge.

Appeal decision (2003 FCA 274)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Trial Division decision (2002 FCT 293)
(*For a printer friendly version, please scroll down to the end of the Judgment)

AstraZeneca v. Apotex (**omeprazole magnesium tablets** (**LOSEC**)), June 20, 2003

Judge finds that Apotex failed to prove that the patent at issue is invalid (Apotex had alleged anticipation, obviousness, double-patenting and inutility) and therefore grants order of prohibition. For further information, please see the lead article on page one of this newsletter.

Full Judgment (2003 FCT 771)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Other Decisions

Apotex v. AstraZeneca (**omeprazole and omeprazole magnesium tablets** (**LOSEC**)), May 26, 2003

Court of Appeal dismisses Apotex' appeal from Order of motions judge. Motions judge had affirmed Order of Prothonotary, staying the proceeding until the final disposition of a proceeding currently before the Ontario Superior Court of Justice. Both cases deal with copyright in drug product monographs.

Court of Appeal decision (2003 FCA 235)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Trial Division decision (2003 FCT 149)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Apotex and Dr. Sherman v. Merck (**enalapril** (**VASOTEC**)), May 26, 2003

Court of Appeal upholds decisions of motions judge, finding Apotex and Dr. Sherman in contempt of court and imposing fines for selling enalapril, after Reasons finding infringement were released. However, Court of Appeal reverses motions judge's finding of contempt by Apotex relating to "aiding and abetting" of third party sales after Order issued, finding that the Order expressly permitted such sales. Apotex' fine reduced to $125,000; Dr. Sherman's fine of $4,500 maintained.

Appeal Decision (2003 FCA 234)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Trial Division decision (penalty) (2001 FCT 589)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Trial Division decision (contempt)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Wyeth-Ayerst v. Attorney General of Canada (**estrogen** (**PREMARIN**)), June 6, 2003

Court of Appeal dismisses Wyeth-Ayerst's appeal of decision of motions judge, dismissing its application for judicial review of a decision by the Minister of Health to release two letters pursuant to a request made under the *Access to Information Act*. The letters were part of Wyeth-Ayerst's representations made in relation to PREMARIN, in connection with proposed amendments to the *Regulations* under the *Food and Drugs Act*.

Appeal Decision (2003 FCA 257)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Trial Division Decision (2002 FCT 133)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Alticor v. Nutravite Pharmaceuticals (**NUTRAVITA**, **NUTRILITE**)), June 9, 2003

Judge dismisses appeal of a decision of the Registrar of Trade-marks, refusing the opposition to an application for the trade-mark NUTAVITA for use in association with "vitamins, minerals and herbs for retail sale through drug stores, pharmacies and health food stores." The Registrar found that there was no reasonable likelihood of confusion between NUTRAVITA and NUTRILITE, registered in association with, among things, vitamin and mineral food supplements and nutrition enhancing food products.

Full Judgment (2003 FCT 718)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Pfizer v. Eli Lilly (**tadalafil**), June 17, 2003

In an action for patent infringement, Pfizer alleges, among other things, that Eli Lilly is threatening to imminently import, market and sell in Canada a pharmaceutical composition containing tadalafil. Judge strikes Pfizer's statement of claim in its entirety on the basis that the plaintiffs have failed to plead sufficient facts to support the allegation that the defendants' allegedly infringing activities are imminent.

Full Judgment (2003 FCT 753)
(*For a printer friendly version, please scroll down to the end of the Judgment)

OTTAWA

55 Metcalfe Street, Suite 900
P.O. Box 2999, Station D
Ottawa, Ontario Canada
K1P 5Y6
t. 613.232.2486
f. 613.232.8440

ottawa@smart-biggar.ca

TORONTO

438 University Avenue
Suite 1500, Box 111
Toronto, Ontario Canada
M5G 2K8
t. 416.593.5514
f. 416.591.1690

toronto@smart-biggar.ca

MONTREAL

1000 de La Gauchetière St. W.
Suite 3400
Montreal, Québec Canada
H3B 4W5
t. 514.954.1500
f. 514.954.1396

montreal@smart-biggar.ca

VANCOUVER

650 West Georgia Street
Suite 2200
Box 11560, Vancouver Centre
Vancouver, B.C. Canada
V6B 4N8
t. 604.682.7780
f. 604.682.0274

vancouver@smart-biggar.ca

EDMONTON

10060 Jasper Avenue, Suite 1501
Scotia Place, Tower Two
Edmonton, Alberta Canada
T5J 3R8
t. 780.428.2960
f. 780.423.6975

edmonton@smart-biggar.ca

www.smart-biggar.ca

New Court Proceedings

New NOC Proceedings

Medicine: **alendronate monosodium trihydrate (FOSAMAX)**
Applicants: Merck & Co, Inc and Merck Frosst Canada & Co
Respondents: Apotex Inc and The Minister of Health
Date Commenced: May 29, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,294,595. Apotex alleges non-infringement and invalidity.

Medicine: **zidovudine (RETROVIR AZT)**
Applicant: GlaxoSmithKline Inc
Respondents: Attorney-General of Canada and The Minister of Health
Date Commenced: June 2, 2003
Comment: Application for an Order, quashing the decision of the Minister to reject the inclusion of Patent No. 2,105,487 on the Patent Register.

Medicine: **alendronate sodium (FOSAMAX)**
Applicants: Merck & Co, Inc and Merck Frosst Canada & Co
Respondents: Apotex Inc and The Minister of Health
Date Commenced: June 20, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,221,417. Apotex alleges non-infringement and invalidity.

Trade-marks Office News

The Trade-marks Office will soon publish a practice notice specifying definitions for pharmaceuticals that will be acceptable in trade-mark applications. A draft practice notice is attached. We will provide the official version once it has been released.

Draft Practice Notice

Contact Info
For more information, or to request a copy of any decision, pleading or legislation, please contact:

Gunars A. Gaikis
ggaikis@smart-biggar.ca

J. Sheldon Hamilton
jshamilton@smart-biggar.ca

Nancy P. Pei (Editor)
nppei@smart-biggar.ca

Pharmaceutical Practice Group

James D. Kokonis, Q.C.
John Bochnovic
Michael D. Manson
Solomon M.W. Gold
David E. Schwartz
Nancy P. Pei
Denise L. Lacombe
James Jun Pan
A. David Morrow
Joy D. Morrow
Tokuo Hirama
Steven B. Garland
Brian G. Kingwell
Thuy H. Nguyen
Sally A. Hemming
John R. Morrissey
Gunars A. Gaikis
J. Christopher Robinson
J. Sheldon Hamilton
Yoon Kang
Daphne C. Ripley
May Ming Lee