SMART & BIGGAR / FETHERSTONHAUGH JUNE 2002

Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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Reference on Patent Listing Quashed – Appeals Pending

In a decision dated May 17, 2002 Madam Prothonotary Aronovitch of the Federal Court, Trial Division quashed a reference initiated by the Minister of Health to determine the eligibility of a patent for listing on the patent register. The question referred by the Minister to the Federal Court was:

> Does a patent list submitted with a supplemental new drug submission meet the requirements of section 4 of the *Regulations* where:
> (a) the patent has not been applied for at the time of the original new drug submission;
> (b) the timing requirements of subsection 4(4) are not met in respect of the original new drug submission; and
> (c) the patent is not directed to the subject matter of the supplemental new drug submission?

We previously reported on the progress of the Reference in the February and May 2002 issues of *Rx IP Update*.

Eli Lilly is a party to the Reference and had moved for an Order to replace the facts constituting the case to be determined on the Reference, and alternatively, sought leave to file evidence. In the further alternative, Lilly and Rx&D (the brand name organization) sought to strike the Reference.

The Prothonotary declined to amend the facts or questions as requested by Lilly, ruling that the questions to be answered on a Reference were within the sole purview and discretion of the Minister.

However, the Prothonotary ruled that ambiguity and a lack of precision in the terms of the Reference would taint the ultimate question on the Reference and that the Minister was not served by placing an imprecise question before the Court. She noted that the Court may not be able to answer the question as presently stated. However, she declined to substitute her own discretion for that of the Minister in respect of the facts or questions on the Reference. Instead, she struck the Reference, with leave to the Minister to amend the facts and question referred to the Court.

Both Lilly and the Minister have appealed the decision, although a hearing has not yet been scheduled. We will continue to follow the progress of the Reference as the matter develops.

J. Sheldon Hamilton

Supreme Court of Canada Hearings

The Commissioner of Patents v. The President and Fellows of Harvard College (Harvard Mouse)

On May 21, 2002 the Supreme Court of Canada heard the Commissioner of Patents' appeal of the Federal Court of Canada's decision that higher life forms are patentable subject matter under the Canadian *Patent Act*. The Court reserved judgment.

We will report the decision of the Court once it has been released.

Press Release

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Pfizer v. Apotex (**azithromycin tablets** (**ZITHROMAX**)), May 3, 2002

Judge orders Apotex to produce samples of its azithromycin tablets and bulk azithromycin used to manufacture the tablets. This order is contingent on Apotex having provided samples of azithromycin tablets to the Minister in its submissions for an NOC. Pfizer's patent is directed to the dihydrate of azithromycin. Apotex' abbreviated new drug submission (ANDS) is based on the monohydrate. Judge accepts affidavit evidence from Pfizer that Apotex' tablets are likely to contain some dihydrate. Judge also orders Apotex to provide portions of the ANDS and the drug master file.

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

In the Matter of a Reference by the Minister of Health regarding a Question as to the Application of Section 4 of the Regulations (**olanzapine** (**ZYPREXA**)), May 7, 2002

Prothonotary strikes the Notice of Application for a Reference made by the Minister of Health. For more information, please refer to the article on page one of this newsletter. The Minister has appealed.

Full Judgment

AstraZeneca v. Reddy-Cheminor (**omeprazole capsules** (**LOSEC**)), May 7, 2002

Court of Appeal dismisses AstraZeneca's appeal of decision refusing AstraZeneca leave to intervene in Reddy-Cheminor's challenge of the Minister's decision not to process its ANDS. For a full discussion of the lower Court's decision, please see the November 2001 issue of *Rx IP Update*.

Full Judgment (Court of Appeal)

Full Judgment (Trial Division)

Other Decisions

Searle v. Merck (**rofecoxib** (**CELEBREX**)), May 9, 2002

Searle is successful in obtaining summary judgment that Merck's VIOXX brand of rofecoxib infringes claim to rofecoxib compound in Searle's patent. Judge finds that the dedication of certain claims in the patent to the public does not affect the rights conferred by the remaining claims in the patent. In this case, Searle's dedication included process claims covering the manufacture of rofecoxib, claims to a pharmaceutical composition containing rofecoxib and claims to the use of the compound rofecoxib to treat inflammatory disease. Trial to proceed with respect to the remaining issues of infringement and validity. Searle is seeking to have the summary judgment decision reviewed.

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

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: **Clarithromycin** (**BIAXIN BID**)
Applicants: Abbott Laboratories and Abbott Laboratories Ltd
Respondents: Genpharm Inc and The Minister of Health
Date Commenced: May 2, 2002
Comment: Application for an order prohibiting the Minister of Health from issuing a notice of compliance for clarithromycin to Genpharm until the expiry of Canadian Patent 2,261,732 ("'732"). Genpharm alleges non-infringement of the patent and further alleges that the '732 patent is listed on the Patent Register in contravention of s. 4(4) of the *Regulations*. Abbott alleges that Genpharm infringes; that Genpharm is estopped from claiming non-infringement based on previous admissions; and that the Notice of Allegation does not comply with the *Regulations*. Abbott further alleges that the allegation of contravention of s. 4(4) of the *Regulations* is improper.

Other New Proceedings

Medicine: **Unidentified**
Applicant: AstraZeneca Canada Inc
Respondent: The Minister of Health
Date Commenced: May 6, 2002; May 13, 2002
Comment: Two Applications for an Order requiring the Minister to refuse to disclose information contained in a regulatory submission originating from AstraZeneca Canada Inc.

Medicine: **Unidentified**
Applicant: Apotex Inc
Respondent: The Minister of Health
Date Commenced: May 10, 2002
Comment: Application for an Order quashing the Minister's decision on April 12, 2002 to dismiss Apotex' first level appeal from a notice of non-compliance (NON) dated December 5, 2001 in respect of Product X and, in the alternative, for an Order requiring the Minster to treat the NON as a Clarifax and to process Apotex' responses to the NON. Apotex further alleges that the Minister did not respond to its first level appeal in a timely fashion (see May 2002 *Rx IP Update*) and that, when the Minister did respond, he improperly indicated that he would not consider a second level appeal.

Medicine: **Unidentified**
Applicant: Apotex Inc
Respondent: The Minister of Health
Date Commenced: May 10, 2002
Comment: Application for an Order requiring the Minister to provide details of the outcome of the Director's reconsideration of Apotex' first level appeal of a notice of non-compliance (NON) for Product X. If the reconsideration maintains the NON, Apotex requests an Order that the Minister provide answers to questions posed by Apotex and to expedite the second level appeal. Apotex advised the Minister on June 1, 2002 that the submission for Product X established bioequivalence on the basis of assessing a metabolite of the parent drug and that this was a proper approach.

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