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IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Can Clinical Trials Constitute 'Use' of a Trade-mark?

Absence of jurisprudence in Canada suggests cautious approach required.

When seeking to register a pharmaceutical trade-mark, a question that occasionally arises is whether use of the trade-mark in clinical trials in Canada satisfies the definition of "use" in the Canadian *Trade-marks Act*. The question is an important one as an incorrect assertion of "use" may jeopardize the validity of the registration.

Section 4(1) of the *Trade-marks Act* provides:

> A trade-mark is deemed to be used in association with wares if, at the time of the transfer of the property in or possession of the wares, in the normal course of trade, it is marked on the wares themselves or on the packages in which they are distributed or it is in any other manner so associated with the wares that the notice of the association is then given to the person to whom the property or possession is transferred. [Emphasis added].

Many clinical trials are "double-blind", and it is therefore clear that there is no "use" of the trade-mark as patients and researchers will be completely unaware as to the brand in question. However, in clinical trials where the trade-mark is marked on the wares or packaging or notice of the association between the trade-mark and the pharmaceutical is given, the key issue is whether transfer of the product in the course of clinical trials is in the "normal course of trade" of the pharmaceutical company.

The word "trade" has been held to contemplate "some payment or exchange for the wares supplied or at least that the transfer of the wares be a part of a dealing in the wares for the purpose of acquiring good-will and profits from the marked goods". As most pharmaceutical companies conduct clinical trials as part of their "normal course of trade" in order to obtain marketing approval and thereby ultimately acquire profits, such activity may arguably satisfy the *Trade-marks Act* definition of "use", notwithstanding that the pharmaceutical is distributed free of charge. Unfortunately, there is no clear Canadian decision on point.

Jurisprudence in the area of test marketing – outside of the pharmaceutical field – is somewhat unsettled but seems to support the view that use in clinical trials may be considered to be "in the normal course of trade", depending upon the particular circumstances.

Whether a court will ultimately determine that use in clinical trials satisfies the definition of "use" within section 4 of the *Trade-marks Act* will depend upon the facts of any given case. Given this uncertainty, a prudent and practical approach is to defer filing a declaration of Canadian use until use of the trade-mark has commenced commercially in the Canadian marketplace. This course of action avoids any risk of invalidity that may arise by relying upon use during a clinical trial. On the other hand, should it become necessary to expedite the issuance of a trade-mark registration due to infringing activity, an applicant that is advised of this uncertainty in the law may nevertheless immediately file a declaration of use based upon "use" during the clinical trial, as a certificate of registration will typically issue within a matter of weeks. We will report on any new developments in the jurisprudence in future issues of *Rx IP Update*.

Mark K. Evans

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Bristol-Myers Squibb v. Biolyse (**paclitaxel** (**TAXOL**)), February 26, 2002

Motion seeking an order for production of Biolyse's New Drug Submission that was requested in a Direction to Attend sent to the Minister's representative, in context of a judicial review application of a decision of the Minister issuing a notice of compliance without requiring Biolyse to serve a notice of allegation. In response to the Direction, the Minister's representative issued a certificate under s.37 of the *Canada Evidence Act* claiming the right to withhold production on the basis of a specified public interest. Judge finds that BMS is entitled to production of Biolyse's NDS, once a suitable protective order is in place. Biolyse has appealed.

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

AstraZeneca v. Apotex (**omeprazole tablets** (**LOSEC**)), February 28, 2002

Judge dismisses Apotex' motion to strike affidavits. With respect to two of the affidavits, Judge finds that the issues to which the evidence was directed had not previously been decided by the Court by way of "observations" made in the context of a summary dismissal motion. The third affidavit, appending affidavits and corresponding cross-examinations, does not constitute hearsay. In the alternative, reliability and necessity had been established for the purpose of admitting the evidence.

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

Other Decisions

Bristol-Myers Squibb v. Apotex (**nefazodone hydrochloride** (**SERZONE-5HT$_2$**)), March 13, 2002

In patent infringement action, Judge dismisses Apotex' appeal of Prothonotary's decision, amending the protective order to include a "Confidential Information - Counsel and Expert Only Class" in respect of commercially sensitive financial information. Apotex has appealed.

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: **Unidentified**
Applicant: Apotex Inc
Respondent: The Minister of Health
Date Commenced: March 18, 2002
Comment: Application for Order requiring the Minister to provide reasons why the NOC for Product X has not issued and to identify each of the patents on any relevant patent list in relation to which the Minister takes the position that Apotex must satisfy the requirements of the *Regulations*.

Medicine: **Cyclosporin capsules** (**NEORAL; SANDIMMUNE**)
Applicants: Novartis Pharmaceuticals Canada Inc and Novartis AG
Respondents: RhoxalPharma Inc and The Minister of Health
Date Commenced: March 18, 2002
Comment: Application for Order of prohibition until expiry of Patents Nos. 1,308,656, 1,332,150 and 2,072,509. RhoxalPharma alleges non-infringement and invalidity.

Medicine: **Omeprazole tablets** (**LOSEC**)
Applicants: AB Hassle, AstraZeneca AB and AstraZeneca Canada Inc
Respondents: Apotex Inc and The Minister of Health
Date Commenced: March 19, 2002
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,025,668 and 2,133,762. Apotex alleges non-infringement.

Medicine: **Diltiazem Hydrochloride Extended Release Capsules** (**CARDIZEM CD**)
Applicants: Biovail Corporation and Galephar PR Inc
Respondents: RhoxalPharma Inc and The Minister of Health
Date Commenced: March 19, 2002
Comment: Application for Order of prohibition until expiry of Patent No. 2,111,085. RhoxalPharma alleges non-infringement and invalidity.

Other New Proceedings

Medicine:	**Sildenafil Citrate** (**VIAGRA**)
Plaintiffs:	Lilly Icos LLC and Eli Lilly Canada Inc
Defendant:	Pfizer Research and Development Company, NV/SA
Date Commenced:	March 1, 2002
Comment:	Action for declaration of invalidity of Patent No. 2,163,446. Lilly pleads that, upon receiving regulatory approval, it intends to sell tadalafil (CIALIS) which might be alleged by Pfizer to constitute infringement of patent.

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