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Rx IP Update

Canadian Pharmaceutical Intellectual Property Law Newsletter

Draft Guidance Documents for Health Canada Review of Look-alike Sound-alike Names Published for Comment

In our December 2003 issue of *Rx IP Update*, we reported that a working group of representatives from the Health Products and Food Branch of Health Canada ("HPFB") released a draft Issue Analysis Summary on Look-alike Sound-alike ("LA/SA") Health Product Names on October 17, 2003. The working group was developed because of a perceived need for a long term strategy to deal with LA/SA drug names.

On March 24, 2004, the working group published responses to stakeholder comments, as well as a final Issue Analysis Summary.

On September 15, 2004, the HPFB released two draft guidance documents to implement both the pre-market recommendations and the post-market recommendations outlined in the Issue Analysis Summary.

Pre-market Recommendations

The HPFB will review all proposed drug names submitted with a new drug submission (NDS), supplemental NDS, abbreviated NDS, supplemental abbreviated NDS, application for a drug identification number, or an administrative submission that involves a change to the name. All submissions will be reviewed within a 90 day period and a name may be disallowed if it is identified as potentially confusing. The sponsor may submit a prioritized list of alternate names, to a maximum of two options. Sponsors are also encouraged to submit a risk assessment and evaluation of the proposed name, supported with data (*e.g.* prescription testing studies (verbal and handwritten studies)), in order to facilitate the name review process.

If the prioritized list of names is rejected entirely, the submission will be placed on a "name hold" until a proposed alternative is accepted. Final review of the proposed name will take place within 90 days of the anticipated date of approval. While the HPFB will work to facilitate a satisfactory solution when confusing co-pending names are identified, priority will ultimately be based on approval date.

The potential for harm will be assessed when determining whether the degree of similarity between names is problematic. The HPFB will take into consideration a number of factors including dosage form, indications and directions for use, strength, Rx or OTC, therapeutic category, clinical setting for dispensing or use, and packaging and labelling.

The full text of the pre-market guidance document can be found here.

Post-market Recommendations

The post-market guidance document is directed at marketed products for which a safety issue regarding the name was not foreseen, as well as for products that were marketed prior to the development of the pre-market name review.

Market authorization holders ("MAHs") are stated to have the responsibility to proactively watch for health product name similarities that could result in a medication error. If the potential for name confusion is found, MAHs are to notify the Marketed Health Products Directorate within the HPFB. The HPFB will also monitor marketed health product names for the potential to contribute to medication errors. Should the HPFB find potential risk, the MAHs involved will be notified in writing with

information on how to proceed. If sufficient evidence of lack of risk is not provided, sales of the drug can be suspended.

The full text of the post-market guidance document can be found here.

Comments on the draft guidance documents are to be submitted by November 15, 2004. We will report on developments in future issues of *Rx IP Update*.

Heather E. Tonner

Court of Appeal Sets Aside Summary Dismissal of Damages Action Against Patentee

Apotex brought a motion for damages and/or profits pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") against Eli Lilly Canada ("Lilly Canada") and the patentee, Eli Lilly and Company ("Lilly US"), as a result of the reversal of an Order of prohibition. Section 8 of the *Regulations* provides for liability by a "first person", defined in the *Regulations* as the person that submits the patent list. Lilly Canada had submitted the patent list. However, Apotex pleaded that Lilly US was liable on the basis that "Lilly US exercises complete control over the operation of Lilly Canada including", among other things, "whether and when Lilly Canada will be permitted to list Lilly US patents on a patent list...". A motions judge had granted Lilly US' motion for summary judgment and dismissed the claim against Lilly US, finding that Lilly US was not a "first person".

On October 27, 2004, the Court of Appeal reversed this determination, finding that "it might emerge on discovery that the degree of control exercised by Lilly Canada was such as to make Lilly US a "first person"", and that "first person" does not necessarily preclude the possibility that both Lilly US and Lilly Canada could be found to be a "first person".

The Court also found that whether a "first person" includes the corporation who directed the submission of the patent list in the name of its subsidiary may depend on whether the profits recoverable are those made by the "first person" or the profits not made by the second person. The Court found that if it was the former, this might support an interpretation of "first person" which includes the corporation that controlled all relevant actions of the corporation who submitted the patent list. Otherwise, the second person may not be able to recover the innovator's profits.

The Court concluded that the issues were sufficiently difficult and required findings of fact that could only be satisfactorily resolved in the context of a trial. Therefore, Lilly US' motion for summary judgment was dismissed.

This decision is significant as it now leaves open the possibility that a patentee may be liable for damages — and indeed, its own profits — as a result of an unsuccessful application for an Order of prohibition. In view of this decision, unless a patentee can successfully strike the generic manufacturer's pleading (for example, on the basis that it had no evidence to support an allegation of control, or the pleading is not adequately particularized), or dismiss it on a summary judgment motion on the basis of positive evidence from the first person that there is no control, a claim against the patentee will have to proceed to trial. If Lilly US wishes to appeal this decision, leave must be obtained from the Supreme Court of Canada.

Apotex v. Eli Lilly (**nizatidine (AXID, APO-NIZATIDINE)**) (2004 FCA 358)

Motions Judge's Decision (2004 FC 502)

Supreme Court of Canada Leave Applications

AstraZeneca v. Apotex (**omeprazole (LOSEC)**), August 9, 2004

AstraZeneca has filed a leave application from a Federal Court of Appeal decision, which dismissed, on the grounds of mootness, AstraZeneca's appeal from an Order dismissing its application for an Order of prohibition.

Court of Appeal Decision (2004 FCA 224)

Bayer v. Apotex (**ciprofloxacin (CIPRO)**), September 22, 2004

Bayer has filed a leave application from a Federal Court of Appeal decision dismissing Bayer's motion to dismiss Apotex's appeal of an Order of prohibition, on the grounds of mootness.

Court of Appeal Decision (2004 FCA 242)

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Abbott v. Pharmascience (**clarithromycin (BIAXIN BID)**), October 1, 2004

Judge grants Order of prohibition, finding that the notice of allegation is deficient, and that Pharmascience failed to discharge its evidentiary burden to justify the allegations of non-infringement and invalidity.

Full Judgment (2004 FC 1349)

Other Proceedings

Eli Lilly v. Apotex (**APO-CEFLACLOR, CECLOR**), October 20, 2004

In a patent infringement action brought by Eli Lilly, Apotex pleaded that Eli Lilly "conspired" with Shionogi to acquire patents from Shionogi for the purpose of preventing others from producing or acquiring cefaclor. Apotex therefore alleged violation of the *Competition Act* and sought damages from Eli Lilly and Shionogi. Motions judge grants summary judgment, dismisses claim against Shionogi and strikes this aspect of the claim against Eli Lilly.

Full Judgment (2004 FC 1445)

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: **bupropion hydrochoride (WELLBUTRIN SR)**

Applicants: Biovail Corporation (dba Biovail Pharmaceuticals Canada), Biovail Laboratories Inc and GlaxoSmithKline Inc

Respondents: Pharmascience Inc and The Minister of Health

Date Commenced: September 22, 2004

Comment: Application for Order of prohibition until expiry of Patents Nos. 1,321,754, 2,142,320 and 2,168,364. Pharmascience alleges non-infringement with respect to the 320 and 364 patents.

Medicine: **olanzapine (ZYPREXA)**

Applicants: Eli Lilly Canada Inc

Respondents: Novopharm Limited, The Minister of Health and Eli Lilly and Company Limited

Date Commenced: September 24, 2004

Comment: Application for Order of prohibition until expiry of Eli Lilly and Company's Patent No. 2,041,113. Novopharm alleges invalidity and takes the position that it need not address certain claims.

Medicine: **permetrexed disodium (AMILTA)**

Applicants: Eli Lilly Canada Inc

Respondents: The Minister of Health and The Attorney General of Canada

Date Commenced: October 1, 2004

Comment: Application for a declaration that Patent No. 2,051,520 is eligible for listing on the Patent Register.

Medicine: **sumatriptan hemisulphate nasal spray (IMITREX)**

Applicants: GlaxoSmithKline Inc and Glaxo Group Limited

Respondents: Novopharm Limited and The Minister of Health

Date Commenced: October 15, 2004

Comment: Application for Order of prohibition until expiry of Patent No. 2,098,302. Novopharm alleges invalidity.

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 3300
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

Other Proceedings

Medicine: **ciprofloxacin i.v. (CIPRO)**
Applicants: Bayer AG, Bayer Healthcare AG and Bayer Inc
Respondents: Sabex 2002 Inc
Date Commenced: September 28, 2004
Comment: Infringement action relating to Patent No. 1,282,006.

Medicine: **ciprofloxacin i.v. (CIPRO)**
Applicants: Bayer AG, Bayer Healthcare AG and Bayer Inc
Respondents: Sabex 2002 Inc and The Minister of Health
Date Commenced: September 28, 2004
Comment: Application for Order quashing the notice of compliance (NOC) granted to Sabex on September 15, 2004. Bayer pleads that the Minister acted unlawfully in issuing the NOC as Sabex did not comply with section 5 of the *Regulations*.

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

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