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IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Proposal by Health Canada on Review of Look-alike Sound-alike Names

In our September 2003 issue of *Rx IP Update*, we reported that Health Canada presently reviews drug names on an informal basis, but that consultations regarding proposed amendments to the review process may take place as early as this Fall.

Recently, a Look-alike/Sound-alike (LA/SA) Working Group, made up of representatives from the Health Products and Food Branch (HPFB), including members of the Therapeutic Products Directorate, was tasked with reviewing and analyzing the issues associated with LA/SA health product names and recommending an appropriate course of action. On October 17, 2003, the Working Group released a draft Issue Analysis Summary entitled "Look-alike Sound-alike (LA/SA) Health Product Names: The Development of a Comprehensive Policy Recommendation."[1]

By way of background, the document describes the current review process and need for a long term strategy as follows:

> Currently, LA/SA drug name issues are handled on a case-by-case basis. Since there is no consistent or formal process within the Branch to review LA/SA aspects of product names, the name review is somewhat arbitrary and depends on initiative, memory, intuition and judgment of staff. Current computer systems are not set up to flag identical or similar names. Furthermore, the subjective nature of similarities between drug names compounds the problem, since names that are similar to one person may not be to another. In addition, the general perception is that there is questionable authority as to whether the *Food and Drugs Act* can be used to require a name change. When a LA/SA drug is identified either pre- or post-market, the sponsor is notified and encouraged to consider changing their product name. Alternatively, they are questioned regarding any proposed remedial measures they can suggest to reduce the potential for medication errors. When such issues have been brought to the manufacturer's attention, HPFB success has been mixed. As a result, there is a general consensus that a long term strategy needs to be developed, in co-operation with stakeholders, to deal with LA/SA drug names.

The LA/SA Working Group's conclusions regarding Health Canada's authority and powers relating to pre- and post-market monitoring of drug names are as follows:

> **Pre-market:** In summary, the LA/SA WG believes that the *Food and Drug Regulations* allow HPFB to adopt a pre-market requirement that the names of drugs not be confusing with one another [see subsection C.08.002.(1), C.08.002.(2), C.08.002.(3) and C.01.014.1(2) of the *Food and Drug Regulations*]. If confusion with another drug name was considered likely and confusion could result in safety concerns, then HPFB could refuse to issue a DIN (new drugs and drugs other than new drugs) and/or NOC (new drugs only), as applicable.
>
> **Post-market:** Section C.01.013. of the *Food and Drug Regulations* requires that, upon request, a manufacturer must submit sufficient evidence by a specified date to establish the safety and effectiveness of a drug for the purposes recommended. When sufficient evidence is not provided, further sales of the drug can be suspended.

1 Health Canada has also recently released a fact sheet relating to Look-alike Sound-alike Health Product Names.

> Upon becoming aware of a safety concern associated with LA/SA name confusion following issuance of an NOC and/or DIN for a drug, the LA/SA WG is of the opinion that HPFB can use C.01.013. to require the manufacturer to establish the safety of the drug under its recommended uses in light of a safety concern identified in relation to its name. If sufficient evidence is not provided, HPFB could consider suspending sales of the drug by way of the C.01.013 process.

The following recommendations are endorsed by the LA/SA Working Group as the best options for reviewing LA/SA names:

> **Pre-market:** A complex computer application should be acquired to screen for LA/SA health product names. Those names that are flagged should be reviewed and if the reviewer cannot come to a decision, it is considered further by an Interdirectorate Name Review Committee. Prior to filing a submission, a sponsor would be required to show that a proposed health product name does not have LA/SA name similarities. Furthermore, the sponsor would have the option of providing a prioritized list of name choices.

> **Post-market:** Potential LA/SA health products should be monitored and, if sufficient risk of harm due to potential medication errors is identified, appropriate market intervention should be initiated (e.g. Fact Sheets, Dear Health Care Professional Letters, name or labelling change to one of the products etc.).

The Proposal is presented as a draft for comment only. On October 20 and 21, 2003, an Invitational National Workshop was held to discuss these issues. A post-workshop report will be released shortly. We will report on developments on this initiative, including a copy of the post-workshop report, in future issues of *Rx IP Update*.

Nancy P. Pei

Canada Introduces Legislation to Amend Patent Act to Permit Exports of Patented Medicines to Developing Countries

On November 6, 2003, the Government of Canada introduced proposed changes to the *Patent Act* and the *Food and Drugs Act*. The stated purpose of the amendments is "to facilitate access to pharmaceutical products to address public health problems afflicting many developing countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." These proposed changes were introduced to implement the World Trade Organization's recent Declaration on the Trade-Related Aspects of Intellectual Property Rights Agreement and Public Health (Doha Declaration).

Parliament gave second reading to the Bill on November 7, 2003, and sent the Bill to a committee for hearings. On November 12, 2003, the Federal government prorogued the current session of Parliament, effectively cancelling Bill C-56. The legislation must now be re-introduced in the next session of Parliament, which is expected to resume on January 12, 2004. Paul Martin, who will become the new Prime Minister on December 12, 2003, has indicated that the Bill will be re-introduced in the new session.

Industry Canada News Release (November 6, 2003)

Bill C-56 (An Act to amend the *Patent Act* and the *Food and Drugs Act*)

Internet Pharmacy Developments

On November 18, 2003, Dr. Mark McClellan, Commissioner of Food and Drugs (US Food and Drug Administration (FDA), Department of Health and Human Services) and Diane Gorman (Assistant Deputy Minister, Health Products and Food Branch, Health Canada) signed a Memorandum of Understanding (MOU). According to a Health Canada news release, the MOU "will further enhance cooperation between Health Canada and the US Food and Drug Administration." In general, the MOU will "better enable the two regulatory authorities to share information on the post-market safety of therapeutic products, information related to the review and evaluation of new product submissions and information on product investigations and enforcement activities...such as cross-border issues."

On November 18, 2003, the Minister of Health issued a news release responding to comments made by Dr. McClellan earlier that day relating to internet pharmacy. The Minister's comments include an assurance that, as of November 17, 2003, "no jurisdiction had reported drug shortages as a result of the practice of internet pharmacy."

Patented Medicines Prices Review Board (PMPRB) Matters

On October 21, 2003, the PMPRB accepted a voluntary compliance undertaking (VCU) from Pfizer for cabergoline (DOSTINEX).

Dostinex - Voluntary Compliance Undertaking

On November 17, 2003, the PMPRB released a document entitled, "Price Increases — Monitoring Compliance with the Guidelines." The document was released as a result of recent reports of possible price increases for some patented medicines and resulting enquiries relating to the PMPRB's Guidelines. The document confirms that the Guidelines limit increases in the prices of patented medicines to increases in the Consumer Price Index (CPI) and reports that "in 2002, the prices of all patented medicines declined, on average, by 1.2% from the previous year."

Price Increases – Monitoring Compliance with the Guidelines

Supreme Court of Canada Leave Applications

Biolyse v. Bristol-Myers Squibb (**paclitaxel for injection** (**TAXOL**)), November 20, 2003

The Supreme Court of Canada has granted Biolyse leave to appeal a decision of the Federal Court of Appeal, which dismissed its appeal of an applications judge's decision. The applications judge had quashed Biolyse's Notice of Compliance (NOC). Biolyse had submitted a New Drug Submission (NDS) for its paclitaxel, which contained many references to and comparisons with TAXOL, but not for the purpose of establishing bioequivalence. The Court of Appeal affirmed the applications judge's finding that the Minister should have required Biolyse to serve a Notice of Allegation (NOA) on BMS, since subsection 5(1.1) of the Regulations applied. The Court of Appeal judgment was reported in our May 2003 issue of *Rx IP Update*.

Pfizer v. Attorney General of Canada (**azithromycin dihydrate tablets** (**ZITHROMAX**)) (**atorvastatin calcium tablets** (**LIPITOR**)), *Schering v. Attorney General of Canada* (**ribavarin capsules and interferon alfa-2b solution for injection** (**REBETRON**)), November 27, 2003

The Supreme Court of Canada has denied leave to appeal a Court of Appeal decision, dismissing appeals from the decision of an applications judge. The applications judge had dismissed applications for judicial review of decisions of the Minister of Health, refusing to list certain patents on patents lists. The Court of Appeal had confirmed the applications judge's finding that the term "filing date" in s.4(4) of the *Regulations* refers solely to the filing date for an application for patent in Canada and therefore the relevant patents were ineligible for listing on Patent Register. The Court of Appeal judgment was reported in our April 2003 issue of *Rx IP Update*.

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Pfizer v. Novopharm (**azithromycin** (**ZITHROMAX**)), October 10, 2003

Judge orders Novopharm to produce samples upon which Novopharm conducted its analysis and to produce portions of its Abbreviated New Drug Submission (ANDS) which set out the process to make bulk azithromycin and pages from its parent company (Teva)'s drug master file incorporated by reference into Novopharm's ANDS. Novopharm has appealed.

Full Judgment (2003 FC 1320)

Bayer v. Apotex (**ciprofloxacin hydrochloride** (**CIPRO**)), October 17, 2003

Judge grants Order of prohibition. Apotex had alleged invalidity on the basis of obviousness and non-infringement, but withdrew its allegation of non-infringement. Apotex has appealed.

Full Judgment (2003 FC 1199)

Merck v. Apotex (**alendronate sodium** (**FOSAMAX**)), October 23, 2003

Apotex had filed affidavits of nine experts in an NOC proceeding. Prothonotary finds that section 7 of the *Canada Evidence Act* requires that a party who proposes to adduce the evidence of more than five experts must seek leave to do so at the time of, or prior to, first tendering the additional evidence and concludes that, "as Apotex has not sought [such] prior leave ... and has not even met Merck's motion with a motion for leave to do so, Apotex is only entitled to rely on the evidence of five expert witnesses." Apotex has appealed.

Full Judgment (2003 FC 1242)

Apotex v. AstraZeneca (**omeprazole magnesium** (**LOSEC**)), November 3, 2003

Court of Appeal dismisses Apotex' appeal from an Order of prohibition. Court of Appeal construes the relevant claim in a manner that Apotex conceded would result in failure of its appeal.

Federal Court of Appeal Decision (2003 FCA 409)

Federal Court Decision (2002 FCT 931)

Lundbeck v. Apotex (**citalopram** (**CELEXA**)), November 12, 2003

Judge dismisses Lundbeck's application for an Order of prohibition with respect to a patent covering the use of citalopram to treat dementia and cerebro-vascular diseases (CVD). Apotex alleged non-infringement on the basis, *inter alia*, that the only use that will be included in its product monograph will be use for the treatment of depression. Judge finds that there "can be no direct infringement" and with respect to indirect or "induced" infringement, Lundbeck has not raised this ground and is now barred from raising it at this late stage.

Full Judgment (2003 FC 1334)

Biovail v. RhoxalPharma (**diltiazem hydrochloride extended release** (**CARDIZEM CD**)), October 31, 2003

Court of Appeal dismisses Biovail's appeal from a decision of a motions judge, dismissing Biovail's appeal from a decision of a Prothonotary. The Prothonotary had dismissed Biovail's motion for production of all relevant portions of RhoxalPharma's ANDS, pursuant to section 6(7) of the *Regulations*. Court of Appeal finds that the timeliness of an application is a consideration which a judge may take into account in deciding whether to order production under section 6(7). Court concludes that the motions judge made no error in holding that Biovail had not met its burden of proof in regard to relevancy of the material sought.

Federal Court of Appeal Decision (2003 FCA 406)

Federal Court Decision (2003 FC 1143)

Other Decisions

Pfizer v. Eli Lilly (**tadalafil** (**CIALIS**)), November 3, 2003

Eli Lilly obtained its NOC for CIALIS on September 17, 2003. Judge dismisses Pfizer's motion for an interim injunction to prevent the import and sale of CIALIS. The interlocutory injunction motion will be heard in the new year.

Full Judgment (2003 FC 1278)

New Court Proceedings

New NOC Proceedings

Medicine: **levodopa/carbidopa controlled-release tablets (SINEMET CR, APO-LEVOCARB)**
Applicant: Apotex Inc
Respondent: The Minister of Health
Date Commenced: October 23, 2003
Comment: Application for Order requiring the Minister to issue Apotex an NOC for APO-LEVOCARB tablets 250 mg/50 mg.

Medicine: **citalopram hydrobromide (CELEXA)**
Applicants: H Lundbeck A/S and Lundbeck Canada Inc
Respondents: Genpharm Inc and The Minister of Health
Date Commenced: November 5, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,353,693. Genpharm alleges non-infringement, invalidity, and that the patent is not properly listed on the Patent Register.

Medicine: **citalopram hydrobromide (CELEXA)**
Applicants: H Lundbeck A/S and Lundbeck Canada Inc
Respondents: Apotex Inc and The Minister of Health
Date Commenced: November 5, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,353,693. Apotex alleges non-infringement.

Medicine: **trastuzumab (HERCEPTIN)**
Applicant: Hoffmann-LaRoche Limited
Respondents: The Minister of Health and The Attorney General of Canada
Date Commenced: November 14, 2003
Comment: Application for an Order requiring the Minister to include Patents Nos. 1,218,613 and 1,341,082 on the Patent Register.

Medicine: **citalopram hydrobromide (CELEXA)**
Applicants: H Lundbeck A/S and Lundbeck Canada Inc
Respondents: Ratiopharm Inc and The Minister of Health
Date Commenced: November 17, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,353,693. Ratiopharm alleges non-infringement and that the patent is not properly listed on the Patent Register.

Other New Proceedings

Medicine:	**omeprazole magnesium (LOSEC)**
Plaintiff:	Apotex Inc
Defendant:	Aktiebolaget Hässle
Date Commenced:	November 17, 2003
Comment:	Action for declaration of invalidity with respect to Patent No. 1,264,751.

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