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IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Controlling Sales by Canadian Internet Pharmacies to US Consumers

With price controls on patented pharmaceuticals in Canada and a favourable exchange rate, drug prices in Canada may be up 50 to 70% cheaper than in the US. American consumers, including some state and municipal governments, are therefore increasingly looking to Canada for cheaper pharmaceuticals. Now, with the proliferation of Canadian Internet pharmacies, these medications are readily available, as evidenced by significant annual sales estimated at $500 million to $1 billion. Such sales raise a number of ethical and legal concerns primarily relating to the safety of US consumers, including that Canadian physicians are co-signing prescriptions for patients that they have not seen and many of these drugs have not been approved in the US.

Efforts that may limit sales of prescription pharmaceuticals to US consumers via Canadian-based Internet pharmacies include the following:

1. The sale in Canada of pharmaceuticals with formulations, packaging, appearance, brand names, and labelling in Canada that differ from those in the US, has the potential to assist in three ways.

   (a) The sale of non Food and Drug Administration (FDA)-approved formulations in Canada may assist in enforcement under the *Food, Drug and Cosmetic Act* as it is illegal to import non FDA-approved drugs. While there is a personal use exemption, the FDA's position is that foreign versions of US approved drugs are not covered.

   (b) US trade-mark law may prevent the parallel importation of "grey market" goods where there are material differences between the imported and domestic products and this difference is likely to deceive or confuse the public.

   (c) Such differences make it obvious to the consumer that the product is not the same as the consumer has received in the US. This may lead the consumer to re-consider such purchases.

2. Domestic ownership of trade-mark registrations may assist in an argument based on grey marketing, as any importation and sale of materially differing grey market goods without the domestic owner's consent may be an infringement, possibly without regard to affiliation between the trade-mark holders.

3. The limiting of sales of pharmaceuticals by manufacturers to Internet pharmacies is the most direct method of control. This approach has been preliminarily considered by the Competition Bureau in Canada and found to be justified, on the basis of the FDA's submission that the importation of pharmaceuticals into the US is illegal. However, Internet pharmacies can also obtain product from sources downstream from the manufacturer.

4. Health care professional associations may assist in limiting the participation of their members, whose participation is obviously necessary to support these pharmacies. The College of Physicians & Surgeons of Ontario, the National Association of Boards of Pharmacy, and the Canadian and American Pharmacist Associations have all voiced their opposition to the practices surrounding Internet pharmacies.

5. Finally, education of the public regarding the threat of counterfeit and contaminated drugs purchased through the Internet may encourage consumers to re-consider such purchases.

Most recently, on October 27, 2003, Health Canada voiced its concerns in a letter sent to pharmacy and medical associations and provincial governments. In this letter, Health Canada states: "Cross-border sales of prescription drugs via the growing practice of internet pharmacy also raise the potential for drug shortages domestically. Health Canada regards this as a very serious matter due to the inherent risk to Canadians' health." However, it is not yet known what specific steps Health Canada will take to address these concerns.

We will continue to follow issues surrounding Internet pharmacies and report on new developments in future issues of *Rx IP Update*.

This article is based on a paper presented at the 2003 Pharmaceutical Trade-marks Group (PTMG) Meeting in Montreal, Canada. Should you wish to obtain a copy of the complete paper, please contact ggaikis@smart-biggar.ca.

Gunars Gaikis

Supreme Court of Canada Leave Applications

Ferring v. Apotex (**desmopressin acetate nasal solution** (**DDAVP** and **MINIRIN**)), August 25, 2003

Ferring has sought leave to appeal a Federal Court of Appeal decision. The Court of Appeal set aside a decision of the applications judge, and reinstated the Minister's decisions to remove Ferring's patent from the Patent Register and issue a Notice of Compliance (NOC) to Apotex for Apo-Desmopressin. For further information regarding the Court of Appeal decision, please see the lead article in the August 2003 issue of *Rx IP Update*.

AstraZeneca v. Novopharm (**felodipine** (**PLENDIL**)), October 10, 2003

AstraZeneca's leave application has been dismissed. AstraZeneca had sought leave to appeal a decision of the Federal Court of Appeal, which dismissed AstraZeneca's appeal of a decision of a motions judge. The motions judge had dismissed AstraZeneca's appeal of a Registrar of Trade-marks decision, allowing Novopharm's opposition to registration of AstraZeneca's application for the trade-mark relating to the appearance (colour and shape) of its felodipine tablets. For further information regarding the Court of Appeal decision, please see the lead article in the March 2003 issue of *Rx IP Update*.

Apotex v. AstraZeneca (**omeprazole** and **omeprazole magnesium tablets** (**LOSEC**)), October 17, 2003

Apotex' leave application has been dismissed. Apotex had sought leave to appeal a decision of the Federal Court of Appeal, which dismissed Apotex' appeal from an Order of a motions judge. The motions judge had affirmed the Order of a Prothonotary, staying the proceeding until final disposition of a proceeding currently before the Ontario Superior Court of Justice. Both cases deal with copyright in drug product monographs. On September 15, 2003, the Supreme Court ordered the leave application to be expedited. The Court of Appeal judgment was reported in the July 2003 issue of *Rx IP Update*.

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

GlaxoSmithKline v. Genpharm (**paroxetine hydrochloride** (**PAXIL**)), October 24, 2003 (confidential reasons for order issued on October 3, 2003)

Judge dismisses GlaxoSmithKline (GSK)'s application for an order of prohibition with respect to a patent containing a claim for "crystalline paroxetine hydrochloride hemihydrate". Judge rejects Genpharm's allegation of invalidity based on obviousness and anticipation. However, Judge finds that GSK has failed to show that Genpharm's allegation of non-infringement is not justified. Genpharm had alleged that its product will contain anhydrate rather than a hemihydrate form of paroxetine hydrochloride. GSK has appealed.

Full Judgment (2003 FC 1248)

Lundbeck v. Genpharm (**citalopram** (**CELEXA**)), October 3, 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). Genpharm alleged non-infringement on the basis that it would market citalopram solely for treatment of depression. Lundbeck's NOC for CELEXA specifies that it is to be used for the symptomatic relief of depressive illness. Judge rejects Lundbeck's arguments that nothing prevents off-label use, dementia includes depression, and studies have shown citalopram to be effective in treating dementia, thus the probability of its patented use. Judge finds that Lundbeck has not established that Genpharm's citalopram would be prescribed for anything but depression and that no convincing evidence was presented that citalopram would be of any use to treat dementia or CVD. Lundbeck has appealed.

The decision that follows addresses whether the patent is properly listed on the Patent Register.

Full Judgment (2003 FC 1145)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Genpharm v. Company X (Lundbeck) (**citalopram** (**CELEXA**)), October 3, 2003

Judge dismisses Genpharm's application to require the Minister to remove a patent from the Patent Register. Genpharm had argued that the patent was improperly listed as it includes claims for the use of citalopram and these uses were not approved by Health Canada. Judge follows *Eli Lilly v. Canada (Minister of Health)* decision (2003 FCA 24), wherein the Court of Appeal found that the issue of relevance is to be defined strictly in terms of the explicit requirements of the *Regulations* and finds that these requirements have been met.

Full Judgment (2003 FC 1148)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Other Decisions

Eli Lilly v. Apotex (**cefaclor** (**APO- CEFACLOR**, **CECLOR**)), October 9, 2003

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 strikes this aspect of the pleading and dismisses counterclaim against Shionogi, finding that "an intention to lessen competition, so long as the means to achieve the end remain within the four corners of the *Patent Act*, is not an intention to lessen competition unduly and is therefore not illegal." Apotex has appealed.

Full Judgment (2003 FC 1171)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Novopharm Limited v. AstraZeneca AB (**felodipine** (**PLENDIL**)), October 17, 2003

Motions judge allows Novopharm's appeal from decisions of the Registrar of Trade-marks and denies registration of two trade-mark applications relating to the appearance of AstraZeneca's felodipine tablets. Judge finds that AstraZeneca has not established that the trade-marks have inherent or acquired distinctiveness.

Full Judgment (2003 FC 1212)
(*For a printer friendly version, please scroll down to the end of the Judgment)

New Court Proceedings

New NOC Proceedings

Medicine:	**clarithromycin (BIAXIN BID)**
Applicants:	Abbot Laboratories and Abbott Laboratories Limited
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	October 7, 2003
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,261,732; 2,258,606; 2,386,527; 2,386,534; 2,277,274; 2,387,361; and 2,387,356. Apotex alleges non-infringement and invalidity with respect to the 732, 527, 534, 274, 361 and 356 patents. Apotex alleges invalidity with respect to the 606 patent.

Medicine:	**ramipril (ALTACE)**
Applicants:	Aventis Pharma Inc and Aventis Pharma Deutschland GmbH
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	October 8, 2003
Comment:	Application for Order of prohibition until expiry of Patent No. 1,246,457. Apotex alleges non-infringement and invalidity.

Medicine: **azithromycin (ZITHROMAX)**
Applicants: Pfizer Canada Inc and Pfizer Inc
Respondents: Apotex Inc and The Minister of Health
Date Commenced: October 17, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,148,071. Apotex alleges non-infringement, invalidity and that the patent is improperly listed on the Patent Register.

Medicine: **sumatriptan succinate tablets (IMITREX)**
Applicants: GlaxoSmithKline Inc and Glaxo Group Limited
Respondents: Pharmascience Inc and The Minister of Health
Date Commenced: October 20, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,105,180. Pharmascience alleges non-infringement and invalidity.

Other New Proceedings

Medicine: **nefazodone hydrochloride (SERZONE-5HT$_2$)**
Applicant: Bristol-Myers Squibb Canada Inc
Respondent: The Minister of Health
Date Commenced: September 26, 2003
Comment: Application for an Order that the Minister not disclose certain records and information filed with Health Canada by the Applicant, pursuant to an *Access to Information Act* request.

Medicine: **alendronate (NOVO-ALENDRONATE, FOSAMAX)**
Plaintiffs: Merck & Co, Inc and Merck Frosst Canada & Co
Defendant: Novopharm Limited
Date Commenced: September 26, 2003
Comment: Patent infringement action regarding Patent No. 2,018,477.

Medicine: **alendronate (FOSAMAX)**
Plaintiffs: Merck & Co, Inc and Merck Frosst Canada & Co
Defendant: Brantford Chemicals Inc
Date Commenced: September 26, 2003
Comment: Patent infringement action regarding Patent No. 2,018,477

Health Canada News

On October 1, 2003, Health Canada released a document entitled *Guidance for Industry: Product Monograph*. The purpose of the document is to assist sponsors in developing product monographs with acceptable form and content.

Guidance for Industry: Product Monograph

Patented Medicines Prices Review Board (PMPRB) Matters

In June 2003, the PMPRB released its study for the Federal/Provincial/Territorial Working Group on Drug Prices, entitled *A Study of the Prices of the Top Selling Multiple Source Medicines in Canada*. The study examines the following questions:

- What is the relationship between prices of generic drugs and the brand name equivalent? Does the ratio of generic-to-brand name drug prices vary depending on the number of generic suppliers and other factors?
- To what extent do the prices of multiple source drugs in Canada differ from prices in other countries?

A Study of the Prices of the Top Selling Multiple Source Medicines

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