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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Update on Actions for Recovery of Losses Under *Notice of Compliance Regulations*

In our September 2001 issue of *Rx IP Update*, we reported on the commencement by Apotex Inc of four actions for recovery of losses brought pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations ("Regulations")*. Section 8(1), which came into force on March 12, 1998, provides:

> 8(1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period
>
> (a) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court is satisfied on the evidence that another date is more appropriate; and
>
> (b) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.

Since then, Apotex has brought at least three more similar actions. A summary of the seven pending actions brought in the Federal Court to date is as follows:

-**Nizatidine (AXID)**: against Eli Lilly and Company and Eli Lilly Canada Inc, commenced February 23, 2001;

-**Norfloxacin (NOROXIN)**: against Merck & Co Inc and Merck Frosst Canada & Co, commenced March 6, 2001;

-**Naproxen slow-release tablets (NAPROSYN SR)**: against Syntex Pharmaceuticals International Limited and Hoffmann-LaRoche Limited, commenced June 29, 2001;

-**Lovastatin (MEVACOR)**: against Merck & Co Inc and Merck Frosst Canada & Co, commenced June 29, 2001;

-**Acyclovir (ZOVIRAX)**: against The Wellcome Foundation and GlaxoSmithKline Inc, commenced September 21, 2001;

-**Pravastatin (PRAVACHOL)**: against Her Majesty the Queen, Bristol-Myers Squibb Canada Inc and Bristol-Myers Squibb Company, commenced March 25, 2002; and

-**Cetirizine hydrochloride (REACTINE)**: against Pfizer Canada Inc, commenced April 23, 2003.

Motions to strike Apotex' claims have been unsuccessful in the nizatidine (2001 FCT 1144 and 2001 FCT 636), norfloxacin ([2002] FCJ No 236), and naproxen slow-release cases (2001 FCT 1375). All of these decisions were affirmed by the Court of Appeal.

In the pravastatin case, Bristol-Myers Squibb was recently partially successful in a motion for partial summary judgment, with respect to Apotex' claim for legal expenses incurred with respect to the underlying proceeding under the *Regulations* (Apotex had consented to a discontinuance on a "without costs basis"). However, Bristol-Myers Squibb was unsuccessful in its motion with respect to Apotex' claim for profits. Bristol-Myers Squibb has appealed.

In the nizatidine and norfloxacin cases, Apotex amended its claims to include a claim based on former section 8 of the *Regulations*, in the event that new section 8 is found to be inapplicable. Former section 8 provides:

> 8(1) The first person is liable to the second person for damage suffered by the second person where, because of the application of paragraph 7(1)(e), the Minister delays issuing a notice of compliance beyond the expiration of all patents that are the subject of an order pursuant to subsection 6(1).

Section 7(1)(e) is the "statutory stay" provision:

> 7(1)(e) The Minister shall not issue a notice of compliance to a second person before the latest of subject to subsections (2), (3) and (4), the expiration of 30 months after the receipt of proof of the making of any application referred to in subsection 6(1)...

Apart from the determination regarding costs in the pravastatin case, the Courts have yet to make any final determinations regarding the scope and applicability of section 8 (old or new) of the *Regulations*. We will report on the progress of these cases and on new proceedings brought under section 8 of the *Regulations* in future issues of *Rx IP Update*.

Nancy P. Pei

Supreme Court of Canada Leave Applications

Leave Applications Filed

Apotex v. AstraZeneca (**omeprazole magnesium tablets** (**LOSEC**)), April 23, 2003

On April 23, 2003, Apotex filed an application seeking leave to appeal a Federal Court of Appeal decision, which dismissed Apotex' motion for leave to file new evidence in the appeal. The appeal resulted from a trial judge's decision to grant an Order of prohibition. The Court of Appeal judgment was reported in the March 2003 issue of *Rx IP Update*.

Pfizer v. Attorney General of Canada (**azithromycin dihydrate tablets** (**ZITHROMAX**))(**atorvastatin calcium tablets** (**LIPITOR**)), May 13, 2003

On May 13, 2003, Pfizer filed an application seeking leave to appeal a decision of the Federal Court of Appeal, which 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. The Court of Appeal judgment was reported in the April 2003 issue of *Rx IP Update* and was discussed in the lead article in the May 2003 issue of *Rx IP Update*.

Decisions Regarding Leave Applications

Percy Schmeiser v. Monsanto Canada (**glyphosate-resistant canola (ROUNDUP READY CANOLA)**), May 8, 2003

The Supreme Court grants Mr. Schmeiser and Schmeiser Enterprises leave to appeal a Federal Court of Appeal decision, dismissing their appeal from a trial judge's decision. The trial judge had found that the applicants had infringed Monsanto's patent by planting a crop of glyphosate-resistant canola having a gene or cell that is the subject of the patent and granted Monsanto an injunction and damages.

Appeal decision (2002 FCA 309)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Trial Division decision (2001 FCT 256)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Apotex v. Parke-Davis (**atorvastatin calcium** (**LIPITOR**)), May 22, 2003

The Supreme Court dismisses Apotex' application for leave to appeal from a Federal Court of Appeal decision, accepting Parke-Davis' arguments that Apotex' Notice of Allegation (NOA) was of no legal effect because there was no evidence that Apotex had filed a New Drug Submission (NDS) by the date of the hearing and that dedication of the relevant patent to the public was a mistake. The Court of Appeal judgment was reported in the December 2002 issue of *Rx IP Update*.

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Procter & Gamble v. Genpharm (**etidronate disodium** (**DIDROCAL**)), May 12, 2003

First summary dismissal motion brought pursuant to s. 6(5)(a) of the *Regulations*. Judge dismisses Genpharm's motion to dismiss Procter's application for Order of prohibition. Genpharm submitted that the relevant patent was not properly listed on the Patent Register as Procter filed the amendment to its patent list to include the patent more than 30 days after the patent issued (based on the date of grant of the patent). Judge finds that that it was not plain and obvious that the patent (a re-issue patent) was not eligible for inclusion on the Patent Register. Genpharm has appealed.

Full Judgment (2003 FCT 583)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Other Decisions

Apotex v. Richter Gedeon (**famotidine** (**APO-FAMOTIDINE, PEPCID**)), May 12, 2003

Court of Appeal dismisses Apotex' appeal of motions judge's decision, requiring Apotex to produce a one-gram sample of famotidine to allow the plaintiff to determine whether Apotex' famotidine is of the claimed Form B. The decision arose in the context of a patent infringement action.

Appeal decision (2003 FCA 221)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Trial Division decision (2002 FCT 1284)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Reddy-Cheminor v. The Minister of Health (**omeprazole magnesium** (**LOSEC**)), May 14, 2003

Judge dismisses Reddy-Cheminor's application for judicial review of a decision of the Minister of Health, refusing to process its Abbreviated New Drug Submission (ANDS) for its version of omeprazole, which referred to the Canadian reference product, LOSEC (omeprazole magnesium). The Minister refused to process the ANDS because omeprazole and omeprazole magnesium are different medicinal ingredients and therefore the submission could not be reviewed as an ANDS. Judge rejects Reddy-Cheminor's reliance on fact that AstraZeneca had filed a Supplemental New Drug Submission (SNDS) to change its product from omeprazole capsules to omeprazole magnesium tablets, as there is no requirement that the medicinal ingredients be identical for an SNDS. Judge finds that the Minister's decision was not patently unreasonable.

Full Judgment (2003 FCT 542)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Parliamentary Hearings regarding *NOC Regulations*

The Standing Committee on Industry, Science and Technology will be holding meetings on June 2, 3, and 4, 2003, to consider the automatic injunction provisions of the *Patented Medicines (Notice of Compliance) Regulations.*

Notice of meeting (June 2, 2003)

Notice of meeting (June 3, 2003)

Notice of meeting (June 4, 2003)

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New Court Proceedings

New NOC Proceedings

Medicine:	**clopidogrel bisulphate (PLAVIX)**
Applicants:	Sanofi-Synthelabo Canada Inc and Sanofi-Synthelabo
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	April 28, 2003
Comment:	Application for Order of prohibition until expiry of Patent No. 1,336,777. Apotex alleges that certain claims are not claims for the medicine itself or the use of the medicine, non-infringement, and invalidity.

Medicine:	**magnesium omeprazole tablets (LOSEC)**
Applicants:	AstraZeneca AB and AstraZeneca Canada Inc
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	May 13, 2003
Comment:	Application for Order of prohibition until expiry of Patent No. 2,186,037. Apotex alleges non-infringement and invalidity.

Medicine:	**azithromycin (ZITHROMAX)**
Applicants:	Pfizer Canada Inc and Pfizer Inc
Respondents:	RhoxalPharma Inc and The Minister of Health
Date Commenced:	May 16, 2003
Comment:	Application for Order of prohibition until expiry of Patent No. 1,314,876. RhoxalPharma alleges non-infringement.

Health Canada News

The Therapeutic Products Directorate has recently released a statistical report regarding the *Patented Medicines (Notice of Compliance) Regulations*.

TPD Statistical Report 2002

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