



IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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Update on Actions for Damages Under *Patented Medicines (Notice of Compliance) Regulations*

In the [June 2003](#) issue of *Rx IP Update*, we reported on the status of pending actions for damages for delay to generic market entry caused by unsuccessful proceedings under the *Regulations*. In this issue of *Rx IP Update*, we update developments since June 2003.

Patentee Not a Proper Defendant

The meaning of “first person” under the damages provision of the *Regulations* was clarified in a March 31, 2004 judgment ([2004 FC 502](#)) relating to the medicine nizatidine (AXID, APO-NIZATIDINE). Despite the fact that a “first person” is defined to be the party holding the Notice of Compliance (NOC) in Canada (typically the Canadian company), Apotex sued both Lilly US (the patentee) and Lilly Canada. The Court granted summary judgment, dismissing the claim against Lilly US, finding that as Lilly US is not a “first person,” it is not a proper party to the action. Apotex’ appeal is scheduled to be heard on October 4, 2004.

Summary Judgment Motions Dismissed

The Court also recently dismissed three motions for summary judgment on a variety of legal issues. As a result, the issues remain to be decided at trial. The decisions are as follows.

- On March 2, 2004, a judge dismissed Merck’s motion for summary judgment on Apotex’ damages claim related to norfloxacin (NOROXIN, APO-NORFLOX). Merck had argued that the new and old version of section 8 (the regulatory provision authorizing the action) did not apply, that the provisions were *ultra vires*, and that the claim for unjust enrichment was not available to Apotex. An appeal is scheduled to be heard on September 4, 2004. ([2004 FC 314](#))
- On March 16, 2004, a judge dismissed a motion by Roche and Syntex for summary judgment to dismiss Apotex’ claim relating to naproxen slow-release tablets (NAPROSYN SR, APO-NAPROXEN SR) in its entirety on the basis that section 8 did not apply. ([2004 FC 383](#))
- On March 31, 2004, a judge dismissed a motion by Lilly Canada for partial summary judgment seeking to dismiss Apotex’ claim for unjust enrichment in an action relating to the medicine nizatidine (AXID, APO-NIZATIDINE). ([2004 FC 502](#))

Furthermore, the Court of Appeal affirmed a previously-reported summary judgment decision.

- On January 27, 2004, the Court of Appeal dismissed an appeal by Bristol-Myers Squibb from a decision dismissing a motion for partial summary judgment on Apotex’ claim for profits for the medicine pravastatin (PRAVACHOL, APO-PRAVASTATIN). ([2004 FCA 43](#))

Limitation Period is Six Years

A six year limitation period was found to be the only relevant limitation period in an action for damages relating to fluconazole (DIFLUCAN, APO-FLUCONAZOLE) under the *Regulations* in a judgment dated February 4, 2004 ([2004 FC 190](#)). The prothonotary refused to grant Pfizer leave to plead a two year limitation period defence, finding that the only applicable limitation period was the six year limitation period found in the *Federal Courts Act*.

Particulars Denied

On May 19, 2004, the Federal Court denied H. Lundbeck's request for particulars regarding the period for which Apotex may claim compensation from Lundbeck in an action relating to citalopram hydrobromide (CELEXA, APO-CITALOPRAM). The prothonotary found that Apotex had clearly set out dates on which the prohibition proceedings were commenced and then discontinued or dismissed. ([2004 FC 728](#))

New Actions

Four new actions have been commenced by Apotex.

- Citalopram hydrobromide (CELEXA, APO-CITALOPRAM): two actions against H. Lundbeck A/S and Lundbeck Canada Inc, commenced March 8, 2004 and March 18, 2004;
- Paroxetine (PAXIL, APO-PAROXETINE): action against GlaxoSmithKline Inc, GlaxoSmithKline PLC, SmithKline Beecham Corporation, Doe Co and all other entities unknown to the Plaintiff which are part of the GlaxoSmithKline group of companies, commenced March 8, 2004; and
- Terbinafine hydrochloride (LAMISIL, APO-TERBINAFINE): against Novartis AG and Novartis Pharmaceuticals Canada Inc, commenced March 8, 2004.

Rx IP Update will continue to report on these proceedings as they advance towards trial.

J. Sheldon Hamilton

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

AstraZeneca v. Apotex (omeprazole magnesium (LOSEC)), April 29, 2004

Judge dismisses application for an Order of prohibition. Apotex alleged non-infringement. AstraZeneca has appealed.

[Full Judgment](#) (2004 FC 647)

AstraZeneca v. Apotex (omeprazole magnesium (LOSEC)), May 25, 2004

Judge allows appeal of a Prothonotary's Order and permits AstraZeneca to file an affidavit which described the results of testing of Apotex' omeprazole product. Judge finds that speedy resolution of the proceeding cannot come at the expense of the court being deprived of relevant and probably conclusive evidence. Apotex' appeal of this decision has been heard and is under reserve.

[Full Judgment](#) (2004 FC 762)

Fournier v. CIPHER (fenofibrate (LIPIDL SUPRA)), June 8, 2004

Judge dismisses Fournier's appeal of a Prothonotary's Order, dismissing Fournier's motion for an Order requiring CIPHER's expert to re-attend cross-examination and produce samples of CIPHER's product. Judge agrees that the samples are not relevant to the proceeding.

[Full Judgment](#) (2004 FC 818)

AstraZeneca v. Apotex (omeprazole (LOSEC)), June 9, 2004

AstraZeneca's application for an Order of prohibition was dismissed. The Minister subsequently issued an NOC to Apotex. Court of Appeal dismisses AstraZeneca's appeal on the basis that the appeal is moot.

[Full Judgment](#) (2004 FCA 224)

Other Decisions

Apotex v. Ontario (Minister of Health & Long-Term Care) (citalopram (CELEXA, GEN-CITALOPRAM, APO-CITALOPRAM)), April 27, 2004

Judge allows applications by Apotex, RhoxalPharma, Pharmascience, and Cobalt for judicial review, quashes the decision of the Minister extending the cut-off date for completion of drug submissions for an Update to the Ontario Drug Benefit Formulary/Comparative Drug Index, orders that the listing of Gen-Citalopram shall not take effect as part of the Update, and orders the Minister to set a new deadline for the completion of drug submissions for the next Update. Judge finds that the applicants suffered procedural unfairness because a deadline was imposed on them that was not imposed on Genpharm. The Minister and Genpharm have sought leave to appeal.

[Full Judgment](#)

Pierre Fabre Médicament v. SmithKline Beecham (IXEL), June 7, 2004

Judge allows appeal of a decision of the Registrar of Trade-marks and rejects opposition to registration of trade-mark IXEL for "produits pharmaceutiques; antidépresseur." Judge rejects allegation of confusion with the registered trade-mark PAXIL covering "pharmaceutical preparations, namely antidepressants." SmithKline Beecham has appealed.

[Full Judgment](#) (2004 CF 811; French decision)

Apotex v. Eli Lilly (cefaclor (APO- CEFACLOR, CECLOR)), June 14, 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. A motions judge dismissed the 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." Court of Appeal reinstates counterclaim and remits the matter back to the judge for further consideration including whether the *Competition Act* can ever apply to an agreement involving the exercise of patent rights.

[Court of Appeal Decision](#) (2004 FCA 232)

[Motions Judge's Decision](#) (2003 FC 1171)

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

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Medicine:
Applicants:
Respondents:
Date Commenced:
Comment:
fosinopril sodium (MONOPRIL)

Abbott Laboratories and Abbott Laboratories Limited

Novopharm Limited and The Minister of Health

May 28, 2004

Application for Order of prohibition until expiry of Patents Nos. 2,387,356; 2,261,732; 2,386,534; 2,386,527; 2,277,274; 2,258,606; 2,387,361; and 2,393,614. Novopharm alleges non-infringement, invalidity, and that the patents are not properly listed on the Patent Register.

Medicine:
Applicants:
Respondents:
Date Commenced:
Comment:
gatifloxacin (TEQUIN)

Bristol-Myers Squibb Canada Co and Kyorin Pharmaceutical Co Ltd

Novopharm Limited and The Minister of Health

May 31, 2004

Application for Order of prohibition until expiry of Patent No. 1,340,316. Novopharm alleges invalidity.

Medicine:
Applicants:
Respondents:
Date Commenced:
Comment:
epirubicin injectable ready-to-use solution (PHARMORUBICIN PFS)

Pfizer Canada Inc and Pharmacia Italia SpA

Mayne Pharma (Canada) Inc and The Minister of Health

June 14, 2004

Application for Order of prohibition until expiry of Patent No. 1,291,037. Mayne alleges non-infringement.

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