



IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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Competition Bureau Closes Inquiry into Alleged Practice of “Evergreening”

On February 27, 2004, the Competition Bureau announced that it has closed its inquiry into the alleged misuse of the *Patented Medicines (Notice of Compliance) Regulations* (“NOC Regulations”) by brand name pharmaceutical companies.

The inquiry commenced on June 9, 2003, and arose from a complaint filed with the Bureau by the National Union of Public and General Employees and other national organizations representing seniors, pensioners, patient advocates and health care activists. The complaint pointed to the alleged evergreening of patents by the addition of patents to the Patent Register maintained by the Minister of Health pursuant to the *Regulations* for a given medicine after the generic manufacturer has served a Notice of Allegation (NOA) regarding that medicine. The allegation was that the addition of patents provides the patentee with the possibility of claiming infringement of those patents, thus delaying the entry of generic drugs beyond the original patent protection period.

The Bureau made the following findings:

- “ 1. The Competition Bureau recognizes that the above-mentioned process can delay the introduction of a generic drug. However, under the NOC Regulations, if the infringement claims were redundant, scandalous, frivolous or vexatious, they could be dismissed by the Federal Court and give rise to potential action for damages by the generic drug manufacturers.
2. At the same time, depending on the information provided by the generic company in the NOA, brand name pharmaceutical patent holders may be acting within the purpose and intent of the NOC Regulations when they seek a Prohibition Order blocking the issuance of an NOC to a generic company. For example, the allegation that the generic drug will not infringe on a patent may be incomplete, incorrect or unjustified in some other way.
3. The NOC Regulations contain specific provisions to address and balance the competitive interests of brand name pharmaceutical patent holders and generic drug manufacturers and to remedy the practice raised in the complaint. Under the civil provisions of the *Competition Act*, there are no provisions for awarding damages in the circumstances described. Furthermore, inquiries under the *Competition Act* relate to specific company behaviour and do not contemplate a non-company specific review of a regulatory regime. In these circumstances, it is the Bureau's view that the *Competition Act* is not the appropriate vehicle to address the allegations raised in the complaint.
4. A number of court decisions over the last several years regarding what constitutes a relevant patent and the time period during which such a patent can be added have somewhat altered the balance contained in the NOC Regulations between the competing interests of the brand name pharmaceutical patent holders and generic drug companies. There is also no ready mechanism in the NOC Regulations for compensating consumers affected by delays in the introduction of generic drugs, thereby creating a possible incentive for brand name pharmaceutical companies to strategically use the NOC Regulations to improperly delay generic drug entry.
5. From a competition policy perspective in particular, the Government may wish to review the current rules to ensure that an appropriate balance is maintained between protecting intellectual property rights and facilitating a competitive supply of pharmaceutical products for Canadian consumers.”

We will continue to monitor matters before the Competition Bureau for items of interest to our readers.

[News Release](#)

[Backgrounder](#)

Nancy P. Pei

Standing Committee Hears Submissions on Proposed Legislation to Facilitate Exports of Patented Medicines to Developing Countries

As reported in our [March 2004](#) issue of *Rx IP Update*, on February 12, 2004, the Government reinstated proposed legislation, Bill C-9, to amend the *Patent Act* and the *Food and Drugs Act* in order to facilitate exports of patented medicines to least-developed and developing countries. The Bill has been referred to the Standing Committee on Industry, Science and Technology for consideration. Submissions of some of the interested parties before the Standing Committee are attached.

[Rx&D \(Canada's Research-Based Pharmaceutical Companies\)](#)

[Canadian HIV/AIDS Legal Network](#)

[CGPA \(Canada's Generic Pharmaceutical Industry\)](#)

Supreme Court of Canada Leave Applications Leave Applications Filed

Apotex v. AstraZeneca and Merck (**lisinopril (APO-LISINOPRIL, ZESTRIL, PRINIVIL)**), March 17, 2004

Apotex has sought an extension of time to seek leave to appeal a decision of the Federal Court of Appeal, which allowed AstraZeneca and Merck's appeal of a motions judge's decision in a patent infringement action. The Court of Appeal denied Apotex leave to amend its statement of defence, to withdraw an admission of infringement. The Court of Appeal judgment was reported in our [January 2004](#) issue of *Rx IP Update*.

Decisions Regarding Leave Applications

Apotex and Dr. Sherman v. Merck (**enalapril (VASOTEC)**), March 5, 2004

Leave has been denied. Apotex had sought leave to appeal a decision of the Federal Court of Appeal. The Court of Appeal had upheld decisions of a motions judge, finding Apotex and Dr. Sherman in contempt of court and imposing fines for selling enalapril, after reasons finding infringement were released. The judgment was reported in the [July 2003](#) issue of *Rx IP Update*.

Ferring v. Apotex (**desmopressin acetate nasal solution (DDAVP and MINIRIN)**), March 5, 2004

Leave has been denied. Ferring had sought leave to appeal a decision of the Federal Court of Appeal. The decision set aside a decision of an applications judge, and reinstated decisions of the Minister to remove Ferring's patent from the Patent Register and to issue a Notice of Compliance (NOC) to Apotex for Apo-Desmopressin. The Court of Appeal decision was reported in the lead article of the [August 2003](#) issue of *Rx IP Update*.

Apotex v. AB Hassle (**omeprazole magnesium (LOSEC)**), March 25, 2004

Leave has been denied in three applications. Apotex had sought leave to appeal a decision of the Federal Court of Appeal (reported in our [December 2003](#) issue of *Rx IP Update*) which dismissed its appeal of an

Order of prohibition. Apotex had also sought leave to appeal two interlocutory decisions, which dismissed Apotex' motions for leave to file new evidence in the appeal before the Federal Court of Appeal. The first interlocutory Order was reported in the March 2003 issue of *Rx IP Update*. The second interlocutory Order was issued without reasons.

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Procter & Gamble v. Genpharm (etidronate disodium (DIDROCAL)), February 12, 2004

Judge grants Order of prohibition. Judge declines to apply doctrine of estoppel to the issue of whether the "kit" claims fall outside the definition of "medicine" in the *Regulations* as she is not satisfied that this particular patent eligibility argument was considered in the previous proceeding. Judge also declines to apply estoppel to Genpharm's invalidity argument, in part on the basis that P&G did not raise the argument until after a decision of the Court of Appeal, applying the doctrine of estoppel against Genpharm to a patent eligibility issue in the same proceeding. Judge concludes that the allegation of invalidity on the basis of obviousness is not justified; the "kit" claims do not fall within the definition of "medicine"; the allegation that the "kit" claims are not infringed is not justified. Genpharm has appealed.

Full Judgment (2004 FC 204)

Apotex v. Merck (norfloxacin (NOROXIN)), March 2, 2004

In an action for damages brought pursuant to section 8 of the *Regulations*, Judge dismisses Merck's motion for summary judgment. Merck had argued that the new and old versions of section 8 do not apply to the facts alleged, that the provisions are *ultra vires* and that the claim for unjust enrichment is not available to Apotex. Judge finds that there is a significant gap in the evidence required to determine the proper interpretation of the provisions. Merck has appealed.

Full Judgment (2004 FC 314)

AstraZeneca v. Apotex (omeprazole (LOSEC)), March 2, 2004

Judge dismisses AstraZeneca's application for an Order of prohibition. Judge finds that the uses sought to be approved by Apotex are limited to those contained in the "Indications and Uses" section of the product monograph and is "not convinced" that issuing the NOC would result in infringement of the patent. AstraZeneca has appealed.

Full Judgment (2004 FC 313)

Reddy-Cheminor v. The Minister of Health (omeprazole magnesium (LOSEC)), March 11, 2004

Court of Appeal dismisses Reddy-Cheminor's appeal of a judge's decision. The judge had dismissed 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.

Court of Appeal Decision (2004 FCA 102)

Applications Judge's Decision (2003 FCT 542)

Pfizer v. The Minister of Health (verapamil (CHRONOVERA)), March 11, 2004

Judge dismisses Pfizer's application for an Order directing the Minister of Health to list a patent on the Patent Register. The Minister had decided that the patent was not eligible as the "dosage form" referred to in the patent was not a claim for a "medicine." Judge finds, "In my opinion, the ... patent does not claim protection for the "medicine" found in Pfizer's CHRONOVERA tablet. Rather, I construe the patent as being for a delivery system for the administration of any one of the 27 listed drugs, including verapamil hydrochloride. The 'essential elements' of this invention are the features of the dosage form that allow for the time-varied delivery of various drugs. The delivery system is protected, not the listed drugs."

[Full Judgment](#) (2004 FC 370)

AstraZeneca v. Apotex (omeprazole magnesium (LOSEC)), March 16, 2004

Judge dismisses AstraZeneca's application for an order of prohibition with respect to two use patents. Apotex had alleged non-infringement. AstraZeneca has appealed.

[Full Judgment](#) (2004 FC 379)

Apotex v. Hoffmann-LaRoche (naproxen slow-release tablets (NAPROSYN SR)), March 16, 2004

In an action for damages pursuant to section 8 of the *Regulations*, Judge dismisses Roche's motion for summary judgment, seeking to dismiss Apotex' claim in its entirety. Judge dismisses motion in view of previous decisions that denied summary judgment in cases that also required the interpretation of section 8. Apotex has appealed the costs aspect of the decision.

[Full Judgment](#) (2004 FC 383)

Other Decisions

Pfizer v. Eli Lilly (tadalafil (CIALIS)), February 11, 2004

Eli Lilly obtained its NOC for CIALIS on September 17, 2003. Judge dismisses Pfizer's motion for an interlocutory injunction, restraining the defendants from offering, selling, distributing or inducing others to use CIALIS for the treatment of male erectile dysfunction.

[Full Judgment](#) (2004 FC 223)

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	mycophenolate sodium (MYFORTIC, CELLCEPT)
Applicant:	Hoffmann-LaRoche Limited
Respondents:	Syntex (USA) Inc, Novartis Pharmaceuticals Canada Inc and The Minister of Health
Date Commenced:	February 26, 2004
Comment:	Application for Order of prohibition until expiry of Syntex' Patent No. 1,333,285. Novartis alleges non-infringement.

Medicine: **clarithromycin (BIAXIN BID)**
Applicants: Abbott Laboratories and Abbott Laboratories Limited
Respondents: Ratiopharm A Division of Ratiopharm Inc and The Minister of Health
Date Commenced: February 27, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 2,393,614. Ratiopharm alleges non-infringement and invalidity.

Medicine: **clarithromycin (BIAXIN BID)**
Applicants: Abbott Laboratories and Abbott Laboratories Limited
Respondents: Pharmascience Inc and The Minister of Health
Date Commenced: March 1, 2004
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,277,274; 2,386,527; 2,386,534; 2,387,356; and 2,386,361. Pharmascience alleges non-infringement.

Medicine: **citalopram hydrobromide (APO-CITALOPRAM, CELEXA)**
Plaintiff: Apotex Inc
Defendants: H. Lundbeck A/S and Lundbeck Canada Inc
Date Commenced: March 8, 2004
Comment: Action brought pursuant to the *Regulations* for damages allegedly suffered by Apotex by reason of commencement of prohibition proceedings by Lundbeck or an accounting of Lundbeck's profits, if Apotex so elects. Apotex also makes a claim based on unjust enrichment and seeks punitive and exemplary damages.

Medicine: **paroxetine (APO-PAROXETINE, PAXIL)**
Plaintiff: Apotex Inc
Defendants: 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
Date Commenced: March 8, 2004
Comment: Action brought pursuant to the *Regulations* for damages allegedly suffered by Apotex by reason of commencement of prohibition proceedings by GlaxoSmithKline or an accounting of GlaxoSmithKline's profits, if Apotex so elects. Apotex also makes a claim based on unjust enrichment.

Medicine: **terbinafine hydrochloride (APO-TERBINAFINE, LAMISIL)**
Plaintiff: Apotex Inc
Defendants: Novartis AG and Novartis Pharmaceuticals Canada Inc
Date Commenced: March 8, 2004
Comment: Action brought pursuant to the *Regulations* for damages allegedly suffered by Apotex by reason of commencement of prohibition proceedings by Novartis or an accounting of Novartis' profits, if Apotex so elects. Apotex also makes a claim based on unjust enrichment.

Medicine: **ondansetron hydrochloride dihydrate injectable (ZOFTRAN)**
Applicants: GlaxoSmithKline Inc and Glaxo Group Limited
Respondents: Mayne Pharma (Canada) Inc and The Minister of Health
Date Commenced: March 11, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 1,319,323. Mayne alleges non-infringement.

Medicine: **ondansetron hydrochloride dihydrate injectable (ZOFTRAN)**
Applicants: GlaxoSmithKline Inc and Glaxo Group Limited
Respondents: Mayne Pharma (Canada) Inc and The Minister of Health
Date Commenced: March 11, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 2,019,944. Mayne alleges non-infringement.

Medicine: **azithromycin monohydrate (ZITHROMAX)**
Applicants: Pfizer Canada Inc and Pfizer Inc
Respondents: Cobalt Pharmaceuticals Inc and The Minister of Health
Date Commenced: March 12, 2004
Comment: Application for Order of prohibition until expiry of Patents Nos. 1,314,876 and 2,148,071. Cobalt alleges non-infringement of the 876 patent and non-infringement, invalidity, and improper listing with respect to the 071 patent.

Medicine: **alendronate sodium (FOSAMAX)**
Applicants: Merck & Co, Inc and Merck Frosst Canada & Co
Respondents: Cobalt Pharmaceuticals Inc and The Minister of Health
Date Commenced: March 15, 2004
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,294,595; 2,221,417; and 2,149,052. Cobalt alleges non-infringement and invalidity with respect to the 595 patent; non-infringement and that certain claims should not be included on the Patent Register with respect to the 417 patent; and non-infringement, invalidity, and that certain claims should not be included on the Patent Register with respect to the 052 patent.

Medicine: **citalopram hydrobromide (APO-CITALOPRAM, CELEXA)**
Plaintiff: Apotex Inc
Defendants: H. Lundbeck A/S and Lundbeck Canada Inc
Date Commenced: March 18, 2004
Comment: Action brought pursuant to the *Regulations* for damages allegedly suffered by Apotex by reason of commencement of prohibition proceedings by Lundbeck or an accounting of Lundbeck's profits, if Apotex so elects. Apotex also makes a claim based on unjust enrichment.

Other New Proceedings

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 3400
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

Medicine: omeprazole (APO-OMEPRAZOLE)
Applicant: Apotex Inc
Respondents: The Minister of Health and The Attorney General of Canada
Date Commenced: February 23, 2004
Comment: Application compelling the issuance of an NOC for APO-OMEPROZOLE 20 mg capsules which states the Canadian reference product.

Medicine: etidronate disodium (CO ETIDRONATE)
Applicant: Proctor & Gamble Pharmaceuticals Canada Inc
Respondents: Cobalt Pharmaceuticals Inc and The Minister of Health
Date Commenced: February 19, 2004
Comment: Application for Order quashing the NOC for CO ETIDRONATE and a declaration that the Minister is prohibited from issuing an NOC to Cobalt until the *Regulations* have been complied with.

Trade-mark: BOTOX
Plaintiff: Allergan Inc
Defendants: Chrisolas Marketing International Ltd, Roderick W. Kirkham, James Creamer, and Richard O'C Whittall
Date Commenced: February 26, 2004
Comment: Trade-mark infringement action regarding nine registered trade-marks, including BOTOX, and action for passing-off with respect to alleged sales of "Botox-in-a-Bottle."

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
Michael D. Manson
Solomon M.W. Gold
David E. Schwartz
Nancy P. Pei
Denise L. Lacombe
James Jun Pan

A. David Morrow
Joy D. Morrow
Tokuo Hiram
Steven B. Garland
Brian G. Kingwell
Thuy H. Nguyen
Sally A. Hemming
Kavita Ramamoorthy

John R. Morrissey
Gunars A. Gaikis
J. Christopher Robinson
J. Sheldon Hamilton
Yoon Kang
Daphne C. Ripley
May Ming Lee
Scott A. Beeser

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