

AstraZeneca Initiates Action for Infringement of Copyright in LOSEC Product Monographs

1

AstraZeneca
Initiates Action for
Infringement of
Copyright in
LOSEC Product
Monographs

2

New Court
Proceedings

AstraZeneca Canada Inc (AstraZeneca) has initiated an action against Apotex in the Superior Court of Justice for Ontario alleging infringement of AstraZeneca's copyright in product monographs for LOSEC tablets (omeprazole magnesium) and LOSEC capsules (omeprazole). AstraZeneca is seeking, among other things, interim and interlocutory injunctions restraining Apotex from infringing AstraZeneca's copyright. As an alternative relief, AstraZeneca is seeking partial summary judgment.

The action, if it proceeds to a determination of the merits, will be (to our knowledge) the first in Canada by a pharmaceutical manufacturer asserting copyright infringement of a product monograph. In Canada, a pharmaceutical manufacturer must file a New Drug Submission with Health Canada, which includes a product monograph. The product monograph is a summary, among other things, of information about the use, conditions of use and safety of the drug.

Apotex has applied for, but has not yet received, government approval to market generic versions of omeprazole magnesium tablets and omeprazole capsules. In connection with other litigation, Apotex placed its proposed product monographs in the public record. AstraZeneca alleges that Apotex' product monographs are substantial reproductions of AstraZeneca's product monographs.

In response to the action, Apotex has initiated proceedings in the Federal Court for expungement of copyright registrations obtained by AstraZeneca for the product monographs.

The ultimate disposition of AstraZeneca's claim for copyright infringement could have significant implications for generic drug approval since generic manufacturers do not independently develop product monographs, relying instead on the innovator's monograph. Generic manufacturers argue that the contents of the product monograph are mandated by the Minister of Health and as a result, either no copyright subsists in the product monograph, or the copyright is owned by the Minister.

We will report on further developments in this area in future issues of *Rx IP Update*.

J. Sheldon Hamilton

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	Pravastatin sodium (PRAVACHOL)
Applicants:	Bristol-Myers Squibb Canada Inc and Bristol-Myers Squibb Company
Respondents:	Pharmascience Inc and the Minister of Health
Date Commenced:	July 31, 2002
Comment:	Bristol-Myers Squibb seeks an Order prohibiting the Minister from issuing a Notice of Compliance (NOC) to Pharmascience for oral administration of pravastatin sodium until after the expiration of Canadian Patent No. 1,323,836. Pharmascience alleges that its product does not infringe.

Medicine:	Clarithromycin (BIAXIN BID)
Applicants:	Abbott Laboratories and Abbott Laboratories Limited
Respondents:	Novopharm Limited and the Minister of Health
Date Commenced:	August 1, 2002
Comment:	The Applicants seek an Order prohibiting the Minister from issuing an NOC to Novopharm until after the expiry of Canadian Patent No. 2,261,732. Novopharm alleges non-infringement and invalidity. The Applicants deny Novopharm's allegations and allege that the Notice of Allegation (NOA) does not comply with the <i>Patented Medicines (Notice of Compliance) Regulations (Regulations)</i> .

Other New Proceedings

Medicine:	Omeprazole (LOSEC)
Plaintiff:	AstraZeneca Canada Inc
Defendant:	Apotex Inc
Date Commenced:	July 16, 2002, Ontario Superior Court of Justice
Comment:	AstraZeneca seeks a declaration that it owns copyright in the product monographs for LOSEC capsules and LOSEC delayed-release tablets and that Apotex' draft monographs for its APO-OMEPRAZOLE products infringe that copyright. AstraZeneca is seeking an injunction, damages, an accounting of profits, and delivery up. AstraZeneca is also seeking an Order obligating Apotex to obtain the approval of the court for any revised monographs and requiring Apotex to advise Health Canada of any injunction enjoining it from copying the monographs.

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:
Plaintiff:
Defendants:
Date Commenced:
Comment:

Fluconazole (APO-FLUCONAZOLE)

Apotex Inc
 Pfizer Canada Inc, Pfizer Corporation and Her Majesty the Queen
 August 1, 2002, Federal Court of Canada
 Apotex claims damages against Her Majesty caused by the unlawful refusal of the Minister of Health to issue Apotex an NOC for APO-FLUCONAZOLE from January 30, 1998 to October 9, 1998. Apotex claims damages against Pfizer caused by Pfizer's initiation of prohibition proceedings pursuant to the *Regulations*; an accounting of profits that Apotex would have made; and disgorgement of Pfizer's revenues attributable to the higher prices.

Medicine:
Applicant:
Respondent:
Date Commenced:
Comment:

Omeprazole (LOSEC)

Apotex Inc
 AstraZeneca Canada Inc
 August 9, 2002, Federal Court of Canada
 Apotex seeks a declaration that no copyright subsists in AstraZeneca's product monographs for LOSEC capsules and tablets and expunging AstraZeneca's copyright registrations for the monographs. Apotex claims that product monographs are not a "work" within the meaning of the *Copyright Act*; that they do not contain any original expression and that they were prepared by the Minister and her delegates. In the alternative, Apotex claims that the product monographs were prepared under the direction and control of the Minister and so Crown copyright subsists therein.

Contact Info

For more information, or to request a copy of any decision, pleading or legislation, please contact:

Gunars A. Gaikis
 ggais@smart-biggar.ca

J. Sheldon Hamilton
 jshamilton@smart-biggar.ca

Daphne C. Ripley (Acting Editor)
 dc Ripley@smart-biggar.ca

Pharmaceutical Practice Group

James D. Kokonis, Q.C.
 John R. Morrissey
 Gunars A. Gaikis
 J. Christopher Robinson
 J. Sheldon Hamilton
 Yoon Kang
 Daphne C. Ripley

A. David Morrow
 John Bochnovic
 Michael D. Manson
 Solomon M.W. Gold
 David E. Schwartz
 Nancy P. Pei
 Denise L. Lacombe

Michael E. Wheeler
 Joy D. Morrow
 Tokuo Hiram
 Steven B. Garland
 Brian G. Kingwell
 Thuy H. Nguyen

Disclaimer

The preceding is intended as a timely update on Canadian intellectual property and regulatory law of interest to the pharmaceutical industry. The contents of our newsletter are informational only, and do not constitute legal or professional advice. To obtain such advice, please communicate with our offices directly. To be put on the *Rx IP Update* mailing list, or to amend address information, please send an e-mail to rxip.update@smart-biggar.ca.