SMART & BIGGAR | FETHERSTONHAUGH

DECEMBER 2004
SPECIAL EDITION

Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Government of Canada Proposes Sweeping Amendments to Linkage Regulations and to Data Protection Provisions

On December 11, 2004, the Government of Canada published proposed amendments to the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") and data protection provisions of the *Food and Drug Regulations*. These amendments are described by the Government as:

> "...a package of regulatory amendments designed to reaffirm the balanced policy intent behind the [Regulations] and to reinforce data protection under the Food and Drug Regulations. If passed, the proposed amendments would bring a greater degree of stability and predictability to the intellectual property environment in the pharmaceutical industry by establishing a firmer upper and lower boundary to the period during which brand-name drugs enjoy market exclusivity."

The proposed "firmer lower boundary" would result from amendments to the *Food and Drug Regulations* that are intended to provide a guaranteed period of market exclusivity of eight years after issuance of the innovator's first notice of compliance (NOC) for a drug, based on data protection.

The proposed "firmer upper boundary" would result from amendments that would severely restrict the ability of innovators to add patents to the Patent Register ("Register") maintained by the Minister of Health pursuant to the *Regulations*, and would limit the patents that must be addressed by generic manufacturers.

I. Proposed Amendments to the Regulations

In general terms, the *Regulations* protect patentees from patent infringement by linking the Minister's ability to approve a generic drug to the patent status of the innovative product. The generic, however, is only required to address patents listed on the Register.

The most significant amendments fall into two categories: (1) patent listing requirements and (2) when a generic must address listed patents.

1. Eligibility requirements for patent listing

The proposed amendments would require that the patent be relevant to the content of the submission in relation to which it is submitted. Also, only those supplemental new drug submissions (SNDSs) for a change in formulation or use will support the listing of a patent in respect of an SNDS. As a result, the requirements for listing would be far stricter than under the present *Regulations*. A patent would be eligible for listing:

(i) in relation to a new drug submission (NDS): if the patent contains a claim for the medicinal ingredient/formulation/use of the medicine, and that ingredient/formulation/use has been approved through issuance of a NOC in respect of that submission, and

(ii) in relation to an SNDS: if the SNDS is for a change in formulation or use, the patent contains a claim for a formulation/use, and that formulation/use has been approved through issuance of a NOC in respect of that SNDS.

2. No requirement to address certain later-listed patents

While the amendments still require that a generic must address all patents listed on the Register before issuance of the generic's NOC, two new provisions would remove the requirement to address certain later-listed patents. In particular:

(i) a generic would not be required to address patents added to the Register in relation to an SNDS filed after the filing date of the generic's submission, and

(ii) a generic need not address patents on the Register in respect of a drug if the drug identification number (DIN) for the innovator's drug has been cancelled.

3. Other amendments

Other proposed amendments include:

- the addition of an allegation, for "use" patents listed in connection with an SNDS, that a generic's submission "does not seek approval for the use of the medicine that is claimed in that patent", and
- repeal of present section 5(1.1), which will clarify that the Regulations are not intended to apply to second-entry drug submissions where the sponsor is required to conduct independent clinical studies to establish the safety and efficacy of its product.

4. Transitional provision

A grandfathering provision would provide that matters relating to patents on the Register as of the coming into force date of the amendments will be dealt with according to the present *Regulations*, except for the new provision which would eliminate the need to address patents when the DIN has been cancelled.

II. Proposed amendments to Data Protection

Data protection is based on international obligations which require that, where a company submits trade-secret data to a regulatory authority when seeking approval for a drug composed of a new active substance, that data is protected from reliance by competitors for a minimum of five years from the date the drug is approved. While there is a data protection provision in the present *Food and Drug Regulations* (section C.08.004.1), a Federal Court of Appeal decision interpreted the provision narrowly such that it rarely, if ever, is triggered.

The proposed amended provision would prohibit the Minister from issuing a NOC for eight years (plus six months if pediatric studies were performed) after the day on which the first NOC was issued to the innovator in respect of the innovative drug if:

(i) the manufacturer, in its submission, directly or indirectly compares the new drug to the innovative drug and the innovative drug contains a medicinal ingredient that had not been approved in Canada before the first NOC was issued to the innovator;

(ii) the comparison forms the basis on which the manufacturer seeks the issuance of an NOC; and

(iii) the medicinal ingredient in the new drug is identical to the medicinal ingredient in the innovative drug.

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 3300
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

It is proposed that the new data protection provisions will only apply to innovators' NDSs that were filed on or after the coming into force date of the amendments.

The proposed amendments provide for a 75-day consultation period, expiring on February 24, 2005[1]. *Rx IP Update* will keep you informed of future developments.

Nancy P. Pei

[1]This is a correction to the original article, which showed the expiration date as February 25, 2005.

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
Keltie R. Sim
J. Christopher Robinson
J. Sheldon Hamilton
Yoon Kang
Daphne C. Ripley
May Ming Lee
Scott A. Beeser
A. David Morrow
Joy D. Morrow
Michael D. Manson
Solomon M.W. Gold
David E. Schwartz
Nancy P. Pei
Denise L. Lacombe
James Jun Pan
John R. Morrissey
Gunars A. Gaikis
Tokuo Hirama
Steven B. Garland
Brian G. Kingwell
Thuy H. Nguyen
Sally A. Hemming
Kavita Ramamoorthy

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 join the *Rx IP Update* mailing list, or to amend address information, please send an e-mail to rxip.update@smart-biggar.ca.

SMART & BIGGAR
FETHERSTONHAUGH