



Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

April 2008
Special Edition

Amendments to linkage Regulations propose removal of "relevance" requirement for patent lists submitted under old *Regulations*

On April 26, 2008, the Government published proposed amendments to the *Patented Medicines (Notice of Compliance) Regulations* ("Regulations") that would undo a 2007 Federal Court decision, upheld by the Federal Court of Appeal, finding that for patent lists submitted under the pre-2006 amended *Regulations*, "relevance" is required between a patent and the submission against which it is listed (*Wyeth Canada v. Ratiopharm Inc.*, 2007 FC 340, rev'd 2007 FCA 264, leave denied).

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 innovator's product. As the generic manufacturer is only required to address patents listed on the Register, listing of patents is critical. The *Regulations* were substantially amended in October 2006 to require for patent listing, among other new requirements, relevance between a patent and the submission against which it is proposed to be listed. At the time, this represented a

significant change to listing requirements, as the previous jurisprudence had established that the pre-amended *Regulations* imposed no such requirement. As explained in the Regulatory Impact Analysis Statement accompanying the proposed amendments, the Government's intention was that patents protected under the *Regulations* prior to the amendments would be "grandfathered". Thus, the transitional provision that accompanied the amendments stated that amended section 4 (relating to patent listing) "does not apply to patents on a patent list submitted prior to June 17, 2006".

The Government expresses its concern that the 2007 Wyeth decision may result in many patents, submitted in full compliance with the listing requirements as they were interpreted and applied prior to June 17, 2006, being deleted from or not added to the Register, which "could result in a sudden and unexpected loss of market exclusivity for a number of innovative drugs" and that this would be inconsistent with the intention of

the Government's decision to grandfather the Register. In addition to the impact of Wyeth, the Government also states that a broader unsettling of the jurisprudence regarding the pre-amended listing requirements would "defeat one of the foremost benefits which the Government sought to achieve in clarifying those rules, namely a reduction in litigation".

The proposed amendments are:

1. A new section would limit the bases upon which the Minister may delist a patent submitted before June 17, 2006 to the following:
 - the patent has expired or has been declared invalid;
 - the Drug Identification Number has been cancelled pursuant to section C.01.014.6(1)(a); and
 - the patent is found under section 6(5)(a) (the summary dismissal provision) to be ineligible (section 6(5)(a) motions going forward would also be restricted; see below).
2. That section would also preclude the Minister from refusing to add a patent on a patent list submitted before June 17, 2006 to the Register "solely on the basis that the patent is not relevant to the submission for a notice of compliance to which the patent list relates, where the submission is a supplement to a new drug submission".

3. A new subsection would preclude the summary dismissal of a proceeding in whole or in part solely on the basis that a patent on a patent list submitted before June 17, 2006 is not eligible for listing.

The proposed transitional provisions are:

1. If a patent submitted before June 17, 2006 was delisted or refused to be added to the Register after March 27, 2007 (the Wyeth decision issued on March 29, 2007), "solely on the basis that the patent is not relevant to the submission for a notice of compliance to which the patent list relates and if that submission is a supplement to a new drug submission", the first person may, within 30 days after the day the amendments comes into force, request that the patent be added to the Register and the Minister shall within 30 days after the request is received (or if it is the case of a refusal to list, within 30 days after the later of the day on which the request is received and the day on which the notice of compliance is issued), add the patent to the Register.
2. The new preclusion relating to summary dismissal motions would not apply to motions brought before April 26, 2008.

Representations may be made within **15 days** after publication, *i.e.* **May 11, 2008**.

SMART & BIGGAR FETHERSTONHAUGH

Barristers & Solicitors • Patent & Trade-mark Agents

OTTAWA

55 Metcalfe Street Suite 900
P.O. Box 2999 Station D
Ottawa ON K1P 5Y6
Canada
t. 613.232.2486
f. 613.232.8440
ottawa@smart-biggar.ca

TORONTO

Box 111 Suite 1500
438 University Avenue
Toronto ON M5G 2K8
Canada
t. 416.593.5514
f. 416.591.1690
toronto@smart-biggar.ca

MONTREAL

Suite 3300
1000 De La Gauchetière Street West
Montreal QC H3B 4W5
Canada
t. 514.954.1500
f. 514.954.1396
montreal@smart-biggar.ca

VANCOUVER

Box 11560 Vancouver Centre
2200-650 West Georgia Street
Vancouver BC V6B 4N8
Canada
t. 604.682.7780
f. 604.682.0274
vancouver@smart-biggar.ca

www.smart-biggar.ca

Pharmaceutical Practice Group

James D. Kokonis, Q.C., B.A.Sc. (Metallurgy), LL.B.
John R. Morrissey, B.Eng. (Elec.Eng.), S.M., LL.B.
Joy D. Morrow, B.Sc., M.Sc. (Cell Bio), LL.B.
Michael D. Manson, B.Sc. (Bio), Dipl.Ed., LL.B.
Tokuo Hiram, B.Sc., M.Sc. (Chem)
J. Christopher Robinson, B.Sc., M.Sc. (Genetics), LL.B.
Steven B. Garland, B.Eng. (Chem.-Biochem.Eng.), LL.B.
David E. Schwartz, B.Sc. (Genetics), LL.B.
Yoon Kang, B.Sc., M.Sc. (Molec.Bio. & Genetics), LL.B.
Geneviève M. Prévost, B.Sc. (Chem), LL.B.
Thuy H. Nguyen, B.Sc., Ph.D. (Biochem.)
Colin B. Ingram, B.A.Sc. (Elec.Eng.), LL.B.
Sally A. Hemming, B.Sc., Ph.D. (Biochem.), J.D.
James Jun Pan, B.Eng. (Eng.Phys.), Ph.D. (Chem.), LL.B.
T. Nessim Abu-Zahra, B.Sc. (Life Sci.), M.Sc. (Pharmacol.), J.D.
Daniel M. Anthony, B.Sc. (Cell Bio. & Genetics), J.D.
Elizabeth A. Hayes, B.Sc. (Biochem.), M.Eng. (Biomed. Eng.)

A. David Morrow, B.Sc. (Physics), LL.B.
John Bochnovic, B.Eng. (Elec.Eng.), S.M., LL.B.
Gunars A. Gaikis, B.Sc.Pharm., LL.B.
Keltie R. Sim, B.Sc. (Mycology), LL.B.
Mark K. Evans, B.Sc., LL.B.
Solomon M.W. Gold, B.Sc., M.Sc. (Bio), LL.B.
J. Sheldon Hamilton, B.A.Sc. (Chem.Eng.), LL.B.
Brian G. Kingwell, B.Sc. (Biochem.), M.Sc. (Mol. Cell Bio), LL.B.
Nancy P. Pei, B.Sc.Pharm., LL.B.
Mark G. Biernacki, B.A.Sc. (Mech. Eng.), LL.B.
Jeremy E. Want, B.Sc. (Chem), LL.B.
Daphne C. Lainson, B.Sc., M.Sc. (Chem), LL.B.
May Ming Wu, B.Sc.Pharm., LL.B.
Christian Bérubé, B.Sc. (Chem), M.Sc. (Inorganic Chem.)
Y. Lynn Ing, B.Sc. (Biochem.), Ph.D. (Molec.Bio.), J.D.
Junyi Chen, B.A. (Chem), M.Sc. (Chem), Ph.D. (Chem), J.D.
David J. Suchon, B.Sc. (Biochem.), LL.B.

Contact Information

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

Yoon Kang
ykang@smart-biggar.ca

Nancy P. Pei (Editor)
nppei@smart-biggar.ca

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.