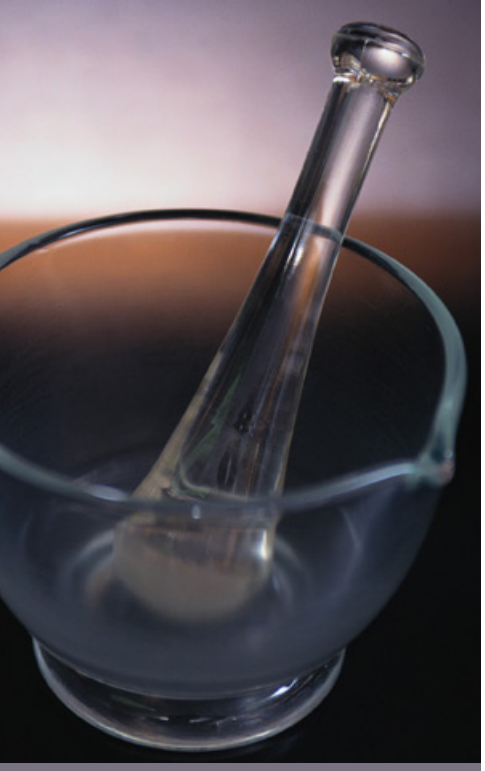

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

June 2008
Special Edition

Amendments to linkage *Regulations* now in force

As reported in the April 2008 Special Edition of *Rx IP Update*, 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). A 15-day comment period followed pre-publication. On June 12, 2008, the *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations* (HTML, PDF) were registered and came into force on that date. As a result, the deadline for delivering a written request to the Minister of Health asking that a patent be added to the Patent Register which was refused for listing or delisted and to which the *Regulations* apply is within 30 days after June 12, 2008. The Regulations will be published in Part II of the Canada Gazette on June 25, 2008.

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 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 RIAS states that the impact of *Wyeth* would be inconsistent with the intention and purpose of the Government's decision to grandfather the Register. Further, many patents submitted in full compliance with the listing requirements as they were interpreted and

applied prior to June 17, 2006, could be deleted from, or not added to, the Register, which could result in earlier than anticipated loss of market exclusivity for a number of innovative drugs. In addition to the impact of *Wyeth*, the Government also states that a broader unsettling of the jurisprudence regarding the pre-amended listing requirements could give rise to a proliferation in litigation, contrary to one of the stated objectives of the 2006 amendments.

Finally, the RIAS states that following pre-publication, "suggestions were made in various media articles that the proposed changes would allow innovative pharmaceutical companies to reinstitute evergreening strategies and delay the market entry of lower-cost generic versions of several top-selling drugs, costing consumers and taxpayers tens of millions of dollars annually". In response, federal officials stated that "evergreening" is no longer possible as a result of the Patent Register "freeze" provision; the transitional measures further ensure that patents added to the Register as a result of the *Regulations* do not impede the market entry of any generic drug for which a regulatory submission is already on file; and currently, only fourteen patents not presently on the Register would be eligible to be added to the Register on the coming into force of the *Regulations*.

The two main differences in the amendments from the initial proposal are:

1. The proposed amendments captured only patents listed against supplemental new drug submissions whereas the *Regulations* no longer include such restriction (and are therefore intended to capture patents listed against both supplemental new drug submissions and new drug submissions), and
2. The transitional provisions now state that a second person is not required to address patents added to the Register as a result of a request under the amendments to do so, where such patent was added to the Register on or after the filing date of the second person's submission.

The amendments are:

1. New section 3.1 limits 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) of the *Food and Drug Regulations*; and
    - the patent is found under section 6(5)(a) (the summary dismissal provision) to be ineligible (however, there is a new restriction on section 6(5)(a) motions brought on or after April 26, 2008; see below).
2. New section 3.1 also precludes 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".
3. New subsection 6(5.1) precludes 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 transitional provisions are:

1. If a patent submitted on a patent list **before June 17, 2006** was delisted or refused to be added to the Register **after March 29, 2007** (the *Wyeth* decision issued on that date), "solely on the basis that the patent is not relevant to the submission for a notice of compliance to which the patent list relates", the first person may, **within 30 days after June 12, 2008** (the day the amendments came 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. A second person is not required to address patents added to the Register as a result of a request under the amendments to do so, where such patent was added to the Register on or after the filing date of the second person's submission.
3. New subsection 6(5.1) (the new preclusion relating to summary dismissal motions) does not apply to motions brought before April 26, 2008 (the date of publication of the proposed amendments).

It should be emphasized that in order to obtain the benefit of some of the amendments, first persons must make requests for listing by the above-mentioned deadline of within 30 days after June 12, 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 Hirama, 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.
Andrew Mandlsohn, B.Sc. (Pharm.), J.D.
David J. Suchon, B.Sc. (Biochem.), LL.B.
A. David Morrow, B.Sc. (Physics), LL.B.
John Bochnovic, B.Eng. (Elec.Eng.), S.M., LL.B.
Gunars A. Gaikis, B.Sc.Phm., 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.Phm., 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.Phm., 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
Elizabeth A. Hayes, B.Sc. (Biochem.), M.Eng. (Biomed. Eng.)

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

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