

Torlys on Food and Drug Regulatory

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Proposed Amendments to the *Patented Medicines (Notice of Compliance) Regulations*

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On April 26, 2008, the government of Canada published for comment proposed amendments to the *Patented Medicines (Notice of Compliance) Regulations*, commonly referred to as the “PM(NOC) Regulations.” These regulations create the regulatory framework for pharmaceutical patents to be listed on Health Canada’s Patent Register.

Most recently, the regulatory framework underwent amendment in October 2006, implementing significant changes to patent listing eligibility requirements regarding patent lists submitted after June 17, 2006. Patents included on earlier filed patent lists (referred to as “grandfathered patents”) were to be subject to the listing requirements applicable before June 17, 2006. In making the decision to grandfather these patents, the government noted the potential unfairness of subjecting listed patents to new eligibility requirements, as well as the possibility of market disruption and investment uncertainty.

Despite the Canadian government’s intent regarding grandfathered patents, a decision of the Supreme Court of Canada released shortly after June 17, 2006, brought about a re-interpretation of the pre-June 17, 2006 listing requirements by the Federal Court of Appeal,¹ bringing them into line with the amended requirements. According to this decision, there must be relevance between the invention claimed in the patent to be listed and the regulatory submission for which the patent list is submitted. Prior jurisprudence stood for the proposition that patents are listed generally against a drug, rather than against the specific drug submission for which the patent list is submitted.

Citing concerns about widespread delisting of or refusal to list grandfathered patents and the consequential sudden and unexpected loss of market exclusivity for a drug, the proposed amendments are designed to address the impact of these recent court decisions.

According to the proposed amendments, the Minister of Health would be prohibited from deleting from the Patent Register patents included on patent lists submitted before June 17, 2006, subject to certain common-sense exceptions (i.e., if a patent has expired or been declared invalid; if the drug in respect of which a patent is listed is no longer marketed; or if a patent has been found ineligible for listing under section 6(5)(a) of the PM(NOC) Regulations).

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¹ *Ratiopharm Inc. v. Wyeth and Wyeth Canada*, 2007 FCA 264.

The proposed amendments would also revise section 6(5)(a) to prevent a generic pharmaceutical manufacturer from seeking to have a prohibition application brought by an innovative manufacturer dismissed solely on the ground that a grandfathered patent does not meet the listing requirements in effect before June 17, 2006. The Minister of Health would also be prohibited from refusing to add to the Patent Register a patent on a patent list submitted before June 17, 2006 solely because the patent is not relevant to the supplement to a new drug submission (SNDS) in relation to which it was submitted.

According to the transitional provisions, it will be possible to “undo” any actions taken by the Minister of Health in relation to grandfathered patents as a result of the above-noted decision of the Federal Court of Appeal. Thus, an innovative drug manufacturer would be able to request relisting of a patent that was deleted from the Patent Register solely because it was not relevant to the SNDS in relation to which it was submitted for listing. Similarly, an innovative manufacturer would be able to request that a grandfathered patent be added to the Patent Register if listing was refused because it lacked relevance to the SNDS in relation to which it was submitted for listing. The addition of a patent to the Register as a result of these transitional provisions would not operate as an impediment to a generic drug manufacturer that has already filed a submission for a notice of compliance. Nor would the proposed amendments to section 6(5) apply to a summary dismissal motion brought under that section before April 26, 2008.

Comment Period

Stakeholders have been invited to submit comments on the proposed amendments before **May 11, 2008**. This relatively short comment period has been justified on the ground that the proposed amendments reaffirm the intended effect of one of the 2006 amendments, thereby obviating the need for a longer consultation period. **1**