

## **REGULATORY IMPACT ANALYSIS STATEMENT** **(This statement is not part of the Regulations)**

### **Description**

These Regulations reinforce the predictability, stability and competitiveness of Canada's intellectual property (IP) regime for pharmaceuticals by reaffirming and clarifying the intended effect of a transitional measure included in an earlier round of amendments to the same instrument. The intention of that measure was to ensure that patents eligible for protection under the *Patented Medicines (Notice of Compliance) Regulations* (PM(NOC) Regulations) as they were prior to October 5, 2006 (i.e., "grandfathered" patents) remain so until expiry.

### *Background*

On October 5, 2006, the PM(NOC) Regulations were amended to restore their original policy intent, which is to balance effective patent enforcement over new and innovative drugs with the timely market entry of their lower priced generic competitors.<sup>1</sup> Part of the 2006 amendments entailed reaffirming the requirements for listing patents on the Minister of Health's (Minister) patent register and clarifying when listed patents must be addressed. These changes were necessary to clarify certain ambiguities in the regulatory language which had given rise to abundant and sometimes conflicting case law, particularly on patent listing issues.

Some of the amendments to the patent listing requirements brought into force in 2006 confirm or build on the interpretation that prevailed in the jurisprudence at the time (e.g., new listing requirements governing what types of supplement to a new drug submission (SNDS) allow for the listing of a new patent on the register<sup>2</sup>). Others depart significantly from, or reverse, that same jurisprudence (e.g., the broadening in scope of eligible subject matter to allow for the listing of dosage form patents<sup>3</sup>).

Given the potential unfairness to patentees that would result from subjecting patents submitted for listing under the PM(NOC) Regulations in conformity with then-applicable rules to new and different requirements, the Government opted to exempt ("grandfather") them from the application of the 2006 changes.<sup>4</sup> In doing so, the

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<sup>1</sup> The Regulatory Impact Analysis Statement (RIAS) accompanying SOR/2006-242 contains an in depth discussion of that policy, as well as the role played by the PM(NOC) Regulations.

<sup>2</sup> Subsection 4(2) of the regulatory instrument referred to in Footnote 1 and *Hoffman-La Roche Ltd. v. Canada (Minister of Health)*, (2005), 253 D.L.R. (4<sup>th</sup>) 644; 2005 FCA 140; (2005), 40 C.P.R. (4<sup>th</sup>) 108.

<sup>3</sup> Paragraph 4(2)(c) of the regulatory instrument referred to in Footnote 1 and *GlaxoSmithKline Inc. v. Canada (Minister of Health)*, (2005), 40 C.P.R. (4<sup>th</sup>) 193; 2005 FCA 197, Pelletier, J.A.

<sup>4</sup> Section 6 of the transitional provisions of the regulatory instrument referred to in Footnote 1 provides that "Section 4 of the *Patented Medicines (Notice of Compliance) Regulations*, as enacted by section 2 of these Regulations, does not apply to patents on a patent list submitted prior to June 17, 2006."

Government's intention was to ensure that grandfathered patents remain subject to the listing requirements as they were interpreted and applied prior to June 17, 2006, the date the 2006 amendments were pre-published in Part I of the *Canada Gazette*. This would avoid any market disruption and investment uncertainty that might otherwise result from the application of the new requirements to patents already listed, or submitted for listing, on the register.

However, shortly after the coming into force of the 2006 amendments, the Supreme Court of Canada rendered a decision under the PM(NOC) Regulations as they were prior to that time.<sup>5</sup> This decision cast doubt on some of the reasoning that had been employed by lower courts in interpreting the old listing requirements. In a subsequent judgment, the Federal Court of Appeal cited the Supreme Court's decision in reversing its own previous ruling that a patent containing a claim for the medicine in a drug is listed generally against the drug, rather than against the specific submission for a notice of compliance (NOC) upon which the patent list is based.<sup>6</sup> In circumstances where the submission in question is an SNDS, the Court came to the view that there must be relevance between the invention claimed in the patent and the change to the drug in respect of which the SNDS was filed.

While it can be said that this new interpretation brings the old patent listing requirements closer into line with how the 2006 amended requirements are intended to operate, the impact of such a marked departure from precedent would be inconsistent with the intention and purpose of the Government's decision to grandfather the register. 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. This could result in earlier than anticipated loss of market exclusivity for a number of innovative drugs.

The Government is also concerned about the possibility that the Court of Appeal's recent decision to revisit its own precedent may mark the beginning of a trend. If the Supreme Court of Canada's reasoning opens the door to a broader unsettling of the jurisprudence on the listing requirements as they were prior to the 2006 amendments, this could give rise to a proliferation in litigation, contrary to one of the stated objectives of the 2006 amendments. To ensure this does not occur, these Regulations amend section 3 of the PM(NOC) Regulations to prohibit the Minister from deleting grandfathered patents from the register, subject to certain common-sense exceptions.<sup>7</sup> The Regulations further amend section 3 to prohibit the Minister from refusing to add any such patent to the

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<sup>5</sup> *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, [2006] 2 S.C.R. 560, 2006 SCC 49.

<sup>6</sup> *Ratiopharm Inc. v. Wyeth and Wyeth Canada* (2007), 60 C.P.R. (4<sup>th</sup>) 375, 2007 FCA 264.

<sup>7</sup> The Minister retains discretion to delete a grandfathered patent from the register where it has expired, lapsed or been declared invalid in an action under the *Patent Act*, has been found ineligible for inclusion on the register under paragraph 6(5)(a) of the PM(NOC) Regulations or where the identification number assigned to the drug in respect of which the patent is listed is cancelled under the *Food and Drug Regulations*.

register solely on the ground that it is not “relevant”, within the meaning given to that term by the Federal Court of Appeal, to the new drug submission (NDS) or SNDS in relation to which it is submitted. It should be noted that these changes are not intended to interfere with, or circumscribe in any way, the Minister’s discretion to refuse to add a patent on other unrelated grounds. A related amendment to section 6 prevents the Court from dismissing an application solely on the ground that a grandfathered patent does not meet the listing requirements as they were prior to the 2006 amendments. This will effectively foreclose further litigation on the proper interpretation of the old listing requirements.

The Regulations contain a number of transitional provisions which undo actions taken by the Minister in relation to grandfathered patents as a result of the above-mentioned decision of the Federal Court of Appeal. These provisions enable a “first person” to make a written request to the Minister that a patent on a patent list which has been deleted from the register solely on the basis that it was not relevant to the submission for a NOC to which the patent list relates be added back to the register. They also enable a first person to make a written request to the Minister that a patent on a patent list which has been refused addition to the register on the same singular basis be added to the register. In the first instance, the Minister will be required to add the patent in question to the register within 30 days after the first person’s request. In the second instance, it will be within 30 days after the first person’s request or the day on which the relevant NOC is issued, whichever is the latter. At the same time, the transitional provisions also provide that a “second person” who has already filed a submission for a NOC comparing its drug to one in respect of which a patent is added to the register as a result of these transitional provisions is not required to comply with the requirements of section 5 of the PM(NOC) Regulations in so far as that patent is concerned. This is consistent with the “frozen” register mechanism brought into effect as part of the 2006 amendments to eliminate repeat cases due to staggered patent listings by first persons, a behaviour referred to by some as “evergreening”.

Finally, the transitional provisions provide that the above-mentioned amendment to section 6 does not apply to a summary dismissal motion brought by a second person under subsection 6(5) on or before April 26, 2008, the date the proposed Regulations were pre-published in Part I of the *Canada Gazette*. This preserves the vested right of a second person to obtain the remedy formerly available under that section, provided the underlying motion was initiated prior to the Government’s announcement of the forthcoming rule changes.

## **Alternatives**

In determining how best to respond to the Federal Court of Appeal decision, the Government considered making a more targeted amendment directed solely to the relevance issue. However, given the significant potential for further such reversals in precedent on other aspects of the old listing requirements, the Government opted for a more holistic approach which limits the circumstances in which the Minister can delete a grandfathered patent from the register and the grounds upon which a second person can

challenge it in court. This will pre-empt the substantial litigation that would otherwise have taken place as a result of the decisions of both the Supreme Court of Canada and Federal Court of Appeal.

## Consultations

The 2006 amendments, including the transitional measures, were the subject of extensive consultations with stakeholders. Given that these Regulations reaffirm the intended effect of one such measure, their pre-publication in Part I of the *Canada Gazette* was followed by a 15-day public comment period.

The Government received forty (40) submissions during this period, primarily from the innovative and generic sectors of the pharmaceutical industry, Provincial health authorities in New Brunswick and Nova Scotia, business development associations, seniors groups, pension plan trustees and labour unions. Twenty-two (22) of the submissions were supportive of the Regulations and eighteen (18) were opposed. Those who supported the Regulations commended the Government for moving quickly in response to the Federal Court of Appeal decision but urged it to go further in safeguarding grandfathered patents and addressing other perceived shortcomings in the intellectual property protection provided to innovative drugs in Canada. Those opposed disputed the Government's characterization of the Regulations as a reaffirmation of previous policy and expressed concern that the shorter-than-average public comment period did not allow for a meaningful assessment of the impact of the proposed changes on health care costs. Opponents also suggested that the Regulations would revive the evergreening activity that had taken place prior to the 2006 amendments.

In addition to the above concerns, the need for clarification on technical issues was identified by stakeholders from both the innovative and generic sectors of the industry in relation to various operational aspects of the Regulations. Issues the Government found to be substantiated have been addressed through appropriate changes to the text of the Regulations or in their description set out above. Specifically, changes were made to the transitional provisions to respond to the generic industry's request that the Government affirm its intent that a second person who has already filed a submission for a NOC is not required to address patents added to the register as a result of requests brought by a first person under these same provisions. Changes were also made to the provisions amending section 3 of the PM(NOC) Regulations to respond to the innovative industry's observation that recent jurisprudence has also applied the Federal Court of Appeal's relevance test not only to patents listed in relation to an SNDS but also to patents listed in relation to a NDS.<sup>8</sup> Accordingly, whereas the proposed Regulations pre-published in Part I of the *Canada Gazette* mentioned only SNDS-listed patents, the Regulations use the phrase "submission for a notice of compliance", which captures both SNDS- and NDS-listed patents.

In addition, both sides of the industry argued strenuously for changes to the transitional provision which enables second persons to continue to prosecute outstanding

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<sup>8</sup> *Nycomed Canada Inc. and Nycomed GMBH v. Novopharm and the Minister of Health*, 2008 FC 313.

subsection 6(5) motions. On the one hand, the generic industry asked that the provision be expanded to cover not only existing subsection 6(5) motions but any motions brought in the future within ongoing prohibition proceedings. On the other, the innovative industry asked that the provision be eliminated in its entirety, thereby preventing ongoing motions from being prosecuted to completion. The Government examined these competing requests and found that eighty-one (81) ongoing proceedings involving thirty-five (35) drugs would benefit if the provision were expanded in the manner sought by the generic sector, and eight (8) motions involving three (3) drugs would be prejudiced if it were eliminated. While compelling arguments were advanced on both sides of the debate, the Government ultimately concluded that the approach taken at pre-publication was most consistent with its overall policy objectives and fairest to the collective interests of all stakeholders.

### **Benefits and Costs**

By clarifying the Government's original intention that grandfathered patents should continue to be eligible for the special protection provided by the PM(NOC) Regulations, the Regulations reaffirm the stability, predictability and competitiveness of Canada's pharmaceutical patent regime. They also reduce the risk of further potential litigation on this issue. Innovative and generic pharmaceutical companies will thus be spared the associated legal costs of such litigation, and the courts the burden of its adjudication.

Following pre-publication of the Regulations in Part I of the *Canada Gazette*, 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.

These claims prompted health authorities in some Provinces to express concern over the impact of the proposed changes on drug expenditures. In response, federal officials at Health Canada and Industry Canada contacted their counterparts in these Provinces to clarify a number of points. Most importantly, federal officials offered reassurance that evergreening was no longer possible under the PM(NOC) Regulations as a result of the 2006 amendments which "freeze" the patent register as of the date the generic drug company files its regulatory submission with the Minister. Federal officials also explained that the proposed transitional measures would 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. Finally, federal officials sought to provide some perspective on the issue by pointing out that currently, only fourteen (14) patents not presently on the register would be eligible to be added to it upon the coming into force of the Regulations.

While the short-term impact of adding these patents to the register is expected to be modest, the Government recognizes that, by limiting the circumstances in which a grandfathered patent can be deleted from the register, or the grounds upon which it can be

challenged in court, the Regulations may have an impact on the timing of market entry of generic versions of some innovative drugs over the longer term. However, any attempt to predict or quantify that impact would be highly speculative at best, given the many variables involved, including litigation strategies, court outcomes and market behaviour. The Government considers these unknown potential costs to be counter-balanced by the benefits of having in place a stable and well functioning patent regime which provides the innovative industry with continued confidence in Canada as a place to invest in research and development and as a market in which to bring new and better products.

### **Compliance and Enforcement**

The courts and the Minister will continue to exercise jurisdiction over issues related to the administration of the PM(NOC) Regulations.

### **Contact**

Susan Bincoletto  
Director General  
Marketplace Framework Policy Branch  
Industry Canada,  
10<sup>th</sup> Floor, East Tower,  
235 Queen Street  
Ottawa, Ontario  
K1A 0H5

Telephone: (613) 952-0736  
Facsimile: (613) 941-8151  
Email: [bincoletto.susan@ic.gc.ca](mailto:bincoletto.susan@ic.gc.ca)