

PATENT ACT

**Regulations Amending the Patented Medicines
(Notice of Compliance) Regulations**

P.C. 2006-1077 October 5, 2006

Her Excellency the Governor General in Council, on the recommendation of the Minister of Industry, pursuant to subsection 55.2(4)^a of the *Patent Act*, hereby makes the annexed *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*.

**REGULATIONS AMENDING THE PATENTED
MEDICINES (NOTICE OF COMPLIANCE)
REGULATIONS
AMENDMENTS**

1. (1) The definitions “claim for the medicine itself”, “claim for the use of the medicine” and “medicine” in section 2 of the *Patented Medicines (Notice of Compliance) Regulations*¹ are repealed.

(2) The definitions “Minister”, “patent list”, “register” and “second person” in section 2 of the Regulations are replaced by the following:

“Minister” means the Minister of Health; (*ministre*)

“patent list” means a list submitted under subsection 4(1); (*liste de brevets*)^{ee}

“register” means the register of patents and other information maintained by the Minister in accordance with subsection 3(2); (*registre*)

“second person” means the person referred to in subsection 5(1) or (2) who files a submission or supplement referred to in those subsections; (*seconde personne*)

(3) Section 2 of the Regulations is amended by adding the following in alphabetical order:

“claim for the dosage form” means a claim for a delivery system for administering a medicinal ingredient in a drug or a formulation of a drug that includes within its scope that medicinal ingredient of formulation; (*revendication de la forme posologique*)

“claim for the formulation” means a claim for a substance that is a mixture of medicinal and non-medicinal ingredients in a drug and that is administered to a patient in a particular dosage form; (*revendication de la formulation*)

“claim for the medicinal ingredient” includes a claim in the patent for the medicinal ingredient, whether chemical or biological in nature, when prepared or produced by the methods or processes of manufacture particularly described and claimed in the patent, or by their obvious chemical equivalents, and also includes a claim for different polymorphs of the medicinal ingredient but does not include different chemical form of the medicinal ingredient; (*revendication de l'ingrédient médicinal*)

^a S.C. 2001, c. 10, s. 2(2)

¹ SOR/93-133

“claim for the use of the medicinal ingredient” means a claim for the use of the medicinal ingredient for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms; (*revendication de l'utilisation de l'ingrédient médicinal*)

2. The heading before section 3 and sections 3 to 5 of the Regulations are replaced by the following:

REGISTER AND PATENT LIST

3. (1) The following definitions apply in this section and in section 4.

“identification number” means a number, preceded by the letters “DIN”, that is assigned for a drug in accordance with subsection C.01.014.2(1) of the *Food and Drug Regulations*. (*identification numérique*)

“new drug submission” means a new drug submission as that term is used in Division 8 of Part C of the *Food and Drug Regulations*, but excludes a new drug submission that is based solely on the change of name of the manufacturer. (*présentation de drogue nouvelle*)

“supplement to a new drug submission” means a supplement to a new drug submission as that term is used in Division 8 of Part C of the *Food and Drug Regulations*, but excludes a supplement to a new drug submission that is based solely on one or more of the matters mentioned in any of paragraphs C.08.003(2)(b) and (d) to (g) and subparagraphs C.08.003(2)(h)(iv) and (v) of those Regulations. (*supplément à une présentation de drogue nouvelle*)

(2) The Minister shall maintain a register of patents and other information submitted under section 4. To maintain the register, the Minister may refuse to add or may delete any patent or other information that does not meet the requirements of that section.

(3) If a patent is listed on the register in respect of a new drug submission or supplement to a new drug submission for a drug for which the identification number has been cancelled under paragraph C.01.014.6(1)(a) of the *Food and Drug Regulations*, the Minister shall delete the patent from the register 90 days after the date of cancellation.

(4) Subsection (3) does not apply if the identification number is cancelled under paragraph C.01.014.6(1)(a) of the *Food and Drug Regulations* because of a change in manufacturer.

(5) If, after an identification number is cancelled under paragraph C.01.014.6(1)(a) of the *Food and Drug Regulations*, an identification number is assigned for the same drug, the Minister shall add to the register the patent that was deleted under subsection (3) when the Minister receives the document required by section C.01.014.3 of the *Food and Drug Regulations* in respect of the drug.

(6) The register shall be open to public inspection during business hours.

(7) No patent on a patent list or other information submitted under section 4 shall be added to the register until after the Minister has issued a notice of compliance in respect of the new drug submission or the supplement to a new drug submission, as the case may be, to which the patent or information relates.

(8) For the purpose of deciding whether a patent, patent list or other information will be added to or deleted from the register, the Minister may consult with officers or employees of the Patent Office.

4. (1) A first person who files or who has filed a new drug submission or a supplement to a new drug submission may submit to the Minister a patent list in relation to the submission or supplement for addition to the register.

(2) A patent on a patent list in relation to a new drug submission is eligible to be added to the register if the patent contains

(a) a claim for the medicinal ingredient and the medicinal ingredient has been approved through the issuance of a notice of compliance in respect of the submission;

(b) a claim for the formulation that contains the medicinal ingredient and the formulation has been approved through the issuance of a notice of compliance in respect of the submission;

(c) a claim for the dosage form and the dosage form has been approved through the issuance of a notice of compliance in respect of the submission; or

(d) a claim for the use of the medicinal ingredient, and the use has been approved through the issuance of a notice of compliance in respect of the submission.

(3) A patent on a patent list in relation to a supplement to a new drug submission is eligible to be added to the register if the supplement is for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient, and

(a) in the case of a change in formulation, the patent contains a claim for the changed formulation that has been approved through the issuance of a notice of compliance in respect of the supplement;

(b) in the case of a change in dosage form, the patent contains a claim for the changed dosage form that has been approved through the issuance of a notice of compliance in respect of the supplement; or

(c) in the case of a change in use of the medicinal ingredient, the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of a notice of compliance in respect of the supplement.

(4) A patent list shall contain the following:

(a) an identification of the new drug submission or the supplement to a new drug submission to which the list relates;

(b) the medicinal ingredient, brand name, dosage form, strength, route of administration and use set out in the new drug submission or the supplement to a new drug submission to which the list relates;

(c) for each patent on the list, the patent number, the filing date of the patent application in Canada, the date of grant of the patent and the date on which the term limited for the duration of the patent will expire under section 44 or 45 of the *Patent Act*;

(d) for each patent on the list, a statement that the first person who filed the new drug submission or the supplement to a new drug submission to which the list relates is the owner of the patent or has an exclusive licence to the patent, or has obtained the consent of the owner of the patent to its inclusion on the list;

(e) the address in Canada for service, on the first person, of a notice of allegation referred to in paragraph 5(3)(a) or the name and address in Canada of another person on whom service may be made with the same effect as if service were made on the first person; and

(f) a certification by the first person that the information submitted under this subsection is accurate and that each patent on the list meets the eligibility requirements of subsection (2) or (3).

(5) Subject to subsection (6), a first person who submits a patent list must do so at the time the person files the new drug submission or the supplement to a new drug submission to which the patent list relates.

(6) A first person may, after the date of filing of a new drug submission or supplement to a new drug submission, and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date in Canada that precedes the date of filing of the submission or supplement, submit a patent list, including the information referred to in subsection (4), in relation to the submission or supplement.

(7) A first person who has submitted a patent list must keep the information on the list up to date but, in so doing, may not add a patent to the list.

(8) The Minister shall insert on the patent list the date of filing and submission number of the new drug submission or the supplement to a new drug submission in relation to which the list was submitted.

4.1 (1) In this section, "supplement to the new drug submission" means a supplement to a new drug submission as that term is used in Division 8 of Part C of the *Food and Drug Regulations*.

(2) A first person who submits a patent list in relation to a new drug submission referred to in subsection 4(2) may, if the list is added to the register, resubmit the same list in relation to a supplement to the new drug submission, but may not submit a new patent list in relation to a supplement except in accordance with subsection 4(3).

5. (1) If a second person files a submission for a notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall, in the submission, with respect to each patent on the register in respect of the other drug,

(a) state that the person accepts that the notice of compliance will not issue until the patent expires; or

(b) allege that

(i) the statement made by the first person under paragraph 4(4)(d) is false,

(ii) the patent has expired,

(iii) the patent is not valid, or

(iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the submission is filed.

(2) If a second person files a supplement to a submission referred to in subsection (1) seeking a notice of compliance for a change to the formulation, a change in dosage form or a change in use of the medicinal ingredient and the supplement directly or indirectly compares the drug with, or makes reference to, another drug that has been marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall, in the supplement, with respect to each patent on the register in respect of the other drug,

(a) state that the second person accepts that the notice of compliance will not issue until the patent expires; or

(b) allege that

(i) the statement made by the first person under paragraph 4(4)(d) is false,

(ii) the patent has expired,

(iii) the patent is not valid, or

(iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the supplement is filed.

(3) A second person makes an allegation under paragraph (1)(b) or (2)(b), shall

(a) serve on the first person a notice of allegation relating to the submission or supplement filed under subsection (1) or (2) on or after its date of filing;

(b) include in the notice of allegation

(i) a description of the medicinal ingredient, dosage form, strength, route of administration and use of the drug in respect of which the submission or supplement has been filed, and

(ii) a detailed statement of the legal and factual basis for the allegation;

(c) include in the material served a certification by the Minister of the date of filing of the submission or supplement; and

(d) serve proof of service of the documents and information referred to in paragraphs (a) to (c) on the Minister.

(4) A second person is not required to comply with

(a) subsection (1) in respect of a patent added to the register in respect of the other drug on or after the date of filing of the submission referred to in that subsection, including a patent added under subsection 3(5); and

(b) subsection (2) in respect of a patent added to the register in respect of the other drug on or after the date of filing of the supplement referred to in that subsection, including a patent added under subsection 3(5).

(5) For the purposes of subsections (3) and (4), if subsection (1) or (2) applies to a submission or supplement referred to in paragraph C.07.003(b) of the *Food and Drug Regulations*, if the drug to which the comparison or reference is made is an innovative drug within the meaning of subsection C.08.004.1(1) of those Regulations and if the date of filing of the submission or supplement is less than six years from the day the first notice of compliance was issued in respect of the innovative drug, the deemed date of filing of the submission or supplement is six years after the date of issuance of the notice of compliance.

(6) A second person who has served a notice of allegation on a first person under paragraph (3)(a) shall retract the notice of allegation and serve notice of the retraction on the first person within 90 days after either of the following dates:

(a) the date on which the Minister notifies the second person under paragraph C.08.004(3)(b) of the *Food and Drug Regulations* of their non-compliance with the requirements of section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1 of those Regulations; or

(b) the date of the cancellation by the second person of the submission or supplement to which the allegation relates.

(7) A first person who has applied for a prohibition order under subsection 6(1) in response to a notice of allegation shall, if the notice is retracted in accordance with subsection (6), apply without delay for a discontinuance of the proceedings.

3. (1) Subsection 6(1) of the Regulations is replaced by the following:

6. (1) A first person may, within 45 days after being served with a notice of allegation under paragraph 5(3)(a), apply to a court for an order prohibiting the Minister from issuing a notice of compliance until after the expiration of a patent that is the subject notice of allegation.

(2) Subsections 6(5) and (6) of the Regulations are replaced by the following:

(5) In a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application in whole or in part

(a) in respect of those patents that are not eligible for inclusion on the register; or

(b) on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents.

(6) For the purposes of an application referred to in subsection (1), if a second person has made an allegation under subparagraph 5(1)(b)(iv) or 5(2)(b)(iv) in respect of a patent and the patent was granted for the medicinal ingredient when prepared or produced by the methods or processes of manufacture particularly described and claimed in the patent, or by their obvious chemical equivalents, it shall be considered that the drug proposed to be produced by the second person is, in the absence of proof to the contrary, prepared or produced by those methods or processes.

(3) Paragraphs 6(7)(a) and (b) of the Regulations are replaced by the following:

(a) order a second person to produce any portion of the submission or supplement filed by the second person for a notice of compliance that is relevant to the disposition of the issues in the proceeding and may order that any change made to the portion during the proceeding be produced by the second person as it is made; and

(b) order the Minister to verify that any portion produced corresponds fully to the information in the submission or supplement.

(4) Paragraph 6(10)(c) of the Regulations is replaced by the following:

(c) the failure of the first person to keep the patent list up to date in accordance with subsection 4(7).

4. (1) Paragraph 7(1)(d) of the Regulations is replaced by the following:

(d) subject to subsection (3), the expiration of 45 days after the receipt of proof of service of a notice of allegation under paragraph 5(3)(a) in respect of any patent on the register,

(2) Paragraph 7(2)(b) of the Regulations is replaced by the following:

(b) the court has declared that the patent is not valid or that no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed.

5. (1) Paragraph 8(1)(a) of the Regulations is replaced by the following:

(a) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court concludes that

(i) the certified date was, by the operation of *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, chapter 23 of the Statutes of Canada, 2004, earlier than it would otherwise have been and therefore a date later than the certified date is more appropriate, or

(ii) a date other than the certified date is more appropriate; and

(2) Subsection 8(4) of the Regulations is replaced by the following:

(4) If a court orders a first person to compensate a second person under subsection (1), the court may, in respect of any loss referred to in that subsection, make any order for relief by way of damages that the circumstances require.

(3) Section 8 of the Regulations is amended by adding the following after subsection (5):

(6) The Minister is not liable for damages under this section.

TRANSITIONAL PROVISIONS

6. 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.

7. (1) Subsection 5(1) of the *Patented Medicines (Notice of Compliance) Regulations*, as enacted by section 2 of these Regulations, applies to a second person who has filed a submission referred to in subsection 5(1) prior to the coming into force of these Regulations and the date of filing of the submission is deemed to be the date of the coming into force of these Regulations.

(2) Subsection 5(2) of the *Patented Medicines (Notice of Compliance) Regulations*, as enacted by section 2 of these Regulations, applies to a second person who has filed a supplement to a submission referred to in subsection 5(2) prior to the coming into force of these Regulations and the date of filing of the supplement is deemed to be the date of the coming into force of these Regulations.

8. Subsection 8(4) of the *Patented Medicines (Notice of Compliance) Regulations*, as enacted by subsection 5(2) of these Regulations, does not apply to an action commenced under section 8 of the *Patented Medicines (Notice of Compliance) Regulations* prior to the coming into force of these Regulations.

COMING INTO FORCE

9. These Regulations come into force on the day on which they are registered.

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Description

These amendments are intended to restore the balanced policy underlying the *Patented Medicines (Notice of Compliance) Regulations* ("PM(NOC) Regulations") by reaffirming the rules for listing patents on the register and clarifying when listed patents must be addressed.

Background

The Government's pharmaceutical patent policy seeks to balance effective patent enforcement over new and innovative drugs with the timely market entry of their lower priced generic competitors. The current manner in which that balance is realized was established in 1993, with the enactment of Bill C-91, the *Patent Act Amendment Act, 1992*, S.C. 1993, c. 2.

On the one end of the balance lies subsection 55.2(1) of the *Patent Act*, better known as the "early-working" exception. In the pharmaceutical industry, early-working allows second and subsequent entry drug manufacturers (typically generic drug companies) to use a patented, innovative drug for the purpose of seeking approval to market a competing version of that drug. Normally, conduct of this kind would constitute patent infringement but an exception has been made so that generic drug companies can complete Health Canada's regulatory approval process while the equivalent innovative drug is still under patent, in order to be in a position to enter the market as soon as possible after patent expiry. The generic pharmaceutical industry estimates that early-working can accelerate the market entry of its products in Canada by some three to five years.

The PM(NOC) Regulations represent the other half of the balance. As explained in the original Regulatory Impact Analysis Statement (RIAS) which accompanied their passage in 1993, in creating the early-working exception, Bill C-91 removed an exclusive right otherwise available to patentees and the PM(NOC) Regulations are therefore required "... to ensure that this new exception to patent infringement is not abused by generic drug applicants seeking to sell their products during the term of the competitor's patent...". The PM(NOC) Regulations do this by linking Health Canada's ability to approve a generic drug to the patent status of the equivalent innovative product the generic seeks to copy. Under the current scheme, a generic drug company which compares its product directly or indirectly with a patented, innovative drug in

order to establish the former's safety and efficacy and secure marketing approval from Health Canada (which comes in the form of a "notice of compliance" or "NOC") must make one of two choices. It can either agree to await patent expiry before obtaining its NOC or make an allegation justifying immediate market entry that is either accepted by the innovator or upheld by the court.

Thus, while early-working is intended to promote the timely market entry of generic drugs by allowing them to undergo the regulatory approval process in advance of patent expiry, the PM(NOC) Regulations are intended to provide effective patent enforcement by ensuring the former does not result in the actual issuance of a generic NOC until patent expiry or such earlier time as the court or innovator considers justified having regard to the generic company's allegation. Despite their seemingly competing policy objectives, it is important that neither instrument be considered in isolation as the intended policy can only be achieved when the two operate in a balanced fashion.

Patent Listing Requirements

Considering the societal imperative of encouraging new and better medical therapies, and the difficulties associated with protecting pharmaceutical patent rights by way of conventional infringement litigation, the PM(NOC) Regulations are intended to operate as a very potent patent enforcement mechanism. The 24-month stay under the regulations serves that purpose by providing innovator companies with the means to pre-empt the market entry of suspected patent infringers. At the same time, it is this very potency which calls for moderation in the application of the PM(NOC) Regulations, lest their effect dominate that of early-working and defeat the overall purpose of the policy. As has been observed by the courts on numerous occasions, the PM(NOC) Regulations are a special enforcement remedy which exists in addition to, not in lieu of, the right to pursue an action for patent infringement.

Consistent with this understanding of the PM(NOC) Regulations is the fact that not every patent pertaining to an approved drug qualifies for enforcement under the scheme. Only those patents which meet the current timing, subject matter and relevance requirements set out in section 4 of the regulations are entitled to be added to Health Canada's patent register and to the concurrent protection of the 24-month stay. Embodied in each of these requirements are certain fundamental principles which must be respected if the PM(NOC) Regulations are to operate in balance with early-working. While the operation of some of these requirements is described in more detail below, a brief discussion of the principles they represent is warranted.

By stipulating that the application filing date of the patent precede the date of the corresponding drug submission, the timing requirement promotes a temporal connection between the invention sought to be protected and the product sought to be approved. This ensures that patents for inventions discovered after the existence of a product do not pre-empt generic competition on that

product. Similarly, the relevance requirement limits the protection of the PM(NOC) Regulations to that which the innovator has invested time and money to test and have approved for sale. This prevents hypothetical innovation from impeding generic market entry and encourages innovators to bring their latest inventions to market. Finally, in only allowing patents to be listed which contain claims for the medicine or its use, the subject matter requirement makes it clear that innovations without direct therapeutic application, such as processes or intermediates, do not merit the special enforcement protection of the PM(NOC) Regulations.

It is recognized that there may be instances where a patent which does not qualify for the protection of the PM(NOC) Regulations is ultimately infringed by the fact of generic market entry. However, the Government's view is that where the patent fails to meet the listing requirements described above, policy considerations tip the balance in favour of immediate approval of the generic drug, and the matter is better left to the alternative judicial recourse of an infringement action. It follows that the continued viability of the regime greatly depends upon the fair and proper application of these listing requirements.

It has come to the Government's attention that an increasing number of court decisions interpreting the PM(NOC) Regulations have given rise to the need to clarify the patent listing requirements. These decisions, which turn on timing and relevance issues, are not the product of judicial error but rather of deficiency in the language of the PM(NOC) Regulations themselves. Of particular concern is the failure of the language to fully account for the range of submission types possible under the *Food and Drug Regulations*, the various pharmaceutical patent claims available under the *Patent Act* and, most importantly, the breadth of scenarios which can arise from the linkage between the two established by the PM(NOC) Regulations.

Timing and Relevance

As mentioned, in order for a patent to be added to the register and be protected under the PM(NOC) Regulations, its application must have been filed prior to the date of the corresponding drug submission. Under the *Food and Drug Regulations*, there are two principal types of drug submission an innovator company may file in order to obtain a NOC in respect of a new drug: a New Drug Submission (NDS) and a Supplement to a New Drug Submission (SNDS). A NDS is filed when approval is first sought for a new drug and contains all of the information necessary to prove that the drug is safe and effective. A SNDS is filed whenever a subsequent change is made to the drug which departs from the information in the NDS in a way that can impact on safety and efficacy.

The PM(NOC) Regulations speak only to the requirement that the patent filing date precede the date of the "submission for a notice of compliance" and do not specify whether this applies to the date of the NDS, the SNDS or both. Until relatively recently however, the timing requirement was treated as applying to the NDS only. This understanding of the provisions changed in 1999, when the Federal Court ruled that patents which were out of time in relation to the NDS could nevertheless be added to the register provided they met the timing requirement in relation to a subsequently filed SNDS¹.

Allowing patents to be listed in this manner is inherently problematic because a SNDS can be filed virtually any time for any number of reasons, ranging from the mundane, such as a change in drug name, to the substantive, such as a change in its indications or formulation. Accordingly, taken to the extreme, this practice has the potential to deprive the timing requirements of any meaningful effect.

In addition to ruling on this timing question, the same Federal Court decision also expressly sanctioned the listing of new formulation patents that do not claim the specific product the innovator is approved to sell. The latter finding was predicated on the court's view that the sole purpose of the PM(NOC) Regulations is the prevention of patent infringement.

Significantly, the ruling in question interpreted the PM(NOC) Regulations as they were prior to their substantial amendment in 1998². That year, the Government introduced a number of changes to the PM(NOC) Regulations designed to improve their operation and reduce and streamline litigation. As further confirmation that the PM(NOC) Regulations were intended to effect a balanced policy objective, the RIAS to the 1998 amendments reiterated the point in the following passage:

The amendments reinforce the balance between providing a mechanism for the effective enforcement of patent rights and ensuring that generic drugs enter the market as soon as possible.

Consistent with maintaining this balance, certain changes will further facilitate the market entry of generic drugs [...]

Among the changes introduced by the 1998 amendments to "facilitate the market entry of generic drugs" were provisions designed to reinforce the patent listing requirements. In particular, the amended PM(NOC) Regulations reaffirm the application of strict time limitations for adding a patent to the register and contain an additional requirement that patents be relevant to the strength, dosage form and route of administration of the approved drug.

Since 1998, the Minister of Health ("Minister") has sought to apply the amendments on timing and relevance in order to place reasonable limits on the ability of innovator drug companies to list new patents on the basis of SNDS filings. The Minister has invoked the timing amendment in opposing attempts by certain innovator companies to add new patents to the register on the basis of a SNDS for a change in drug or company name. Similarly, the Minister has applied the relevance requirement in an effort to prevent innovators from adding formulation patents to

¹ *Apotex v. Minister of Health* (1999), 87 C.P.R. (3d) 271 (F.C.T.D.), affirmed 11 C.P.R. (4th) 538 (F.C.A.)

² SOR/98-166

the register which are not product-specific. The Minister also sought more general guidance on these questions through the filing of a reference with the Federal Court, but the matter was dismissed on procedural grounds following vigorous resistance from parties opposed to its terms³.

Against the above background, in January 2003, the Federal Court of Appeal rendered a precedent-setting decision based on the amended PM(NOC) Regulations which reaffirmed the right of innovator companies to list formulation patents that do not claim the formulation approved for sale⁴. The court came to this view on the basis of what it felt to be the plain wording of the relevance provision and notwithstanding the explanatory language on product specificity in the 1998 RIAS. In so doing, the court appears to have reinvigorated the single purpose approach to interpreting patent listing requirements, as epitomized by the 1999 decision on SNDS filings discussed above. It has also accentuated a split in the jurisprudence as to the policy underlying the PM(NOC) Regulations.

The Government is concerned that the combined effect of the above described jurisprudence is a weakening of the listing requirements, potentially to the point of redundancy. Such was the reasoning of the Federal Court of Appeal in a more recent case involving a patent list submitted on the basis of a SNDS for a change in drug name⁵. In refusing to allow a patent to be listed in this manner, the court recognized that the change in name in that case was part of a strategy designed to overcome the time limitation for filing a patent list under section 4, which, if sanctioned, would render the time requirements embodied in that section meaningless. The Court of Appeal subsequently expanded on this line of reasoning to refuse a new patent listed on the basis of a SNDS for a change in manufacturing site⁶. The court recognized that both such changes (i.e. in name or manufacturing site) could not possibly be relevant to any potential claim for infringement of a patent for a medicine and were therefore outside the scope of section 4.

Although a change in drug or company name or a change in manufacturing site now appear to have been ruled out as an opportunity to add new patents to the register, the ambit of remaining changes in respect of which a SNDS can be filed is considerable, and the possible combinations of submission type and patent claims all the more so. Requiring the courts to rule on each of these piecemeal without adequate direction in the language of the PM(NOC) Regulations can only result in confusion, uncertainty and further unintended consequences.

To date, these unintended consequences include the possibility that an innovator company may delay generic market entry by listing new and sometimes irrelevant patents on the basis of minor

³ *Patented Medicines (Notice of Compliance) Regulations (Ont.) (Re)*, 2002 FCT 1000

⁴ *Eli Lilly Canada Inc. v. Canada (Minister of Health)*, 2003 FCA 24

⁵ *Ferring Inc. v. Canada (Attorney General)*, 2003 FCA 274

⁶ *Hoffmann-La Roche Ltd. v. Canada (Minister of Health)*, 2005 FCA 140

product revisions. The result is a blurring of the lines between the original product, as approved via the NDS, and the "changed" version, as approved via the SNDS, such that generic manufacturers may be prevented from entering the market with a competing version of the original innovator product even when the original patents have long since expired or been addressed.

In fact, the Government has observed instances of SNDS filings being used to list multiple new patents over time in a manner that results in repeat 24-month stays against the same generic competitor. While the possibility of repeat stays due to later listed patents is expressly contemplated under the PM(NOC) Regulations, their recurrence near and after expiry of the original product patents can only operate to delay generic competition in a manner that is inconsistent with the balanced policy objectives early-working and the PM(NOC) Regulations were intended to serve.

Although as matters stand, these instances are exceptional, they do involve drugs of significant commercial value. They also have the potential to serve as a model other innovator companies may be tempted to emulate. In this regard, the Minister has reported a significant increase in new patents being listed on the basis of SNDS filings recently⁷. In many of these cases, the SNDS does not materially change the original drug or is not directly relevant to the patent being submitted for listing.

Purpose of Amendments

The primary purpose of these amendments is to pre-empt further such behaviour by restoring the original policy intent of the PM(NOC) Regulations. This entails reaffirming the requirements innovators must meet to list patents on the register and clarifying when these patents must be addressed by their generic competitors. In addition, a number of ancillary amendments are being made with a view to reducing unnecessary litigation and improving the overall effectiveness of the regime. These were developed in response to specific concerns expressed by stakeholders following pre-publication of an earlier round of proposed amendments in the *Canada Gazette*, Part I, on December 11, 2004.

Changes to patent listing requirements

As mentioned, in order for a patent to qualify for protection under the PM(NOC) Regulations, it must be relevant to the drug product the innovator is approved to sell. This requirement serves certain policy objectives, outlined above, but also recognizes the practical limits of the Minister's role as administrator of the PM(NOC) Regulations.

To the extent that the efficient functioning of the regime depends upon a threshold determination of what patents can be

⁷ Therapeutic Products Directorate Statistical Report 2005, *Patented Medicines (Notice of Compliance) Regulations*: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/patnrep_mbrevrp_2005_e.pdf

listed, in making that determination the Minister can only be called upon to assess the relationship between the patent and the drug described in the innovator's submission for a NOC. A broader inquiry into the relationship between the patent and any potentially equivalent generic drug is not relevant to the listing question.

The amendments reflect this by further entrenching the concept of product specificity as the key consideration required of the Minister in applying the listing requirements under section 4 of the PM(NOC) Regulations. They do so through more precise language respecting the intended link between the subject matter of a patent on a patent list and the content of the underlying submission for a NOC in relation to which it is submitted. In addition, under the amendments, only certain clearly defined submission types will provide an opportunity to submit a new patent list.

In terms of what may be listed in relation to the NDS, the amendments stipulate that only patents filed prior to the NDS and which claim certain subject matter described therein may be added to the register in relation to the original form of the drug. This will facilitate the market entry of generic versions of the original innovator product as soon as possible after expiry of the original patents. To meet these criteria, a patent with a filing date anterior to that of the NDS must contain at least one of the following four claims: (1) a claim for the approved medicinal ingredient, (2) a claim for the approved formulation containing that medicinal ingredient, (3) a claim for the approved dosage form, or (4) a claim for an approved use of the medicinal ingredient.

It will be noted that amended section 4 no longer contains an explicit requirement that a patent contain a "claim for the medicine itself". However, in keeping with well settled law on the scope of protection afforded by that phrase, the PM(NOC) Regulations will continue to allow the listing of patents containing either a claim for the approved formulation or a claim for the approved medicinal ingredient.

For the purposes of amended section 4, the terms "formulation" and "medicinal ingredient" are intended to bear their established meaning under the extensive body of case law interpreting a "claim for the medicine itself". The term "formulation" thus refers to the physical mixture of medicinal and non-medicinal ingredients administered to the patient by means of the approved drug. The term "medicinal ingredient", in turn, refers to the substance in the formulation which, once administered, is responsible for the drug's desired effect in the body.

In light of the greater specificity being brought to these concepts, these amendments repeal the existing definitions in section 2 of the PM(NOC) Regulations relating to the "medicine", and replace these with definitions for "claim for the medicinal ingredient", "claim for the use of the medicinal ingredient" and "claim for the formulation".

A definition for the first of these phrases is necessary to ensure that product-by-process patents continue to qualify for protection under the regulations, and to confirm that the same is true of patents for biologic drugs. It also serves to clarify, in so far as small molecule drugs are concerned, that patents claiming different crystalline, amorphous, hydrated and solvated forms of the approved medicinal ingredient (i.e. "polymorphs") are eligible for listing when submitted in relation to the NDS, but that different

chemical forms, such as salts and esters, are not. This accords with Health Canada policy on what constitutes an "identical medicinal ingredient" for the purposes of establishing pharmaceutical equivalence under section C08.001.1 of the *Food and Drug Regulations*. None of these changes is intended to disturb prior jurisprudence to the effect that patents claiming intermediates or metabolites of the medicinal ingredient are ineligible for listing.

Although the definition for "claim for the use of the medicinal ingredient" in these amendments is unchanged from the current definition for "claim for the use of the medicine", a point of clarification regarding the intention underlying this aspect of the PM(NOC) Regulations is in order. It is acknowledged that the regulatory language employed in the health and safety context to describe the use for which a medicinal ingredient in a drug is sometimes at odds with the manner in which claims are drafted in the many different kinds of so-called "use patents" which exist in the pharmaceutical realm. Examples of the latter include kit claims, "Swiss-type" claims and claims for dosing regimens. However, the combined effect of the definition under this part and the requirement that the claimed use be one described in the underlying NDS should be to limit the eligibility of use patents to those which contain a claim to an approved method of using the medicinal ingredient, for an approved indication. This link should be apparent from a comparison of the claims in the patent with the relevant portions of the product monograph and labelling for the approved drug.

Whereas the above described amendments to section 4 are intended to clarify existing policy by reinforcing the link between the subject matter of a patent and the content of the NDS, other changes mark an expansion in that policy. In particular, the scope of eligible subject matter is being broadened to include patents for approved dosage forms.

When seized of the question, courts have consistently held that the current language "claim for the medicine itself" in section 4 is insufficient to support the listing of dosage form patents. However, in light of representations from the innovative industry regarding the significant therapeutic advantages afforded by novel dosage forms, the Government has come to the view that inventions in this area merit the special protection of the PM(NOC) Regulations. This is particularly true where biologic drugs are concerned, as effective administration of the medicinal ingredient is often dependent on the development of new and innovative delivery mechanisms. Amended section 4 thus contains new language necessary to implement this change, and a new definition for the phrase "claim for the dosage form" has been added to section 2 in order to clarify the scope of protection this change is intended to effect.

Although amended section 2 defines the phrase "claim for the dosage form" in very general terms, in order to accommodate future advancements in this field, the intent is to provide protection for the novel delivery system by which the approved medicinal

ingredient, or a formulation containing that ingredient, is administered to the patient. Examples include controlled-release tablets and capsules, implants and transdermal patches. As with other eligible subject matter, a dosage form patent must include a claim to the specific dosage form described in the NDS (typically as identified in the notification issued by the Minister pursuant to paragraph C08.004(1)(a)). In addition, it must contain a claim that includes within its scope the approved medicinal ingredient. This latter requirement is meant to ensure that a patent directed solely to a device, such as an intravenous stand or a syringe, does not meet the definition of "dosage form" and remains ineligible for listing.

The amendments to section 4 also formally confirm the right to list new patents on the basis of SNDS filings and introduce listing requirements governing that right. Under these requirements, a patent which had been applied for prior to the filing of an SNDS may be submitted in relation to that SNDS provided the purpose of the latter is to obtain approval for a change in use of the medicinal ingredient (i.e. a new method of use or new indication), a change in formulation or a change in dosage form and the patent contains a claim to the formulation, dosage form or use so changed. This will protect and encourage legitimate and substantive incremental innovation of direct therapeutic application. New patents claiming novel physical forms of the approved medicinal ingredient will not be eligible for listing in this manner.

In keeping with existing practice, the amendments to section 4 include a provision expressly allowing innovators to carry forward patent lists submitted in relation to a NDS by resubmitting them in relation to a supplement to that NDS. A finding of ineligibility in respect of one patent on a patent list should not prevent the carrying forward of the remaining patents on that list.

The amendments also eliminate the unnecessary and somewhat ambiguous distinction in current section 4 between an "existing" patent list and an "amendment" to such a list. Under the amendments, each time an innovator submits new patents to the Minister these shall be considered as comprising a unique and stand alone patent list. This will be the case regardless of which of subsections 4(5) or 4(6) is relied upon in submitting the list and notwithstanding the presence of any preexisting patents on the register for the same form of the drug described in the submission to which the list relates.

Lastly, in order to minimize any market disruption and investment uncertainty resulting from the above described changes to section 4, the amendments include a grandfathering provision which provides that patents submitted for listing prior to June 17, 2006, the date of pre-publication in the *Canada Gazette*, Part I, remain subject to the listing requirements as they were interpreted and applied prior to that date.

Changes to the requirements governing when listed patents must be addressed

Under the amendments to section 5, a generic manufacturer that files a submission or supplement for a NOC in respect of a generic version of an innovative drug is only required to address the patents on the register in respect of the innovative drug as of that filing date. Patents added to the register thereafter will not give rise to any such requirement. The register will thus be "frozen" in respect of that generic manufacturer's regulatory submission. Subsequent submissions originating from additional generic manufacturers would each benefit from the same freezing mechanism, as of their respective dates of filing with the Minister. As a corollary to this frozen register concept, generic manufacturers will no longer be permitted to initiate the process for challenging a patent under the PM(NOC) Regulations (i.e. through the service of a notice of allegation – "NOA") until that same filing has occurred. The combined effect of these two new rules will significantly curtail the incidence of repeat cases, whether due to multiple NOAs on the part of generic manufacturers or multiple patent listings on the part of innovators.

Although freezing the register and eliminating early NOAs is thought to be the most expedient solution to the problem of multiple stays under the PM(NOC) Regulations, considerable confusion could result from the immediate application of these changes to preexisting facts. The transitional rules accompanying the amendments thus provide that, for those generic manufacturers that have already filed a submission or supplement for a NOC in respect of a generic version of an innovative drug with patents on the register, the filing date for the purposes of amended section 5 is deemed to be the date the amendments come into force.

While not a transitional matter, a similar deeming function will apply to generic drug submissions filed under C.07.003. of the *Food and Drug Regulations*, which escape the 6-year prohibition on filing under concurrent amendments to the data protection provisions in the *Food and Drug Regulations*. Where such a submission is for a generic version of an innovative drug and that innovative drug would otherwise benefit from the new data protection term, the filing date of the submission for the purposes of section 5, if it is less than six years from the day on which the first NOC was issued in respect of the innovative drug, will be deemed to be six years from that day.

The amendments also repeal subsection 5(1.1). That provision was introduced in 1999, when it became apparent that a generic company could avoid compliance with the PM(NOC) Regulations by making an indirect comparison to an innovator's drug with patents on the register. However, a subsequent ruling from the Federal Court of Appeal established that the pre-existing triggering provision, subsection 5(1), was sufficiently broad to capture avoidance strategies founded on indirect reliance⁸. Repeal of subsection 5(1.1) is also consistent with the Supreme Court of Canada's recent decision in the "Biolyse case"⁹, which confirmed that the PM(NOC) Regulations do not apply to second and subsequent entry drug submissions where the sponsor of the submission

⁸ *Merck & Co. v. Nu-Pharm Inc.* (2000), 5 C.P.R. (4th) 138

⁹ *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26

is required by the Minister to conduct independent clinical studies to establish the safety and efficacy of its product.

Notwithstanding the repeal of subsection 5(1.1), amended section 5 will continue to feature two triggering provisions, in order to better mirror the structure of section 4. Subsection 5(1) will apply to a generic manufacturer that files an initial submission for a NOC for a generic version of an innovative drug. Subsection 5(2) will apply whenever the manufacturer files a supplement to that submission for a change in formulation, change in dosage form or a change in use of the medicinal ingredient. Distinguishing between the two types of submissions in this manner should also serve to accelerate the drug review process as the Minister will no longer be required to verify each and every supplement for compliance with the PM(NOC) Regulations.

It should be noted that while amended subsection 5(1) is geared towards abbreviated new drug submissions (ANDS), the provision speaks only of a "submission for a notice of compliance". The lack of precision on this point is purposeful in order that the PM(NOC) Regulations may catch "hybrid" or "paper" NDS type submissions when approved on the basis of a direct or indirect comparison or reference to an innovative drug in substantially the same fashion as an ANDS. Similarly, despite the Supreme Court's ruling in the Biolyse case, there is no mention of "bioequivalence" in either of the new triggering provisions, as the PM(NOC) Regulations are intended to apply equally to biologic drugs which, unlike small molecule pharmaceuticals, sometimes do not work through the bloodstream.

Amendments have also been made to section 5 to clarify the Government's intention with regard to the scope of protection afforded by the PM(NOC) Regulations to "use patents". The revised language in subparagraphs 5(1)(b)(iv) and (2)(b)(iv) makes it clear that in determining whether an allegation of non-infringement of a use patent is justified, the court should limit its inquiry to whether acts of infringement will occur by or at the behest of the generic manufacturer. This will resolve conflicting jurisprudence on this question¹⁰ and facilitate the market entry of generic drugs where the facts as assumed or proven indicate that the manufacturer does not intend to market its product for the patented use.

Finally, in striving to keep litigation to a minimum, amended section 5 also imposes an obligation on the generic manufacturer to retract an NOA in the event that the submission or supplement to which it relates is either withdrawn by the Minister for non-compliance with the *Food and Drug Regulations* or cancelled by the manufacturer. However, that obligation is subject to a grace period of 90 days, in order to afford the sponsor of a submission found to be non-compliant a reasonable opportunity to have that finding overturned. Where a retracted NOA has already given rise to prohibition proceedings, the innovator, upon being informed of the retraction, is required to apply for a discontinuance of those proceedings in a timely fashion.

¹⁰ *Pharmascience Inc. v. Sanofi-Aventis Canada Inc.*, 2006 FCA 229. *Procter & Gamble Pharmaceuticals Canada, Inc. v. Canada (Minister of Health)*, 2002 FCA 290. *AB Hassle v. Canada (Minister of National Health and Welfare)*, 2002 FCA 421

Sections 4 and 5 aside, the amendments also include a provision targeted at innovators who would seek to forestall generic competition by withdrawing the original form of the product from the market in order to deprive generic manufacturers of an immediate Canadian Reference Product. The provision in question would require the Minister to delete any patents on the register in respect of a drug which no longer has an active Drug Identification Number (DIN), thus resulting in the loss of protection under the PM(NOC) Regulations for that drug. However, this provision will not apply where the withdrawal of the DIN is due to a change in the manufacturer of the drug. As the reason for DIN withdrawal is not always immediately apparent, the Minister's duty to delete the patents is subject to a 90-day grace period. Reassignment of the DIN and resumption in the marketing of the drug by the manufacturer will result in the Minister re-listing earlier-deleted patents.

Last among the substantive changes proposed by these amendments are refinements to the section 8 damages provision. The first such change is to further specify the matters the court may take into account when calculating the period of delay for which an innovator may be held liable under that section. The second is to confirm that the Minister cannot be held liable for any delay under that section. The third is to remove the word "profits" from the provision prescribing the remedies available to a generic manufacturer seeking compensation for any loss arising from that delay.

On this last point, the Government is aware of a number of ongoing section 8 cases in which it is argued that in order for this provision to operate as a disincentive to improper use of the PM(NOC) Regulations by innovative companies, the term "profits" in this context must be understood to mean an accounting of the innovator's profits. While reserving comment on the proper interpretation of the term in these cases, which have been shielded from this change by transitional provisions, in light of the proposed tightening of the listing requirements under amended section 4, and of the introduction of the frozen register mechanism under amended section 5, the Government believes that this line of argument should no longer be open to generic companies that invoke section 8.

Finally, these amendments include a number of consequential changes in wording or numbering to reflect the substantive modifications discussed above.

Alternatives

As previously noted, the Government proposed an alternative set of amendments to those described above, which was pre-published in the *Canada Gazette*, Part I, on December 11, 2004. As will be explained below, the present proposals were conceived in response to the extensive representations received from interested parties following that earlier pre-publication.

Maintaining the status quo was not considered a viable option given the current imbalance in the PM(NOC) Regulations, as explained above.

As mentioned, these amendments are being promulgated jointly with amendments to the data protection provisions in the *Food and Drug Regulations* and, together, are designed to bring a greater degree of stability and predictability to the pharmaceutical marketplace by establishing a firmer upper and lower boundary to the period during which innovative drugs enjoy market exclusivity.

The amendments to data protection will set the lower boundary by prohibiting generic companies from seeking an NOC until 6 years after the issuance of the NOC for the innovative drug and will prohibit actual issuance of the NOC until 8 years after that same date. Eligible innovative drugs (i.e. which contain a new chemical entity - "NCE") will thus receive an internationally competitive, guaranteed minimum period of market exclusivity. This is expected to have a minimal impact on the timing of generic market since in the majority of cases data protection runs concurrently and is eclipsed by the much longer term of protection available under a patent (i.e. 20 years). The amendments to the PM(NOC) Regulations will set the upper boundary by facilitating the market entry of generic versions of innovative drugs immediately following expiry of the relevant patents, as was originally intended.

In the course of conceiving the amendments, the Government conducted a retrospective assessment of the regulatory proposals for the period 1998 to 2002, and found that, with a data protection term of 8 years, the impact of the amendments on health care costs would have been very close to cost neutral. While it is not possible to definitively forecast future costs versus savings under the amended regimes, present trends suggest that the amendments could result in a significant net savings to the health care system in the years to come. This is due to the declining trend in drugs containing NCEs entering the market in the last few years and the corresponding increase in emphasis by some innovative companies on extending exclusivity over known best sellers through strategic patenting behaviour.

Consultation

Pre-publication of the earlier proposed amendments was followed by a 75-day period during which interested persons could submit written representations to the sponsoring departments. Industry Canada received representations on its proposed amendments from approximately 20 separate sources, including innovative and generic pharmaceutical companies, their respective trade associations, BIOTEC Canada, provincial governments, members of Parliament and consumer groups. Health Canada received a like number of submissions on its proposed amendments to data protection, from substantially the same sources. In addition, representatives from various quarters of both the innovative and generic pharmaceutical industries met with officials from the two departments on several occasions during the pre-publication period to elaborate orally on their written submissions.

While the views of individual stakeholders reflected their own unique perspective on the proposed amendments, some common ground did emerge during the pre-publication period. Most significant in this regard was a shared inclination that the Government should consider an alternative model of amendments which would see the Canadian system aligned more closely with that of the United States (US). Although there appeared to be agreement in principle on this point, stakeholders held varying views as to the particular features of the US system thought to be worthy of import. This can be attributed to an underlying divergence in opinion between the innovative and generic pharmaceutical industries as to the nature and scope of the multiple stay phenomenon the amendments should seek to redress.

From the generic industry's standpoint, multiple stays are a concern only in so far as they arise from multiple patents being listed sequentially over time by innovators, a practice they consider *ipso facto* "abusive". Because the amendments would continue to require a generic manufacturer to address patents listed after the date of its drug submission, the industry contends that abusive multiple stays will continue unabated. In advocating convergence with the US system, the generic industry is primarily seeking the adoption of the frozen register concept recently introduced in that country in response to similarly observed patent listing behaviour on the part of innovative drug companies there¹¹.

While sources on the innovative side of the industry recognize that the stated purpose of the amendments is to curb the occurrence of multiple stays, they observe that many such stays are due to the ability of generic manufacturers to serve multiple NOAs in respect of the same patents, and not to the listing behaviour of innovators. In their view, the former is the converse of the latter, and no less abusive in nature. Accordingly, the innovative industry asserts that any consideration of a frozen register option must also have regard for measures which would restrict the circumstances in which NOAs can be served upon them by generic manufacturers. To this end, they call for the introduction of a US-style "no-filing" term of data protection which would prohibit a generic manufacturer from seeking regulatory approval for an equivalent version of an innovative drug until a certain number of years after the latter's approval, during which time no NOAs could be advanced by the generic.

Despite stakeholders' competing emphasis on different aspects of US law, there appeared to be some degree of rapprochement between the two sides of the industry on the merits of moving toward a more US-style regime. In light of this and of the intense resistance manifested by stakeholders toward the amendments proposed on December 11, 2004, Industry Canada and Health Canada developed the framework for a US-style alternate set of amendments to the PM(NOC) Regulations and to the *Food and Drug Regulations*.

¹¹ *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, Sec. 1101

A document describing the above framework was circulated to industry stakeholders for another round of informal consultations between July and September 2005. Further written representations were received and further meetings were held between officials from both departments and representatives from the innovative, generic and biotech sectors of the pharmaceutical industry.

Based on the outcome of these informal consultations, the Government is proceeding with the present set of amendments to implement the no-filing data protection term sought by innovative companies, coupled with the frozen register mechanism sought by their generic counterparts. Other, lesser measures are also proposed, mainly with view to increased convergence with US law. As before, these amendments are expected to bring a greater degree of stability and predictability to the intellectual property environment for pharmaceuticals.

Pre-publication of the present amendments in the *Canada Gazette*, Part I, took place on June 17, 2006, and was followed by a 30-day consultation period during which Industry Canada and Health Canada received approximately thirty submissions, predominantly from the same industry stakeholders mentioned above, but also from a number of Provincial government authorities responsible for either health care or economic development portfolios. Whereas economic development authorities expressed strong support for the amendments, and urged the Government to proceed swiftly to final publication, health authorities requested an extension in the consultation period in order to allow for federal-provincial dialogue and to gain a better understanding of the impact of the amendments. In response to that request, on September 18, 2006, Health Canada and Industry Canada officials hosted an information session on the amendments attended by representatives of the Provincial and Territorial ministries of health.

In terms of stakeholder reaction to the June 17 pre-publication, the generic pharmaceutical industry endorsed the proposed "freezing" of the patent register but maintained its view that the amendments as a whole are weighted in favour of the innovative industry. The generic industry's key concerns were with the proposed increase in the data protection from 5 to 8 years, the proposed deletion of the term "profits" from the remedies provision in section 8 and the proposal to expand the eligibility requirements to allow for the listing of dosage form patents.

Reaction from the innovative industry was more equivocal, with the majority of companies supportive of the proposed increase in data protection but a minority strongly opposed to the proposed tightening of the patent eligibility requirements. As regards the "profits" issue, innovators were pleased with its proposed deletion, noting that there is no equivalent remedy under US law for a generic that has been delayed due to the operation of the automatic stay. For its part, BIOTEC Canada urged the Government to increase the proposed term of data protection to 10 years for biologics, in light of the longer development time required to bring these products to market.

In addition to the above, each side of the industry expressed concern with competing aspects of the transitional provisions and both expressed a desire for greater clarity around the meaning of certain key terms such as "medicinal ingredient", "formulation" and "dosage form", although with diametrically opposed views as to how those terms should be defined. A number of technical adjustments to the amendments were made as a result of these submissions but no substantive revisions. Stakeholders also sought clarification on a number of lesser issues which have been addressed through changes in wording to the present impact analysis statement in order to better reflect the intent behind the amendments.

As a final note, certain generic drug companies also argued very forcefully that the Government should incorporate measures in these amendments to address what they perceive as diminishing market incentives in their industry. More specifically, they contend that innovators are increasingly entering into licencing arrangements with willing generic companies (so-called "authorized generics") in order to pre-empt genuine generic competitors and retain market share past patent expiry. This practice, which is also said to be prevalent in the US, is currently being studied by the US Federal Trade Commission. While the Government is of the view that there is insufficient information on the impact of this practice on market dynamics in the industry to support regulatory action at this time, it will be examining this practice more closely in response to these concerns.

Compliance and Enforcement

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

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