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Amendments to Linkage Regulations and Data Protection Approved

Sweeping amendments to the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") and to the data protection provision of the *Food and Drugs Regulations* came into force on October 5, 2006 and will be formally published on October 18, 2006 [see links to amendments, now published, below]. These amendments are substantially the same as those proposed on June 17, 2006 (see June 2006 Special Edition of *Rx IP Update*), the key elements of which are (i) a "frozen" Patent Register under the amended *Regulations*, combined with more restrictive patent listing requirements and (ii) a six-year no-filing period for generic submissions and an eight-year period of market exclusivity for "innovative drugs" under the new data protection provision.

I. Amendments to the Regulations

Regulations Amending the Patented Medicines (Notice of Compliance) Regulations (HTML) (Bilingual PDF/official)

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. The generic manufacturer, however, is only required to address patents listed on the Register.

The most significant amendments fall into two categories: (1) patent listing requirements and (2) when a generic must address listed patents.

1. Eligibility requirements for patent listing (section 4)

a. Relevance requirement

Amended section 4 requires that, in order to be listed on the Register, the patent must be relevant to the submission in relation to which it is submitted. Also, only those supplemental new drug submissions (SNDSs) for a change in formulation, dosage form, or use will support the listing of a patent. As a result, the requirements for listing are now — apart from now extending to dosage form patents — far stricter that under the previous *Regulations*. A patent is eligible for listing:

(i) in relation to a new drug submission (NDS): if the patent contains a claim for the medicinal ingredient, the formulation that contains the medicinal ingredient, the dosage form, or the use of the medicinal ingredient, and the medicinal ingredient, formulation, dosage form, or use has been approved through the issuance of a notice of compliance (NOC) in respect of the submission;

(ii) in relation to an SNDS: if the SNDS is for a change in formulation, dosage form or use of the medicinal ingredient, the patent contains a claim for the changed formulation, dosage form, or use and a NOC has issued in respect of that SNDS; and

(iii) if the timing requirements are met: the patent list must be submitted with the specific submission to which the patent list relates or within 30 days after the issuance of the patent if its Canadian filing date precedes the filing date of that submission.

These new provisions will appear to apply to patents on a patent list submitted on and after June 17, 2006 (the publication date of the proposed amendments).

b. Dosage form patents eligible for listing

The amended Regulations now permit the listing of dosage form patents. A "claim for the dosage form" is defined as "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 or formulation".

The RIAS states, "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".

2. No requirement to address later-listed patents (section 5)

The "frozen" Register referred to above is achieved by the repeal of present section 5(2), which requires a generic manufacturer to address all patents added to the Register before the second person's NOC is issued. This is coupled with an explicit provision that limits the patents that must be addressed by a generic manufacturer to those listed prior to the filing date of its submission (NDS or a supplement for a change to the formulation, dosage form or use of the medicinal ingredient).

In addition to generic manufacturers that file their submissions after October 5, 2006, the coming into force date, these new provisions will also apply to generic manufacturers who have filed a submission prior to October 5, 2006, but for those second persons/submissions, the "freezing" date is October 5, 2006.

3. Damages provision amendment (section 8)

Section 8 provides for liability by the innovator where a prohibition application is withdrawn or discontinued, is dismissed, or a prohibition Order is reversed on appeal. Former section 8(4) provided, "The court may make such order for relief by way of damages or profits as the circumstances require in respect of any loss referred to in subsection (1)". The reference to "profits" grounded the basis of claims by generic manufacturers to innovators' profits. Amended section 8(4) no longer includes reference to profits, but is applicable only to actions commenced on or after October 5, 2006.

4. Allegation of non-infringement regarding "use" patents (sections 5(1)(b)(iv) and 5(2)(b)(iv))

While the wording of the former provision regarding allegations of non-infringement has not been substantially amended, the RIAS states as follows:

> 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 question… 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.

5. Other amendments

Other amendments include:

(i) repeal of present subsection 5(1.1) (as proposed in 2004);

(ii) no notice of allegation (NOA) may be served until the generic manufacturer files its submission (previously, a submission was required to be filed only where the generic alleged non-infringement) (section 5(3)(c));

(iii) the Minister must delete patents from the Register 90 days after the date of cancellation of a drug's drug identification number (DIN) (unless such cancellation arises because of a change in manufacturer) but must re-list the patents when the DIN is re-activated (sections 3(3)-(5));

(iv) the summary dismissal provision has been amended to permit dismissal "in whole or in part" (section 6(5)).

The RIAS also notes that, in response to concerns expressed by generic companies, the Government will be examining the "practice" of innovators "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".

II. Amendments to Data Protection

Regulations Amending the Food and Drug Regulations (Data Protection) (HTML) (Bilingual PDF/official)

Data protection is based on international obligations (Article 1711 of the North American Free Trade Agreement (NAFTA) and paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)). These obligations require that where a company submits confidential data to a regulatory authority when seeking approval for a drug composed of a new active substance, the data is protected from reliance by competitors for a certain period of time after the date the drug is approved. While there was a data protection provision in the former *Food and Drug Regulations* (section C.08.004.01), the Federal Court of Appeal (*Bayer v. Attorney General of Canada*) interpreted the previous provision narrowly such that it was rarely, if ever, triggered.

1. Term of protection

The amendments prohibit the issuance of a NOC to a manufacturer that makes a direct or indirect comparison to an "innovative drug" until eight years after issuance of the innovator's first NOC for the innovative drug and an additional six months if the innovative drug has been the subject of clinical trials designed and conducted for the purpose of increasing the knowledge of the behaviour of the drug in pediatric populations.

Furthermore, a manufacturer that make a direct or indirect comparison to the innovative drug will not be permitted to file such a submission until six years after issuance of the innovator's first NOC for the innovative drug.

Neither of these restrictions apply where the innovator consents to an earlier NOC issuance or regulatory filing.

2. Triggers for data protection

a. "Innovative drug"

Data protection applies where a comparison is made to an "innovative drug", which is defined as "a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph".

The RIAS states as follows with respect to variations not referenced in the definition:

> For other arguable variations not included in the list, such as metabolites, an assessment will be made as to whether or not approval is being sought primarily on the basis of previously submitted clinical data (i.e. without the support of new and significant clinical data) or not.

The RIAS further states that while combinations of previously approved medicinal ingredients are not eligible for an additional data protection term, "[w]here two or more innovative drugs are sold in combination, a generic manufacturer will not be allowed to file or receive a notice of compliance, as the case may be, until expiry of the latest data protection term".

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b. "Direct or indirect comparison"

A generic company falls within the data protection provision where it "seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug".

3. Transition

The new data protection provision applies to drugs that have received or will receive a NOC on or after June 17, 2006. The proposed amendment would have applied data protection only to drugs that received a NOC after the coming into force date.

4. Marketing requirement

Data protection will not apply if the innovative drug is not being marketed in Canada.

5. Register of innovative drugs

The amendments require the Minister to maintain a register of innovative drugs which will include the name of the drug, the medicinal ingredient, and the date on which the data protection and, where applicable, pediatric extension, will terminate.

As noted, these amendments are sweeping and it remains to be seen how the new provisions will be interpreted. We will report on new developments in future issues of *Rx IP Update*.

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