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CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Proposed Amendments to Linkage Regulations and Data Protection Published

On June 17, 2006, proposed amendments to the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") and to the data protection provision of the *Food and Drugs Regulations* were published. The new proposals replace earlier proposed amendments, which were published on December 11, 2004 but were not adopted (see the December 2004 special edition of *Rx IP Update*).

Former Proposed Amendments to the Regulations

Former Proposed Amendments to Data Protection

The Regulatory Impact Analysis Statement accompanying the proposed amendments to the *Regulations* states that the proposed amendments would implement "the no-filing data protection term sought by the innovative industry, coupled with the frozen register mechanism sought by their generic counterparts".

I. Proposed Amendments to the Regulations

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 innovative product. The generic, 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)

The proposed amendments are similar to the 2004 proposal and would require that the patent 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 would be far stricter that under the present *Regulations*. A patent would be eligible for listing:

(i) **in relation to a new drug submission (NDS):** if the patent contains a claim for the medicinal ingredient, a formulation, dosage form that contains the medicinal ingredient, 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 the 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 filing date precedes the filing date of that submission.

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

2. No Requirement to Address Later-listed Patents (Section 5)

The "frozen" Register referred to above would be 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 would limit 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).

These new provisions would apply to a generic manufacturer who has filed a submission prior to the coming into force date of the amendments, but for those second persons/submissions, the "freezing" date would be the coming into force date. However, if a generic manufacturer escapes the six-year prohibition on filing under the proposed new data protection provision (see below), the "freezing" date would be six years from the date of the innovator's first NOC.

3. Other Amendments

Other proposed amendments include:

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

(ii) no notice of allegation (NOA) may be served until the generic manufacturer files its submission;

(iii) the reference to "profits" in section 8 would be deleted, applicable only to section 8 actions commenced on and after the coming into force date; and

(iv) the Minister must delete patents from the Register when the drug's drug identification number (DIN) has been cancelled (unless such cancellation arises because of a change in manufacturer) but must re-list the patents when the DIN is re-activated.

II. Proposed Amendments to Data Protection

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 competition for a certain period of time after the date the drug is approved. While there is a data protection provision in the present *Food and Drug Regulations* (section C.08.004.01), the Federal Court of Appeal (*Bayer Inc. v. Canada (Attorney General)* (1999), 87 C.P.R. (3d) 293 (F.C.A.)) has interpreted the provision narrowly such that it rarely, if ever, is triggered.

The proposed amendments, consistent with the 2004 proposal, would provide a guaranteed minimum period of market exclusivity of **eight years** and an **additional six months** of data protection to drugs that have been the subject of clinical trials in children. Furthermore, there would be a **six-year no-filing period** for generic submissions.

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Data protection would apply if a generic manufacturer seeks a NOC for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug. "**Innovative drug**" 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 transitional provision would apply the new data protection provision to drugs for which a NOC is issued on and after the coming into force date of the amendments.

There will be a 30-day consultation period for both sets of proposed amendments, which will expire on **July 17, 2006.**

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