OSLER

Canada's patent linkage regulations get long-awaited makeover

JULY 18, 2017 6 MIN READ

Related Expertise

- Intellectual Property
- Pharmaceuticals and Life Sciences

Authors: J. Bradley White, Nathaniel Lipkus, Vincent M. de Grandpré

On July 15, 2017, the Government of Canada proposed major amendments to the *Patented Medicines (Notice of Compliance) Regulations* (*Regulations*), the patent linkage scheme that forms the cornerstone of pharmaceutical and biologics patent litigation in Canada. The proposed amendments include the following key changes:

- proceedings under the *Regulations* will now be by way of action, not application
- actions under the *Regulations* will now finally determine whether asserted patent claims are invalid or non-infringed by a pending drug submission
- in certain circumstances, first persons will be allowed to assert patents and patent claims not listed on the Patent Register
- first persons will now be able to renounce the 24-month regulatory stay, allowing earlier competitive market entry in order to avoid liability for section 8 damages
- section 8 damages, if any, can now include compensation to a second person for permanent loss of market share

These proposed amendments are subject to a short 15-day consultation period and are expected to be adopted in September 2017.

Background and summary of proposed changes

Since 1993, the *Regulations*, Canada's equivalent to the U.S. Hatch-Waxman Act, have sought to balance the rights of patentees with the rights of generic companies to seek abbreviated drug approval from the Minister of Health. Over the years, however, the *Regulations* showed their limitations, most notably because they required patentees to proceed by way of applications for an order to prohibit the Minister of Health from approving a generic drug. This scheme had undesirable consequences for litigants – for example, patentees often could not appeal the dismissal of applications for orders of prohibition against the Minister of Health or, because cases under the *Regulations* did not finally determine the issues between the parties, patents were often re-litigated in follow-on infringement or impeachment actions. This resulted in a lack of certainty for the parties and "at risk" launches for generic companies. The proposed amendments seek to address these, and other, perceived shortcomings.

Although the proposed amendments are extensive, the basic structure of the *Regulations* will remain the same. The scope of eligible patents for listing will remain the same. The Patent Register will remain frozen, so that generic or biosimilar applicants (so-called "second persons") need only address patents that were listed on the Patent Register at the time of filing their drug submissions. The stay of generic or biosimilar approval will remain 24 months, and section 8 damages will remain available for generic or biosimilar companies

kept off the market due to the 24-month stay. However, it is also proposed that the *Regulations* change in material ways:

1. Changes to the Patent Register: The Minister of Health will be given broad powers to actively maintain the Patent Register, which will include not only patents, but also "certificates of supplementary protection" (CSPs), which were introduced into Canadian law in the *CETA Implementation Act*, adopted after the signature of the Canada-European Union Comprehensive Economic and Trade Agreement.

2. New notice of allegation (NOA) requirements: Although proceedings will be by way of action, generic and biosimilar manufacturers (second persons) will still be required to serve an NOA. The NOA will need to be detailed only in respect of invalidity allegations. The *Regulations* will now give the parties some latitude to provide limited information about non-infringement before a proceeding is commenced. The practical effect of the changes, and what will be considered adequate details in the NOA, will no doubt be the subject of cases to come.

3. Documents/information to be provided with NOAs: NOAs will need to include a searchable electronic copy of the relevant portions of the second person's drug submission and copies of all documents relied upon in support of invalidity allegations. The second person will have a continuous disclosure obligation with respect to its drug submission while litigation under the *Regulations* is pending. The second person may impose reasonable confidentiality obligations on the first person, and the first person can apply to vary these obligations.

4. Nature of the action: First persons will no longer seek a prohibition order against the Minister of Health, but rather declarations that making, using, selling or constructing a drug in accordance with the second person's drug submission will infringe the patent or CSP, along with other available remedies. Second persons will be able to bring counterclaims to impeach a patent/CSP or to obtain a declaration of non-infringement. On receipt of an NOA, first persons/patentees may assert unlisted patents or patents not subject to the NOA if infringement of these collateral patents could result from a second person's regulatory submission.

5. 24-month stay: A first person who brings an action under the *Regulations* will be able to renounce the 24-month stay, without prejudice to its rights under the *Patent Act*. This strategy will allow a first person to avoid the risk of section 8 damages and will provide greater flexibility as to the scope of the action.

6. Section 8 damages: Following an unsuccessful action for patent infringement brought under the *Regulations*, a second person will be able to sue all former plaintiffs for section 8 damages. Plaintiffs could include the first person, a patentee or any party claiming under the patent (for example, corporate affiliates of the first person). The section 8 damages period will no longer be limited by the end date of the proceeding brought under the *Regulations*.

New challenges

The proposed amendments to the *Regulations* strive to overcome perceived shortcomings in the current *Regulations*, and achieve the dual objectives of affording patentees full rights of appeal and providing finality for litigants. However, the new *Regulations* will give rise to new challenges, including the following:

- **New strategic flexibility:** New provisions, such as the ability of first persons and

patentees to assert previously irrelevant claims or to renounce the 24-month stay, will require both first and second persons to make new and potentially difficult choices to manage their commercial and legal risks.

- **Applicability of existing case law:** For several years, litigants will face uncertainty about the applicability of current case law regarding several issues that are affected by these amendments to the *Regulations*. These issues will include the sufficiency of NOAs and the standard of review of patent listings.
- **Impact on biologics:** The amended *Regulations* contain no provisions unique to biosimilars or other non-generic products. Unlike the situation in the United States, the Canadian government chose to not craft a regulatory pathway or patent linkage system designed to address the unique patent, regulatory and commercial aspects of biosimilars. It remains to be seen whether the *Regulations* framework will be well-suited to this new product class.

For assistance in navigating the new environment created by these amendments to the *Regulations*, please contact J. Bradley White (bwhite@osler.com), Vincent M. de Grandpré (vdegrandpre@osler.com) or Nathaniel Lipkus (nlipkus@osler.com).