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LIFE SCIENCES IN CANADA, 2ND EDITION

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The pages in this work were reissued in December 2021 and updated to reflect that date in the release line. Please note that we did not review the content on every page of this work in the December 2021 release. We will continue to review and update the content according to the work's publication schedule. This will ensure that subscribers are reading commentary that incorporates developments in the law as soon as possible after they have happened or as the author deems them significant.

Changes to chapter and heading numbering may have occurred. Please refer to the Correlation Table in the front matter if you wish to confirm references.

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Life Sciences Law in Canada provides a roadmap for protecting the intellectual property associated with medicines, medical devices, and natural health products in Canada, for getting them on to the market and for keeping them on the market. All the legislation and regulations applicable to companies carrying on business in Canada in the life sciences, be they major, established pharmaceutical companies or small, fledgling start-ups, is examined in detail.

This release features updates to Chapter 8 *Patented Medicines (Notice of Compliance) Regulations* and Chapter 13 *Tax Issues Facing Life Science Companies*. As well, Appendix 10O, the Trade-Marks Act Table of Concordance, and Appendix 10P, the Trademarks Regulations Table of Concordance, in Chapter 10 are updated.

Highlights

- ***Patented Medicines (Notice of Compliance) Regulations* — Policy Concerns Addressed by the NOC Regulations —** The *NOC Regulations* have been compared and contrasted with analogous legislation in the United States known as the *Hatch Waxman Act of 1984* (Pub.L. No. 98-417). Although both the U.S. and Canadian regimes are intended to promote early generic market entry, the Canadian *NOC Regulations* do not confer substantive legislative protection of individual commercial interests of the "first mover" generic entrant. Early generic entrants have argued that the "first mover advantage" ought to be protected as against later generic entrants, in the context of their seeking an earlier trial date and judgment, in order to provide an incentive for generic market entry. However, the Federal Court and the Federal Court of Appeal were not persuaded that the NOC Regulations bestow upon the first generic any rights to an earlier hearing relative to any other interested party. In addition, once action(s) are commenced in the Federal Court, parties' procedural rights will be governed by the Federal Courts Rules, which invoke additional policy considerations, including Rule 3 (interpretation of the rules "so as to secure the just, most expeditious and least expensive determination of every proceeding on its merits") as well as the equitable use of scarce judicial resources. Therefore, for example, the 24-month period provided in the *NOC Regulations* has not been interpreted to mandate a decision within 24 months, since such an interpretation would mean that "the Court would have to neglect its other litigants in favor of the pharmaceutical industry": *Apotex Inc. v. Bayer Inc.*, 2020 FCA 86, 2020 CarswellNat 8200, 2020 CarswellNat 1574.
- ***Patented Medicines (Notice of Compliance) Regulations* — Initiating Proceedings — Time Limit for Commencing Proceedings —** Upon being served with a Notice of Allegation by a second person, a first person has up to 45 days to commence an action to benefit from the *NOC Regulations*. A first person who receives an NOA but does not commence an action under subsection 6(1) of the *NOC Regulations* within 45 days will forfeit the right to bring a patent infringement action against the second person, unless the first person did not have a "reasonable basis for bringing an action under that subsection." (*Patented Medicines (Notice of Compliance) Regulations,* SOR/93-133, s. 6.01).

This 45-day period is intended to be a strict and final deadline, reflecting Parliament's intent of bringing certainty and finality to pharmaceutical patent litigation. This is in contrast to the old *NOC Regulations* which did not preclude subsequent infringement actions following an application under the *NOC Regulations*. Furthermore, the *NOC Regulations* have a particular primacy whereby they "override any other Act or regulation including the Federal Court Act and the Federal Courts Rules." There are limited circumstances that constitute reasons outside of a "reasonable basis for bringing an action". The Regulatory Impact Analysis Statement accompanying the new *NOC Regulations* state that possible situations include "where the information provided by the second person was false, materially misleading, or materially incomplete (including as a result of a subsequent change in the generic product)."

- **Selected Tax Issues Facing Life Science Companies — Scientific Research and Experimental Development — Administrative Criteria Examined by CRA On Audit —** In August 2021, the Canada Revenue Agency published its new *Guidelines on the eligibility of work for scientific research and experimental development (SR&ED) tax incentives* [the "Guidelines"], replacing the *Eligibility of Work for SR&ED Investment Tax Credits Policy* of April 24, 2015. Although the definition of SR&ED given in subsection 248(1) of the *Income Tax Act* has not changed, the new Guidelines provide simplified explanations of program requirements and clear breakdowns of what constitutes eligible work according to the CRA. In the new Guidelines, the CRA expresses the position that the three SR&ED criteria can be significantly simplified as two key requirements that must be met: the "Why" requirement and the "How" requirement. The CRA takes the position that both the scientific or technological uncertainty and the scientific or technological advancement criteria will be met when the objective of the work undertaken is the generation or discovery of knowledge that advances the understanding of science or technology. The knowledge developed must be conceptual (e.g., theories or prediction models) rather than factual (e.g., data or measurements). The Guidelines also explain how to determine if new scientific or technological knowledge is required as part of a project.

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