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## LIFE SCIENCES LAW IN CANADA, 2ND EDITION

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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 7 (Patent Enforcement), Appendix 10P (Trademarks Regulations — Table of Concordance), Appendix A (Patent Act) and Appendix M (Food and Drug Regulations, Part C Drugs).

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## Highlights

**Chapter 7. Patent Enforcement – 7.6. Defences to Infringement – (2) Invalidity –** This chapter has been updated to include discussion of recent developments in case law and legislation. In *Eli Lilly Canada Inc. v. Apotex Inc.*, 2024 CarswellNat 1176, 2024 FCA 72, 2024 A.C.W.S. 1921, the Federal Court of Appeal confirmed that a patent specification may be sufficient even if some amount of non-inventive, trial and error experimentation would be required to put the invention into practice, so long as it is not undue. In this case, the plaintiffs' patent concerned the use of tadalafil (among other compounds) and its physiologically acceptable salts in the treatment of erectile dysfunction. The plaintiffs marketed an alleged invention of the patent with their drug CIALIS. The plaintiffs claimed that the defendants infringed their patent and brought an action. The defendants' motion for summary judgment was granted. The trial judge found various claims of patent were invalid for overbreadth and insufficiency. The action was dismissed. The trial judge relied on its conclusion that a physiologically acceptable salt as contemplated therein would have to be stable and pure, not degraded, and the testimony of the plaintiff's expert that any salts made by POSITA as contemplated by the patent would not be pure and stable. The trial judge found that no salt as claimed was invented. To reach its conclusion of invalidity for insufficiency, the trial judge relied on its construction of the term "physiologically acceptable salt" and evidence that such salt could not be made by POSITA. The plaintiffs appealed and the appeal was dismissed. A person skilled in art, armed with a common general knowledge at the relevant time, would have understood that "physiologically acceptable" salt certainly required the salt be non-toxic and to not cause harm. POSITA would also have understood that the salt needed to be stable and pure, not degraded. The expert testimony was weighed properly. The trial judge understood that the proper interpretation of the term depended on POSITA's understanding. Further, the use of the term "non-toxic" to describe claimed salts did not necessarily determine the scope of "physiologically acceptable". It was open to the trial judge to conclude that non-toxicity was not only a requirement of physiologically acceptable salt in the context of a patent. The construction of the term "physiologically acceptable" was not purposeless or contrary to the principles of claim construction. Reliance on "the amalgamated use of terms physiologically with pharmaceutically acceptable" did not "obviously elevate threshold beyond what was merely not toxic or not harmful for body". In the context of the discussion of these terms, in which "physiologically acceptable" and "pharmaceutically acceptable" are synonymous, the use of the word "amalgamated" was simply recognition that both contribute to the elevated threshold. Common general knowledge was properly taken into account. The need to conduct a minor research project was not a determinant factor for insufficiency of patent disclosure in the case at bar. However, the finding of invalidity for insufficiency was valid. The trial judge relied on testimony from the plaintiffs' expert to the effect that salt formation is unpredictable, and "the search for salt requires lot of experimental work and requires skilled person to exercise some degree of inventiveness", this was enough to support the conclusion of insufficiency.