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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 contains updates to Chapter 2. Regulation of Products Under the Cannabis Act, Chapter 7. Patent Enforcement and Chapter 8. Patented Medicines (Notice of Compliance) Regulations.

### Highlights

**Chapter 7. Patent Enforcement – § 7:6. Defences to Infringement – (2) INVALIDITY** – The following is an excerpt from this section –

Another mode of invalidating a patent is by alleging double patenting— i.e., that a patent was already granted for the same invention. The prohibition on double patenting arises from the idea that an inventor is entitled to only one patent for each invention and is intended to address concerns about “evergreening” of monopolies through successive patent claims. [*NCS Multistage Inc. v. Kobold Corporation*, 2025 FCA 187, 2025 CarswellNat 4372 (F.C.A.) at paras. 51–54] However, the Federal Court has suggested that double patenting may be a valid ground of invalidity even where the two patents in question expire on the same date. [*NCS Multistage Inc. v. Kobold Corporation*, 2025 FCA 187, 2025 CarswellNat 4372 (F.C.A.) at paras. 58–59] There are two types of double patenting. “Same invention” double patenting prohibits issuance of a second patent where the claims of the two compared patents are identical or coterminous. “Obviousness” type double patenting prohibits the issuance of a second patent where the claims are not patentably distinct from those of an earlier patent or, put another way, where there is no inventive difference between them.

**Chapter 8. Patented Medicines (Notice of Compliance) Regulations**  
**– § 8:8 Initiating Proceedings at the Federal Court – (2) ON OR AFTER**  
**SEPTEMBER 21, 2017 –** The following is an excerpt from this section –

Recently, in *Janssen v. Pharmascience*, also involving macitentan, the Federal Court held that internal business plans, including marketing and sales forecasts, are relevant to allegations of infringement by inducement since these documents might reveal that a second person knew or ought to have known how its generic would be used. [*Janssen Inc. v. Pharmascience Inc.*, 2025 FC 389 at paras. 24-31]

The Federal Court and Federal Court of Appeal also tackled induced infringement in three decisions relating to paliperidone palmitate. These cases involved Janssen’s patent for a particular dosing regimen of paliperidone palmitate for treatment of schizophrenia. The claimed regimen was generally a 150 mg-eq loading dose on day 1, followed by a 100 mg-eq loading dose on day 8 +/- 2, then followed by 75 mg-eq maintenance doses monthly +/- 7 days – a separate regimen was also claimed for renally impaired patients.

In *Janssen v Teva*, [*Janssen Inc. v. Teva Canada Ltd.*, 2020 FC 593, rev’d 2023 FCA 68] Teva sought approval for a paliperidone injectable product, and its product monograph contained references to the claimed dosage and timing requirements. Teva argued, with supporting evidence, that physicians would not look at generic product monographs and would adjust dosage and timing based on individual patient characteristics. The Federal Court agreed and held that, if physicians exercised their own skill and judgment in determining the dosing regimen, the generic could not be said to have influenced the act such that the infringement would not otherwise have occurred. The Federal Court determined that the second prong of the inducement test set a “high bar”, requiring “but for” causation which is “quite different from an ‘encouragement to infringe’”. [*Janssen Inc. v. Teva Canada Ltd.*, 2020 FC 593 at paras. 263-264] On appeal, the Federal Court of Appeal reversed this decision based on a lengthy review of the case law. In so doing, the Federal Court of Appeal made certain key findings on the law and relevant facts for inducement.

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