



## Gowlings: Leadership in life sciences

Gowlings' national team of experienced life science professionals will help you navigate the issues that affect the growth and success of your business. Talk to us about:

### SUBSEQUENT ENTRY BIOLOGICS:

**Issue:** Canada is in the process of laying the ground rules for sponsors of SEBs (known as biosimilars in Europe and follow-on biologics in the U.S.). Canada's first SEB was approved in Canada late April. The issue is important as the market for biologics grows, and competition for these products and alternate versions of them, intensifies.

**Gowlings leadership:** Gowlings offers strategic advice to secure appropriate patent claims, eligibility for listing under the *Patented Medicines (Notice of Compliance) Regulations* and data protection/data exclusivity, and litigation services as needed. Visit our SEB portal at [biosimilars.ca](http://biosimilars.ca)

### PHARMA/BIOTECH PRICING

**The issue:** The Patented Medicine Prices Review Board (PMPRB) is the federal price regulator with jurisdiction over the price of patented medicines once a patent is issued. Despite public consultation, there is no resolution to address manufacturers' concerns that proposed changes to the PMPRB legislation would make it harder for them to price their drugs appropriately. Consultations are ongoing.

**Gowlings leadership:** We offer strategic advice on policy formulation, dealing with federal regulators, hearings before the PMPRB, and submissions for review by the Common Drug Review and Canadian Expert Drug Advisory Committee.

### PATENT PROSECUTION

**The issue:** Canadian patent rules require a Declaration of Entitlement *before* a filing date in Canada and this confirms the applicant's entitlement to apply for and be granted a patent. The Declaration can form part of the Petition or be filed separately. It is to document only those events that occurred before the application's filing date. The entitlement can result from an assignment, an employment agreement, an oral agreement, a consent; a court order; a change of name; or a merger. Transitional provisions allow applications with a Canadian or PCT filing date prior to June 2, 2007 to file either an assignment or an Entitlement Declaration.

**Gowlings leadership:** Our top-ranked patent team can help you determine what to file, when to file and how to file it.

### TRADE MARKS

**The issue:** It's important to protect an official mark and avoid misstatements during the application process. Registrants also need to know about changes in trade mark registrations, such as the new the cooling-off period, a practice for opposition proceedings granting extensions of time (maximum nine months), which can be requested by the opponent or the applicant in a trade mark proceeding.

**Gowlings leadership:** Gowlings has the depth and breadth of experience to register, commercialize, and offer strategic advice to manage, license and enforce your portfolio.



## **IP LITIGATION**

**The issue:** Two typical patent litigation proceedings are: actions for infringement or impeachment; and, "PMNOC Regulation" applications (not actions) that are otherwise similar to proceedings under Hatch Waxman. Most actions and all PMNOC Regulation applications proceed in the Federal Court of Canada. There is little forum shopping. There are no jury trials. There are stream-lined depositions (only one person examined as of right; speaks for party); and, the successful party is entitled to reasonable legal costs and disbursements. There is also no file wrapper estoppel or Markman hearings.

**Gowlings leadership:** More leading ranked IP litigators than any other Canadian firm, with more than a century of IP litigation experience, Gowlings understands product life cycle issues, and can integrate patent issuance, patent register listing and enforcement, to assist you.

## **PRODUCT LIABILITY**

**The issue:** Product failures leading to personal injury and/or property loss can materially affect manufacturers, importers, sellers or distributors in any industry, at any time and can lead to costly and disruptive litigation.

**Gowlings leadership:** Mitigate your risk. Respond quickly. Get back to business as soon as possible with the help of Gowlings' leading product liability and class action teams. Also, our insurance expertise will assess whether you are covered when it counts.

Learn more at [www.gowlings.com/lisig](http://www.gowlings.com/lisig)

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