

# IP PROTECTION AND REGULATORY LAW IN THE LIFE SCIENCES

**ONE UNIQUE** aspect of obtaining patent protection for life sciences-related technologies in Canada is the suite of regulatory and compliance matters that come into play. These regulatory schemes exist largely to balance the accessibility of life sciences innovations with intellectual property protection.

## Patented Medicines (Notice of Compliance) Regulations

The *PMNOC Regulations* establish Canada's "patent linkage" system. Under this scheme, the Minister of Health maintains a Patent Register listing patent(s) related to an approved small molecule or biologic drug. The minister is then prohibited from granting regulatory approval to a manufacturer of a drug seeking marketing authorization based on a comparison or reference to the drug that is listed on the Patent Register unless and until the manufacturer addresses the listed patent(s).

A patent is eligible to be listed on the Patent Register only if it includes a claim for a medicinal ingredient, formulation, dosage form medicinal ingredient, or use of a medicinal ingredient for which regulatory approval for sale in Canada has been granted or will be pending when the patent issues. To add a patent to the Patent Register, the applicant must submit a "patent list" to Health Canada within 30 days after issuance of the patent if a related regulatory submission has been filed. If such a submission has not yet been filed when the patent issues, the patent list must be filed together with the regulatory submission.

## Certificates of Supplementary Protection (CSPs)

CSPs were introduced in Canada in 2017 to compensate for delays in drug approval before Health Canada. A CSP gives the holder and their legal representatives rights

granted by the patent set out in the CSP for up to two years after expiry of the patent. CSPs are available for both small molecules and biologics. These rights are not extended to making, constructing, using, or selling for the purposes of exporting.

To be eligible for a CSP, a patent must claim a medicinal ingredient (MI), combination of MIs, or a use of an MI or combination thereof contained in a drug for which marketing authorization has been granted by way of a Notice of Compliance (NOC) issued by Health Canada. The MI or combination thereof must not have been previously approved and there must not have been a prior CSP granted for the MI or combination thereof. Further, MIs that differ from each other with respect to a prescribed variation will be treated as the same MI. The Federal Court has also considered the CSP Regulations and provided further guidance on eligibility (see articles on Bereskin & Parr's website: "[Federal Court finds Minister of Health's refusal of BELSOMRA CSP unreasonable, remits for redetermination](#)" and "[Federal Court of Appeal Affirms Minister's Decision that CSP Eligibility Requires Claim for Active Ingredients and Excludes Formulations Claims](#)").

Deadlines for filing CSPs must be monitored carefully. The new drug submission (NDS) on which the NOC issued must have been filed in Canada within 12 months after first related regulatory filing in the EU or any country thereof, the US, UK, Australia, Switzerland, or Japan. Further, the unextendable deadline for filing a CSP application is the later of 120 days after the issuance of the patent or 120 days after the marketing authorization has issued.

## Data protection

Irrespective of whether a patent exists, Canada provides eight years of data protection under

the *Food and Drugs Act* for an "innovative drug" containing a medicinal ingredient not previously approved by Health Canada. This data exclusivity period applies to both small molecules and biologics. Under this scheme, a manufacturer may not file a drug submission referencing an innovative drug within six years of the initial authorization of the innovator drug, with an additional two-year period that applies before marketing authorization can be granted. Where clinical trials relating to the use of the drug in pediatric populations have been conducted, an additional six months of exclusivity may be added to the eight-year term.

## Patented Medicine Prices Review Board (PMPRB)

The PMPRB is a federal administrative body created under the *Patent Act* with the mandate of ensuring that the price of patented medicines sold in Canada is not "excessive." The PMPRB reviews prices of patented medicines sold in Canada based on comparison to prices in other markets. If a price is found to be excessive, the board can impose remedies including ordering a reduction in the price of the medicine and/or payment to Canada of a specified sum.

The scope of the PMPRB's jurisdiction has been at issue of late, both before the courts and with proposed amendments to the Patented Medicines Regulations (see articles on Bereskin & Parr's website: "[Supreme Court of Canada Takes a Pass on Patented Drug Price Dispute](#)"; "[Canada Drops its Most Controversial Patented Drug Pricing Amendments](#)"; and "[Proposed Canadian Drug Pricing Rules Delayed by Feds and Battered by Courts](#)"). However, the government of Canada recently dropped some of their more contentious proposed amendments, confirming that for the time being the PMPRB's jurisdiction will remain limited to the control of excessive prices resulting from patent monopoly. The list of countries that the PMPRB uses for comparison will be updated, including the removal of the United States and Switzerland. **■**

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