

Protecting your Canadian Market

NOC Regulations

The *Patented Medicines (Notice of Compliance) Regulations (NOC Regulations)* link Canada's *Food and Drug Regulations* and *Patent Act*, providing for a preliminary assessment of patent issues while Health Canada evaluates the safety and efficacy of a generic drug or Subsequent Entry Biologic (SEB).

The Minister of Health maintains a Patent Register, listing patents eligible for protection under the *NOC Regulations*. There are strict eligibility requirements for listing a patent on the Patent Register: the patent must contain a claim to the specific medicinal ingredient, use of the medicinal ingredient, formulation containing the medicinal ingredient or dosage form for which approval is ultimately granted. Patent claims should be reviewed for listing eligibility prior to issuance. The timing for listing a patent on the Patent Register is not extendable. Regulatory and patent departments should communicate regularly to ensure each department is aware of the relevant patents, regulatory submissions, and timelines.

If a generic or SEB company files a submission for regulatory approval comparing its product to an approved product with a patent(s) listed on the Patent Register, that company must either agree to await expiry of the listed patent(s) or allege that the patent(s) are not infringed or are invalid. The innovator may then start a court proceeding and the Minister cannot grant approval to the generic company for 24 months, or until the court proceeding concludes in favour of the generic company, whichever is earlier. If the proceeding concludes in favour of the innovator, the Minister cannot grant approval to the generic company until the patent expires.

Proceedings under the *NOC Regulations* are preliminary in nature and do not affect the validity or infringement of the patent in a full court action for patent infringement or invalidity. Thus, the unsuccessful party may start such an action, and the outcome of such case is not pre-determined by the result of the NOC Proceeding.

The Patent Register is “frozen” on the date a generic or SEB company files its submission for an NOC. Any patent added to the Patent Register after that date need not be addressed by that generic or SEB company. Thus, it may be worth expediting prosecution of relevant patents to ensure they are listed before the Patent Register is frozen.

Data Protection

A generic or SEB company is prevented from filing its regulatory submission until 6 years after the date the first NOC is issued for an innovative drug. This gives the innovator those years to try to ensure that all relevant patents are issued and listed on the Patent Register. The generic company cannot receive its NOC for an additional 2 years, during which time the parties can conduct proceedings under the *NOC Regulations*. A further 6-months is provided if the innovator conducts pediatric trials.

Conclusion

There is an important interplay among the *Patent Act*, *Food and Drug Regulations*, and the *NOC Regulations*, as they relate to patented medicines in Canada. Thus, it is important for companies and their legal representatives to be aware of the rights provided under these regimes, and the associated timelines.

Highlights

Canada has two regulatory regimes that interact with the patent system as it applies to biological and pharmaceutical products: the *NOC Regulations* and Data Protection. Being aware of these regimes will ensure that your company can take full advantage of the benefits they provide.

