

The sole purpose of the Register is to prevent patent infringement in certain circumstances. Only a company that applies for, or already has, an NOC for an approved, patented drug may be eligible to take advantage of this specialized process. While only certain types of patents qualify, Health Canada clearly stated that biologic patents are eligible for the Register (Health Canada, 2015). To be eligible for listing, a patent must claim either an approved:

- Medicinal ingredient;
- Formulation that contains the medicinal ingredient;
- Dosage form; or
- Use of the medicinal ingredient.

The Patent Register also has strict, nonextendable time limits. A patent can be listed at one of two times:

- A patent that is issued at the time of filing an NDS (or supplementary NDS) must be listed at the time of filing the submission; or
- A patent application that has a filing date before the filing of the NDS (or supplementary NDS), must be listed within 30 days after the issuance of the patent.

Health Canada vets all requests to list patents on the Register. If a patent is refused listing, Health Canada gives the requestor the opportunity to make written arguments in favor of listing.

14.3.3 PATENT REGISTER PROCEDURE

In order to receive marketing authorization, the biosimilar company must address freedom-to-operate with respect to patents on the Health Canada Patent Register. If there are no relevant patents on the Patent Register, then Health Canada will not have to hold up drug approval pending resolution of patent issues. The Patent Register provides significant benefits to a patent owner by keeping a competitor from entering the market. In contrast, prior to the creation of the Patent Register, the patent owner often had to use conventional patent litigation to chase a competitor for patent infringement *after* the medicine was already on the market. This created inefficiencies since interlocutory injunctions are difficult to obtain and it takes a long time to bring a patent infringement case to a trial. The brand-name company would lose significant market share in the meantime.

The preemptive NOC Proceeding is a faster and cheaper way to keep a competitor off the market than a patent infringement trial. The filing of the NOC Proceeding starts an automatic 24-month stay of NOC issuance to the biosimilar company (it is, in effect, like an injunction). The NOC may only be issued when the patent expires or the biosimilar company wins the NOC Proceeding. In contrast, as mentioned above, it is typically very difficult to obtain an interlocutory injunction against a competitor in Canada in a patent infringement lawsuit.

A disadvantage of filing the NOC Proceeding is in the event that the generic or biosimilar company wins, the patent owner may be liable to the competitor for