Patients patents

A grassroots education campaign on pharmaceutical patents

Glossary of Patent Terminology

Pharmaceutical Patent

A form of legal protection that gives a pharmaceutical manufacturer the exclusive right to sell a new originator medication for a certain period; in Canada, 20 years from the date of filing.[1] During this time, no other manufacturer is allowed to make, use or sell a generic or biosimilar version of the originator medication. This helps the originator manufacturer recover the money it spent on research and development and to profit from their discovery for the life of the patent.

Primary & Secondary Patents

A primary patent protects the original active ingredient of a medication. This is the strongest form of patent protection.

Secondary patents often cover small modifications to the medication, such as:

- New formulations (e.g., from a tablet to an extended-release version)
- New delivery methods (e.g., an injection instead of a pill)
- New combinations (mixing two old drugs together)

Originator pharmaceutical manufacturers file multiple secondary patents to block generic or biosimilar entry. Many secondary patents offer little or no new medical benefit, but they extend the “patented price” of the medication.

[1] Health Canada: Guidance Document: Patented Medications Regulations, January 2025

Originator Medication

The first version of a medication Health Canada has approved for sale is known as the "originator" or brand-name medication.

Generic Medications

Generic medications such as aspirin or ibuprofen are small molecules that are chemically synthesized. They contain identical active ingredients as the originator medications and are considered the same in terms of dosage form, safety, effectiveness and intended use. Generic medications incur significantly less developmental costs and are offered at a significantly less price than an originator drug medication. For example, in Canada, the generic version of ibuprofen costs approximately 90% less than its brand-name originator (Advil, Motrin).

Biosimilar Medications

Biologics are made from living organisms like yeast and bacteria and are much larger and more complex in nature than conventional, small molecule medicines such as over-the-counter ibuprofen or by-prescription methotrexate.

As patents expire for originator biologic medicines, other manufacturers produce biologic medicines that are called biosimilars. To receive Health Canada's approval, a biosimilar must demonstrate it is as safe and effective as the originator. Manufacturers that make biosimilars do not incur the same developmental costs in order to bring the biosimilar to market and will therefore offer it at a lower price (up to 30-50% in Canada).

Biosimilars have been approved for use in Canada since 2009 and for use in inflammatory arthritis since 2014. Sixty-four biosimilars are currently approved by Health Canada.

Patent Exclusivity in Canada

A legal right that prevents others from making, selling, or using a medication protected by patent rights until the expiry of the last relevant patent. Unlike regulatory exclusivity, which is automatic, patent exclusivity depends on filing and maintaining patents and the outcome of any subsequent patent litigation.

How It Works in Canada:

- The legal right of the primary patent (on the active ingredient) lasts for a certain period of time.
- Although the patent term in Canada is 20 years from the date of filing, there is a critical distinction between this basic patent timeline and the length of a drug's monopoly: for drug patents, the patent clock starts ticking as soon as the application is filed, which typically occurs early in the drug research and development process. This means a significant portion of the patent term may elapse before the drug ever reaches the market, reducing the manufacturer's real time without competition (called market exclusivity) - approximately 8-12 years in Canada.
- Secondary patent rights (on formulations, dosages, or delivery methods) can extend the period of market monopoly.
- If a generic or biosimilar manufacturer challenges a patent listed on the Patent Register, the patent linkage system delays the regulatory approval of that generic or biosimilar for an automatic 24-months.

Why It Matters:

- Manufacturers file multiple secondary patents to create a "patent thicket", extending their monopoly.
- Even if the original patent expires, secondary patents can block generics for years.

Example: The drug Humira (adalimumab) had a primary patent that expired in 2017, but the manufacturer filed dozens of additional patents, keeping biosimilars off the Canadian market until 2021.

Regulatory Exclusivity

A government-granted period of time during which a pharmaceutical manufacturer has exclusive rights to its clinical trial data. Even if a drug's patent has expired, generics and biosimilars cannot apply for approval until this exclusivity period ends.

How It Works in Canada:

- New innovative medicines get 8 years of regulatory exclusivity before generics or biosimilars can be approved.

Why It Matters:

- Generic and biosimilar manufacturers cannot reference the originator medication's clinical data to get approval for their generic or biosimilar medicines during this period.
- This delays competition even if there are no active patents on the medication.

Example: A biologic medicine approved in 2020 will have regulatory exclusivity until 2028, meaning no biosimilar can obtain regulatory approval until that year – even if the drug's patent expired in 2025.

Evergreening

A tactic used by pharmaceutical manufacturers to extend a drug's patent beyond its original 20-year limit by making minor changes and filing new patents. This delays generics and biosimilars from entering the market. For example, a company may change the dosage form (from a tablet to an extended-release capsule) or create a new injection device to get a new patent and extend its monopoly on the medication.

Patent Thicket

A strategy where a pharmaceutical manufacturer files dozens (or even hundreds) of overlapping patents on a single medication to make it harder for generics and biosimilars to enter the market.

Patent Linkage System

A legal system in Canada that automatically blocks a generic or biosimilar medication from being approved for 24 months if the originator brand-name manufacturer asserts a patent listed on the Patent Register.