Patients patents

A grassroots education campaign on pharmaceutical patents

ABOUT THE PATIENTS AND PATENTS CAMPAIGN

Millions of patients around the world – including those living with arthritis, cancer, inflammatory bowel disease, multiple sclerosis and many other life threatening and chronic diseases – are impacted by the growing costs of prescription medications. One of the drivers of high costs for medications is the misuse of intellectual property (IP) protections by pharmaceutical manufacturers to extend their patent and delay the availability of affordable generic and biosimilar medications.

Patients and patents is an international patient organization led initiative aimed at increasing patient community and public understanding of how drug patents are supposed to serve both patients and healthcare systems. The campaign co-leaders are Arthritis Consumer Experts (Canada), the Australian Patient Advocacy Alliance (Australia), and Crohn's & Colitis Foundation (USA).

Understanding how drug patents work in Canada[1]

A pharmaceutical manufacturer of a new prescription medication spends many years researching and developing a new medication before it can be approved by Health Canada and made available to the public. During this process, one or more patents may be granted to the pharmaceutical manufacturer that developed this new medication.

Patents give pharmaceutical manufacturers the exclusive right to sell a new, "originator" medication in Canada for 20 years from the date of filing.[2] 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.

[1] Government of Canada: Patents: Learn the basics, October 2024

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

However, this timeline can be misleading because the patent often gets filed early in the research and development process, long before the medication is approved and ready for patients. By the time the new medication reaches the market, several years of the patent have already passed. This means the company's real time without competition (called market exclusivity) is often shorter – around 8 to 12 years in Canada.

Generic and biosimilar medications can be made available to the public after Health Canada has approved them as safe and effective. Once approved, generic and biosimilar medications can enter the market at a lower cost (up to 95% for generics and 30–50% for biosimilars), potentially saving healthcare systems billions of dollars. Generic and biosimilar manufacturers do not incur the same early research and development costs to bring the medication to market and can therefore offer it at a lower price.[3]

A. Key Steps in the drug patent process

1. **Patent Application:**

   Pharmaceutical manufacturers file patent applications with the Patent Office, which is part of the Canadian Intellectual Property Office (CIPO).[4]

2. **Patent Examination:**
   The Patent Office reviews the application to determine if the invention is patentable.

3. **Patent Grant:**
   If the application is approved, a patent is granted, giving the company exclusive rights for 20 years from the date of filing.

4. **Listing on the Patent Register:**
   The originator pharmaceutical manufacturer can list the relevant patents on a public Patent Register maintained by the Health Minister.

5. **Generic Drug Application and Litigation:**
   Generic or biosimilar manufacturers can apply to Health Canada for market approval. However, they must address the patents listed on the Patent Register, which can lead to litigation with the originator manufacturer.

[3] Canadian Agency for Drugs and Technologies in Health (CADTH): Biosimilar Drugs: Your Questions Answered
[4] Government of Canada: Behind the scenes at Canada's Patent Office, February 2025

B. Responsible parties in the Drug Patent Process

1. **Canadian Intellectual Property Office (CIPO):**
   Responsible for examining patent applications and granting patents.

2. **Health Canada:**
   Regulates the approval of medications, maintains the patent register, and ensures that generic and biosimilar manufacturers address the originator manufacturer's patents before receiving market approval.

3. **Pharmaceutical Manufacturers (Originator and Generic/Biosimilar):**
   Originator manufacturers develop new medications , while generic and biosimilar manufacturers aim to bring more affordable versions to market after patents expire.

The Goal of Patents

Patents allow the originator manufacturer to recover its research and development costs before competitors enter the market with affordable alternatives, like generics and biosimilars.

Developing a new drug is expensive and time-consuming — on average, it takes 10–15 years and costs over $1 billion CAD.

Benefits of Patents

- Encourages pharmaceutical manufacturers to invest in the development of new, life- and disability-saving medications.
- Allows pharmaceutical manufacturers to recoup the billions spent on research and development, clinical trials, and regulatory approvals.
- Brings new medications to patients who need them most.

Misuse of Patent Protection

Pharmaceutical manufacturers can employ legal strategies to extend their protection from market competition by applying for additional patents. When filing for these additional patents, pharmaceutical manufacturers might claim they've "improved" their formula by changing the non-therapeutic ingredient(s) in their formulation.

By filing for additional patents, manufacturers can create "monopolies" on old medications, delaying competition from generics and biosimilars medications for years - even decades. These strategies to extend patent protection can result in patients and healthcare systems continuing to pay for medications at the "patented price" rather than at much more affordable post-patent prices.

Key consequences of patent extension for patients

- **Higher drug costs:** Patients pay higher prices for longer periods, delaying access to more affordable alternatives.
- **Financial hardship:** Many must choose between paying for medications and other essentials like food or housing.
- **Delayed or interrupted treatment:** Leads to disease progression, disability, and lower quality of life.
- **Reduced adherence:** Patients may skip or ration medication due to cost, impacting treatment effectiveness and increasing risk of hospitalizations, surgery and disease progression.
- **Emotional distress and mistrust:** Patients often feel helpless or betrayed when they learn how the system prioritizes profit over patient care.

Why This Matters Now

Some pharmaceutical manufacturers are extending patent protection through tactics like "evergreening" (adding patents for minor changes) and "patent thicketing" (filing dozens of overlapping patents) to delay competition far beyond the original protected period.

Patients and patents education campaign

The campaign aims to educate patients, health care providers, policymakers, and the public about how pharmaceutical patents can benefit and potentially harm patients and healthcare systems – especially for chronic disease management that requires timely, continuous access to disability-sparing or life-saving medications.

Additional resources

To learn more, here are additional resources:

- STAT, Do drugs get cheaper when their patents expire, Nov. 4, 2024, available at https://www.youtube.com/watch?v=t-zZFOUa7Vw&t=266s
- Patrick Kelly, How Pharmaceutical Patents Make Drugs Expensive, Aug. 3, 2024, available at https://www.youtube.com/watch?v=nwBKnMONoFM&t=2s
- Priti Krishtel, TED talk. Dec. 2019, available at https://www.youtube.com/watch?v=-3y6_7_5PcQ.

How you can get involved

Patients or patient organizations can get involved by sharing our resources.

Download and share our **Social Media Kit** for Facebook, Instagram, X, and LinkedIn here - **remember to use the #Patientsandpatents hashtag**.