Patients patents

A grassroots education campaign on pharmaceutical patents

COMMON QUESTIONS ABOUT PATENTS AND THEIR IMPACT ON PATIENTS

ABOUT PATENTS

Q1: What are pharmaceutical patents?

A: A pharmaceutical manufacturer may spend years researching and developing a new medication before it can be possibly approved in Canada. Pharmaceutical manufacturers that have developed a new medication often seek a form of legal protection known as a patent right, which gives them the exclusive right to make and sell the medication for a set period without competition. This allows pharmaceutical manufacturers to recover the money they spent on research and development to bring the medication to market.
When the patent expires, 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.

Q2: Why are generics and biosimilars more affordable than brand-name originators?

A: Developing an originator biologic medication is costly and time-consuming—on average, it takes 10–15 years and costs over $1 billion CAD.

Generic and biosimilar manufacturers do not incur the same early research and development costs to bring the product to market and can therefore offer it at a lower price.[1]

[1] Canadian Agency for Drugs and Technologies in Health (CADTH): Biosimilar Drugs: Your Questions Answered

Q3: Why are some medications still so expensive, even though they have been available for decades?

A: Canadians pay some of the highest drug prices in the world. One of the drivers of higher medication costs is the misuse of patent protections by pharmaceutical manufacturers which may delay the availability of affordable generic and biosimilar medications for years, or even decades.

Pharmaceutical manufacturers of originator medicines may use legal maneuvers such as "evergreening" (adding patents for minor changes) and "patent thicketing" (filing dozens of overlapping secondary patents) to extend their market monopoly.

Example: Humira (adalimumab) – used to treat inflammatory forms of arthritis and inflammatory bowel disease.

- The original patent expired in 2017, but the manufacturer filed dozens of additional patent applications, extending market monopoly until 2021 in Canada.
- Total cost of this delay: Over $1 billion in additional drug spending for Canada's public drug plans.

Q4: How do originator brand-name manufacturers delay competing generic and biosimilar medications entry into the market?

A: Manufacturers use patent strategies (e.g. secondary patents on formulations, dosages or delivery methods) to extend their market monopoly, which block competition and keep their medication at the "patented price."

Common tactics used to delay affordable medications:

- **Evergreening:** Filing new patents on minor changes (e.g., different dosages, coatings, or packaging) to extend exclusivity.
- **Patent Thickets:** Flooding the system with dozens of overlapping patents to create legal and financial barriers for competitors.
- **Patent Linkage System:** In Canada, the regulatory approval of generic/biosimilar medicine can be delayed automatically by 24-month if the originator manufacturer list one or more patents on the Patent Register and asserts these patents against the generic or biosimilar manufacturers, even if the patents are likely invalid or not infringed.

Q5: How does delayed access to generics and biosimilars impact patients?

A: Most people living with inflammatory arthritis like rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and lupus require lifelong medications to prevent permanent joint damage.

While safe and effective, Health Canada approved generics and biosimilars are blocked from entering the market due to the drug patents, and patients have limited treatment options. Delayed access to affordable treatment options can have negative effects on health outcomes:

- Without affordable alternatives, patients must use higher cost originator brand-name medications or go without treatment.
- Delayed or interrupted treatment gaps can lead to disease progression, disability and lower quality of life.

High medication prices can also lead to inconsistent treatment adherence, resulting in poor health outcomes.

- **Example:** A person with inflammatory arthritis who cannot afford their advanced therapy may skip treatment or ration or take lower doses to make their prescriptions last longer or stop taking the medication altogether.
- Reduced medication adherence can cause worsening symptoms, increased pain, loss of mobility, hospitalization, surgery, loss of job, or permanent joint damage.

Q6: How does misuse of patent protection affect out-of-pocket medication costs for patients?

A: One in four Canadians currently cannot afford their prescription medications. Misuse of patent protection can result in patients continuing to pay for medications at the “patented price” rather than at much more affordable post-patent prices. Higher out-of-pocket medication costs have multiple impacts for patients:

- Patients pay for high-priced medications for years longer than necessary.
- Some patients must choose between paying for medicine or necessities like food, rent, or utilities.
- Financial hardship leads to debt, stress, and sacrificing other aspects of care.
- Patients often feel helpless or betrayed when they learn how the system prioritizes profit over patient care.

Q7: What are the emotional and psychological effects of high medication prices?

A: Patients who cannot afford their medication may feel forced to choose between their health and their financial stability. The constant financial strain creates stress, anxiety, and feelings of helplessness. Many patients experience guilt or distress if they must ask for financial help to afford medication.

Q8: How does misuse of patent protection increase healthcare costs for everyone?

A: Misuse of patent protection keeps healthcare costs high by forcing public and private drug plans to pay for medications at the “patented price” rather than at lower post-patent prices. Private health insurers may pass these higher medication costs onto patients through increased premiums and co-pays. Additionally, public drug plans may have less funding for new medications and other essential health services for people living with a chronic disease like inflammatory arthritis.

Q9: Does the misuse of patent protection affect the development of new drugs?

A: Yes, manufacturers may prioritize extending old drug patents over researching and developing new medications. In this case, patients may lose access to potential treatment breakthroughs.

If pharmaceutical manufacturers focused on innovation rather than patents, patients could potentially see more new and effective treatments enter the market, and more quickly.

ABOUT THE PATIENTS & PATENTS CAMPAIGN

Q9: Is there a need for a patient organization-led education campaign on pharmaceutical patents?

A: The percentage of patients who fully understand pharmaceutical patent law is generally quite low. Various studies and surveys suggest that the public, including patients, have limited knowledge and understanding of pharmaceutical patents and their impact on patients.

The campaign aims to deliver evidence-based education on pharmaceutical patents and demonstrate that while they help drive research and innovation, they can also affect patient health and access to affordable medications.

Q10: Who is leading Patients and patents?

A: Patients and patents is being co-led by:

- Arthritis Consumer Experts (Canada)
- Australian Patient Advocacy Alliance (Australia)
- Crohn’s & Colitis Foundation (USA)