# Debunking False Narratives about the Patent System: Biopharmaceutical Companies Extend Market Exclusivity Through So-Called "Evergreening" Practices

Critics often claim that biopharmaceutical companies strategically obtain frivolous patents later in a product's lifecycle to prolong periods of patent protection and delay generic entry. These claims are premised on the notion that so-called "secondary patents," defined by these critics as patents on inventions other than a medicine's active ingredient, are inherently problematic. Here's what you need to know about how these claims misrepresent the evidence on biopharmaceutical patenting practices, the R&D process, and innovations that matter to patients:



1. **Biopharmaceutical R&D is an ongoing process that continues long after initial FDA approval.**
   Companies often first identify a new active ingredient and then may file a patent application on it. Following this, companies continue investing in R&D and conduct clinical trials to demonstrate a medicine is safe and effective, resulting in inventions that can include its formulation, methods of delivery or treating a particular disease, and manufacturing processes—each eligible for patent protection. Following initial FDA approval, companies may work to improve the medicine or run subsequent clinical trials to demonstrate the medicine is effective in the treatment of a different disease or patient population entirely; likewise, each invention coming out of this post-approval R&D may receive its own patent, as U.S. law limits each patent to a single invention.

2. **Despite common rhetoric, new patents do not extend the terms of older patents.**
   Rather, each patent has its own basic 20-year term. If, during the R&D process, companies make an additional discovery about an invention that was already disclosed in an earlier-filed patent application, they may be able to file a continuation application. Importantly, continuation patents do not extend the term of the original patent and a continuation patent's term starts at the original patent application's filing date, often truncating the term to less than 20 years. This system ensures companies are able to receive full patent protection for medicines researched and developed over time, while also encouraging early disclosure of inventive subject matter to the public to advance scientific inquiry and ultimately facilitate generic entry.

**3. The patent system does not support filing of frivolous patents.**
Claims that biopharmaceutical companies can obtain meaningless patents on trivial improvements are unfounded. The USPTO will only grant a patent after it finds that the invention meets all the statutory patentability requirements, including that the invention is useful as well as new and non-obvious when compared to the knowledge in the relevant field at the time the application was filed.

**4. Post-approval R&D is an important source of treatment options for patients.**
Medicines are prescribed for new uses twice as often as their initial indication.[i] The patent system encourages biopharmaceutical companies to expand the uses of existing products to different diseases and patient populations. For example, post-approval R&D led medicines initially developed for use in rheumatoid arthritis to be approved for many other autoimmune conditions that share similar molecular pathways.[ii] In oncology, post-approval R&D often demonstrates significant clinical benefits of approved therapies in different forms of cancer, stages of disease or populations. Approximately half of all approved uses in cancer were approved after the initial use and more than 60 percent of solid tumor cancer treatments that fight cancer before it spreads were developed post-approval.[iii, iv] While post-approval new uses are remarkably valuable to patients, research shows that if average periods of market exclusivity were reduced by 5 years over the past decade, patients would have 32 fewer of these treatments and 1 million lives would have been lost.[v]



[i] EBRI, What Employers Should Know About the Inflation Reduction Act and Drug Development, May 2025. Available here.
[ii] Arthritis Foundation, DMARDs, Available here.
[iii] Advi, Implications of the Inflation Reduction Act on Developing Treatments for Cancer Before It Spreads, May 2025. Available here.
[iv] Genia Long. (2026) Trends in industry-sponsored clinical trial activity since passage of the Inflation Reduction Act. Journal of Medical Economics 29:1, pages 957-971. Available here.
[v] Tomas Philipson et al., Policy Brief The Impact of Intellectual Property Protection on Post-Approval Innovation, March 2026. Available here.

5. **Claims of evergreening are often based on flawed and invalidated methodological approaches for projecting time to generic entry.** Critics often rely on faulty methodologies, including those relied on by activist groups such as I-MAK and certain academics that aggregate numbers of patents and exclusivities to estimate when generic entry may occur. Yet, in 2024 the USPTO conducted its own analysis of data associated with 25 new drug applications and mapped the scope and duration of patent protection and regulatory exclusivities associated with those products concluding "simply quantifying raw numbers of patents and exclusivities is an imprecise way to measure the intellectual property landscape of a drug product because not every patent or exclusivity has the same scope."[i] A 2023 analysis by Lietzan and Acri examining this approach in a UC San Francisco School of Law database that projected periods of patent protection found that across 224 drugs, actual generic entry occurred on average 7 years earlier than predicted in the database.[ii]

6. **The average market exclusivity period for drugs has remained consistent for decades regardless of an increase in patenting on medicines over the same period.** In its 2024 analysis the USPTO found no correlation between the number of patents on a drug and length of actual market exclusivity.[iii] Over the years, a wealth of research by legal scholars, experts and others has pointed to consistent periods of time to generic entry for brand drug products, averaging between 12-14 years, even as those products may involve numerous inventions and have been associated with a greater number of corresponding patents over the past decade. [iv, v, vi, vii,viii, ix]

[i] U.S. Patent and Trademark Office (2024), Drug Patent and Exclusivity Study. Page 57. Available here.
[ii] Lietzan, E., & Acri, K. M. L. (2023). Solutions still searching for a problem: A call for relevant data to support 'evergreening' allegations. Fordham Intellectual Property, Media & Entertainment Law Journal, 33(3), 788-873.
[iii] U.S. Patent and Trademark Office (2024), Drug Patent and Exclusivity Study. Available here.
[iv] Grabowski et al. (August 2021). Continuing trends in U.S. brand-name and generic drug competition. J Med Econ. 24(1): 908-17. Available here.
[v] Lietzan E., Acri K. (September 2022). Solutions Still Searching for a Problem: A Call for Relevant Data to Support 'Evergreening' Allegations. U Missouri School of Law. Available here.
[vi] Gupta C. (February 2021). One Product, Many Patents: Imperfect Intellectual Property Rights in the Pharmaceutical Industry. SSRN. Available here.
[vii] Beall R., Darrow J., Kesselheim A. (January 2019). Patent Term Restoration for Top-Selling Drugs in the United States. Drug Discov. Today. 24(1):20-25. Available here.
[viii] Wang B., Liu J., Kesselheim A. (April 2015). Variations in Time of Market Exclusivity Among Top-Selling Prescription Drugs in the United States. JAMA Intern. Med. 175(4):635-637. Available here.
[ix] Morris, E.M., Kresh, J. (May 2024). Pharmaceutical "nominal patent life" versus "effective patent life," revisited. Center for Intellectual Property x Innovation Policy Working Paper. Available here.