

Debunking False Narratives about the Patent System: Biopharmaceutical Companies Block Competition Through So-Called “Patent Thickets”

Critics of our IP system often claim that biopharmaceutical products are excessively patented imposing insurmountable hurdles to generic competition. Yet, evidence has failed to show a link between patent counts and the timing of generic entry. Here's what you need to know about biopharmaceutical patenting practices in the US and generic competition.



1.

It is not unusual for complex products like medicines to have more than one patent. Medicines are highly complex products that often incorporate multiple inventions that can include the active ingredient, formulation, dosage form, use of a medicine in a particular disease, or ways of manufacturing the medicine. However, as each U.S. patent can only claim a single invention, multiple patents are typically necessary to cover all the inventions that make up a biopharmaceutical product and indeed drugs are associated with an average of about four patents.ⁱ Due to the iterative, ongoing nature of drug discovery, development, and clinical trials, other patented inventions occur after the initial invention of the drug substance as more is learned about the medicine and its commercial applicability. On average, it takes 10-15 years and \$2.6 billion to develop a single new medicine.ⁱⁱ The patent system balances the goals of ensuring full protection of medicines to enable biopharmaceutical companies to make these investments, including for inventions made over time, while encouraging early disclosure of inventions to the public through patent applications to advance scientific inquiry and ultimately facilitate generic entry.



2.

Biopharmaceutical companies patent less than other sectors but invest more. The USPTO itself has stated, “with respect to multiple patents that cover a single product, multiple patents associated with a single marketed product are not unique to the pharmaceutical industry and are a common practice in many innovative industries, especially for complex products.”ⁱⁱⁱ To place this observation in context, according to the Intellectual Property Owners Association’s report of top U.S. patentees of 2024, most of the top patent-owning companies belong to the tech sector, while just 2.3% of the top 300 are in the biopharmaceutical sector.^{iv} Importantly, the same report shows the combined number of patents granted to these companies were less than a third of the patents granted to the tech company topping the list.^v While this sector patents less than other manufacturing industries, it invests over \$12 million in R&D for every patent issued – which is more than any other sector.^{vi} Yet, when it comes to sales generated per patent, the industry is squarely in the middle - demonstrating the biopharmaceutical industry’s significant risk in drug development where even vital investments won’t always be successful and able to generate sales.^{vii}

ⁱ Hemphill, C. Scott, and Bhaven N. Sampat. 2025. “Patents, Innovation, and Competition in Pharmaceuticals: The Hatch-Waxman Act after 40 Years.” *Journal of Economic Perspectives* 39 (2): 27–52. Available <https://www.aeaweb.org/articles?id=10.1257/jep.20241423>

ⁱⁱ DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*, 47, 20-33. Available <https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub>

ⁱⁱⁱ Drug Patent and Exclusivity Study, U.S. Patent and Trademark Office. Page 58. Available https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf

^{iv} Intellectual Property Owners Association, “Top 300 Organizations Granted U.S. Patents in 2024,” January 2025. Available <https://ipo.org/wp-content/uploads/2025/01/2024-Top-300-Patent-Owners-List.pdf>

^v *Ibid*

^{vi} NDP Analytics. (April 2025). The Economic Performance of IP-Intensive Manufacturing and Service Industries in the United States, 2012 – 22. <https://ndpanalytics.com/wp-content/uploads/IP-Report-April-2025-Final.pdf>.

^{vii} *Ibid*



3.

Numbers of patents do not predict market exclusivity for medicines. In response to assertions by industry critics regarding patenting activity on drugs and increasing exclusivity periods, and at the request of a U.S. Senator, the USPTO released a study in 2024 that found no correlation between the number of patents on a product and length of actual market exclusivity. Over the years, a wealth of research from legal scholars and experts 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.^{ix, x, xi, xii, xiv}



4.

Claims that excessive litigation hurdles impede generic entry are not supported by the facts. First, evidence suggests generic manufacturers are increasingly challenging innovator patents in Hatch-Waxman litigation reflecting a system working as intended. In 1995, just 9% of brand drugs had a generic challenge patents via a paragraph IV certification. By 2019, 81% of drugs had such challenges.^{xv} Second, as judges and litigators are well aware, the number of patents and claims in a portfolio does not reflect what is actually litigated and certainly does not reflect the number of claims that make it to trial. It is common for courts to require parties to narrow the patents and/or claims asserted for purposes of trials across technologies, and courts can even have dedicated rules for Hatch-Waxman cases.^{xvi} Consequently, only a few patents, and perhaps only a few claims total, are ultimately adjudicated.



5.

The U.S. has the most robust generic system in the world. Not only do generics represent a larger share of total prescriptions in the U.S. – representing 90% dispensed – but they are also much cheaper than in other developed countries. As a result, the average price of prescriptions filled through Medicare and Medicaid is 18% less than in other OECD countries.^{xvii} Due to this built-in system of cost containment, retail and physician-administered medicines are projected to remain constant at 14% of total U.S. health care spending through 2030, exactly the same share as over the last decade.^{xviii}

^{viii} Drug Patent and Exclusivity Study, U.S. Patent and Trademark Office. Available https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf

^{ix} Grabowski et al. (August 2021). Continuing trends in U.S. brand-name and generic drug competition. *J Med Econ.* 24(1): 908-17. Available https://www.tandfonline.com/doi/10.1080/13696998.2021.1952795?url_ver=Z39.88-2003&rft_id=ori:rid:crossref.org&rft_dat=cr_pub%20pubmed#abstract

^x 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 <https://ir.lawnet.fordham.edu/iplj/vol33/iss4/2/>

^{xi} Gupta C. (February 2021). One Product, Many Patents: Imperfect Intellectual Property Rights in the Pharmaceutical Industry. *SSRN.* Available https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3748158

^{xii} 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 <https://www.sciencedirect.com/science/article/abs/pii/S1359644618301417?via=ihub>

^{xiii} 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 <https://pubmed.ncbi.nlm.nih.gov/25664700/>

^{xiv} 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 <https://cip2.gmu.edu/2024/05/20/pharmaceutical-nominal-patent-life-versus-effective-patent-life-revisited/>

^{xv} Grabowski et al. 2021. Continuing trends in U.S. brand-name and generic drug competition. *J Med Econ.* 24(1). 908-17. https://www.tandfonline.com/doi/10.1080/13696998.2021.1952795?url_ver=Z39.88-2003&rft_id=ori:rid:crossref.org&rft_dat=cr_pub%20pubmed#abstract

^{xvi} See MJ Summersgill, AL Major, H Hanson, "Claim Limits and Claim Narrowing: Tools that Promote Efficiency and Fairness, IP & Technology Law Journal, Vol. 36, No. 7, July-Aug. 2024. https://www.wilmerhale.com/-/media/files/shared_content/editorial/publications/documents/20240711-ip-tech-law-journal--claim-limits-and-claim-narrowing-tools-that-promote-efficiency-and-fairness.pdf; *Scheduling Order for Hatch-Waxman Patent Infringement Cases*, Chief Judge Connolly, U.S. District Court for the District of Delaware, <https://www.ded.uscourts.gov/sites/ded/files/chambers/Scheduling%20Order%20for%20Hatch-Waxman%20Patent%20Infringement%20Cases.pdf>

^{xvii} Philipson T., Zhang D., Zhao Q. (June 2025). International Comparison of Prices for Drug Prescriptions. *University of Chicago.* Available <https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2025/06/Policy-Brief-International-Price-Differences-for-Drug-Prescriptions-June-7.docx.pdf>

^{xviii} Altarum Institute. Projections of the Non-Retail Prescription Drug Share of National Health Expenditures. July 2022. Available <https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2025/06/Policy-Brief-International-Price-Differences-for-Drug-Prescriptions-June-7.docx.pdf>