

**Statement for the Record
by the Biotechnology Innovation Organization
Before the Subcommittee on Courts, Intellectual
Property, Artificial Intelligence, and the Internet**

**“Medicines and IP: Balancing Innovation and Access”
June 4, 2026**

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide this testimony to the Subcommittee on Intellectual Property, Artificial Intelligence, and the Internet on this important topic.

BIO is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech startups to some of the world’s largest biopharmaceutical companies—all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients’ lives.

The United States remains a global leader in the biosciences. In 2023, bioscience companies employed 2.29 million Americans across nearly 150,000 individual business establishments with a footprint in every U.S. state. The bioscience industry continues to employ a highly-skilled and STEM-intensive workforce that is reflected in its high-wage jobs. In 2023 the average U.S. bioscience worker earned more than \$132,000 per year, which is \$60,000 or 83 percent more than the nation’s private sector average. The total economic impact of the bioscience industry on the U.S. economy, as measured by overall output, totaled more than \$3.2 trillion in 2023.¹

That leadership is being challenged by our foreign competitors, especially the People’s Republic of China. As the National Security

¹ Teconomy Partners, The U.S. Bioscience Economy: Driving Economic Growth and Opportunity in States and Regions (2024), available at <https://bio.widen.net/s/hflmb92hwx/the-us-bioscience-economy-driving-economic-growth-and-opportunities-in-states-and-regions>

Commission on Emerging Biotechnology has warned, “America has led in biotechnology since the 1970s, but the landscape is rapidly changing. A little over a year ago, we asserted that the United States was still ahead, despite considerable efforts by the People’s Republic of China to surpass us. We now believe the United States is falling behind in key areas of emerging biotechnology as China surges ahead.”²

Biotechnology is an intellectual property intensive enterprise. The well documented lengths to which our foreign competitors have gone to steal our IP, and the work of this Subcommittee has so amply documented, illustrate just how critical IP protections are to our leadership in this field. While BIO continues to believe that IP theft remains a critical national security threat, our leadership will ultimately depend on whether we continue to value and protect our IP here at home. Short-sighted Supreme Court decisions, and proposals now pending before Congress, threaten to undermine what was once the Gold Standard of IP law. Our global leadership hangs in the balance.

BIO believes that the Subcommittee has framed the question correctly. Successfully balancing legal protections for innovators with public access to new cures remains the challenge. Our patent system reflects a social contract between the public and innovators. Article 1, section 8, clause 8 of the Constitution empowers Congress “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” In return for that limited protection, innovators must make their inventions public so the world can learn from them, and they become public domain.

IP ENABLES BIOTECH INNOVATION AND PROPELS THE QUINTESSENTIALLY AMERICAN ENTREPRENEURIAL JOURNEY

The vast majority of BIO’s members are small and medium sized enterprises (SMEs) that currently do not have products on the market. As such, BIO’s members rely heavily on the strength and scope of their IP to generate investments needed to develop and commercialize their technologies. The strength of the global IP system, therefore, is critical to

² National Security Commission on Emerging Biotechnology, Final Report: Message from the Chair and Vice Chair (April 2025), available at <https://www.biotech.senate.gov/final-report/chapters/>

realize and deliver promising biotechnology solutions to humanity by providing a framework to unite and empower biotech innovators and their ecosystems to improve lives.

Strong and predictable IP systems cultivate partnerships around the world, enhance knowledge sharing, support the entrepreneurial journey, and ultimately ensure that innovation is resourced and funded so that technologies with the potential to deliver better care for patients and products for consumers are developed. Biotechnology business models for human health solutions are built on collaborations between universities, small biotechnology companies, venture capital, and larger private company partners. Governments support this model, and benefit from the development of biotechnology innovations into products when they establish enabling environments for innovation.

The human health biotechnology industry relies heavily on patents, trade secrets, and regulatory data protection for legal certainty needed to attract investments. The development of a single biotechnology product often takes scientists more than a decade to commercialize, and billions of dollars of capital investment, a significant amount of which comes from private sources.³

Biotechnology product development is also fraught with high risk – the vast majority of researched biotech therapies fail to reach the marketplace. Fully 90% of all candidates fail to make it all the way through clinical trials to FDA approval. In addition, while biotech health inventions are entitled to the same patent term as all other inventions – twenty years from the time they are filed – they face the additional hurdle of a rigorous pre-launch regulatory review process during which they may lose between eight to ten years of the patent life.

Venture capital firms invest in capital-intensive, long-term, and high-risk research and development endeavors only if they believe that there will be an attractive return on their investment. Patents and regulatory data protection help provide this assurance. Intellectual property plays an important role in

³ “Private Sector’s Critical Role in Biomedical Innovation”, Cost & Value of Biopharmaceuticals - <https://www.bio.org/toolkit>

the entire cycle, from the earliest steps of idea generation through bringing a product to market. According to a patent survey conducted by researchers at the University of California Berkeley, 73% of the biotechnology entrepreneurs reported that potential funders, such as venture capitalists, angel investors, and commercial banks, indicated patents were one of the most important factors in their investment decisions.⁴ Without strong and predictable patent protection, investors will shy away from investing in biotech innovation and will simply put their money into projects or products that are less risky – without regard to the great value that biotechnology offers society.

PHARMACEUTICAL PATENTS DO NOT UNDULY HINDER GENERIC COMPETITION

While extravagant claims have been made that pharmaceutical patents delay competition well beyond the 20-year patent term envisioned under the Patent Act, real world experience tells a different story.

For example, Professor Robin Feldman, in her article *May Your Drug Price be Evergreen*,⁵ paints “an image of a system that provides for repeated creation of competition-free zones, pushing a competitive market further and further out into the future. The problem is not only pervasive and persistent, but it is also growing across time.” I-MAK, in its 2018 brochure *Overpatented, Overpriced* similarly writes of monopoly periods of 40 years or more during which pharmaceutical originator companies are said to “block competition.”⁶

Despite claiming to prove that generic or biosimilar competition is being “blocked” and “pushed out further and further into the future,” none of these authors seems to have made an effort to ascertain when, in the real world, such competition does occur. The “Evergreen Drug Patent Database”⁷ at UC College of the Law, San Francisco, for example, purports to document strategies “used by pharmaceutical companies to extend the life of their drug

⁴ Graham, Stuart J. H. and Sichelman, Ted M., Why Do Start-Ups Patent? (September 6, 2008). Berkeley Technology Law Journal, Vol. 23, 2008, available at <http://ssrn.com/abstract=1121224>

⁵ Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, Pages 590–647, available at: <https://academic.oup.com/jlb/article/5/3/590/5232981>

⁶ <https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>

⁷ <https://www.uchastings.edu/2022/02/02/evergreen-drug-patent-database-center-forinnovation/#:~:text=Evergreening%20is%20a%20strategy%20used,often%20based%20on%20minor%20modifications>

patents and monopoly periods by obtaining additional protections” without once accounting for actual generic entry dates. As a result, the database inaccurately lists hundreds of drugs that already had years of real-world generic competition as purportedly still benefiting from “extended monopolies.”⁸

Yet, the actual time an originator drug spends in the market in the absence of generic or biosimilar competition, and the market entry dates of generic and biosimilar drugs, are all amenable to empirical study. Much information is already available in the published literature. If Prof. Feldman’s and I-MAK’s claims to ever-extended monopolies are right, one would expect real-world launch dates of generic or biosimilar drugs to occur later and later.

This is not the case. For small molecule drugs, the time from FDA approval of an originator drug until the date a generic first enters the marketplace has been studied extensively since at least the mid-1990s. Different authors using a range of methodologies have reported notably similar results. Lietzan and Aciri, in a study of 224 New Drug Applications report an average time to generic entry of 11.3 years; for the 79 New Molecular Entity drugs in their sample the average time was 13.3 years.⁹ An earlier study by the same authors of 227 new drugs that had received patent term extension (PTE) under 35 USC 156 between 1984 and 2018 yielded a mean effective market life of 12.62 years.¹⁰ Beall et al., in a study of 170 top selling drugs with a first generic equivalent approved between 2000 and 2012, found that originator drugs that had received PTE yielded a median effective market life of 13.75 years, compared with 10.0 years for drugs that were ineligible for PTE.¹¹ Wang et al. reported a median period of 12.5 years for 175 new drugs

⁸ A published audit of the UC Hastings database found that generic competition launched, in fact, on average 84 months (seven years) before the Hastings Database implies it would. E. Lietzan and K. Aciri, Solutions Still Searching for a Problem: A Call for Relevant Data to Support “Evergreening” Allegations. *Fordham Intell. Prop., Media & Entertainment. L. J.* 33, 2022, available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4230310 Other methodological problems have also been documented: <https://cip2.gmu.edu/2021/03/04/uc-hastings-evergreendrug-patent-search-database-a-look-behind-the-statistics-reveals-problems-with-this-approach-to-identifying-andquantifying-so-called-evergreening/>

⁹ E. Lietzan and K. Aciri, Solutions Still Searching for a Problem: A Call for Relevant Data to Support “Evergreening” Allegations. *Fordham Intell. Prop., Media & Entertainment. L. J.* 33, 2022, available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4230310

¹⁰ E. Lietzan and K. Aciri, Distorted Drug Patents, 95 *WASH. L. REV.* 1317, 1326-29 (2020)

¹¹ Reed F. Beall et al., Patent Term Restoration for Top-Selling Drugs in the United States, 24 *DRUG DISCOVERY TODAY* 20, 20 (2019).

(ranging from about 13.8 years for NMEs to 10 years for new formulations).¹² Gupta (2020) reports an average time to generic entry of 13.3 years for a set of 370 new drugs.¹³ Hemphill and Sampat, in a cohort of 119 NME drugs approved 2001-2010 found the period from originator approval to generic entry of 12.1 years.¹⁴ Grabowski et al. report that new molecular entities experiencing initial generic entry in 2017-2019 had yielded an effective market life of 14.1 years (13 years for those with sales over \$250 million).¹⁵ Their studies also document that the average time to generic entry has been remarkably stable (around 13.5 years) since at least the mid-1990s.

More recently, the USPTO and the FDA examined the issue with similar results. The 2024 Drug Patent and Exclusivity Study¹⁶ confirmed what decades of experience and independent research had long documented. The average period of exclusivity across these products is 11.4 years — less than the 20-year length of a full patent term.

According to the study, “[f]or at least some of the drug products studied, a generic launch occurred before all of the Orange Book-listed patents associated with that drug product expired. For these products, the study provides data on the actual years of market exclusivity enjoyed by the [New Drug Application] applicant prior to the generic launch date. For the drug products in the study with identified launch of generic competition, the market exclusivity ranged from about 3 to about 16 years.”¹⁷ As the USPTO noted, “[t]he results illustrate that 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 . . . [S]imple counts of patents can be misleading when every patent is counted equally, because the number of patents does not provide a

¹² B. Wang et al., Variations in Time of Market Exclusivity Among Top-Selling Prescription Drugs in the United States, *JAMA Intern Med.* 2015;175(4):635-637, available at

<https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2109854>

¹³ C. Gupta, One Product, Many Patents: Imperfect Intellectual Property Rights in the Pharmaceutical Industry, 2021, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3748158

¹⁴ Hemphill and Sampat, *J. Health Econ.* 31 (2012) 327-339

¹⁵ Grabowski et al., Continuing Trends in U.S. Brand Name and Generic Drug Competition, 24 *J. MEDICAL ECONOMICS* 908 (2021)

¹⁶ USPTO, Drug Patent and Exclusivity Study (2024) at 4, available at

https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf

¹⁷ *Id.* at 4.

clear picture of the landscape without a review of the scope of the claims in each patent.”¹⁸

The mere existence of an unexpired patent does not foreclose competition. As the PTO study notes, “[T]his study identifies several examples of such follow-on patents . . . In some of these examples, the data indicates that a generic competitor drug was approved and launched, while later patents directed to follow-on innovation and listed in the Orange Book were still in force. For example, a generic competitor launched a competing product to LIPITOR, before all the patents expired.”¹⁹

This research indicates that legislation attempting to limit the number of patents an innovator may obtain or enforce will not enhance competition. It will rather limit the ability of innovators to obtain capital and further what is already a risky and time consuming business model.

CONTINUATION PATENTS AND TERMINAL DISCLAIMERS ARE NOT BEING ABUSED BY INNOVATORS

Proponents of the “Eliminating Thickets to Increase Competition Act” or the “ETHIC Act” have argued that patent families joined by terminal disclaimers represent a particular form of patent abuse and patentees should be limited to enforce only one patent in a family.

Perhaps the most curious aspect of the proposed legislation is that it would apply only to drug patents, violating the longstanding principle of technology neutrality in our patent system. This policy would run completely counter to the findings of a recent study of large patent families by the USPTO’s Office of Patent Quality Assurance (OPQA) which found that, while large patent families are found across technologies, “[l]arge patent families were not commonly found in allowed pharma applications.”²⁰ This finding is of special interest because the study was prompted by congressional

¹⁸ Id. At 57.

¹⁹ Id. at 5.

²⁰ USPTO, Office of Patent Quality Assurance, Studying Applications with Large Patent Families (June 2025), available at https://www.uspto.gov/sites/default/files/documents/USPTO_Hour_Large_Patent_Family_Study_Final_06042_025_CleanCopy_brand508c.pdf

inquiries into supposed pharmaceutical “patent thickets.”²¹ The USPTO found the exact opposite to be true. OPQA Director Sandie Spyro noted, “[t]his study was in large part, again, driven by concerns regarding drug pricing, but the population, it was a very small amount [of] our sample set.”²²

This proposed legislation would render patents unenforceable without any showing of invalidity. There is no precedent for nullifying duly granted patents in this way. The evidence argues against the reasons given for its enactment.

PHARMACEUTICAL PATENTS ARE HIGH QUALITY

Some have argued that pharmaceutical patents are of exceptionally poor quality and Congress needs to take aggressive steps to reign in this supposed abuse. Again, the facts speak otherwise.

In a study of patents challenged in Patent Trial and Appeal Board, the USPTO found that “Orange Book-listed patents have had a greater percentage of claims upheld in a final written decision.”²³ If anything, pharmaceutical patents are of higher quality than those of other technologies.

CONCLUSION

Our patent system serves the important function of fostering innovation and US global leadership in the life sciences. This continued leadership is being challenged for our foreign competitors, especially the People’s Republic of China. Further weakening patent protections would aid our foreign competitors at the expense of this strategically important sector. Doing so, when the facts clearly indicate that allegations of anticompetitive abuse of the patent system hindering access to medicines are demonstrably false, would harm our security, our economy, and public health with no benefit to patients.

Thank you for the opportunity to present these comments.

²¹ Letter to the Honorable Howard Lutnick from Members of Congress (Dec. 5, 2025) available at https://arrington.house.gov/uploadedfiles/patent_thickets_letter_to_commerce_final_12.5.25.pdf

²² Dani Kass, USPTO Says Study Disproves Pharma Patent Thicket Claims, Law360 (June 4, 2025).

²³ USPTO Orange Book Patent/Biologic Patent Study, FY 25 Update at 4, available at https://www.uspto.gov/sites/default/files/documents/Orange_Book_Biologics_Trial_Stats_July_2025.pdf