Biocom
California's Advocate for Life Science

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Written Statement for the Record
Prepared for the U.S. House Committee on the Judiciary
Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
Concerning Hearing Titled *Medicines and IP: Balancing Innovation and Access*

Submitted for the Record: May 29, 2026

Biocom appreciates the opportunity to submit this statement for the record regarding the upcoming hearing entitled *Medicines and IP: Balancing Innovation and Access*.

Biocom is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics, and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors, and service providers. Biocom drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products and technologies that improve health and quality of life. California's life sciences industry generates over $395 billion in total economic output, supports 1.15 million jobs, and produces $65.6 billion in labor[1].

The United States has built the world's most successful biomedical innovation ecosystem through a unique partnership among federal agencies, research institutions, academic centers, private investors, entrepreneurs, and innovative companies. Strong and reliable patent protections are a foundational component of that ecosystem. They provide the certainty necessary to attract capital, support technology transfer, encourage risk-taking, and ultimately deliver new medicines and cures to patients.

Patents Enable High-Risk Biomedical Innovation

Life science innovation is unlike most other sectors of the economy. Developing a new therapy often requires years of research, extensive clinical testing, significant regulatory review, and substantial capital investment before a product ever reaches a patient. The overwhelming majority of investigational therapies fail before commercialization, making biomedical innovation one of the highest-risk investment environments in the world.

Patents provide the predictability necessary for investors and innovators to undertake these risks. Without strong intellectual property protections, it becomes significantly more difficult for companies to secure the financing needed to advance promising discoveries through development, clinical trials, manufacturing, and regulatory approval. Investors are far less likely to support high-risk scientific ventures if the intellectual property underlying those investments can be weakened, taken away, or subjected to increased uncertainty. A strong patent system therefore does not merely reward successful innovation; it enables that innovation to occur in the first place.

[1] Biocom California 2025 Economic Impact Report Databook. https://www.biocom.org/eir/

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Small Innovators Depend on Reliable Patent Rights

Much of today's biomedical innovation originates from small companies, university spinouts, and startup enterprises pursuing breakthrough therapies in areas such as cancer, rare diseases, neurological disorders, cell and gene therapies, and precision medicine, among many others. Many early-stage innovators operate for years without generating revenue and depend on outside investment to sustain research and development efforts. These companies often possess few assets beyond their scientific expertise and intellectual property portfolios. Patents are frequently their most valuable business asset and serve as the basis for attracting investment, forming partnerships, licensing technology, and advancing products toward commercialization.

Policies that increase uncertainty surrounding patent rights can have a disproportionate impact on smaller innovators, which don't have the resources to face increased costs, reduced predictability, and weakened IP protections. Congress should carefully consider the effect that patent-related reforms may have on the next generation of innovative companies developing future treatments and cures.

Patents and Technology Transfer Work Together to Deliver Patient Benefits

Strong patent protections are essential to the success of the technology transfer system that has made the United States the global leader in scientific commercialization. The Bayh-Dole Act transformed federally funded research by allowing universities and small businesses to retain title to inventions developed with federal support and license those technologies for commercial development. Prior to the Bayh-Dole Act, many federally funded research candidates remained undeveloped and promising technologies and medicines never reached patients. The landscape Bayh-Dole enabled has led to the creation of thousands of startups, millions of jobs, and countless products that have improved and saved lives.

The success of Bayh-Dole depends on the availability of meaningful intellectual property protections. Patents provide the legal framework that allows universities, research institutions, and small businesses to attract private-sector partners willing to invest the substantial resources necessary to transform scientific discoveries into approved products. Weakening patent protections would undermine the incentives that have made the American technology transfer system the global standard and could slow the translation of federally funded research into patient benefit.

The Complexity of Life Science Products Requires Several Patents

Recent policy discussions have increasingly focused on concerns regarding alleged "patent thickets" in the biopharmaceutical sector. While promoting competition and patient access remains an important policy objective, any reforms should be grounded in evidence and carefully evaluated for their impact on future innovation. Multiple studies and analyses, including findings from the U.S. Patent and Trademark Office, have cast doubt on claims that so-called patent thickets are a primary driver of delayed generic or biosimilar competition. The USPTO's 2024 Drug Patent and Exclusivity Study and subsequent analyses regarding large patent families found little evidence supporting the

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narrative that the number of patents associated with a medicine directly delays competition or prevents generic entry[2]. In practice, generic and biosimilar manufacturers generally need only address patents relevant to their proposed products, and courts routinely employ case-management tools that focus litigation efficiently on representative claims rather than requiring every patent in a portfolio to be litigated.

Follow-On Innovation and Continuation Practice Strengthen Innovation

The narrative surrounding "evergreening" similarly overlooks the realities of biomedical research and development. Biomedical discoveries rarely occur as a single breakthrough followed by immediate commercialization. Instead, innovation is iterative. Researchers build upon foundational discoveries to develop improved formulations, manufacturing methods, delivery mechanisms, dosing regimens, diagnostics, and additional therapeutic applications. These follow-on innovations often represent significant scientific advances and can meaningfully improve patient outcomes and safety. Protecting these advancements encourages continued investment in improving therapies and expanding treatment options for patients.

The patent system has long recognized and supported this process through continuation practice and the ability to seek patent protection for improvements and additional inventions arising from the same underlying scientific platform. Continuation applications and terminal disclaimers are longstanding and legitimate features of the U.S. patent system that promote administrative efficiency and appropriate patent examination. These subsequent inventions are subject to the same statutory patentability requirements as any other invention, including novelty, utility, and nonobviousness. The USPTO often requires terminal disclaimers for closely related inventions to ensure that patents remain commonly owned and expire simultaneously, preventing any improper extension of the patent term.

Proposals to significantly restrict the ability of innovators to enforce valid patents by limiting assertion rights to a single patent within broadly defined "patent groups" could undermine the existing Hatch-Waxman Act and Biologics Price Competition and Innovation Act (BPCIA) frameworks, enable strategic gaming by generic or biosimilar applicants, increase uncertainty for investors, and disproportionately harm smaller biotechnology companies.

Importantly, limiting the ability of innovators to protect legitimate improvements would discourage investment in continued research and development and could reduce incentives to pursue new therapeutic applications and technological advancements.

Strong Patents Are Essential to U.S. Competitiveness

The United States currently leads the world in biotechnology and biopharmaceutical innovation, but that leadership cannot be taken for granted. Foreign competitors, particularly China, are investing aggressively in biotechnology, advanced manufacturing, artificial intelligence, and life

[2] *Drug Patent and Exclusivity Study*, U.S. Patent and Trademark Office; *Studying Applications with Large Patent Families*, U.S. Patent and Trademark Office, at 3.

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sciences. These efforts are supported by substantial government resources and long-term strategic planning designed to challenge U.S. leadership in critical technologies.

To remain globally competitive, the United States must continue to foster an environment that rewards innovation, attracts investment, and encourages scientific entrepreneurship. Stable and reliable patent protections are a critical component of that environment. Policies that weaken patent rights, increase litigation uncertainty, or discourage investment in research-intensive industries risk undermining America's competitive advantage at a time when global competition is intensifying.

At a time when foreign competitors, particularly China, are aggressively investing in biotechnology and advanced technologies, policymakers should carefully consider whether weakening reliable U.S. patent protections could unintentionally undermine American leadership in biomedical innovation and reduce incentives for the development of future lifesaving treatments.

Conclusion

America's biomedical innovation ecosystem has produced groundbreaking therapies, strengthened the economy, created high-quality jobs, and improved the lives of patients around the world. Strong patent protections have been a central pillar of that success. As the Committee evaluates pharmaceutical patent policy, we encourage policymakers to recognize the essential role patents play in supporting investment, enabling technology transfer, encouraging scientific risk-taking, fostering competition through innovation, and maintaining U.S. leadership in the life sciences.

Thank you for your consideration of these recommendations. For additional information, please contact Biocom's Federal Advocacy Manager, Megan Kastner, at mkastner@biocom.org. Biocom stands ready to work with Congress to ensure that the United States continues to maintain a patent system that promotes discovery, rewards innovation, and delivers the next generation of lifesaving treatments to patients.

Sincerely,
Tim Scott

President & CEO
Biocom