NATIONAL ASSOCIATION OF Manufacturers

June 4, 2026

The Honorable Darrell Issa
Chair
Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
Committee on the Judiciary
U.S. House of Representatives
Washington, DC 20515

The Honorable Hank Johnson
Ranking Member
Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
Committee on the Judiciary
U.S. House of Representatives
Washington, DC 20515

Re: *Medicines and IP: Balancing Innovation and Access* Hearing

Dear Chair Issa and Ranking Member Johnson,

The National Association of Manufacturers ("NAM") appreciates the opportunity to share manufacturers' support for the Bayh-Dole Act and its critical role in biopharmaceutical innovation and commercialization ahead of today's hearing on *Medicines and IP: Balancing Innovation and Access*.

The NAM is the largest manufacturing association in the United States, representing manufacturers of all sizes across all 50 states and in every industrial sector. Manufacturing contributes $2.96 trillion to the U.S. economy annually and employs nearly 13 million people in the U.S. Manufacturers in the U.S. conduct the majority (52.9%) of all private-sector R&D in the nation. In the drive for continual innovation, biopharmaceutical companies make up the largest share of that investment, accounting for 36.1% of all manufacturing R&D, spending $146.1 billion in 2023.[1, 2] In fact, the industry invests 20 times more than it did in the 1980s; over the last 40 years, pharmaceutical R&D investment has compounded at over 9% a year.[3]

Biopharmaceutical companies are among the most innovative manufacturers—researching, developing, and producing incredible new medicines that treat and cure complex conditions. On average, bringing a medicine to market requires an investment of approximately $2.3 billion[4] over 10 to 15 years.[5] Further, just 12% of the investigational drugs that enter a phase I clinical trial are ultimately

[1] U.S. Bureau of Economic Analysis, "Table 5.6.5. Private Fixed Investment in Intellectual Property Products by Type," U.S. Department of Commerce, https://apps.bea.gov/iTable/?reqid=19&step=2&isuri=1&categories=survey&_gl=1*s8r6xc*_ga*MTAzNzYwOTg4OC4xNzA3NzY0NTQz*_ga_J4698JNNFT*MTcwOTA2MzE0NS40LjEuMTcwOTA2NTMzMC42MC4wLjA.#eyJhcHBpZCI6MTksInN0ZXBzIjpbMSwyLDNdLCJkYXRhIjpbWyJjYXRlZ29yaWVzIiwiU3VydmV5Il0sWyJOSVBBX1RhYmxlX0xpc3QiLCIzMzEiXV19.

[2] National Association of Manufacturers, "Facts About Manufacturing," https://nam.org/mfgdata/facts-about-manufacturing-expanded/.

[3] National Association of Manufacturers (2023), "Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing," https://documents.nam.org/COMM/NAM-Creating%20Cures,%20Saving%20Lives_FINAL3.pdf.

[4] Deloitte. "Seize the digital momentum: Measuring the return from pharmaceutical innovation 2022" (January 2023). Available at https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-seize-digital-momentum-rd-roi-2022.pdf.

[5] Pew Charitable Trusts. "From Lab Bench to Bedside: A Backgrounder on Drug Development" (March 2014). Available at https://www.pewtrusts.org/en/research-and-analysis/articles/2014/03/12/from-lab-bench-to-bedside-a-backgrounder-on-drug-development.

approved by the FDA, meaning the other 88% fail along the way[6]—to say nothing of the many discoveries that never make it to clinical trials. This cycle of discovery and development makes biopharmaceutical manufacturers economic engines—the industry invests more than $100 billion annually, which accounted for $355 billion in value-added output to the U.S. economy in 2021, and supports an additional 4.1 jobs for every person employed by a biopharmaceutical manufacturer.[7]

For patients with diseases and conditions that do not yet have a cure or therapy, continued R&D into potential medicines is paramount. Manufacturers work tirelessly to help these patients overcome their afflictions so they can lead healthy and happy lives. For patients with diseases or conditions with existing therapies, manufacturers continue to work to find better medications that work faster, have fewer side effects, and keep patients well over the long term. The possibility of new and improved prescription drugs, and improved public health, drives biopharmaceutical manufacturers to continue extensive R&D.

U.S. leadership in science, technology, and innovation, along with economic growth and global competitiveness, requires a robust domestic scientific enterprise. Manufacturing has always relied on inventors for new products and on engineers to determine how to build them—but the digitalization of the modern manufacturing shop floor has made scientific breakthroughs and rapid technological evolution more vital than ever for our industry. Today's manufacturers play a critical role in transforming research discoveries into scalable products, processes, and technologies that strengthen supply chains and support quality jobs.

To fulfill this role, manufacturers require a stable, pro-growth policy environment that includes protection of the Bayh-Dole Act and other aspects of the U.S. intellectual property (IP) system that enable technology transfers.

As this Subcommittee knows, IP rights give legal protection to creativity and invention, providing an essential incentive for creators and inventors to make bold, risky investments. As such, IP protections are critical for biopharmaceutical manufacturing. Manufacturers support robust legal protection of their IP rights, in particular patents, to ensure that their inventions will be secure as they produce life-saving and life-improving therapies and medications. Clearly defined IP rights, supported by a stable policy environment, also give inventors and creators the confidence to collaborate and improve manufacturing processes and products.

Protecting the Bayh-Dole Act

The Bayh-Dole Act of 1980 is an important part of the legal framework protecting IP and incentivizing scientific and technological discovery. Bayh-Dole promotes the development of federally funded discoveries into commercial products, such as prescription drugs. Before the Bayh-Dole Act, the fruits of federally funded research often remained stuck in the lab, as private-sector entrepreneurs and investors were unwilling to license innovative technologies given the uncertain path to commercialization. Just 4% of patents stemming from federally-funded research had been licensed to private companies prior to Bayh-Dole. By allowing the entities—universities, federal laboratories, and small businesses—that conduct this research to own and license patents for the resulting inventions, Bayh-Dole led to an explosion in the number of such patent licenses, enabling not only the

[6] DiMasi, Joseph A., Grabowski, Henry G., and Hansen, Ronald W. "Innovation in the pharmaceutical industry: New estimates of R&D costs." J Health Econ. 2016; 47:20-33.

[7] National Association of Manufacturers. "Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing" (October 2023). Available at https://documents.nam.org/COMM/NAM-Creating%20Cures,%20Saving%20Lives_FINAL3.pdf.

commercialization of those inventions, but also sustaining more than six million jobs and adding nearly $2 trillion to U.S. GDP since 1996.[8]

Manufacturers have been concerned by proposals to allow federal agencies to seize patent rights licensed by manufacturers from federally-funded research institutions, unless the licensees abided by arbitrary price controls—the imposition of which would violate Bayh-Dole. The NAM advocated strongly against the Biden Administration's "march-in" proposal and was heartened when the Trump Administration recognized that it was ill-advised by declining to make the draft guidance permanent. Manufacturers urge that the draft guidance be officially rescinded.

Similarly, manufacturers would have significant concerns with any new federal actions that create disincentives to the transfer into the marketplace of inventions stemming from federally funded research. This would include any proposal to impose a tax on the royalties that universities earn from licensing patented discoveries made with federal grants. While intended to give U.S. taxpayers a return on their investment in that research, such a misguided proposal would ignore that the taxpayer *already* receives a considerable return on this investment, in the form of the veritable torrent of economic activity and jobs spurred by Bayh-Dole and the massive corporate and personal tax revenue generated by that economic activity. Biopharmaceutical discoveries also have the added return of increasing people's health and improving their lives. Imposing such a tax would weaken technology transfers, in two ways: by undermining Bayh-Dole's incentive for companies to take on the expensive and risky follow-on investment required to turn a lab discovery into a marketable product, and by leading federally funded research institutions to scale back their efforts to license their inventions.

Maintaining a Pro-Innovation Patent Registration Fee System

More broadly, manufacturers would have significant concerns with any new proposal to increase federal revenue by replacing the current flat fee for patent registration and maintenance with any kind of percentage-based charge on the assessed value of a patent. Taxing an economic activity often discourages that activity. Such a tax on innovation and its commercialization would disrupt efforts to maintain and strengthen America's global technological and scientific leadership.

Such a proposal could also stifle business creation, especially new ventures primarily based on patented innovations. These patents often represent a startup's primary assets, which it can use to attract early-stage venture capital while it operates at a loss for years, as is often the case. Forcing a resource-limited company to pay a significant annual tax based on a patent's potential, but unproven, value would drain cash flow away from essential R&D and scaling efforts.

It is also unclear how the U.S. Patent and Trademark Office would assign a precise, non-arbitrary annual value to patents. Patent valuation is often speculative, volatile, and dependent on future market conditions. An inaccurate or inflated government-assigned value would lead to endless litigation and inject massive uncertainty into the IP system, chilling investment.

Manufacturers caution against imposing patent fees indexed on patent value, which would make the U.S. a global outlier and potentially drive R&D investment and manufacturing to countries with more pro-innovation IP regimes.

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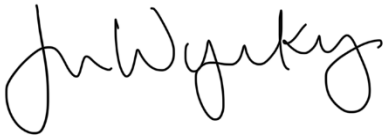
The Subcommittee plans to examine greater access and affordability as part of this hearing, goals that biopharmaceutical manufacturers share. Biopharmaceutical manufacturers are committed to lowering costs for patients, while ensuring innovation continues in the United States.

[8] See https://autm.net/AUTM/media/SurveyReportsPDF/2024-US-AUTM-Infographic-Fillable.pdf.

Manufacturers appreciate the Subcommittee's focus on this topic and look forward to working together to ensure that the U.S. IP system continues to incentivize innovation and technology transfers so America remains the leader in biopharmaceutical innovation.

Sincerely,

Franck Journoud
Senior Director, Technology Policy



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