June 10, 2026

The Honorable Bill Cassidy, M.D.
Chairman, Committee on Health, Education, Labor, and Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, D.C. 20510

Re: USIJ Opposition to the Medication Affordability and Patent Integrity Act and the Ensuring Timely Access to Generics Act of 2025 — Request to Remove Both Bills from the June 17 HELP Committee Markup

Dear Chairman Cassidy:

The Alliance of U.S. Startups and Inventors for Jobs (USIJ) writes to respectfully raise concerns with two bills currently on the Senate HELP Committee's scheduled June 17 markup: the Medication Affordability and Patent Integrity Act and the Ensuring Timely Access to Generics Act of 2025. USIJ is a coalition of American inventors, startups, venture investors, and research institutions dedicated to preserving a strong, reliable U.S. patent system — the cornerstone of American technological leadership and the foundation upon which our nation's biopharmaceutical industry was built.

USIJ shares Congress's commitment to ensuring that Americans have access to affordable medications. We recognize that prescription drug costs impose real burdens on patients, families, and the healthcare system. But USIJ urges this Committee to distinguish between policies that genuinely expand access and reduce costs for patients, and policies that merely weaken patent rights — undermining the incentive structures that have made the United States the global leader in biopharmaceutical innovation. Both bills before the Committee on June 17 fall into the latter category. Rather than lowering drug prices, they would erode the patent system that drives the very discoveries patients depend on.

The stakes could not be higher. The United States biopharmaceutical sector is among the most consequential drivers of American economic strength and global competitiveness. U.S. companies discover and develop more new medicines than any other nation — not by accident, but because our patent system provides the predictability and legal certainty that incentivize the extraordinary capital investment that drug development requires. A single successful drug can require over $2.5 billion in R&D investment and more than a decade of clinical development, with no guarantee of success. Patent protection is the mechanism that enables and supports that tremendous risk, and by which patients ultimately receive breakthrough treatments that would otherwise never be developed. Any legislation that undermines that system does not help patients.

I. The Medication Affordability and Patent Integrity Act Would Burden Innovators and the USPTO Without Benefiting Patients

The Medication Affordability and Patent Integrity Act would impose sweeping new disclosure obligations on life sciences companies, requiring them to submit extensive — and potentially confidential — information related to drug approval to the U.S. Patent and Trademark Office (USPTO). USIJ opposes this bill for three distinct reasons.

- **No demonstrated problem justifies this intervention.** There is no systemic, documented evidence that biopharmaceutical companies are withholding material information from the USPTO in a manner that hinders the patent examination process. Legislation of this scope and consequence should be grounded in evidence of a real problem, not in speculative or anecdotal claims advanced by those who wish to curtail patent rights broadly.
- **The USPTO cannot absorb this mandate.** Director Squires has identified the agency's 837,928-application backlog as an "absolute dumpster fire" and a "total betrayal of American inventors." Layering extensive pharmaceutical disclosure review obligations onto an already overburdened agency will divert examiner time and resources away from core patent examination, delay patent grants across all technology sectors, and ultimately harm the American inventors and startups that depend on timely, high-quality patent protection.
- **Compliance traps will invalidate legitimate patents and chill R&D investment.** The bill's administrative requirements are complex and cumbersome. Accidental or technical non-compliance — not bad faith, not fraud, but paperwork error — could result in patent invalidation. The prospect of having a core asset wiped out by a compliance misstep will cause precisely the chilling effect on R&D investment that policymakers seeking to promote innovation should be working to prevent. Investors will reduce capital commitments. Startups will struggle to attract funding. New treatments will not be developed.

The Medication Affordability and Patent Integrity Act will not lower drug prices. It will lengthen the wait for new medications, weaken innovators' ability to attract investment, and impose regulatory costs on an agency already struggling to fulfill its core mission.

II. The Ensuring Timely Access to Generics Act Is Legally Unsound and Addresses a Problem That Does Not Exist

The Ensuring Timely Access to Generics Act is premised on the claim that pharmaceutical companies routinely "extend" patent exclusivity to block generic competition. That premise is legally incorrect and empirically unsupported.

- **It is not legally possible to "extend" a patent's lifespan.** A U.S. patent grants exclusivity for a fixed statutory term. It expires. It cannot be renewed or extended by the patent holder. Filing new patents on genuine innovations related to a drug is not "extension" — it is the normal and expected functioning of the patent system, in which incremental advances receive incremental protection. The bill conflates legitimate innovation with abuse, and in doing so would penalize precisely the kind of iterative scientific progress that delivers better treatments to patients.
- **Generics already dominate the U.S. market.** Generic drugs account for more than 90 percent of all prescriptions filled in the United States. Biosimilars, while still scaling, are making meaningful inroads in the biologics market. The Hatch-Waxman Act and the Biologics Price Competition and Innovation Act already provide robust, carefully balanced

frameworks for generic and biosimilar entry. Before Congress legislates to "fix" a system of generic access, it should ask: what evidence demonstrates that this system is broken?

- **Weakening patent rights is not a drug pricing solution — it is a drug development deterrent.** If the underlying premise of this bill is that pharmaceutical companies should face shorter or narrower patent protection, Congress should be prepared to accept the consequence: fewer new drugs. The nations that have most aggressively weakened pharmaceutical patent rights have not become leaders in drug development. They have become dependent on the innovation driven by the U.S. patent system — the system this bill would erode.

III. A Strong Patent System Is the Right Policy Foundation for Both Innovation and Affordability

USIJ urges the Committee to reject both bills and to focus instead on policies that strengthen the U.S. patent system and reinforce American biopharmaceutical leadership. For more than 200 years, the U.S. patent system has empowered American inventors, entrepreneurs, startups, and universities to lead the world in technological innovation and economic prosperity. The biopharmaceutical sector is one of the clearest examples of that leadership in action — delivering the COVID-19 vaccines, the cancer immunotherapies, the Alzheimer's treatments, and the rare disease breakthroughs that have transformed modern medicine and saved millions of lives.

That leadership is not self-sustaining. It depends on a patent system that provides reliable, enforceable rights that give investors the confidence to commit the extraordinary capital that drug development requires. Legislation that undermines patent quality, validity, or enforceability — even legislation framed as protecting patients — will reduce the capital flowing to drug development, slow the pipeline of new treatments, and ultimately harm the American patients it purports to help.

USIJ stands ready to work with this Committee and with Congress on evidence-based policies that promote both robust innovation and meaningful affordability. We believe those goals are complementary — but only if pursued through approaches that respect the foundational role of the patent system in driving the discoveries that patients need.

For these reasons, USIJ respectfully requests that the Medication Affordability and Patent Integrity Act and the Ensuring Timely Access to Generics Act of 2025 be removed from the June 17 HELP Committee markup. We would welcome the opportunity to discuss these concerns with you or your staff at your earliest convenience.

Respectfully submitted,

Chris Israel
Executive Director
Alliance of U.S. Startups and Inventors for Jobs (USIJ)

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cc: Members of the Senate Committee on Health, Education, Labor, and Pensions