5 Ways the Medication Affordability and Patent Integrity Act Would Weaken U.S. Innovation

Supporters of the Medication Affordability and Patent Integrity Act (S.2658) claim it would prevent drug companies from obtaining supposedly low quality patents by gaming the USPTO and FDA submission process. But it ignores the significant protections already in place, which have been shown to work. Yet, by imposing harsh and unnecessary additional regulatory requirements on drug innovators, the bill would weaken patents, which are critical to encouraging investment in American biotechnology and medical treatments.

Here are five reasons the bill would do more harm than good:

1. It Distorts the FDA's and USPTO's Roles

The FDA judges medicines for safety and efficacy. The USPTO judges inventions for patentability. Drugmakers prepare FDA and USPTO submissions at different times, for different purposes, and under different legal standards.

S.2658 would collapse those key distinctions.

The bill would require drugmakers to send FDA drug-application materials to the USPTO — flooding patent examiners with thousands of pages of documents not relevant to their work.

Laws already punish companies that knowingly withhold relevant information from their FDA submissions and patent applications. Increasing paperwork requirements wouldn't stop bad actors from lying – it would only slow the work of bringing new drugs to patients.

2. It Puts Hard-Earned Intellectual Property at Risk

S.2658 would lower the legal standard required to strip away patent rights — preventing a patent's enforcement due to honest mistakes, not just intentional misconduct. Companies that purchase patents could be punished for failure to comply with the requirements of the bill by previous owners.

S.2658 would also endanger legally protected trade secrets. The bill doesn't include sufficient safeguards to ensure confidential materials submitted to the FDA remain secure when transferred to the USPTO.

By weakening these forms of IP, the bill would make even the most transformative breakthroughs far riskier for investors to finance.

3. It Creates a Legal Trap for Innovators

Under S. 2658, even minor inconsistencies between FDA and USPTO filings could potentially render a patent invalid. Those risks would force drug innovators to spend more time scrutinizing regulatory submissions and less time developing new medicines.

That would also incentivize companies to comb their competitors' submissions for any mistake they could weaponize in court. The result would be higher compliance costs, more litigation, and could disincentivize open communication between drugmakers and regulators.

The Federal Circuit devised today's strict standards for patent challenges after lower thresholds produced what it called a "plague" of litigation. Congress shouldn't recreate that failed system.

4. It Undermines Fairness Across Industries

America's patent laws are designed to protect inventions consistently across industries. But S.2658 could leave life-science patents weaker than other sectors.

The bill would saddle drug patents with more disclosure requirements and greater litigation risks. That could push investors to move capital into other areas, leading to the development of fewer innovative medicines.

It would also set a harmful precedent. If Congress weakens drug patents for political reasons, investors will rightly worry that protections in other fields could be next.

5. It Weakens U.S. Competitiveness

America's strong patent system is the foundation of our biotech leadership. S.2658 would erode that foundation at exactly the wrong time.

Foreign rivals like China are investing aggressively in biotechnology — and rapidly closing the gap. To stay on top, the United States will need to pull more private capital into biopharmaceutical research and development.

Strengthening patent rights is the best way to encourage continued investment in the next generation of treatments.

Bottom Line:

There's no evidence that companies are systematically gaming the USPTO and FDA submission processes. S.2658 would impose substantial risks on innovators without solving any repeated patterns of abuse.

Congress should be working to make drug innovation more efficient — not creating unnecessary and harmful regulatory friction.