June 15, 2026

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

The Honorable Bernie Sanders
Ranking Member
Senate Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Dear Chairman Cassidy and Ranking Member Sanders:

I write on behalf of the Council for Innovation Promotion (C4IP) to express our opposition to the Medication Affordability and Patent Integrity Act (S. 2658).[1] While C4IP shares lawmakers' commitment to ensuring affordable access to generic and biosimilar medicines, this legislation would do nothing to advance that goal. What it would do is single out one field of technology—pharmaceutical and biologic patents—for a uniquely punitive disclosure-and-forfeiture regime that strips away the safeguards distinguishing honest error from deliberate deception, all to address a problem the record does not show exists—and to do so at the very moment American leadership in biotechnology faces its most serious challenge in a generation. C4IP previously raised these substantive concerns about the bill's nearly identical predecessor, S. 2780, in the last Congress.[2]

By way of background, C4IP is a bipartisan coalition chaired by two former directors of the U.S. Patent and Trademark Office (USPTO), Andrei Iancu and David Kappos, who served under the Trump and Obama administrations, respectively. Our board also includes two retired judges of the U.S. Court of Appeals for the Federal Circuit, former Chief Judge Paul Michel and Judge Kathleen O'Malley. It also features two distinguished public servants: Lamar Smith, former U.S. Representative for Texas's 21st congressional district and Chairman of the House Judiciary Committee, and Gary Locke, former Governor of Washington, U.S. Secretary of Commerce, and U.S. Ambassador to China under President Obama. Our mission is to promote strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere.

[1] S. 2658, 119th Cong. (2025), https://www.congress.gov/119/bills/s2658/BILLS-119s2658is.pdf.

[2] Letter from Frank Cullen, Exec. Dir., Council for Innovation Promotion, to Chairman Bernie Sanders & Ranking Member Bill Cassidy, S. Comm. on Health, Educ., Labor & Pensions (Aug. 26, 2024) (regarding S. 2780, 118th Cong.), https://c4ip.org/wp-content/uploads/2024/08/C4IP-Letter-RE-The-Medication-Affordability-and-Patent-Integrity-Act.pdf.

S. 2658 would require sponsors and holders of drug and biologic applications to submit to the USPTO information "material to patentability" that they provide to the FDA, along with the FDA's responses, and to certify to each agency that their submissions are consistent. Most consequentially, it would add a new section 274 to the Patent Act giving accused infringers a defense whenever the patent owner—or any predecessor owner—"negligently or intentionally" failed to disclose required information. As we cautioned in our earlier letter, that structure invites infringers to weaponize minor reporting discrepancies against otherwise valid patents.

The section 274 defense essentially creates a dramatic and unjustified change in the doctrine of inequitable conduct. Sitting *en banc* in *Therasense, Inc. v. Becton, Dickinson & Co.*, the Federal Circuit (the appellate court that hears all patent appeals) held that a patent may be rendered unenforceable for nondisclosure only on clear and convincing evidence of a specific intent to deceive the USPTO, and it expressly rejected negligence—even gross negligence—as a sufficient basis.[3] S. 2658 discards that standard, and for one field of technology alone. A clerical oversight in a voluminous cross-agency submission could hand an infringer a complete defense even though no one intended to deceive and the patent is otherwise valid. And because the defense reaches the conduct of any "predecessor owner," a company that acquired a patent in good faith could lose it over an earlier owner's honest mistake that it had no way to discover. No patent owner in any other industry is held to anything approaching this standard.

The bill compounds the problem by reviving a materiality standard the same court deliberately abandoned. To define what must be disclosed, S. 2658 incorporates the USPTO's regulatory standard—the broad "Rule 56" formulation[4]—rather than the narrower "but-for" standard *Therasense* adopted, under which information is material only if the USPTO would not have allowed the claim had it known.[5] The court rejected the Rule 56 standard for a reason squarely on point: paired with a forgiving intent threshold, it had produced a "plague" of inequitable-conduct charges that drove up litigation costs, discouraged

[3] Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc) (requiring clear and convincing evidence of a specific intent to deceive and rejecting negligence and gross negligence).

[4] 37 C.F.R. § 1.56 (explaining that information is material if, inter alia, it "establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim").

[5] *Id.* at 1290–91 (adopting but-for materiality and rejecting the Rule 56 standard). The court preserved a narrow exception for affirmative egregious misconduct—such as an unmistakably false affidavit—which is material *per se* but still requires clear and convincing proof of intent to deceive. *Id.* at 1292–93. Deliberate misrepresentation to the USPTO thus remains fully actionable without any negligence standard. *See* Belcher Pharms., LLC v. Hospira, Inc., 11 F.4th 1345 (Fed. Cir. 2021) (affirming unenforceability where the patentee withheld from the USPTO statements it had made to the FDA).

settlement, burdened the courts, and strained the USPTO.[6] As the Federal Circuit wrote, "[u]nder [the USPTO's] standard, inequitable conduct could be found based on an applicant's failure to disclose information that a patent examiner would readily agree was not relevant to the prosecution after considering the patentee's argument."[7] By writing that rejected standard into statute and yoking it to a mere-negligence trigger, S. 2658 would recreate—by legislative command, and for a single industry—the very conditions the Federal Circuit spent years dismantling.

None of this is justified by any evidence of a systemic problem. There is no record of frequent or deliberate deception of the USPTO or FDA by pharmaceutical patentees. To the contrary, inequitable conduct is still one of the most routinely pleaded defenses in pharmaceutical patent litigation—generic and biosimilar challengers have every incentive to raise it—yet it rarely succeeds, precisely because the misconduct it alleges is rare.[8] And in the uncommon case of genuinely inconsistent statements to the two agencies, existing doctrine already works: in *Belcher Pharmaceuticals, LLC v. Hospira, Inc.*, the Federal Circuit affirmed that the patent was unenforceable. The case the bill's proponents invoke to show new legislation is needed in fact shows that it is not.

The bill's "consistency" rationale is also misconceived, and in any event already addressed. The FDA and the USPTO ask fundamentally different questions: the FDA asks whether a product is safe, effective, and adequately manufactured—often by comparing it to an existing medicine—while the USPTO asks whether a claimed invention is novel and nonobvious over the prior art. Where statements do genuinely conflict on a matter of fact, current law already compels candor and punishes concealment. Indeed, in 2022, the USPTO issued formal guidance—since incorporated into the Manual of Patent Examining Procedure—making explicit that the existing duty of disclosure extends to statements made to other federal agencies, including the FDA, and that inconsistent positions must be promptly corrected.[9] The duty to disclose material information and remain consistent across agencies thus already exists. What S. 2658 would add is not that duty, but a punitive

[6] *Therasense*, 649 F.3d at 1289–90 (describing the "plague" of inequitable conduct and its costs to the courts, to settlement, and to the USPTO).

[7] *Id.* at 1294.

[8] Inequitable conduct is among the most frequently pleaded defenses in patent litigation yet rarely succeeds, even under the more forgiving standards that existed before *Therasense*. *See* Christian E. Mammen, *Controlling the "Plague": Reforming the Doctrine of Inequitable Conduct*, 24 Berkeley Tech. L.J. 1329 (2009) (defense raised in roughly 40% of patent cases in 2007, and data also shows a widening gap between pleading and success between 2000-2008), https://btlj.org/data/articles2015/vol24/24_4/24-berkeley-tech-l-j-1329-1398.pdf.

[9] Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board, 87 Fed. Reg. 45,764 (July 29, 2022), https://www.govinfo.gov/content/pkg/FR-2022-07-29/pdf/2022-16299.pdf; *see also* MPEP § 2001.06(e) (citing *Belcher*).

new remedy for breaching it—forfeiture of patent rights on a merely negligent omission, untethered from the materiality and intent limits the courts have built into the inequitable conduct doctrine.

These distortions are not speculative. Because materiality is not self-applying—every judgment about what is material can be second-guessed years later by an infringer hunting for a forfeiture defense, and under a negligence standard the patentee need not have judged in bad faith to lose—the only safe course is to over-disclose. Rational applicants will route to the USPTO essentially everything touching the chemistry, manufacturing, and controls section of a drug or biologic application. The Federal Circuit foresaw exactly this dynamic: even under the existing, more demanding duty of disclosure, the threat of unenforceability already drives applicants to inundate examiners with marginally relevant prior art disclosed out of caution rather than genuine significance. Empirical research in the years since confirms the problem has only grown—a shrinking share of filings now accounts for the bulk of cited art, much of it bearing ever less relationship to the claimed invention, while examiners make little use of the applicant submissions they receive, relying instead on their own searches.[10] The result is not better examination but worse—examiner time diverted from finding and applying the closest prior art toward sifting regulatory files that bear little on patentability, at an office already straining under historic backlogs.

S. 2658 also places trade secrets at risk. Much of the manufacturing and analytical information it would route to the USPTO is among the most sensitive material a company holds. The FDA has long experience and a developed framework for protecting such data; the USPTO does not, because patent prosecution files are presumptively public. The bill acknowledges the mismatch by directing the USPTO to craft protective procedures, but it sets no deadline—while the disclosure obligations take effect on enactment. Innovators would thus be forced to file their most sensitive data before the agency has built the systems to safeguard it. That exposure is especially hard to justify because the information serves no examination purpose: with narrow exceptions not relevant here, prior art must be publicly available, so a company's own confidential analytical data is not prior art and will virtually never supply the basis for a rejection.

[10] *Therasense*, 649 F.3d at 1289 (anticipating that the threat of unenforceability would lead applicants to over-disclose). That prediction has held: a small minority of applications now generate the bulk of patent citations, with the average cited reference bearing steadily less technological relationship to the citing patent. *See* Jeffrey M. Kuhn, Kenneth A. Younge & Alan C. Marco, *Patent Citations Reexamined*, 51 RAND J. Econ. 109 (2020) (analyzing citation data through 2014); *see also* Christopher A. Cotropia, Mark A. Lemley & Bhaven Sampat, *Do Applicant Patent Citations Matter?*, 42 Research Policy 844 (2013) (finding that examiners rely almost exclusively on prior art they locate themselves rather than on applicant submissions).

Finally, a change of this magnitude should be made in the committee of jurisdiction. S. 2658 amends Title 35 and rewrites a foundational doctrine of patent enforcement, yet it bypasses the Senate Judiciary Committee and the patent-law expertise that resides there. The substance deepens the concern. Since the first Patent Act in 1790, the U.S. patent system has been technology-neutral—one set of rules for every field, leaving markets and science, rather than the government, to determine where innovation flows. S. 2658 would break with that tradition by singling out a single industry for a uniquely punitive regime. Once Congress signals that patent rights may be selectively weakened for whatever sector is politically salient, no field can rely on the stability of its rights—and it is that stability that underwrites the long-horizon investment on which American innovation depends. The bill should be weighed as patent policy, with consequences across the entire system, not as one more lever in the drug-pricing debate.

These risks are especially ill-timed. American leadership in biopharmaceutical innovation is neither natural nor permanent: as recently as 1990 the industry was centered in Europe, and the United States became its global hub only after a series of deliberate policy choices—prominent among them the strengthening of patent rights through the Bayh-Dole Act, the creation of the Federal Circuit, and Hatch-Waxman itself. That leadership is now under direct and well-documented pressure from China, which has made biopharmaceutical dominance a national strategic priority, now leads the United States in pharmaceutical patent filings, and saw its companies grow from roughly 1% of global clinical trials in 2009 to nearly 30% in 2024 even as the U.S. share declined. As C4IP recently testified before the House Judiciary Committee's intellectual property subcommittee, innovation ecosystems are difficult to build and, once they migrate abroad, far harder to reclaim.[11] It would be hard to design a measure more at odds with that reality than one that singles out the very industry China has targeted and makes its patents costlier to obtain, less reliable to hold, and easier to defeat in litigation. Whatever its sponsors intend, S. 2658 would erode the foundation of the capital-intensive, high-risk research that defines drug development, at precisely the moment that foundation matters most. To keep weakening patent protection for this industry, in proposal after proposal, is to gamble with a strategic asset the country cannot easily rebuild.

[11] Written Statement of Jamie Simpson, Chief Policy Officer & Counsel, Council for Innovation Promotion, Before the Subcomm. on Courts, Intellectual Property, Artificial Intelligence, and the Internet, H. Comm. on the Judiciary, Hearing on "Medicines and IP: Balancing Innovation and Access" (June 4, 2026), https://www.congress.gov/119/meeting/house/119346/witnesses/HHRG-119-JU03-Wstate-SimpsonJ-20260604.pdf; see also Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System*, Info. Tech. & Innovation Found. 4 (Mar. 2019), https://www2.itif.org/2019-bayh-dole-act.pdf (describing the emergence of the United States as a leader in biopharmaceuticals).

For these reasons, C4IP respectfully urges the Committee not to advance S. 2658, particularly at a moment when preserving American biopharmaceutical leadership has rarely been more important. We appreciate your consideration and would welcome the opportunity to discuss these issues further.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)

cc:

Members of the Senate Committee on Health, Education, Labor, and Pensions
Sen. Chuck Grassley, Chairman, Senate Committee on the Judiciary
Sen. Dick Durbin, Ranking Member, Senate Committee on the Judiciary
Sen. Thom Tillis, Chairman, Senate Judiciary Subcommittee on Intellectual Property
Sen. Adam Schiff, Ranking Member, Senate Judiciary Subcommittee on Intellectual Property
Sen. Maggie Hassan, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Josh Hawley, Member, Senate Committee on the Judiciary