August 26, 2024

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

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

Dear Chairman Sanders and Ranking Member Cassidy:

I write on behalf of the Council for Innovation Promotion (C4IP) to voice our organization's concerns with the Medication Affordability and Patent Integrity Act (S. 2780) as currently written. While C4IP appreciates lawmakers' interest in ensuring timely and affordable access to generic and biosimilar medications, we believe this legislation poses substantial risks to America's innovation system.

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 from the Court of Appeals for the Federal Circuit, former Chief Judge Paul Michel and Judge Kathleen O'Malley. Our mission is to promote strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere.

The Medication Affordability and Patent Integrity Act (S. 2780) would require life sciences innovators to share volumes of unnecessary and confidential information related to drug approval with the USPTO.[1] Under the bill, firms would also have to provide lengthy certifications stating that all information submitted to the FDA and USPTO is consistent.[2] Supporters of the bill claim that these disclosures would increase transparency and prevent companies from making contradictory statements to agencies.

[1] https://www.congress.gov/118/bills/s2780/BILLS-118s2780is.pdf

[2] https://www.congress.gov/118/bills/s2780/BILLS-118s2780is.pdf

But these burdensome new rules aim to solve a problem that simply does not exist. There is no evidence indicating intentional, frequent, or systematic deception of the USPTO or FDA by pharmaceutical manufacturers. Nor is there any proof that the USPTO inappropriately grants patents for "inherent" aspects of novel drugs, as the bill's supporters claim. In addition, as noted below, the information these respective agencies need — and request — to conduct their very different assessments fundamentally differs.

Further, current policies already provide strong deterrents against any perceived potential for misconduct. For example, existing rules can render patents unenforceable if applicants are found to have engaged in inequitable conduct during the patent evaluation process.[3][4] Moreover, if fraudulent data is found within an application submitted to the FDA, the agency can withhold or even withdraw its approval.[5]

Put another way, lawmakers are contemplating a major overhaul of a well-functioning system because of false narratives – not because of rigorous analysis of true facts.

In addition to addressing a non-existent problem, the bill's requirements for extensive cross-reporting between agencies raise several concerns. First, it risks overwhelming the USPTO with volumes of FDA-related information, such as clinical data, much of which is irrelevant to patentability. The USPTO's resources are already stretched thin, and this would only make present long delays even worse. Second, it would add more administrative steps, costs, and delays to the already lengthy process of filing patent applications and seeking regulatory approval for novel medicines. Ultimately, this could mean that patients have to wait longer for revolutionary new therapies.

There's also a risk that an unintentional failure to comply with these complex new rules could be used as a weapon against life sciences innovators seeking to defend their IP in court. Patent infringers could conceivably use any small discrepancy in reporting to justify their efforts to invalidate an otherwise valid patent. Empowering infringers in this way would present yet another barrier to small innovators trying to transform their ideas into tangible solutions that benefit the public.

[3] Therasense, Inc. v. Becton, Dickinson and Co., 649 F.3d 1276 (Fed. Cir. 2011)

[4] https://www.primerus.com/article/inequitable-conduct-patent-cases

[5] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-120100-fraud-untrue-statements-material-facts-bribery-and-illegal-gratuities#:~:text=When%20FDA%20finds%2C%20based%20on,of%20an%20amendment%20or%20supplement

The bill also raises concerns about the protection of trade secrets and confidential information. The drug approval process necessarily involves sharing sensitive data with the FDA.[6] Requiring the same information to be shared with the USPTO — which generally discloses information submitted to support new patent applications — could result in proprietary data being made public.

Thank you for considering our perspective on this important matter. We welcome the opportunity to meet and discuss any of these issues in further detail.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)

cc:

Sen. Dick Durbin, Chairman, Senate Committee on the Judiciary
Sen. Lindsey Graham, Ranking Member, Senate Committee on the Judiciary
Sen. Chris Coons, Chairman, Senate Judiciary Subcommittee on Intellectual Property
Sen. Thom Tillis, Ranking Member, Senate Judiciary Subcommittee on Intellectual Property
Sen. Patty Murray, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Robert P. Casey, Jr., Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Tammy Baldwin, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Christopher Murphy, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Tim Kaine, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Maggie Hassan, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Tina Smith, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Ben Ray Luján, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. John Hickenlooper, Member, Senate Committee on Health, Education, Labor and Pensions

[6] https://www.skadden.com/-/media/files/publications/2018/02/protecting_trade_secrets_disclosed_to_the_fda.pdf

Sen. Ed Markey, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Rand Paul, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Susan Collins, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Lisa Murkowski, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Mike Braun, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Roger Marshall, M.D., Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Mitt Romney, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Tommy Tuberville, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Markwayne Mullin, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Ted Budd, Member, Senate Committee on Health, Education, Labor and Pensions
Rep. Adam Schiff, Member, House Judiciary Subcommittee on Courts, Intellectual Property, and the Internet
Rep. Zoe Lofgren, Member, House Judiciary Subcommittee on Courts, Intellectual Property, and the Internet
Rep. Madeleine Dean, Member, House Judiciary Subcommittee on Courts, Intellectual Property, and the Internet
Rep. Glenn Ivey, Member, House Judiciary Subcommittee on Courts, Intellectual Property, and the Internet