



Andrei Iancu, Co-Chair
David Kappos, Co-Chair
Judge Paul Michel (Ret.), Board Member
Judge Kathleen O'Malley (Ret.), Board Member
Frank Cullen, Executive Director

September 25, 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:

In advance of the Committee's September 26, 2024, Executive Session, I am writing to express the Council for Innovation Promotion's serious concerns regarding the Medication Affordability and Patent Integrity Act (S. 2780). This legislation would introduce unnecessary bureaucratic requirements into the patent application process that could significantly slow the development of future medicines by undermining innovators' confidence in intellectual property protections.

The Council for Innovation Promotion (C4IP) is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere. C4IP is 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.

The Medication Affordability and Patent Integrity Act would require drug developers, including start-ups and small biotechnology companies, to comply with complex and overlapping disclosure and certification requirements if they are seeking both patent protection and applying for approval of a new drug application, even though the different agencies' processes involve different concerns and accordingly, different information.

This proposal is ultimately based on an unfounded premise. Existing law already provides serious and significant consequences for instances of fraud. Innovators can have their patents rendered unenforceable if found to have made false statements to the USPTO.

Despite the lack of a demonstrable problem, the bill would require life sciences innovators to hand over volumes of extraneous and often confidential information related to drug approval to the USPTO. We believe this would have numerous negative unintended consequences.

First, the information submitted to the drug approval authorities often would have relation to the invention that is the subject of a patent application. Information about human safety, for example, may have no bearing on a patent application for new methods of creating a class of potential active ingredients. But the bill's impact would be to require duplicate disclosure to both the FDA and USPTO, putting hundreds or thousands of pages of information before a patent examiner that they are expected to consider. Not only is this a poor use of government resources, but forcing the USPTO to review this volume of irrelevant information could exacerbate delays in the patent application process, ultimately meaning that novel treatments take longer to reach patients.

Second, the bill would require sensitive data, typically kept confidential by the FDA, to be shared with the USPTO, which generally makes all information related to the examination of a patent application public. Without further changes, including fundamental changes reversing the openness of a patent's entire history, this confidential information is likely to become public and potentially broadly disseminated. Besides there being no clear reason to disallow trade secrets (which the FDA is authorized to protect), this sea change opens the doors to other would-be competitors, including state actors such as China, to take advantage of this newly free resource to bolster their own efforts to out-innovate the United States in biotech and other critical fields.

More broadly, the Medication Affordability and Patent Integrity Act would erode faith in the intellectual property rights relied upon by life science innovators and innovators across all fields. The legislation would introduce a new avenue for challenging the validity of existing patents. A company's failure to comply perfectly with the legislation's complicated certification and reporting requirements, even if

completely unintentional, could be used as a weapon for infringers seeking to invalidate their competitor's intellectual property in court. This could also add strain on courts and litigants who may be compelled to raise this issue in every case, slowing the process and potentially increasing the cost of already expensive litigation.

Previously, C4IP wrote to the Committee outlining these problems in the hopes that they would be addressed in a later draft of the bill. Unfortunately, we continue to have concerns and, at this time, must ask you to vote against this legislation.

Thank you for your attention to this timely matter. We are available to answer any questions you may have.

Sincerely,

A handwritten signature in black ink, appearing to read 'Frank Cullen', is positioned below the word 'Sincerely,'.

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)

cc:

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

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