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Judge Paul Michel (Ret.), Board Member
Judge Kathleen O'Malley (Ret.), Board Member
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April 2, 2025

The Honorable Chuck Grassley Chairman Senate Committee on the Judiciary 224 Dirksen Senate Office Building Washington, DC 20510 The Honorable Dick Durbin Ranking Member Senate Committee on the Judiciary 224 Dirksen Senate Office Building Washington, DC 20510

Dear Chairman Grassley and Ranking Member Durbin,

I am writing on behalf of the Council for Innovation Promotion (C4IP), 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 Presidents Trump and Obama, 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.

We write today with serious concerns about four bills <u>pending</u> before the Senate Judiciary Committee: the Drug Competition Enhancement Act (S. 1040), the Affordable Prescriptions for Patients Act (S. 1041), the Interagency Patent Coordination and Improvement Act of 2025 (S. 1097), and the Preserve Access to Affordable Generics and Biosimilars Act (S. 1096).

While well-intentioned, each of these proposals risks weakening the predictability, reliability, and effectiveness of the U.S. patent system. Though the stated intent of these bills is to foster competition, their practical impact would undermine foundational principles of intellectual property protection that drive innovation across numerous industry sectors critical to the American economy — not only biopharmaceuticals but also the high-tech, manufacturing, telecommunications, and consumer products industries.

Two of these bills — the Drug Competition Enhancement Act and the Affordable Prescriptions for Patients Act — rely on widely debunked misconceptions about how patents function. The Affordable Prescriptions for Patients Act targets the so-called problem of "patent thickets," which is rooted in the misconception that multiple patents protecting different aspects of an invention inherently hinder competition. Yet, an extensive study by the U.S. Patent and Trademark Office (USPTO) showed no correlation between the number of



patents protecting an invention and reduced competition, including in the life sciences field. Multiple patents protecting distinct aspects of a single product are commonplace across many industries, especially tech and life sciences. Smartphones, automobiles, and renewable energy technologies regularly rely on multiple patents to protect the totality of an innovation.

Similarly, the Drug Competition Enhancement Act addresses the perceived issue of "product hopping," a term inaccurately suggesting that innovators attempt to block competition by making tiny modifications to existing products while ceasing production of prior versions of those products. In reality, improvements, or "follow-on" innovation, deliver profound consumer benefits and are essential to progress in all sectors. For example, such innovations have dramatically improved safety features in vehicles, enabled more efficient semiconductor technologies, and expanded the accessibility and usability of consumer electronics.

Specifically regarding pharmaceuticals, a March 2025 report from the Information Technology and Innovation Foundation (ITIF) emphasizes that follow-on drug innovations frequently deliver significant patient benefits, improved health outcomes, and broader economic advantages. Penalizing such innovation, as this bill proposes, sets a troubling precedent that would disincentivize investment to improve technology, harming American competitiveness.

We are also <u>concerned</u> about the Interagency Patent Coordination and Improvement Act of 2025, which would impose needless regulatory complexity by mandating new coordination between the USPTO and other federal agencies. Imposing this sort of duplicative paper shuffling will increase uncertainty and discourage innovation without a clear benefit, setting a troubling precedent for needlessly introducing complication into patent prosecution in other areas of technology.

Similarly, the Preserve Access to Affordable Generics and Biosimilars Act introduces rigid presumptions about anti-competitive behavior that would replace careful, case-by-case analysis with sweeping generalizations. This shift risks chilling legitimate patent enforcement and lawful settlement agreements that are essential for resolving disputes efficiently and fairly.

Ultimately, these four bills, while presented as targeted pharmaceutical reforms, would erode the broader intellectual property ecosystem that underpins America's global innovation leadership. Intellectual property rights encourage businesses of all sizes across all sectors to invest in risky, costly, and transformative research and development. Undermining those rights will lead to fewer innovations reaching the market, slower economic growth, and diminished global competitiveness.



An additional concern is that these bills appear to advantage foreign drug manufacturers from China and other countries. <u>Almost half</u> of the generic prescriptions filled in the United States in 2022 were supplied by Indian drugmakers, and <u>approximately 17%</u> of our active pharmaceutical ingredients (APIs) came from China over the past decade. By weakening the United States' intellectual property system, these bills effectively hand a strategic advantage to such foreign drug manufacturers from China and elsewhere.

We respectfully urge the Committee to reject these bills and maintain America's careful balance between innovation and competition — a balance that is essential for continued American leadership in technological advancement, job creation, and economic prosperity.

Thank you for your attention to this important matter. We would welcome the chance to provide additional information or briefing materials at your convenience.

Sincerely,

Frank Cullen

Executive Director

Council for Innovation Promotion (C4IP)