June 3, 2026

The Honorable Darrell Issa
Chairman
House Judiciary Subcommittee
on Courts, Intellectual Property,
Artificial Intelligence, and the
Internet
2108 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry J. "Hank"
Johnson, Jr.
Ranking Member
House Judiciary Subcommittee
on Courts, Intellectual Property,
Artificial Intelligence, and the
Internet
2240 Rayburn House Building
Washington, DC 20515

Dear Chairman Issa and Ranking Member Johnson:

The Council for Innovation Promotion (C4IP) writes in advance of the House Judiciary Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet hearing, "Medicines and IP: Balancing Innovation and Access," scheduled for June 4, 2026. We appreciate the Subcommittee's attention to these important issues. IP policy plays a central role in determining whether the United States remains the world's leading environment for high-risk medical innovation and whether the next generation of lifesaving therapies will be discovered, developed, and commercialized here in America.

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 Presidents Trump and Obama, respectively. Our board further includes two retired judges from the 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.

We are concerned that much of the discussion surrounding pharmaceutical patents has become untethered from both the realities of biopharmaceutical research and development (R&D) and the appropriate utilization of the patent system by the pharmaceutical and other critically important industry sectors. Activists and some

policymakers frequently advance claims regarding terminal disclaimers and so-called "patent thickets," "evergreening," and "serial litigation" that are either unsupported by evidence or that fundamentally misunderstand how innovation occurs in technologically complex industries. These narratives risk encouraging Congress to weaken patent rights in ways that would undermine investment in future medical breakthroughs while doing little to meaningfully improve patient access or affordability.

One recurring claim is that pharmaceutical innovators improperly obtain large numbers of patents on a single medicine in order to block competition. This is mistaken. It should be unsurprising that sophisticated products are often associated with numerous patents. A single medicine may embody a range of distinct technological advances developed at different points in the research process. The resulting patents reflect the reality that scientific progress unfolds over time and that important discoveries are often made in stages.

Indeed, the same dynamic exists throughout the innovation economy. The USPTO itself has found that large patent family applications can be found across all disciplines and technologies, but are "not commonly found" in pharma applications. Yet critics often single out pharmaceutical patents while ignoring these practices elsewhere.

It is also common to see the existence of terminal disclaimers presented as evidence of so-called patent gamesmanship on the part of pharmaceutical innovators. In reality, terminal disclaimers are longstanding safeguards within patent law that prevent improper term extension. When multiple patents are linked by a terminal disclaimer, the later patent must expire at the same time as the earlier patent and remain under common ownership. These requirements exist precisely to prevent the type of term-stacking critics claim to oppose.

These legal tools also provide an opportunity for applicants to pursue additional claims that more precisely describe an invention as technical understanding develops. Particularly in complex fields like biotechnology and pharmaceuticals, inventors often seek to cover aspects of the invention not claimed in the original patent or identify wording that more accurately captures the invention. Terminal disclaimers permit those additions and refinements to receive patent protection without extending the original exclusivity period.

Patents linked by terminal disclaimers are still fully examined patents. They must satisfy the same standards, like novelty, non-obviousness, and enablement, as every other patent issued by the USPTO. Filing a terminal disclaimer does not relieve the applicant of any patentability requirements.

The Eliminating Thickets to Increase Competition (ETHIC) Act is premised on many of these misunderstandings. The bill would significantly restrict the ability of innovators to assert their IP rights by preventing patent holders, specifically in the pharmaceutical sector, from asserting more than one patent from a certain patent group in infringement cases. As a result, it could prevent innovators from fully protecting the scope of their inventions even where multiple independently valid patents are infringed.

In this way, the reform would represent a major departure from ordinary principles of IP law. And if Congress selectively weakens the enforceability of certain patents based on unsupported narratives regarding so-called "patent thickets," it will inevitably reduce confidence in the reliability of the American patent system. Such uncertainty is especially problematic in industries like biopharmaceuticals, where companies and investors must commit large sums to long-term, high-risk research before a product ever reaches a patient.

Claims regarding pharmaceutical "evergreening" are similarly misleading. Some use the term to describe the practice of obtaining additional patents on improvements and other developments related to an existing medicine, which they argue can extend market exclusivity and delay competition.

This narrative ignores the fact that R&D does not end when a medicine first receives approval from the U.S. Food and Drug Administration (FDA). Companies may discover new disease indications, safer formulations, improved delivery systems, more convenient dosing regimens, or entirely new methods of administration. These developments can produce substantial benefits for patients as well as healthcare systems.

Patents covering those later discoveries do not extend the life of earlier patents. Nor are they automatically granted. Each patent application must independently satisfy the statutory requirements established by Congress and enforced by the USPTO. The patent system appropriately rewards genuine innovation, including post-approval innovation, because continued research and improvement are central to medical progress.

The evidence further undermines the claim that these patent practices are improperly delaying generic competition. Research has found that generic competition typically emerges about 14 years after approval of a branded medicine. That period is substantially shorter than the nominal patent term available under U.S. law.

Some commentators have also attacked ordinary Hatch-Waxman litigation practices under the label of "serial litigation." These claims likewise ignore the realities of pharmaceutical R&D and patent prosecution. Importantly, existing legal doctrines already prevent abusive relitigation of identical issues. Generic manufacturers also possess substantial ability to challenge patents they believe are invalid. Characterizing all later-filed patent litigation as abusive ignores both the complexity of pharmaceutical innovation and the careful balance Congress established under Hatch-Waxman.

We are also concerned by efforts to expand and legitimize the use of "skinny labeling" strategies through legislation such as the Skinny Labels, Big Savings Act. Under current law, generic manufacturers may seek approval for products that omit patented uses from their labels and must refrain from actively marketing for the omitted indication. But in practice, these products may still be prescribed and used "off-label" for patented indications, allowing generic firms to benefit from innovative discoveries without undertaking the costly research necessary to develop them.

By weakening protections for methods of use, the Skinny Labels, Big Savings Act would undermine incentives for one of the most important forms of pharmaceutical innovation -- discovering new therapeutic uses for existing medicines.

More broadly, Congress should approach proposals to weaken pharmaceutical patent protections with great caution. The United States leads the world in biopharmaceutical innovation because our legal system has historically provided reliable IP protections that support private investment in risky and expensive research. That leadership is not guaranteed.

At a time when China is investing enormous resources in biotechnology, weakening the reliability of American patent rights would place U.S. innovators at a serious competitive disadvantage. China's state-directed economic system allows it to subsidize strategic industries regardless of commercial viability. By contrast, here in the United States, innovation is driven primarily through private investment. And investors are far more likely to fund ambitious life sciences research when the legal framework protecting the resulting inventions is stable and dependable.

It is for all of these reasons that the Subcommittee should carefully scrutinize claims that the patent system is being systematically abused by pharmaceutical innovators. Much of the rhetoric surrounding terminal disclaimers and so-called "patent thickets," "evergreening," and related issues is unsupported by the evidence and inconsistent with the findings of the USPTO itself. Congress should not weaken the IP framework that has made the United States the global leader in medical innovation based on misconceptions about how patents actually operate.

We appreciate the Subcommittee's attention to these issues and welcome the opportunity to engage with Congress on future policies that preserve American innovation leadership.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)

cc:

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Rep. Ben Cline, Member, House Judiciary Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
Rep. Scott Fitzgerald, Member, House Judiciary Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
Rep. Russell Fry, Member, House Judiciary Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
Rep. Lance Gooden, Member, House Judiciary Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
Rep. Sydney Kamlager-Dove, Member, House Judiciary Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
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Rep. Deborah Ross, Member, House Judiciary Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet