Dear Juli:

We'd like to offer our perspective on the important role intellectual property protections play in supporting medical innovation, promoting competition, and expanding treatment options for patients, in advance of the June 4, 2026 House Judiciary Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet hearing on pharmaceutical patents.

Our organization, the Pacific Research Institute, is a California-based, non-profit think tank committed to promoting freedom, opportunity, and personal responsibility for all Americans by advancing free-market policy solutions.

We have both spent decades studying the various factors that influence drug development, investment, and patient access. America's leadership of the global biomedical innovation ecosystem depends on policies that reward discovery, protect intellectual property, encourage private investment, and allow competition to flourish through generic and biosimilar market entry.

In recent years, this policy framework has come under growing scrutiny from those who argue that the patent system impedes competition and contributes to higher drug costs. These critics argue that pharmaceutical companies use large numbers of patents to delay generic competition and extend market exclusivity beyond what Congress intended.

As the Subcommittee evaluates claims about so-called "patent thickets," "evergreening," and related jargon, it is important to distinguish between rhetoric and evidence.

The mere existence of multiple patents associated with a medicine should not raise concerns about abuse. As the U.S. Patent and Trademark Office has observed, simple patent counts can be misleading, as not all patents carry the same scope, significance, or practical effect.

Scientific progress is also incremental. As researchers learn more about how therapies work and identify ways to improve their use, additional inventions may emerge that are distinct from the original breakthrough.

Once a drug garners regulatory approval, researchers often continue studying whether that medicine can treat additional diseases, be delivered more conveniently, or serve different patient populations. This post-approval research frequently produces meaningful benefits for patients.

Some critics of these follow-on patents argue that their primary purpose is to delay generic competition rather than protect genuine innovation.

This narrative is incorrect.

The patent system does not rubber-stamp post-approval innovations. Rather, it subjects later patents to the same requirements as any other invention, approving those it deems new, useful, and non-obvious.

Nor does a later patent pertaining to a new formulation, method of use, or delivery mechanism reset the clock on the patent for the original compound.

Studies examining actual market exclusivity periods have repeatedly found that branded medicines typically face generic competition after roughly 13 to 14 years -- far sooner than the basic 20-year patent term.

This point is central to the Subcommittee's inquiry. Using patent counts as a proxy for competitive harm risks misdiagnosing the problem and encouraging policy changes that could weaken valid property rights without improving patient access to novel medicines.

Similar arguments have been directed at terminal disclaimers and continuation patents. Terminal disclaimers are well-established features of patent practice. They are used when a later patent is closely related to an earlier patent owned by the same applicant. They ensure that the later patent does not extend beyond the term of the earlier one.

In other words, terminal disclaimers generally cut patent terms short rather than extend them. Their use should not be taken as a sign that a patent lacks merit. Like other patents, those associated with terminal disclaimers must still satisfy the same standards for patentability.

This is particularly relevant to the debate surrounding the ETHIC Act. Much of the rationale for the legislation rests on the notion that terminal disclaimers are evidence of patent abuse. That premise is deeply misguided.

Treating patents subject to terminal disclaimers as inherently suspect would risk creating a two-tier patent system that departs from basic principles of patent law and weakens protections for legitimate inventions.

Continuation patents are another area where the rhetoric outpaces the evidence. They are often cited as a proxy for so-called "evergreening." They are not.

Continuation patents do not provide a new patent term. Instead, they allow inventors to refine and pursue claims based on information disclosed from the outset in an earlier application. That process can be especially valuable in

biopharmaceutical research, where discoveries often unfold over many years and scientific understanding continues to develop long after an initial patent filing.

The same can be said for claims questioning the legitimacy of pharmaceutical patent litigation. It is sometimes suggested later patent disputes are merely a means for innovators to delay generic competitors from entering the market. In reality, the development and approval of medicines is a lengthy process. Patent issues can arise at different stages along the way. Later litigation may simply reflect the normal operation of the Hatch-Waxman framework rather than an attempt to delay generic entry.

That framework has served patients well. The Hatch-Waxman Act was designed to preserve incentives for risky innovation while creating a reliable pathway for generic competition. The result has been a U.S. pharmaceutical research ecosystem that remains the world's leading source of new medicines. Generics, meanwhile, are widely available, accounting for roughly 90% of prescriptions filled in the United States.

Weakening patent enforcement would needlessly undermine a system that is working as Congress intended.

Developing a new medicine can take 10 to 15 years and cost billions of dollars. Most medicines that enter clinical trials never receive regulatory approval. Investors fund this work because the patent system offers them a limited period of exclusive sales during which drug companies have the chance to earn a return that can cover the costs of developing not just the successes but the failures, too.

Weakening the practical value of patents would change those incentives. The effects would likely be felt most acutely by smaller biotechnology companies and researchers pursuing treatments for high-risk health challenges like cancer, Alzheimer's disease, and rare diseases, where effective therapies have proved elusive.

Many of tomorrow's most revolutionary therapies exist today only as uncertain scientific hypotheses. Policies that make it harder to protect successful inventions would make high-risk research less attractive to investors -- and reduce the chances that promising therapies ever reach patients.

As the Subcommittee considers these issues, we respectfully encourage careful attention to the evidence, the practicalities of drug development, and the long-term costs of weakening patent protections. The United States has become the world's medicine chest because it has maintained an innovation ecosystem that rewards risk-taking, protects property rights, and allows competition to emerge after a limited period of exclusivity. That system has produced extraordinary gains for patients in the United States and around the world.

Please contact us if you have any questions.

Sincerely,

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