September 15, 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:

On behalf of the Council for Innovation Promotion, we write to correct several misleading statements made by witness Rachel Goode during the Subcommittee's June 4 hearing, "Medicines and IP: Balancing Innovation and Access," and in subsequent written materials submitted on behalf of Fresenius Kabi regarding pharmaceutical patents linked by terminal disclaimers.

As explained below, those materials repeatedly characterize patents linked by terminal disclaimers as duplicative, invalid, or devoid of independent innovative value -- conclusions that do not follow from the existence of a terminal disclaimer. We therefore respectfully urge the Subcommittee to disregard those characterizations, and the conclusions that depend upon them, as it considers the ETHIC Act and other proposals affecting patent rights.

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.

Three statements in particular illustrate the problem.

First, Goode equates patents subject to terminal disclaimers with "duplicate" patents. She argues that "there is no economic reason that a patent holder would ever disclaim part of a patent term if they weren't forced to after an obviousness-type double patenting rejection," and that applicants who believe their inventions are patentably distinct should instead contest the rejection before the examiner.

That argument rests on an outdated understanding of how patent terms are measured under modern patent law. Before 1995, a patent's term typically lasted 17 years from the date the patent was issued. A later-issued continuation therefore expired later than its parent, and a terminal disclaimer surrendered real term. Since the Uruguay Round Agreements Act took effect on June 8, 1995, however, patents have a 20-year term measured from their earliest filing date rather than their issue date. Patents in the same family share that date, so absent other adjustments they already expire on the same day.

As a result, an applicant who files a terminal disclaimer usually does not do so in connection with patent term at all. What the applicant does give in connection with a terminal disclaimer is the freedom to assign or license the related patents separately. Applicants file terminal disclaimers because doing so is faster and far less expensive than litigating a double patenting rejection through the examiner and, if necessary, on appeal. Goode's argument assumes that filing a terminal disclaimer requires surrendering meaningful patent term, but under current law, there is usually very little term at stake.

Second, she states that terminally disclaimed patents "add no value to American innovation." This rests on the same mistaken premise -- that related claims are duplicative. Indeed, the term "double patenting" is a misnomer.

Related applications that may lead to terminal disclaimers are not duplicative. Rather, they allow patent applicants and the USPTO to examine discrete parts of complex inventions one at a time. For example, a continuation application allows applicants to pursue different sets of patent claims supported by the same original disclosure -- such as broader or narrower claims or claims directed to different aspects of an invention. Dividing up claim sets among separate applications often helps simplify examination. And, as noted above, terminal disclaimers ensure that related claims remain under common ownership.

The fact that continuation applications share the same disclosure does not mean they contain duplicative claims. Separate patents in the same family may present different questions of validity and infringement; a patent with claims directed to formulations is likely to be challenged on different prior art than a patent with claims directed to a method of treatment -- even though both patents may stem from the same original disclosure.

Even overlapping claims are not identical claims. It is both expected and appropriate that claims within a patent, and across patents in the same family, overlap in subject matter. Claims of differing scope each do real work, and together they secure protection for the full scope of what the inventor actually invented rather than for whichever embodiment happened to be claimed first.

This is what makes the patent bargain work. Inventors disclose their inventions to the public in exchange for protection commensurate with what they contributed. Where inventors cannot reliably obtain protection for the full scope of their invention, that bargain breaks down, and trade secrecy becomes the rational alternative -- leaving the public with no disclosure at all.

One of the many dangers of the ETHIC Act is that it penalizes related claims solely because they are filed in more than one application. The legislation does not condition its restrictions on a finding that a patent is invalid, technologically unimportant, commercially valueless, or literally duplicative. Instead, it groups commonly owned patents and applications based on their terminal-disclaimer relationships and restricts how patents within that group may be asserted. That is not a solution directed to a real problem; it is a disincentive to patent protection per se.

Third, Goode states that "terminal disclaimer practices allow endless attempts to defend the same invention, turning invalid patents into years of extra monopoly profits while litigation drags on." This is incorrect for multiple reasons.

As discussed above, terminally disclaimed patents are not the same; they are related, which is permissible. And patents are not automatically invalid because they are related. Terminal disclaimers simply treat related patent claims as though they were in a single patent for purposes of determining patent term and common ownership. A terminal disclaimer also does not insulate a claim from validity review. The USPTO may reconsider related issued claims through proceedings before the Patent Trial and Appeal Board (PTAB) or the Central Reexamination Unit (CRU), and federal courts may hold related claims invalid in litigation.

Additionally, if a related patent claim has been held invalid or unpatentable, there will not be endless attempts to defend enforcement. Related claims will be addressed if and as they are enforced, just like all other patent claims. And the validity of closely related claims will usually be resolved whether they are asserted or not, because of overlapping legal and factual issues with claims that are asserted.

That exposes a broader problem with characterizing the ETHIC Act as a patent-quality measure. The Act does not invalidate patents, cancel patent claims, improve examination, or require a determination that an affected patent should never have been issued. It restricts the assertion of patents solely based on their terminal-disclaimer relationships. If particular patents are invalid, the appropriate response is to challenge them through the mechanisms Congress has established for determining patentability and validity -- not to treat the existence of a terminal disclaimer as a substitute for that inquiry.

Any discussion of the ETHIC Act should proceed from an accurate understanding of continuation practice, obviousness-type double patenting, and terminal disclaimers. The existence of a terminal disclaimer does not indicate that a patent merely duplicates another patent. Rather, it reflects the operation of longstanding patent doctrines that allow applicants to pursue related claim sets while ensuring common ownership and a common expiration date.

For these reasons, we encourage the Subcommittee to reject the ETHIC Act and any other legislation based on faulty claims about terminal disclaimers and continuation applications.

We appreciate the Subcommittee's attention to these issues and respectfully submit this clarification for the record.

Sincerely,

Coke Morgan Stewart
President and CEO
Council for Innovation Promotion (C4IP)