September 24, 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 C. "Hank" Johnson, Jr.
Ranking Member
House Judiciary Subcommittee on Courts,
Intellectual Property, Artificial Intelligence, and the Internet
2240 Rayburn House Office Building
Washington, DC 20515

Re: Setting the Record Straight on Terminal Disclaimers and the ETHIC Act

Dear Chairman Issa and Ranking Member Johnson:

We, the undersigned academics and public interest groups working to improve Americans' access to affordable medicines, write in response to the letter submitted by the Council for Innovation Promotion (C4IP) on September 15, 2026, regarding the Subcommittee's June 4 hearing, "Medicines and IP: Balancing Innovation and Access."[1] The C4IP letter asks the Subcommittee to disregard testimony and materials that "characterize patents linked by terminal disclaimers as duplicative, invalid, or devoid of independent innovative value."[2] We respectfully submit that it is the C4IP letter, not the earlier testimony, that mischaracterizes the law, the economics of patenting, and the practical reality of the pharmaceutical market.

[1] Letter from Coke Morgan Stewart, President & CEO, Council for Innovation Promotion, to Hon. Darrell Issa, Chairman, and Hon. Henry C. "Hank" Johnson, Jr., Ranking Member, Subcomm. on Courts, Intellectual Property, Artificial Intelligence, and the Internet, H. Comm. on the Judiciary (Sept. 15, 2026) (C4IP Letter), https://c4ip.org/wp-content/uploads/2026/09/C4IP-Letter-RE-Hearing-on-Medicines-and-IP.pdf.
[2] *Id.* at 1.

A terminal disclaimer is, in the Federal Circuit's words, "a strong clue that a patent examiner and, by concession, the applicant, thought the claims in the continuation lacked a patentable distinction over the parent."[3] But it is only a clue. Because a terminal disclaimer "does not give rise to a presumption that a patent subject to [it] is patentably indistinct from its parent patents," a court "may not presume that assertions of a parent patent and a terminally-disclaimed continuation patent against the same product constitute the same cause of action."[4]

Accordingly, courts must give each terminally disclaimed patent its own claim-by-claim analysis, which means each such patent can support a separate cause of action for patent infringement. This is precisely why the ETHIC Act targets patents linked by terminal disclaimers: they enable the formation of patent thickets that impose a substantial burden on generic and biosimilar manufacturers seeking to enter the U.S. market in a timely fashion and provide price competition, because they often need to be addressed in court. Patents linked by terminal disclaimers thus impede the availability of affordable medications in the U.S.

We address the three principal arguments in the C4IP letter in turn.

1. Terminal Disclaimers Buy Additional Patents to Assert Against Rivals.

C4IP asserts, without support, that applicants file terminal disclaimers because doing so is "faster and far less expensive than litigating a double patenting rejection," and that "under current law, there is usually very little term at stake."[5] Both assertions are misleading.

First, C4IP omits the most important advantage. Filing a terminal disclaimer does not merely increase efficiency; it increases the likelihood of an applicant obtaining a patent. A compliant disclaimer obviates an examiner's obviousness-type double patenting rejection as of right, while an attempt to contest it may fail. **What a terminal disclaimer therefore buys is the assurance of a separate patent to enforce against rivals**.

The blockbuster drug mirabegron (Myrbetriq) litigation illustrates how so-called child patents that are linked to the same (parent) patent via terminal disclaimers can be used to repeatedly block generic competition. Astellas brought five successive lawsuits against generic competitors based on child patents that, despite

[3] *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1168 (Fed. Cir. 2018).
[4] *Id.*
[5] C4IP Letter at 2.

differences in claim language, covered the generic drug in essentially the same way as the parent patent and therefore presented the same barrier to generic entry.[6] These five lawsuits led to ten years of litigation, delaying and deterring generic entry.[7]

Second, limited patent term is not the same as very little economic value. The House Committee on Oversight and Reform found that AbbVie collected nearly $16 billion in U.S. net revenue from adalimumab (Humira) in 2020 alone — more than $40 million a day.[8] Given the income-generating potential of a single day of patent coverage, the fact that applicants willingly disclaim any duration of a patent's term is evidence that obtaining an additional enforceable patent is economically valuable.

The critical value of a terminal disclaimer lies in what it gives the patent holder: a separate, individually enforceable patent. This effect is cumulative. Each disclaimer adds another patent to a group covering a single invention family. A brand manufacturer holding dozens of them can transform a single dispute with a generic or biosimilar manufacturer into a war of attrition, multiplying the cost and complexity of litigation and delaying market entry for cheaper alternatives.

Humira is the quintessential example. Beyond the basic patent, which expired at the end of 2016, AbbVie obtained numerous additional patents.[9] According to one peer-reviewed study of the 73 U.S. patents in AbbVie's core Humira portfolio — those covering the product, its formulations, and methods of treatment — 59 patents, roughly 80%, were "not directed to new, non-obvious inventions."[10] Another peer-reviewed study, analyzing AbbVie's Humira litigation, found that 105 asserted patents were clustered into just 24 patent groups linked by terminal

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[6] Timothy Bonis, Aaron S. Kesselheim & S. Sean Tu, *Serial Patent Litigation: An Emerging Strategy to Delay Entry of Generic Competition*, 3 Health Affairs Scholar, no. 12, Dec. 2025.

[7] *Id.*; Press Release, Astellas Pharma Inc., *Astellas Reaches Settlement Agreements with Lupin and Zydus in Myrbetriq® Patent Litigation* (Feb. 12, 2026), https://newsroom.astellas.com/2026-02-12-astellas-reaches-settlement-agreements-with-lupin-and-zydus-in-myrbetriq-patent-litigation.

[8] Staff of H. Comm. on Oversight & Reform, 117th Cong., *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* 4 (2021) (reporting nearly $16 billion in U.S. net revenue for Humira in 2020). The daily figure is derived from that annual total.

[9] *Mayor & City Council of Baltimore v. AbbVie Inc.*, 42 F.4th 709, 711 (7th Cir. 2022); *see also* Ryan Knox & Gregory Curfman, *The Humira Patent Thicket, the Noerr–Pennington Doctrine and Antitrust's Patent Problem*, 40 Nature Biotechnology 1761, 1761 (2022) (reporting that AbbVie applied for at least 247 patents, of which 132 were granted, and that 90% of the filings were made after Humira was already on the market).

[10] Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars, an American Problem*, 9 Journal of Law and the Biosciences 1, 18–19 (2022) (finding that "80% of the U.S. Humira patents are not directed to new, non-obvious inventions").

disclaimers, representing at most 24 patentably distinct inventions.[11] AbbVie used its outsized portfolio to extract settlements that delayed U.S. biosimilar entry by five years compared to Europe.[12]

2. Different Patent Claims Are Not Different Inventions.

C4IP argues that terminally disclaimed patents are not duplicative because they contain "different sets of patent claims supported by the same original disclosure."[13] That the claims differ is a given: claims identical to those of an earlier patent are barred outright as statutory double patenting, which no terminal disclaimer can cure.[14]

But C4IP's own argument gives away the larger point. Because a continuation's claims must find support in the original disclosure, the continuation can reach nothing the applicant had not already disclosed.[15] No invention that was not already described and enabled in the original patent's disclosure can be claimed in a continuation patent. The applicant simply puts additional claims that draw support from the original disclosure into a separate patent application.

For the purposes of the ETHIC Act and the patent thicket problem, the issue is not whether the patent claims are literally "duplicative," but whether they represent genuinely new and non-obvious inventions. Many terminally disclaimed patents cover minor variations — a different formulation, a particular method of treatment, or a manufacturing process — that generally do not represent meaningful therapeutic advances to patients.[16]

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[11] Bernard Chao, Ryan Whalen, Aaron S. Kesselheim & S. Sean Tu, *Clearing Dense Drug-Patent Thickets*, 391 New England Journal of Medicine 2180 (2024).

[12] *AbbVie*, 42 F.4th at 714–15 (all U.S. suits "settled on terms that permit the biosimilar drugs to enter the U.S. market during 2023," while the parallel European litigation "was settled with an October 2018 entry date").

[13] C4IP Letter at 2.

[14] 35 U.S.C. § 101; *Manual of Patent Examining Procedure* (MPEP) § 804(II)(A) ("If it is determined that the same invention is being claimed twice, 35 U.S.C. 101 precludes the grant of the second patent regardless of the presence or absence of a terminal disclaimer."); *see Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438 (C.C.P.A. 1970).

[15] 35 U.S.C. § 120 (conditioning benefit of the earlier filing date on the invention being disclosed in the manner provided by § 112(a) in the earlier-filed application); MPEP § 201.07 ("The disclosure presented in the continuation must not include any subject matter which would constitute new matter if submitted as an amendment to the parent application.").

[16] S. Sean Tu, Rachel Goode & William B. Feldman, *Biologic Patent Thickets and Terminal Disclaimers*, 331 JAMA: Journal of the American Medical Association 355 (2024) (129 of 271 patents — 48% — litigated in biosimilar disputes from 2010 through April 2023 carried terminal disclaimers. The study also found that patents with terminal disclaimers had proportionally more formulation claims (30% vs. 10%) and method of treatment claims (33% vs. 26%) than those without terminal disclaimers, but fewer composition claims (4% vs. 8%) and manufacturing technique claims (36% vs. 52%)).

Moreover, double patenting is widespread. One 2025 study found that "double patenting is growing, with terminal disclaimers now being filed for over 15% of all patents, over 50% of litigated patents, and over 60% of patents covering FDA-approved drugs."[17] This is not a sign of robust innovation; it is a sign of a system being gamed.[18]

3. The ETHIC Act Targets the Right Problem.

C4IP argues that the ETHIC Act is not a patent-quality measure because it does not invalidate patents or improve examination, but instead restricts assertion based solely on terminal disclaimer relationships.[19] This is precisely the point. The ETHIC Act is a competition measure, and it targets the operative mechanism — the enforcement of multiple, commonly owned patents linked by terminal disclaimers.

C4IP claims that "if particular patents are invalid, the appropriate response is to challenge them through the mechanisms Congress has established."[20] But **the primary mechanism for challenging patent validity — district court litigation — is prohibitively expensive and time-consuming**.[21] It took ten years of district court litigation against Astellas — and payments of $210 million to it — for generic drug makers to sell mirabegron in the U.S. free of infringement liability.[22] Patent Trial and Appeal Board (PTAB) proceedings once promised a more affordable pathway, but changes brought on by the Trump Administration's U.S. Patent and Trademark Office leadership, including some made by C4IP's own members while in those roles, have severely restricted access to it.[23]

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[17] Mark A. Lemley & Lisa Larrimore Ouellette, *Fixing Double Patenting*, 74 American University Law Review 1013, 1013 (2025) (emphasis added).

[18] The Federal Trade Commission has reached the same conclusion, warning that "the strategic use of terminal disclaimers can facilitate the growth of patent thickets with multiple patents claiming essentially the same invention." Comment of the Fed. Trade Comm'n on the U.S. Patent & Trademark Office's Proposed Rule, *Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting* 2 (July 9, 2024).

[19] C4IP Letter at 3.

[20] *Id.*

[21] *See* Bonis, Kesselheim & Tu, *supra* note 6 (Hatch-Waxman cases cost generic manufacturers $6.2 million on average, a sum that can exceed the short term profits available from entry) (citing American Intellectual Property Law Association, *2023 Report of the Economic Survey* (2023)); *see also* Michael A. Carrier & S. Sean Tu, *Why Pharmaceutical Patent Thickets Are Unique*, 32 Texas Intellectual Property Law Journal 79 (2024).

[22] Bonis, Kesselheim & Tu, *supra* note 6; Press Release, *supra* note 7.

[23] Congress designed inter partes review to provide "quick and cost effective alternatives to litigation." H.R. Rep. No. 112-98, pt. 1, at 48 (2011). The USPTO has since narrowed that alternative by administrative action. In *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (designated precedential on May 5, 2020, under Director Andrei Iancu, now co-chair of C4IP's board), the Board claimed discretion to deny institution on account of parallel litigation rather than the merits of the petition before it. Then Acting Director Coke Morgan

Requiring a generic or biosimilar manufacturer to challenge dozens or hundreds of patents, one by one, is not a viable remedy; it is a barrier to entry. That is why limiting a patent owner to asserting one patent per Patent Group in an infringement action, as the ETHIC Act does,[24] is essential to reducing the litigation burden on competitors and allowing them to bring lower-cost alternatives to market. This is a targeted, proportionate response to a system being consistently gamed by brand manufacturers seeking any basis on which to extend revenue streams on drug products that have been profitable for over a decade and often longer.

Conclusion

The C4IP letter asks the Subcommittee to reject the ETHIC Act because it wants to uphold a practice that has been used to build some of the most aggressive patent thickets in the pharmaceutical industry. We urge the Subcommittee to rely on the evidence and the practical realities of the pharmaceutical market, not on C4IP's misleading characterizations. The ETHIC Act is a necessary step toward restoring balance to the patent system and ensuring that American patients have timely access to affordable medicines.

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

Sincerely,

Public Interest Patent Law Institute (PIPLI)

Initiative for Medicines, Access & Knowledge (I-MAK)

R Street Institute

Professor Aaron S. Kesselheim
Program On Regulation, Therapeutics, And Law (PORTAL)

Stewart — now C4IP's President and CEO, and the signatory of the letter to which we respond — expanded that practice. Memorandum from Coke Morgan Stewart, Acting Dir., USPTO, *Interim Processes for PTAB Workload Management* (Mar. 26, 2025). According to the Office's own data, the institution rate has since fallen from roughly 65% in October 2024 to roughly 37% in February 2026. Eileen McDermott, *USPTO Stats Show IPR Institution Rate Has Plummeted by 43%*, IPWatchdog (Apr. 8, 2026), https://ipwatchdog.com/2026/04/08/uspto-stats-show-ipr-institution-rate-plummeted/.

[24] *See* ETHIC Act, S. 2276, 119th Cong. § 2 (2025) (proposed 35 U.S.C. § 271(e)(7)(A), (D)(i)).

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