IPPI The IP Policy Institute
The University of Akron School of Law
Promoting progress in innovation & creativity through scholarship & policy

The ETHIC Act and Terminal Disclaimers in Pharmaceutical Development

Douglas S. Park

IPPI: The IP Policy Institute
The University of Akron School of Law

November 2026

The ETHIC Act and Terminal Disclaimers in Pharmaceutical Patenting

Douglas S. Park

IPPI: The IP Policy Institute, The University of Akron School of Law | November 2026

Executive Summary

The Eliminating Thickets to Increase Competition Act (the "ETHIC Act") would permit a patent owner suing a generic or biosimilar applicant to assert only one patent per defendant from a group of patents connected by terminal disclaimers and would bar additional suits on the rest. The proposal assumes that such patents impose competitive barriers on generic and biosimilar manufacturers, but the available evidence does not establish that premise. The restriction could instead lengthen prosecution, increase the costs of patent examination and make subsequent, useful biopharmaceutical innovations more difficult to protect.

- Empirical research does not establish that higher patent counts, much less patents connected by terminal disclaimers, delay generic entry. In fact, existing mechanisms under the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act ("BPCIA") help generic and biosimilar applicants identify relevant patents, litigate disputes, and enter the market more easily. The ETHIC Act, however, would force patent owners to choose a single patent from each group when they first sue, earlier than either the Hatch-Waxman Act or the BPCIA requires and even before discovery has taken place.
- Terminal disclaimers allow researchers to patent later developments related to earlier inventions without extending the original patent term or fragmenting ownership. This accommodation is especially useful in biopharmaceutical development, where it often takes years of additional research to realize the particular form of a medicine that can be used safely and effectively. The ETHIC Act would make terminal disclaimers much less useful to researchers and risks disincentivizing further research and development into drug products.
- By making terminal disclaimers less useful, the ETHIC Act could induce more applicants to contest obviousness-type double patenting (ODP) rejections, increasing examination and appellate workloads. Some applicants who

succeed in contesting those rejections could obtain patents with longer terms than they would have received by filing terminal disclaimers, while restrictions on the enforceability of other patents could discourage investment in subsequent innovations.

Introduction

The ETHIC Act is one of the latest legislative proposals aimed at so-called "patent thickets" allegedly surrounding pharmaceutical products.[1] Critics claim that biopharmaceutical companies obtain large numbers of patents, often described as "thickets," to discourage generic and biosimilar manufacturers from bringing lower-priced versions of brand-name medicines to market. The bill supposedly mitigates one alleged form of patent gamesmanship: obtaining "duplicative" patents that cover obvious variations on what the biopharmaceutical companies had already patented.

The ETHIC Act would limit a patent owner to asserting only one patent from each group of patents connected by terminal disclaimers and prevent them from asserting any of the patents from that group in later litigation against that same party. Its premise is that patent thickets deter generic and biosimilar competition and that limiting the number of such patents asserted in litigation would reduce litigation costs and make generic and biosimilar entry easier.

That premise fails for two reasons. First, empirical studies have not established that increases in the number of patents associated with a drug delay generic entry, much less that patents connected by terminal disclaimers cause such delays. Moreover, the Hatch-Waxman Act and the BPCIA provide mechanisms for identifying relevant patents and resolving infringement disputes before generic or biosimilar market entry. Courts can also manage litigation of overlapping patent claims, further weakening the assumption that each additional patent in a related group necessarily increases the burden of litigation.

Second and more importantly, terminal disclaimers are not simply a means for obtaining additional patents. Instead, they allow inventors to continue building on earlier discoveries, to protect subsequent developments, and to protect their investments in doing so without unduly extending or fragmenting the resulting patent protections. Such mechanisms are particularly important in the long, iterative, and uncertain development cycles that characterize science-based, research-intensive industries such as biopharmaceuticals.

The proposed ETHIC Act thus would serve no purpose other than to impose substantial costs on patent administration and incremental innovation, without solving any actually existing problems.

The Alleged Competitive Harm Has Not Been Demonstrated

The case for restricting terminally disclaimed patents relies on the claim that those patents materially increase the difficulty generics and biosimilars face when entering the market, but the available evidence does not establish this premise.

First, no evidence establishes that increasing numbers of patents on a drug delay generic or biosimilar competition. Studies report that the period from brand-name launch to generic entry has remained approximately twelve to fourteen years, even as some critics allege increasing numbers of patents per drug.[2] The PTO's Drug Patent and Exclusivity Study cautions that patent counts alone do not reliably indicate the duration of exclusivity, and other IPPI research has found no statistically significant correlation between the number of patents and actual generic entry.[3] These findings do not exclude the possibility that particular patents affect entry, but they do not establish the broader causal relationship on which the ETHIC Act appears to depend.

Second, the claim that terminally disclaimed patents impede generic and biosimilar competition is difficult to reconcile with procedures Congress has established to identify and litigate relevant patents. For small-molecule drugs, the Orange Book provides notice of patents that qualify for listing, while the BPCIA patent dance and the Purple Book provide avenues for identifying patents potentially relevant to biosimilars. The Hatch-Waxman Act and the BPCIA also allow patent disputes to be litigated before a generic or biosimilar product enters the market, reducing the need to incur potential infringement damages simply to obtain judicial review.[4] Courts may further limit the number of asserted claims or claims to be construed, while permitting additional claims when they raise distinct issues.[5] Courts typically impose those limits only after the parties have taken discovery and the court can ascertain what issues are actually being raised. The ETHIC Act would instead fix the choice when the action is filed and make it permanent as against that party.

These procedures do not eliminate patent-clearance or litigation expenses, but they reduce burdens associated with identifying the relevant patents and resolving

disputes before entry. Accordingly, the case for a new restriction on patent assertion cannot rest solely on a count of patents associated with a drug product.

Terminal Disclaimers Protect the Continuing Innovation Necessary for Drug Development

Patent protection in biopharmaceutical development often begins before a company knows which of the compounds disclosed in an early application can become a useful medicine. Years of preclinical research, clinical testing, and formulation work may reveal that only a particular molecule, salt, dosage form, or method of administration offers the necessary combination of safety, efficacy, and manufacturability. Later patent applications may therefore claim narrower embodiments or other improvements that are closely related to earlier discoveries. Such claims may reflect substantial additional work even where some might regard them as obvious variations of earlier claims.

The interaction of obviousness-type double patenting ("ODP") and terminal disclaimers accommodates the closely related inventions that often emerge during an extended program of biopharmaceutical research. ODP is a judicially created doctrine intended to prevent the use of patents on inventions that are not patentably distinct to extend the period of exclusivity associated with an earlier patent. A terminal disclaimer allows an applicant to resolve an ODP rejection while retaining patent protection for a subsequent invention that otherwise meets the requirements for patentability. It does so by relinquishing any portion of the later patent's term that would extend beyond the reference patent and, under PTO rules, generally requiring the patents to remain under common ownership for the later patent to be enforceable.[6] This procedure allows developers to seek protection for narrower embodiments, formulations, dosing regimens, and other innovations identified through additional research, without extending the earlier patent's period of protection or dividing related rights among separate owners.

Filing a terminal disclaimer is not an admission that the later invention is obvious, however.[7] Nor does it excuse the later application from satisfying the other statutory requirements for patentability. Instead, it provides a practical way to resolve an ODP question without prolonged examination or appeal, thereby facilitating the protection and disclosure of the successive improvements often needed to turn an early discovery into a medicine that is safe and effective for patients.

This accommodation is consistent with congressional measures intended to permit researchers to build on their earlier work. The Cooperative Research and Technology Enhancement ("CREATE") Act expanded the circumstances in which certain disclosures from qualifying joint research would not defeat the patentability of subsequent inventions. The America Invents Act subsequently excluded certain commonly owned or jointly researched disclosures from prior art. Neither measure displaced the separate ODP doctrine, however, so applicants may still face ODP rejections even when their earlier work cannot be used as statutory prior art. Terminal disclaimers provide a way to protect subsequent inventions without improperly extending the earlier patent term.[8]

In terms of their effect on litigation, patents connected by terminal disclaimers more closely resemble additional claims to the original patents rather than entirely separate patents. The related patents remain linked in the public patent record, generally expire no later than the specified reference patent, and can be enforced only while commonly owned.[9] Their existence, without more, does not establish that terminal disclaimers diminish the advantages of the statutory pathways available to generic and biosimilar applicants.

The companion analysis examines the function of ODP and terminal disclaimers, together with the evidence concerning patent counts and generic market entry, in greater detail.[10]

Why the Likely Effects of the ETHIC Act Would Be Counterproductive

The ETHIC Act would make terminal disclaimers substantially less useful to applicants anticipating patent litigation. A disclaimer that now allows the applicant and examiner to resolve an ODP rejection could later prevent assertion of all but one patent in the related group. Applicants would therefore have stronger incentives to contest at least some ODP rejections through continued examination and appeal rather than file disclaimers. One likely consequence would be more contested prosecution and greater demands on PTO and appellate resources.

The timing of that choice compounds the problem. A patent owner suing a generic or biosimilar applicant could assert only one patent from each group in the action and could not later sue that party on another patent from the same group.[11] The choice would come before discovery, which provides vital information about the generic or biosimilar product that lets a patent owner narrow its case. That is why

courts generally require narrowing in stages, as the information becomes available, allowing additions as needed. The ETHIC Act, by contrast, would force selection of patents to be asserted well before the necessary information is available and then bar any later correction.

Some applicants contesting ODP rejections might also establish that later-claimed inventions are patentably distinct from the earlier claims. In those cases, the patents could issue without terminal disclaimers and retain any additional term that the applicants otherwise might have surrendered. Thus, instead of shortening the period during which related patents can be asserted, the legislation could encourage some applicants to seek full-term patents. Whether that would occur in a particular case would depend on the merits of the ODP rejection and the patents' applicable expiration dates.

More importantly, the proposal could affect investment in subsequent improvements. Biopharmaceutical development may require refinements in formulation, dosage, delivery, and manufacturing that become apparent only after the initial patent application is filed. Some later inventions will be patentably distinct, but others may trigger ODP rejections even after substantial research. A restriction that reduces the enforceability of related patents could diminish incentives to invest in, disclose, and protect such developments. That potential cost is especially significant in an industry where clinical research is expensive and many projects never result in an FDA-approved product.

The bill would also reduce the value of patents that already exist. Although the Act applies only to generic and biosimilar applications submitted after enactment, it would affect the value of many patents that have already been issued with terminal disclaimers that were filed long before the patent applicants could know what the future implications of those disclaimers might later be.[12] A terminal disclaimer filed under current law leaves each patent in the group enforceable as long as they are commonly owned. The Act, if passed now, would make many of those patents valueless because they can no longer be asserted against a given defendant. Each additional patent in a group, and the research that produced it, would be worth correspondingly less, leaving patent owners with no way to undo the effects of disclaimers they had no way of anticipating at the time they were filed.

In sum, the ETHIC Act would restrict assertion of patents linked by terminal disclaimers even though the evidence does not demonstrate that such patents systematically delay generic or biosimilar competition. The resulting incentives could

increase contested ODP proceedings, enlarge PTO and appellate workloads, and encourage some applicants to seek patents without term disclaimers. At the same time, the bill could weaken patent protection for later developments that provide meaningful benefits to patients. In the absence of demonstrated competitive gains, these potential costs weigh against the proposed restriction.

References

[1] ETHIC Act, H.R. 3269, 119th Cong. (2025-26), https://www.congress.gov/bill/119th-congress/house-bill/3269/text; see also S. 2276, 119th Cong. (2025).

[2] Morris, E. M., & Kresh, J. (2024). Pharmaceutical "Nominal Patent Life" Versus "Effective Patent Life," Revisited. Intellectual Property Policy Institute, the University of Akron; Grabowski, Long, & Mortimer, (2021), "Continuing trends in U.S. brand-name and generic drug competition," J. Med. Econ., 24(1), 908–917; Lietzan & Acri, *Distorted Drug Patents*, 95 Wash. L. Rev. 1317, 1363 (2020); Lietzan & Acri, *Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations*, 33 Fordham Intell. Prop. Media & Ent. L.J. 788, 840 (2023); Kannappan S, Darrow JJ, Kesselheim AS, Beall RF, "The timing of 30-month stay expirations and generic entry: A cohort study of first generics," (2013-2020) Clin Transl Sci. 2021 Sep; 14(5):1917-1923.

[3] Morris, E. M., & Kresh, J. (2024). Pharmaceutical "Nominal Patent Life" Versus "Effective Patent Life," Revisited. Intellectual Property Policy Institute, the University of Akron; U.S. Patent & Trademark Off., Drug Patent and Exclusivity Study, 58-59 (2024), https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf.

[4] 42 U.S.C. § 262(l)(2)–(l)(6); 21 U.S.C. § 355(b)(1), (c)(2) (patent listing requirements); 35 U.S.C. §§ 271(e)(2)(A), (C) (creating artificial acts of infringement).

[5] Robert A. Matthews, Jr., "Limiting number of claims or terms that will be construed," *Annotated Patent Digest* § 3:17, June 2026 update, Westlaw; see, e.g., *In re Katz Interactive Call Processing Patent Litigation*, 639 F.3d 1303, 1309, 1312 (Fed. Cir. 2011), and *Nuance Comms., Inc. v. ABBYY USA Software House, Inc.*, 813 F.3d 1368, 1376 (Fed. Cir. 2016), acknowledging patentees' due process rights to add patents or claims only with specific justification that the new claims introduce issues not already substantially addressed by other included claims.

[6] 37 C.F.R. § 1.321(c)–(d).

[7] See, e.g., *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1167–68 (Fed. Cir. 2018).

[8] Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Pub. L. No. 108-453, § 2, 118 Stat. 3596 (amending pre-AIA 35 U.S.C. § 103(c)); 35 U.S.C. § 102(b)(2)(C), (c).

[9] 37 C.F.R. § 1.321(c)–(d); In re Braithwaite, 379 F.2d 594, 601 (C.C.P.A. 1967); see also Gideon Parchomovsky & R. Polk Wagner, Patent Portfolios, 154 U. Pa. L. Rev. 1 (2005).

[10] Emily Michiko Morris and Douglas S. Park, Obviousness-Type Double Patenting and Terminal Disclaimers in Biopharmaceutical Development, (Oct. 30, 2026) (forthcoming 2026).

[11] ETHIC Act, H.R. 3269, § 2(a) (adding 35 U.S.C. § 271(e)(7)(A), (C)).

[12] ETHIC Act, H.R. 3269, § 2(b).

About the Author

Douglas S. Park is a Research Fellow at the Center for Intellectual Property Law & Technology (UAIP) and IPPI: The IP Policy Institute and a Visiting Research Assistant Professor with The University of Akron School of Law.

Professor Park joined Akron Law in the spring of 2024 as a Research Fellow. He brings a wealth of experience to UAIP and IPPI.

About IPPI: The IP Policy Institute

IPPI: The IP Policy Institute is a Washington, D.C.-area based intellectual property law research center founded in early 2025 with The University of Akron School of Law. The IPPI team comes from the former Center for Intellectual Property x Innovation Policy (C-IP^2), which operated at George Mason University Antonin Scalia Law School from 2012 to early 2025.

For more information about IPPI, please visit **www.uakron.edu/law/IPPI**.

Contact Information

IPPI: The IP Policy Institute
The University of Akron School of Law
1201 Wilson Boulevard
Arlington, VA 22209

Email:

- Email us at IPPI@uakron.edu

Follow us on social media:

- LinkedIn: https://www.linkedin.com/company/the-ip-policy-institute-ippi/
- YouTube: @IPPolicyInstitute
- X: @IPPolicyInst
- Bluesky: @IPPI-akron-bsky.social