H.R. 3269 / S. 2276 • The ETHIC Act

Eliminating Thickets to Increase Competition Act • 119th Congress

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Key Takeaways

- **Brand-name drug manufacturers accumulate thickets of patents on their drugs that they then use to delay generic and biosimilar competition**. Studies show many of these patents are obvious variations of earlier patents, granted only after applicants file "terminal disclaimers."
- **The ETHIC Act allows one patent per group of obvious variation patents to be asserted against generic or biosimilar competitors in litigation**, while maintaining brand-name manufacturers' ability to enforce any patents that fall outside these patent groups.
- **The ETHIC Act substantially reduces the number of patents that could be enforced against generic or biosimilar competitors in litigation**, making market entry of generics and biosimilars faster and more efficient, leading to greater health care savings and broader patient access.
- In contrast to the ETHIC Act, **the Affordable Prescriptions for Patents Act does not address much of the problem of patent thickets**, because it affects far fewer patents and only ~1/4 as many drugs. The ETHIC Act is a more comprehensive reform bill that promotes innovation and affordability.

Background

Generic and biosimilar drugs lower prescription drug costs and expand patient access to essential medicines, but are only available once patents on the brand-name drug expire or are overturned in court.

Brand-name drug manufacturers can hold dozens (sometimes hundreds) of patents on a single drug, protecting not only the active ingredient but also how the drug is made and administered. This "**patent thicket**" strengthens or prolongs a brand-name manufacturer's period of exclusivity during which time the drug is extremely costly.[1]

Many patents in drug patent thickets are filed well after the drug has been FDA-approved. Most of these patents are so-called **continuation patents**, which by definition do not disclose anything new because they are obvious variations of earlier patents. To get continuation patents approved by the USPTO, companies file a **terminal disclaimer**, which makes the follow-on patent expire at the same time as the parent.[2] The USPTO permits this legal strategy since the overall expiration date is not lengthened, but granting the continuation patent increases the **density of the thicket**. Studies show drug companies file and litigate continuation patents at higher rates than other industries, consistent with using patents to prevent competition, rather than to protect innovation.[3][4]

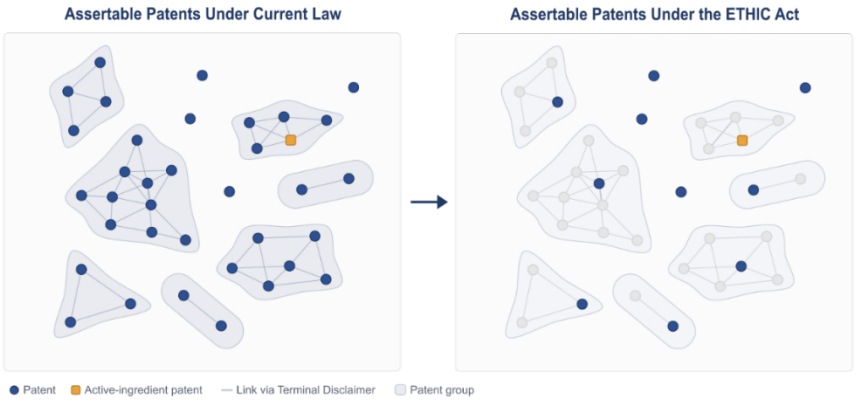
Brand-name manufacturer patenting practices result in a dense thicket of nearly identical patents that each must be challenged, making it harder and more expensive for generic and biosimilar manufacturers to make lower-cost therapies available to patients.

DRUG PATENT THICKETS		
96% of patents issued after FDA approval cover aspects other than drug active ingredients[5]	**200%** increase in continuation patents on small-molecule drugs granted from 2000 to 2015[6]	**36%** of litigated small-molecule drug patents were continuations filed 5+ years after the original patent[3]

Key Provisions

The ETHIC Act amends procedures under the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act to address drag on the drug market that comes from non-innovative, obvious patents. The ETHIC Act would expand access to lower-cost prescription drugs while preserving incentives for meaningful innovation.

Commonly owned patents linked by terminal disclaimers would be treated as a single "**patent group**." In any infringement lawsuit against a generic or biosimilar manufacturer, the brand-name manufacturer could assert **no more than one patent from each group** and **could not file separate lawsuits to circumvent that limit**.



The ETHIC Act would not change how patents are examined or granted by the USPTO, nor would it alter how patents are listed with the FDA. The bill's effects are limited to litigation involving groups of patents directed to obvious variants of the same invention.

Incentives to innovate would remain intact because manufacturers could still enforce legitimate patents but **must select one patent within each related patent group**.

Potential Impacts

The ETHIC Act can meaningfully reduce patent litigation burdens and promote timely market entry of generics and biosimilars, given the prevalence of terminal disclaimers on drug patents.

TERMINAL DISCLAIMERS (OBVIOUS VARIATION PATENTS)	
45% and 33% of small-molecule and biologic drug patents have terminal disclaimers (2002–2023)[7]	**48%** of patents asserted in biologic-biosimilar litigation had terminal disclaimers (2010-2023)[8]

The patent portfolios of two blockbuster drugs, **adalimumab (Humira)** and **lenalidomide (Revlimid),** provide an illustrative example of the potential impact of the ETHIC Act:[9]

IMPACT OF THE ETHIC ACT ON BLOCKBUSTERS		
	Adalimumab (Humira)	**Lenalidomide (Revlimid)**
Patents asserted under existing law	105	30
Patents assertable under the ETHIC Act	24	12
Reduction from existing portfolio	**-77%**	**-60%**

The ETHIC Act also restricts use of "**serial patent litigation**," in which drug companies bring successive lawsuits based on new continuation patents after earlier suits have settled, to further delay competition.[10]

Had the ETHIC Act been in effect, biosimilar firms for 9 of 12 biologics involved in patent litigation between 2010 and 2023 would have faced fewer patents in litigation.[11] The fact that the ETHIC Act also includes small-molecule drugs expands the scope of the legislation to hundreds more products.

Response to Criticism

Some have charged that the ETHIC Act would undermine drug companies' incentive to innovate.[12][13] However, the bill would **leave companies with the ability to enforce their strongest patent within each patent group** and would have **no effect on patents without terminal disclaimers** (i.e., patents on original, distinct, and non-obvious innovations).

The ETHIC Act only applies when a company has acknowledged that the newer patent is an obvious variation of an older one. **Limiting the ability of obvious variation patents to be asserted in litigation incentivizes firms to pursue more meaningful drug innovation.**

Comparison with the Affordable Prescriptions for Patients Act (S.1041)

The ETHIC Act is distinct from the **Affordable Prescriptions for Patients Act (APPA)**.[14] While both bills limit the number of patents a drug company can assert, they differ in scope and mechanism.

Only 3 (25%) of 12 originator biologics involved in biosimilar litigation from 2010-2023 would have had fewer patents litigated under the APPA.[11]

	ETHIC Act	APPA		Limitations of the APPA
Products Covered	**Small-molecule drugs** and **biologics**	**Biologics only**	➤	Applies to **only ~1/4 of FDA-approved drugs**.[15]
Number of Litigated Patents	**1 patent** per "patent group." **All other, non-obvious patents can be enforced**.	**Up to 20 patents** in the defined category, no more than 10 of which could have been issued after the initial patent exchange between parties. **Courts may increase the limit for good cause.**	➤	Biologics are protected by a median of 14 patents, meaning **the 20-patent cap may not consistently limit patent assertions**.[15]
Types of Patents Affected	Applies to **patents that are obvious variations of previously filed patents (i.e., have a terminal disclaimer)**. These patents, by definition, cannot disclose anything new.	Applies to **patents filed >4 years after FDA approval** and patents on manufacturing processes not used by the brand-name manufacturer.	➤	**Many patents are filed before or within the first 4 years after FDA approval** and would be exempt.
	Applies to patents regardless of filing date or claim type (e.g., active ingredient, formulation, method of treatment, manufacturing process).	Patents filed prior to FDA approval and **all method-of-use patents are exempt**.	➤	**Method-of-use patents are explicitly excluded**, despite these patents being a key tool used to delay market competition.[16][17]
Conditions for Any Limits to Apply		Biosimilar manufacturers must **comply with disclosure obligations** under existing law.	➤	Brand-name manufacturers alleged non-compliance in 90% of biosimilar legal challenges from 2010 to 2023.[11] **Even unsupported allegations could exempt patents from the cap**.

The ETHIC Act reaches more of the drug patent thicket problem by covering all FDA-approved drugs and biologics. It preserves the patent system's incentives for genuine innovation by targeting only patents that the patent holder has acknowledged are obvious variations of earlier patents. By preventing brand-name manufacturers from asserting all obvious patents in a group, the ETHIC Act will help generics and biosimilars reach patients without harming innovation.

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