Patents and Drug Pricing

Why Weakening Patent Protection Is Not in the Public's Best Interest

Image: Getty Images/apomares

Heather M. Petruzzi, Jerry A. Salvatore, and Patrick E. Nyman

The price of branded drugs in the United States has been and continues to be a hot topic. While various causes have been alleged, recent attention has focused heavily on the U.S. patent system. Lawmakers, the U.S. Patent and Trademark Office (USPTO), and even the former president have called for or sought to push through substantial changes to the patent system that weaken pharmaceutical patents. Blaming the patent system, however, overstates the impact patents have on drug prices. The correlation between the number of pharmaceutical patents associated with a product and competition is far from clear (as even the USPTO has found[1]), and by many metrics the patent system is working as intended. Yet many proposed "solutions" have treated patents as an easy fix without considering downstream ramifications.

This article discusses the importance of patents, the current frameworks in which generic and biosimilar manufacturers may rely on the innovator's (e.g., branded company's) research and development (R&D) to market their own products, recent governmental actions to weaken pharmaceutical patents, and why blaming patents for high drug prices oversimplifies a complex system and ignores the need to incentivize innovation. Finally, this article offers a few guiding principles for what change could look like.

Heather M. Petruzzi is a partner at WilmerHale in Washington, D.C., where her practice focuses on patent litigation, counseling, and post-grant practice in the life sciences sector. She can be reached at heather.petruzzi@wilmerhale.com. **Jerry A. Salvatore** is a counsel at WilmerHale in Washington, D.C., where his practice focuses on patent litigation and counseling in both the life sciences and hi-tech sectors. He can be reached at jerry.salvatore@wilmerhale.com. **Patrick E. Nyman**, PhD, is a senior associate at WilmerHale in Washington, D.C., where his practice focuses on patent litigation and counseling in the life sciences sector. He can be reached at patrick.nyman@wilmerhale.com.

Published in *Landslide*, Volume 17, Number 3, 2025.

The Patent System Was Designed to Promote the Progress of Science and Useful Arts

The American patent system traces its lineage to the Constitution, and it serves a crucial role in establishing a balance between encouraging (and rewarding) innovations while also ensuring that the public benefits from the technological advances of others. Put simply, a patent provides its owner with a set of time-limited, exclusive rights to practice the inventions covered by the patent, thus encouraging innovators to disclose their inventions without the fear that others will steal them. After those expire, the public is free to use the patented innovation. This basic principle is true regardless of whether the patent covers a life-saving drug, a new golf club design, or a component in a mobile phone.

Patents in the pharmaceutical industry protect the substantial investment in pharmaceutical research, development, and regulatory approval necessary to bring a new drug to market. As the Congressional Budget Office found in 2021, the expected cost to develop a new drug was as much as $2 billion,[2] while other entities have estimated it takes more than 10 years of research and well over $2 billion to bring a new product to market.[3] Moreover, patents provide market certainty as to who owns which inventions, which protects investment in innovation. For example, it is estimated that nearly 90% of drugs entering clinical trials fail to make it to market. As such, branded pharmaceutical companies must earn enough revenue on their drugs during their exclusivity period to fund existing and future development projects, knowing that the majority of their innovations will not reach the market. Indeed, after patent protection expires and competitors enter the market, it is rare for the branded drug to be used to fill the prescription over an often cheaper alternative: According to a 2022 Food and Drug Administration (FDA) study, approximately "91% of all prescriptions in the United States are filled as generic drugs."[4]

Generic drug companies (or biosimilar companies) sell products at substantially reduced costs, but they also have reduced R&D costs because they rely on prior clinical trials. And the trade-off is allowing the brand drug an exclusivity period.[5] This is how the patent system in the pharmaceutical industry is *supposed to work*: provide a limited period of exclusivity to the newest innovations to reward past research and fund existing and future R&D, and then open the field to low-cost generics for all time. To take just one example, in 2011 Lipitor was a blockbuster drug that was the best-selling drug of all time, and its active ingredient (atorvastatin) remains the most prescribed drug today.[6] However, by 2011 its compound and enantiomer patents expired, so generics entered the market and the price rapidly decreased.[7] Today, drugs such as Ozempic receive the most patent-based criticism, but it is only a matter of time before those drugs end up in similar positions to Lipitor.

CONGRESS PASSED REGIMES FOR BOTH BRAND AND GENERIC/BIOSIMILAR COMPANIES THAT CAREFULLY BALANCE THE NEED TO ENCOURAGE INNOVATIONS (E.G., ALLOW THE BRAND TO EARN REVENUE ON ITS SUBSTANTIAL R&D AND REGULATORY COSTS AND FUND FUTURE RESEARCH) WITH THE NEED TO ENCOURAGE COMPETITION WITH GENERICS AND BIOSIMILARS TO ENSURE LONG-TERM AFFORDABILITY.

Both generic/biosimilar manufacturers and brand innovators serve important roles in the pharmaceutical industry and health care system. Congress passed regimes for both brand and generic/biosimilar companies that carefully balance the need to encourage innovations (e.g., allow the brand to earn revenue on its substantial R&D and regulatory costs and fund future research) with the need to encourage competition with generics and biosimilars to ensure long-term affordability. The Drug Price Competition and Patent Term Restoration Act (also known as the Hatch-Waxman Act) applies to small molecules, and the Biologics Price Competition and Innovation Act (BPCIA) applies to biologics (e.g., larger drugs that are derived from natural, biological sources such as animals

or microorganisms as opposed to synthesized in a laboratory).

The Hatch-Waxman Act was a compromise for both branded and generic drug companies.[8] Previously, generic drug companies had to conduct their own clinical trials, which was expensive and led to higher prices. The Hatch-Waxman Act allows a "generic to piggy-back on the pioneer's approval efforts," such as through relying on the branded company's clinical testing, which speeds up "the introduction of low-cost generic drugs to market, . . . thereby furthering drug competition," while maintaining incentives for innovation.[9]

The BPCIA was designed "to help provide patients with greater access to safe and effective biological products."[10] Following the BPCIA, there were two established pathways for the approval of a biologic product. While the first pathway is for the brand, the second is for a biosimilar manufacturer (similar to a generic manufacturer), which "may piggyback on the showing made by the manufacturer (sponsor) of a previously licensed biologic (reference product)" in seeking approval.[11] This second option provides a cheaper path to approval because it requires fewer studies. Like Hatch-Waxman, it also balanced the abbreviated pathway and incentives for innovation. And like the Hatch-Waxman Act, the BPCIA "facilitates litigation during the period preceding FDA approval so that the parties do not have to wait until commercial marketing to resolve their patent disputes."[12]

These legislative solutions have been successful. For example, the percentage of generic drugs filling prescriptions increased from 19% prior to the Hatch-Waxman Act to 91% today.

Recent Governmental Actions to "Weaken" Pharmaceutical Patents

Discussions on drug pricing are nothing new, but the past few years have seen governmental actors, including the former president, the USPTO, and Congress, place an intensified focus on the patent system and drug pricing. Below are several notable examples.

Actions Taken by the Former President

On July 9, 2021, President Biden issued an executive order on "Promoting Competition in the American Economy."[13] He called for the USPTO and FDA to work together and "help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law."[14] The FDA quickly followed, writing a letter to the USPTO stating its view that

> [s]ome of the challenges that the public and the Administration face with respect to drug pricing . . . seem to stem from . . . brand use of the patent continuation process to create patent thickets, product hopping, and evergreening[] being used in ways that unduly extend market monopolies and keep drug prices high without any meaningful benefits for patients.[15]

Actions Taken by the USPTO

Once former Director Vidal took office, the USPTO responded to the FDA in July 2022, proposing various "solutions" including "applying greater scrutiny to continuation applications in large families" and "[r]evisit[ing] obviousness-type double patenting practice."[16] Then, the USPTO sent a series of requests for comment (RFCs) and notices of public rulemaking (NPRMs).

- An October 2022 RFC requested the public's comment on most of the proposed solutions and actions discussed in the USPTO's July 6, 2022, letter to the FDA and the June 8, 2022, letter from certain senators to the USPTO referenced below.[17] A November 2022 notice and RFC seeking feedback on USPTO-FDA initiatives also discussed those letters and the executive order.[18]
- An April 2024 NPRM for patent fees included several fee increases directed toward continuation practice, terminal disclaimers, and patent term extension (PTE).[19] These fee increases were often well above inflation-adjusted increases (e.g., over three times the inflation-adjusted fee for PTE). The NPRM's terminal disclaimer fee schedule also incentivized applicants to file a terminal disclaimer before receiving an obviousness-type double patenting (OTDP) rejection, and it further increased terminal disclaimer fees if the applicant attempted to overcome the rejection.[20]
- A May 2024 NPRM proposed requiring applicants filing terminal disclaimers to agree not to enforce any claim of a patent tied by terminal disclaimers to another patent that has had (1) any claim held invalid under 35 U.S.C. § 102 or § 103 (after appeals have been exhausted) or (2) a statutory disclaimer filed for any claim after a challenge under § 102 or § 103 was made on the disclaimed claims.[21] This NPRM would substantially change the judicially made doctrine of OTDP, potentially rendering patents unenforceable based on references that are not statutory prior art.[22]

At the same time, former Director Vidal began issuing director review decisions that limited discretionary denial of inter partes review (IPR) petitions, which allowed more IPR challenges and serial petitions to proceed and to reach a final decision,[23] potentially in response to a letter from Congress regarding "a disturbing rise in discretionary denials of IPR petitions."[24] That letter, relying only on general statistics regarding IPR discretionary denials, focused on the pharmaceutical industry and how the patent system has "allowed drug companies to engage in anti-competitive practices that drive up the cost of drugs and keep competitors from entering the market."[25]

Actions Taken in Congress

The legislative branch has also addressed pharmaceutical patents, including:

- The Committee on Oversight and Reform in the House of Representatives issued an extensive report on pharmaceutical pricing in December 2021 that heavily focused on the patent system as the reason for high prices.[26] And pharmaceutical companies and other organizations are frequently brought to testify before congressional committees.
- Members of Congress regularly propose legislation directed to changes in the patent system, but two recent bills of note addressed "patent thickets," continuation practice, and terminal disclaimers in the pharmaceutical industry specifically.[27]

"A bill to address patent thickets" (the Welch-Arrington bill) would place substantial one-sided limits on patent holders in generic or biosimilar litigation: Only a single patent per group sharing any terminal disclaimer relationship could be asserted, with no exceptions.[28] The Affordable Prescriptions for Patients Act of 2023, which passed the Senate in July 2024, aims to accomplish similar goals—reduce "patent thickets" by limiting the number of patents that can be asserted in a case.[29] It contains exceptions to account for countervailing actions from biosimilar companies such as not providing sufficient information on product features or making material changes after patents have been asserted.

- Members of Congress have also devoted significant attention to putting pressure on the USPTO through letters. As noted above, members of Congress have sent multiple letters regarding concerns with patents and pharmaceutical pricing. Most of these letters have expressly blamed the patent system for high drug prices. Perhaps most notably, on June 8, 2022, a group of senators sent a letter to former Director Vidal less than two months after she was sworn in, claiming that "patent thickets" were a major impediment to lower prices, and calling for a variety of potential actions that would be echoed by the USPTO proposed rulemakings discussed above.[30]

Actions Taken by Other Governmental Actors

Other governmental actors have also considered the patent system and drug pricing, primarily via the Bayh-Dole Act. In December 2023, the National Institute of Standards and Technology (NIST) published draft guidance on when to exercise "march-in rights" under Bayh-Dole and included as a factor "the reasonableness of the price and other terms at which the product is made available to end-users."[31] The FTC published comments supporting this proposed framework, describing an interpretation of "reasonable terms" in 35 U.S.C. § 201(f) as including price as part of its plain meaning.[32] This was contrary to prior regulations and understandings of the bill as it was passed.[33] Similarly, the NIH published a request for information in May 2024, proposing that prospective licensors of Bayh-Dole-related inventions prepare an "access plan" including, for example, market analyses and strategies to ensure sufficient access to licensed products.[34]

Blaming the Patent System for Drug Pricing Is an Overly Simplistic Rationale in a Complex Industry

These recent attempts to modify the patent system to, in effect, weaken pharmaceutical patents, underscores the focus on the patent system and drug pricing. But evidence shows that the patent system in the pharmaceutical space is functioning how it is supposed to: It allows the innovator to earn revenues on substantial R&D investments and to perform future research, while allowing public access to that innovation upon patent expiration.

First, branded drugs (and other drugs without generic competition) represent only a small share of the number of prescriptions filled. As previously noted, not only is it estimated that about 91% of filled prescriptions are filled with generics or biosimilars, but there are approved, marketed generic drugs for each of the top 20 most prescribed drugs.[35] Thus, the patent system, with respect to the drug industry, is working as intended. This large share of prescriptions filled by generics coupled with the fact that the top prescribed drugs all face generic competition demonstrate the opportunity for generic drugs to drive down prices. And the limited patent term allows companies to earn revenues on investments in R&D costs, and to continue investment in new R&D for the *next* generation of medicines. Indeed, taking aim at the top revenue grossing drugs (and their patents) (1) ignores that these drugs only account for a small portion of the total number of prescriptions filled in the United States, (2) ignores that these drugs received patents because of their novel and nonobvious advances over then-existing drugs, and (3) disregards how patents encourage innovation in the first place, thereby facilitating treatment advances.

EVIDENCE SHOWS THAT THE PATENT SYSTEM IN THE PHARMACEUTICAL SPACE IS FUNCTIONING HOW IT IS SUPPOSED TO: IT ALLOWS THE INNOVATOR TO EARN REVENUES ON SUBSTANTIAL R&D INVESTMENTS AND TO PERFORM FUTURE RESEARCH, WHILE ALLOWING PUBLIC ACCESS TO THAT INNOVATION UPON PATENT EXPIRATION.

Second, the connection between the number of patents covering a drug and time to generic entry is far from clear. Certain groups commonly cited by Congress (e.g., I-MAK and UC Hastings Database[36]) have produced various studies arguing that the "patent system is not working as intended and the public is paying the price,"[37] and that the pharmaceutical industry has been unfairly "extend[ing] the life of their drug patents and monopoly periods by obtaining additional protections, often based on minor modifications."[38] These studies appear to have had an outsized effect on governmental actors' views toward the patent system. However, in the years since these studies first came out, the conclusions drawn and methodologies used have been called into question by scholars,[39] Congress, and most recently the USPTO itself.[40]

Pursuant to Senator Tillis's letter raising concerns with the lack of scrutiny on these studies, the USPTO conducted "an independent assessment and analysis of certain sources and data that are being relied upon by those advocating for patent-based solutions to drug pricing."[41] The study provides an approach for researchers to study the time from approval of a new drug application (NDA) to the first launch of a generic drug.[42] After analyzing 25 NDAs and related generic competition, the study concluded that pharmaceutical market exclusivity from the time of NDA approval to the launch of a first generic competitor is "influenced by a complex interplay of patent law and FDA statutes and regulations," and how in some cases, "the timing of the entry of generic products is not fully reflected by a computation of patents and exclusivities and competition could be affected by other factors."[43] Notably, the USPTO study expressly *rejected* methodologies used by I-MAK and UC Hastings Database, pointing out, for example, that their analyses include factors that are "not a meaningful metric."[44] The study's conclusions are consistent with other studies assessing time to generic entry, which have found, for example, average generic entry times of about 13 years, and that "patent thickets" have little effect on extending patent life.[45]

Third, R&D spending in the pharmaceutical industry has generally trended upward,[46] which shows that companies are reinvesting revenues to fund new treatments as intended by the system. Indeed, the Congressional Budget Office showed in 2021 that the percentage of pharmaceutical companies' net revenues that go into R&D activities is significantly higher than in other industries.[47]

Moreover, as one would expect, when pharmaceutical patents expire and generic products enter the market, the price of a given drug comes down, which in turn further promotes patient access. Using the prior example of Lipitor, the out-of-pocket cost for patients dropped from about $40 to ultimately under $5.[48]

Fourth, many industries obtain multiple patents covering one product, not just the pharmaceutical industry. For example, although the term "patent thicket" is frequently used in reference to the pharmaceutical industry, many industries have multiple patents around a single product. For example, LG Electronics lists over 500 patents as associated with its "Broadcasting (ATSC DTV Standard related)" feature, Titleist has dozens of patents covering one type of golf ball, and Nike has at least 300 patents on a sneaker style.[49] Moreover, when looking at the companies with the most patents granted in a year, none of the top 10 is a pharmaceutical company, and generally pharmaceutical companies make up only a very small sliver of the companies listed.[50] And suggestions that pharmaceutical patents are "bad" or "weak" are unfounded: Pharmaceutical patents withstand invalidity challenges at a better rate than other technology areas, suggesting instead that the innovations (and subsequent patents) in the pharmaceutical industry are generally more novel and innovative when compared to other industries.[51]

Finally, the "solutions" to addressing concerns with pharmaceutical patents have generally gone too far without considering downstream consequences. Two prominent examples of this are the Welch-Arrington bill and the recent string of USPTO proposed rulemakings. As discussed above, the Welch-Arrington bill would allow only a single patent per group sharing any terminal disclaimer relationship to be asserted, with no exceptions. This bill does not consider potential countervailing actions from generics and biosimilars such as failure to engage in the BPCIA's "patent dance" or changes to the accused product or manufacturing process such that the initially asserted patent no longer reads on the product—even if another patent in the family does. And as discussed above, the recent USPTO proposal to revamp terminal disclaimers seeks to overhaul the judicially made doctrine of OTDP and its implications on terminally disclaimed patents, allowing challengers to render unenforceable every claim of multiple patents (regardless of scope) by proving the invalidity of a single claim. Even a group of former directors, deputy directors, and commissioners took the "unusual step" of submitting a letter to former Director Vidal, stating that "[t]hese proposed rules provide perverse incentives and threaten serious harm to America's innovation economy."[52]

Commonsense Action

The above critiques are not meant to dismiss the need for affordable medicines, nor to suggest that the patent system cannot be improved. Below, we propose some guiding principles for potential reform.

First, solutions specific to the pharmaceutical industry must consider countervailing actions from generics and biosimilars. Any solution should ensure that generic entry occurs when a patent is expired, invalid, or not infringed, and *not* due to loopholes in the law. Federal legislation or rules focused on actions by branded companies should also consider countervailing actions from generics and biosimilars aimed at preventing innovators from asserting valid and infringed patents, for example, by hiding certain product information.

Second, any solutions should also recognize that potential deficiencies of the patent system are not unique to the pharmaceutical industry. For example, although some senators expressed concern that USPTO discretionary denial of IPR petitions is preventing proper review of pharmaceutical patents, they cited only general statistics and did not identify any analysis of how frequently petitions against pharmaceutical patents specifically are discretionarily denied.[53] Critics have also complained about high numbers of weak patents for pharmaceutical companies, but companies from other industries have *more* patents issuing that are *more* likely to be invalidated in litigation or IPRs.[54] If problems connected to the patent system are industry-agnostic, then the solutions should be also industry-agnostic, and the effects should be considered across industries. For example, concerns about continuation practice and the perception that the USPTO grants too many

weak pharmaceutical patents as continuation applications should be addressed in a technology-agnostic way such that the same statutory patentability standards apply. As one example, the government can increase USPTO examiner training or provide examiners with additional resources and time to consider whether to grant a patent in all technologies. And any industry-specific patent changes must not upset the balance between innovation and access inherent in the Hatch-Waxman Act and BPCIA.

Third, any solutions should recognize that there is much more to drug prices—and prices of health care generally—than patents and patent exclusivity. Of course, it is to be expected that a product covered by a patent should be some degree more expensive than one without a patent—that is part of the quid pro quo of our patent system. But what that degree should be is not a question for the patent system to resolve. And as the USPTO 2024 report itself acknowledged, "pharmaceutical market exclusivity from the time of NDA approval to the launch of a first generic competitor is influenced by a complex interplay of patent law and FDA statutes and regulations."[55]

The patent system is not a feasible means to address pricing in any sector. Instead, the patent system serves to balance other important interests, such as rewarding and incentivizing innovation while ensuring long-term access to such innovations. Indeed, Congress and the executive branch have a wide range of means for addressing affordability,[56] and targeting the patent system is much more likely to harm American innovation than it is to address drug pricing. ■

Endnotes

1. U.S. Pat. & Trademark Off., Drug Patent and Exclusivity Study 1 (2024) [hereinafter USPTO Study], https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf.

2. *Research and Development in the Pharmaceutical Industry*, Cong. Budget Off. (Apr. 2021), https://www.cbo.gov/publication/57126 (estimated cost to develop drug ranges from less than $1 billion to more than $2 billion).

3. Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 20, 25 (2016).

4. U.S. Food & Drug Admin., Office of Generic Drugs 2022 Annual Report 1 (2023), https://www.fda.gov/media/165435/download?attachment.

5. New drugs may have patent exclusivity as well as regulatory exclusivity. 21 U.S.C. §§ 355(a), 355(j)(5)(F), 355(a), 360. This article focuses on patent exclusivity.

6. *Lipitor Became World's Top-Selling Drug Despite Uncertain Beginning*, Denver Post (Dec. 28, 2011), https://www.denverpost.com/2011/12/28/lipitor-became-worlds-top-selling-drug-despite-uncertain-beginning/; Matej Mikulic, *Leading 20 U.S. Pharma Products by Total Prescriptions in 2022*, Statista (Oct. 7, 2024), https://www.statista.com/statistics/233986/top-us-pharma-products-by-prescriptions/ (atorvastatin has been prescribed more than 100 million times).

7. *See* Matej Mikulic, *Atorvastatin Out-of-Pocket Cost in the U.S. from 2004 to 2022*, Statista (Nov. 5, 2024), https://www.statista.com/statistics/825214/atorvastatin-out-of-pocket-cost/.

8. 130 Cong. Rec. 23,627, 23,764 (Aug. 10, 1984) (statement of Sen. Orrin Hatch).

9. FTC v. Actavis, Inc., 570 U.S. 136, 142–43 (2013).

10. *Biological Product Innovation and Competition*, U.S. Food & Drug Admin. (Apr. 10, 2024), https://www.fda.gov/drugs/biosimilars/biological-product-innovation-and-competition.

11. Sandoz Inc. v. Amgen Inc., 582 U.S. 1, 7 (2017).

12. *Id.*; *see also* 35 U.S.C. § 271(e)(2)(C)(i), (ii).

13. Promoting Competition in the American Economy, Exec. Order No. 14,036, 86 Fed. Reg. 36987, 36997 (July 9, 2021).

14. *Id.*

15. Letter from Janet Woodcock, Acting Comm'r of Food & Drugs, to Andrew Hirshfeld, Acting USPTO Dir. 4–5 (Sept. 10, 2021), https://www.uspto.gov/sites/default/files/documents/EO14036-FDALettertoPTO.pdf.

16. Letter from Katherine K. Vidal, USPTO Dir., to Robert M. Califf, Comm'r of Food & Drugs 6 (July 6, 2022), https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf. The heads of the USPTO and FDA jointly published an article the same day further outlining their plans. Kathi Vidal & Robert M. Califf, *The Biden Administration Is Acting to Promote Competition and Lower Drug Prices for All Americans*, U.S. Pat. & Trademark Off. (July 6, 2022), https://www.uspto.gov/blog/the-biden-administration-is-acting. As of December 13, 2024, Vidal is no longer the director of the USPTO.

17. Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. 60130 (Oct. 4, 2022).

18. Joint USPTO-FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments, 87 Fed. Reg. 67019 (Nov. 7, 2022).

19. Setting and Adjusting Patent Fees During Fiscal Year 2025, 89 Fed. Reg. 23226 (Apr. 3, 2024).

20. *Id.* at 23248–49. Following public feedback, the USPTO moderated certain fees, including, for example, not implementing the tiered fee structure for terminal disclaimers and reducing the PTE fee increase. Setting and Adjusting Patent Fees During Fiscal Year 2025, 89 Fed. Reg. 91898 (Nov. 20, 2024).

21. Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting, 89 Fed. Reg. 40439 (May 10, 2024). The USPTO eventually withdrew this proposed rule, citing "resource constraints," but left the door open for future rulemaking or other reform. Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting; Withdrawal, 89 Fed. Reg. 96152 (Dec. 4, 2024).

22. *See* 35 U.S.C. § 102(b)(2)(C). As an example of its breadth, if patent X had a terminal disclaimer over patent Y, which itself had a terminal disclaimer over patent Z, the invalidation under § 102 or § 103 of any single claim in patent Z would render all claims of patent X unenforceable. 89 Fed. Reg. at 40443.

23. *See, e.g.*, Ford Motor Co. v. Neo Wireless LLC, No. IPR2023-00763, Paper 28, at 11 (P.T.A.B. Mar. 22, 2024) (Vidal).

24. Letter from Sens. Patrick Leahy, Ron Wyden, Debbie Stabenow, Elizabeth Warren & Richard Blumenthal & Congs. Bobby L. Rush, Darrell Issa, Anna G. Eshoo, Tom Tiffany, Pramila Jayapal & Victoria Spartz to Acting USPTO Director Andrew Hirshfeld (Sept. 16, 2021), https://www.law.berkeley.edu/wp-content/uploads/2021/11/Letter-to-PTO-Re-Discretionary-Denials-and-Drug-Pricing-Signed.pdf.

25. *Id.*

26. H. Comm. on Oversight & Reform, Drug Pricing Investigation: Majority Staff Report (2021), https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf.

27. A third bill, titled Stopping Pharma's Ripoffs and Drug Savings for All Act, H.R. 6436, 118th Cong. (2023), would require patent holders in generic or biosimilar litigation to demonstrate "distinct inventions" or else disclaim PTE of one patent over another.

28. S. 3583, 118th Cong. (2024).

29. S. 150, 118th Cong. (2023).

30. Letter from Sens. Patrick Leahy, Richard Blumenthal, Amy Klobuchar, John Cornyn, Susan M. Collins & Mike Braun to Kathi Vidal, USPTO Dir. 1 (June 8, 2022), https://fingfx.thomsonreuters.com/gfx/legaldocs/gdpzyeojjvw/IP%20PATENTTHICKETS%20letter.pdf.

31. Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. 85593 (Dec. 8, 2023).

32. U.S. Fed. Trade Comm'n, Comment on Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights 9 (Feb. 6, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/2024.02.06March-InRightsComment.pdf.

33. *See, e.g.*, 37 C.F.R. pts. 401, 404; *Our Laws Help Patients Get New Drugs Sooner*, Wash. Post (Apr. 10, 2002), https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/ (Senators Bayh and Dole stating that "Bayh-Dole did not intend that government set prices on resulting products").

34. National Institutes of Health (NIH) Office of Science Policy (OSP): Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning, 89 Fed. Reg. 45003 (May 22, 2024).

35. *See Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. Food & Drug Admin. (Feb. 14, 2025), https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book (each of the drugs in Statista's "Leading 20 U.S. Pharma Products by Total Prescriptions in 2022," *supra* note 6, have an approved generic product); *Top 100 Most Commonly Prescribed Generic Prescription Drugs*, HealthPartners, https://www.healthpartners.com/content/dam/brand-identity/pdfs/plan/top100-rxlist-wi.pdf (last visited Feb. 23, 2025) (including prices for average cost per 30-day supply).

36. UC Hastings Database is shorthand for the Evergreen Drug Patent Database.

37. I-MAK, Overpatented, Overpriced: Curbing Patent Abuse: Tackling the Root of the Drug Pricing Crisis (2022), https://www.i-mak.org/wp-content/uploads/2023/01/Overpatented-Overpriced-2023-01-24.pdf.

38. *Evergreen Drug Patent Search*, UC Hastings, https://sites.uclawsf.edu/evergreensearch/ (last visited Feb. 23, 2025).

39. Numerous legal scholars have criticized the reliability of I-MAK and UC Hastings Database. *See, e.g.*, Adam Mossoff, *Unreliable Data Have Infected the Policy Debates Over Drug Patents*, Hudson Inst. 2–3 (Jan. 2022), https://s3.amazonaws.com/media.hudson.org/Mossoff_Unreliable%20Data%20Have%20Infected%20the%20Policy%20Debates%20Over%20Drug%20Patents.pdf; Erika Lietzan & Kristina Acri née Lybecker, *Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations*, 33 Fordham Intell. Prop., Media & Ent. L.J. 788, 788–89 (2023); Emily Michiko Morris & Joshua Kresh, *Pharmaceutical "Nominal Patent Life" Versus "Effective Patent Life," Revisited*, Ctr. for Intell. Prop. x Innovation Pol'y (May 20, 2024), https://cip2.gmu.edu/2024/05/20/pharmaceutical-nominal-patent-life-versus-effective-patent-life-revisited/.

40. *See* USPTO Study, *supra* note 1.

41. *Id.* at 1.

42. *Id.* ("The purpose of the study is to provide a baseline approach that researchers and policy makers can use in future analysis for examining the number of years from the time a New Drug Application (NDA) is first approved until the first launch of a generic.").

43. *Id.* at 59.

44. *Id.* at 13.

45. *See, e.g.*, Henry Grabowski et al., *Updated Trends in US Brand-Name and Generic Drug Entry*, 19 J. Med. Econ. 836 (2016); Morris & Kresh, *supra* note 39.

46. *See Research and Development in the Pharmaceutical Industry*, *supra* note 2 (reporting pharmaceutical industry's ratio of net revenue to R&D spending "has been trending upward since 2012" and exceeded 25% percent in 2018 and 2019).

47. *Id.* at fig. 1.

48. *See* Mikulic, *supra* note 7.

49. *Patents*, LG, https://www.lg.com/us/patent (last visited Feb. 23, 2025); *Titleist Patent Marking*, Titleist, https://www.titleist.com/patents (last visited Feb. 23, 2025); Alison Noon, *Puma Must Face Nike's Flyknit Patent Infringement Claims*, Law360 (Oct. 10, 2018), https://www.law360.com/articles/1091010/puma-must-face-nike-s-flyknit-patent-infringement-claims.

50. *See, e.g.*, Intell. Prop. Owners Ass'n, Top 300 Organizations Granted U.S. Patents in 2024 (2025), https://ipo.org/wp-content/uploads/2025/01/2024-Top-300-Patent-Owners-List.pdf.

51. *See, e.g.*, Steve Brachmann, *Report Shows Drug Patents Fare Better in IPR Proceedings at PTAB*, IPWatchDog (July 18, 2017), https://ipwatchdog.com/2017/07/18/drug-patents-fare-better-ipr-proceedings-ptab/id=85628/; *PTAB Orange Book Patent/Biologic Patent Study: FY24 Q2 Update*, U.S. Pat. & Trademark Off. 1 (Mar. 31, 2024), https://www.uspto.gov/sites/default/files/documents/orange_book_biologics_study_march2024.pdf.

52. Letter from Drew Hirschfeld, Andrei Iancu, David Kappos, Laura Peter & Russell Slifer to Katherine K. Vidal, USPTO Dir. 1 (May 28, 2024), https://ipwatchdog.com/wp-content/uploads/2024/05/Hirshfeld-Iancu-Kappos-Peter-Slifer-Letter-on-Docket-PTO-P-2024-0003.pdf. This letter also referenced the April 2024 NPRM proposing greatly increased fees, stating that the USPTO "is evidently attempting to significantly deter, if not eliminate, continuations practice." *Id.* at 2.

53. Letter from Sens. Leahy et al., *supra* note 24.

54. *See supra* note 49 and accompanying text.

55. USPTO Study, *supra* note 1, at 59. Even if a new drug is not covered by a patent, a generic product may not be available due to regulatory exclusivity.

56. While beyond the scope of this article, other countries (with less expensive drugs than the United States) utilize different distribution means than in the United States. And in the United States, Congress has considerable legislative power beyond patents to create change.