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Committee on the Judiciary, Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
U.S. House of Representatives

"Medicines and IP: Balancing Innovation and Access"

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Chairman Issa, Ranking Member Johnson, and Members of the Subcommittee, my name is Krista Carver, and I am a partner at Covington & Burling LLP. I have represented innovative biopharmaceutical companies on regulatory matters for almost two decades. I also teach FDA Law at the College of William & Mary Law School. The Pharmaceutical Research and Manufacturers of America (PhRMA) recommended me to testify today, though the views I express are my own.

Thank you for the opportunity to participate in this hearing and to provide perspectives on the balance of reliable patent rights and access to affordable medicines, including generics and biosimilars, to sustain the United States' innovative edge in today's environment. Maintaining America's leadership in these respects is a critical priority. Our balanced legal framework for promoting biopharmaceutical innovation and access to generic and biosimilar medicines, as reflected in the Hatch-Waxman Amendments, the Biologics Price Competition and Innovation Act (BPCIA), and the patent laws, has resulted in substantial achievements that have benefited patients. America leads the world in biopharmaceutical innovation and also has the world's strongest generic drug industry and a growing biosimilars industry.

Despite these achievements, the benefits of our system are not reaching all patients. This issue warrants careful attention. Changes aimed at improving patient access to medicines should not be based on unfounded claims of so-called patent thickets, however. Rather, they should be tailored to ensure they achieve reductions in patient out-of-pocket costs for medicines. Claims that the patent system is to blame for delaying generic or biosimilar competition are based on flawed data and misleading narratives. Implementing major changes to the law based on these narratives would threaten the future of biopharmaceutical research and development (R&D) to the detriment of patients. Moreover, although America's continued leadership in biopharmaceutical innovation is a critical priority, it is not a foregone conclusion. Maintaining this leadership requires a well-functioning, science-based regulatory system and a strong and reliable intellectual property (IP) system.

I. The Importance of Maintaining the Balance Built into the Hatch-Waxman Amendments and BPCIA for Patients, United States Leadership in Biopharmaceutical Innovation, and the U.S. Economy.

The U.S. biopharmaceutical sector leads the world in the development of new medicines for patients, and it also has the strongest generic drug industry. This leadership would not be possible without an IP system that incentivizes biopharmaceutical companies to take risks in R&D for innovative therapies that address unmet medical needs, as well as foundational laws such as the Hatch-Waxman Amendments and BPCIA, which balance the public health interests in providing incentives to develop new medicines and facilitating approval of generic and biosimilar medicines.

These laws have been a clear success. For example, today's generic drugs now make up 90% of prescriptions dispensed in the United States, an increase from 75% in 2009 and 19% in 1984.[1] In contrast, on average, generic drugs represent only 41% of dispensed prescription drugs in thirty-three comparable Organisation for Economic Co-operation and Development (OECD) countries.[2] The price of a generic drug in the United States is, on average, 67% of the price of generic drugs in these OECD countries.[3] FDA has approved more than eighty biosimilars, and these drugs produced savings of $20.2 billion in 2024 alone.[4] Collectively, cumulative savings to the U.S. health care system from generic and biosimilar medicines reached $3.4 trillion over the ten-year period ending in 2024.[5]

The Hatch-Waxman Amendments and BPCIA also have resulted in substantial achievements in biopharmaceutical innovation. Since 2000, biopharmaceutical companies have launched more than 900 novel drugs in the United States.[6] A January 2026 FDA publication reported that 70% of novel drugs approved in 2025 were first approved in the United States.[7] Further, American patients have access to 85% of new medicines, compared to an average of 38% of patients across G20 countries.[8] The coverage of new medicines also is faster in the United States, with patients in other OECD countries waiting an average of 3.4 years longer than U.S. patients for coverage of new medicines.[9]

Biopharmaceutical innovation has led to significant advancements in improving outcomes for American patients. For example, in a study of changes in mortality associated with cancer drug approvals in the United States from 2000 to 2016, researchers found that deaths per 100,000 people across the fifteen most common tumor types declined by 24%, and new cancer medicines prevented more than a million deaths across these tumor types.[10] As another example, in the early 2000s, treatment options for hepatitis C offered patients limited success, with patients often suffering lifelong infections. The approval of direct-acting antiviral (DAA) drugs effectively cured the disease, with one study finding that, among Medicaid enrollees alone, 284,580 patients had been cured of hepatitis C from 2013 through 2021.[11] The author also found that the cost of curing the disease using DAAs was lower than a single year of costs from

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[1] FDA, 40th Anniversary of the Generic Drug Approval Pathway (Sep. 23, 2024); Ass'n for Accessible Medicines, The U.S. Generic & Biosimilar Medicines Savings Report, at 13 (Sept. 2025) (AAM Report); IQVIA Institute for Human Data Science, Medicines Use and Spending in the U.S. A Review of 2018 and Outlook to 2023, at 5 (May 2019).

[2] A.W. Mulcahy et al., International Prescription Drug Price Comparisons at V, RAND Corp. (Sept. 2024).

[3] *Id.*

[4] FDA, Biosimilar Product Information (content current as of May 15, 2026); Ass'n for Accessible Medicines, The U.S. Generic & Biosimilar Medicines Savings Report, at 10 (2025).

[5] AAM Report at 14.

[6] S.E. Knox et al., FDA Approvals of Specialty Drugs, 2000-2024, 4 Health Affairs Scholar 1 (Feb. 2026); FDA, New Drug Therapy Approvals 2025, at 6 (Jan. 2026).

[7] FDA, New Drug Therapy Approvals 2025, at 6 (Jan. 2026).

[8] PhRMA, Global Access to New Medicines Report, at 11 (Apr. 2023).

[9] *Id.*

[10] J. MacEwan et al., Changes in Mortality Associated with Cancer Drug Approvals in the United States from 2000 to 2016, 23 J. Medical Econ, 1558, 1558 (2020).

[11] M.C. Roebuck, Impact of Direct-Acting Antiviral Use for Chronic Hepatitis C on Health Care Costs in Medicaid: Economic Model Update, 28 Am. J. Managed Care 630, 630 (2022).

managing the disease and forecasted that, by the end of 2026, DAAs will have generated cumulative net savings to Medicaid in excess of $43 billion.[12]

These medicines and the medical advancements that they enable require major investments in R&D, which are undertaken at substantial risk. On average, it takes an innovator between ten and fifteen years and costs $2.6 billion to develop a single new medicine, with only 12% of new molecular entities entering clinical trials ultimately receiving FDA approval.[13] IP is critical to enable biopharmaceutical companies to recoup their investments in this lengthy, costly, and highly risky R&D process and to reinvest revenues toward R&D for more new therapies for patients.

The balance struck in the Hatch-Waxman Amendments and BPCIA has fueled substantial R&D activity that has brought countless patients new treatments. For example, over the last decade, PhRMA's member companies alone have invested more than $850 billion in the search for new treatments and cures.[14] The U.S. biopharmaceutical industry accounts for half of all U.S. investments in health and biomedical research and development.[15] Indeed, the biopharmaceutical industry spends a larger share of its revenues on R&D in the United States (34%) than any other industry.[16]

These investments also drive U.S. economic growth. The biopharmaceutical sector directly employs more than one million people and supports more than 3.8 million additional jobs for a total employment impact of almost 5 million.[17] Its economic footprint is similarly substantial: the innovator industry generated more than $800 billion in direct output and supported an additional $850 billion in activity across suppliers and related sectors, for a combined contribution exceeding $1.65 trillion to the U.S. economy.[18]

The balance achieved by Congress through the Hatch-Waxman Amendments and BPCIA has produced tremendous successes that have saved many patients' lives, improved many more, and made America the world's leader in biopharmaceutical innovation and generic medicines. Recently, however, U.S. scientific and engineering investment has dropped relative to the rest of the world, and China alone accounts for nearly a third of the increase in global R&D growth since 2000.[19] Which country leads the next era of biopharmaceutical innovation will depend in part on the laws that the United States maintains and adopts.

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[12] *Id.*

[13] J.A. DiMasi et al., Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. Health Econ. 20 (2016) (2013 dollars); PhRMA, Research and Development Policy Framework (last visited June 1, 2026).

[14] PhRMA, Research and Development Policy Framework (last visited June 1, 2026).

[15] TEConomy Partners LLC, Biopharmaceutical Industry-Sponsored Clinical Trials: Impacting State Economics at i, (Mar. 2025).

[16] A. Chandra et al., Comprehensive Measurement of Biopharmaceutical R&D Investment, 23 Nature Revs. Drug Discovery 652 (2024); A. Powaleny, New Research: American Biopharmaceutical Investment in R&D Drives Transformational Innovation (2024).

[17] PhRMA & TEConomy Partners LLC, The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates, at 1 (May 2024).

[18] *Id.* at 2.

[19] PhRMA, Global Access to New Medicines Report, at 13 (2023).

II. IP Encourages Critical Innovation in Post-Approval Improvements and New Uses That Serve Patients.

Innovation does not stop at discovery of an active ingredient or FDA approval of a medicine. Thus, it is not unusual for medicines to incorporate multiple inventions that bring substantial public health benefits. These innovations—including new formulations, new delivery systems, new routes of administration, new dosing schedules, improved manufacturing processes, and new uses—provide many important benefits. They may address unmet medical needs; provide new treatment options; improve product safety, effectiveness, or quality; enhance quality of life; or improve adherence by reducing treatment burdens. As biopharmaceutical R&D is an ongoing and iterative process that builds over time, companies may first identify a new active ingredient. They then continue investing in R&D to identify a medicine's formulation, delivery, manufacturing process, and use for treating a particular disease and to demonstrate a medicine is safe and effective through clinical trials. Following FDA approval, companies may continue to invest in subsequent trials to improve upon formulations, delivery systems, routes of administration, dosing schedules, and manufacturing processes and to identify new uses.

For example, FDA's report on "New Drug Therapy Approvals 2025" highlights 16 "important approvals" of "new formulations, drug-device combinations, new dosage forms," and other product changes, explaining:

> New formulations of approved drugs can offer significant therapeutic advances. Similarly, new dosage forms (such as from a capsule to a chewable tablet for those unable to swallow pills, or a needle to an oral solution for patients who are afraid of needles) can help increase adherence, make sure patients take the proper dose, and improve quality of life for patients who must use the medication on a prolonged basis.[20]

These innovations also may improve clinical outcomes and reduce use of health care services, such as hospitalizations. For example, FDA's report notes the approval of Zusduri (mitomycin), which was approved in a new formulation to treat certain forms of bladder cancer. FDA emphasized that the product "forms a semi-solid gel in the bladder for sustained drug release, providing a pharmacological alternative to repeated surgical interventions."[21] Drug-device delivery systems also can enable targeted delivery of a drug, e.g., directly to a tumor, to improve outcomes and reduce side effects. As another example, long-acting injectable forms of oral treatments for schizophrenia have allowed for administration of these medicines as infrequently as once every 6 months. Long-acting dosage forms have also led to improved adherence and savings driven primarily by lower hospitalizations and outpatient care.[22] Development of subcutaneous and oral formulations of drugs previously approved in intravenous form can enable home administration of medicines and save patients hours in an infusion clinic.

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[20] FDA, New Drug Therapy Approvals 2025, at 27.

[21] *Id.* at 28.

[22] Z. S. Predmore et al., Improving Antipsychotic Adherence Among Patients With Schizophrenia: Savings for States, 66 Psychiatr. Serv. 343 (2015); R. Bera, et al., Hospitalization Resource Utilization and Costs Among Medicaid Insured Patients With Schizophrenia With Different Treatment Durations of Long-Acting Injectable Antipsychotic Therapy, 34 J. Clin. Psychopharmacol. 30 (2014).

Improvements in methods of manufacturing also play a significant role. Advances in manufacturing processes can improve medicines, such as by removing potential impurities that could affect the quality of the medicine. In some cases, because product and process innovations are often intertwined, innovator firms (and, for that matter, generic and biosimilar firms) develop more precise analytical methods and manufacturing techniques—such as optimized process parameters or novel purification steps.

Post-approval R&D on new uses has delivered critical progress in treatment of diseases such as cancer and cardiovascular disease. As reported in literature, "[a]s many as 60–75% of new oncology drugs are approved for multiple indications."[23] For example, one study reported that cancer drugs that were first FDA-approved as new molecular entities or original biologics from 2008 to 2018 "were approved for a median of two subsequent indications and often gained indications in an additional cancer type (60.7%), new line of therapy (50.0%), or combination (41.1%)," the last of which can enable additive or synergistic effects in cancer treatment.[24] Among cardiovascular medicines, approximately half of all approved uses and three-quarters of industry-funded clinical trials occurred after initial approval of a medicine.[25] Almost 30% of all post-approval uses treat patients with orphan diseases.[26] More generally, approximately half of small molecule medicines and biologics have been approved for at least one new use.[27] FDA's report on New Drug Therapy Approvals 2025 highlighted more than thirty important new uses for previously approved medicines, including new treatments for cancers, blood disorders, cardiovascular diseases, rare diseases, and inflammatory conditions.[28]

Novel indications require substantial R&D investments with no guarantee of success. New indications often require large, expensive Phase 3 trials. Based on trial data from both new and existing molecules, some analyses estimate that the outlay for a Phase 3 clinical trial is $31.3 million to $214.4 million across therapeutic areas.[29] This outlay represents the expense of running a trial and does not incorporate whether the trial is a success or failure. Other estimates set the mean total outlay for a Phase 3 trial at $255.4 million based on data from new molecules.[30] New uses may require three to ten years to develop.[31]

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[23] J. A. Patterson et al., Subsequent Indications in Oncology Drugs: Pathways, Timelines, and the Inflation Reduction Act, 59 Ther. Innov. Regul. Sci. 102, 103 (2025).

[24] *Id.* at 107, 108.

[25] *See* H. Grabowski & G. Long, Post-Approval Indications and Clinical Trials for Cardiovascular Drugs: Some Implications of the US Inflation Reduction Act, 27 J. Med. Econ. 463, 466 (2024); *see also* H. Grabowski, J. A. DiMasi, & G. Long, Postapproval Innovation For Oncology Drugs And The Inflation Reduction Act, 43 Health Affairs 1400 (2024).

[26] *See* IQVIA Inst., Proliferation of Innovation Over Time, at 14 (Feb. 2025).

[27] *Id.* at 3 ("Over half of [novel active substances] approved between 2000 and 2023 received at least one expansion post-initial approval. This trend was consistent across both biologics (47%) and small molecules (52%)").

[28] FDA, New Drug Therapy Approvals 2025, at 18–21 (Jan. 2026).

[29] *See* A. Sertkaya et al., Costs of Drug Development and Research and Development Intensity in the US, 2000–2018, 7 JAMA Network Open 1, 7 (2024) (using 2018 dollars).

[30] J. A. DiMasi et al., Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. Health Econ. 20, 24 (2016) (using 2013 dollars).

[31] *See* E. Lietzan, Paper Promises For Drug Innovation, 26 Geo. Mason L. Rev. 168, 177-78 (2018).

Despite these extensive R&D efforts, unmet medical needs remain. Patients today with the vast majority of diseases have no approved therapies. For example, one source stated that "less than 22% of the world's recognized diseases have FDA-approved treatments" and "over 95% of rare diseases have no treatment."[32] Investments to study approved drugs for diseases with no treatment options hold promise to address these unmet medical needs, and incentives to fuel this research are therefore critical.

III. Narratives that "Patent Thickets" Delay Generic and Biosimilar Competition and Cause High Drug Prices Are Inaccurate and Misleading, and the ETHIC Act Will Discourage Innovation and Invite Gamesmanship.

A. Allegations that "Patent Thickets" Increase Effective Patent Life and Forestall Generic and Biosimilar Competition Are Based on Flawed Research and Misleading Narratives.

Critics of the IP system frequently assert that biopharmaceutical products have an excessive number of patents, forming "thickets" that delay market entry of generic drugs and biosimilars. These critics fail to appreciate the ongoing, iterative nature of innovation and the ongoing public health need to incentivize continued R&D that brings product improvements to patients. They oversimplify the role of patent protection and do not provide convincing data showing a link between the number of patents covering a given product and either generic/biosimilar entry dates or drug prices actually paid by patients.

These commentators use a variety of normative terms to describe biopharmaceutical patents. They distinguish between what they call "primary" patents, which they alternatively define as covering the active ingredient or the "backbone" structure of a biological product—and "secondary," "tertiary," and "ancillary" patents.[33] Some publications define "secondary patents" as patents on formulations and methods of use and "tertiary patents" as patents on delivery devices.[34] Another publication defines "ancillary" patents" as patents that "cover critical features of the biologic's active ingredient that enable it to act on the molecular target and achieve the desired therapeutic effect, such as glycan profiles, oxidation levels, or other physiochemical properties."[35] In any case, these terms differentiate between patents in a way not seen in other industries. Moreover, these hierarchical labels differentiate between patents in a manner inconsistent with federal patent laws, which classify inventions based on subject matter rather than perceived scope or importance.[36]

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[32] EveryCure, The Problem (last visited June 1, 2026).

[33] *E.g.*, Comment from Fresenius Kabi, Inc., at 3; *see also id.* at 24 ("it is common for branded drug companies to file a principal patent on the drug peptide sequence (i.e., the 'backbone' of the drug)"); T. W. Teng et al., Tertiary Patents on Drugs Approved by the FDA, 7 JAMA Health Forum e255909 (2026).

[34] T. W. Teng et al., Tertiary Patents on Drugs Approved by the FDA, 7 JAMA Health Forum e255909, 2/13 (2026); M. A. Carrier & S. S. Tu, Why Pharmaceutical Patent Thickets Are Unique, 32 Tex. Intell. Prop. J. 79, 82 (2024).

[35] R. Goode & W. B. Feldman, Ancillary Product Patents to Extend Biologic Patent Life: Research Letter, 330 JAMA. 2117 (2023).

[36] *See, e.g.*, 35 U.S.C. § 101 ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.")

These terms appear intended to suggest that any patent other than a so-called primary patent presents concerns. For example, one author asserted that "secondary patents" are "aimed at complicating generic entry and extending patent life."[37] Another asserted that "ancillary patents" are "inappropriately extending product patent protection for biologics by staggering claims on specific technical features of the same drug to later and later."[38] These terms lack precision, as some authors using these terms suggest that "primary" patents cover the active ingredient, whereas others say it covers only *part* of the active ingredient (i.e., the "backbone"). This inconsistency highlights that these labels are meant to diminish the value of these inventions.

These distinctions reflect a lack of appreciation for the iterative nature of pharmaceutical innovation. Innovation does not and should not stop at identifying an active pharmaceutical ingredient or the "backbone" structure of a biological product. Indeed, it cannot. FDA does not approve raw active ingredients or biological product sequences in isolation; rather, it approves finished products that include a specific formulation, dosage form, and labeling identifying approved uses supported by nonclinical and clinical studies. Thus, for a product to be approvable and usable by patients, the innovator must continue its R&D efforts once it discovers a "primary" innovation. These efforts result in important innovations, and thus it is not unusual for medicines to incorporate multiple inventions. The drug substance, formulation, dosage form(s), and manufacturing process, as well as the medicine's use in a particular disease population, could all be patentable inventions if they meet the statutory criteria for a patent. These R&D efforts and innovations also benefit patients. For example, authors raising concerns with "ancillary patents" concede that these patents "cover *critical* features of the biologic's active ingredient."[39]

Product changes and new methods of manufacturing can be invented at any point in the product lifecycle, and thus patent applications for them can also be filed throughout the product lifecycle. New methods of manufacturing, e.g., methods that reduce the potential for immunogenicity, are often invented years after a biologic is discovered or has obtained regulatory approval. Manufacturers also may invent novel methods for purifying proteins that are more efficient or allow for more precise recovery of specific proteins. As discussed above, product improvements offer important benefits for patients.

Critics frequently cite the sheer number of patents on a particular drug as problematic.[40] But the raw number of patents provides no information about the scope of those patents, the number of claims in them, their effects on timing of generic or biosimilar competition, or their impact on patient out-of-pocket costs for medicines. Indeed, there is nothing improper about earning multiple patents, and companies in other industries hold more patents than

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[37] M. Carrier & S. Sean Tu, Why Pharmaceutical Patent Thickets Are Unique, 32 Tex. Intell. Prop. J. 79, 82 (2024) (citing S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 Wash. U. L. Rev. 1673, 1707–08. (2022)).

[38] Comment from Fresenius Kabi, Docket No. PTO-P-2022-0037-0013, at 2 (Jan. 17, 2023).

[39] R. Goode & W.B. Feldman, Ancillary Product Patents to Extend Biologic Patent Life: Research Letter, 330 JAMA 2117 (2023) (emphasis added).

[40] *See* A. Hung & C.P. Gross, Patent Listing Challenges by the Federal Trade Commission: A New Approach to Promoting Drug Affordability, JAMA Intern. Med. (2026); R. Goode & B. Chao, Biological patent thickets and delayed access to biosimilars, an American problem, 9 J.L. & Biosci. 1 (2022); S. Sean Tu et al., Changes in the Number of Continuation Patents on Drugs Approved by the FDA, 330 JAMA 469 (2023).

pharmaceutical companies.[41] One report showed that, between 2012 and 2022, the biopharmaceutical industry invested more in R&D per patent issued than any other industry, but ranked in the middle of the pack for annual issued patents as compared to other high-IP industries, trailing publishing/software, computer design, medical equipment, and machinery.[42] None of the top twenty patent holders in 2025 were biopharmaceutical companies and only three appeared in the top 100.[43]

Commentators who criticize the number of patents on pharmaceuticals allege that these patents make BPCIA litigation prohibitively expensive.[44] For example, they assert that "on average it costs $774,000 to challenge [a] patent in an inter partes review or post-grant review" and "[f]ederal court litigation is even more expensive."[45] The data cited in support of these claims are anecdotal, however. The data were obtained from an AIPLA survey that asked AIPLA members to estimate "costs incurred within the relatively recent past" through various stages of litigation with respect to a single patent covering a small molecule.[46] This statistic does not address costs of litigation involving multiple patents. Indeed, efficiencies in litigation costs concerning patents for a single product, e.g., the potential to rely on the same expert witnesses and commonality in relevant prior art, are expected.

Critics also frequently claim that a high number of patents results in delay of biosimilar or generic entry and that drug products are being protected for more than the twenty-year patent term.[47] Generic drugs enter the market on average thirteen to fourteen years after initial FDA approval, and this period has remained consistent for over a decade.[48] The market exclusivity period was even shorter for the most successful drug products, just 10.3 to 13.7

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[41] *E.g.*, *Mayor & City Council of Balt. v. AbbVie Inc.*, 42 F.4th 709, 712 (7th Cir. 2022) ("If AbbVie made 132 inventions, why can't it hold 132 patents? The patent laws do not set a cap on the number of patents any one person can hold—in general, or pertaining to a single subject . . . Tech companies . . . have much larger portfolios of patents.").

[42] N.D. Pham, The Economic Performance of IP-Intensive Manufacturing and Service Industries in the United States, 2012-22, at 18 (Fig. 14) (2025).

[43] The Patent 300® Report (2026).

[44] R. Goode et al., Biological patent thickets and delayed access to biosimilars, an American problem, J. L. Biosci. 1, 19 (2022); L.G. Abinader, Patent Thickets Increase Costs and Delay Access to Medicines for Young Adult Patients Generation Patient.

[45] R. Goode et al., Biological patent thickets and delayed access to biosimilars, an American problem, J. L. Biosci. 1, 19 (2022).

[46] Am. Intellectual Prop. Law Ass'n, 2021 Report of the Economic Survey, at 3, 61 (2021).

[47] *See, e.g.*, M.A. Carrier & S. Sean Tu, Why Pharmaceutical Patent Thickets Are Unique, 32 Tex. Intell. Prop. J. 79, 82–83 & 87 (2024) (describing "a large web of patents to deter or delay competitor market entry"); Rachel Goode & William B. Feldman, Ancillary Product Patents to Extend Biologic Patent Life: Research Letter, 330 JAMA 2117 (2023) ("Ancillary product patents . . . extended the expected duration of protection by a median of 10.4 years (range, 2.4–17.9 years) beyond the primary patents.")).

[48] H. Grabowski et al., Continuing Trends in U.S. Brand-name and Generic Drug Competition, 24 J. Med. Econ. 908, 911 (2021); *see also* E. Lietzan & Kristina M.L, 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, 840 (finding that 224 new drug applications averaged 11.3 years of market exclusivity and new chemical entities averaged 13.34 years).

years.[49] Further, data show that among brand biologic products that were approved in 2010 and 2011, i.e., the months leading up to the enactment of the BPCIA and following, the average time to first biosimilar launch was 13.7 years.[50] Additionally, one analysis found no correlation between biosimilar approval-to-launch intervals and the number of patents asserted against the biosimilar applicant in BPCIA litigation.[51] For example, in one case, the BPCIA litigation involved thirty-seven patents and the time from biosimilar approval to launch was 1.2 months, whereas in another case involving two patents, the time from biosimilar approval to launch was nearly identical at 1.1 months.[52] As these data suggest, the purportedly high number of patents covering some medications does not impose outsized hurdles for biosimilar manufacturers.

Indeed, the United States Patent and Trademark Office (USPTO) Drug Patent and Exclusivity Study concluded that "simple counts of patents can be misleading when every patent is counted equally, because the number of patents does not provide a clear picture of the landscape without a review of the scope of the claims in each patent."[53] USPTO further explained that "multiple patents associated with a single marketed product are not unique to the pharmaceutical industry and are a common practice in many innovative industries, especially for complex products."[54] In the report, the agency stressed that "patent expiration dates, like the number of patents, may not be predictive of the timing of actual launch of competing products," "because not all listed patents may be infringed by a generic product."[55]

Moreover, with respect to BPCIA, some applicants for biosimilar products decline to engage in existing mechanisms provided by Congress to streamline patent disputes. The BPCIA established detailed procedures whereby the biosimilar applicant and the manufacturer of the reference product engage in a structured, pre-litigation exchange of information regarding the product.[56] The intent of this so-called "patent dance" is to seek to resolve patent disputes before the biosimilar reaches the market. The Supreme Court in *Sandoz v. Amgen*,[57] however, held that the "patent dance" is optional. Some applicants have decided not to use these congressionally endorsed procedures for narrowing the number of patents for litigation. Others fail to provide sufficient information about their application and manufacturing information to enable narrowing of disputed patents before the initiation of litigation.[58] In one case, the biosimilar applicant provided the reference product sponsor with no notice of its biosimilar

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[49] H. Grabowski et al., Continuing Trends in U.S. Brand-name and Generic Drug Competition, 24 J. Med. Econ. 908, 912 (Table 1) (2021).

[50] Ass'n for Accessible Medicines, The IRA Hurts Generic and Biosimilar Medication Competition, (second table), Blog (last visited June 2, 2026).

[51] Comment from Biotechnology Innovation Organization (BIO), Docket No. PTO-P-2022-0037-0054, at 2, 3 (Feb. 6, 2023).

[52] *Id.* at 4.

[53] USPTO, Drug Patent and Exclusivity Study, at 57 (June 12, 2024).

[54] *Id.* at 58.

[55] *Id.* at 59.

[56] Public Health Service Act (PHSA) § 351(l).

[57] 582 U.S. 1 (2017).

[58] *E.g.*, Complaint at 20–24, *Amgen Incl v. Fresenius Kabi USA, LLC* (D.N.J.-Oct. 4, 2024) (No. 1-25-cv-01080) (outlining noncompliance with BPCIA by Fresenius Kabi).

application before FDA approved that application, depriving both sides the opportunity to resolve patent disputes in advance.[59]

Finally, critics fail to acknowledge that biosimilars can have different "ancillary features" from the reference product. The BPCIA requires that biosimilars be "highly similar" to the reference product "notwithstanding minor differences in clinically inactive components"—not identical to the reference product.[60] FDA's guidance contemplates, for example, that differences in glycosylation patterns, impurities, and other "ancillary" features may be permissible if the statutory biosimilarity requirements are met.[61]

B. The ETHIC Act Will Discourage Innovation.

The Eliminating Thickets to Increase Competition Act ("ETHIC Act"), H.R. 3269, would force innovator biopharmaceutical companies to forfeit valid patent rights arbitrarily and irrevocably. Innovator companies would be required to choose a single patent per "Patent Group" to enforce against a generic or biosimilar applicant and would be precluded from asserting any other patent in the same Patent Group against the applicant—making potentially dozens of patents across Patent Groups unenforceable against the applicant. This special rule to shield generic and biosimilar companies from liability for infringement of valid patents would discourage innovation in the United States and constitute a seismic shift in patent law that would upend the Hatch-Waxman and BPCIA balance. The Act's mechanism for compelling this forfeiture is also concerning.

***First*, the ETHIC Act broadly defines Patent Groups in a manner that treats patents on legally distinct inventions as interchangeable.**[62] Biopharmaceutical companies innovate not just new active ingredients, but also new drug products, new methods of manufacturing, and new methods of treatment—all of which meaningfully improve the safety and efficacy of medicines, as well as patient outcomes. Even if innovator companies wanted one patent that encompassed each of those innovations, the realities of patent prosecution make it unlikely. Such innovations may be covered by different related patents that may be tied by terminal disclaimers. Yet, the Act would penalize innovators for following standard patent prosecution practice. For example, despite the difference in patentable coverage between drug substance and method of manufacturing innovations that might fall within different patents in a Patent Group, the Act could force innovator companies to choose one of the patented innovations to enforce and forfeit their valid rights to enforcing the other patented innovation.[63]

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[59] Complaint at 9–10, *Regeneron Pharms., Inc. v. Sandoz, Inc.* (N.D.W.V. Aug. 26, 2024) (No. 1-24-cv-00085) (outlining various failures of Sandoz to comply with BPCIA patent dance with multiple reference product manufacturers over years).

[60] PHSA § 351(i)(2)(A).

[61] *See*, *e.g.*, FDA, Final Guidance for Industry, Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations, at 11, 15 (Sept. 2025).

[62] As an initial matter, the ETHIC Act arbitrarily focuses on patents, even though each patent may contain multiple distinct claims (*i.e.*, inventions). *See, e.g.*, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) ("The claim defines the scope of a patent grant."). Patent Groups may thus include patents with claims that were never subject to a rejection for obviousness-type double patenting.

[63] *See* H.R. 3269 § 2(a) (119th Cong.) (defining "Patent Group" as "2 or more commonly owned patents or applications that—(I) are identified on 1 or more disclaimers under section 253 to another commonly owned patent; or (II) are subject to 1 or more disclaimers under section 253 to another commonly owned patent.

***Second,* the ETHIC Act deprives innovator companies of the ability to enforce valid patent rights and would enable generic and biosimilar manufacturers to engage in gamesmanship.** The Act forces innovator companies to choose one patent per Patent Group at the outset of litigation without the technical information necessary to evaluate which patents, if any, the generic or biosimilar manufacturer may infringe.

In patent litigation, as in standard civil litigation, plaintiffs pursue discovery to develop an evidentiary record. They may exchange documents, take depositions, and perform inspections to assess the strength of their claims.[64] Plaintiffs then use that information to decide how to narrow claims before trial. That sequence is intentional and consistent with the carefully calibrated frameworks outlined in the Hatch-Waxman Amendments and BPCIA, both of which were designed to streamline patent disputes. Under those statutes, Congress does not require innovator companies to forfeit potential claims of patent infringement rights *before* receiving technical information.

In contrast, under the ETHIC Act, innovator companies may be forced to select patents for suit without ever receiving the technical information needed to evaluate which patents may be infringed and may be precluded from "bring[ing] any additional actions . . . asserting a patent in the same Patent Group against that party."[65] In other words, innovators may be forced to select a patent from a Patent Group without sufficient information to make an informed choice. Indeed, abbreviated drug applicants may withhold this information intentionally to force this result. Many generic and biosimilar manufacturers already decline to provide innovators with sufficient information about their products and manufacturing processes in advance of litigation.[66] The ETHIC Act would only further encourage that practice—effectively transforming litigation into a guessing game where innovators lose valid patent rights without the ability ever to assess claims of patent infringement. The Act also contains no exception for innovators to seek the court's permission to assert additional patents based on new information that was not reasonably available at the time of the lawsuit's filing, e.g., because it was intentionally withheld, resulted from a generic or biosimilar applicant's amendments to its application, or only became available later (e.g., testing of future manufacturing runs or information about generic marketing practices that emerge after product approval).

Because the innovator's patent selections are irrevocable, the Act would effectively permit generic and biosimilar manufacturers to infringe all non-selected patents. Further, generic and biosimilar manufacturers could wait for an innovator to make selections before strategically altering their products and manufacturing processes in a manner that would infringe other patents. This one-sided approach stands in stark contrast to the balanced frameworks established in the Hatch-Waxman Amendments and BPCIA and departs from

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(ii) For purposes of clause (i)(I)—(I) each patent or application that identifies the same patent or application on a disclaimer under section 253 is part of the same Patent Group; and (II) each patent or application that is identified on a disclaimer under section 253 is part of the same Patent Group as the patent or application subject to the disclaimer.").

[64] *See, e.g.*, Federal Rules of Civil Procedure 26—37 (Disclosures and Discovery).

[65] H.R. 3269, 119th Cong. § 2(a) (2025).

[66] *See, e.g.*, Complaint at ¶¶ 22—23 *Regeneron Pharms., Inc. v. Sandoz, Inc.* (N.D.W.V. Aug. 26, 2024) No.1-24-cv-00085, ("Sandoz is attempting to stretch acceptable non-compliance with § 262(*l*) [of the BPCIA] to a point where a reference product sponsor, like Regeneron, is deprived entirely of any ability to resolve patent issues before FDA approval of a biosimilar product, creating an unnecessary emergency for the Court.").

fundamental principles of general civil litigation, where parties are permitted to investigate facts through discovery before narrowing their claims.

***Third*, the ETHIC Act raises serious constitutional concerns and conflicts with international law.** The Act may be unconstitutional as it requires the federal government to take an unlimited number of patent rights without providing any compensation.[67] Innovator biopharmaceutical companies would lose the right to exclude others from infringing valid patents and the right to pursue damages resulting from such conduct.

The legislation also conflicts with the technology neutrality principles set forth in international law. Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights states that "patents shall be available and patent rights enjoyable *without discrimination* as to the place of invention, the field of technology and whether products are imported or locally produced."[68] The Act provides a liability shield for abbreviated drug applicants only. Such a marked departure from the agreement could weaken confidence in the U.S. patent system.

IV. Providing Adequate Incentives to Study Approved Medicines for New Uses Is a Public Health Priority, But the Skinny Labels Act Would Instead Erode Incentives for the Study of New Uses.

The Skinny Labels, Big Savings Act, H.R. 6485 ("Skinny Labels Act") would create a novel exception for generic drug applicants and other abbreviated applicants who seek to use "skinny labeling," thereby shielding them from liability for induced patent infringement in specified circumstances. This proposal implements some stakeholders' proposals in response to the Federal Circuit's decision in two cases, *GSK v. Teva* and *Hikma v. Amarin*.

This legislation is not needed to ensure the continued availability of skinny labeling. As an initial matter, the Supreme Court is actively reviewing the *Hikma* case and is expected to issue an opinion soon. In any case, *GSK* and *Hikma* are consistent with longstanding law that requires fact-specific consideration of inducement. Under this law, many generic drug manufacturers have successfully utilized skinny labeling over the more than forty years since the enactment of Hatch-Waxman.

The Skinny Labels Act also presents policy concerns. It would create a regime in which no neutral arbiter assesses the adequacy of a generic manufacturer's "carve-out" of patented information from their drug labeling. It also would create an industry-specific shield from inducement liability, effectively treating generic manufacturers more favorably than competitors in any other technology sector. Finally, it would undercut incentives for R&D investments in new uses of approved drugs.

1. Background on Skinny Labeling and Section viii Statements

By statute, generic applications must address listed patents for the innovator drug. In doing so, generic applicants have several choices. First, they may certify that they will wait for patent expiry to market the generic drug (a Paragraph III certification).[69] Second, they may

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[67] U.S. Const. amend. V (Takings Clause).

[68] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1869 U.N.T.S. 299 (emphasis added).

[69] *See* FDCA §§ 505(j)(2)(A)(vii)(III) & 505(j)(2)(B)(iii).

certify that the patent is invalid or will not be infringed by the generic drug's manufacture, use, or sale (a Paragraph IV certification).[70] Third, for method-of-treatment patents, generic applicants may file a "section viii statement" averring that the listed patent "does not claim a use for which the applicant is seeking approval."[71]

When a generic applicant avails itself of this third choice, the applicant must omit—or "carve out"—all references to the patented use from the proposed labeling, resulting in "skinny labeling."[72] Moreover, FDA does not assess the adequacy of the carve-out. FDA plays a "ministerial role" in patent issues. Indeed, FDA acknowledges that it has neither the statutory authority nor the expertise to review generic labeling to ensure it avoids inducement.[73] The responsibility for assuring that patented information is omitted from generic labeling has always fallen on the generic applicant that chooses a skinny labeling strategy.[74] FDA has recognized that the courts are the appropriate forum for disputes about the adequacy of the carve-out.[75]

The Hatch-Waxman Amendments thus balanced the need to encourage biopharmaceutical innovation in new uses of existing medicines with the need to promote access to generic medicines. On one side of the ledger, Congress created an abbreviated pathway for generic drugs, one part of which allows generic companies to seek approval only for non-patented uses of the innovator drug while properly "carving out" a patented use. On the other side of the ledger, Congress provided incentives to ensure that biopharmaceutical companies would continue studying drugs for new uses by maintaining the applicability of the Patent Act for inducement liability.

Under the Patent Act "[w]hoever actively induces infringement of a patent shall be liable as an infringer."[76] "To prevail on a theory of induced infringement, a plaintiff must prove (1) direct infringement and (2) 'that the defendant possessed specific intent to encourage another's infringement and not merely that the defendant had knowledge of the acts alleged to constitute infringement.'"[77] In the generic drug context, the labeling plays a role in discerning generic applicants' intent. Indeed, prior to marketing a generic drug, induced infringement is generally based on whether the generic drug labeling would induce a physician or a patient to infringe a patent, that is, whether the labeling "encourage[s], recommend[s], or promote[s] infringement" by physicians or the patient.[78]

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[70] *See id.* §§ 505(j)(2)(A)(vii)(IV) & 505(j)(2)(B)(iii).

[71] *Id.* § 505(j)(2)(A)(viii).

[72] FDA, Letter to Dexmedetomidine Hydrochloride Injection NDA Holder/ANDA Applicant, Docket No. FDA-2014-N-0087, at 5 (Aug. 18, 2014) (citing 21 C.F.R. §§ 314.92(a)(1) and 314.94(a)(12)(iii)); *see* 72 Fed. Reg. 21,266, 21,269 (Apr. 30, 2007).

[73] 68 Fed. Reg. 36,676, 36,683 (June 18, 2003).

[74] *E.g.*, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1332 (Fed. Cir. 2021).

[75] 68 Fed. Reg. at 36,683.

[76] 35 U.S.C. § 271(b).

[77] *Genentech, Inc. v. Sandoz, Inc.*, 592 F. Supp. 3d 355, 364 (D. Del. 2022) (quoting *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1129 (Fed. Cir. 2018)), *aff'd*, 55 F. 4th 1368 (Fed. Cir. 2022).

[78] *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015).

2. *GSK* and *Hikma* Did Not "Nullify" the Skinny Labeling Pathway, and Literature Suggesting a Drop-off in Skinny Labeling Uses Flawed Methodology.

Consistent with precedent, the Federal Circuit's opinions in *GSK* and *Hikma* employed a fact-specific inducement analysis focusing on the adequacy of the generic company's labeling carve-out as well as statements of the generic manufacturer concerning the patented use.

In *GSK*, the Federal Circuit upheld a jury verdict that Teva induced infringement of GSK's patent on a method of treating congestive heart failure with carvedilol, which GSK marketed under the brand name Coreg.[79] In *Hikma*, the Federal Circuit found that the district court had improperly dismissed Amarin's case against Hikma because Amarin's allegations plausibly stated a claim for induced infringement of patents claiming a method of using icosapent ethyl, which Amarin markets under the brand name Vascepa.[80]

Some critics have asserted—or assumed—that Teva and Hikma drafted proper skinny labeling.[81] But neither *GSK* nor *Hikma* is a case where a generic manufacturer was found liable for inducement based on properly drafted skinny labeling—or based solely on its labeling at all. In *GSK*, the Federal Circuit noted Teva's labeling was not in fact "skinny."[82] Similarly, the adequacy of Hikma's carve-out is a disputed factual question in its case.[83] Also, in both cases, the plaintiffs alleged that the generic applicant's other statements induced infringement. Specifically, Teva had discussed the patented use in its marketing materials and a press release.[84] Similarly, the *Hikma* opinion emphasized that "the allegations of the complaint transform this case from a pre-approval, label-only induced infringement claim to one where the alleged infringement is based on the generic manufacturer's skinny label as well as its public statements and marketing of its already-approved generic product," which included marketing materials, press releases, and sales figures for the patented indication.[85] Moreover, generic manufacturers using skinny labeling have prevailed in several cases that post-date *GSK*.[86] These subsequent decisions, which distinguish *GSK*, confirm that that skinny labeling remains viable for generic drug manufacturers. Indeed, Hikma is the only generic manufacturer that Amarin

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[79] *E.g.*, *GSK*, 7 F.4th at 1332.

[80] *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 104 F.4th 1370 (Fed. Cir. 2024).

[81] *See, e.g.*, Br. for the U.S. as Amicus Curiae, at 15, *Hikma Pharms USA Inc. v. Amarin Pharma, Inc.* (S. Ct. 2025) (No. 24-889) ("FDA approved Hikma's ANDA, including its carved-out or 'skinny'" labeling"); *id* at 26 ("Hikma's skinny labeling cannot properly be treated as evidence of culpable encouragement to infringe."); M. Carrier, Skinny Labels' Importance for Drug Competition, Wisc. L. Rev. Forward, at 11-12 (2026).

[82] *GSK*, 7 F.4th at 1328.

[83] *See First Am.* Compl. ¶¶ 130–135, *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, No. 20-1630-RGA, 2021 WL 9316574 (D. Del. filed Jan. 25, 2021).

[84] *GSK*, 7 F.4th at 1328, 1335–36.

[85] *Amarin*, 104 F.4th at 1377, 1379 .

[86] *See H. Lundbeck A/S v. Lupin Ltd.*, Nos. 2022-1194, -1208, -1246, slip. op at 14-15 and n.7 (Fed. Cir. Dec. 7, 2023); *Zogenix, Inc. v. Apotex Inc.*, No. 21-1252-RGA, 2023 WL 5835828, at *3-5; *Novartis Pharms. Corp. v. Kennedy*, 156 F.4th 626 (D.C. Cir. 2025).

sued for making statements that encourage use of icosapent ethyl for its patented method of use.[87]

Despite the fact-specific nature of the Federal Circuit opinions in *GSK* and *Hikma*, some stakeholders have alleged that these decisions threaten the viability of the skinny label pathway.[88] A recently published article by Ziaks and others purported to provide data showing that "fewer first generic entrants may be relying on skinny labels in the wake of [*GSK*]."[89] Other authors have cited this study as finding "that, *among brand-name drugs susceptible to the practice*, skinny labeling fell from 56% in 2021 to 43% in 2022 to only 20% in 2023."[90] Specifically, Ziaks et al. stated:

> Between 2021 and 2023, there were 290 first-time generic prescriptions, of which 269 were excluded because they were tentatively approved, duplicates, or versions of brand-name drugs that were not susceptible to skinny labeling[.] Among the remaining 21 brand-name drugs susceptible to skinny labeling, 9 (43%) were approved through the skinny label pathway, including 5 of 9 in 2021 (56%), 3 of 7 in 2022 (43%), and 1 of 5 in 2023 (20%).[91]

The authors thus purport to answer the question of whether *GSK* reduced the number of generic applications with section viii statements and skinny labeling. But due to the article's flawed methodology, it does not provide a reliable answer to that question.[92] Ziaks et al. focused their analysis on only a handful of generic drugs approved between 2021 and 2023 and thus excluded many innovator products that could be candidates for skinny labeling.

The authors disregarded 269 out of 290 generic approvals during this time frame—many of which are relevant to this question—from their analysis. First, they excluded tentatively approved ANDAs. If the goal is to determine whether ANDA applicants are reducing use of the section viii statement, tentative approvals are relevant because applications may contain section viii statements and be awaiting approval for other reasons (such as other patents or statutory exclusivity). Similarly, if the question is how many generic applicants are submitting section viii statements, the submissions of all generic applicants are relevant, yet the authors only "included only one generic prescription entry per brand-name drug in cases of multiple approved ANDAs."[93] This methodology inevitably would result in undercounting. For example, if all ten

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[87] Brief for Respondents, Reply Brief for Petitioners, *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, 2026 WL 838212, at *41, ("*Every other* generic icosapent ethyl drug remains on the market with the same label and respondents have not sued them.").

[88] *E.g.*, T. Ziaks et al., Frequency of First Generic drugs approved through "skinny labeling," 2021 to 2023, 31 J Manag Care Spec Pharm. 343 (2025) (Ziaks); S. Tu & A. Kesselheim, Preserving Timely Generic Drug Competition with Legislation on "Skinny Labeling," 115 Clin. Pharmacology & Therapeutics 22 (2024).

[89] Ziaks, at 348.

[90] M. Carrier, Skinny Labels' Importance for Drug Competition, Wisc. L. Rev. Forward, at 24 (2026) (emphasis added).

[91] Ziaks, at 345.

[92] As an initial matter, the authors do not disclose the list of the 21 drugs analyzed, which makes replicating their analysis challenging.

[93] Ziaks, at 344.

generic applicants for a single listed drug submitted section viii statements, the authors would have only counted one of these cases. The methodology also excludes generic drugs that were not marketed although there is no reason to exclude these applications from a sample set that is intended to assess the frequency at which generic manufacturers are submitting section viii statements. Generic applicants might decide not to launch their products for an array of reasons, e.g., manufacturing constraints.

After excluding all of these relevant applications, the authors are left with a sample size of only seven drugs for 2022 and five drugs for 2023. This limited number of products cannot reliably detect trends or causal effects. This article therefore does not provide reliable data indicating a reduction in section viii statements submitted since *GSK*.

Other authors argue that generic labeling "cannot, and should not, be used as the sole basis for an inducement finding,"[94] because "generics are required by FDA to mimic the brand's label."[95] But generic applicants using skinny labeling are invoking an *exception* to the same labeling requirement. FDA's regulations generally require the generic drug to have the "same" labeling as the listed drug, but allow differences to enable a generic applicant's "omission of an indication or other aspect of labeling protected by patent."[96] The "same labeling" requirement thus does not strip generic applicants of choice. They may choose to challenge a method-of-treatment patent, wait for its expiry, or employ skinny labeling and a section viii statement. If they choose the last option, they must carve out the patented use to avoid inducement liability.

Ignoring the content of generic labeling in inducement analysis would not only be unprecedented, but also it would permit gamesmanship. Where the generic drug has not entered the market, labeling is almost invariably the main evidence of infringement in such cases. In *AstraZeneca v. Apotex*—a case decided more than a decade before *GSK*—"the district court found that Apotex 'was aware of and certainly concerned about the potential infringement problem posed by its label,' but nevertheless decided to proceed with the label."[97] The Federal Circuit affirmed the district court's finding of inducement. If labeling were not a factor in the inducement analysis, generic applicants could pursue the type of strategy that Apotex did while avoiding inducement liability.

3. The Skinny Labels Act Would Grant Generic Companies Special Treatment Under Inducement Law and Stifle Incentives for Innovation.

The Skinny Labels Act would create a shield from inducement liability that would be unique to abbreviated drug applicants and distinct from all other fields of technology.

In relevant part, the bill would provide that the following "shall not be acts of direct, induced, or contributory infringement" of a method-of-treatment patent listed in the Orange Book: (1) submitting an abbreviated application that includes a section viii statement with proposed skinny labeling; (2) promoting or commercially marketing a drug product "with the [approved] labeling"; and (3) describing the drug "as a generic of, or therapeutically equivalent

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[94] J.S. Sherkow & P.R. Gugliuzza, Infringement by Drug Label, 78 STAN. L. REV. 131, 188 (Jan. 2026).

[95] P.R. Gugliuzza and J.S. Sherkow, Corcept v. Teva Oral Argument: Infringement by Drug Label, Again, PATENTLY-O (July 8, 2025) (Blog Post).

[96] 21 C.F.R. § 314.94(a)(8)(iv).

[97] *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1059 (Fed. Cir. 2010).

to, the listed drug."[98] The safe harbor applies "only if" the applicant's labeling, promotion, or commercial marketing "does not reference" the patented use that was the subject of the section viii statement. The bill includes an analogous liability shield for biosimilar applications submitted. The legislation is also retroactive, applying to "conduct that occurs before, on, or after the date of enactment of this Act," including ongoing proceedings.[99]

This bill appears intended to implement generic industry proposals that argue FDA's approval of generic labeling should preclude inducement liability without any chance that a case would proceed beyond the motion-to-dismiss stage.[100] For example, marketing of the product with the approved skinny labeling could not be an act of inducement under the bill. But this approach fails to ensure that there is a neutral arbiter of disputes concerning the adequacy of a carve-out. FDA's review of proposed skinny labeling is no substitute for judicial review. FDA focuses on public health issues and does *not* confirm that the generic labeling or the applicant's marketing materials raise no inducement concern.[101] Indeed, FDA lacks the statutory authority and expertise to review patent claims to assess the adequacy of a carve-out, and the agency acknowledges that courts are the appropriate forum for disputes about these issues.[102] But the bill would provide that marketing of the generic product with its approved skinny labeling is not an act of inducement. If the courts cannot police the adequacy of skinny labeling, innovators will have no recourse where generic applicants adopt labeling strategies with known inducement problems—like Apotex did in *AstraZeneca*.

The bill's proviso that the liability shield does not apply if the abbreviated drug applicant "does not reference" the patented use appears insufficient to address these concerns. For example, it is unclear if an *implicit* reference to the patented use that, when evaluated with all other facts, does amount to inducement under current law would nevertheless be protected under the safe harbor. If so, the bill would enable "wink-and-nod" messages designed to spur infringing uses while staying just shy of an explicit instruction.

The Skinny Labels Act also would provide special protection from inducement liability for abbreviated applicants relative to innovators in all other industries. For example, manufacturers of software and telecommunications equipment benefit from no shield from inducement liability; in each, a court, looking at the totality of allegations, considers whether the

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[98] H.R. 6485 § 2(a)(2).

[99] H.R. 6485 § 2(b).

[100] *See, e.g.*, Reply Brief for Petitioners, *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, 2026 WL 1047175, at *18–19 ("If the Court were to affirm, companies would abuse § 271(b) by arguing that any statement—or any omission—suffices to state an inducement claim that requires 'the benefit of discovery' and is 'not proper for resolution on a motion to dismiss.' Pet.App.14a, 18a-19a. That is not, and certainly should not be, the law."); Brief for Ass'n for Accessible Medicines as Amicus Curiae Supporting Petitioners, *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, 2026 WL 596439, at *25 ("Any determined plaintiff can write a complaint that will survive a motion to dismiss under the low bar set by the Federal Circuit.").

[101] *See GSK*, 7 F.4th 1320, 1332 (Fed. Cir. 2021) ("FDA plays no role in determining patent infringement").

[102] 68 Fed. Reg. 36,676, 36,683 (June 18, 2003).

plaintiff has stated an inducement claim.[103] Considering the public benefits of new methods of use, this special treatment for abbreviated drug applicants is not warranted.

Further, the bill would undermine patents directed to methods of treatment. Specifically, the bill would fundamentally harm innovators' IP by providing abbreviated drug applicants with a shield from inducement liability. Protecting IP rights is critical to maintaining the balance that Congress struck in Hatch-Waxman between encouraging generic market entry and incentivizing continued clinical research on approved products. Tipping the balance further toward benefitting generic drugs through legislation would upend the Hatch-Waxman balance and ultimately come at the cost of new treatments for patients.

Finally, the bill contains several other problematic provisions. First, the bill would apply retroactively to all ongoing litigation, including cases on appeal, which would disturb settled rights, change the rules for ongoing cases mid-stream, and call into question the status of pending cases. Second, the bill would unnecessarily provide a liability shield for section 505(b)(2) applications and biosimilar applications, which need not have the same labeling as the listed drug. Indeed, the prevalence of biosimilars with skinny labeling suggests that biosimilar companies have not encountered challenges executing labeling carve-outs. Per one publication, 66.7% of approved biosimilars had skinny labeling.[104] Therefore, there is no basis to provide section 505(b)(2) and biosimilar applicants with a shield from inducement liability.

V. Additional Topics on Balancing Innovation and Access

A. Legislation to Address Alleged "Product Hopping" Should Recognize the Benefit of Post-Approval R&D.

The term "product hopping" is often used to oversimplify and diminish the value of post-approval innovation in approved medicines. Critics use this term to characterize changes to FDA-approved medicines as minor and clinically unimportant and allege that marketing of these products interferes with generic or biosimilar competition on the original FDA-approved product.

Improvements in previously approved medicines—such as new dosage forms, new routes of administration, new delivery devices, and new uses—offer important benefits to patients. The IP system is designed to incentivize this type of continued innovation to improve health outcomes. Further, these new products increase consumer choice, and IP protections on them do not prevent approval of generic or biosimilar versions of the first-generation product. Existing antitrust law also already provides effective tools to address conduct that is anticompetitive. Case law has addressed circumstances involving a "hard switch," where a

[103] *See, e.g.*, *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1322 (Fed. Cir. 2009) (regarding software products, "[a] plaintiff may still prove the intent element [of induced infringement] through circumstantial evidence"); *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 700 (Fed. Cir. 2008) (regarding wireless voice and data communications patents, affirming a jury instruction to consider "all of the circumstances" relevant to the alleged induced infringement and concluding that "[t]aken as a whole," the record provided substantial evidence to support the jury verdict).

[104] A. C. Egilman et al., Frequency of Approval and Marketing of Biosimilars With a Skinny Label and Associated Medicare Savings, Research Letter, Jama Internal Med., at E2 (Nov. 28, 2022).

company withdraws—or effectively withdraws—a first-generation product from the market.[105] The FTC has also been active in the space, including by bringing enforcement actions.[106]

Legislation to address "product hopping" threatens to chill innovation. This legislation would presume that the marketing of improved products is anticompetitive even where the first-generation product remains available. Specifically, it would presume that a manufacturer committed an unfair method of competition if it engaged in a "soft switch"—a broad and ill-defined concept. Under the legislation, a soft switch would occur if, during a specified time period lasting at least three years, the manufacturer launched a new product—called a "follow-on product" in the bill—and "took actions" with respect to the first-generation product that "unfairly disadvantage" the first-generation product "relative to the follow-on product . . . in a manner that impedes competition from a generic drug or a biosimilar."[107]

The "unfairly disadvantage" text is nebulous and could potentially capture many routine activities involved in launching a new medicine. Moreover, the definition of "follow-on product" is unduly broad, capturing any "change, modification, or reformulation to the same manufacturer's previously approved drug or biological product that shares an indication, in whole or in part," with the first-generation product. It therefore could include products with different active ingredients, different combinations of active ingredients, and products expressly found by FDA to be clinically superior to the first-generation product.

This proposal risks discouraging companies from pursuing meaningful improvements to their products that would benefit patients due to the threat of antitrust liability and would place a cloud over ordinary commercialization and innovation decisions. Any change to the law to address "product hopping" should ensure that it does not chill R&D that brings important product improvements to patients.

B. Orange Book Listing Serves An Important Notice, and Stays of Approval Enable Orderly Resolution of Patent Issues.

Some stakeholders have called for limiting patents that are listed in the Orange Book, including due to concerns that "improper listing" can lead to a stay of generic approval.[108] Limiting patent listings or thirty-month stays based on them would introduce uncertainty by requiring generic applicants to assess infringement risk without Orange Book listings and could lead to more burdensome litigation.

Patent listing is a statutory requirement. The Federal Food, Drug, and Cosmetic Act states that sponsors "shall" submit patents that meet the listing criteria, and FDA publishes

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[105] *See Abbott Lab'ys v. Teva Pharms. USA, Inc.*, 432 F.Supp. 2d 408 (D. Del. 2006); New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015).

[106] Compl., *Federal Trade Commission v. Reckitt Benckiser Group PLC*, No. 1:19CV00028 (W.D. Va. July 11, 2019); *see also* FTC, FEDERAL TRADE COMMISSION REPORT ON PHARMACEUTICAL PRODUCT HOPPING (2022).

[107] H.R. 2873, 117th Cong. (2021).

[108] *See, e.g.*, Press Release, FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book', FTC (Sept. 14, 2023); Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments, 85 Fed. Reg. 33169 (June 1, 2020).

them in the Orange Book.[109] The listing process advances the Hatch-Waxman balance. Specifically, patent listings alert prospective generic applicants to patents that could reasonably be asserted in connection with commercial marketing of their products. By consolidating this information in a single, publicly accessible source, the Orange Book streamlines identification of relevant patents and facilitates efficient assessment of infringement risks, thereby reducing the likelihood that a generic applicant will overlook a patent and face subsequent liability or an injunction.

The thirty-month stay affords the parties time to resolve disputes before commercial marketing of a potentially infringing product.[110] By allowing patent litigation and regulatory review to proceed in parallel rather than sequentially, this framework has contributed to the efficient expansion of the generic marketplace and facilitated earlier access to lower-cost products. Further, such stays arise only if a Paragraph IV certification is filed and litigation is initiated within forty-five days; they are not automatic.[111] If the sponsor elects not to bring suit, generic applicants still benefit from the transparency provided by Orange Book listing. Hatch-Waxman also contains built-in safeguards to ensure that the stay is not unduly long: the thirty-month stay ends early if the generic applicant wins the patent case,[112] and the court can shorten the stay if the innovator "failed to reasonably cooperate in expediting the action."[113] Moreover, pursuant to the amendments made to the Hatch-Waxman Amendments in 2003, Congress generally imposed a limit of one thirty-month stay per abbreviated application.[114]

Ultimately, limiting patent listings would introduce greater uncertainty by requiring generic applicants to assess infringement risk without a comprehensive and reliable source of patent information. Because innovators would retain the right to enforce unlisted patents, generics could face unexpected infringement claims and potential damages after launch. This uncertainty could increase reliance on costly, time-sensitive preliminary injunction proceedings and encourage more "at-risk" launches before district courts have resolved patent litigation, thereby depriving innovators of the opportunity to enforce or defend patents prior to launch—a benefit that Hatch-Waxman was designed to provide.[115] Such launches would complicate litigation by introducing damages issues and exposing generic applicants to significant financial risk. Restricting the number of listed patents would also reduce opportunities for generic applicants to obtain 180-day exclusivity through Paragraph IV certifications, thereby weakening incentives to challenge patents and develop generic drugs.

Like articles on patent thickets, recent articles critiquing patent listing have focused on the number of patents listed. For example, a recent research letter assessed FTC's efforts from 2023 to 2025 to challenge Orange Book listings of device-directed patents.[116] It reports that

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[109] FDCA § 505(b)(1)(A)(viii); *see also id.* § 505(c)(2).

[110] *See* FDCA §§ 505(c)(3)(C), (j)(5)(B)(iii).

[111] *Id.*

[112] *Id.* §§ 505(c)(3)(C)(i), (j)(5)(B)(iii)(I).

[113] *Id.* §§ 505(c)(3)(C), (j)(5)(B)(iii).

[114] *Id.*

[115] *See* H.R. REP. NO. 98-857, pt. 1, at 28 (1984).

[116] J. Leon et al., Delisting of Pharmaceutical Patents Challenged by the Federal Trade Commission, JAMA Internal Med. (2026).

companies "complied with" 177 of 197 patent delisting requests.[117] The authors further reported that for nineteen of the thirty-four products that were the subject of challenged patent listings, the total length of protection from Orange Book-listed patents decreased during the study period, from a median of 22.3 (17.0–25.6) years to 17.0 (13.1–19.0) years. The authors' analysis appears to focus on the length of any related patent protection as measured by the last expiring patent, as opposed to the date of generic entry, despite the USPTO's conclusions in its 2024 report that "simple counts of patents can be misleading."[118] Also, the article includes products that experienced generic competition before the FTC sent its letters.[119] The authors conclude that "[b]y easing barriers to generic entry, delisting device patents from the Orange Book could contribute to improved affordability for patients and payers on several high-cost therapies."[120] Yet, they fail to provide evidence linking the delisting of patents to faster generic entry or reduced out-of-pocket patient costs.

Moreover, it is inappropriate to characterize retroactively the device component patent listings as improper because they were made in good faith. Indeed, the industry urged FDA to address the issue for well over a decade.[121] FDA opened a docket in 2020 on patent listing issues, including device component patent issues,[122] to which PhRMA and others responded,[123] and in 2021, Congress ordered preparation of FDA and GAO reports on the issue.[124] Upon review of the docket entries, FDA acknowledged divergent views on the listing of device component patents, and, in 2023, GAO cited those findings after stakeholder engagement.[125] Since then, the Federal Circuit issued an opinion on the issue.[126] Given the long-standing uncertainty about these issues and industry's repeated requests for clarity, it is inappropriate for the government to characterize retroactively device component patent listings as improper since they were made in good faith.

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[117] *Id.* at E1.

[118] USPTO, Drug Patent and Exclusivity Study (June 12, 2024), at 57.

[119] J. Leon et al., Delisting of Pharmaceutical Patents Challenged by the Federal Trade Commission, JAMA Internal Med. E2 & E3 (2026) (including Spiriva and Restasis).

[120] *Id.* at E1.

[121] *E.g.*, Comment from PhRMA, Docket No. FDA-2011-N-0830-0016 at 8, 8 at n.24 (June 8, 2015).

[122] Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments, Docket No. FDA-2020-N-1127; *see also* Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments, 85 Fed. Reg. 33169 (2020).

[123] Comment from PhRMA, Docket No. 2020-N-1127-0016 at 2 (Aug. 31, 2020) ("PhRMA urges FDA to clarify that patents claiming the device constituent of a drug-device combination product approved in a new drug application ('NDA') or a component thereof are drug product patents subject to Orange Book listing requirements.").

[124] Orange Book Transparency Act of 2020, Pub. L. No. 116-290 (Jan. 1. 2021).

[125] FDA, THE LISTING OF PATENT INFORMATION IN THE ORANGE BOOK at 24 (2022); GAO, GENERIC DRUGS: STAKEHOLDER VIEWS ON IMPROVING FDA'S INFORMATION ON PATENTS at 27 (2023).

[126] *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of New York, LLC*, 124 F.4th 898 (Fed. Cir. 2024).

C. Patent Settlements Are Procompetitive and Facilitate Timely Generic and Biosimilar Entry.

Patent settlements are central to the success of the Hatch-Waxman and BPCIA frameworks. These settlements often accelerate the market entry of generic and biosimilar drugs. Indeed, settlements are a critical option for follow-on applicants given the risk of losing patent litigation. For example, in Hatch-Waxman lawsuits litigated to trial in 2023 and 2024, district courts also found infringement of valid patents in 60% to 69% of cases, respectively.[127] When a generic manufacturer loses in litigation with respect to a patent, the generic drug cannot be approved until the patent expires.[128]

Patent settlements have allowed hundreds of generic and biosimilar drugs to enter the market years before patent expiry, generating considerable cost savings for patients. One study found that settlements on eighty-four molecules between 2014 and 2023 saved the healthcare system more than $420 billion.[129] Moreover, the FTC has remained active in reviewing patent settlements for potential anticompetitive effect in the years following the Supreme Court's decision in *FTC v. Actavis*, which provide that courts must apply a rule-of-reason analysis to evaluate whether patent settlements are anticompetitive on a case-by-case basis.[130] In its 2025 report covering fiscal year 2021, FTC noted that thirty-three of the 199 settlements received involved so-called "reverse payments" to generic drug companies, all of which were limited to litigation fees.[131] The FTC has acknowledged that payment of litigation expenses are unlikely to raise antitrust concerns.[132]

Because the FTC has authority to challenge individual settlement agreements and its 2025 report does not suggest a problem with patent settlement agreements, legislation is not needed to address patent settlements. Indeed, legislation that would restrict patent settlements could instead delay patient access to generic and biosimilar products, for example if it leads to generic and biosimilar manufacturers losing in the litigation when a settlement would have allowed earlier entry.

D. Legislation on Citizen Petitions Should Ensure That Companies May Raise Important Issues with FDA and Protect First Amendment Rights.

Citizen petitions are a critical, First Amendment-protected mechanism for raising scientific, safety, and public policy concerns with FDA. Indeed, FDA interprets a citizen petition as *required* for bringing certain requests regarding abbreviated applications to FDA.[133]

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[127] M. W. Bourke & A. P. Wharton, 2024 Hatch-Waxman Year in Review, Nat'l L. Rev. (Jan. 15, 2025).

[128] *See* 35 U.S.C. § 271(e)(4)(A).

[129] IQVIA Institute for Human Data Science on Behalf of AAM, Assessment of the Impact of Settlements (June 2025).

[130] *Fed. Trade Comm'n v. Actavis, Inc.*, 133 S.Ct. 2223, 2237 (2013).

[131] Federal Trade Commission, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2021, at 1 (Jan. 2025).

[132] Federal Trade Commission, Reverse Payments: From Cash to Quantity Restrictions and Other Possibilities (Jan. 2025).

[133] *See* FDCA § 505(q)(1)(A); FDA, Guidance for Industry: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act (Sept. 2019).

Furthermore, the public nature of the citizen petition process affords all interested stakeholders an opportunity to provide input on issues raised in a petition. This transparent process thus helps FDA achieve its mission of protecting and advancing the public health.

Although some critics have claimed that citizen petitions are used to delay generic competition, these assertions do not take into account the statute, FDA guidance, and precedent. Since 2007, FDA has had the authority to deny summarily a petition that requests the agency to take any form of action relating to an abbreviated application if FDA determines that the petition was submitted primarily to delay application approval and does not on its face raise valid scientific or regulatory issues. Since this provision was enacted in 2007, I am aware of only one instance in which FDA summarily denied a petition pursuant to this clear authority.[134] Meritless petitions are therefore not a significant issue for the agency, and FDA has existing tools to dispose of such petitions.

In its most recent report under the citizen petition process for fiscal year 2023, FDA found no evidence that petitions were submitted with the primary intent to delay approval and confirmed that no biosimilar, ANDA, or 505(b)(2) approvals were delayed as a result of 505(q) petitions.[135] Similarly, this report noted that "the number of 505(q) petitions submitted has generally trended downward in the past few years."[136]

Further, statistics on the number of "denied" citizen petitions must be viewed in context.[137] The statute requires FDA to respond to a citizen petition within 150 days, but, in practice, FDA often issues placeholder responses that do not comment on the merits of the petition. Frequently cited analyses of citizen petition denial trends do not differentiate between petitions that are substantively denied and summarily denied.[138] As a result, these analyses overstate the percentage of petitions denied on their merits.

Claims regarding "serial" petitioning also must be viewed in context. When FDA does not substantively respond to a petition, companies may refile a petition to continue the request. Some refer to as a "serial" petition even though FDA never answered the petition in the first place. Claims that so-called "serial" petitions delay competition ignore the FDA policy that is at the root of multiple petitions.

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[134] *See* FDA Response, Docket No. FDA-2021-P-1211, at 3 (Dec. 15, 2021) (denying petition regarding Vasostrict and stating that the petition "appears to have been submitted with the primary purpose of delaying [ANDA] approval"). FDA also stated its intent to refer that matter to the Federal Trade Commission for investigation.

[135] FDA, Sixteenth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action, FY 2023, at 4.

[136] *Id.*

[137] *See, e.g.*, M. Carrier et al., Citizen Petitions: Long, Late-Filed, and At-Last Denied, 66 Am. U. L.R 305, 306 (2016) ("FDA granted an astonishingly low 8% of petitions, rejecting a full 92%"); Carrier et al., Citizen Petitions: An Empirical Study, 34 Cardozo L. Rev. 249, 249 (2012) ("The study concludes that the FDA has granted 19% of citizen petitions and has denied 81%.").

[138] *See, e.g.*, M. Carrier et al., Citizen Petitions: Long, Late-Filed, and At-Last Denied, 66 Am. U. L.R 305, 306 (2016); Carrier et al., Citizen Petitions: An Empirical Study, 34 Cardozo L. Rev. 249, 249 (2012).

The right of a citizen to petition the U.S. government is a constitutionally protected right.[139] There also are effective checks in place to ensure that the citizen petition process is not abused. Beyond summary denials, antitrust lawsuits are available for sham petitions and a petitioner forfeits its First Amendment immunity from antitrust liability if its petition is a sham—that is, it is objectively baseless and is designed solely for the purpose of using government process to harass a competitor.[140] This threat of litigation is a significant incentive for petitioners to file citizen petitions only when they raise substantive, non-frivolous arguments.

Overall, citizen petitions constitute an important, constitutionally protected mechanism for providing input to FDA on key issues concerning medicines. Any legislation on this topic should not undermine this core function of the petitioning process.

Thank you for the opportunity to appear today, and I would be happy to answer your questions.

[139] *See Eastern R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127, 136-37 (1961); *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972).

[140] *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993).