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The University of Akron School of Law

Promoting progress in innovation & creativity through scholarship & policy

November 23, 2026

The Honorable Chuck Grassley
Chairman
The Honorable Richard J. Durbin
Ranking Member
Committee on the Judiciary
United States Senate
Washington, DC 20510

Re: Submission for the Record, "Prescribing Sunshine: How Competition & Transparency Lowers Prescription Drug Costs" (November 17, 2026)

Dear Chairman Grassley and Ranking Member Durbin:

We write on behalf of IPPI: The IP Policy Institute, an academic research center at The University of Akron School of Law, to submit the enclosed research for the record of the Committee's November 17 hearing. We respectfully request that this letter and its enclosures be included in the hearing record.

We share the Committee's commitment to affordable medicines and timely generic and biosimilar competition.

Several claims made at the hearing about biopharmaceutical patents and publicly funded research, however, do not hold up against the evidence. Those claims were offered in support of the Eliminating Thickets to Increase Competition (ETHIC) Act (S. 2276), the Drug Competition Enhancement Act (S. 1040), the Medication Affordability and Patent Integrity Act (MAPIA) (S. 2658), and related bills. We address five of them below.

1. Patent counts do not predict when generics enter the market.

Witnesses pointed to the number of patents on medicines as evidence of abuse. Testimony alleged "patent thickets" around existing medicines and asserted that 74 percent of drug patents issued from 2005 to 2015 were for products already on the market.[1]

[1] Merith Basey, Chief Exec. Officer, Patients For Affordable Drugs Now, Written Statement Before the S. Comm. on the Judiciary 4–5 (Nov. 17, 2026) [hereinafter Basey Statement].

Counting every patent associated with a drug says nothing about what those patents cover. Patents on new uses and formulations developed after launch will, by definition, issue for products already on the market, and none of them stops generic copying of the original product.

Market outcomes confirm that patent counts do not drive the timing of generic entry. The time from brand launch to first generic entry has held at roughly 13 to 14 years for decades, even as reported patent counts rose.[2] A study of a sample of 131 of 2012's top-selling drugs found no significant correlation between the number of patents on a drug and its effective patent life,[3] and the U.S. Patent and Trademark Office (USPTO) has concluded that neither patent counts nor expiration dates reliably predict when competing products launch.[4]

Assuming that patent counts are significant obstacles to generic entry also disregards the advantages that the Hatch-Waxman Act[5] gives to generic manufacturers, advantages that competitors in no other industry enjoy. They need not repeat the brand company's clinical trials; they rely instead on the Food and Drug Administration's (FDA's) finding that the brand drug is safe and effective and show only that their product is bioequivalent. They may also develop and test their products before the brand's patents expire and resolve patent disputes before launch, and the first applicant to challenge a patent listed in the FDA's Orange Book earns a potentially lucrative 180 days as the only generic on the market if its challenge clears the way to launch.[6] Many listed patents never become obstacles at all: brand companies decline to sue in more than a third of these patent challenges.[7]

The system works as designed. Generic entry stays on schedule, and generics now fill about 90 percent of U.S. prescriptions.[8] Today's breakthrough medicines become tomorrow's generics and biosimilars with predictable regularity.

2. Terminal disclaimers tie related patents to one term and one owner.

The ETHIC Act would let a patent owner suing a generic or biosimilar applicant assert only one patent from each group linked by terminal disclaimers, which testimony presented as a way to stop companies from "weaponiz[ing] duplicative patents."[9] The same testimony concedes that terminal

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[2] Henry Grabowski, Genia Long & Richard Mortimer, *Continuing Trends in U.S. Brand-Name and Generic Drug Competition*, 24 J. Med. Econ. 908 (2021); *see generally* Mark Schultz & Jennifer Brant, with Douglas Park, *Pharmaceutical "Patent Thickets": Separating Myth from Reality* (IPPI & Innovation Insights, May 2026) (enclosed) [hereinafter *Patent Thickets*].

[3] Emily Michiko Morris & Joshua Kresh, *Pharmaceutical "Nominal Patent Life" Versus "Effective Patent Life," Revisited* (May 20, 2024), https://blogs.uakron.edu/ualawip/2024/05/20/pharmaceutical-nominal-patent-life-versus-effective-patent-life-revisited/.

[4] U.S. Patent & Trademark Off., *Drug Patent and Exclusivity Study* 58–59 (2024).

[5] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

[6] 21 U.S.C. § 355(j); 35 U.S.C. § 271(e)(1)–(2); *see* Mark Schultz & Jennifer Brant, with Douglas Park, *Pharmaceutical Patent "Evergreening": Separating Myth from Reality* 9–10 (IPPI & Innovation Insights, May 2026) (enclosed) [hereinafter *Evergreening*].

[7] S. Kannappan et al., *The Timing of 30-Month Stay Expirations and Generic Entry: A Cohort Study of First Generics, 2013–2020*, 14 Clinical & Translational Sci. 1917 (2021).

[8] U.S. Food & Drug Admin., *Generic Drug Facts* (2022), https://www.fda.gov/drugs/generic-drugs/generic-drug-facts; *Patent Thickets*, *supra* note 2, at 3.

[9] Basey Statement, *supra* note 1, at 7.

disclaimers "do not extend the expiration date of the original patent."[10] Setting this common expiration date is their function.

Far from weaponizing patents, terminal disclaimers serve to limit them. A terminal disclaimer surrenders any term beyond the earlier patent and makes the later patent enforceable only while both remain commonly owned.[11] Such a group is "tantamount for all practical purposes to having all the claims in one patent,"[12] and litigating it resembles litigating one patent with many claims. A disclaimer is also not an admission of obviousness.[13]

The growing use of terminal disclaimers follows from Congress's own choices.[14] Beginning in 1984, and again in the Cooperative Research and Technology Enhancement (CREATE) Act and the America Invents Act, Congress excluded a company's commonly owned work, and later work done under joint research agreements, from the prior art that can defeat its later applications.[15] Because that work cannot be cited against the company's later applications, USPTO patent examiners police closely related inventions through obviousness-type double patenting, which a terminal disclaimer resolves.[16]

The ETHIC Act would force a patent owner to choose before anyone knows which patents matter. The owner would have to pick its one patent from each linked group when it files suit, before discovery shows which claims the generic or biosimilar product actually practices, and could not assert the others against the same defendant later.[17] Courts avoid exactly this problem by narrowing asserted claims and patents in stages as the facts develop.[18] Under the bill, the outcome could turn on an early guess rather than on the merits.

Penalizing terminal disclaimers would carry real costs. The likely results are more contested examination at the USPTO, some patents issuing at full term without disclaimers, and weaker incentives to invest in the formulation and dosing work that turns early discoveries into medicines.[19]

The testimony's one concrete example does not support the bill. It asserts that Stelara biosimilars "likely would have arrived sooner" had the ETHIC Act been law.[20] The facts show otherwise.

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[10] *Id.* at 6.

[11] 37 C.F.R. § 1.321(c)–(d) (2025); *see* Douglas S. Park, *The ETHIC Act and Terminal Disclaimers in Pharmaceutical Development* 4 (IPPI Policy Brief, Nov. 2026) (enclosed) [hereinafter Park, *ETHIC Act*].

[12] *In re Braithwaite*, 379 F.2d 594, 601 (C.C.P.A. 1967).

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

[14] Emily Michiko Morris & Douglas S. Park, *Obviousness-Type Double Patenting and Terminal Disclaimers in Biopharmaceutical Development* 1–2 (IPPI Policy Brief, Nov. 2026) (enclosed) [hereinafter Morris & Park].

[15] Patent Law Amendments Act of 1984, Pub. L. No. 98-622, § 103, 98 Stat. 3383, 3384; Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Pub. L. No. 108-453, 118 Stat. 3596; 35 U.S.C. § 102(b)(2)(C), (c); Park, *ETHIC Act*, *supra* note 11, at 5; Morris & Park, *supra* note 14, at 9.

[16] Morris & Park, *supra* note 14, at 9.

[17] S. 2276, 119th Cong. (2025); *see* H.R. 3269, 119th Cong. § 2(a) (2025) (proposed 35 U.S.C. § 271(e)(7)(A), (C)).

[18] *See Nuance Commc'ns, Inc. v. ABBYY USA Software House, Inc.*, 813 F.3d 1368, 1376 (Fed. Cir. 2016); *In re Katz Interactive Call Processing Pat. Litig.*, 639 F.3d 1303, 1309, 1312 (Fed. Cir. 2011).

[19] Park, *ETHIC Act*, *supra* note 11, at 5–7; Morris & Park, *supra* note 14, at 3–5.

[20] Basey Statement, *supra* note 1, at 7.

Stelara is not a patent thicket story. The first biosimilar, Amgen's Wezlana, was approved in October 2023 and launched on January 1, 2025, under a May 2023 settlement of patent litigation.[21] In that litigation, Janssen asserted a relatively modest number of patents, six in all: the patent on Stelara's active ingredient, a patent on treating ulcerative colitis, and four patents on manufacturing methods.[22]

The ETHIC Act would not have changed that litigation in any way that mattered. The four manufacturing patents form two families, each solving a different production problem: one controls glycan levels and the other controls C-terminal lysine levels.[23] Janssen sought a preliminary injunction on one patent from each family, and the two have different priority dates.[24] Even under the bill, Janssen could have asserted four of the six patents, including both patents on which it sought an injunction.[25] The bill would not have changed when Amgen could launch.

Nor does Stelara suggest that a stricter limit is warranted. The six patents cover four different inventions: the active ingredient, a medical use, and two separate manufacturing advances. Developing a biologic requires many such advances after the initial discovery, and patents are what make the investment in them worthwhile. Within each manufacturing family, terminal disclaimers let Janssen protect closely related variations on the same advance without extending patent term.[26]

3. Later patents cannot extend earlier ones, and the improvements they protect are real.

Testimony portrayed moving patients to "slightly modified" products as part of "endless opportunities to protect their monopolies."[27] That description misstates both the law and the science.

Patent law does not allow later filings to extend earlier patents. Patents expire twenty years from filing, subject only to narrow, formula-bound adjustments.[28] A later patent on an improvement cannot revive an expired patent or stop generics from copying the original product.

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[21] Press Release, U.S. Food & Drug Admin., FDA Approves Interchangeable Biosimilar for Multiple Inflammatory Diseases (Oct. 31, 2023), https://www.fda.gov/news-events/press-announcements/fda-approves-interchangeable-biosimilar-multiple-inflammatory-diseases; Venable LLP, *Amgen Launches Wezlana™ as the First Stelara® Interchangeable Biosimilar Through Optum's Nuvaila*, JD Supra (Jan. 2025), https://www.jdsupra.com/legalnews/amgen-launches-wezlana-tm-as-the-first-5034283/; *J&J, Amgen End Clash Over Biosimilar of Lucrative Stelara*, Bloomberg L. (May 23, 2023), https://news.bloomberglaw.com/ip-law/j-j-amgen-settle-patent-suit-on-biosimilar-of-lucrative-stelara.

[22] First Amended Complaint, *Janssen Biotech, Inc. v. Amgen Inc.*, No. 1:22-cv-01549 (D. Del. Feb. 21, 2023) (asserting U.S. Patent Nos. 6,902,734; 10,961,307; 8,852,889; 9,217,168; 9,475,858; and 9,663,810).

[23] U.S. Patent No. 9,217,168 (filed Mar. 14, 2013) ("Methods of Cell Culture"); U.S. Patent No. 9,475,858 (PCT application filed July 6, 2012) (claiming priority to provisional application filed July 8, 2011) ("Cell Culture Process"); U.S. Patent No. 9,663,810 (filed Nov. 16, 2015) (continuation of application No. 13/829,333, which issued as the '168 patent); U.S. Patent No. 8,852,889 (filed Jan. 8, 2014) (continuation of application No. 14/131,005, which issued as the '858 patent).

[24] Plaintiff's Opening Brief in Support of Its Motion for a Preliminary Injunction, *Janssen Biotech*, No. 1:22-cv-01549 (D. Del. Mar. 1, 2023).

[25] S. 2276; *see* H.R. 3269 § 2(a).

[26] *See* Morris & Park, *supra* note 14, at 1–3.

[27] Basey Statement, *supra* note 1, at 8, 13.

[28] 35 U.S.C. §§ 154(a)(2), (b), 156.

Predictions that assume otherwise consistently fail. For example, the oft-cited University of California, San Francisco (UCSF) Evergreen Drug Patent Database purports to demonstrate evergreening. However, an audit of 224 drugs in the database showed that generics entered on average seven years earlier than the database predicted.[29]

Improvements that critics dismiss as trivial are often clinically meaningful. Testimony cited Symbravo, a migraine treatment approved in January 2025, whose patents separately claim methods of providing "pain relief" and "pain freedom."[30] The distinction was characterized at the hearing as "verbal manipulation."[31] For both patients and the FDA, the difference is real. Pain relief means reducing moderate or severe pain to mild or no pain; pain freedom means no pain at all. Symbravo's FDA-approved label reports them as separate endpoints. On sustained pain freedom from 2 to 24 hours, the outcome claimed in one of the two patents, Symbravo outperformed rizatriptan alone in its principal efficacy trial.[32]

Post-approval research also brings proven medicines to new patients and better forms of treatment. About two-thirds of oncology drugs first approved from 2008 through 2018 later gained at least one additional indication, often approved as a first-choice treatment.[33] Delivery advances such as subcutaneous Keytruda also benefit patients, replacing a 30-minute infusion with an injection of a minute or two.[34] Patents on these advances cover only the advance itself and do not block generic versions of the original product.[35]

4. Public funding builds part of the scientific foundation for new medicines; private investment develops them.

Witnesses also overstated the role of public funding in developing new medicines. Testimony asserted that the National Institutes of Health (NIH) funds most drugs "from basic research all the way through to clinical trials," and the hearing included the suggestion that 95 percent of new drugs "start with" NIH research.[36] The written testimony made a narrower claim, that more than 99 percent of drugs approved from 2010 to 2019 benefited from federal research support.[37]

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[29] Erika Lietzan & Kristina M.L. Acri, *Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations*, 33 Fordham Intell. Prop. Media & Ent. L.J. 788 (2023); *see Evergreening*, *supra* note 6, at 11–13.

[30] Basey Statement, *supra* note 1, at 5–6 (citing U.S. Patent No. 11,135,295 cl. 1; U.S. Patent No. 11,207,328 cl. 1).

[31] *Prescribing Sunshine: How Competition & Transparency Lowers Prescription Drug Costs: Hearing Before the S. Comm. on the Judiciary*, 119th Cong., at 2:28:18–2:28:48 (Nov. 17, 2026), https://www.judiciary.senate.gov/committee-activity/hearings/prescribing-sunshine-how-competition-and-transparency-lowers-prescription-drug-costs-11-17-2026 [hereinafter Hearing Webcast].

[32] Symbravo (meloxicam and rizatriptan) Tablets, Prescribing Information § 14 (Axsome Therapeutics, Inc. 2025).

[33] J.A. Patterson et al., *Subsequent Indications in Oncology Drugs: Pathways, Timelines, and the Inflation Reduction Act*, 59 Therapeutic Innovation & Regul. Sci. 102 (2025); Mark Schultz & Jennifer Brant, with Douglas Park, *Continuous Innovation: The Value of Post-Approval R&D* 2 (IPPI & Innovation Insights, July 2026) (enclosed) [hereinafter *Continuous Innovation*]; *Patent Thickets*, *supra* note 2, at 11.

[34] *Continuous Innovation*, *supra* note 33, at 12.

[35] *Evergreening*, *supra* note 6, at 5, 7–8.

[36] Hearing Webcast, *supra* note 31, at 2:08:26, 1:44:25.

[37] Basey Statement, *supra* note 1, at 12.

The study behind that statistic does not support the broader claims. A closer look at its data, and at its authors' own conclusions, shows a division of labor: public funding largely supports basic research on biological targets, while industry develops the drugs.

The study linked NIH funding to 354 of the 356 drugs it examined, but it counted a drug as linked if a literature search for the drug or its biological target turned up any NIH-funded publication.[38] A target is the specific molecule a drug acts on, usually a protein such as a receptor or enzyme. NIH funds research so broadly across potential targets that every target in the study had been the subject of NIH-funded work. Any drug acting on a known target was therefore counted as NIH-linked, whether or not the research behind that link had anything to do with the drug.

The study's breakdown of funding reinforces the problem with attributing funding for target research to specific drugs. Research on targets is earlier, more fundamental work, not applied research on particular drugs, and it accounted for 83 percent of the NIH funding the study identified.[39] Association with a drug's target is neither development of the drug nor proof that the drug originated in NIH research.

Basic research on a target relates to a drug much as a public highway relates to a trucking company. A highway makes a trucking company possible, but it does not buy the trucks, hire the drivers, or win the customers, and no one would say the public built the company.

The study's headline comparison of NIH and industry spending rests on the same conflation of basic research funding with drug development. It finds NIH spending per approval "not less than" industry spending only because of an accounting choice: it charges each drug that was first to act on a new target the entire cost of NIH research on that target, a mean of $1.34 billion, even though, by the study's own estimate, each target supports about 2.85 drugs on average.[40]

Industry also conducts basic research of its own. In a Tufts Center for the Study of Drug Development review of the most transformational drugs of the past quarter century, the private sector was the predominant contributor to more than a quarter of basic science milestones, while leading most discovery, manufacturing, and clinical development milestones.[41]

The authors of the study cited in testimony acknowledge the division of labor. They conclude that the public sector contributes substantially to "foundational knowledge" but less to development, and that industry "is primarily responsible for product development."[42]

A direct link between NIH funding and the inventions protecting these drugs is far rarer than the 99 percent figure suggests. A companion study by two of the same authors found that only 29 of

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[38] Ekaterina Galkina Cleary, Matthew J. Jackson, Edward W. Zhou & Fred D. Ledley, *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010–2019*, 4 JAMA Health F. e230511, at 3–4 (2023) [hereinafter Galkina Cleary et al.].

[39] *Id.* at 4.

[40] Galkina Cleary et al., *supra* note 38, at 1, 4, 7–8.

[41] Ranjana Chakravarthy, Kristina Cotter, Joseph DiMasi, Christopher-Paul Milne & Nils Wendel, Tufts Ctr. for the Study of Drug Dev., *Public and Private Sector Contributions to the Research & Development of the Most Transformational Drugs of the Last 25 Years* 1 (2015), *published in revised form as Public- and Private-Sector Contributions to the Research and Development of the Most Transformational Drugs in the Past 25 Years: From Theory to Therapy*, 50 Therapeutic Innovation & Regul. Sci. 759 (2016).

[42] Galkina Cleary et al., *supra* note 38, at 8.

the 297 drugs with patents were protected by a patent produced by an NIH-funded research project on the drug or its target.[43] Measured by dollars, the link is weaker still. Less than 1 percent of the roughly $164 billion in NIH funding the study linked to these drugs went to the research projects that produced those patents.[44]

Read closely, the testimony's own supporting evidence shows that crediting NIH-funded basic science with developing new medicines greatly overstates the public sector's role, important as that research is to scientific advancement. It also overlooks the private investment, secured by patents, that turns scientific discoveries into medicines.

5. Both MAPIA and the Drug Competition Enhancement Act address problems that existing law already covers.

MAPIA would sharply expand the grounds for holding patents unenforceable. It would require manufacturers to certify that their submissions to the FDA and the USPTO are consistent and would create a non-disclosure defense to infringement. This defense would effectively make patents unenforceable for negligent as well as intentional failures to disclose inconsistent statements, whether or not the omission would have changed the USPTO's decision. The Federal Circuit's standard requires both intent to deceive and but-for materiality.[45]

Existing law already addresses inconsistent statements, and it recognizes that statements to the two agencies often differ for good reason: the agencies ask different questions, at different times, under different legal standards.[46] Applicants already owe a duty of candor to the USPTO.[47] The FDA must withdraw approval of an application that contains an untrue statement of material fact, and under its Application Integrity Policy it can call into question all of an applicant's pending submissions.[48] Knowingly false statements to either agency are also a federal crime.[49] The USPTO can already request drug information from the FDA, and it has clarified that the duty of disclosure

[43] Fred D. Ledley & Ekaterina Galkina Cleary, *NIH Funding for Patents That Contribute to Market Exclusivity of Drugs Approved 2010–2019 and the Public Interest Protections of Bayh-Dole*, 18 PLoS ONE e0288447, at 1, 5–6 (2023).

[44] *Id.* at 6–7; *see also* Bhaven N. Sampat & Frank R. Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?*, 30 Health Affs. 332 (2011) (finding that while nearly half of drugs approved from 1988 to 2005 were associated with patents citing public-sector research, fewer than one in ten were directly covered by a public-sector patent).

[45] S. 2658, 119th Cong. § 2(a) (as reported July 28, 2026); Douglas Park, *Fact Sheet on the Medication Affordability and Patent Integrity Act* 4 (IPPI, Nov. 2026) (enclosed) [hereinafter MAPIA Fact Sheet]; *see Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290–91 (Fed. Cir. 2011) (en banc); Basey Statement, *supra* note 1, at 11.

[46] *See aaiPharma Inc. v. Thompson*, 296 F.3d 227, 241 (4th Cir. 2002); *Neptune Generics, LLC v. Eli Lilly & Co.*, 921 F.3d 1372, 1377 (Fed. Cir. 2019); MAPIA Fact Sheet, *supra* note 45, at 1–2.

[47] 37 C.F.R. § 1.56 (2025).

[48] 21 U.S.C. § 355(e); 21 C.F.R. § 314.150(a)(2)(iv) (2025); Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy, 56 Fed. Reg. 46,191 (Sept. 10, 1991).

[49] 18 U.S.C. § 1001.

reaches inconsistent statements made to other agencies.[50] Intentional deception involving material information already renders a patent unenforceable under the inequitable conduct doctrine.[51]

Nor is there evidence of a gap for MAPIA to fill. Generic and biosimilar manufacturers have every incentive to find inconsistencies and the means to do so: much of a brand company's application becomes public after approval, and challengers obtain the rest through discovery in patent litigation.[52] Yet the testimony identifies no material inconsistency that existing rules failed to reach.

MAPIA would instead revive a problem the courts have already solved. By extending unenforceability to negligent omissions, it would bring back the overdisclosure and litigation that the Federal Circuit called a "plague" in *Therasense*.[53]

The Drug Competition Enhancement Act likewise targets conduct that existing law already reaches. Namenda, the testimony's own product-hopping example, shows as much. As the testimony acknowledges, the New York Attorney General obtained an injunction under existing antitrust law against the planned withdrawal of the original Namenda IR in favor of the newer, extended-release Namenda XR, before generic IR versions launched, a so-called "hard switch."[54]

The Drug Competition Enhancement Act also lacks an evidentiary basis and would reach well beyond the conduct it targets. No evidence suggests that product hopping continues to delay generic or biosimilar entry. Worse, the bill is not confined to product changes timed to imminent generic or biosimilar entry, a limit that even some critics of product hopping endorse.[55] Nor does it account for the often significant benefits that improved versions of medicines offer patients.[56]

In each case, the claims offered in support of these bills do not hold up against the evidence. The enclosed papers set out this evidence in detail. We would welcome the opportunity to discuss them with Members and Committee staff.

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[50] 21 U.S.C. § 372(d) (permitting the Director to ask the FDA "to furnish full and complete information with respect to such questions relating to drugs as the Director may submit concerning any patent application"); Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board, 87 Fed. Reg. 45,764, 45,765 (July 29, 2022); *see also* U.S. Pat. & Trademark Off., Manual of Patent Examining Procedure § 2001.06(e); 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50 (2025).

[51] *Therasense*, 649 F.3d at 1290.

[52] 21 C.F.R. §§ 314.430(e), 601.51(e) (2025) (providing for disclosure of approved new drug and biologics license applications); *id.* §§ 314.430(g), 601.51(f) (withholding manufacturing methods, quality control procedures, formulas, and similar data); Fed. R. Civ. P. 26(b)(1); MAPIA Fact Sheet, *supra* note 45, at 3 & n.9.

[53] *Therasense*, 649 F.3d at 1289 (quoting *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988)); MAPIA Fact Sheet, *supra* note 45, at 3–4.

[54] Basey Statement, *supra* note 1, at 8; *see New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015).

[55] Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 Notre Dame L. Rev. 167, 201 (2016).

[56] *See generally Continuous Innovation*, *supra* note 33.

Respectfully submitted,

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Enclosures:

1. Mark Schultz & Jennifer Brant, with Douglas Park, *Pharmaceutical "Patent Thickets": Separating Myth from Reality* (May 2026)
2. Mark Schultz & Jennifer Brant, with Douglas Park, *Pharmaceutical Patent "Evergreening": Separating Myth from Reality* (May 2026)
3. Mark Schultz & Jennifer Brant, with Douglas Park, *Continuous Innovation: The Value of Post-Approval R&D* (July 2026)
4. Douglas S. Park, *The ETHIC Act and Terminal Disclaimers in Pharmaceutical Development* (IPPI Policy Brief, Nov. 2026)
5. Emily Michiko Morris & Douglas S. Park, *Obviousness-Type Double Patenting and Terminal Disclaimers in Biopharmaceutical Development* (IPPI Policy Brief, Nov. 2026)
6. Douglas Park, *Fact Sheet on the Medication Affordability and Patent Integrity Act* (IPPI, Nov. 2026)