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Lowering Drug Prices by Reviving Skinny Labels and Patent Challenges and Addressing Patent Thickets

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Hearing on "Medicines and IP: Balancing Innovation and Access"
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I. Introduction

A. Drug prices too high; patients unable to afford needed medicines. Why?
   1. Brand drug companies abuse system by delaying generic and biosimilar entry
      a) Examples: building and enforcing patent thickets, claiming that skinny labels induce patent infringement
      b) This conduct cannot be justified by innovation
   2. At the same time, the U.S. Patent and Trademark Office (PTO), which could directly address these issues, has been kneecapped by recent changes

B. Congress can address these abuses and rebalance the system

II. My Background

A. I have studied pharmaceuticals as co-author of leading IP/antitrust treatise; author of more than 160 articles (80 on pharmaceuticals); drafter of 25 "amicus" briefs on behalf of hundreds of professors; and one frequently cited in media (2000+ times) and courts (including Supreme Court)

III. Generic Competition

A. Use of prescription drugs widespread in society; affordability is crucial issue facing patients
B. Hatch-Waxman Act designed to work together with state substitution laws on the books to lower drug prices
C. The rules fostering generic competition historically were clear and effective but now are out of balance
D. There are two ways for a generic to reach the market while patents are at issue:
   1. **First** is litigation. Generics filing a "Paragraph IV" certification claiming a patent is invalid or not infringed commit an artificial act of infringement that allows the brand firm to sue
   2. Just by filing suit in a timely fashion, the brand gets an *automatic* 30-month stay of FDA approval
   3. Generics must fight through multiple patents on each drug, roughly 7 and 17 according to two studies in the small-molecule setting (which has fewer patents than the biologics setting).[1]
   4. They must confront patents of questionable validity as the secondary patents (not covering the active ingredient) are invalidated 68% of the time when litigated to a final decision.[2]
   5. Losing on even a single patent means being ordered to stay off the market.
E. As discussed in the next section, the **second** way involves "skinny labels."

IV. Skinny Labels

A. For "method of use" patents, the generic may "carve out" patented uses from the brand label
B. As an example, for Amarin's drug Vascepa, generic Hikma entered with a skinny label that described only treating very high triglycerides, carving out the patented method of reducing the risk of heart attacks and strokes

[1] Caroline Horrow, Sarah M.E. Gabriele, S. Sean Tu, Ameet Sarpatwari, & Aaron S. Kesselheim, *Patent Portfolios Protecting 10 Top-Selling Prescription Drugs*, 2024 JAMA INTERN. MED. 810 (2024) (17 in setting of top-selling prescription drugs); Theodore W. Teng, S. Sean Tu, Helen Mooney, Liam Bendicksen, Sarah M. E. Gabriele, Olivier J. Wouters, & William B. Feldman, *Tertiary Patents on Drugs Approved by the FDA*, 2026 JAMA HEALTH FORUM 1, 4 (7 for "tertiary" (device) patents).

[2] C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1386–87 (2013); *see also* Errol B. Taylor & Fredrick M. Zullow, *Focusing Only on Active Ingredient Patents Ignores Case Law Success Rates: Formulation and Method-of-Use Patents Provide Significant Protection for Medicines*, BLOOMBERG LAW, Oct. 28, 2011 (Federal Circuit upheld method-of-use patents in only 29% of cases).

C. For 15 brand drugs whose first competition between 2015 and 2019 was a skinny label generic, competition led to 2.5 years earlier of generic competition and 34% lower prices, saving Medicare Part D $15 billion.[3]
D. Other studies found that skinny labels were used in connection with roughly half of brand drugs susceptible to the practice.[4]
E. Despite skinny labels' benefits and importance for the Hatch Waxman Act, the Federal Circuit has recently found that skinny labels themselves or common skinny-label conduct "induces" patent infringement
   1. Such conduct includes referencing a "generic version" and referring to sales figures
   2. This is gravely concerning:
      a) A skinny label is how the system works (with the generic label otherwise needing to match the brand label);
      b) So is calling a product generic, which is how the doctor knows it's safe and approved; and
      c) Other "anodyne" statements not directed to doctors do not change this equation.[5]
F. Likely as a result of the first Federal Circuit decision upholding a verdict against a generic for typical skinny-labeling conduct (*GSK v. Teva* (2020)), the practice fell from 56% (2021) to 43% (2022) to 20% (2023).[6]
G. The Skinny Labels, Big Savings Act would address these concerns by making clear that commonplace conduct like the label itself, referring to a "generic version" or "therapeutic equivalent," or making truthful statements that do *not* reference the patented indication does not constitute infringement

V. Patent Thickets

A. Of industries with patent thickets, pharmaceuticals present the most concern:
   1. *Licensing*: Unlike electronics/computer/semiconductor industries, which need to cross-license, brand drug companies have all the patents they need to enter the market (they can't be blocked by generics/biosimilars)
   2. *Regulatory barriers*: Unlike high tech industries, pharmaceuticals are governed by a unique regulatory regime
      a) In addition, brand firms layer duplicate patents on product features that must be matched by generics/ biosimilars while tech companies differentiate their products and engage in innovation
   3. *Market concentration*: In contrast to high tech industries like consumer electronics and semiconductors, it costs hundreds of millions of dollars for biosimilars to enter the market
B. For Humira (blockbuster drug, previously top seller in world):
   1. Initially approved in 2002, active ingredient patent expired in 2016
   2. In original empirical research,[7] Sean Tu and I found that shortly before the active ingredient patent expired…
      a) The number of patents tripled
      b) Litigated "continuations" (which are based on earlier patent applications and can't add new material) increased from (based on patent filing dates) 35% (2003-13) to 98% (2014-20).[8]
         (2) Continuations often don't reflect innovation, as the specification discloses no new information to the public and the most common rejection is "obviousness-type double patenting," which prevents an applicant from receiving a second set of claims that is obvious based on the first
C. General continuations
   1. We compared the pharmaceutical industry (Orange Book and Purple Book) with high tech (electric digital processing and semiconductor devices).[9]
   2. We found that the pharmaceutical industry uses continuations much more than high tech: 45% Orange Book and 57% Purple Book vs. 20% electric digital processing and 14% semiconductors
   3. We also observed that this is a recent phenomenon, with pharmaceutical continuations increasing from (based on patent filing date) 28% in 2000 to 74% in 2020
   4. We found similar results for litigated continuations and method-of-use patents.[10]

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[3] Alexander C. Egilman, Aaron S. Kesselheim, Ameet Sarpatwari, & Benjamin N. Rome, *Estimated Medicare Part D Savings from Generic Drugs with a Skinny Label*, 177:6 ANNALS OF INTERNAL MEDICINE, Apr. 30, 2024.

[4] Bryan S. Walsh, Ameet Sarpatwari, Benjamin N. Rome, & Aaron S. Kesselheim, *Frequency of First Generic Drug Approvals With "Skinny Labels" in the United States*, 181(7) JAMA INTERNAL MEDICINE (July 2021); Therese J. Ziaks, Chukwubuikem M. Akanegbu, Alexander C. Egilman, & Aaron S. Kesselheim, *Frequency of First Generic Drugs Approved Through "Skinny Labeling," 2021 to 2023*, 31 J. MANAGED CARE & SPECIALTY PHARM. 343 (2025).

[5] Brief for the United States as Amicus Curiae Supporting Petitioners at 26–30, *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, No. 24-889 (Feb. 2026).

[6] Ziaks et al., *supra*.

[7] Michael A. Carrier & S. Sean Tu, *Why Pharmaceutical Patent Thickets Are Unique*, 32 TEXAS INTELLECTUAL PROP. L. J. 79 (2024).

[8] *Id.* at 88–92.

[9] The high tech categories are based on "CPC (Cooperative Patent Classification) codes" with the highest number of continuation patents.

D. These findings are consistent with former FDA Commissioner Scott Gottlieb's observation that thickets of biologics are "purely designed to deter entry of approved biosimilars."[11]

E. They also are consistent with the concern of former HHS Secretary Alex Azar: "There's a deal in our Hatch-Waxman statute. There's a deal in the biosimilar legislation. It says you get the exclusive right to practice this molecule and this patent, up to this date, and at that point 'Katy, bar the door' – full generic competition, full biosimilar competition. Stop the gamesmanship … stop the evergreening."[12]

F. The ETHIC Act would address thicket abuses by limiting patent owners in litigation to one patent per cluster linked by terminal disclaimers

1. This would not harm innovation since the patents linked by terminal disclaimers are often the result of obviousness type double patenting rejections, with the applicant receiving the (obvious) patent only by promising to cut short its term

VI. Patent Office Procedures

A. Many patents are not valid, with roughly 45% across all industries overturned in court,[13] rising to roughly 70% for drug patents not covering the active ingredient.[14]

1. This is not a surprise given (1) limited time, (2) warped incentives, and (3) ex parte nature of process:
2. Time: On average, examiners have only 19 hours to review patents, within which they must read the application, search for prior art, compare prior art with the application, write a rejection, respond to an applicant's arguments, and (often) conduct an interview with the attorney.[15]
3. Incentives: Michael Frakes & Melissa Wasserman have shown that "the vast majority of the PTO's budget is gained through fees that the Agency collects only if a patent is granted" and that this result is particularly likely in industries where patents are more likely to be renewed (like pharmaceuticals).[16]
4. Examiners are hampered by the ex parte nature of the process, able to communicate with only the applicant, who is not required to search for prior art.[17]

B. America Invents Act (AIA): According to the drafters, the purpose of the AIA was to ensure that the patent system "reflects the constitutional imperative" to "establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs."[18]

1. As the Supreme Court explained, Congress "sought to weed out bad patent claims efficiently."[19]
2. Litigation is expensive, costing $3.5 million on average in cases with more than $25 million at risk.[20]

C. Application to pharmaceuticals

1. The system has been frequently used; between 2012 and 2025, roughly 1400 inter partes review (IPR) petitions challenged pharmaceutical patents.[21]

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[10] *Id.* at 103–10.

[11] *Remarks from FDA Commissioner Scott Gottlieb, M.D., as prepared for delivery at the Brookings Institution on the release of the FDA's Biosimilars Action Plan*, PR NEWSWIRE, July 18, 2018, https://www.prnewswire.com/news-releases/remarks-from-fda-commissioner-scott-gottlieb-md-as-prepared-for-delivery-at-the-brookings-institution-on-the-release-of-the-fdas-biosimilars-action-plan-300683127.html.

[12] Chester "Chip" Davis, Jr., *After the Prescription Is Written, Another Challenge: Abandonment*, PHARMA BOARDROOM, June 1, 2026, https://pharmaboardroom.com/articles/after-the-prescription-is-written-another-challenge-abandonment/.

[13] John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 194, 205 (1998) (courts invalidated 46% of patents between 1989 and 1996); Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 384–85 (2000) (alleged infringers prevailed in 42% of patent cases that reached trial between 1983 and 1999).

[14] *See* Taylor & Zullow (71%), Hemphill & Sampat (68%), *supra*.

[15] *E.g.*, Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence form Micro-Level Application Data*, NBER, at 8, July 2014, https://www.nber.org/papers/w20337.pdf.

[16] Michael D. Frakes & Melissa F. Wasserman, *Does Agency Funding Affect Decisionmaking?: An Empirical Assessment of the PTO's Granting Patterns*, 66 VAND. L. REV. 67, 79, 88 (2013).

[17] *E.g.*, Michael A. Carrier, *Response to Senator Grassley's Questions for the Record, Sen. Jud. Comm. Hearing on "IP and the Price of Prescription Drugs: Balancing Innovation and Competition,"* at 3-4 (May 28, 2019), https://www.judiciary.senate.gov/imo/media/doc/Carrier%20Responses%20to%20QFRs.pdf.

[18] America Invents Act, H.R. REP. NO. 112-98, pt. 1, at 40 (2011).

[19] Thryv, Inc v. Click-To-Call Techs., LP, 590 U.S. 45, 54 (2020).

[20] AIPLA REPORT OF THE ECONOMIC SURVEY 2025, at I-168 (2025).

2. The system is effective, with the Federal Circuit affirming the PTAB in its entirety 78% of the time, which is higher than the affirmance rate for district courts in litigation.[22]
3. Example 1: Dementia-treating Exelon; Novartis patented a patch long after the active ingredient was known
   a) The district court found it difficult to understand the expert opinions ("both arguments seem logical"; "the better method for resolving this dispute is based on credibility").[23]
   b) In contrast, the PTAB found the invention obvious based on the widespread understanding that the active ingredient would degrade without an antioxidant, with the Federal Circuit praising the Board for citing "ample record evidence."[24]
   c) Generic entry quickly followed, with the price falling roughly 75%.[25]
4. Example 2: prostate-cancer-treating Zytiga; Janssen Biotech patented a combination of the active ingredient with a steroid
   a) The PTAB found the combination, a "standard regimen" at the time, obvious, and the Federal Circuit affirmed.[26]
   b) The generic then entered and the price fell from $88/dose to $2 to $19/dose, leading to as much as 98% savings on a drug that the World Health Organization lists as one of the "essential medicines for priority diseases" and a "minimal medicine needs for the basic healthcare system."[27]

D. IPR is critical but plummeting, with a 61% institution rate (Jan.-Aug. 2024) falling to 28% (Oct 2024-Aug. 2025),[28] and petitions per month falling (roughly) from 120 (Apr.-Aug. 2025) to 30 per month (Dec. 2025-Apr. 2026).[29]

E. *Discretionary denials*: Most broadly, the Patent Office Director has recently issued numerous discretionary denials that prevent consideration of IPRs on the merits

F. *Settled expectations*: As one primary example, starting in 2025, the Patent Office rejected IPR petitions because the patent owner had "settled expectations" that the patent wouldn't be challenged (in particular after 6 years in force)
   1. As an example of the harms from this manufactured policy, Amgen filed an IPR challenging BMS patents on cancer-treating Opdivo
   2. According to Amgen, the '320 patent is "a follow-on patent claiming obvious dosing regimens for Opdivo."[30]
   3. The Director ruled that the patent was in force for 7 years so he would not disturb the patent
   4. Belying any settled expectations, in 2022 (after the patent was in force 4 years), the patentee *abandoned* nearly the same claims in Europe.[31]

G. Patent Office administrative procedures like IPR are crucial to ensuring that invalid patents do not erroneously prolong unwarranted monopolies but recent changes like discretionary denials and settled expectations remove questionable patents from scrutiny

VII. Conclusion

A. The pharmaceutical regulatory regime currently is not as effective as it has been given courts' undermining the skinny label pathway and drug companies' accumulation of patent thickets

B. The Skinny Labels, Big Savings and ETHIC Acts would directly address these problems

C. The Patent Office needs to return to its critical role providing an expert tribunal that prevents unwarranted patent monopolies from delaying more affordable drugs

D. The conduct discussed in this statement has nothing to do with limiting innovation and everything to do with protecting patient health

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[21] PTO, *PTAB Orange Book Patent/Biologic Patent Study FY 25 Update* at 13, https://www.uspto.gov/sites/default/files/documents/Orange_Book_Biologics_Trial_Stats_July_2025.pdf.

[22] Jason Rantanen, *Online Symposium: The PTAB, The Director, and The Federal Circuit*, FEDCIRCUITBLOG, Feb. 9, 2022, https://fedcircuitblog.com/2022/02/09/online-symposium-the-ptab-the-director-and-the-federal-circuit/.

[23] Novartis Pharms. Corp. v. Par Pharm., Inc., 48 F. Supp. 3d 733, 757 (D. Del. 2014).

[24] Novartis AG v. Noven Pharms. Inc., 853 F.3d 1289, 1295 (Fed. Cir. 2017).

[25] Charles Duan, *On the Appeal of Drug Patent Challenges*, 72 AM. U. L. REV. 1177, 1197 (2023).

[26] BTG Int'l Ltd. v. Amneal Pharms. LLC, 923 F.3d 1063, 1074 (Fed. Cir. 2019).

[27] Duan, *supra*, at 1204.

[28] William A. Meunier, Peter J. Cuomo, Kevin C. Amendt, & Amy LoBue, *The PTAB Pendulum Swings: How IPR Denials are Reshaping Patent Owner and Challenger Strategies*, MINTZ, Aug. 28, 2025, https://www.mintz.com/insights-center/viewpoints/2231/2025-08-28-ptab-pendulum-swings-how-ipr-denials-are-reshaping.

[29] PTO, *PTAB Trial Statistics April 2026* at 5, https://www.uspto.gov/sites/default/files/documents/April_2026_Trial_Statistics.pdf.

[30] Petitioner's Request for Director Review of Decision Denying Institution of *Inter Partes* Review at 4, *Amgen v. BMS*, Case No. IPR2025-00601 (PTAB Aug. 25, 2025).

[31] *Id.*