Questions for the Record from Representative Issa for Michael Carrier

"Medicines and IP: Balancing Innovation and Access"

June 4, 2026

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1. How do you respond to the argument that acquiring a significant number of patents to protect a product is common in many industries, and yet the negative connotations around so-called thickets only really seem to attach to pharmaceuticals?

    a. Follow on question: From a policy perspective, how is the biopharmaceutical industry different than other industries when it comes to patenting?

    b. Follow on question: Does holding pharmaceuticals to a different standard, compared to other technologies or products, undermine international commitments on adopting technologically neutral patent policies?

Questions for the Record from Representative Johnson for Michael Carrier

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1. In your opening statement, you said that brand-name manufacturers get "an automatic 30-month stay" after filing a lawsuit, and during this time no generic competitors can enter the market. Please provide additional context regarding this statement, including the history and purpose of the 30-month stay and the consequences it has had for generic competition. Please also discuss potential alternatives to this framework that would maintain or improve the law's current balance between incentivizing novel innovation and promoting timely access to generics and biosimilars.

2. In your opening statement, you said that "Inter Partes Review has fallen dramatically in the past year or so." Please provide peer-reviewed data supporting this claim and a brief summary of the methodology used to estimate the decline. In addition, please discuss what you believe to be the reasons for this decline and how they could inform future policymaking in Congress.

3. In your opening statement, you pointed to recent remarks from the CEO of Pfizer regarding an approaching "loss of exclusivity wave" and the resulting effect on drug company revenue. Please specify which remarks you were referring to.

4. In response to a question from Congresswoman Zoe Lofgren, you stated that the *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.* Federal Circuit decision from 2021 has led to a reduction in skinny labeling from 56% to 20% over a couple of years, according to a peer-reviewed survey. Please provide this survey, specify where in the survey the figures you referenced are from, and briefly explain its methodology.

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Response to Rep. Issa's Questions for the Record

House Judiciary Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet

Hearing on "Medicines and IP: Balancing Innovation and Access"

June 4, 2026

I. Patent Thickets: Negative pharma connotations

A. Of industries with patent thickets, pharmaceuticals present unique 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. One example is Humira (blockbuster drug, previously top seller in world):
   1. Initially approved in 2002, active ingredient patent expired in 2016
   2. In original empirical research,[1] 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).[2]
         (1) Continuations often don't reflect innovation, as the specification discloses no new information 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. Industry-wide continuations
   1. We compared the pharmaceutical industry (Orange Book and Purple Book) with high tech (electric digital processing and semiconductor devices).[3]
   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.[4]

D. These findings of unique harms with pharmaceutical patent thickets are consistent with former FDA Commissioner Scott Gottlieb's observation that thickets of biologic patents are "purely designed to deter entry of approved biosimilars."[5]

E. The findings 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."[6]

II. Patent Thickets: Biopharma industry different

A. For reasons detailed in Part I, the biopharma industry is different than other industries

B. See, in particular, differences in licensing, regulatory barriers, market concentration, and patent continuations

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

[2] *Id.* at 88–92.

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

[4] *Id.* at 103–10.

[5] *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.

[6] 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/.

III. Patent Thickets: International commitments

A. The Hatch Waxman Act and Biologics Price Competition and Innovation Act (BPCIA) already apply different rules to pharmaceuticals than other industries

B. Article 30 of TRIPS provides "Exceptions to Rights Conferred," ensuring that "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

C. The Hatch Waxman Act, BPCIA, and (for that matter) proposed ETHIC Act do not (and would not) conflict with the "normal exploitation of the patent" and would not "unreasonably prejudice the legitimate interests of the patent owner," and this is especially the case given the "legitimate interests of third parties."

D. The Hatch Waxman Act, for example, is characterized by a nuanced equilibrium between generic competition and brand-firm innovation
   1. Generic competition: Generics can experiment on the drug during the patent term and rely on the brand's clinical studies, and "first filers" can obtain a 180-day exclusivity period
   2. Brand innovation: Brands can obtain patent term extension, nonpatent market exclusivity, and an automatic 30-month stay
   3. Equilibrium: Representative Henry Waxman underscored the "fundamental balance of the bill," and the House Energy and Commerce Committee explained that allowing early generic challenges "fairly balanced" the exclusionary rights of patent owners with the "rights of third parties."[7]
   4. Similarly, the House Judiciary Committee concluded that it "has merely done what the Congress has traditionally done" in IP law: "balance the need to stimulate innovation against the goal of furthering the public interest."[8]
   5. Third parties have interests—in fact, *vital* interests given the importance of prescription drugs—in affordability
   6. As the drafters recognized in passing the Act, generic competition would "do more to contain the cost of elderly care than perhaps anything else this Congress has passed."[9]

E. In addition, the proposed ETHIC Act would address pharmaceutical 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

[7] Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 45 (2009); *see generally id.* at 41–47 (providing sources for material discussed in this section).

[8] *Id.*

[9] 130 CONG. REC. 24427 (statement of Rep. Waxman).

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Response to Rep. Johnson's Questions for the Record

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I. 30-month stay

A. 30-month stay included in Hatch Waxman Act as benefit to brand firms
   1. Generic competition: Generics can experiment on the drug during the patent term and rely on the brand's clinical studies, and "first filers" can obtain 180-day exclusivity period
   2. Brand innovation: Brands can obtain patent term extension, nonpatent market exclusivity, and a 30-month stay.[10]
   3. The drafters highlighted the balance between innovation and public interest at the core of the Hatch Waxman Act.[11]

B. Designed to mirror period of litigating patent lawsuits
   1. In 2002, the FTC explained that the 30-month stay approximates 25-month periods for (1) FDA approval of generic applicants filing paragraph IV certifications that are not sued and (2) the average period between the filing of a complaint and a district court decision.[12]

C. Reduces competition because brand firm gets automatic delay of generic entry
   1. Delay unique since there's no need to obtain preliminary injunction
   2. Applies regardless of strength of patent
   3. In other words, even patents likely to be invalidated or found not infringed provide automatic 30-month stay
   4. This exclusivity is more powerful than a patent
      a) A generic could enter "at risk" before a patent is found to be invalid or not infringed
      b) The 30-month stay doesn't allow such entry

D. Even assuming 30-month stay needed, should be used only for the types of patents for which it was designed: drug substance (active ingredient), drug product (formulation and composition), and method of use.[13]

E. System has been abused as drug firms list patents in Orange Book and receive unwarranted 30-month stays
   1. *E.g.*: Patents on Risk Evaluation and Mitigation Strategies (REMS) that claim method of controlling drug's distribution, not method of using drug
   2. *E.g.*: Patents on inhaler that don't mention the active ingredient.[14]

II. Inter partes review (IPR)

A. The number of IPR petitions has recently declined dramatically based on recent PTO changes like…
   1. Discretionary denials: Most broadly, the Patent Office Director has issued numerous discretionary denials that prevent consideration of IPRs on the merits
   2. 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)

B. Recent figures show IPR plummeting:
   1. One source showed an institution rate that fell from 61% (Jan.-Aug. 2024) to 28% (Oct 2024-Aug. 2025).[15]
   2. The PTO itself showed petitions per month falling (roughly) from 120 (Apr.-Aug. 2025) to 30 (Dec. 2025-Apr. 2026).[16]

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[10] Carrier, *Unsettling Drug Patent Settlements*, 108 MICH. L. REV. at 41–47 (providing sources).

[11] *Id.* at 45 (quoting Rep. Waxman and committee reports).

[12] FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 39 (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

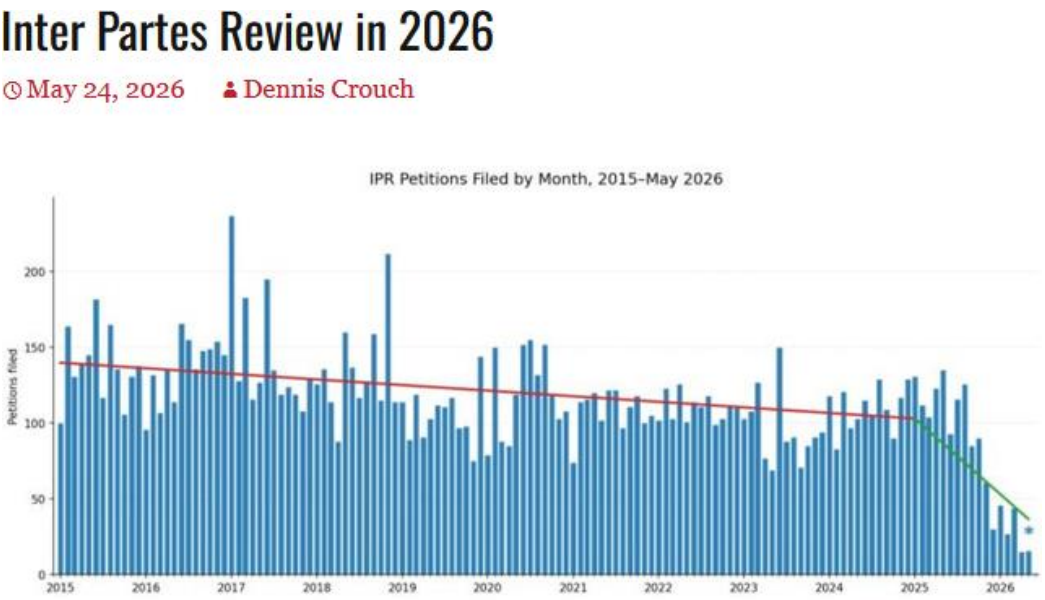
[13] 21 C.F.R. § 314.53(b)(1).

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

[15] 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.

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

C. The leading patent blog, PatentlyO, recently tracked IPR petitions by month from May 2015 through May 2026. As it explained:
   1. "For most of that decade, filings hovered in a band between 100 and 185 per month, with a long-run trend line sloping gently downward. Then something dramatic happened: beginning in 2025, filings fell off a cliff. The numbers for 2026 are the lowest since the AIA's post-grant review system was fully operational."[17]
   2. "The story of 2025 was collapsing institution rates. Director Squires assumed personal control of all institution decisions in October 2025 and proceeded to [grant] petitions at a rate approaching zero. The story of 2026 is the market's response. Practitioners have done the math: if IPR petitions are denied at the front end regardless of merit, the cost-benefit calculus no longer works."[18]
   3. "The IPR system, at least in its original form as a cost-effective alternative to district court litigation for challenging patent validity, is functionally suspended."[19]
   4. The article depicted the IPR decline graphically:



D. In addition, a peer-reviewed article explained that the "aggressive application of discretionary denials" in the summer of 2025 led to constraints on the administrative pathway and that the "novel" settled-expectations rationale was "unprecedented."[20]
   1. At the time of publication in November 2025, Director Squires had "issued 34 decisions, denying all 34 petitions (100%) with no explanation, no reasoning, and no analysis."[21]

E. The purpose of the America Invents Act (AIA), according to the drafters, 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."[22]
   1. 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.[23]

F. Patent Office administrative procedures like IPR are crucial to ensuring that invalid patents do not erroneously prolong unwarranted monopolies and legislation could ensure that the AIA is enforced as it was supposed to be

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[17] *Inter Partes Review in 2026*, PATENTLYO, May 24, 2026, https://patentlyo.com/patent/2026/05/inter-partes-review-in-2026.html.

[18] *Id.*

[19] *Id.*

[20] S. Sean Tu, Arti Rai, & Aaron S. Kesselheim, *Recent Changes in Discretionary Denials of Drug Patent Challenges*, HEALTH AFFAIRS SCHOLAR, at 1 (Nov. 11, 2025).

[21] *Id.* at 2.

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

[23] 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/.

III. Pfizer CEO statement

A. In January 2025, Fierce Pharma, a leading industry publication, reported on the J.P. Morgan Healthcare Conference, where "pharma CEOs are tasked with assuring and convincing investors that they've positioned their companies to overcome expected challenges."[24]

B. The publication reported that on the previous day, "three Big Pharma leaders took center stage and addressed concerns about future patent expirations head-on" and "[i]n separate presentations, the CEOs of Bristol Myers Squibb, Pfizer, and Merck laid out their plans to overcome high-profile losses of exclusivity (LOEs) slated to dent sales through the end of the decade."[25]

C. In particular, in a discussion with a J.P. Morgan analyst, "Pfizer CEO Albert Bourla said there's 'clearly a LOE wave that is coming' for the company."[26]

D. The article continued: "The LOE wave will cost Pfizer an expected $17 billion to $18 billion in annual revenues and is 'coming in gradually' between 2026 and 2028, the CEO said."[27]

IV. Decline in skinny labels

A. In 2020, in the case of *GSK v. Teva*, the Federal Circuit issued its first decision upholding a verdict against a generic for typical skinny-labeling conduct.[28]

B. In response to a question from Congresswoman Zoe Lofgren, I referenced a study that showed a significant decline in skinny labeling after that decision from 56% to 20%.[29]

C. The study was published in the Journal of Managed Care & Specialty Pharmacy, which is a peer-reviewed medical journal published by the Academy of Managed Care Pharmacy

D. The study found that "[b]etween 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."[30]

1. These exclusions make sense since the effects of court decisions on generics' use of skinny labels is only relevant in terms of *actual* market entry
   a) Tentative approval does not reveal actual market entry
   b) Duplicates should not be included since any chilling effects of court decisions would be observed most directly in the setting of the first generic to reach the market
   c) The authors found a brand drug susceptible to skinny labeling if it had (1) "2 or more indications" and (2) "remaining patents or exclusivities at the time of generic prescription approval."
   d) This makes sense since a skinny label requires (1) at least 2 indications (one patented and one unpatented) and (2) remaining patents or exclusivities so the generic has something to carve out

E. After cabining the universe of potential generics appropriately, the authors concluded that "[a]mong 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%)."[31]

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[24] Eric Sagonowsky, *JPM25: BMS, Pfizer, and Merck CEOs Address Key Patent Cliffs and Plans To Replace Sales*, FIERCEPHARMA, Jan. 14, 2025, https://www.fiercepharma.com/pharma/jpm25-bms-pfizer-and-merck-ceos-address-key-patent-cliffs-and-plans-backfill-sales.

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021).

[29] 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, 345 (2025).

[30] *Id.*

[31] *Id.*