



USPTO DATA PROVES THE PROPOSED USPTO PTAB RULEMAKING WOULD HAVE NO IMPACT ON GENERIC MARKET ENTRY OR DRUG PRICING

BACKGROUND

The United States Patent and Trademark Office's (USPTO) proposed Notice of Proposed Rulemaking regarding "Revision to Rules of Practice before the Patent Trial and Appeal Board" (PTAB) will have no meaningful effect on U.S. drug pricing. Pharmaceutical patents are rarely challenged through PTAB proceedings, and the Hatch-Waxman Act provides the established, specialized, and appropriate legal framework for adjudicating drug patent disputes that affect generic market entry.

KEY FACTS

1. Biotech and Pharmaceutical Patents Are Rarely Challenged at PTAB

USPTO's PTAB Orange Book patent/biologic patent study from July 2025¹ shows that America Invents Act proceedings play almost no meaningful role in pharmaceutical patent disputes.

- The **overwhelming majority of PTAB challenges are filed on electrical or computer sector patents** (software, telecommunications, electronics). AIA petitions from 2012 – July, 2025 (total of 18,648):
 - Electrical/Computer: 62% (10,333 petitions)
 - Mechanical/Business Method: 23% (3,925 petitions)
 - Chemical: 5% (1,021 petitions)
 - Orange Book/FDA approved: 3% (574 petitions)
 - Biologics: 2% (343 petitions)

¹https://www.uspto.gov/sites/default/files/documents/Orange_Book_Biologics_Trial_Stats_July_2025.pdf

- The same data shows the role of AIA challenges has decreased over time:
 - Challenges to Orange Book-listed patents have fallen from a peak of 7.5% of all petitions filed in FY2016 to less than 1.4% of all petitions filed in FY2024
 - 5 AIA challenges to Orange Book-listed patents 2024.
 - 13 AIA petitions challenging biologic patents in 2024.
- Pharmaceutical companies rarely use Inter Partes Review (IPR) or Post-Grant Review (PGR) as their primary mechanism to challenge competitor drug patents

2. The Hatch-Waxman Act Provides the Established Framework

The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) created a comprehensive, specialized system for pharmaceutical patent disputes:

- Paragraph IV Certifications: Generic manufacturers may file Abbreviated New Drug Applications (ANDAs) with Paragraph IV certifications challenging listed patents, triggering federal district court litigation and automatic 30-month regulatory stays.
- Orange Book Listings: Brand drug manufacturers list relevant patents in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book").
- 180-Day Generic Exclusivity: First generic ANDA filer receives market exclusivity incentive.
- Specialized Expertise: Federal district courts follow specific procedures for and have developed substantial expertise in pharmaceutical patent litigation through decades of Hatch-Waxman cases.

This system was **purpose-built to balance innovation incentives with generic competition** and has functioned successfully for over 40 years.

3. Why PTAB Policies and Procedure Do Not Impact Drug Pricing

Several structural factors explain why PTAB proceedings do not meaningfully affect drug pricing policies and/or generic drug market entry:

- Timing Mismatch: PTAB proceedings typically take 12-18 months, while Hatch-Waxman litigation proceeds on parallel or faster timelines with automatic regulatory stays protecting brand manufacturers.
- Limited Scope: PTAB can only review limited patentability issues; Hatch-Waxman litigation addresses infringement, validity, enforceability, and other critical issues in a single proceeding.
- Strategic Disadvantages: Generic manufacturers challenging drug patents gain significant strategic advantages through Hatch-Waxman's 180-day exclusivity provision that PTAB cannot replicate.

- FDA Integration: The Hatch-Waxman framework is integrated with FDA approval processes in ways that PTAB proceedings cannot match.

POLICY IMPLICATIONS

Any assertion that modifications to PTAB rules would impact drug pricing conflates patent policy generally with pharmaceutical pricing specifically. Moreover, it rests on the following demonstrably false premises:

- The assertion that pharmaceutical patent disputes are filed at PTAB at higher volumes than they actually are – roughly 5% of all AIA challenges over the past decade.
- Completely ignoring the comprehensive Hatch-Waxman framework specifically designed for drug patent challenges.

The real determinants generic market entry include:

- Hatch-Waxman litigation outcomes in federal district courts.
- FDA approval timelines for generic ANDAs.
- Patent litigation settlement agreements.
- Exclusivity periods (both patent and regulatory).

None of these factors would be altered by changes to PTAB practice rules.

CONCLUSION

The proposed PTAB rulemaking has nothing to do with drug pricing because pharmaceutical patents operate within a distinct legal ecosystem established by the Hatch-Waxman Act. Generic and biologic manufacturers seeking to challenge drug patents overwhelmingly rely on Paragraph IV certifications and federal district court litigation as compared to PTAB proceedings.

Any claims linking PTAB rule revisions to drug affordability concerns lack evidentiary support and mischaracterize how pharmaceutical patent disputes are actually resolved in the United States.