# PUBLICATION

## USPTO Proposes Dramatic Restrictions on Patent Challenges Through Inter Partes Review

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**The United States Patent and Trademark Office (USPTO) has published proposed regulations that would fundamentally transform the inter partes review (IPR) landscape, potentially eliminating IPR as a viable option for many patent challengers. Published as RIN 0651-AD89 (Docket No. PTO-P-2025-0025), these amendments to 37 C.F.R. § 42.108 would create a "one and done" system where patents that survive any initial validity challenge – regardless of its quality or completeness – becomes virtually immune from subsequent IPR proceedings. Both the patent owner and the company facing patent assertion must understand these changes and adjust their litigation strategies accordingly.**

## The New Regulatory Framework

### 1. Mandatory Stipulations Upon Institution (§ 42.108(d))

The proposed amendments would require petitioners to stipulate that they will not pursue any invalidity challenges under 35 U.S.C. §§ 102 or 103 in other venues if the Patent Trial and Appeal Board (PTAB) institutes IPR. This goes significantly beyond current estoppel provisions under 35 U.S.C. § 315(e), which only applies after a final written decision and is limited to grounds that were raised or reasonably could have been raised.

**Practical Impact:** Companies facing patent assertion would be forced to make an all-or-nothing decision at the IPR filing stage. If you file an IPR petition and it is instituted, you forfeit all anticipation and obviousness defenses in district court – even those not included in your petition. This dramatically raises the stakes for IPR filings and may discourage challenges to questionable patents.

### 2. Absolute Bar Following Prior Challenges (§ 42.108(e))

Perhaps most significantly, the proposed amendments would prohibit IPR institution against claims that have survived any prior §§ 102/103 validity challenge in district court, the International Trade Commission (ITC), or previous USPTO proceedings. Unlike the current discretionary framework under 35 U.S.C. § 325(d), this creates a mandatory bar with no exceptions for new prior art or arguments.

**Practical Impact:** If you are the second or subsequent defendant sued on a patent, you may have no IPR option if an earlier defendant mounted any validity challenge – even if that challenge was poorly executed, settled early, or based on inferior prior art. This "first mover" problem particularly benefits non-practicing entities (NPEs) who can strategically select weak first defendants.

### 3. Parallel Proceedings Prohibition (§ 42.108(f))

The proposed amendments would categorically bar IPR institution when a district court trial or ITC determination "will more likely than not" occur before the PTAB's deadline for a final written decision. This replaces the current discretionary *Fintiv* analysis with a bright-line rule.

**Practical Impact:** Patent owner plaintiffs can effectively block IPR access by filing in rocket dockets like the Western District of Texas, where trials routinely occur within 18 months. Even if circumstances change – such as trial delays or potential stays – the initial "more likely than not" determination would be binding.

### 4. Limited "Extraordinary Circumstances" Exception (§ 42.108(g))

The proposed amendments permit subsequent IPR challenges only under "extraordinary circumstances," which are significantly narrowed to situations such as prior bad faith conduct or intervening changes in the law. Discovery of new prior art, inadequate prior representation, or clear errors in earlier proceedings would not qualify. Frivolous or abusive petitions would be subject to sanctions and attorneys' fees.

**Practical Impact:** The exception is so narrow as to be virtually meaningless for most patent defendants. Even breakthrough prior art discovered after an initial challenge would not justify a second IPR attempt against the patent.

## Strategic Implications for Your Business

### 1. For Companies Facing Patent Assertions: Immediate Actions Required

- **Coordinate with Co-Defendants:** If you face assertions alongside other defendants, immediately establish coordination agreements regarding IPR strategy. The first filer may determine everyone's fate.
- **Accelerate Prior Art Searches:** Conduct comprehensive prior art searches immediately upon receiving notice of potential assertions. Waiting until after litigation commences may be too late.
- **Evaluate Forum Options:** Consider proactive declaratory judgment actions in favorable venues to avoid rocket dockets that trigger the parallel proceedings bar.

### 2. For Patent Owners: New Enforcement Advantages

- **Strategic First Suits:** Consider initially suing smaller, less sophisticated defendants who may mount inadequate validity challenges, thereby immunizing your patents from subsequent IPR attacks.
- **Rocket Docket Filings:** Filing in fast-moving courts can effectively eliminate IPR risk through the parallel proceedings bar.
- **Settlement Leverage:** The proposed rules significantly increase settlement leverage, as defendants cannot rely on subsequent IPR opportunities if initial challenges fail.

### 3. For Technology Companies with Patent Portfolios: Portfolio Management Considerations

- **Defensive Publication Strategies:** With reduced IPR availability, preventing competitor patents through defensive publications becomes more critical.
- **Prosecution Strategy:** Expect more aggressive examination challenges as IPR becomes less available for post-grant correction.
- **Freedom-to-Operate (FTO) Analyses:** Conduct more thorough FTO analyses earlier, as post-assertion challenge options will be limited.

### 4. Industry-Specific Impacts:

**Pharmaceutical and Biotechnology**
The proposed amendments particularly benefit branded pharmaceutical companies by making it harder for generic manufacturers to challenge patents through IPR. Subsequent generic filers may be bound by inadequate challenges from first filers, potentially extending market exclusivity.

**High Technology and Software**
Technology companies facing assertions from NPEs will be most negatively impacted. NPEs can leverage the rules to protect weak patents by ensuring initial challenges come from resource-constrained defendants, then asserting those "validated" patents against major industry players.

**Manufacturing and Consumer Products**
Companies in competitive industries where cross-assertions are common must carefully consider whether IPR remains viable given the mandatory stipulation requirements. District court litigation may become the only option for comprehensive validity challenges.

## Recommended Actions

1. **Submit Comments:** The comment period remains open until November 17, 2025. Companies should submit detailed comments explaining how these rules would impact innovation and competition in their industry.

2. **Review Existing Litigation:** Companies that may face patent assertions should immediately assess any pending patent disputes to determine whether IPR petitions should be filed before the new rules may take effect.

3. **Update IP Policies:** Companies that may face patent assertions should revise internal procedures for responding to patent assertions, emphasizing early coordination with counsel and comprehensive prior art searches.

4. **Budget Adjustments:** Anticipate higher patent defense costs as district court litigation becomes the primary venue for validity challenges.

5. **Insurance Reviews:** Evaluate whether current IP insurance coverage adequately addresses the increased litigation risks under the new framework.

## Conclusion

The USPTO's proposed rules represent the most significant restriction on IPR accessibility since the America Invents Act created the procedure in 2012. By essentially creating a "one and done" system for validity challenges, the rules would restore many of the inefficiencies and inequities that IPR was designed to address. While the USPTO frames these changes as promoting efficiency and quiet title, the practical effect would likely be to shield questionable patents from review while dramatically increasing litigation costs for innovative companies. Immediate action is required to address these proposed changes through the comment process and to adjust litigation strategies in anticipation of their potential implementation.

If you have any questions about the USPTO proposed patent review restrictions, please contact Edward D. Lanquist and Lea Speed.