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Seven U.S. Patent Law Issues from 2025 What EPO and Southeast Asian Applicants Should Know

Based on analysis by Professor Dennis Crouch (University of Missouri School of Law / Patently-O), with additional context and practice pointers for international audiences.

Disclaimer: This article is for general information only and is not legal advice.

2025 was an unusually consequential year for U.S. patent practice. Inter partes review (IPR) - the PTAB trial process that many international companies relied on as a fast, comparatively cost-contained validity challenge - effectively slowed to a crawl. At the same time, U.S. courts tightened scrutiny of damages experts, while the USPTO moved to fill policy gaps on patent eligibility (§ 101) and AI-related inventorship issues. Below are seven developments worth keeping on your radar, written to be understandable without U.S.-centric assumptions.

Quick takeaways

- IPR is no longer a predictable "go-to" invalidation route; plan district court and alternative PTO pathways earlier.
- Damages wins are increasingly fragile on appeal unless the damages expert ties royalty numbers to claim limitations and concrete evidence.
- The USPTO's new Subject Matter Eligibility Declaration (SMED) framework encourages applicants to build an evidentiary record of technical improvement for § 101.
- USPTO policy is trending toward "don't ask, don't tell" on AI involvement - but inventorship law (and litigation risk) has not changed.
- Prosecution laches remains rare, but continuation strategy should be documented with legitimate reasons to avoid an "ambush" narrative.
- Two Supreme Court petitions highlight growing power of abandoned applications and later-published filings as prior art (including "secret springing" art).
- For pharmaceuticals, "skinny labels" are not a guaranteed safe harbor if marketing and public statements are read as encouraging a patented use.

1. The Collapse of Inter Partes Review (IPR) as a Reliable Challenge Tool

For many non-U.S. companies, IPR became the closest U.S. analogue to EPO opposition: a specialist tribunal (the PTAB) applying a lower burden of proof than district court litigation, with tight timelines and claims construed using the "plain and ordinary meaning" approach. It was never identical to opposition - IPR is limited to patents and printed publications and carries estoppel risks - but it often provided a comparatively efficient way to challenge an asserted U.S. patent.

Key point: The biggest 2025 shift is practical, not theoretical: even well-prepared IPR petitions may be denied at the institution stage without explanation, and those denials are largely insulated from appeal (35 U.S.C. § 314(d) and related Supreme Court precedent).

What changed in 2025

Professor Crouch describes an “effective shutdown” of new IPR institutions after Director John Squires took office in September 2025, with institution dropping to “around 4%” by December 2025. He reports that denials increasingly consider factors beyond merits, such as whether the patent issued more than six years earlier, whether it has been challenged before, and whether the petitioner is on an “Entity List” tied to an enemy state. He also notes that Sotera-style stipulations (used to reduce duplication between PTAB and district court) no longer reliably avoid denial.

Some useful numbers (why the “4%” figure startled everyone)

Context matters because PTAB institution rates historically sat far above single digits. USPTO Trial Statistics show an overall IPR institution rate around 69% in FY2024 and around 50% in FY2025 (reflecting broader policy shifts). But Crouch’s December 2025 snapshot focuses on Director-level decision-making in that period: out of 105 institution decisions, 99 were denied and only 4 instituted (approximately 3.8%).

Updates Since December 2025

More recently within the first month of 2026, it appears that the rates for IPR Institutions are raising, with the latest numbers as of January showing a rebound of around 35-55%, which is still below the historical 60-80%..

Examples of the new discretionary “filters” (as described by Crouch)

- Age of the patent (e.g., issued more than six years ago) based on settled expectation rationale.
- Repeat challenges to the same patent (prior petitions).
- Inconsistent claim construction in district court and at PTAB.
- Petitioner affiliation (e.g., appearance on a government “Entity List”).
- A reduced practical role for stipulations intended to streamline parallel district court litigation (e.g., Sotera).

Why foreign applicants should care

If your organization relied on IPR as a predictable “second line” defense (or as leverage to settle), that playbook needs updating. As IPR becomes harder to access, disputes are more likely to stay in U.S. district court, where discovery is broad, timelines can be longer, and damages exposure can be higher. For patentees, the reduced IPR threat can strengthen enforcement leverage - but only if the patent is drafted to survive district court validity attacks (especially enablement and written description).

Practice pointers

- Front-load invalidity planning: identify your best 102/103 references early, even before litigation escalates, because you may end up in district court.
- Consider alternative PTO routes where appropriate (e.g., ex parte reexamination), while weighing business and timing realities.
- If you do file an IPR, assume discretionary denial is a real risk considering the relatively high initial attorney and expert fees along with government filing fees; plan parallel district court arguments and stay strategy accordingly.
- For patent owners: assume fewer IPR challenges does not eliminate risk - it shifts it. Draft and prosecute with 112 robustness and litigation-readiness in mind.

2. Why Courts Are Rejecting Patent Damages Experts

U.S. patent damages can feel alien to non-U.S. practitioners because they are often tried to a jury and then heavily policed on appeal. Most cases turn on a “reasonable royalty” theory: a judge and jury reconstruct a hypothetical license negotiation that would have occurred just before infringement began. The expert’s job is to translate technical contribution into a defensible number using evidence (licenses, industry practice, product economics) and legal constraints (apportionment, comparability, and reliable methodology).

Key point: In 2025, the Federal Circuit signaled less patience for experts who ‘name a number’ without a provable link between (i) what the claims require and (ii) why the proposed royalty matches the value of that claimed technology.

What courts said was wrong (in plain terms)

- Treating a license as a “comparable” without showing that it really covers the same technology and economic circumstances.
- Converting lump-sum settlements into a per-unit royalty rate without reliable data supporting the conversion.
- Using royalty bases that reflect the value of an entire product (or portfolio) without apportioning to the patented feature(s).
- Failing to connect the royalty rate to specific claim limitations (not just the product label or marketing name).

EcoFactor v. Google (en banc) - the cautionary tale

In EcoFactor, a jury awarded about \$20M in lump-sum damages. The patentee’s expert (Kennedy) testified that prior licenses established an \$X “per unit” royalty. The Federal Circuit vacated and ordered a new trial on damages, finding the opinion lacked “sufficient facts or data” under Rule 702.

A key nuance: the prior agreements were lump-sum licenses. The court noted that the license language did not support the claim that the licensees agreed to a per-unit royalty rate; in at least one license, the agreement expressly stated the amount was “not based upon sales and does not reflect or constitute a royalty.” The expert also lacked sales data or documentation showing

how the lump sums were calculated and relied substantially on testimony reflecting a “general understanding” of the market.

Jiaxing v. CH Lighting - EcoFactor spreads

Later in 2025, Jiaxing applied EcoFactor’s lens and remanded for a new damages trial, instructing the district court to reassess the reliability of the damages expert’s testimony under Rule 702 and EcoFactor. The message: even after a jury verdict, expert methodology and the evidentiary record can determine whether damages survive appeal.

Practice pointers (especially for foreign patentees and licensors)

- Treat licensing records like future evidence: document what the license covers, why the rate was chosen, and how it relates to the patented technology.
- Avoid “portfolio blur” where possible: if multiple patents or products are bundled, preserve internal apportionment logic contemporaneously.
- Build a claim-limitation value story early: which limitations matter, what technical problem they solve, and how that maps to customer demand or cost savings.
- For multi-jurisdiction deals: align U.S. damages theories with global licensing strategy, but assume U.S. courts will demand granular comparability proof.

3. Patent Eligibility (§ 101): New USPTO Guidance and “Technical Improvement” Declarations

Section 101 is U.S.-specific in both language and culture. Under the Alice/Mayo framework, claims can be invalid if they are directed to an “abstract idea” and lack an “inventive concept” beyond conventional implementation. International applicants often experience this as unpredictable, especially for software and AI-adjacent inventions. While EPC practice asks whether a claim has a “technical character/technical effect,” § 101 asks a different question and has developed through U.S. case law rather than statute text alone.

Key point: The USPTO cannot bind U.S. courts on § 101 validity, but it is now actively shaping examination by encouraging evidence-backed narratives of technical improvement.

What changed in 2025

With Congress stalled on eligibility reform and the Supreme Court declining multiple opportunities to revisit Alice/Mayo, the USPTO began filling the vacuum. Crouch reports that Director Squires urged the Office to focus on §§ 102, 103, and 112 rather than § 101, and that the PTAB’s reversal rate for § 101 rejections in ex parte appeals doubled compared to the prior year.

December 2025: Subject Matter Eligibility Declarations (SMEDs)

On December 4, 2025, the USPTO issued guidance (via memorandum) introducing Subject Matter Eligibility Declarations (often called SMEDs): a structured way for applicants to submit declaration evidence aimed at patent-eligibility issues. The memos emphasize that eligibility rejections - especially at Alice Step 2 (conventional / inventive concept) - should not be

treated as purely conclusory. Instead, where an applicant supplies competent evidence of a technical improvement or non-conventional feature, examiners must address that evidence.

Why evidence matters (a U.S. nuance that surprises foreign applicants)

A recurring theme in U.S. eligibility law is that “conventionality” can involve factual questions. In litigation, the Federal Circuit has held that evidence can create a factual dispute that blocks early dismissal in some cases (even though ultimate eligibility remains a legal question). SMEDs are the USPTO’s attempt to channel that evidentiary idea into prosecution.

What an effective “technical improvement” declaration tries to do

- Identify the technical problem in the prior art (not a business goal).
- Explain how the claim solves that technical problem in a concrete way (architecture, data flow, system behavior).
- Tie the improvement to measurable or observable effects (speed, memory, reliability, security, bandwidth, error rates, model stability).
- Address conventionality: what is non-routine about the claimed combination, and why.

Examples of the “kind” of story the USPTO is crediting

Because the SMED program is new, public examples of successful prosecution are still emerging. But the USPTO’s 2025 Appeals Review Panel (ARP) decision in *Ex parte Desjardins* illustrates the type of record the Office appears to favor: the invention was framed as improving machine-learning model training (e.g., preventing catastrophic forgetting and reducing storage/compute burdens) rather than as merely automating an abstract idea. The December 2025 USPTO memos also include practical examples showing how evidence can move a claim from “abstract” to “technical improvement.”

Practice pointers (how to draft for both the USPTO and later court scrutiny)

- Draft the specification like a technical whitepaper: clearly state the technical problem, prior approaches, and why they fail.
- Put technical effects in the claims where possible (not just in marketing language).
- Collect evidence early: benchmark data, test logs, diagrams, and engineer declarations prepared close to filing are often more credible.
- Use SMEDs strategically: they can be powerful at the USPTO, but ensure they are consistent with the specification and avoid introducing “new matter.”
- If your commercial plan includes U.S. enforcement, draft as though a skeptical judge will read the patent later; prosecution success alone is not the finish line.

4. AI Inventorship: USPTO Policy vs. Legal Reality

The headline rule is stable: under U.S. law, only natural persons can be inventors. The Federal Circuit’s decision in *Thaler v. Vidal* confirmed that AI systems cannot be named as inventors.

The unsettled practical question is what happens when AI tools materially influence the inventive process but humans sign the inventor declaration.

Key point: USPTO policy is moving toward non-inquiry, but inventorship defects can still become litigation landmines. Treat AI use as a governance issue, not just a drafting convenience.

2024 vs. 2025 guidance (why practitioners noticed a pivot)

Topic	2024 USPTO approach	Revised 2025 USPTO approach
Core rule	Inventors must be natural persons; AI can be used as a tool, but at least one human must make a significant contribution to each claim.	Still requires natural-person inventors and human conception; rescinds the 2024 guidance framework and emphasizes that the Office will presume the named inventor's statements.
Joint inventor test	Discussed applying traditional joint-inventor concepts to AI-assisted inventions.	Clarifies that the Pannu joint-inventor factors apply to multi-human inventors and are not a test for AI involvement.
Office inquiry / disclosure	Raised questions about how to evaluate AI-assisted contributions; combined with separate 2024 practice guidance on AI tools.	Expressly states the USPTO will not investigate AI involvement absent a reason, and there is no general duty to disclose AI use.
Practical implication	Encouraged careful, fact-specific assessment and documentation of human contributions.	Reduces examination friction, but does not reduce litigation risk if inventorship is challenged.

Separate but related: the USPTO's April 2024 guidance on AI tools in practice states there is no general obligation to disclose AI tool use, but practitioners must review submissions for accuracy and, importantly, should disclose to the USPTO if they know a claim lacks significant human contribution.

What should practitioners consider doing now?

A. Ask inventors early and explicitly

Add a short "AI use" module to the invention disclosure process. The goal is not to punish AI use; it is to create a defensible inventorship record.

- Which AI tools were used?
- What prompts were used and what outputs were produced (high level is often sufficient)?
- Who selected, modified, or combined the AI output into the final solution?
- What experiments, simulations, or implementations confirmed the solution actually works?

B. When should a claim limitation not be presented?

A practical (non-mystical) threshold is: do not claim a limitation if no natural person can credibly testify that they conceived it as a "definite and permanent" part of the invention. If the best explanation is "the AI suggested it and we copied it," that is a risk signal.

Common risk patterns include:

- The only novel feature is an AI-proposed mechanism, and the team cannot explain why it works beyond repeating the AI's output.
- The limitation was adopted verbatim without human selection among alternatives or integration choices that add inventive contribution.
- There is no contemporaneous documentation showing a human recognized the limitation's role in solving the technical problem.

Safer patterns include human selection and integration: the AI proposes options, but humans choose a specific option for a technical reason, adapt it, test it, and understand its operation well enough to claim it. Document the human decision points.

C. Do you need to preserve AI chat logs?

There is no blanket USPTO rule requiring applicants to keep AI chat transcripts. However, AI records can cut both ways: they may help prove human contribution (good) but can also create confidentiality and discovery exposure (bad). A pragmatic approach is to (i) use approved, confidential tools; (ii) preserve key invention records (prompt summaries, decision logs, test results) in a controlled system; and (iii) coordinate retention practices with counsel, especially if litigation is foreseeable.

Practice pointers

- Assume inventorship will be scrutinized later even if the USPTO does not ask about AI.
- Keep the invention story human-readable: what did the inventors do, decide, and validate?
- Train teams not to paste confidential data into public AI tools; U.S. guidance flags confidentiality and duty-of-candor risks.
- If there is doubt about a limitation's human conception, reframe the claim around what the human team actually contributed and can explain.

5. Prosecution Laches and “Egregious Misconduct” in Continuation Practice

Continuation practice is a uniquely powerful U.S. feature: applicants can keep a patent family pending through continuation filings and pursue different claim scope over time, as products and markets evolve. For many international businesses, this feels counterintuitive compared to European practice, where post-filing claim flexibility is more constrained.

Key point: The Federal Circuit confirmed that long continuation strategies are generally lawful - but an extreme fact pattern plus prejudice can still trigger the equitable defense of prosecution laches.

What happened in Google v. Sonos

Crouch highlights the Federal Circuit's August 2025 decision in Google v. Sonos, which reversed a district court finding of unenforceability based on prosecution laches. Sonos prosecuted continuations over about thirteen years (from its September 2006 provisional to its April 2019 shift in claim scope) and later asserted claims against products that did not exist at

Joseph Sofer jssofer@ipsilon-ip.com ; 110 West 40th Street, Suite 2001, New York, NY 10018 (212)697-2800

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the time of the earliest filings. The Federal Circuit held that strategic continuation practice, without more, was not enough; prosecution laches requires unreasonable and unexplained delay plus prejudice.

So what is “egregious misconduct”?

Courts describe prosecution laches as an extraordinary remedy. The cases that succeed usually involve affirmative misconduct: intentional delay tactics that extend patent exclusivity or surprise competitors who invested based on apparent claim scope. Classic examples in the case law include patterns of serial refiling with minimal substantive prosecution, or deliberate manipulation that resembles “submarine” patent behavior.

Examples often cited as risk signals

- Repeated continuation filings coupled with tactics that intentionally prevent examination from reaching finality (without a legitimate technical or business reason).
- Large, unexplained gaps where prosecution is strategically stalled to wait for an industry to develop.
- Claim amendments timed to target an established market after competitors have made substantial investments, combined with evidence of intent to ambush.
- Prejudice evidence: competitors can show they relied on the apparent scope of the earlier claims and were harmed by the delayed broadening.

Practice pointers

- Document legitimate reasons for continuation timing (standards evolution, product rollout, claim set management, divisionals, commercial uncertainty).
- Avoid needless delay tactics; if you need time, build a clean record explaining why.
- Periodically audit long-lived families: ensure the file history reads like responsible prosecution, not strategic obstruction.

6. Abandoned Applications as Prior Art: The Lynk Labs and Agilent Questions

This issue matters because it shapes what can be used to invalidate a patent - and where. International teams often assume “prior art” must have been publicly discoverable before the filing date. U.S. law partly agrees (printed publications require public accessibility), but it also creates a special category of earlier-filed U.S. applications that become prior art as of their filing date once they publish - even if they were secret at the time.

Key point: Two Supreme Court petitions spotlight whether IPR should allow “secret springing” prior art and whether abandoned applications should be presumed enabling.

A quick primer: pre-AIA vs. AIA

Before the America Invents Act (AIA), 35 U.S.C. § 102(e) treated certain earlier-filed U.S. applications/patents as prior art as of their U.S. filing date. Those documents could be ‘secret’

until publication, but once published they counted retroactively. IPR did not exist pre-AIA; validity disputes played out in examination, reexamination, or district court.

After the AIA, the analogous rule is § 102(a)(2). The controversy is procedural: IPR petitions are limited by statute to “patents and printed publications” (35 U.S.C. § 311(b)). So, if a reference wasn’t publicly accessible until after the challenged patent’s critical date, is it really eligible “prior art” for IPR purposes?

A simple timeline example (why foreign teams find this weird)

- 2019: Competitor files U.S. application A (not public yet).
- 2020: You file U.S. application/patent family B.
- 2021: Application A publishes.
- Result: Under § 102(a)(2), A can act as prior art against B as of A’s 2019 filing date (even though it was ‘secret’ in 2020). The Lynk Labs dispute asks whether A should also be usable in IPR (where grounds are limited to patents/printed publications).

Lynk Labs v. Samsung: “printed publication” as temporally agnostic

In January 2025, the Federal Circuit held that a later-published patent application could be used in an IPR as prior art as of its filing date, reasoning that “printed publication” is “temporally agnostic.” Under this approach, the timing question comes from § 102’s prior-art rules, not from the phrase “printed publication” itself. Lynk Labs has asked the Supreme Court to review this, arguing it creates invalidity based on documents inventors could not have found when they filed.

Why the Federal Circuit went that way

The court’s logic can be summarized as: § 311(b) answers “what kinds of documents can an IPR use?” (patents and printed publications), while § 102 answers “when does that document count as prior art?” (e.g., as of filing date under § 102(a)(2)). Once a patent application publishes, it is a “printed publication” type of document; and § 102(a)(2) supplies the earlier effective date.

Agilent v. Synthego: should abandoned applications be presumed enabling?

A second petition (Agilent v. Synthego) raises a different but related concern: when an anticipatory reference is asserted, should it be presumed enabling, even if it is an abandoned application with prophetic examples? The Supreme Court requested a response in December 2025. The debate is about how far “paper disclosures” can go in knocking out issued patents, especially in fields (like biotech) where operability and efficacy are hard-won.

Why this matters internationally

These cases expose a structural asymmetry: issued patents go through examination and carry a presumption of validity, yet can be invalidated in IPR on a preponderance standard using unexamined or abandoned applications. For global companies, this increases the importance of early filing strategy, monitoring competitor filings, and building robust 112 support so that your own patents can withstand aggressive validity challenges.

Practice pointers

- When assessing freedom-to-operate or invalidity, search for earlier-filed U.S. applications that may publish later and still become powerful prior art.
- Draft with robust enablement/written-description support; weak 112 foundations are increasingly exploited when IPR or litigation becomes the main battleground.
- In portfolio strategy, filing early (and filing well) matters more if “secret” earlier filings can later be weaponized.

7. Skinny Labels and Induced Infringement: Explained Simply

This topic is pharma-specific, but its logic is broadly useful: U.S. infringement liability often turns on “intent” and “encouragement,” not just on formal compliance.

Key point: A generic drug label that carves out a patented use is helpful, but it is not always a complete shield if other communications plausibly encourage the patented use.

The regulatory setup

Under the Hatch-Waxman framework, a generic manufacturer can seek FDA approval through an ANDA. If some indications are still protected by method-of-use patents, the ANDA applicant may file a “section viii” statement and omit (carve out) the patented use from its label - creating a “skinny label.” The intended policy balance is: allow competition for unpatented uses while respecting patented ones.

Where the patent risk creeps back in

U.S. law also recognizes “induced infringement”: you can be liable if you actively encourage someone else to practice a patented method. That means courts may look beyond the four corners of the FDA label to marketing, press releases, and other communications that influence prescribing behavior.

Amarin v. Hikma (pending Supreme Court petition)

In Amarin v. Hikma, the Federal Circuit held that allegations about Hikma’s carved-out label, combined with public statements and marketing materials, plausibly stated a claim for induced infringement. The court pointed to press releases describing the product as a “generic version” of the branded drug and references to sales figures dominated by the carved-out (patented) cardiovascular use, plus removal of certain disclaimers. The U.S. Solicitor General recommended Supreme Court review to clarify how inducement should work in the skinny-label context.

A non-lawyer analogy

Think of a product with a user manual: if you remove the instructions for a prohibited use (the skinny label), but your advertising and public messaging still strongly signals that prohibited use, a court may treat that as encouragement - even if the formal manual is compliant.

Practice pointers (brand and generic perspectives)

- Align regulatory and marketing teams: the label strategy must match outward-facing messaging.
- Train commercial teams and distributors on what must not be said (or implied) about carved-out indications.
- Use clear disclaimers consistently when referencing the brand drug; avoid ambiguous “generic equivalent” messaging where it could be read as promoting the carved-out use.
- For brands: plead and prove inducement using the full context (label + marketing + market realities) rather than label language alone.

Conclusion

The unifying theme across these seven issues is institutional rebalancing. When Congress and courts leave gaps, the USPTO and the Federal Circuit recalibrate through procedure, evidentiary standards, and guidance. For international applicants, the practical lesson is to treat U.S. patent strategy as an integrated package: (i) prosecution drafting that anticipates litigation proof burdens, (ii) evidence building (technical improvement, licensing rationale, inventorship documentation), and (iii) governance for AI-assisted innovation.

Selected sources and further reading

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- *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).
- *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014).
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