

When the window closes: the new timing of patent value in life sciences

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Olga Partington, director in Sterne Kessler's biotechnology and chemical practice group, shares why a patent's vulnerability peaks when it is young, rather than when it is most valuable, under the PTAB's new framework

For most of the last decade, a life science patent's greatest vulnerability emerged after commercialisation, when competitors had reason to challenge it. Companies competing directly sometimes moved earlier, but they were the exception and did so by choice rather than necessity. Recent Patent Trial and Appeal Board (PTAB) changes have shifted that vulnerability to the beginning of a patent's life, rewarding challengers who move early.

What changed

Institution has always been discretionary, but that discretion expanded significantly in 2025. Then-acting Director Coke Morgan Stewart rescinded prior limits on discretionary denials and adopted a bifurcated institution framework that introduced "settled expectations" as a threshold consideration. Interim Processes for PTAB Workload Management (March 26 2025). Director Squires later centralised institution decisions in the director's office. Memorandum and Open Letter (October 17 2025); see also memorandum (March 11 2026). Institution rates subsequently fell, PTAB petitions declined more than 60% year-over-year, and ex parte reexamination requests began to exceed new PTAB petitions ([Unified Patents, Patent Dispute Report: First Half 2026.](#))

Settled expectations emerged in *iRhythm* and were further developed in *Intel v Proxense*, where the PTAB held that patents more than nine years old generally create settled expectations weighing against institution absent compelling circumstances. IPR2025-00363 et al, Paper 10 (PTAB June 6 2025); IPR2025-00327 et al, Paper 12 (PTAB June 26 2025); *see also Dabico Airport Sols v AXA Power ApS*, IPR2025-00408, Paper 21 (PTAB June 18 2025) (designated informative). Commentators have since identified an effective six-year settled-expectations threshold ([Kaiser, Marando & Carter, 'What Is Settled and What Are Our Expectations After iRhythm?', The Patent Lawyer \(August 5 2025\).](#))

The doctrine is contested, and a certiorari petition remains pending. *Google v VirtaMove*, No 25-1230 (US) (petition for certiorari pending). If it falls, much of what follows may change. But it governs today, and the denials, forgone challenges, and business practices it has already shaped will likely outlast the doctrine itself.

The vulnerability window

A patent's exposure over its life is now a curve, not a constant. In life sciences, commercially significant formulation, dosing, and method patents often issue near commercialisation. Because later-filed patents frequently determine franchise exclusivity, they spend critical years within the period of greatest procedural vulnerability.

Procedural vulnerability is not the same as challenge likelihood. Many young patents face no challenge from the broader field until their commercial importance becomes apparent, by which time much of the challenge window may have closed. Timing therefore carries independent strategic significance.

For years, challengers could afford to wait. Post-grant review was largely underused because inter partes review remained available later. Once delay itself became a basis for denial, that strategy largely lost its value.

During the first nine months after issuance, a patent remains subject to post-grant review, which permits the broadest range of challenges before any settled expectations can arise. For several years thereafter, inter partes review remains available and no settled-expectations shield has attached.

The patent is also weakest on the merits during this period. Secondary considerations such as commercial success, industry praise, licensing, and market adoption take time to develop. A young patent is therefore doubly exposed: challenge is easiest when supporting evidence is scarcest.

Exposure is front-loaded and runs counter to where portfolio attention typically goes. Yet this is also when an estate is most adaptable: continuations remain pending, claims can evolve, and coverage can be refined.

For the patent owner

The patents facing the greatest challenge risk are now often the newest ones. Economic importance and challenge vulnerability peak at different times. A strategy focused solely on the most valuable assets may overlook those most vulnerable to challenge.

This regime largely favours patent owners. Age now provides protection that prosecution alone cannot buy. But the shield is fact dependent. *iRhythm* turned on the petitioner's delay despite documented awareness, while *Proxense* emphasised whether meaningful reliance had developed around the patent. Reliance must be visible.

An owner who never commercialises, licenses, marks, or otherwise demonstrates reliance may reach year seven without the facts that make the doctrine persuasive. Those same facts often strengthen both the procedural shield and the merits through evidence of commercial success, licensing, and market adoption.

The distinction between a patent and a patent estate also becomes critical. A young patent can be challenged; a well-constructed estate can absorb challenges while claims continue to evolve. During the vulnerable years, portfolio resilience may matter more than the strength of any single patent.

Young companies face a related problem. Their most important financing, partnership, and acquisition discussions often occur while their portfolios remain young, before the protections associated with age and reliance have developed. As a result, the cost of building resilience arrives earlier in a company's life cycle.

For the challenger

The same clock runs in reverse, and the change is more disruptive. A patent thicket can no longer be viewed as a static catalogue of claims to clear whenever market entry approaches. It is a set of closing windows. A thicket that matures becomes more formidable not necessarily because its claims are stronger, but because time has passed and avenues of challenge have narrowed.

The clock does not press evenly on all challengers. A competitor already in the field knows which young patents threaten it before the market does; a challenger with no position learns that a patent matters only once its importance surfaces, often after the best windows have closed.

For the positioned challenger, awareness is a liability already carried: it starts the clock, and the evidence often comes from the challenger. In *iRhythm*, it was the petitioner's own information disclosure statement. Once awareness is provable, a future challenge depreciates.

The post-grant review window is now premium territory, and the constraint on using it is judgement, not infrastructure. Monitoring competitor patents as they issue is cheap; identifying which will matter before the market prices them in is the hard part. Waiting for commercial certainty, once prudent, now carries a procedural cost.

Moving early carries its own risk. A challenger that acts before commercial activity or litigation may preserve its challenge but lack standing to appeal an adverse decision.

The escape hatches are therefore worth developing. Where a patent owner seeks to show reliance, a challenger benefits from demonstrating that meaningful reliance has not yet emerged.

Portfolio surveillance consequently moves earlier in the business cycle. Patent review increasingly begins years before launch, partnering, or market entry. The option to challenge has become a wasting asset.

The clock, not the claim

Under the current PTAB framework, two patents with identical validity profiles may present very different risk depending on where they sit on the clock.

For diligence, the consequence is concrete. Analysis can no longer focus solely on validity, scope, and freedom-to-operate. It must also consider patent age, remaining challenge opportunities, evidence of awareness, signs of reliance, and the flexibility provided by pending continuations.

Patent diligence has long treated IP as a question of scope and validity. There is now a third dimension: time. The question is no longer only whether a patent can be challenged, but whether the window to challenge it remains open.



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