Coordinating Life Sciences IP Strategies In The US And EU

By **Paul Calvo** (July 8, 2026)

Paul Calvo

Postgrant practice for life sciences patents is being restructured on both sides of the Atlantic at the same time. These changes are not incremental. They reframe the calculus of where, when and how postgrant challenges are mounted and defended.

A reconfigured Patent Trial and Appeal Board, a resurgent ex parte reexamination practice, a Unified Patent Court now issuing its first wave of substantive appellate decisions, and a stable European Patent Office opposition system together make forum selection a board-level question.

This article focuses on the most consequential developments of the last several months — U.S. Patent and Trademark Office Director John Squires' March 11 manufacturing memorandum, the May 14 precedential **decision** in Magnolia Medical Technologies Inc. v. Kurin Inc., and the Unified Patent Court Central Division's May 4 revocation of the remdesivir patent — and the coordination obligations that follow.

The PTAB's Structural Reset

For over a decade, inter partes review functioned as a high-powered tool for challengers, with institution rates and postinstitution cancellation rates both running 60%-70%. That dynamic has been comprehensively reversed in roughly 15 months.

Three documents define the reset: The rescission of the 2022 Fintiv memorandum on Feb. 28, 2025; acting Director Coke Morgan Stewart's March 26, 2025, interim process memorandum, which bifurcated institution and introduced the settled expectations factor; and Squires' March 11, 2026, memorandum on additional discretionary institution considerations.

The numbers track the policy. Institution rates fell from about 69% in early 2025 to 37% by February this year, and PTAB filings in the first quarter of 2026 collapsed 64% year-over-year.

A discretionary denial order dated Feb. 24 shows that Squires has discretionarily denied 64% of the petitions he has reviewed personally. The compression is deliberate.

The March 11 Memorandum

The March 11 memorandum is the single most concrete development on which European-headquartered patent owners should focus.

It directs the PTAB to weigh three new factors when deciding on institution: (1) whether products accused of infringement in a parallel proceeding are manufactured in the U.S., or are tied to investments in American manufacturing; (2) whether the patent owner's competing products are U.S.-manufactured; and (3) whether the petitioner is a small business that has been sued for infringement of the patent.

Several operational details matter. The director will look beyond final assembly to include U.S.-made components and U.S.-made products sent abroad for further processing.

For method claims, the relevant product is the device used to carry out the method. Small-business status will be assessed against Small Business Administration size standards and Title 37 of the Code of Federal Regulations, Section 1.27(a).

The memo applies prospectively to any IPR or postgrant review where the patent owner's discretionary brief is not yet due.

The first application came quickly. On May 19, in Tesla Inc. v. Bulletproof Property Management LLC, Squires declined to discretionarily deny institution of seven IPRs against vehicle gear selection control patents, expressly citing Tesla's evidence that the accused products are manufactured in the U.S. The USPTO designated the decision informative on June 15.

Tesla v. Bulletproof sets the proof template: Petitioners now produce affirmative manufacturing evidence in preinstitution briefing, and patent owners must be ready to challenge it and to assemble their own competing-product manufacturing record.

Recent Director Denials: Some Cases That Now Matter

Four director decisions beyond the manufacturing memo define the practical environment.

Dabico Airport Solutions Inc. v. AXA Power ApS, decided June 18, 2025, is a foundational settled-expectations case: Stewart denied institution sua sponte because the challenged

patent had been in force for almost eight years, imposing on the petitioners an affirmative burden to address discretionary factors up front. The working rule of thumb appears that patents in force for six years or more attract a strong settled-expectations presumption.

Tianma Microelectronics Co. v. LG Display Co., a precedential decision from March 18, **holds** that foreign governments and entities in which foreign governments hold a stake are not permitted petitioners under Title 35 of the U.S. Code, Section 312(a); petitions that fail to address the issue may be vacated and denied.

For European life sciences patent owners facing challenges from petitioners with sovereign wealth fund or state-aligned ownership, Tianma is now a frontline argument.

Magnolia Medical Technologies Inc. v. Kurin Inc., a precedential decision from May 14, may be one of the most important Squires decisions to date. Squires denied institution where the petitioner had already litigated similar invalidity grounds in district court and lost.

He framed the policy as such: PTAB challenges should be a quick, cost-effective alternative to district court, not an expansion of it; the discretion to deny is rooted in the public interest, not private vindication.

Magnolia elevates several previously informative considerations — multiple petitions, parallel litigation, examiner error, inconsistent claim construction and settled expectations — to precedential status.

Finally, two May 12 precedential designations — Ford Motor Co. v. AutoConnect Holdings LLC and Terumo BCT Inc. v. Haemonetics Corp. — **penalize** petitioners that advance inconsistent positions in district court after PTAB institution, for example, indefiniteness in court alongside Title 35 of the U.S. Code, Section 102 and Section 103, grounds at the PTAB. The USPTO vacated institution decisions that had already been granted, and denied institution in both cases.

The cumulative effect is that the discretionary-denial menu is now substantially broader. A patent owner facing an IPR petition from a non-U.S. manufacturing petitioner, on a patent in force for more than six years, where the petitioner has already raised invalidity in district court — a profile common in life sciences — now has at least three independently sufficient grounds for discretionary denial.

Reexamination as the New Challenger Default

Challengers responded predictably. Ex parte reexamination requests rose 66% to 726 filings in 2025. The appeal is structural: high grant rate, no standing requirement, limited third-party participation postinitiation and, critically, no estoppel.

A failed requester remains free to relitigate invalidity in district court, whereas an unsuccessful IPR petitioner is estopped from any ground that was or could have been raised.

Patent owners have, however, narrowed the asymmetry. Effective April 5, an official gazette notice from Squires gives patent owners the right to file a 30-page paper opposing the existence of a substantial new question of patentability before the USPTO decides whether to order reexamination.

The countervailing limit on reexamination remains claim cancellation power: roughly 14% historically, compared to IPR's 60% to 70%. The strategic question is whether lower cancellation rates and an estoppel-free profile outweigh IPR's greater destructive potential under the current institution risk. The default toward IPR no longer holds.

The European Dimension: EPO Opposition and the UPC

EPO opposition remains the most cost-effective postgrant challenge forum globally — a nine-month window, written procedure, no U.S.-style discovery, and decades of inventive-step, novelty and sufficiency case law.

The UPC, three years in, has become substantive precedent. Revocation actions account for over 40% of UPC filings, and the UPC Court of Appeal is now issuing the substantive guidance practitioners have been waiting for. Three recent decisions frame the practical stakes.

Three UPC Cases to Cite

Amgen

In Amgen Inc. v. Sanofi-Aventis Deutschland GmbH and Others on Nov. 25, 2025, the Court of Appeal **set aside** the Munich Central Division's 2024 revocation of Amgen's PCSK9 antibody patent, upholding the patent and awarding costs.

Sanofi and Regeneron applied for rehearing on Jan. 26. Suspensive effect was refused on March 20, and the rehearing application was denied on March 24.

The court placed the burden of proving a reasonable expectation of success on the party asserting invalidity — a significant evidentiary shift for life sciences. Its reasoning closely tracked the EPO problem-solution approach while preserving UPC flexibility on realistic starting points, pointing to greater EPO/UPC convergence than the early UPC cases suggested.

This is the case to cite when arguing that UPC revocation is not a presumption of invalidity.

Gilead

In Gilead v. Academy of Military Medical Sciences on May 4, the UPC Central Division in Milan revoked European Patent 3 854 403 in its entirety, finding the claim to lack an inventive step. The insufficiency attack was dismissed.

It is the most prominent UPC life sciences revocation of the past several months and a useful counterpoint to Amgen: Where prior art and motivation are well-developed, the UPC will revoke, and quickly.

Milan applied the Court of Appeal's framework from its decisions in Amgen v. Sanofi and Meril v. Edwards last year, and tracked the EPO problem-solution more closely than early UPC cases suggested it would.

Insulet

In Insulet v. EOFlow, the Milan Central Division rejected Insulet's provisional measures in December 2025, and the Court of Appeal upheld that result on March 18.

The case is being cited for the Court of Appeal's guidance on confidentiality and trade secret protection, a recurring concern for life sciences companies when their UPC pleadings expose technical know-how.

Two short procedural notes complete the picture.

On June 2, the Court of Appeal confirmed UPC long-arm jurisdiction over European patents following the Court of Justice of the European Union's decision in BSH v. Electrolux last

year, holding that the UPC cannot decline jurisdiction where the defendant is domiciled in a UPC contracting state.

And in Nokia v. Geely on April 20, the Mannheim Local Division granted an ex parte antisuit injunction against a Chinese interim-license application.

Both extend UPC reach in ways European life sciences companies with global portfolios should track.

Coordination Risk and Practical Implications

The acute coordination risk for European patent owners is the potential for parallel EPO and UPC proceedings on the same patent to produce conflicting claim-scope or validity outcomes.

Amgen v. Sanofi/Regeneron illustrates a problem: The UPC Central Division revoked in 2024, the Court of Appeal upheld in November 2025 and the U.S. Supreme Court reached the opposite enablement conclusion in Amgen v. Sanofi in 2023.

The practical obligation is to monitor parallel EPO opposition, UPC revocation, and PTAB or district court proceedings on the same family; flag claim-construction divergence early; and coordinate before conflicting decisions create an uncorrectable record.

For European life sciences patent owners, the picture is one of heightened complexity rather than uniformly increased risk.

In the U.S., the PTAB is the most patent-owner-friendly it has been since America Invents Act institution, and the new factors — particularly the manufacturing memo and the precedential Tianma bar on foreign-government petitioners — are unusually amenable.

In Europe, EPO opposition still offers value, and the UPC has added a faster, higher-stakes revocation track now producing usable Court of Appeal precedent in Amgen v. Sanofi/Regeneron and Meril v. Edwards. The opt-out decision is now a live portfolio management question.

Three practical steps follow.

First, postgrant monitoring must track EPO opposition and UPC revocation on the same

patent simultaneously, with explicit escalation when claim-scope divergence emerges.

Second, the PTAB's discretionary factors — manufacturing footprint, small-business status, settled expectations, foreign-government real party-in-interest and parallel-litigation conduct — should be integrated into IPR response strategy at the preinstitution stage, with manufacturing evidence assembled before the petition is filed, not after.

Third, patent owners should anticipate reexamination as an opening move and keep a 30-page preorder brief template ready under the April 5 procedure.

Postgrant strategy has always required forum-selection discipline. The current moment demands more: transatlantic coordination that treats PTAB, EPO and UPC proceedings as components of a single IP risk architecture rather than independent silos.

The PTAB's reset, culminating in the March 11 manufacturing memorandum and the May 14 Magnolia precedential decision, has materially recalibrated U.S. postgrant risk in favor of patent owners for the first time since AIA institution.

The UPC has, simultaneously, produced its first wave of substantive life sciences precedent in Amgen v. Sanofi/Regeneron and the Milan remdesivir revocation.

Companies that treat these changes as sequential rather than concurrent will find themselves structurally behind.

Paul Calvo is a director at Sterne Kessler Goldstein & Fox PLLC.

[1] USPTO, "USPTO rescinds memorandum addressing discretionary denial procedures" (Feb. 28, 2025). https://www.uspto.gov/about-us/news-updates/uspto-rescinds-memorandum-addressing-discretionary-denial-procedures.

[2] USPTO, "Interim Process for PTAB Workload Management" (Acting Director Stewart, Mar.

26,
2025). https://www.uspto.gov/sites/default/files/documents/InterimProcessforPTABWorkloadManagement.pdf.

[3] USPTO Director John A. Squires, "Additional Discretionary Institution Considerations — U.S. Manufacturing and Small Business Use of AIA Proceedings" (Mar. 11, 2026). https://www.uspto.gov/sites/default/files/documents/Director_Memo_Additional_Discretionary_Considerations_20260311.pdf.

[4] Dabico Airport Solutions Inc. v. AXA Power ApS , IPR2025-00408, Paper 21 (P.T.A.B. June 18, 2025) (Acting Director).

[5] Tianma Microelectronics Co. Ltd. v. LG Display Co. Ltd. , IPR2025-01579, Paper 12 (Director Mar. 18, 2026) (precedential).

[6] Magnolia Medical Technologies Inc. v. Kurin Inc. , IPR2026-00097, Paper 17 (Director May 14, 2026) (precedential).

[7] Tesla Inc. v. Bulletproof Property Management LLC , IPRs (Director May 19, 2026; designated informative June 15, 2026).

[8] Ford Motor Co. v. AutoConnect Holdings LLC , IPR2025-01342, -01383, -01524, Paper 27 (Director May 12, 2026) (precedential); Terumo BCT Inc. v. Haemonetics Corp. , IPR2025-01374, -01391, Paper 20 (Director May 12, 2026) (precedential).

[9] Patent-Detectives, "PTAB Filings Collapse 64% in Q1 2026 While Ex Parte Reexamination Filings Surge" (Apr. 27, 2026). https://www.patent-detectives.com/en/ptab-q1-2026-ipr-decline-reexam-surge-en/.

[10] USPTO, "Official Gazette Notice — Patent Owner Pre-Order Submissions in Ex Parte Reexamination" (effective Apr. 5, 2026).

[11] Sanofi-Aventis & Regeneron v. Amgen, UPC_CoA_528/2024 & UPC_CoA_529/2024 (Court of Appeal, Nov. 25, 2025); rehearing/suspensive-effect application refused, UPC_CoA_641/2025 (Mar. 20, 2026).

[12] Gilead Sciences Inc. v. Academy of Military Medical Sciences, UPC_CFI_552/2025 (Central Division Milan, May 4, 2026).

[13] Court of Appeal Decision, UPC_CoA_312/2025 et al. (June 2, 2026) (long-arm jurisdiction following BSH v. Electrolux, C-339/22); see UPC Law Decisions Archive. https://upc.law/decisions/.

[14] Insulet Corp. v. EOFlow, UPC_CFI (Milan Central Division, Dec. 4, 2025), aff'd UPC_CoA (Mar. 18, 2026).