Life Sciences Report 2026

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Transactional Snapshot – Life Sciences M&A and Capital Markets

By Ryan J. Udell, Brian D. Short, and Peter Jaslow

Trends in 2026 M&A Dealmaking

By Ryan J. Udell

Newsflash. Life sciences M&A is officially back!

> **"The first half of 2026 we saw 86 life sciences M&A transactions close, representing a total deal value of $196 billion (and a 141% increase in deal value over the same period last year) and the best start to the year since 2019.[1]"**

As we predicted coming out of the J.P. Morgan Healthcare Conference in January, the ingredients were in place for a strong year for dealmaking, and the industry delivered. A significant and enduring trend is a movement over the last several years to focus on de-risked assets. Companies with Phase II assets and beyond now comprise approximately 70% of deals as compared to only 50% of assets in 2021.

No surprise, Phase III and approved assets command the greatest premiums.[2] Also, interestingly, participation has not been limited to big pharma and big biotech; mid-sized companies have also been more active this year. Most of the M&A are billion dollar or so "bolt-ons" thus far, but the "mega-merger" logjam may be breaking, and we expect to see one or more of those in the near term.

Key Drivers of the M&A Surge

The principal catalyst for the M&A surge is the patent cliff.[3] It has been reported that approximately $305 billion in revenue is at risk due to loss of exclusivity over the next six to seven years. And, despite a restock of the pipeline over the last few years, there is still a massive shortfall to get back to current revenues—forget about growth. Also, the acceleration of innovation in certain sectors has spurred M&A as companies jockey to place bets on novel technologies. While this is not new, the clock is ticking. Further, pharma has copious amounts (approximately $14 trillion) of dry powder on their balance sheets to address their revenue problem. Valuation multiples for acquisition targets generally remain well below historical averages, providing flexibility to pay premiums for assets that can restock the proverbial cupboards. These conditions and the moderating of geopolitical and regulatory risk will make for a continued frothy dealmaking environment this year and into next. While we have not yet seen a so-called mega-merger (we last saw these in 2019—AbbVie and Allergan and BMS and Celgene), the current conditions also suggest that it is only a matter of time before we see one or more, as large horizontal deals are the most efficient way to address the industry's revenue problem.

Hot Areas

Areas seeing the most activity thus far this year are cardiometabolic and obesity, late-stage oncology, immunology, central nervous system, radiopharmaceuticals, and AI-enabled diagnostics. These areas should continue to attract a lot of attention for their revenue generation and first-to-market potentialities.

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1 Baral, Subin. (2026, July). M&A in Life Sciences Surges in 2026 with Record Deal Value [Written analysis with data thumbnail] [Post.] LinkedIn. https://www.linkedin.com/posts/subin-baral-94461718_ey-lifesciences-dealmaking-activity-7483173460790116352-KA-3/

2 J.P. Morgan (2026). Q2 2026 Biopharma Licensing and Venture Report. J.P. Morgan.

3 Stifel. (2026). Q2 Biopharma Market Update. Stifel, Nicolaus & Company.

Private Equity as a Willing Optimization Partner

One byproduct of the push to replace revenue is optimizing strategy and resources. Private equity is emerging as a key player, by acquiring neglected or non-core assets such as tools divisions, CDMO units, and/or older brands.

This has opened a window for the lower to mid-cap life sciences and pharma companies to get in on the M&A frenzy. A great example of a deal that captures the zeitgeist in 2026 across all facets of execution is United Therapeutics' acquisition of Thymmune in July. Here we have a $22 billion market cap company purchasing a promising cell therapy portfolio in a deal primarily structured around milestones ($160 million) with an upfront payment ($140 million). We'll investigate the prevalence of milestone/CVR deal structures more in the next section.

Special Focus on Contingent Value Rights (CVR)

While not new to life sciences dealmaking, recognizing the need to acquire novel technologies that may not be as de-risked, sharing of that risk in a deal is often accomplished with the use of contingent deal structures. One commonly used risk share mechanic is the contingent value right. Indeed, you are seeing these in roughly 1/3 of public target deals. CVRs condition payment of a good portion of the consideration in a transaction to certain clinical, regulatory and/or commercial milestones. While this is a tool to get to a deal where valuation gaps could have otherwise been insurmountable, given the potentially large amounts tied up in them, they must be carefully drafted or they can lead to significant disputes. As the acquirer will be operating the target's business post-closing, CVR provisions are heavily negotiated, with the most negotiated (and litigated) term being the level of efforts that the acquirer will need to employ to attempt to achieve the milestones. Acquirers prefer a standard that is subjective (from the most aggressive of "sole and absolute discretion" to "commercially reasonable efforts" tied to the buyer's investment metrics) whereas targets prefer an objective standard ("commercially reasonable efforts" of a comparable company taking into account cost or disregarding the payment of the milestone payment). Milestones are also a key negotiation point, with acquirers preferring narrow achievement paths and targets arguing for broader ones. And, depending on leverage, market practice tends to be the use of severable per-milestone payments, rather than an "all or nothing" approach. We expect the use of CVRs to continue in dealmaking, so it is important to pay attention to the language, as courts have been clear that they will not intervene to use equity to re-allocate a risk that was assigned by the definitive agreement.

All signs point toward a bullish end to the year in life sciences M&A. With so few differentiated assets with near-term potential in the right areas, and the need to replace revenue, the competition for good assets should remain fierce! We encourage dealmakers to be mindful of regulatory uncertainty, as always. Here's to more deals and more innovation!

Capital Markets – Revival or Reconfiguration?

By Brian D. Short and Peter Jaslow

While it is evident that the capital markets (especially in the life sciences space) are not anywhere near the feverish peaks of 2021, we are tracking signs of life that may be encouraging. What is exciting is that, as a result of macro trends, we might be seeing a shift in corporate development philosophy for late-stage capital raising among biotechs toward licensing as a public financing alternative.

Per J.P. Morgan's Q1 2026 Biopharma and Venture Report, six biopharma IPOs raised approximately $1.8 billion in Q1 2026 alone, already exceeding the total value of biotech IPOs completed during all of 2025. While that is encouraging in itself, it is important to note that this is more indicative of a narrow reopening of the public markets than a wider restoration of capital flow, and upon closer examination, an extension of trends we tracked last year.

> **"Nearly every life sciences company that has priced an IPO this year has met some combination of the following criteria: a Phase 2+ asset, a robust investor syndicate and resume of big-ticket venture deals, clinical proof-of-concept, and/or differentiated, proven platforms with an easy path to regulatory approval."**

Companies finding success in the public markets this year are in similar target areas to (a) companies currently finding lots of success in M&A exits and (b) companies that priced IPOs in 2025: obesity, oncology, AI drug discovery, and cardiovascular.

Digging deeper into interwoven mechanics and behaviors of the capital markets as they pertain to life sciences reveals a much more interesting picture—that of what appears to be a reconfiguration rather than a pure reversion to the mean. In our edition of this report last year, we noted the increase in follow-on offerings for fundraising in capital markets. The transactional flow for follow-ons continued to be strong in H1 2026, acting as sort of a "quality check" for publicly traded life sciences companies (i.e. public companies doing all the "right things" can look to closing secondary offerings as an affirmation of their approach). Royalty monetization transaction streams remain steady as publicly traded biotech and pharma companies (particularly ones contingent on partnered assets) keep them in the playbook to secure equity value while winning immediate cash flow for late-stage clinical trials and commercialization. PIPEs (private investments in public equity) have provided some utility (although not at the levels seen pre-2022) as an "event-based" alternative financing tool to help fund, in particular, development or pre-revenue stage companies in advance of a specific readout (e.g. late clinical-stage data drop or an NDA) while also attaching closely to licensing deals to extend runway to the next catalyst. This leads us to licensing emerging as the new linchpin of capital raising: J.P. Morgan recorded $82.7 billion in announced licensing deals in Q1 2026, an astronomical amount considering we were encouraged by several billions raised in IPOs!

Are IPOs back or have we entered a whole new paradigm? Perhaps a bit of both. IPO ambitions are certainly still on the table for certain life sciences companies that can muster up the right blend of product, area, and syndicate quality. Seats at the table are declining, however, particularly for early-stage and more speculative assets. We expect, however, that alternative capital sources, such as upfront licensing of development-stage assets, will continue to shape the way private biotechs and some publicly traded companies within the life sciences industry raise money. In 2026, we encourage stakeholders to look beyond the IPO as endgame and be dynamic in your approach to corporate development. Milestones (both literal and figurative) now provide a more palpable cadence in growth than ever. We are seeing companies kicking out future royalty and milestone streams for immediate cash, or licensing at or before an IPO to gain validation from a credible pharma diligence process and build runway. Timing matters tremendously in 2026 and companies must be prepared to navigate an environment that favors de-risking strategies more than ever.

There is hope for the IPO and follow-on markets to remain strong going into H2 2026, but stakeholders need to be decisive and deliberate before exploring the capital markets. Life sciences companies with public ambitions going into H2 2026 and eventually 2027 should focus heavily on advancing products toward concrete milestones with late-stage data along with governance and corporate housekeeping. Make sure your equity structure is propped up on stable accounting and refresh your option plan, maintain Section 409A compliance, and clean up early exercise terms, repurchase rights, and vesting acceleration triggers. You want to be audit-ready sooner than later, so don't hesitate to engage a Public Company Accounting Oversight Board-registered auditor and complete two to three years of audited financials on IPO timelines. From an IP perspective, you want to get ahead of potential inventorship issues that never hesitate to strike in late-stage IPO prep by building diligence-ready data rooms. Since most IPO-ready biotech companies are late-clinical-stage in 2026, these companies should be prepared to show audit trails for key endpoints, protocol deviations handling, and Data and Safety Monitoring Board (DSMB) processes and safety reporting as part of a greater data integrity/inspection readiness strategy. By getting these pieces along with many others in order, biotech and pharma companies with public ambitions will best position themselves to ride the surprisingly resilient wave of life sciences capital raising going into EOY 2026.

Life Sciences Real Estate Trends – What to Expect

By Sara A. McCormick and Bart I. Mellits

The next phase of the life sciences real estate market may look different from what we have seen in recent years.

> **"Recent market data shows that while demand for laboratory spaces has decreased across many U.S. markets, demand for pharmaceutical manufacturing investment continues to increase."**[4]

This trend may reflect the industry's efforts to reduce pharmaceutical industry's reliance on foreign manufacturers by increasing domestic manufacturing capacity.[5]

Development of pharmaceutical manufacturing will likely follow a different trajectory from what we observed with laboratory space. Laboratory space is often dependent upon venture capital funding and a speculative research timeline. In contrast, manufacturing facilities are tied to long-term operational requirements and FDA-regulated production activities already underway. Manufacturing investments therefore tend to involve larger capital commitments and longer occupancy periods tied directly to ongoing production and are unlikely to relocate in response to short-term market fluctuations.

This shift may create opportunities extending beyond traditional life sciences leasing. From a real estate vantage point, these manufacturing facilities require substantial utility infrastructure, specialized construction, environmental permission, transportation access, and long-term site control. As a result, future life sciences transactions may increasingly involve development partnerships, infrastructure commitments, entitlements negotiations, and regulatory compliance considerations rather than conventional laboratory leasing agreements.

With growing demand for clinical and research buildings, value may be found in properties capable of supporting biologics production, cell therapy operations, nuclear medicine production, and other advanced pharmaceutical operations necessary to pursue successful deliveries.

Data Ownership in Life Sciences Transactions: Why It Matters More Than Ever in the Age of AI

By Harry A. Levin

Data continues to be one of the most valuable assets in life sciences transactions. As pharmaceutical and biotech companies increasingly seek to leverage AI and machine learning technologies to accelerate drug discovery, optimize clinical trials, and develop personalized therapies, the strategic importance of data, such as proprietary drug research, patient information, and clinical trial results, has grown in importance. This shift is transforming how parties negotiate and structure deals, with data ownership, access rights, format, and usage restrictions now occupying a central place at the transaction table. For dealmakers and their counsel, understanding the legal and commercial implications of data scope, data ownership, and use of data are essential to capturing value and mitigating risk in an evolving landscape.

Scope of Data

In any deal, the parties first consider the scope and source of data. In 2026, data creation and collection are faster than ever, accelerating the pace at which

4 Tucker White, An Uneven Reset: U.S. Life Sciences Lab/R&D Leasing Lagged Pre-COVID Norms in 2025, Avison Young (Mar. 5, 2026), https://www.linkedin.com/posts/subin-baral-94461718_ey-lifesciences-dealmaking-share-7483173457585696768-feu7/

5 Pharma Tariffs 2026: Supply Chain & Manufacturing Impacts, IntuitionLabs (May 23, 2026), https://intuitionlabs.ai/articles/pharma-tariffs-2026-supply-chain-onshoring

valuable datasets are generated and refined. As a result, more life sciences deals consider not only the data that parties already own at the Effective Date, but also the data that they might individually own in the future and that they might jointly create through their collaboration. Additionally, it is not uncommon to negotiate the use of third-party data that is combined or synthesized with existing data or synthetic data that is manufactured by AI tools. Life sciences deals are increasingly incorporating highly negotiated defined terms for each category of data, and these defined terms are increasingly covering data that is manufactured, synthesized, or generated.

As data volumes grow, dealmakers are experiencing longer diligence cycles and an increased need for audits. Understanding where data comes from, how it is generated, and what rights the purported owner has in the data is key to mitigating future risk. This requires a more rigorous diligence effort, such as tracing data provenance, verifying chain of title, and confirming that appropriate consents, licenses, and regulatory approvals are in place. In an environment where data can be aggregated, transformed, or synthesized across multiple sources, parties are investing more time and resources to ensure that the data assets being acquired or licensed are free of encumbrances and fit for their intended purpose. Further, these obligations continue post-signing, so parties are increasingly asking for complex audit rights to ensure ongoing compliance.

Data Ownership

Data ownership in life sciences agreements can take many forms, and the structure chosen often depends on the nature of the transaction, the relative bargaining power of the parties, and the strategic value of the underlying data. In some deals, one party retains sole ownership of all data generated or used in connection with the collaboration. This approach is common when a sponsor funds a clinical trial, or a licensor contributes proprietary datasets. Material contributions of capital and prior intellectual property often lead to sole ownership. In others, data may be jointly owned, with each party holding an undivided interest and the right to use, license, or exploit the data independently (or subject to negotiated restrictions). Ownership may also be allocated based on inventorship principles, particularly where the data relates to patentable discoveries, or by technology type (if each party is contributing distinct technologies), such as distinguishing between raw data, processed data, analytical results, and algorithms.

Increasingly, parties highly negotiate who owns improvements, derivative works, and new data generated from existing datasets. This issue frequently arises when AI systems are trained on licensed data or when parties collaborate on iterative research. Additionally, there are more AI summaries or infographics that can be quickly generated from a massive dataset. In some instances, the consumable summary or infographic has separate and distinct value causing ownership rights to be separately negotiated.

Data Use

Beyond ownership, parties must carefully negotiate data use rights and restrictions. Even where a party has access to valuable data, the scope of permitted use is often tightly controlled. Common restrictions include requirements to use data only in compliance with applicable laws and regulations, which are particularly important in life sciences given the overlay of privacy laws (such as HIPAA and GDPR), FDA regulations, and state data protection statutes.

> **“Increasingly in 2026, life science companies are leveraging AI agents and automated workflows, which can use and create data.”**

Agreements frequently prohibit reverse engineering of datasets or algorithms, as well as any attempt to re-identify anonymized or de-identified patient data. Occasionally, when the parties have competitive pressure, competitive use restrictions are also included, preventing a party from using licensed data to develop or support products or services that compete with the data provider’s own offerings. In addition, parties often limit data use to a specified field of use, such as a specific therapeutic or diagnostic area, indication, or technology platform. Alternatively, fields of use can be specified by internal research use only or external commercial use limitations. These field-of-use restrictions ensure that the data provider retains the ability to monetize the data in other contexts while granting the licensee meaningful rights within the agreed scope.

Increasingly in 2026, life science companies are leveraging AI agents and automated workflows, which can use and create data. Some parties require strict AI prohibitions with respect to certain data while others allow AI use under certain specifically defined restrictions. Strict prohibitions are becoming less common as AI use becomes more ubiquitous, especially in research and analysis settings. More typically, parties are prohibiting public AI tools that transfer ownership to the service provider and allow AI tools under an enterprise license that provides adequate cybersecurity assurances and preserves ownership of intellectual property rights.

The value of data assets in life sciences transactions will likely continue to accelerate, raising the importance of scope of data, data ownership and data use during the negotiation. Understanding these terms is essential for finding value and managing risk in an environment that is quickly changing.

Key Trends in 2026 Life Sciences Patent Prosecution

By Scott D. Marty, Ph.D. and Sommer S. Zimmerman, Ph.D.

The Uncertain Landscape of Obviousness-Type Double Patenting

Life sciences companies have long relied on evergreening strategies to strengthen patent exclusivity around innovative therapies. Obviousness-type double patenting (ODP), which prevents patentees from effectively extending patent life through a second patent on a patentably indistinct invention, has always been a consideration in this calculus, but practitioners have generally operated with a clear understanding of its boundaries. That understanding is in flux and recent developments have only deepened the uncertainty.

In *Ex parte Baurin* (Appeal No. 2024-002920), the USPTO Director convened an Appeals Review Panel (ARP) to rehear the Board's earlier reversal of the Examiner's ODP rejections. The ARP reversed the Board and sustained the rejections but its reasoning raises as many questions as it answers. As an initial matter, the ARP concluded that the exception recognized in *Allergan USA, Inc. v. MSN Laboratories Private Ltd.* did not apply to the facts of *Baurin*, finding that none of *Allergan*'s three conditions was met. The ARP then relied on the anti-harassment rationale (the risk that separate owners of patents covering obvious variants could bring independent infringement suits) as an independent basis sufficient to sustain an ODP rejection, even where no term-extension concern was present. While this represents the Office's current position, the ARP itself acknowledged that its analysis was compelled by existing Federal Circuit precedent and expressly invited the court to clarify whether ODP rejections can rest on the anti-harassment rationale alone.

It remains to be seen whether this interim position will hold. *Ex parte Baumeister* (Appeal No. 2026-000193), in which a different PTAB panel reached the opposite conclusion from the Board's original *Baurin* decision and the same conclusion as the ARP, is now on appeal to the Federal Circuit as *In re: Ablynx N.V.* (Appeal No. 26-1333). The Federal Circuit's resolution of *Baumeister* could yield binding precedent that either validates or rejects the anti-harassment rationale as a standalone basis for ODP and may fundamentally reshape how patent families are structured and prosecuted. Until that guidance arrives, the ARP has proposed a framework under which examiners would focus on comparing patent-term filing dates across families and actual filing dates within families, but has instructed USPTO personnel to continue following pre-*Allergan* practice under MPEP § 804 in the interim. Definitive guidance is not yet available, and practitioners should treat the current landscape as unsettled. Companies with large patent portfolios built through continuation strategies should evaluate their exposure and prepare for a range of outcomes as the resolution of these proceedings may alter the boundaries of patent family management.

Enablement and Written Description Requirements are Narrowing the Path Forward

The ODP uncertainty arrives alongside an increasingly demanding, but increasingly nuanced, standard for patent claims under 35 U.S.C. § 112. In the wake of the Supreme Court's decision in *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023), the Federal Circuit has applied rigorous scrutiny to whether broad genus claims in the life sciences are truly enabled across their full scope. Written description requirements have similarly tightened. For pharmaceutical and biotechnology companies, this means that broad claims covering antibodies, nucleic acid constructs, and chemical genera will likely face a narrower path to allowance than they did even a few years ago. Two recent decisions illustrate the boundaries the court is drawing.

In *Teva Pharmaceuticals International GmbH v. Eli Lilly & Co.*, 172 F.4th 1367 (Fed. Cir. Apr. 16, 2026), the court reversed a judgment as a matter of laws (JMOL) of invalidity, holding that method-of-treatment claims directed to treating headaches using humanized anti-CGRP antagonist antibodies were both enabled and adequately

described. The court distinguished *Amgen* on the grounds that the claims were directed to the *therapeutic use* of a well-known genus and not to the antibodies themselves. Because anti-CGRP antagonist antibodies were well known in the prior art, humanization was a routine procedure, and the specification disclosed that all humanized versions would treat headache, the court held that the relevant "research assignment" (*i.e.*, whether the antibodies treat headache) was already completed in the specification, making any additional effort to identify and make every possible antibody "more akin to extra credit than a necessary research assignment." Written description requirements have similarly tightened, though *Teva* again shows that the representativeness inquiry varies with the nature of the invention: where a well-known genus is used as part of a different invention, fewer disclosed species may suffice to satisfy the written description requirement.

By contrast, in *Wyeth LLC v. AstraZeneca Pharmaceuticals LP*, 2026 U.S. App. LEXIS 20004 (Fed. Cir. July 9, 2026), the court affirmed a JMOL of invalidity for lack of enablement of method-of-treatment claims directed to treating gefitinib/erlotinib-resistant non-small cell lung cancer using irreversible EGFR inhibitors. The specification disclosed only three compounds with *in vitro* data, provided no working examples of dosing in human patients, and offered only broad "general" and "projected" dosage ranges. Critically, unrebutted trial evidence showed that two of the three disclosed compounds exceeded maximum tolerated doses in humans across all disclosed ranges, and the specification left determination of a therapeutically effective unit dosage entirely to the skilled artisan's judgment. The court held that a specification cannot rely solely on the knowledge of a skilled artisan to supply the novel aspects of an invention, and that *in vitro* data alone are insufficient to enable claims that contemplate daily administration to a patient.

The convergence of these trends creates a strategic squeeze. If an applicant pursues broad claims up front it risks invalidation under § 112 in the post-*Amgen* environment, where courts increasingly find that a limited number of working examples cannot enable a vast genus. As *Teva* and *Wyeth* illustrate, this risk is not confined to composition-of-matter claims—method-of-treatment claims face the same scrutiny, and the outcome turns on the adequacy of the specification's guidance across the full claimed scope rather than on claim type alone. But if an applicant instead pursues narrower, species-by-species claims across multiple applications, it risks triggering ODP rejections across its patent families. The result is a narrowing window within which to build layered patent protection. Life sciences companies should consider investing in more robust initial disclosures and, where possible, diversifying claim strategies across patent families.

The Supreme Court Clarifies Skinny-Label Protections for Generic Entry

On June 4, 2026, the U.S. Supreme Court issued a landmark decision in *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.* (No. 24-889) that significantly strengthens the practical value of the Hatch-Waxman Act's Section viii "carve-out" pathway for generic manufacturers. Under this framework, a generic company can avoid patent lawsuits if it "carves out" or excludes patented uses from its label—a so-called "skinny label." The Federal Circuit previously allowed Amarin's induced-infringement claims to proceed based largely on Hikma's press releases, AB-rating references, and statements describing its product as a "generic version" of Vascepa®, despite Hikma having fully carved out Amarin's patented cardiovascular-risk-reduction indication. The Supreme Court reversed, holding that induced infringement requires affirmative, targeted conduct that actively encourages infringement. Ordinary distribution, lawful statements about generic equivalence, and FDA-required or industry-standard communications, without more, are not sufficient.

For branded life sciences companies, the decision raises the bar for enforcing method-of-use patents against skinny-label generic manufacturers. Complaints must now identify concrete statements or actions by the generic company that specifically point to the patented use such as sales scripts, physician-facing materials, payer presentations, or promotional content connecting the generic product to the protected indication. Brand name companies should reassess their patent prosecution strategies, use-code descriptions, and Orange Book listings to ensure patent claims map tightly to unavoidable portions of a generic label. For generic manufacturers, *Hikma* provides increased confidence in skinny-label launches but demands disciplined consistency: all communications—from FDA labels to investor materials to sales training—must align with the approved carve-out. The decision does not create a categorical safe harbor, but it meaningfully reduces the risk of litigation that previously made the Section viii pathway unreliable in practice.

Changes to PTAB and Takeaways for Life Sciences Stakeholders

By Caryn Borg-Breen, Ph.D., Kenneth H. Sonnenfeld, Ph.D., and Margaret Sonnenfeld, Ph.D. (Brivanlou)

Since early 2025, the Patent Trial and Appeal Board (PTAB) has shifted toward a more restrictive, Director-controlled institution regime. Expanded use of discretionary denials—including revived *Fintiv*-based considerations and "settled expectations" factors—has resulted in fewer inter partes review (IPR) proceedings being instituted and has made it more difficult to challenge issued patents. These changes generally strengthen and de-risk patent portfolios, particularly for branded pharmaceutical and biotechnology companies. However, the large number of institution- and merits-stage reversals and late-stage interventions by the Director increases uncertainty complicating patent litigation strategy.

Director Control

A central development has been the consolidation of institution authority in the Director, replacing prior panel-based decision-making with broad discretionary review authority, formalized as a separate discretionary-briefing track. This procedural change began in early 2025 under former Acting Director Coke Morgan Stewart and was expanded under Director John Squires such that now all institution decisions, both discretionary and merits-based, are made by the Director and the decisions are rendered as summary orders without detailed reasoning. The result is that there is no substantive transparency or ability to appeal the decision. This shift has contributed to fewer instituted proceedings and reduced predictability for petitioners.

Expanded Grounds for Denial

Discretionary denial has also broadened through new and expanded factors, including broader discretion based on *Fintiv* factors in cases of parallel district court litigation (including reduced impact of *Sotera* stipulations), new factors relating to "settled expectations" of the patent owner, investors and the public in cases of long-held patents, requirements for identification of the real party in interest, sovereignty and domestic policy considerations, cross-forum consistency, serial or repetitive challenges, preference for PGRs over IPRs, and considerations of administrative error, efficiency, and fairness. Collectively, these factors provide the Director with latitude to deny institution even if petitions present strong merits.

Declining Institution Rates and Appeal Pendency

Following the 2025 policy changes, PTAB institution rates have declined significantly. According to data published by the USPTO, in October 2024 the average institution rate was 60-70% and as of July 2026 the overall institution rate had dropped to 30-40%, with significantly more institution denials than grants.

> **"Average appeal pendency (defined as average months from Board receipt date to final decision) is also greatly reduced across all technology areas, falling from over 13 months in May 2025 to just ~7.5 months as of July 2026 (although bio/pharma appeals pendency is longer at ~8.5 months)."**

These changes appear to be a direct result of the expanded use of discretionary denials and the centralization of institution authority within the Director's office.

Institution Flips and Merits Interventions

Since Director Squires assumed control over institution decisions, a large number of petitions have been retroactively denied, de-instituted, or de-referred. For example, in *Revvo Technologies v. Cerebrum Sensor Tech*, the Director vacated the Board's institution grant on the basis that Revvo was

arguing different claim construction positions and then cited this decision in denying numerous petitions that were already slated for merits review. These "institution flips" have increased uncertainty in PTAB practice, as parties face reduced predictability regarding whether instituted or denied proceedings may later be reversed.

The current Director has further used the Director Review process to intervene in cases during the merits phase. In October 2025, Director Squires withdrew institution in *Interactive Communications Int'l v. Blackhawk Network* even though the PTAB had already issued a final written decision (FWD) and ultimately vacated that decision, treating it as if it had never issued and rendering the decision non-appealable. Several cases are now on appeal to the Federal Circuit, where the scope of Director authority is being challenged. In March 2026, the Director *sua sponte* ordered rehearing of the PTAB's 2025 decision in *Ex Parte Baurin* regarding obviousness-type double patenting and how it applies to Patent Term Adjustment. These merits-stage interventions raise significant questions regarding appellate rights and procedural finality for both patent owners and petitioners.

Takeaways for Life Sciences Companies

These recent PTAB developments mean that it will be much harder for life sciences companies to invalidate patents before the PTAB. IPRs have historically been a preferred means for biosimilar applicants to challenge key biologic patents, although less commonly used by generic filers pursuing small molecule generics. The stricter scrutiny of IPR petitions thus benefits life sciences patent owners.

Data from the PTO demonstrates that the recent PTAB changes have just shifted patent challengers toward *ex parte* reexaminations instead of IPRs.

> **"USPTO data shows that filings for *ex parte* reexams increased significantly in the first half of 2026 (now totally ~75% of post-grant filings) coincident with the decline in PTAB filings (now hovering near ~25%)."**

Ex parte reexams present certain advantages for patent challengers including reduced filing fees, anonymity, and greater flexibility in bringing prior art challenges without estoppel risks in subsequent litigation as well as double patenting challenges. In addition, the USPTO's new "pre-order" procedure gives patent owners a free opportunity to present arguments against a Substantial New Question of patentability early prior to reexam institution, with only limited opportunity for requesters to respond. However, there are significant drawbacks for patent challengers engaged in *ex parte* reexams including the inability to raise §§ 101 and 112 challenges and the inability to directly interact with the examiner while the patent owner is free to conduct examiner interviews, submit expert declarations, amend claims, and present arguments in favor of patentability. Further, a successful reexam may have the effect of making the challenged patent "bulletproof" if upheld, particularly if the USPTO's proposed "one and done" rules package advances.

Theoretically, the recent PTAB changes may shift patent challenges to district court although the data does not support this. District court litigation is favorable for patent owners who enjoy a presumption of validity and heightened standard for proving invalidity. However, district court challenges can be very slow and costly for both the patent owner and the patent challenger.

In addition, recent PTAB changes may shift patent challenges to PGRs, to the extent available. However, because PGRs must be filed within nine months of patent grant, many patents are not available for PGR challenge. According to the USPTO, the number of PGR petitions filed remains small.

The more restrictive and unpredictable environment before the PTAB will thus reshape strategies of patent owners and patent challengers alike. The lack of transparency and predictability surrounding Director actions complicates litigation strategy, settlement dynamics, and portfolio valuation.

For life sciences in-house IP counsel intent on challenging patents before the PTAB, we recommend filing petitions sooner rather than later to avoid denials based on settled expectations, and early consideration of factors that go beyond the merits including discretionary factors relating to RPI and how the petition matches the institution's currently stated goals. Patent owners should strategically plan for discretionary denial briefing and expect that future patent challenges are likely to occur in one forum only, and if before the PTAB file only one petition per patent absent exceptional circumstances.