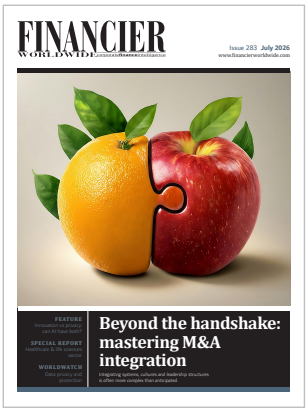

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Patent strategy and regulation: key considerations for life sciences in 2026 and beyond

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The life sciences sector in 2026 is maturing under evolving regulatory frameworks and intensifying intellectual property (IP) scrutiny. For early-stage companies and their financial investors, legal strategy, particularly around patents and regulation, has become inseparable from valuation, dealmaking and long-term viability. The traditional model of 'innovate, patent and exit' is giving way to a far more nuanced landscape shaped by judicial tightening of patent standards and a more volatile and unpredictable regulatory environment. These forces make it increasingly difficult for companies and investors to maintain enough flexibility to anticipate and successfully navigate ever-shifting market pressures.

This article examines key patent and regulatory considerations facing the life sciences sector in 2026 and offers practical insights for companies and investors navigating this increasingly complex environment.

The patent cliff and its transactional ripple effects

The patent cliff is nothing new but remains one of the most significant forces shaping life sciences companies. The term refers to the sudden, severe drop in revenue that a company experiences when a highly

profitable product loses market exclusivity. This loss of exclusivity (LOE) occurs due to expiring patents or regulatory exclusivities. GlobalData projects that more than $230bn in US pharmaceutical revenues will be subject to expiring exclusivities between 2025 and 2030. Powerhouse drugs such as Keytruda, Januvia, Janumet, Opdivo and Eliquis will lose exclusivity and will be subject to intense competition as generics and biosimilars enter the market. This LOE of key products is driving a surge in M&A, as large pharmaceutical companies seek to replenish pipelines through acquisition of early-stage companies and their clinical-stage assets.

For early-stage pharma and biotech companies developing innovative products, this creates both opportunity and pressure. On one hand, interest in and potential acquisition of these companies has increased; on the other, experienced buyers and investors are increasingly demanding: (i) clean and defensible patent portfolios; (ii) late-stage or de-risked clinical data; and (iii) clear, sophisticated and well-executed regulatory strategies, especially for very early-stage product candidates.

Smaller companies positioning for an exit need to recognise that asset due diligence extends beyond patent ownership. Diligence scrutiny will necessarily include licensing structures, encumbrances and the transferability of rights. Weaknesses in these areas can materially weaken valuation or derail transactions altogether.

For investors, the value in the asset, and the start-up as a whole, is directly tied to the sophistication of the patenting strategy. A sophisticated strategy includes an array of patent families having diverse and layered patent architecture protecting the asset. This diversity ideally includes specific picture claims of the product candidate, its use, and its manufacture. The portfolio should also include layered patents with broader claims to insulate the product candidate from attempts to design around. To be clear, it is not the number of patents that is important, but the variety of claims intentionally directed to protect the asset from multiple angles that provides leverage. Sophistication with patent portfolios plays out through diligence which necessarily goes beyond the number of patents in play and looks directly at enforceability, scope and alignment with regulatory exclusivities.

Heightened patentability standards and litigation risk

The US patent landscape for life sciences, and particularly for biologics, diagnostics and platform technologies, continues to evolve in ways that raise the bar for early-stage innovators.

Enablement and written description. Recent case law has reinforced stringent requirements for enablement and written description, particularly for broad 'genus' claims covering classes of antibodies or molecular targets. Courts are demanding more detailed experimental support and narrower claim drafting, limiting the ability of companies to secure sweeping protection for promising product candidates early in development.

Despite this, the importance of having a diverse claim architecture was recently borne out in a precedential opinion from the Federal Circuit. In *Teva Pharms. Int'l GmbH v. Eli Lilly & Company*, the court held that patent claims directed to methods of treating headache using a certain genus of antibodies satisfied the written description and enablement requirements of 35 USC section 112. Importantly, the Federal Circuit distinguished the Supreme Court's 2023 *Amgen v. Sanofi* decision on the ground that a method-of-treatment claim reciting the use of a genus of antibodies differs from a composition-of-matter claim to the genus itself.

Subject matter eligibility. At the same time, subject matter eligibility challenges persist, especially for innovations in personalised medicine, gene sequencing, bioinformatics and diagnostics, where discovering the relationship between genes or proteins and diseases is central. To help applicants overcome section 101 rejections, the US Patent and Trademark Office (USPTO) has updated its guidance, including allowing applicants to submit subject matter eligibility declarations under Rule 132.

But such assistance and patent issuance does not guarantee courts will agree with the USPTO's patentability conclusion in any challenge to validity under section 101. And although policy discussions around reforms such as the Patent Eligibility Restoration Act could reshape patent eligibility, uncertainty remains, requiring careful claim strategy and portfolio diversification.

Obviousness-type double patenting. While broad patent portfolios are highly regarded, they must be strategically monitored. The interaction between patent term adjustment (PTA) and obviousness-type double patenting (ODP) remains unsettled. The decision in *Allergan USA v. MSN Laboratories* clarified that a first-filed, first-issued patent with valid PTA cannot be invalidated by a later-filed child patent that expires earlier. This decision is important in that, if patent claims are structured correctly across parent and child applications within the same family, the end of a patent's term, which is often the most lucrative years of a product's life, is protected.

Keeping things interesting, in March 2026, John Squires, director of the USPTO, convened an Appeals Review Panel to reexamine *Ex Parte Baurin,* a 2025 rehearing decision of the PTAB with respect to ODP, which relied on *Allergan* despite having different facts – namely that the reference patent and the application were not part of the same family and did not share a common priority date. As the law of ODP evolves, early-stage companies need to appreciate how it affects their portfolios and be prepared to address the possible scenarios through diligence.

Patents remain foundational but have never been sufficient on their own. Regulatory sophistication, clinical quality and strategic alignment across legal domains are now central to value creation.

For early-stage companies, these developments have several implications. First, there are frontloaded R&D costs. More data is needed earlier to support patent filings and enable broader claims. Second, there is portfolio complexity. Companies must build layered protection (composition, method, manufacturing and use claims). And third, there is increased invalidation risk. Weak patents may not survive post-grant challenges or litigation.

Investors, in turn, must recalibrate valuation models that historically relied on broad, early-stage patent protection. IP is still critical, but its durability cannot be assumed.

Regulatory turmoil creates new opportunities and new risks

The Food and Drug Administration's (FDA's) regulatory environment has never been more tumultuous and uncertain than in the past 18 months. Department of Government Efficiency-related staffing cuts, voluntary and involuntary resignations and retirements of senior-level leaders across the agency, including most recently the departure of Martin A. Makary, MD, commissioner of the FDA, and the Make America Healthy Again movement with its shifting policy approaches for many product categories continue to challenge life sciences companies and investors seeking to complete transactions or public offerings.

The directional impact of these factors has been mixed as between different product types and

categories. Outlined below are some examples.

For mature therapeutic areas, such as cardiovascular, metabolic and primary-care conditions, the review and approval standards are, and remain, relatively established and familiar.

Sponsors of oncology drugs and other 'orphan' products are – despite two high-profile unexpected FDA denials of orphan drug applications in the past year – seeing potentially beneficial changes in approval standards and review timing, aimed at speeding to market potentially-life-saving or life-extending therapies based on more liberal use of various alternative regulatory pathways (fast-track, breakthrough therapy designation, accelerated approval) and potential approvals based on surrogate endpoints and positive earlier-stage clinical data. Of particular note, in early 2026, the FDA launched a 'Framework for Accelerating Development of Individualized Therapies for Ultra-Rare Diseases', with the "priority to remove barriers and exercise regulatory flexibility to encourage scientific advances and deliver more cures and meaningful treatments for patients suffering from rare diseases".

Cellular and gene therapy products may also benefit from recent policy evolution, particularly with respect to more-flexible manufacturing and chemistry, manufacturing and controls-related standards for these complex products. For example, in January 2026, the FDA published details on its "increase[d] flexibility on requirements for cell and gene therapies to advance innovation", with Dr Makary noting that "[regulatory flexibility must be tailored for cell and gene therapies [to]… address the unique characteristics of cell and gene therapies and foster more innovation".

Vaccines, on the other hand, have seen the greatest challenges, as Robert F. Kennedy, Jr, secretary of the Department of Health and Human Services, has revamped essentially the entire vaccine advisory committee process, called into question vaccines more broadly, and in the process triggered legal challenges that create continued uncertainty in this space.

These factors raise a number of important deal-related considerations for regulated companies and life sciences investors. First, the underlying data remain crucially important, and while some categories may benefit from more-flexible data standards, quality (of the data) and category (of the product) matter more than ever. Diligence efforts should be especially vigilant about low-quality or unfocused data sets. Second, companies should establish, and investors should expect to see, sophisticated regulatory infrastructure, a clear assessment of where on the current regulatory-policy spectrum the product candidate resides, and a well-designed and well-executed regulatory strategy that aligns with the data and category-specific regulatory landscape applicable to the product candidate.

Finally, one big-picture FDA policy change that is especially important for life sciences companies and their financial backers to understand is the new real-time public release of complete response letters (CRLs) issued for deficient new drug and biologics applications. CRLs are responses to applications issued when the FDA has determined that it cannot grant an approval of an application in its present form. CRLs may be based on various reasons, most commonly safety and efficacy concerns and manufacturing deficiencies. Previously, CRLs were not made public while an application was still pending, but as the FDA stated in support of the policy: "[f]or far too long, drug developers have been playing a guessing game when navigating the FDA. Drug developers and capital markets alike want predictability. So today we're one step closer to delivering it to them, with an ultimate goal of bringing cures and meaningful treatments to patients faster."

The FDA's CRL release policy, including its specific capital markets justification, puts added pressure on drug developers and life sciences investors alike to more carefully vet the clinical and regulatory quality of a company's development programme and product candidate. An immediately released CRL that appears to contradict prior more-optimistic company announcements

about clinical trial results could cause swift and more impactful negative consequences on share prices or the ability of the company to attract new financing or to go public. This puts a higher onus on companies to be especially objective in describing clinical and regulatory milestone events, and on investors to more closely evaluate the clinical and regulatory minutiae of product development data and strategies.

Conclusion

The legal landscape for life sciences in 2026 is defined by convergence: patent law, regulatory policy and financial strategy are increasingly interdependent. For early-stage companies and their investors, success depends on navigating this intersection in-depth and with precision.

Patents remain foundational but have never been sufficient on their own. Regulatory sophistication, clinical quality and strategic alignment across legal domains are now central to value creation. As the sector continues to evolve, those who integrate these considerations early will be best positioned to capitalise on the opportunities ahead. ■

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