10 US Patent Pressure Points For EU Life Sciences Cos.

By **Paul Calvo** (May 27, 2026)

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As evidenced by the meeting of global stakeholders at the European Patent Office in February, substantive patent law harmonization continues to be a focus for promoting innovation.

For European life sciences companies with U.S. ambitions, there continues to be a number of U.S.-specific issues that, if ignored, can have a substantial impact on therapeutic commercialization.

Understanding and getting ahead of these issues provides the ability for U.S. patent coverage to operate as a strategic business asset, protecting pipeline value in biologics and cell and gene therapies, supporting partnering and licensing, and enabling investment and M&A decisions, while staying aligned with clinical, regulatory and chemistry, manufacturing and control realities.

Early choices on how to position platform inventions; draft claims for antibodies and protein therapeutics, engineered cell products or gene therapies; manage disclosure around abstracts and congress presentations; and coordinate inventorship across cross-border R&D and external collaborations often determine whether U.S. rights become a durable value driver or an expensive source of uncertainty during diligence, enforcement or challenges.

This article identifies 10 pressure points and frames the practical questions that European in-house patent counsel should be raising before they become problems.

1. Subject-Matter Eligibility Under Section 101

The framework established by the U.S. Supreme Court in its 2012 decision in Mayo v. Prometheus Laboratories and 2014 decision in Alice Corp v. CLS Bank continues to exclude naturally occurring phenomena and abstract ideas from patentability, with no direct European counterpart.

For European companies with portfolios that include diagnostic methods, biomarker correlations or companion diagnostic claims, this is not an abstract risk — it is an unavoidable issue.

The threshold question for U.S. counsel should be asked at the application and claim drafting stage, not at examination: Does the claim recite something beyond a natural relationship, and if so, what is the inventive concept?

Aligning with R&D to document what constitutes "something more" that encompasses a technical transformation, and drafting claims that tie the method to a concrete therapeutic decision or device step, preserves eligibility options. Moreover, personalized medicine claims incorporating diagnostic steps will need to be drafted to avoid potential divided infringement issues.

In December 2025 and again in April, the U.S. Patent and Trademark Office formalized subject matter eligibility declarations, voluntary Rule 132 declarations applicants can submit to provide factual evidence of a claimed invention's technical improvement.

Subject matter eligibility declarations are only effective where the specification already describes the technical problem and solution; they cannot add new matter. European applicants with U.S. specifications that were drafted primarily against EPO standards should audit those filings now for subject matter eligibility declaration readiness.

2. Enablement and Written Description: The Functional Claiming Problem

The U.S. Court of Appeals for the Federal Circuit's 2023 decision in Amgen v. Sanofi **confirmed** that broad functional claims to antibody genera, defined by what they do rather than what they are, face stringent enablement challenges.

Written description similarly demands that the specification demonstrate possession of the full scope claimed, not merely the exemplified embodiments.

For European practitioners accustomed to the EPO's breadth-of-claim practice on antibodies or therapeutic proteins, the U.S. standard can be more demanding. The practical alignment needed is with your R&D team: How many structural embodiments are actually reduced to practice before filing, and does the specification disclose them with enough specificity to support the claim scope you intend to prosecute?

For cell therapy and gene therapy assets where vector variants, transgene sequences and chimeric antigen receptor constructs proliferate, this question must be answered modality by modality, not at the portfolio level.

3. Prosecution History Estoppel and Claim Construction

Amendments made to overcome prior art or eligibility rejections create estoppel that forecloses the doctrine of equivalents for the surrendered subject matter. This is a permanent limitation — it travels with the patent into any enforcement or licensing context.

The discipline required is to treat each claim amendment as a strategic decision, not a procedural response. Before making an amendment, determine what equivalents are being surrendered and whether a response-with-remarks, without amendment, is viable.

For European companies with default practices that might be to negotiate claim scope through amendment during examination, the shift to a remarks-first posture in U.S. prosecution is often underappreciated.

Last July, in Colibri Heart Valve v. Medtronic CoreValve, the Federal Circuit **reversed** a $106 million jury verdict because the patentee's cancellation of a retracting claim during prosecution barred it from arguing that retracting was equivalent to pushing.

The case underscores that cancellation of an independent claim can create prosecution history estoppel for a related surviving claim, not just amending the claim language. European applicants adapting EPO claim sets for U.S. filings should review what is being canceled against what equivalents may be needed for enforcement.

4. PTAB Strategy vs. EPO Opposition Practice

Inter partes review and post grant review at the Patent Trial and Appeal Board is structurally distinct from EPO opposition in ways that matter commercially.

Petitions at the PTAB are granted at a rate that, while declining, remains significant for life sciences claims. The adversarial dynamic is also different from opposition: PTAB proceedings move on a compressed 12-month schedule, apply the Phillips claim construction standard and generate estoppel against the petitioner for grounds that were raised or reasonably could have been raised.

European companies holding U.S. patents should conduct pregrant PTAB risk assessments on key claims and budget for post-grant defense as a cost of ownership, not an exception. For companies considering challenging a competitor's U.S. patent, the estoppel risk of an unsuccessful IPR or PGR must be modeled before filing — particularly if U.S. litigation is

anticipated.

This said, the PTAB institution landscape has been substantially overhauled since early 2025. The USPTO rescinded the Fintiv memorandum issued by former Director Kathi Vidal, instituted a new bifurcated discretionary denial process and introduced settled expectations as a stand-alone basis for denial.

Institution rates hit a five-year low of 50% in fiscal year 2025, with July-September monthly rates falling to 24%-27%.

In March, a director memorandum also **introduced** U.S. domestic manufacturing as an explicit factor in discretionary briefing, a consideration that may weigh against European petitioners.

5. Prior Art and Disclosure Traps

The America Invents Act one-year grace period for the inventor's own disclosures is broader than its European Patent Convention counterpart, but narrower than commonly assumed. It does not protect a U.S. application filed more than 12 months after a first public disclosure regardless of where or in what form that disclosure occurred.

Publications on clinicaltrials.gov, scientific meeting presentations, investigator brochures, press releases announcing clinical data or partnerships, and data room materials shared under confidential disclosure agreements that are later found to have circulated without restriction can all generate prior art.

The alignment needed is with your R&D and communications teams: Every external communication involving data should be reviewed before release, and a U.S. provisional application should be on file before the first abstract or clinical trial submission. In multiparty collaborations, the disclosure risk is compounded with a collaborator's publication becoming prior art against your own application.

6. Inventorship and Ownership in Cross-Border Collaborations

U.S. inventorship is a legal conclusion based on contribution to the conception of at least one claim, not on employment status, authorship credit or scientific contribution.

Errors in inventorship are correctable, but can be weaponized in litigation or diligence to

challenge patent validity and ownership. In cross-border R&D between a European parent and a U.S. subsidiary, a contract research organization or an academic collaborator, the question of who conceived what, and when, is frequently underdocumented.

Establish a laboratory notebook and conception documentation protocol aligned with U.S. legal standards before the collaboration begins, and review inventorship for each patent application in the family. Ownership is a separate question governed by assignment documents and employment agreements, and it is best to negate any issues at the outset rather than them being brought up during diligence.

With respect to new advances in artificial intelligence, the USPTO issued revised inventorship guidance for AI-assisted inventions in November 2025, rescinding the February 2024 guidance and eliminating the Pannu factor analysis for single-inventor scenarios.

The revised framework is unambiguous: AI tools are instruments, not inventors, and the traditional human conception test applies uniformly. For European biotechs using AI platforms in drug discovery, especially in cross-border collaborations where scientists on both sides interact with AI systems, the question of which human contributors actually conceived the claimed subject matter must be answered rigorously before filing.

7. Continuation Practice and Obviousness-Type Double Patenting

The U.S. continuation system is a commercially powerful tool available to a life sciences patentee, and one of the most underutilized by European-led companies unfamiliar with it.

A continuation allows the filing of new claims supported by the original specification, with the original filing date, at any point while the parent application is pending.

Applied systematically, it enables a portfolio to track commercial development, for example, claims covering the molecule as first characterized, manufacturing methods as they are refined, etc., and maintain pendency of the patent family during development.

The strategic question for U.S. counsel is which continuation to file next, not whether to file one. The constraint is obviousness-type double patenting, which prevents the extension of exclusivity through claims that are not patentably distinct from an earlier patent in the family.

Timely terminal disclaimers address obviousness-type double patenting in most circumstances, but must be managed proactively — particularly where different legal entities hold different family members, and also in cases where patent term adjustment and patent term extension may come into play.

8. Interplay Between Regulatory Approval and Patent Positioning

For small molecules, the Orange Book listing framework is well understood by most European practitioners.

For biologics and cell/gene therapies, the interplay between regulatory approval and patent positioning is less familiar and more consequential.

Under the Biologics Price Competition and Innovation Act, a reference product sponsor must engage in a formal patent disclosure and negotiation process with a biosimilar applicant within defined windows.

The patents identified for litigation in that process are limited, and patents that are not listed or not timely asserted can be forfeited for certain enforcement purposes.

Align with regulatory and chemistry, manufacturing and control teams to ensure that formulation, manufacturing process and analytical method patents are identified and prosecuted on a timeline that supports listing and BPCIA participation.

For cell and gene therapies, the regulatory-to-patent interface is still evolving, but the same principle applies, manufacturing-related claims need to be in the portfolio before the biologics license application is filed, not after.

9. Patent Term Extension and Supplementary Protection Certificates

U.S. patent term extensions and European supplementary protection certificates share a common policy objective — restoring patent term lost to regulatory review — but differ in scope, eligibility and strategic use.

U.S. patent term extensions are available for a single patent per product, extends the patent term by up to five years and is subject to a maximum post-extension term of 14 years from approval.

Selecting the right patent for patent term extension is a strategic decision that requires modeling exclusivity scenarios across the portfolio, in coordination with regulatory counsel on the expected approval timeline.

European companies that default to protecting the compound patent for patent term extension may leave more commercially valuable patents unextended.

The decision should be made with explicit modeling of which patent, if extended, maximizes the commercial exclusivity window and should be revisited as the regulatory timeline develops.

With the EU Pharma Package reaching provisional agreement in December 2025, key IP-adjacent changes include a reduction in baseline market protection from 8+2 to 8+1 years; an expanded Bolar exemption covering pricing, reimbursement and procurement tender submissions during the supplementary protection certificate term; and new access conditionality provisions that can trigger loss of market protection for failure to launch.

The compression of European exclusivity timelines increases the relative commercial weight of U.S. patent term extension, making correct patent selection and the obviousness-type double patenting/terminal disclaimer interaction more consequential, not less.

10. Litigation Economics and Enforcement Posture

U.S. patent litigation is likely the most expensive in the world, and life sciences litigation is the most expensive segment within it.

A district court case through trial routinely costs each side several million dollars; a Hatch-Waxman case involving multiple Paragraph IV challenges can involve simultaneous proceedings across multiple patents and defendants. For European companies that have not yet been defendants in U.S. litigation, the economics are often underestimated.

Litigation readiness is a portfolio design criterion, not a reactive posture. This means building claim scope that can be asserted without undue estoppel risk, maintaining a continuation strategy that allows claim adjustment as competitors' products come to market, and conducting freedom-to-operate analyses on key U.S. competitors as a standing business intelligence function.

For business development teams, understanding which U.S. patents in a target company's portfolio are defensible, and which are likely litigation targets, is part of deal valuation, not post-close integration.

Conclusion

The pressure points discussed above are persistently costly for European companies because the decisions they require are made at the interface of legal, scientific, regulatory and commercial functions. Unfortunately, that interface may not be well organized, especially in the early stages of a company.

European patent counsel coordinating a U.S. filing program should ask the R&D team what is actually reduced to practice before a broad functional claim is filed; ask the compliance team when the biologics license application timeline implies a patent term extension election must be made; and ask the business development team what claim scope a prospective partner needs to see to assign value at term sheet.

The structural features of U.S. patent law reward exactly the kind of proactive, cross-functional IP strategy that creates durable commercial value. The 10 issues above are the recurring points at which that strategy either engages or fails to.

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