

6 Ways Biotechs Can Manage Double Patenting Rejection Risk

By **Carla Kim and Brian Dudley** (October 22, 2026)

At a time when the U.S. Patent and Trademark Office has urged applicants to submit fewer, more focused references by imposing escalating information disclosure statement, or IDS, size fees, a recent ruling may point in the opposite direction.

An August decision by the Patent Trial and Appeal Board's Appeals Review Panel about a Sanofi patent application, *Ex parte Baurin*, could force applicants to disclose an ever-expanding universe of later-filed applications. That tension has sent ripples through the patent community, creating unexpected risks for maintaining patent portfolios.

Although applicants have faced such rejections for years, they were relatively uncommon until recently, and applicants generally understood that later-filed, later-expiring patents ordinarily would not serve as the basis for an obviousness-type double patenting, or ODP, rejection in an earlier-filed, earlier-expiring application.

However, the *Baurin* panel effectively ended that presumption. The panel interpreted the narrow safe harbor recognized by the U.S. Court of Appeals for the Federal Circuit in 2024 in *Allergan USA Inc. v. MSN Laboratories* as applying only to the earliest-filed, first-issued application in a single family.^[1] In doing so, the panel drastically expanded the world of potential ODP reference patents. Under *Baurin*, later-filed, later-expiring patents may now serve as reference patents for ODP rejections in earlier-filed applications, with earlier priority dates.

A potential source of further guidance is in the decision about another Sanofi patent application, *In re: Ablynx NV*, which is currently pending before the Federal Circuit. That appeal, however, may not provide a complete answer to the questions raised by *Baurin*.

The issue in *Ablynx* is limited to whether an ODP rejection may be maintained solely to address the potential for harassment by multiple assignees when the challenged claims would not create an unjustified extension of patent term. However, a pending application may continue to accrue or ultimately receive patent term adjustment, or PTA, until issuance.

The USPTO has therefore taken the position that the possibility of PTA creates a potential for an unjustified extension of patent term, even if the application's term would not otherwise extend beyond that of the asserted ODP reference. Accordingly, even if the Federal Circuit rejects ODP based solely on the antiharassment rationale, its decision may not control where a pending application is eligible for PTA unless the applicant can otherwise eliminate the possibility of a PTA-based term extension, such as through a terminal disclaimer.

Therefore, practitioners should account for the USPTO's current approach while preserving challenges and protecting applicants' patent interests. This article identifies six areas requiring increased diligence in managing biotech and pharmaceutical portfolios.



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1. Assessing Materiality After Baurin

The duty of disclosure under Title 37 of the Code of Federal Regulations, Section 1.56, requires that applicants submit to the patent office any and all references that may be "material to the patentability" of a pending claim.[2] Materiality is defined, in part, as information that "establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim." [3]

Historically, patent practitioners assessing information material to patentability focused primarily on prior art, while also considering whether to cross-cite co-pending applications in the same family or priority chain that could support an ODP rejection.

Under the USPTO's current approach in Baurin, practitioners should consider whether later-filed applications — including applications claiming one or more species filed years after an earlier genus application — could support an ODP rejection against the earlier-filed claims. Managing large portfolios may therefore require ongoing review to identify later filings that may warrant disclosure in the pending applications.

In addition, given the current uncertainty, applicants should discuss the scope, cost and timing of supplemental IDS filings with relevant stakeholders, then document the resulting disclosure decisions.

2. Valuating Terminal Disclaimers Options

Applicants should consider filing a terminal disclaimer over the asserted ODP reference patent, rather than automatically contesting an ODP rejection. In many cases, the practical risk of a terminal disclaimer — principally its effects on patent term and enforceability — is limited, while challenging the rejection under the USPTO's current approach may be costly and uncertain. If those risks are low, a terminal disclaimer may provide the most efficient path to allowance.

That option becomes more complicated when related applications do not share common ownership. For example, a company may solely own an earlier platform application but jointly own a later application covering a collaborator's specific use. Under Baurin, the later-filed application could support an ODP rejection against the platform claims.

Unless the parties can align ownership or rely on an applicable statutory mechanism for treating the applications as commonly owned, however, the applicant may be unable to file an effective terminal disclaimer. Aligning ownership may be impractical or inconsistent with the parties' negotiated commercial arrangements.

3. Managing Collaboration-Related Risks

Congress enacted the Cooperative Research and Technology Enhancement, or CREATE, Act to prevent a collaborator's separately owned work from being used as prior art against inventions arising from joint research. Originally codified in Title 35 of the U.S. Code, Section 103(c), before the America Invents Act, the safe harbor now appears in Section 102(c), which treats qualifying subject matter developed under a joint research agreement, or JRA, as commonly owned for purposes of the statutory prior-art provisions.

Although a later-filed application arising under a qualifying JRA may serve as the basis for an ODP rejection, the CREATE Act's deemed-common-ownership framework allows the

parties to address the rejection through a terminal disclaimer. That option may not be available, however, when ODP is asserted against an earlier-filed platform application based on a later-filed, later-expiring species application because the JRA was not in effect on or before the effective filing date of the platform invention.

Avoiding collaboration may eliminate this risk, but that may not be practical in a lot of circumstances.

Another approach may be to structure the collaboration agreement to preserve common ownership for ODP purposes. For example, the party that owns the platform technology could solely own the later species application while granting the collaborator an exclusive license. This structure may preserve the ability to file a terminal disclaimer in the earlier-filed application while still providing the collaborator with the negotiated commercial rights.

This structure may not be workable when both parties contribute equally important platform technologies, especially when inventors from both parties jointly develop the resulting species combining the two. Even a single overlapping inventor may support an ODP rejection, while the lack of common ownership may prevent the parties from filing a terminal disclaimer.[4] In that circumstance, sole ownership by either party may not reflect the parties' respective contributions or commercial expectations, making the ODP risk more difficult to address through ownership and licensing terms alone.

4. Exercising Portfolio Management Vigilance

The Baurin approach also requires careful coordination of filing and abandonment practices. Before filing a later species application — particularly under the Track One program — applicants should assess whether expedited issuance could create an ODP problem for an earlier-filed platform application.

Applicants also should not abandon a later-filed, later-expiring patent merely because the technology or collaboration is no longer active; once that patent expires, it may remain an ODP reference, but a terminal disclaimer cannot be filed over it.[5]

Careful portfolio oversight is therefore essential to identify potential ODP issues before filing or abandonment decisions eliminate available options. Coordinating the timing, ownership, prosecution and maintenance of related applications can reduce ODP risk and preserve the ability to file a terminal disclaimer when needed.

5. Using Terminal Disclaimers to Eliminate Patent-Term Extension Concerns

If the Federal Circuit holds in *Ablynx* that the risk of harassment by multiple assignees, standing alone, cannot support an ODP rejection, applicants may have another option. An applicant could voluntarily file a terminal disclaimer in the rejected application based on a patent other than the asserted ODP reference — specifically, one that expires earlier than that reference.

Because the terminal disclaimer would limit the enforceable term of the resulting patent notwithstanding any otherwise available PTA, it would eliminate the possibility that PTA could extend the patent term beyond the disclaimer date. The disclaimer could therefore remove the term-extension rationale discussed above and leave antiharassment as the only asserted basis for the ODP rejection.

This approach is not ideal because it may surrender otherwise available patent term. But if a

terminal disclaimer over the later-filed, later-expiring reference is unavailable — such as where the relevant rights are not commonly owned — it may provide a path to overcoming the rejection. The strategy would depend on Ablynx being decided narrowly and favorably to the patent owner, with the Federal Circuit rejecting ODP where antiharassment is the only remaining concern.

6. Preparing to Traverse an ODP Rejection

If a terminal disclaimer is unavailable, the applicant must either amend the claims, if possible, or traverse the rejection on the merits. The appropriate response may depend on whether the examiner applies the one-way or two-way ODP test.

The one-way test asks whether the challenged claim would have been obvious over the reference claim. In the example above, the question is whether the earlier genus claim would have been obvious over the later-filed species claim.

The two-way test asks both whether the genus claim would have been obvious over the species claim and whether the species claim would have been obvious over the genus claim. Because the examiner must establish obviousness in both directions, the two-way test is generally more favorable to applicants.

Eligibility for the two-way test is narrow. A later filing date alone is not sufficient; the test applies only when the USPTO, rather than the applicant, caused the later-filed application to issue first.

Applicants should therefore prosecute important claims in earlier-filed applications promptly and avoid applicant-caused delays. Early genus applications should also claim important disclosed subject matter to reduce the risk of ODP from later-filed species applications.

Applicants should also minimize prosecution delays, including unnecessary extensions of time, that could be attributed to them and foreclose reliance on the two-way test.

For now, Baurin reflects the USPTO's current ODP approach and expands the potential universe of reference patents. Earlier genus claims may face ODP rejections based on species applications filed years later. Applicants should therefore coordinate portfolio review, ownership and collaboration terms, IDS practice, filing and abandonment decisions, and prosecution timing to identify ODP risks early and preserve available responses, including terminal disclaimers and the two-way test.

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[1] Allergan USA Inc. v. MSN Laboratories, 111 F.4th 1358 (Fed. Cir. 2024).

[2] 37 C.F.R. 1.56(a).

[3] 37 C.F.R. 1.56(b)(1).

[4] See *In re: Hubbell* , 709 F.3d 1140, 1147-49 (Fed. Cir. 2013).

[5] See *In re: Collect LLC* , 81 F.4th 1216, 1226 (Fed. Cir. 2023).