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What Data Says About Biologics-Related Ex Parte Challenges

By **Fievel Lim, Michael Green and John Molenda** (July 10, 2026, 6:08 PM EDT)


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Recent patent-owner-friendly rule changes to the Patent Trial and Appeal Board's inter partes review and postgrant review procedures may hinder future challenges, inducing petitioners to consider an alternative procedure, ex parte reexamination.

Following up on our January Law360 guest article examining biologics-related IPRs and PGRs from Sept. 16, 2012, through Dec. 31, 2025, we have used the same time frame to conduct an in-depth analysis of the 67 reexaminations challengers filed and their resolution by the U.S. Patent and Trademark Office.[1]

Our analysis reveals that while reexamination has a number of procedural disadvantages relative to IPRs and PGRs, reexamination may emerge as an alternative for challenging certain biologics-related patents, as foreshadowed by recent reports that reexamination requests have now eclipsed IPR filings across all technologies.[2]

Analysis of Biologics-Related Reexamination Requests

Timing and Volume of Requests

Over the 13-year time frame of study, we identified 67 biologics-related reexamination requests filed by patent challengers.[3] The timing of those requests is summarized in Figure 1.

The number of reexamination requests filed annually against biologics patents was relatively small, ranging from 10 at the high point in 2019 to two at the low point in both 2023 and 2025.

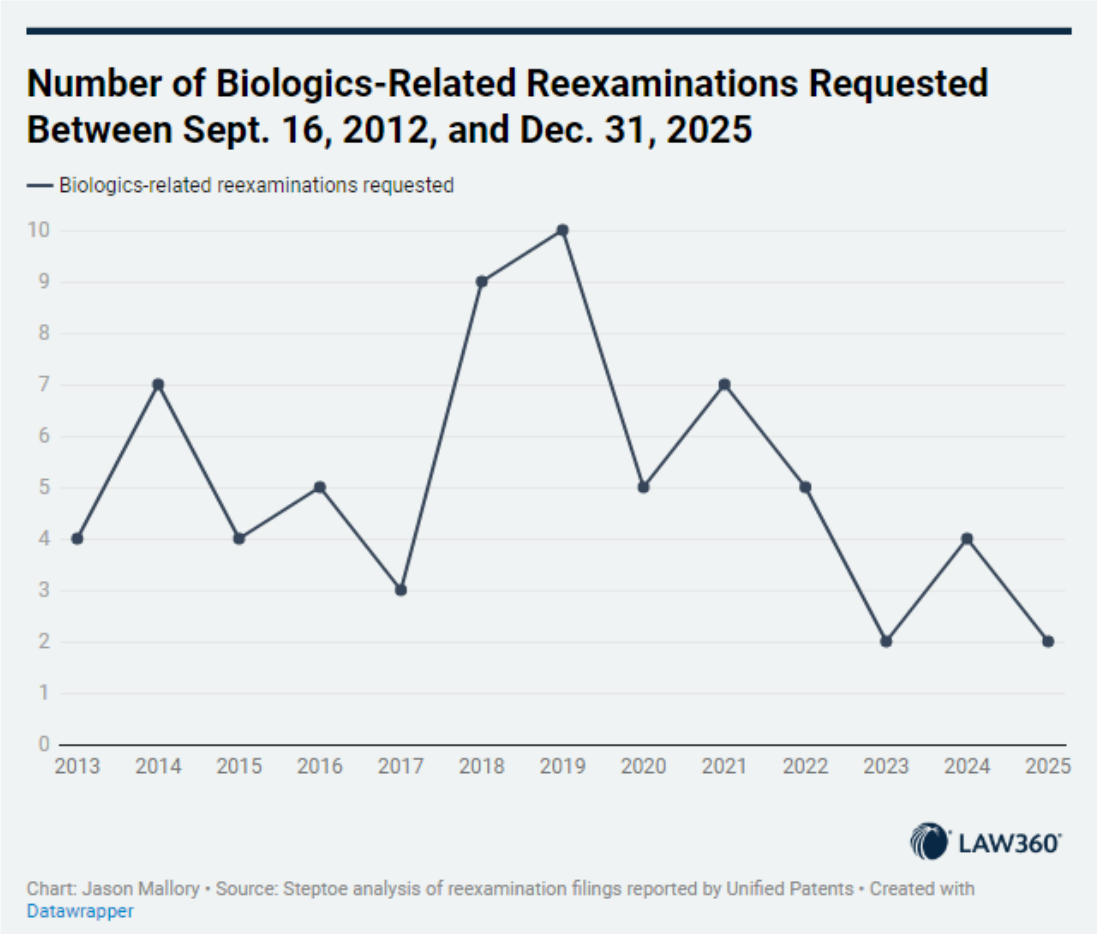
During this time frame, patent challengers substantially favored IPRs over reexaminations, as the number of IPR petitions (330) exceeded the number of reexamination requests (67) by almost sixfold.[4]

Those numbers are consistent with the fact that reexamination has several disadvantages relative to IPRs for patent challengers, most notably the requester's limited involvement after filing the request and the patent owner's ability to readily amend the claims.[5]

Additional disadvantages include the lack of a definitive timeline to conclude the proceedings[6] and the

requester's inability to terminate the proceedings,[7] which can impede settlement.

FIGURE 1



Despite these important disadvantages, reexamination does have several advantages over IPR proceedings, which may explain why some patent challengers have chosen the reexamination route.

Chief among them are lower cost, due to the requester's limited involvement;[8] the fact that reexamination decisions do not give rise to estoppel in litigation;[9] anonymity;[10] and the USPTO's reduced ability to deny review of the challenge for reasons beyond the merits, known as discretionary denial.[11]

As to the last point, the only reason the USPTO may discretionarily deny a reexamination request is previous consideration of the same prior art or arguments, but the USPTO may deny IPRs for many additional reasons.[12]

And while PGRs possess many of the same advantages and disadvantages as IPRs, it is interesting to note that unlike IPRs, patent challengers significantly favored reexaminations (67) over PGRs (43).

That difference may be attributed to the far narrower time frame in which patents may be challenged by PGR relative to IPR — nine months post-issuance versus anytime thereafter — as well as the greater scope of PGR estoppel relative to IPR estoppel.[13]

Those disadvantages of PGRs appear to outweigh their key advantage, namely the ability to raise non-prior-art-based defenses, such as written description and enablement.

Impact of Recent Rule Changes to USPTO Procedures

One advantage of reexamination over IPR and PGR for patent challengers is less susceptibility to discretionary denial.

In 2025, this advantage grew appreciably as the USPTO introduced several patent-owner-friendly changes to IPR and PGR procedures.[14]

By contrast, the USPTO made no patent-owner-friendly changes to reexamination procedures in 2025. As a consequence, filing trends shifted dramatically.

Prior to the policy changes, IPR petition filings across all technologies had been stable. On average, between 80 and 130 IPR petitions and between 20 and 40 reexamination requests were filed every four weeks.[15]

But starting in the fall of 2025, these trends reversed.[16] By early 2026, filings over a four-week period reached a high point of 130 for reexaminations and a low point of 11 for IPRs,[17] though counterintuitively, the early numbers revealed the opposite trend in the biologics space.[18]

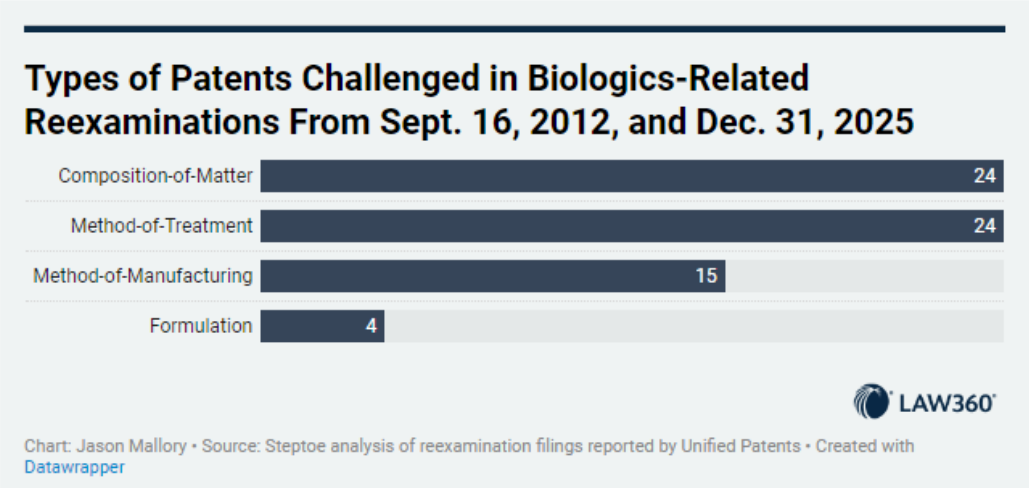
Apparently in response to this spike, in 2026 the USPTO introduced patent-owner-friendly rule changes to reexamination, including allowing patent owners to respond to a challenger's request for reexamination.[19]

While the impact of these changes is not yet reflected in the data, we believe that it is fair to expect that the current 94% grant rate for biologics-related reexamination requests discussed above will decrease by some degree.[20]

Types of Patents Challenged

We next analyze the types of patents challenged by reexamination, focusing on the predominant claim type for each patent.[21] Reexamination challenges by type of patent claim are summarized in Figure 2.

FIGURE 2



Each of these types of challenges is explored in detail below.[22]

Composition of Matter

The data reveals that the biologics patents most challenged by reexamination have been composition-of-matter patents (24 out of 67 petitions, or 36%) and included challenges to patents relating to Yescarta,[23] Avastin[24] and Remicade.[25][26]

This data is counterintuitive for two reasons.

First, many composition-of-matter patents, such as those directed to the sequence or functional properties of an active ingredient, are typically obtained early in a product's life cycle.

As such, they are often among the earliest patents to expire and would seemingly be the least likely to be challenged by a potential market entrant who might otherwise simply wait for such patents to expire.

Second, challenging this type of patent is often difficult given the limited availability of prior art, and the challenges that are often most effective — lack of written description and enablement — may not be asserted in reexamination proceedings.[27]

What may resolve this tension is the fact that composition-of-matter patents typically play a central role in blocking market entry, and potential market entrants may conclude that even if challenging such patents faces the hurdles noted above, the relatively low cost of filing a reexamination request is worth the expense of potentially getting to market earlier.[28]

Method of Treatment

Method-of-treatment patents were challenged as frequently as composition-of-matter patents (24 out of 67 petitions, 36%) and included challenges to patents relating to Remicade,[29] Zolgensma,[30] and Avonex.[31][32]

This high proportion may be due to two reasons: (1) the notion that these types of patents are particularly vulnerable to obviousness attacks and (2) that these types of patents often claim indications and dosing regimens set forth in the reference product's label, making those patents potentially effective at blocking market entry.[33]

Method of Manufacturing

Method-of-manufacturing patents (15 out of 67 petitions, or 22%) were challenged less frequently than method-of-treatment and composition-of-matter patents, which may be attributable to difficulties in locating invalidating prior art, just as with biologics-related IPRs and PGRs.[34][35]

Examples of challenged patents include process patents relating to Eylea,[36] Prolastin[37] and animal protein-free onabotulinum toxin A.[38]

Formulation

The least frequently challenged patents were formulation patents (4 out of 67 petitions, or 6%), and

included challenges relating to Eylea[39] and Moderna's developmental flu vaccine.[40][41]

The relatively small number is somewhat counterintuitive given that formulation patents, like method-of-treatment patents, are commonly perceived as relatively vulnerable to obviousness attacks.[42]

But it may be explained by the fact that clearing a path through these types of patents may not be immediate or necessary.[43] That is because challenger companies' product formulations may differ from the claimed formulations, making noninfringement arguments more effective than validity challenges.[44]

Analysis of Biologics-Related Reexamination Dispositions

We next explore the disposition of biologics-related reexaminations, including threshold decisions on whether to order reexamination, ultimate merits decisions and appellate decisions.

Decisions on Whether to Order Reexamination

Turning first to the threshold decision, in which the USPTO assesses whether the patent challenger's request (1) shows a substantial new question, or SNQ, and (2) is barred by Section 325(d), the data reveal that grant rates heavily favor challengers. The USPTO has ordered 94% of reexaminations (63 out of 67) and denied only 6% (4 out of 67), as Figure 3 below shows.

FIGURE 3

By contrast, IPRs and PGRs were instituted at a rate of 63%.[45] The high reexamination order rate appears to have been driven by both the relative ease of demonstrating an SNQ,[46] as well as the USPTO's limited discretionary denial ability.

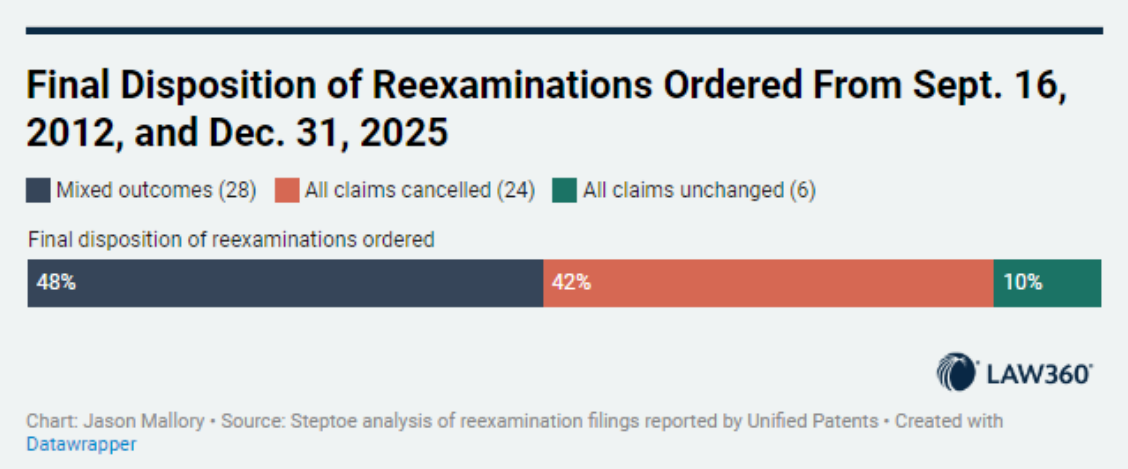
We expect the order rate to drop to some degree in view of the new procedure allowing the patent owner to file a preorder paper addressing whether the patent challenger has demonstrated an SNQ.[47]

Merits Decisions

Of the 63 cases where reexamination was ordered, the USPTO reached a merits determination in nearly all of them (58). As for the remainder, the patent owner disclaimed all challenged claims in two cases, and three cases remain pending.

In those cases where the USPTO reached a merits determination, all challenged claims were canceled in 24, or 41%.[48] The challenged claims had a mixed outcome, i.e., a mix of confirmation, cancellation and amendment,[49] in 28, or 48%. Interestingly, all challenged claims were confirmed without amendment in a mere six, or 10%. This data is summarized in Figure 4 below.

FIGURE 4



The rate of all challenged claims being canceled in ordered reexaminations (41%) is substantially lower than the cancellation rate in instituted IPRs (67%)[50] and PGRs (77%),[51] but those numbers must be viewed carefully, particularly in view of the differences between IPR, PGR and reexamination procedures.

While all claims being canceled is a useful metric of success, patent challengers can also achieve success in IPRs and PGRs, but not reexaminations, via favorable settlements once the PTAB has rendered a positive institution decision.

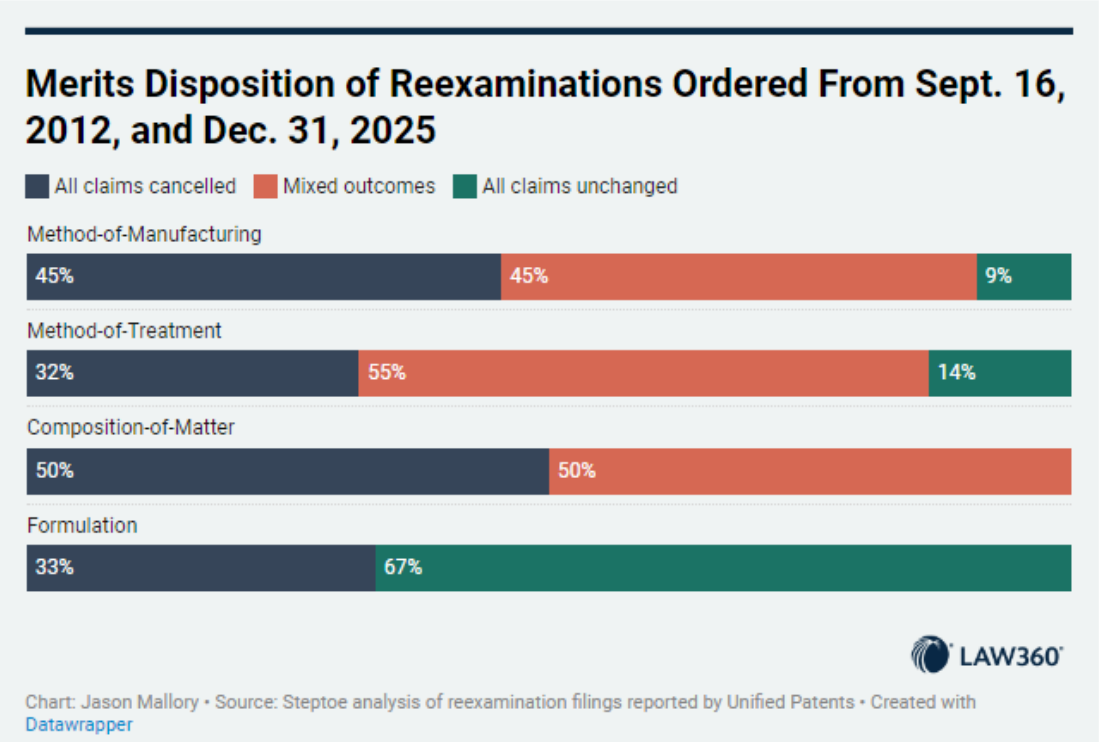
The cancellation rates for IPRs and PGRs may thus effectively undercount successful outcomes when comparing outcomes for IPRs and PGRs relative to reexaminations.

At the same time, the fact that the USPTO orders reexaminations at a substantially higher rate (94%) than instituting IPRs and PGRs (63% for both) offsets, at least to some degree, the lower cancellation rate of reexaminations relative to IPRs and PGRs.[52][53]

As for merits dispositions by patent type, the data show that requesters succeeded in rendering all claims canceled in 50% of reexaminations involving composition-of-matter patents (11 out of 22), 45% involving method-of-manufacturing patents (5 out of 11), 33% involving formulation patents (1 out of 3) and 32% involving method-of-treatment patents (7 out of 22). This patent-specific data is summarized in Figure 5.

Rates of merits dispositions holding all challenged claims canceled in reexaminations for each patent type individually were consistently lower than their IPR counterparts: method-of-treatment patents (32% versus 77%), composition-of-matter patents (50% versus 52%), method-of-manufacturing (45% versus 64%), and formulation patents (33% versus 58%).[54]

FIGURE 5



Appellate Decisions

Turning to appeals, patent owners appealed to the PTAB only five of the 58 reexaminations that reached a merits decision (9%), with each appeal arising from a decision canceling all claims.

As of Dec. 31, 2025, the PTAB had decided all five appeals: Three decisions were affirmed, one was dismissed for failure to pay the requisite fees and one was reversed. One of the PTAB affirmances was further appealed, which was affirmed again by the U.S. Court of Appeals for the Federal Circuit,[55] while the remaining PTAB decisions were not appealed.[56]

Conclusion

The data reveals that over the last 13 years, challengers to biologics-related patents have preferred IPRs by nearly sixfold over reexaminations.

That preference is apparently based on certain procedural disadvantages inherent to reexamination, including its ex parte nature, the ease with which a patent owner can amend claims, the lack of definitive timeline for resolution and the inability of a requester to terminate the proceedings.

But the recent implementation of several patent-owner-friendly discretionary denial rules, which have already reduced IPR institution rates, may diminish that preference.

The data reveals that the USPTO ordered reexamination in 94% of cases, a rate far higher than the institution rate for IPRs (63%).

Notably, not a single reexamination request we analyzed was denied for discretionary reasons. And

while the USPTO canceled all challenged claims in only 41% of ordered reexaminations, a rate appreciably lower than for instituted IPRs (67%), these numbers must be viewed carefully due to differences in institution rates and procedures between IPRs and reexaminations.

At the same time, reexaminations are typically much lower in cost than IPRs, do not give rise to estoppel in litigation and may be filed anonymously. We are thus not surprised by recent reports that, across all technologies, reexamination requests have now eclipsed IPR filings, though we have not yet observed the same trend in the biologics realm.

As for PGRs, patent challengers already prefer reexaminations, apparently in view of the limited window for bringing PGRs after patent issuance and the broad scope of estoppel associated with PGRs.

We expect that preference to grow for the same reasons as IPRs, though that growth may be mitigated by two factors.

First, the impact of discretionary denial rule changes is somewhat alleviated for PGRs.

As the USPTO proclaimed in its precedential July 16, 2025, decision in Multi-Color Corp. v. Brook & Whittle Ltd., PGR proceedings are favored over IPRs, given that PGR challenges must occur shortly after patent issuance.[57]

Second, the USPTO canceled all challenged claims at an appreciably lower rate in ordered reexaminations (41%) than in instituted PGRs (77%). But as with IPRs, those cancellation rates must be viewed carefully due to differences in institution rates (94% for reexamination and 63% for IPR) and procedures between PGRs and reexaminations.

So while reexamination has several procedural disadvantages relative to IPRs and PGRs, reexamination may emerge as an attractive alternative for challenging certain biologics-related patents, especially when challengers seek to avoid discretionary denial for reasons beyond Section 325(d).

And that may particularly be the case where challenges involve composition-of-matter and method-of-manufacturing patents, which have 50% cancellation rates in ordered reexaminations.

Cases involving relatively complex factual and legal issues, however, may be more suitable for IPR or PGR, as the adversarial process provides the challenger more opportunities to develop the record and respond to patent owner arguments.

IPRs and PGRs may also be preferable when challenging method-of-treatment patents, where the success rates are appreciably higher than for reexaminations.

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[1] Just as we did in our analysis of IPRs and PGRs, we included reexaminations in this article when the challenged patents involved compositions or formulations of "biological products" as defined by 42 U.S.C. § 262, 21 CFR § 600.3, and 9 CFR § 101.2, or involved manufacturing, or treating a disease with, such compositions or formulations. We excluded reexaminations involving diagnostic patents.

[2] Dennis Crouch, Decimation: Ex Parte Reexamination Eclipses the IPR, PatentlyO (May 2, 2026) available at https://patentlyo.com/patent/2026/05/decimation-ex-parte-reexamination-eclipses-the-ipr.html ("Crouch I"); see also Theresa Schliep, PTAB Petitions Continue to Plummet As Reexams Surge, Law360 (Apr. 17, 2026) available at https://www.law360.com/articles/2466468/ptab-petitions-continue-to-plummet-as-reexams-surge.

[3] This number does not include two reexaminations that the PTO terminated on procedural grounds without considering whether the requests raised a substantial new question of patentability (SNQ) as required to order the proceeding under 35 U.S.C. § 303. This number also does not include two instances in which a patent owner, the University of Pennsylvania, sought to preempt future invalidity challenges by twice seeking reexamination of its own patent relating to antibodies against EGFR. In the first case, all claims remained unchanged, and in the second, one claim was amended and many new claims were added. See Reexamination Nos. 90/014218 and 90/014282 (challenging U.S. Patent No. 7,625,558).

[4] See Lim et al., supra note 2, at 1.

[5] Davis I, supra note 6. While a requester may try to mitigate its lack of involvement by preemptively rebutting a patent owner's future arguments in support of patentability, such mitigation may be challenging given the difficulty in predicting what a patent owner may or may not argue.

[6] Davis I, supra note 6.

[7] MPEP § 2210.

[8] Before recent rule changes, a requester's only potential opportunity for post-filing involvement was a reply to an optional post-order statement by the patent owner. 37 CFR §§ 1.535, 1.550 (g). But a requester is generally deprived of that opportunity due to the patent owner foregoing the statement. Jason D. Eisenberg, The Dilemma with Patent Owner Statements Post-Reexamination Order, Sterne, Kessler, Goldstein & Fox Insights (Sept. 30, 2024) available at https://www.sternekessler.com/news-insights/insights/the-dilemma-with-patent-owner-statements-post-reexamination-order/.

[9] While § 315(e) and § 325(e) provide for IPR and PGR estoppel, respectively, no corresponding statute exists for reexamination. As such, a challenger may raise the same invalidity grounds in litigation that it raised or reasonably could have raised during reexamination proceedings. It is also worth noting that pending reexaminations cannot be terminated due to IPR or PGR estoppel, unlike pending IPRs and PGRs, which can. In re Gesture Tech. Partners, LLC, 160 F.4th 1317, 1321 (Fed. Cir. 2025).

[10] A reexamination requester may be identified as the law firm, rather than the client. Notably, the vast majority (57/67, 85%) of reexaminations were requested anonymously, suggesting that anonymity is an attractive feature to requesters in the biologics field. As for the few publicly-identified

requesters, Neuralstem requested multiple reexaminations against Stemcells California's patents relating to HuCNS stem cells. Reexamination Nos. 90/013375 (challenging U.S. Patent No. 7,115,418), 90/013347 (challenging U.S. Patent No. 5,851,832), 90/013322 (challenging U.S. Patent No. 6,497,872), and 90/013323 (challenging U.S. Patent No. 7,361,505). Bayer Healthcare Pharmaceuticals requested reexamination of Biogen's patents relating to Avonex®. Reexamination No. 90/014423 (challenging U.S. Patent No. 7,588,755). At the same time, Thrombolytic Science International and Biod challenged patents relating to thrombolytic therapy and acellular amnion-derived compositions, respectively. Reexamination Nos. 90/014116 (challenging U.S. Patent No. 9,211,317) and 90/013712 (challenging U.S. Patent No. 9,132,156). Additionally, the requesters identified themselves in three reexaminations relating to chemically modified hemoglobin, with Logtale filing two and Ikor filing one. Reexamination Nos. 90/013510 (challenging U.S. Patent No. 7,989,593), 90/013568 (challenging U.S. Patent No. 7,504,377), and 90/013569 (challenging U.S. Patent No. 7,494,974).

[11] Under 35 U.S.C. §§ 314, 324, and 325(d), the PTO possesses authority to exercise its discretion to deny proceedings for reasons beyond the merits. Sections 314 and 324 apply only to IPR and PGR proceedings, respectively, and no corresponding statute for reexamination exists. By contrast, section 325(d) applies to IPR, PGR, and reexamination proceedings. In re Vivint, Inc., 14 F.4th 1342, 1353-54 (Fed. Cir. 2021).

[12] See id. Additional common reasons for denial of an IPR include parallel litigation (Fintiv), serial PTAB proceedings (General Plastic), and the age of the patent (settled expectations).

[13] See Lim et al., supra note 2, at 8, 9 & n.35.

[14] Id. at 2 & n.7. Those changes included, inter alia, (1) rescission of guidance that helped petitioners avoid denial based upon parallel litigation, (2) introduction of denial based upon several new factors, notably including settled expectations, and (3) creation of a separate round of briefing affording patent owners more space to advocate for discretionary denial. Id. On top of those changes, the PTO has further proposed new IPR rules that would require a petitioner to surrender all anticipation and obviousness arguments in other proceedings against the challenged patent. Revision to Rules of Practice Before the Patent Trial and Appeal Board, 90 FR 48335 (Oct. 17, 2025). Those rules would prevent a petitioner from maintaining IPR proceedings if, in another proceeding, a challenged claim (1) has been found not invalid as anticipated or obvious or (2) will likely be adjudicated on those grounds before the final written decision is due.

[15] Crouch I, supra note 9.

[16] Id.

[17] Id.

[18] Reexamination filings dropped 50% (4 to 2) from 2024 to 2025, while the volume of IPR (12 to 21) and PGR (4 to 13) filings each increased.

[19] The PTO began allowing patent owners to file a pre-order paper "providing information useful to make the substantial new question [SNQ] determination." Director John A. Squires, U.S. Pat. & Trademark Off., Off. Gazette Notice, Pre-order Procedure Regarding Substantial New Question Determination in ex parte Reexamination Proceedings, https://www.uspto.gov/sites/default/files/documents/og-preorder-snq-apr2026.pdf (Apr.

1, 2026) ("Squires Notice"). Prior PTO regulations prevented the consideration of patent owner responses submitted before a reexamination was ordered. 37 CFR §§ 1.530(a), 1.540. To implement this change, the PTO left those regulations in place, but "waived" them. Squires Notice at 3. The PTO may waive its regulations in an "extraordinary situation" and "when justice requires." 37 CFR § 1.183. In this instance, the PTO viewed the high volume of reexamination requests being filed as such an extraordinary situation justifying waiver. Squires Notice at 3. According to one commentator, the use of waiver rather than amendment to implement this new rule suggests that this rule may only be a temporary measure. Dennis Crouch, Extraordinary by Design: How the USPTO Is Bypassing Its Own Reexamination Rules, PatentlyO (Apr. 15, 2026) available at https://patentlyo.com/patent/2026/04/extraordinary-by-design-how-the-uspto-is-bypassing-its-own-reexamination-rules.html ("Crouch II").

The PTO also began to require that anonymous requests challenging patents that have been the subject of a completed PTAB proceeding must provide an affirmative statement that IPR estoppel does not bar the real-party-in-interest from filing the request. U.S. Pat. & Trademark Off., Update Regarding the Filing of Anonymous Requests for Ex Parte Reexamination, available at https://www.uspto.gov/subscription-center/2026/update-regarding-filing-anonymous-requests-ex-parte-reexamination (Feb. 6, 2026). PTO regulations had required a statement that the requester not be estopped, but did not explicitly require the same of the requester's real-party-in-interest. 37 CFR § 1.510(b)(6). This change deters anonymous third-party requesters from repeatedly requesting reexaminations to challenge patents that have survived a PGR or IPR, as the PTO considers reexamination requests that lack the required statements to be "incomplete." MPEP § 2227.

[20] See Joshua Martineau & Jarom Kesler, New USPTO Procedure May Be A Boon For Patent Owners, Law360 (May 22, 2026) available at https://www.law360.com/ip/articles/2473409/new-uspto-procedure-may-be-a-boon-for-patent-owners; see also Ryan Davis, New Patent Owner Filings Expected To Drive Down Reexams, Law360 (Apr. 8, 2026) available at https://www.law360.com/articles/2462917/new-patent-owner-filings-expected-to-drive-down-reexams.

[21] In our previous articles we characterized patents based on the predominant claim type (composition-of-matter, formulation, method-of-manufacturing, or method-of-treatment). We follow that approach here.

[22] We note that unlike with IPR and PGR petitions, where a majority of challenges relate to FDA-approved products, a minority of reexamination requests relate to FDA-approved products. See, e.g., infra notes 30-32, 36-38, 43-44, 46 and accompanying text. Rather, the patent estate that was the most frequent target of challenges was that of SNIPR's developmental genetically-modified bacteriophage product, with seven reexamination requests filed against that estate. Reexamination Nos. 90/014877 (challenging U.S. Patent No. 10,920,222), 90/015048 (challenging U.S. Patent No. 11,291,723), 90/015047 (challenging U.S. Patent No. 11,351,252), 90/014705 (challenging U.S. Patent No. 10,953,090), 90/014681 (challenging U.S. Patent No. 10,920,222), 90/014230 (challenging U.S. Patent No. 9,701,964), and 90/014184 (challenging U.S. Patent No. 9,701,964). Another frequent target for challenges was the natural killer cell therapy patent estate of National University of Singapore and St. Jude Children's Research Hospital, with five requests filed. Reexamination Nos. 90/014883 (challenging U.S. Patent No. 10,829,737), 90/014882 (challenging U.S. Patent No. 10,774,309), 90/014779 (challenging U.S. Patent No. 9,511,092), 90/014353 (challenging U.S. Patent No. 9,511,092), and 90/014175 (challenging U.S. Patent No. 9,511,092).

[23] Reexamination Nos. 90/013790 (challenging U.S. Patent No. 7,741,465) and 90/013630 (challenging U.S. Patent No. 7,741,465).

[24] Reexamination No. 90/014063 (challenging U.S. Patent No. 8,314,225).

[25] Reexamination No. 90/012851 (challenging U.S. Patent No. 6,284,471).

[26] When comparing reexamination filings against composition-of-matter patents to IPR and PGR filings against such patents, any conclusions that may be drawn appear limited. While the number of challenges to composition-of-matter patents was far higher for IPRs (72) compared to reexaminations (24), the percentage of challenges against composition-of-matter patents was lower for IPRs (22%) than for reexaminations (36%). At the same time, while the number of challenges was about the same for PGRs (25) and reexaminations (24), the percentage of challenges was far higher for PGRs (58%) than for reexaminations (36%). The relatively high proportion of PGR challenges suggests that patent challengers favor that proceeding given one's ability to bring lack of written description and enablement challenges.

[27] See Mark A. Lemley & Jacob S. Sherkow, The Antibody Patent Paradox, 132 Yale L.J. 994, 1020-37 (2023) (describing effectiveness of written description and enablement arguments in challenging functional claims covering antibodies).

[28] See John Molenda & Richard Praseuth, Current Trends in Biologics-Related Inter Partes Reviews, Law360 (July 20, 2017) available at **https://www.law360.com/articles/942459/current-trends-in-biologics-related-inter-partes-reviews**, at 2.

[29] Reexamination Nos. 90/013031 (challenging U.S. Patent No. 8,383,120) and 90/012881 (challenging U.S. Patent No. 7,846,442).

[30] Reexamination No. 90/014290 (challenging U.S. Patent No. 9,926,574).

[31] Reexamination No. 90/014423 (challenging U.S. Patent No. 7,588,755).

[32] The number and percentage of challenges to method-of-treatment patents were higher for IPRs (149, 45%) compared to reexaminations (24, 36%). By contrast, the number of PGRs filed (12) was only half of the number of reexaminations (24), and the percentage of challenges was likewise lower for PGRs (28%) than for reexaminations (36%). The lower percentage of challenges brought by PGR may reflect that these patents are often susceptible to obviousness attacks, which may be best suited for reexamination and IPR to avoid the risk of PGR estoppel.

[33] See Molenda & Praseuth, supra note 35, at 2.

[34] See Molenda & Praseuth, supra note 35, at 4.

[35] The number of challenges to method-of-manufacturing patents by reexamination (15) was fewer than for IPRs (39) but greater than for PGRs (1). Nonetheless, the percentage of challenges against method-of-manufacturing patents for reexaminations (22%) was almost identical to the percentage for IPRs (21%) but again greater than the percentage for PGRs (2%). The low numbers concerning PGR challenges may reflect difficulty in bringing non-prior-art-based defenses against method-of-manufacturing patents and overarching concerns regarding estoppel.

[36] Reexamination No. 90/014449 (challenging U.S. Patent No. 10,406,226).

[37] Reexamination No. 90/013008 (challenging U.S. Patent No. 6,462,180).

[38] Reexamination Nos. 90/015635 (challenging U.S. Patent No. 11,147,878) and 90/015636 (challenging U.S. Patent No. 11,203,748).

[39] Reexamination No. 90/014448 (challenging U.S. Patent No. 10,464,992).

[40] Reexamination No. 90/014167 (challenging U.S. Patent No. 9,872,900).

[41] The number of reexaminations (4) was fewer than the number of IPRs (39), though nearly identical to the number of PGRs (5). In terms of percentages, challenges to formulation patents were low across the board for all types of challenges, representing a mere 6% of reexaminations and only 12% of IPRs and PGRs. As with reexaminations, the low numbers of IPRs and PGRs may reflect patent challengers' abilities to design formulations different than those claimed, as well as an acknowledgement that obviousness arguments in the context of biologics-related formulation patents face certain unique challenges. See Lim et al., supra note 2, at 5 & n.17.

[42] See Michael Green et al., A Comprehensive Overview of PTAB Trends for Biologics, Law360 (June 26, 2023) available at https://www.law360.com/articles/1692966/a-comprehensive-overview-of-ptab-trends-for-biologics, at 3.

[43] Id.

[44] Id.

[45] See Lim et al., supra note 2, at 4, 11.

[46] Multiple commentators have noted that the standard for the PTO ordering a reexamination (SNQ) is lower than the standard for the PTO instituting an IPR or PGR (a "reasonable likelihood" that petitioner will prevail in showing that at least one claim is unpatentable). See, e.g., Lionel M. Lavenue et al., EPR Academy, Part 1 of 6: Introduction to EPR – Understanding Ex Parte Reexamination at the USPTO, Finnegan Insights (Oct. 21, 2025) available at https://www.finnegan.com/en/insights/articles/epr-academy-introduction-to-epr-understanding-ex-parte-reexamination-at-the-uspto.html; Katie E. Hyma et al., EPRx 201: The Risks and Rewards of Ex Parte Reexamination, Fish Insights (Apr. 4, 2025) available at https://www.fr.com/insights/ip-law-essentials/eprx-201-the-risks-and-rewards-ofex-partereexamination/.

[47] See supra notes 26-27 and accompanying text.

[48] Interestingly, the rate of all challenged claims being cancelled in biologics-related reexaminations (41%), is appreciably higher than the rate across all technologies (24%) for approximately the same period. The rate across all technologies was calculated by analyzing the PTO's cancellation data between September 2012 and September 2025. Compare U.S. Pat. & Trademark Off., Ex Parte Reexamination Historical Statistics, https://www.uspto.gov/sites/default/files/documents/ex_parte_historical_stats_.pdf at 1-2 (2025) with U.S. Pat. & Trademark Off., Ex Parte Reexamination Historical Statistics, https://www.uspto.gov/sites/default/files/documents/ex_parte_historical_stats_roll_up_3.pd

f at 13-14 (2018).

[49] Amendments can vary widely in their impact on the challenged patent. On the one hand, amendments required by the examiner may significantly narrow the claims. But on the other hand, the patent owner may be able to add new claims beyond those it already possesses.

[50] See Lim et al., supra note 2, at 6.

[51] Id. at 11.

[52] See Sections III.A-B, supra.

[53] We expect reexamination order rates to drop to some degree due to recent changes to reexamination procedures, see supra notes 26-27 and accompanying text, just as biologics-related IPR institution rates have dropped due to recent changes to IPR procedures, see Lim et al., supra note 2.

[54] As for the comparison to PGRs, given the low number of final written decisions for PGRs (9), a meaningful comparison by patent type could not be drawn.

[55] See In re Janssen Biotech, Inc., 880 F.3d 1315 (Fed. Cir. 2018).

[56] The rate of reexamination appeals to the Federal Circuit (2%) was substantially lower than the rates for IPRs (85%) and PGRs (44%). One explanation for this lower rate may be the fact that only the patent owner may appeal a reexamination decision. Another reason may be the simpler reexamination process, which may give rise to a more limited appellate record and thus fewer appealable issues.

[57] Multi-Color Corp. v. Brook & Whittle Ltd., PGR2025-00025, Paper 10 at 2-3 (PTAB July 16, 2025) (precedential).