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Checking In On Biologics-Related Patent Review Trends

By **Fievel Lim, Michael Green and John Molenda** (January 30, 2026, 6:14 PM EST)


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From the creation of the Patent Trial and Appeal Board on Sept. 16, 2012, through Dec. 31, 2025, petitioners have filed a total of 330 biologics-related inter partes review petitions and 43 post-grant review petitions.[1]

We have conducted an in-depth review of those petitions and their resolution by the PTAB and the U.S. Court of Appeals for the Federal Circuit, and identified a number of trends and correlated those trends to concurrent developments in the biopharma industry and legal landscape.

Our analysis of over 13 years of data has confirmed our view that IPRs and PGRs have functioned as potent weapons for challenging biologics-related patents, both for innovators seeking to launch new biologics and applicants seeking to launch biosimilars.[2]

Recent policy changes by the U.S. Patent and Trademark Office may in some cases blunt those weapons, particularly when challenging certain types of biologics patents. Such changes may in some cases induce petitioners to favor PGRs over IPRs or even abandon both approaches altogether in favor of ex parte reexamination.

Overall Timing and Volume of Biologics-Related IPR Petitions, Including Types of Patents Challenged

Timing and Volume of Filings

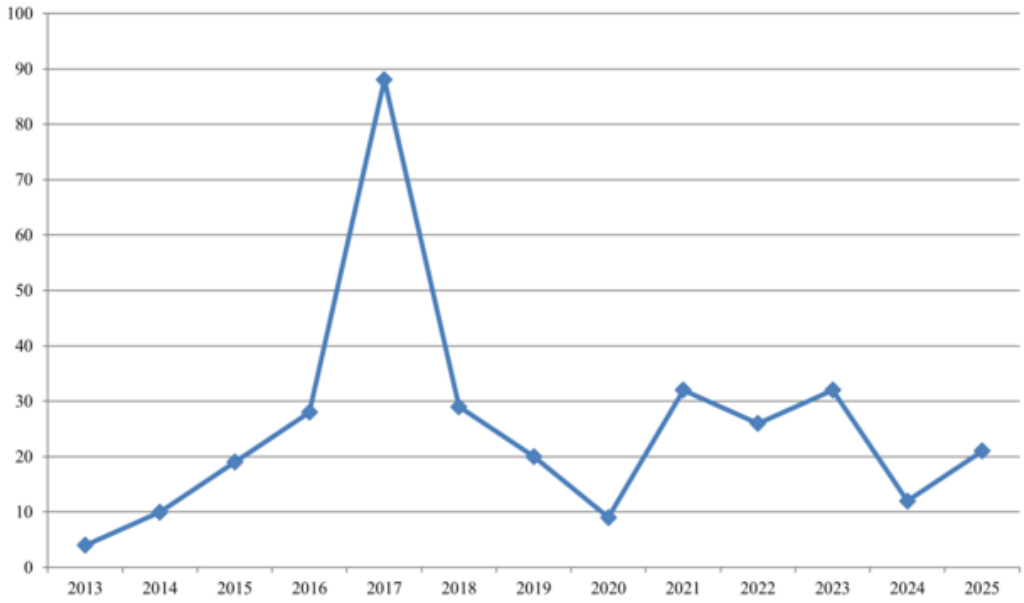
Over the 13-year time frame of study, a robust data set of 330 biologics-related IPR petitions arose.

Following a slow start in 2013 and 2014, where petitioners filed a mere 14 petitions in those years combined, those numbers rose to about 25 per year in 2015 and 2016.[3]

A sharp rise followed in 2017, which turned out to be the high-water mark of IPR filings, with 88 petitions filed that year, accounting for over 25% of the biologics-related IPR petitions filed since the inception of the procedure.[4]

The number of petitions generally held steady from 2018 to 2023, with about 20 to 30 petitions filed per

Figure 1: Number of Biologics-Related IPR Petitions Filed Between Sept. 16, 2012, and Dec. 31, 2025



year, save for a drop in 2020 to nine, likely attributable to the COVID-19 pandemic.[5] The number of petitions dropped again in 2024 to 12, with no apparent explanation.

In 2025, the number of petitions returned to prior levels with 21 filed, though these numbers may have been higher but for the patent-owner-friendly changes to institution procedures promulgated by the USPTO that year.[6]

In particular, the USPTO modified how it evaluates whether to discretionarily deny institution, i.e., deny institution for reasons beyond a petition's merits.[7] Looking forward, the USPTO has proposed new rules that would continue its patent-owner-friendly trajectory, potentially further discouraging IPR challenges.[8]

Since our Law360 guest article in June 2023, patents in the Eylea estate were again among those most frequently challenged, with nine IPRs filed against that estate.[9][10] Merck's Keytruda[11] estate also became a common target for challenges, with the same number filed against it in that time frame. Patents relating to AAV gene therapy technology were likewise frequently targeted.[12]

Types of Patents Challenged

Across the entire 13-year time frame of the IPR procedure,[13] the most challenged patents have been method-of-treatment patents, at 149 out of 330 petitions challenged, or 45%.[14]

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, thereby blocking market entry.[15]

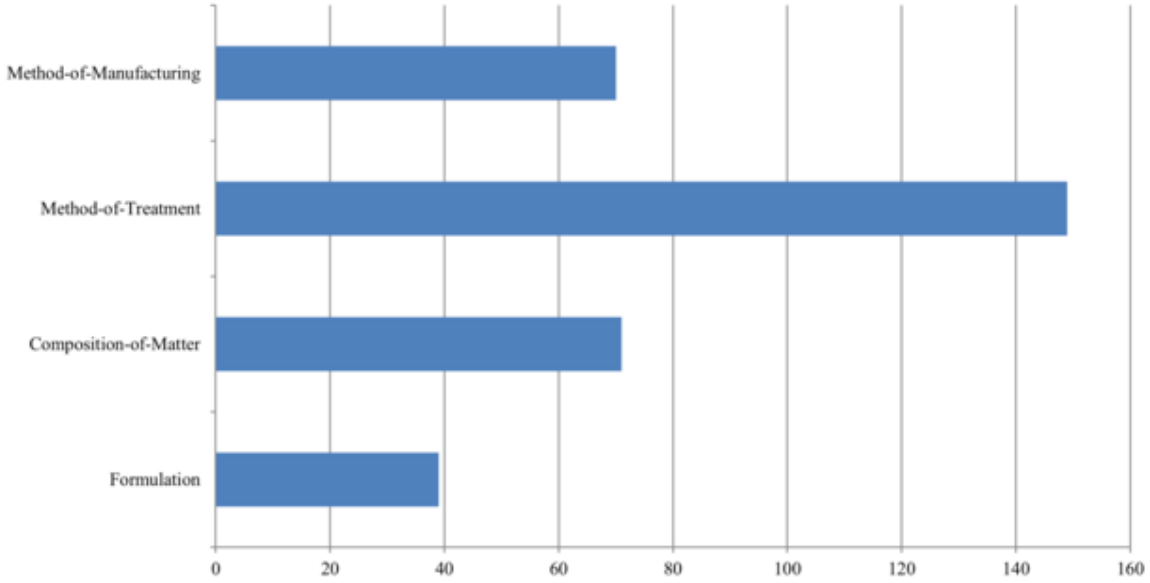
The second-most-challenged patents were composition-of-matter patents, at 72 out of 330 petitions challenged, or 22%.[16] That type of patent likewise plays a central role in blocking market entry, but the number of petitions is considerably lower relative to method-of-treatment patents.

That lower number may reflect difficulties in locating invalidating prior art, and that the challenges that are typically most effective — lack of written description and enablement — may not be asserted in IPR proceedings.[17]

At the same time, method-of-manufacturing patents, at 70 out of 330 petitions challenged, or 21%, were challenged at about the same rate as composition-of-matter patents, which again may reflect difficulties in locating invalidating prior art.[18][19]

The least-frequently-challenged patents were formulation patents, with 39 out of 330 petitions challenged, or 12%.[20] The relatively small number is surprising given that formulation patents, like method-of-treatment patents, are commonly perceived as being vulnerable to obviousness attacks, though design-around strategies may render such attacks unnecessary.[21]

Figure 2: Types of Patents Challenged in Biologics-Related IPR Petitions From Sept. 16, 2012, to Dec. 31, 2025



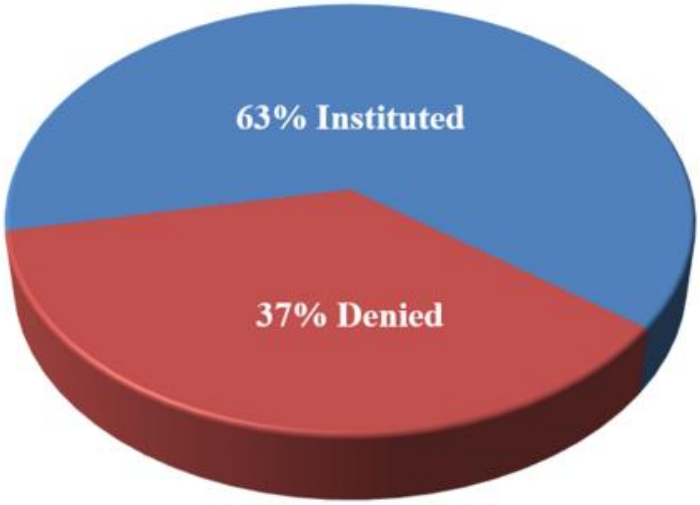
Institution and Final Written Decisions of Biologics-Related IPRs

We next explore how the USPTO has approached rendering institution decisions and final written decisions, or FWDs, on biologics-related IPRs.[22] Turning first to institution,[23] the data reveal that institution rates tend to favor challengers, with the USPTO instituting 63% of petitions (180 of 284) and denying 37% of petitions (104 of 284).

Notably, after implementation of new institution procedures on March 26, 2025, the institution rate has been only 37.5% (6 of 16) — well below the overall rate since September 2012 — though the sample size is small.

That recent drop is consistent with, though not quite as dramatic as, the reduced institution rate for challenges across all technologies of 18% (44 of 246) since USPTO Director John Squires assumed authority for institution decisions in October 2025.[24]

Figure 3: Disposition of IPR Petitions at the Institution Phase From Sept. 16, 2012, to Dec. 31, 2025



With respect to institution rates by patent type, the USPTO instituted a surprising 69% of IPRs involving composition-of-matter patents (45 of 65), showing that petitioners were able to locate strong prior art in most challenges.

Going forward, however, institution rates for challenges to composition-of-matter patents may decrease. That is because such challenges may be most susceptible to discretionary denial based upon settled expectations, as composition-of-matter patents are often the earliest to issue in a product's life cycle.

As for method-of-treatment patents, the USPTO instituted about 67% of IPRs (86 of 128), a figure consistent with the perceived vulnerability of such patents. The USPTO instituted about 58% of IPRs challenging method-of-manufacturing patents (33 of 57), which was higher than expected, given perceived difficulties in locating sufficiently strong prior art.

Interestingly, the data showed that challenges to formulation patents were instituted at a rate of only 47% (16 of 34), despite the conventional wisdom of formulation patents being particularly vulnerable to obviousness attacks.

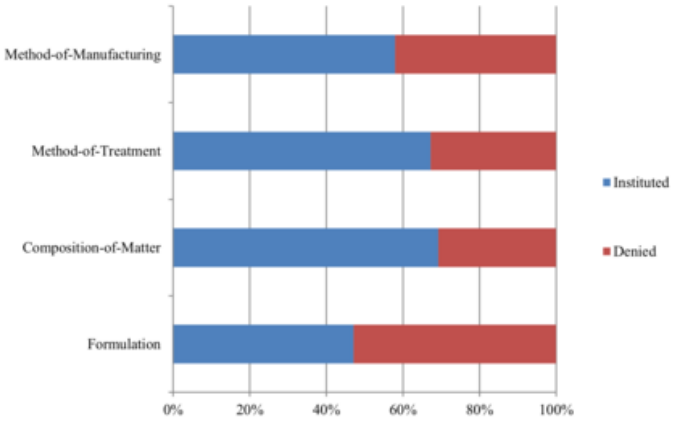
One possible explanation for the lower rate may be the lack of "a generic approach for protein formulation," given "[t]he exquisite sensitivity of protein structure, function, and stability to the primary sequence," according to the PTAB's 2016 decision in Momenta Pharmaceuticals Inc. v. Bristol-Myers Squibb Co.[25]

In any event, these data underscore the importance of formulation patents in the life-cycle management of biologics-related products.

Turning next to FWDs and other postinstitution outcomes, of the 180 biologics-related IPRs instituted as of Dec. 31, 2025, the USPTO resolved 119 by an FWD on the merits and resolved 56 by settlement or termination. Five remain pending.

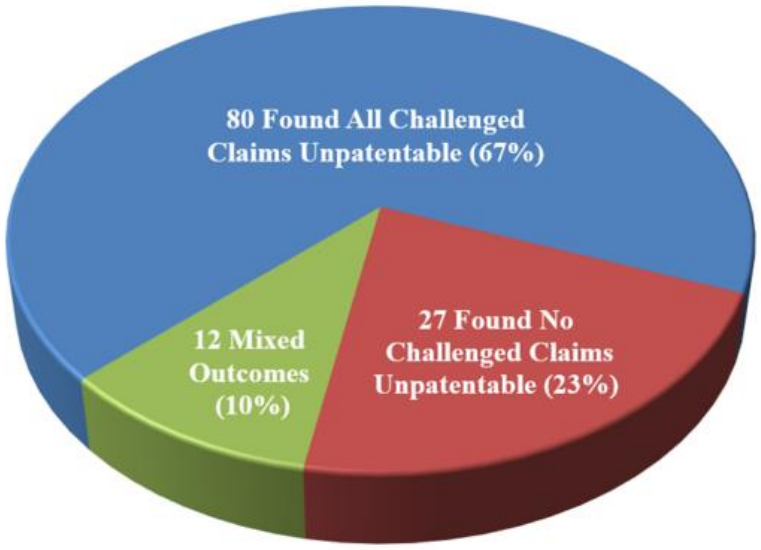
Petitioners achieved considerable success in the 119 IPR petitions resolved on the merits. The USPTO

Figure 4: Disposition of IPR Petitions, per Patent Type, at the Institution Stage From Sept. 16, 2012, to Dec. 31, 2025



decided about 67% of petitions in the challenger's favor (80 of 119) and roughly 23% in the patentee's favor (27 of 119), while about 10% had mixed outcomes (12 of 119).[26]

Figure 5: Disposition of IPR Petitions Postinstitution From Sept. 16, 2012, to Dec. 31, 2025

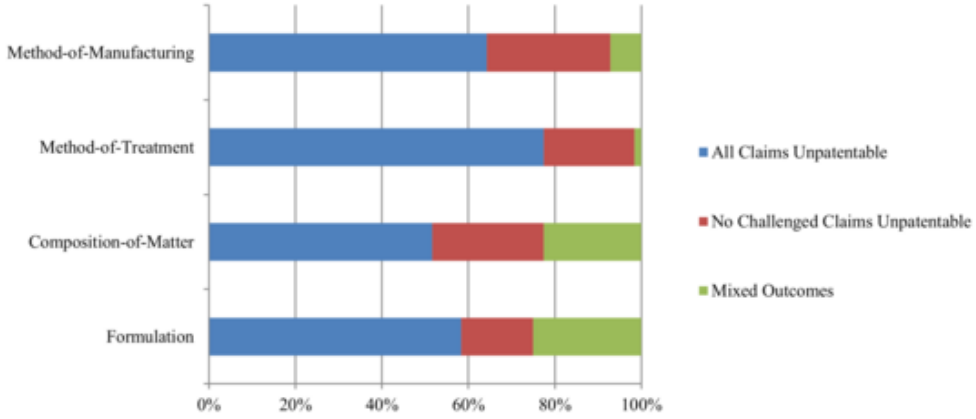


As for postinstitution disposition by patent type, the data show that petitioners succeeded in proving all challenged claims unpatentable in about 77% of IPRs involving method-of-treatment patents (48 of 62).

Petitioners achieved similar success in about 52% of IPRs involving composition-of-matter patents (16 of 31).

Petitioners achieved such success in about 58% of IPRs (7 of 12) involving formulation patents and 64% of IPRs (9 of 14) involving method-of-manufacturing patents, but this data should be viewed with caution, given the limited number of decisions on the merits.

Figure 6: Percent Disposition After Institution Stage per Patent Type From Sept. 16, 2012, to Dec. 31, 2025

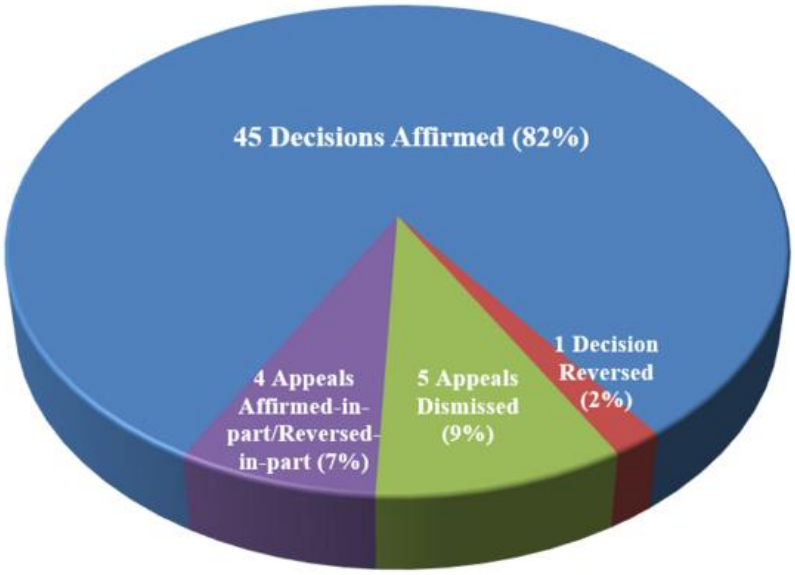


Appellate Dispositions of Biologics-Related IPRs

Turning next to biologics-related IPR appeals, 105 decisions have been appealed from the PTAB to the Federal Circuit.[27] As of Dec. 31, 2025, the Federal Circuit had decided 55 of 105 appeals.

The Federal Circuit affirmed 45 decisions on every issue (82%), reversed one decision on every issue (2%), affirmed-in-part and reversed-in-part in four appeals (7%), and dismissed five appeals (9%).[28]

Figure 7: Appellate Dispositions of 55 Cases From Sept. 16, 2012, to Dec. 31, 2025



This high affirmance rate appears largely attributable to the substantial deference the Federal Circuit affords the PTAB's factual findings underlying its patentability determinations.[29] And perhaps not surprisingly, given the high value of the products involved, nearly 85% (101 of 119) of IPR FWDs pertaining to biologics-related patent challenges have been appealed to the Federal Circuit.

Focusing on the decisions since our last guest article in June 2023, the Federal Circuit has issued 13 decisions: nine affirmances on every issue and four affirmances-in-part and reversals-in-part.

Affirmances on every issue included one involving a patent relating to Regeneron Pharmaceuticals Inc.'s Eylea,[30] three involving patents relating to CSL Behring LLC's Hemgenix gene therapy,[31] one involving a patent related to Restem LLC's developmental COVID-19 treatment using umbilical stem cells,[32] and two involving patents related to guide RNA used in CRISPR technology.[33]

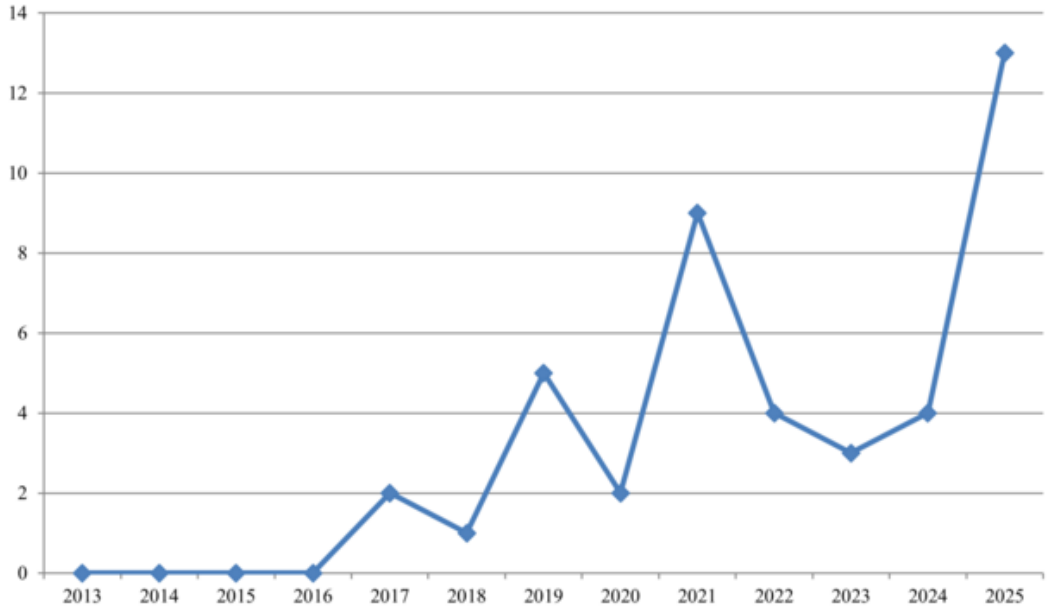
The six remaining decisions involved patents relating to Cytiva's Protein A chromatography resin products, with two affirmed on every issue and four affirmed-in-part and reversed-in-part.[34]

Biologics-Related PGRs

PGR challenges to biologics-related patents were far less common than IPR challenges, with IPR challenges outnumbering PGR challenges by a ratio of more than seven to one.[35]

Not a single biologics-related PGR petition was filed from the inception of the procedure on Sept. 16, 2012, through 2016. From 2017 to 2024, the number of petitions filed per year ranged from one to nine, with the number reaching a high point of 13 in 2025.

Figure 8: Number of Biologics-Related PGR Petitions Filed Between Sept. 16, 2012, and Dec. 31, 2025



Overall, only 43 biologics-related PGRs have been filed since the inception of the procedure, and for that reason, any conclusions that may be drawn from the existing data must be viewed with caution.

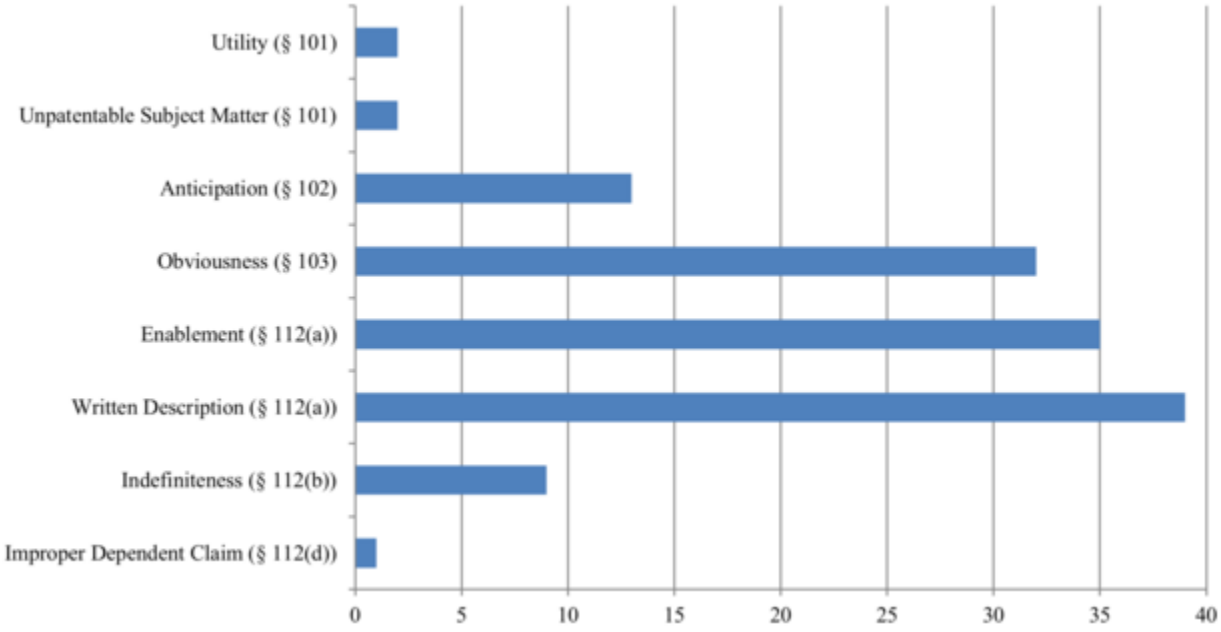
It should also be noted that a single filer, Merck, has brought over one-third (19 of 43) of all biologics-related PGR petitions. Merck has filed 15 of those petitions since November 2024, challenging patents relating to PH20 polypeptides to clear a path for its Keytruda Qlex product.[36]

Those PGRs add to the several IPRs relating to Merck's Keytruda product noted above.[37] Merck's remaining PGR petitions relate to pneumonia vaccines and combination therapies involving a PD-1

antagonist with a TIGIT inhibitor.[38]

The reluctance of the biopharma industry to file PGR petitions relative to IPR petitions is likely due to the potentially far greater estoppel impact arising from PGR proceedings on district court litigations involving the same patent.[39]

Figure 9: Frequency of Statutory Grounds Alleged in PGRs Filed Through Dec. 31, 2025



Some of the recent changes to institution procedures may further deter PGRs, as with IPRs.[40] But one change, the use of settled expectations as a discretionary consideration, may affect PGRs less than IPRs, or even promote PGR challenges.

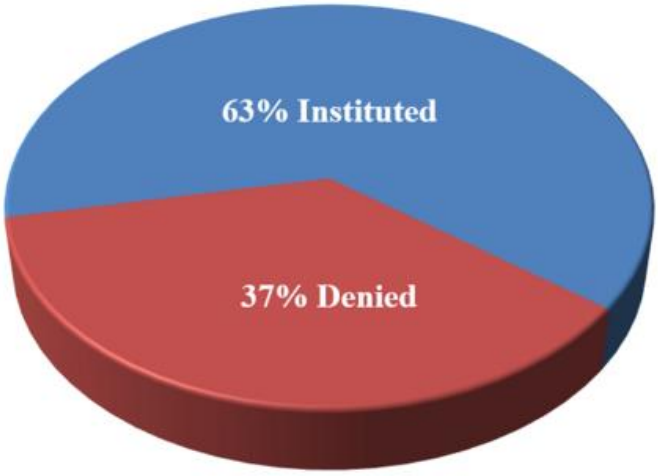
That is because such challenges are limited to newly issued patents, thus occurring before settled expectations can arise.[41] For this reason, the director has proclaimed that PGRs are favored.[42]

Looking at the 43 PGR petitions by patent type, 25 petitions challenged composition-of-matter patents (58%), 12 petitions challenged method-of-treatment patents (28%), one petition challenged a method-of-manufacturing patent (2%), and five petitions challenged formulation patents (12%).

Turning to the statutory grounds for those challenges, the data indicate that written description (39 of 43 petitions) and enablement (35 of 43) were the most frequent, consistent with the common understanding that they are among the most effective arguments in the biologics realm, particularly as to composition-of-matter patents.[43]

With respect to the resolution of the 43 PGRs as of Dec. 31, 2025, 38 have reached the institution stage, with the USPTO instituting 24 (63%) and denying institution of 14 (37%).[44]

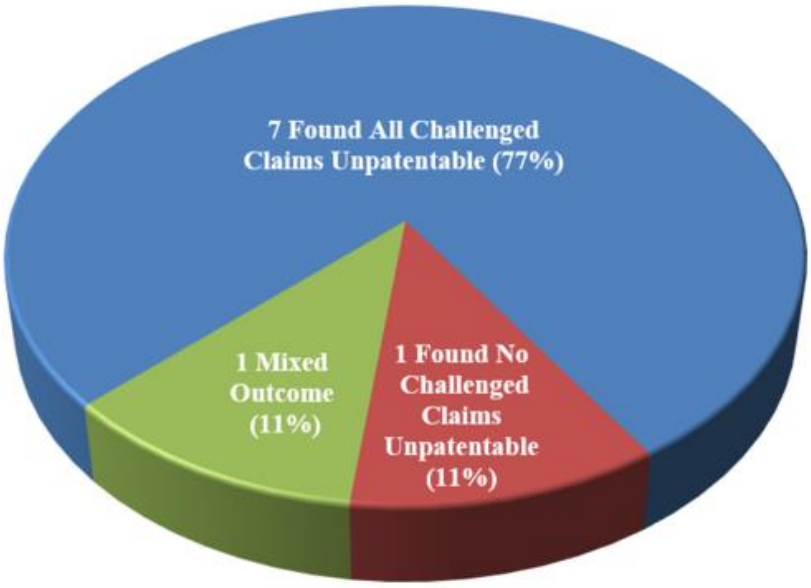
Figure 10: Disposition of PGR Petitions at the Institution Phase From Sept. 16, 2012, to Dec. 31, 2025



The PGR institution rate of 63% mirrors the IPR institution rate, which is somewhat counterintuitive in view of the availability of additional statutory grounds to challenge patent claims in PGR proceedings.

Of the 24 instituted petitions, all challenged patent claims were held unpatentable in seven FWDs, some but not all claims were held unpatentable in one FWD, no claims were held unpatentable in one FWD, one petition was resolved by settlement, and 14 petitions remain pending.

Figure 11: Disposition of PGR Petitions Postinstitution From Sept. 16, 2012, to Dec. 31, 2025



Conclusion

Petitioners have filed 330 biologics-related IPR petitions over the last 13 years, affording a robust picture of statistical trends in biologics-related IPRs.

The lion's share of petitions have involved challenges to method-of-treatment patents (45%), with many fewer challenges to composition-of-matter patents (22%), method-of-manufacturing patents (21%) and formulation patents (12%).

The overall institution rate for biologics-related IPR petitions has tended to favor challengers, with the USPTO granting 63% of petitions and denying 37%, though that grant rate has recently dipped following the USPTO's implementation of new institution procedures.

As for institution rates by patent type, the USPTO instituted review in about 69% of cases involving composition-of-matter patents, about 67% for method-of-treatment patents, about 58% for method-of-manufacturing patents, and about 47% for formulation patents.

For the 119 instituted IPRs resolved by an FWD, petitioners achieved considerable success, with roughly 67% of decisions holding all claims unpatentable and 10% more holding at least some claims unpatentable.

Petitioners achieved particular success in IPRs involving method-of-treatment patents, with about 77% of FWDs holding all claims unpatentable. Petitioners also achieved favorable outcomes in challenging other patent types, with 64%, 58% and 52% of FWDs holding all claims unpatentable for method-of-manufacturing patents, formulation and composition-of-matter patents, respectively.

About 85% (101 of 119) of biologics-related FWDs were appealed, with the Federal Circuit affirming in 82% of its decisions.

As for PGRs, the biopharma industry's willingness to use them remains limited, with only 43 petitions filed since the inception of the procedure. There has been a recent uptick, with 13 petitions filed in 2025, though most relate to a single product.

Certain recent changes to institution procedures appear to favor PGRs over IPRs, particularly those relating to the settled-expectations aspect of the discretionary denial analysis, and thus may tip the scales toward PGRs going forward.

In sum, the data suggest that IPRs and PGRs can be an attractive and effective weapon to challenge biologics-related patents, both from the standpoint of innovators and biosimilar applicants.

While the USPTO has implemented patent-owner-friendly institution procedures, early data suggest that IPRs and PGRs continue to be instituted, though the IPR rate appears to be reduced.

These new procedures may induce patent challengers to employ PGRs over IPRs or opt for other procedures entirely, such as ex parte reexaminations, which rose 66% across all technologies from 2024 to 2025.[45]

We expect the biopharma industry to continue employing these procedures as market conditions, product launches and discretionary factors warrant, and we look forward to analyzing future statistical trends and the reasons underlying them.

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John Molenda is a partner and co-chair of the health and life sciences practices at the firm.

[1] We included petitions 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 therefore excluded petitions involving, for example, patents primarily relating to diagnostics or basic research.

[2] This conclusion is consistent with those set forth in prior articles analyzing trends in biologics-related IPRs and PGRs. 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; Justin Rosinski et al., Unpacking The Latest Trends In Biologics-Related IPRs, Law360 (June 4, 2021) available at https://www.law360.com/articles/1390911/unpacking-the-latest-trends-in-biologics-related-iprs; 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.

[3] As explained previously, the relatively low numbers from 2013 to 2014 may be attributed to the biopharma industry's reluctance to employ post-grant procedures generally and unfamiliarity with the new IPR procedure specifically, not to mention the lack of an immediate need to employ such procedures given that most biosimilar programs were in their infancy. See Molenda & Praseuth, supra note 3, at 3. By 2015 and 2016, such programs had sufficiently advanced such that the need to clear patents blocking market entry had become sufficiently acute. Id.

[4] As we also explained previously, the 2017 spike may be attributed to path-clearing activity by both biosimilar applicants striving to bring their biosimilars to market and innovators aiming to bring various new antibody therapies and vaccines to market. See Rosinski et al., supra note 3, at 3-4 & nn. 7-12.

[5] Notably, as a result of COVID-19, drug developers experienced a slowdown in clinical development in 2020. Brijesh Sathian et al., Impact of COVID-19 on Clinical Trials and Clinical Research: A Systematic Review, 10(3) Nepal J. Epidemiology 878, 886 (2020).

[6] PTAB petitions across all technologies declined by almost 6% from 2024 to 2025. Theresa Schliep, PTAB Denials, Reexams & New Patent Suits Rose In 2025, Law360 (Jan. 15, 2026) available at https://www.law360.com/ip/articles/2430239/ptab-denials-reexams-new-patent-suits-rose-in-2025 ("Schiliep I").

[7] For example, the PTO rescinded its more petitioner-friendly guidance regarding discretionary denial in view of parallel litigation, which had made dispositive various factors such as whether the petition had compelling merits. Ryan Davis, PTAB Denial Rules Shaken Up By Fintiv Memo Withdrawal, Law360 (Feb. 28, 2025) available at https://www.law360.com/articles/2304602/ptab-denial-rules-shaken-up-by-fintiv-memo-withdrawal. At the same time, the PTO also introduced new bases for discretionary denial such as "settled expectations," which is the concept that, as time passes following a patent's issuance, a

patent owner develops "expectations" that the patent will not be challenged at the PTAB. Ryan Davis, Patent Landscape Shifts As Squires Takes On Key PTAB Role, Law360 (Oct. 21, 2025) available at https://www.law360.com/articles/2401378/patent-landscape-shifts-as-squires-takes-on-key-ptab-role ("Davis II"). Settled expectations generally appear to arise when a patent has been in force for at least six years. Id. The PTO also created a separate round of discretionary denial briefing, thereby affording patent owners additional briefing space to advocate for discretionary denial. U.S. Pat. & Trademark Off., Interim Director Discretionary Process, available at https://www.uspto.gov/patents/ptab/interim-director-discretionary-process (Oct. 3, 2025) ("Interim Process"). It is also worth noting that the Director has expedited decisions denying institution by assuming responsibility for issuing those decisions and generating terse orders. Theresa Schliep, Squires Institutes 8 Patent Reviews, Denies 16 Others, Law360 (Jan. 20, 2026) available at https://www.law360.com/articles/2432086/squires-institutes-8-new-patent-reviews-denies-16-others ("Schliep II").

[8] Ryan Davis, Proposed New Rules Would Cut Off Many PTAB Challenges, Law360 (Oct. 16, 2025) available at https://www.law360.com/articles/2400377. Those new rules, for example, would require petitioners to surrender all anticipation and obviousness arguments in other proceedings against the challenged patent and prevent IPRs from being instituted or maintained if it is more likely than not that a decision on the validity of the challenged claims would be rendered in another proceeding before the final written decision is due. Id.

[9] See Green et al., supra note 3, at 1.

[10] See Samsung Bioepis Co., Ltd. v. Regeneron Pharms., Inc., IPR2023-01312 (filed Aug. 18, 2023, challenging claims of U.S. Patent No. 10,464,992); IPR2025-00176 (filed Nov. 20, 2024, challenging claims of U.S. Patent No. 11,084,865); Biocon Biologics Inc. v. Regeneron Pharms., Inc., IPR2024-00201 (filed Nov. 20, 2023, challenging claims of U.S. Patent No. 10,888,601); IPR2024-00298 (filed Dec. 18, 2023, challenging claims of U.S. Patent No. 11,253,572); Celltrion, Inc. v. Regeneron Pharms., Inc., IPR2024-00260 (filed Dec. 14, 2023, challenging claims of U.S. Patent No. 11,253,572); IPR2025-00456 (filed Jan. 15, 2025, challenging claims of U.S. Patent No. 11,084,865); Formycon AG v. Regeneron Pharms., Inc., IPR2025-00233 (filed Dec. 2, 2024, challenging claims of U.S. Patent No. 11,084,865); Fresenius Kabi SwissBioSim GmbH v. Regeneron Pharms., Inc., IPR2025-01268 (filed July 14, 2025, challenging claims of U.S. Patent No. 11,084,865); IPR2025-01269 (filed July 14, 2025, challenging claims of U.S. Patent No. 10,828,345).

[11] See Merck Sharp & Dohme LLC v. The Johns Hopkins Univ., IPR2024-00240 (filed Nov. 30, 2023, challenging claims of U.S. Patent No. 11,591,393); IPR2024-00622 (filed Mar. 4, 2024, challenging claims of U.S. Patent No. 10,934,356); IPR2024-00623 (filed Mar. 4, 2024, challenging claims of U.S. Patent No. 11,325,974); IPR2024-00624 (filed Mar. 4, 2024, challenging claims of U.S. Patent No. 11,325,975); IPR2024-00625 (filed Mar. 4, 2024, challenging claims of U.S. Patent No. 11,339,219); IPR2024-00647 (filed Mar. 13, 2024, challenging claims of U.S. Patent No. 11,649,287); IPR2024-00648 (filed Mar. 13, 2024, challenging claims of U.S. Patent No. 11,643,462); IPR2024-00649 (filed Mar. 13, 2024, challenging claims of U.S. Patent No. 11,629,187); IPR2024-00650 (filed Mar. 13, 2024, challenging claims of U.S. Patent No. 11,634,491).

[12] See Novartis Gene Therapies, Inc. v. Genzyme Corp., IPR2023-01044 (filed June 30, 2023, challenging claims of U.S. Patent No. 10,429,288); IPR2023-01045 (filed June 30, 2023, challenging claims of U.S. Patent No. 10,429,288); Sarepta Therapeutics, Inc. v. The Trs. of the Univ. of Pa., IPR2024-00580 (filed Feb. 21, 2024, challenging claims of U.S. Patent No. 11,680,274); Sarepta Therapeutics, Inc.

v. Genzyme Corp., IPR2025-01194 (filed June 26, 2025, challenging claims of U.S. Patent No. 9,051,542); IPR2025-01195 (filed June 26, 2025, challenging claims of U.S. Patent No. 7,704,721); IPR2026-00149 (filed Nov. 25, 2025, challenging claims of U.S. Patent No. 12,013,326); IPR2026-00150 (filed Nov. 25, 2025, challenging claims of U.S. Patent No. 12,031,894); IPR2026-00166 (filed Dec. 2, 2025, challenging claims of U.S. Patent No. 12,298,313); IPR2026-00167 (filed Dec. 2, 2025, challenging claims of U.S. Patent No. 11,698,377); IPR2026-00168 (filed Dec. 2, 2025, challenging claims of U.S. Patent No. 12,123,880).

[13] As in our previous articles we characterized patents based on the predominant claim type, i.e., composition-of-matter, formulation, method-of-manufacturing, or method-of-treatment.

[14] Examples of challenges to method-of-treatment patents include most of the recent challenges to patents relating to Eylea® and Keytruda®. See supra notes 11-12.

[15] See Molenda & Praseuth, supra note 3, at 2.

[16] An example of a recent challenge to a composition of matter patent is Samsung Bioepis Co., Ltd. v. Alexion Pharms., Inc., IPR2023-00933 (filed May 18, 2023, challenging claims of U.S. Patent No. 9,732,149), relating to Soliris®.

[17] 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); infra note 36.

[18] See Molenda & Praseuth, supra note 3, at 4.

[19] Examples of recently challenged process patents include those directed to methods of preventing AAV aggregation and methods for producing heterodimeric antibodies. Sarepta Therapeutics, Inc. v. Genzyme Corp., IPR2025-01195 (filed June 26, 2025, challenging claims of U.S. Patent No. 7,704,721); Xencor, Inc. v. Merus N.V., IPR2025-00604 (filed Feb. 11, 2025, challenging claims of U.S. Patent No. 9,358,286).

[20] Five of the new petitions challenging formulation patents were related to Eylea®. See supra note 11.

[21] See Green et al., supra note 3, at 1.

[22] On March 26, 2025, the Director began issuing discretionary denial decisions separately from the PTAB's institution decisions. Interim Process, supra note 8. On October 17, 2025, primary responsibility for institution decisions shifted from the PTAB to the Director. Davis II, supra note 7. The PTAB has maintained, however, responsibility for FWDs. For simplicity, we refer to all decisions as being made by the PTO. And for analytical consistency, we have considered decisions to either (1) discretionarily deny institution or (2) deny institution on the merits as a denial of institution.

[23] Our analysis of overall institution rates and institution rates for specific patent types does not include the 8 of 330 petitions that were awaiting an institution decision as of December 31, 2025, as well as the 38 of 330 petitions that were terminated or settled prior to the institution decision, leaving 284.

[24] See Schliep II, supra note 8. Discretionary denial has played a significant role in the reduced institution rate, as discretionary denial increased by 630% from 2024 to 2025. Id.

[25] See Momenta Pharms., Inc. v. Bristol-Myers Squibb Co., IPR2015-01537, Paper 37 at 8 (PTAB Dec. 22, 2016) (crediting prior art teachings as to challenges involved in protein formulation and holding formulation claims not unpatentable).

[26] A mixed outcome generally arises from an FWD finding some challenged claims unpatentable while finding others patentable. But a mixed outcome also arose in a case—decided before SAS Inst. Inc. v. Iancu, 584 U.S. 357, 363 (2018)—where not all claims were instituted, though the Board ultimately found the instituted claims unpatentable.

[27] Of those 105 appeals, 101 (96%) were from FWDs, including 68 appeals (65%) from FWDs in which all claims were held unpatentable, 25 appeals (24%) from FWDs in which no claims were held unpatentable, 8 appeals (8%) from FWDs in which some but not all claims were held unpatentable. Of the remaining 4 appeals, 2 (2%) were from denials of institution and 2 (2%) were from denials of pre-institution stage dismissals on sovereign immunity grounds. By patent type, 59 appeals (56%) involved method-of-treatment patents, 23 appeals (22%) involved composition-of-matter of patents, 12 appeals (11%) involved method-of-manufacturing patents, and 11 appeals (10%) involved formulation patents.

[28] This affirmance rate is consistent with (though slightly higher than) other reported affirmance rates of IPR decisions across all technologies. See, e.g., Daniel F. Klodowski et al., Federal Circuit PTAB Appeal Statistics for September-November 2025, Finnegan at the PTAB Blog (Dec. 30, 2025) available at https://www.finnegan.com/en/insights/blogs/at-the-ptab-blog/federal-circuit-ptab-appeal-statistics-for-september-november-2025.html (reporting that the Federal Circuit affirmed IPR decisions on every issue at a rate of 75%). It should be noted that six decisions that the Federal Circuit vacated and remanded in light of United States v. Arthrex, Inc., 141 S. Ct. 1970, 1972 (2021) were not categorized based on that outcome. Rather, we categorized each of those cases based on their post-remand outcome: four cases settled, one decision was appealed again and then reversed, and one case remains pending (awaiting oral argument date in second Federal Circuit appeal).

[29] See In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000) (establishing deferential substantial evidence standard as the standard of review for Board-related fact finding).

[30] See Regeneron Pharms., Inc. v. Novartis Pharma AG, No. 2023-1334, 2024 WL 4258368 (Fed. Cir. Sept. 23, 2024).

[31] See uniQure Biopharma B.V. v. Pfizer Inc., No. 2023-1404, 2025 WL 1465627 (Fed. Cir. May 22, 2025).

[32] See Restem, LLC v. Jadi Cell, LLC, 130 F.4th 941 (Fed. Cir. 2025).

[33] See Agilent Techs., Inc. v. Synthego Corp., 139 F.4th 1319 (Fed. Cir. 2025).

[34] See Cytiva Bioprocess R&D AB v. JSR Corp., 122 F.4th 876 (Fed. Cir. 2024).

[35] As distinguished from IPR petitions, which can be filed no earlier than nine months after a patent issues, PGR petitions must be filed within the first nine months after patent issuance. Compare 35 U.S.C. § 311(c) (IPR) with 35 U.S.C. § 321(c) (PGR). And while IPRs allow for the assertion of only anticipation (§

102) and obviousness (§103) as grounds for unpatentability, PGRs allow for the assertion of any statutory ground of unpatentability, most notably written description (§ 112(a)), enablement (§ 112(a)), and indefiniteness (§ 112(b)). Compare 35 U.S.C. § 311(b) (IPR) with 35 U.S.C. § 321(b) (PGR).

[36] See Merck Sharp & Dohme Corp. v. Halozyme, Inc., PGR2025-00003 (filed Nov. 12, 2024, challenging claims of U.S. Patent No. 11,952,600); PGR2025-00004 (filed Nov. 26, 2024, challenging claims of U.S. Patent No. 12,018,298); PGR2025-00006 (filed Dec. 10, 2024, challenging claims of U.S. Patent No. 12,152,262); PGR2025-00009 (filed Dec. 27, 2024, challenging claims of U.S. Patent No. 12,123,035); PGR2025-00017 (filed Jan. 17, 2025, challenging claims of U.S. Patent No. 12,110,520); PGR2025-00024 (filed Feb. 21, 2025, challenging claims of U.S. Patent No. 12,060,590); PGR2025-00030 (filed Feb. 4, challenging claims of U.S. Patent No. 12,054,758); PGR2025-00033 (filed Mar. 7, 2025, challenging claims of U.S. Patent No. 12,049,652); PGR2025-00039 (filed Mar. 28, 2025, challenging claims of U.S. Patent No. 12,104,185); PGR2025-00042 (filed Apr. 15, 2025, challenging claims of U.S. Patent No. 12,037,618); PGR2025-00046 (filed Apr. 29, 2025, challenging claims of U.S. Patent No. 12,091,692); PGR2025-00050 (filed May 7, 2025, challenging claims of U.S. Patent No. 12,077,791); PGR2025-00053 (filed June 6, 2025, challenging claims of U.S. Patent No. 12,195,773); PGR2025-00052 (filed June 27, 2025, challenging claims of U.S. Patent No. 12,264,345).

[37] See supra note 12.

[38] See Merck Sharp & Dohme Corp. v. Genentech, Inc., PGR2021-00039 (filed Jan. 20, 2021, challenging claims of U.S. Patent No. 10,626,174); PGR2021-00036 (filed Jan. 7, 2021, challenging claims of U.S. Patent No. 10,611,836); Merck Sharp & Dohme Corp. v. Wyeth LLC., PGR2017-00017 (filed Mar. 24, 2017, challenging claims of U.S. Patent No. 9,399,060); PGR2017-00016 (filed Mar. 22, 2017, challenging claims of U.S. Patent No. 9,399,060).

[39] See Green et al., supra note 3, at 4 & n.34.

[40] See supra note 8.

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

[42] Id.

[43] See, e.g., Lemley & Sherkow, supra note 18.

[44] Of the remaining petitions that did not reach the institution stage, 2 were terminated pre-institution and 3 remain pending.

[45] See Schliep I, supra note 7.