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A Comprehensive Overview Of PTAB Trends For Biologics

By **Michael Green, Larry Kass and John Molenda** (June 26, 2023, 6:43 PM EDT)


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From the creation of the Patent Trial and Appeal Board on Sept. 16, 2012, through April 27, 2023, petitioners have filed a total of 280 biologics-related inter partes review petitions and 24 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. As part of that review, we have identified a number of trends and correlated those trends to concurrent developments in the biopharma industry.

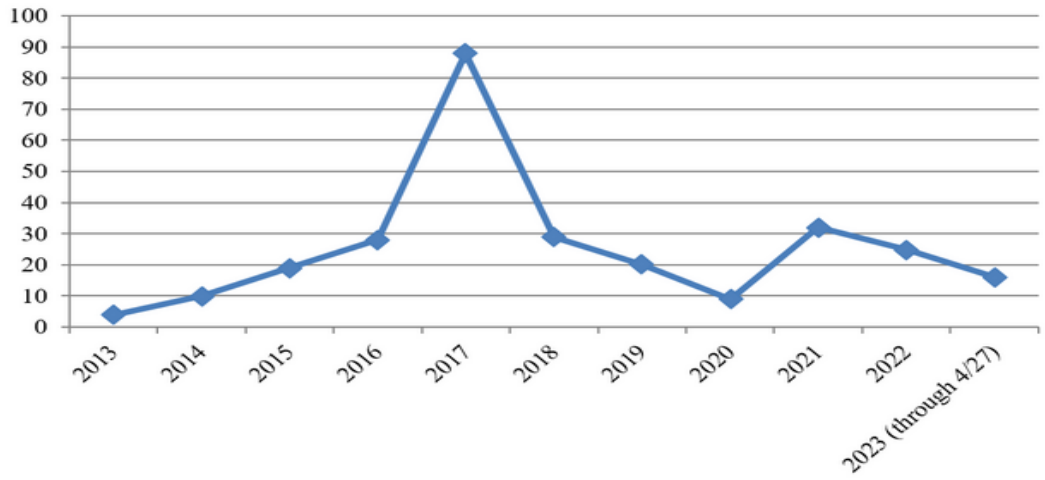
Our analysis of over 10 years of data has confirmed our view that IPRs and PGRs are potent weapons for challenging biologics-related patents, both on the part of innovators seeking to launch new biologics and applicants seeking to launch biosimilars of existing biologics.[2]

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

Timing and Volume of Filings

With a 10 ½-year time frame to draw from, we have acquired a robust data set of 280 biologics-related IPR petitions to analyze. The timing of those petitions[3] is summarized below in Figure 1:

Figure 1: Number of Biologics-Related IPR Petitions Filed Between Sept. 16, 2012, and April 27, 2023



After a slow start in 2013 and 2014 with a mere 14 petitions combined,[4] those numbers rose to about 25 per year in 2015 and 2016.[5]

A sharp rise followed in 2017, which turned out to be the high-water mark, with 88 petitions filed that year, accounting for over 30% of the 280 biologics-related IPR petitions filed since the inception of the procedure.[6]

The number of petitions subsequently returned to pre-2017 levels: from 2018 to 2022, there was an average of about 25 petitions per year, reaching a low of 9 in 2020 and a high of 32 in 2021. In 2023, the number of petitions appears poised for an uptick, with 16 already filed in the first four months of that year.

Since our 2021 analysis in Law360, the most frequent challenges have been to the patent estates of Regeneron Pharmaceuticals Inc.'s Eylea[7] and F. Hoffmann-La Roche Ltd.'s Actemra[8] products, with biosimilar manufacturers filing 16 and 9 challenges, respectively, in that time frame.

Notably, Fresenius Kabi USA LLC's IPR challenges against the Actemra estate successfully facilitated settlement without the need to resort to district court litigation.[9]

Additionally, equipment used in the manufacture of biologics has been frequently targeted, such as Cytiva's protein A chromatography resin[10] and Organovo's bioprinter.[11]

Types of Patents Challenged

Across the entire 10 ½-year time frame of the IPR procedure, the most challenged patents[12] have been method-of-treatment patents, at 125 out of 280 petitions, or 45%.[13]

This high proportion of challenges 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 more effective at blocking market entry.[14]

The second-most challenged patents were composition-of-matter patents, at 64 out of 280 petitions, or 23%.

While composition-of-matter patents likewise play a central role in blocking market entry, the considerably lower number of petitions relative to method-of-treatment patents may be attributable to difficulties in locating invalidating prior art, and the fact that the most effective challenges for this patent type are typically lack of written description[15] and lack of enablement,[16] grounds that may not be asserted in IPR proceedings.[17]

In any event, many of the challenged patents related to blockbuster drugs, so these challenges were likely essential to enable petitioners to market their respective biosimilar products.[18]

Method-of-manufacturing patents, at 60 out of 280 petitions, or 21%, were challenged at about the same rate as composition-of-matter patents, which again may be attributable to difficulties in locating invalidating prior art.[19] Examples of processes challenged since our last article include preserving nucleic acids,[20] culturing cells,[21] isolating antibodies[22] and bioprinting.[23]

The least frequently challenged patents were formulation patents, at 31 out of 280 petitions, or 11%.

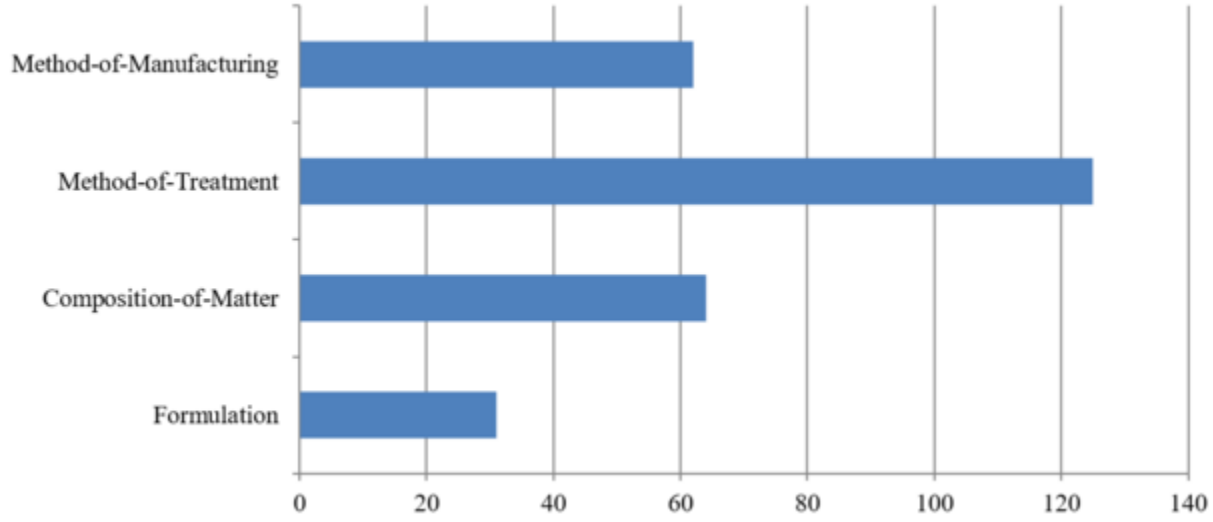
The relatively small number of challenges is surprising given that formulation patents, like method-of-treatment patents, are commonly perceived as relatively vulnerable to obviousness attacks.

The need to clear a path through these types of patents, however, may not be immediate or necessary given that challenger companies' product formulations may differ from the claimed formulations, making noninfringement arguments more effective than validity challenges.

In any event, three of the new petitions challenging formulation patents were to, perhaps unsurprisingly, the estates of Eylea[24] and Actemra.[25]

The data regarding challenges by patent type are summarized below in Figure 2:

Figure 2: Types of Patents Challenged in Biologics-Related IPR Petitions From Sept. 16, 2012, to April 27, 2023

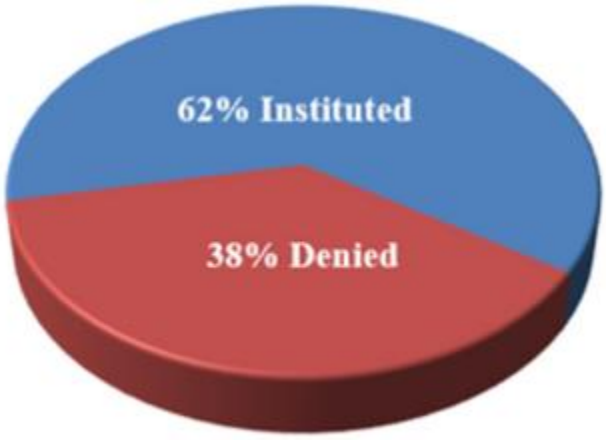


Institution and Final Written Decisions of Biologics-Related IPRs

We next explore how the PTAB has approached rendering institution decisions and final written decisions, or FWDs, on biologics-related IPRs.

Turning first to institution,[26] the data reveal that institution rates tend to favor challengers, with the PTAB instituting 62% of petitions, or 143 out of 229, and denying 38% of petitions, or 86 out of 229, as may be seen in Figure 3 below: [27]

Figure 3: Disposition of IPR Petitions at the Institution Phase From Sept. 16, 2012, to April 27, 2023



With respect to institution rates by patent type, the PTAB instituted a surprising 71% of IPRs involving composition-of-matter patents, or 37 out of 52, showing that petitioners were in fact able to locate strong prior art in most challenges.

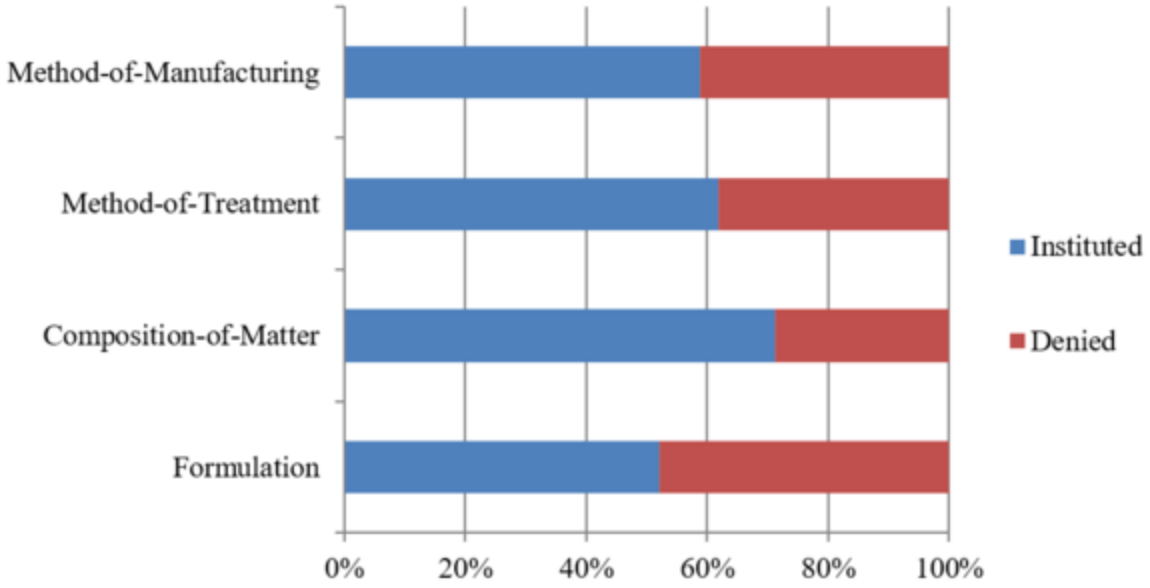
The PTAB instituted about 60% of IPRs challenging method-of-treatment patents, or 63 out of 102, a figure consistent with the perceived vulnerability of such patents.

The PTAB instituted about the same percentage of IPRs for method-of-manufacturing patents, 30 out of 51, 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 about 52%, or 12 out of 23, despite formulation patents being viewed as particularly vulnerable to obviousness attacks.

This data underscores the importance of formulation patents in the life cycle management of biologics-related products. Institution data by patent type are summarized below in Figure 4:

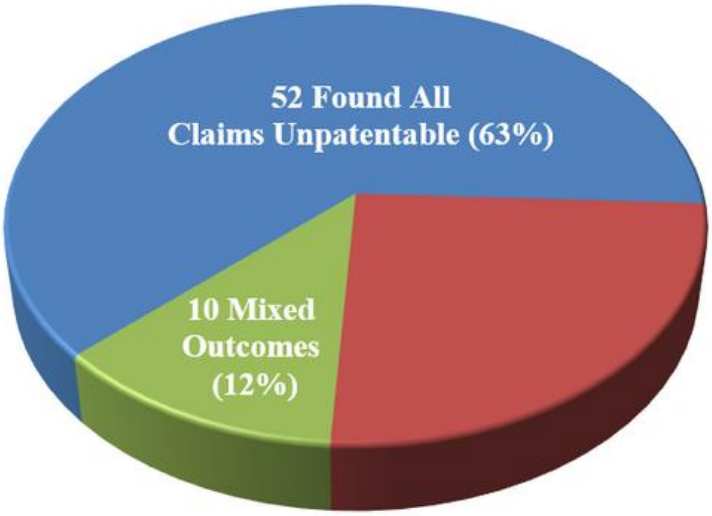
Figure 4: Disposition of IPR Petitions, per Patent Type, at the Institution Stage From Sept.16, 2012, to April 27, 2023



Turning next to FWDs and other post-institution outcomes, 143 biologics-related IPRs had progressed past the institution stage as of April 27, with 83 resolved by an FWD on the merits, 38 resolved by settlement or termination, and 22 not yet resolved by the PTAB.

Petitioners in the biologics space achieved considerable success in the 83 IPR petitions resolved on the merits. As depicted in Figure 5 below, about 63% of petitions, or 52 out of 83, were resolved in the challenger's favor, roughly 25%, or 21 out of 83, were resolved in the patentee's favor and about 12%, or 10 out of 83, had mixed outcomes:

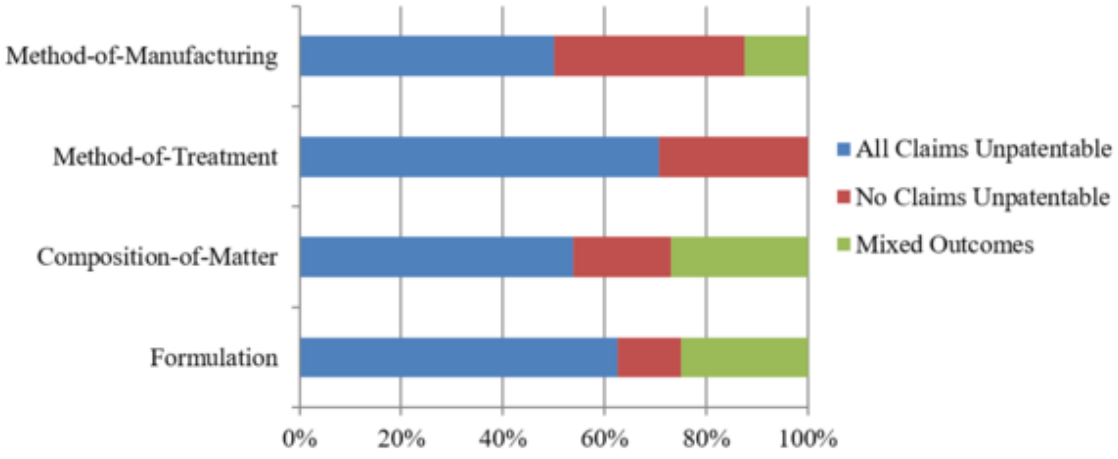
Figure 5: Disposition of IPR Petitions Post-Institution From Sept. 16, 2012, to April 27, 2023.



As for post-institution disposition per patent type, the data show that petitioners succeeded in proving all claims unpatentable in 71%, or 29 out of 41, of IPRs involving method-of-treatment patents, as well as 54%, or 14 out of 26, of IPRs involving composition-of-matter patents.

Petitioners achieved such success in about 66%, or 5 out of 8, of IPRs involving formulation patents, and 50%, or 4 out of 8, of IPRs involving method-of-manufacturing patents, but this data should be viewed with caution given the limited number of FWDs on the merits. These patent-specific data are summarized below in Figure 6:

Figure 6: Percent Disposition After Institution Stage per Patent Type From Sept. 16, 2012, to April 27, 2023



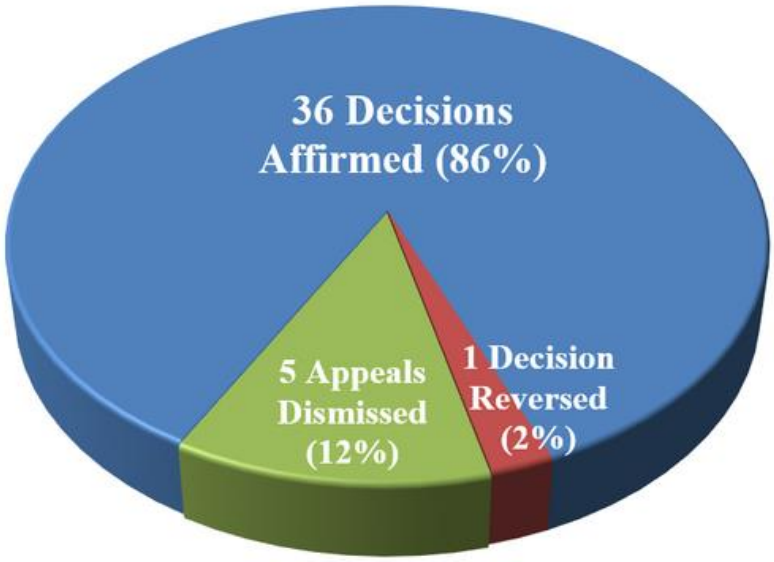
Appellate Dispositions of Biologics-Related IPRs

Turning next to biologics-related IPR appeals, 73 decisions have been appealed from the PTAB to the Federal Circuit, representing about 25% of all biologics-related IPR petitions filed since the inception of the IPR procedure.[28]

As of April 27, the Federal Circuit had decided 42 of 73 appeals; the remaining 31 appeals were either awaiting appellate resolution or settled by the parties. As shown in Figure 7 below, the Federal Circuit

affirmed 36 decisions, or 86%, on every issue, reversed one decision, or 2%, on every issue, and dismissed the remaining five appeals, or 12%:[29]

Figure 7: Appellate Dispositions of 42 Cases From Sept. 16, 2012, to April 27, 2023



This high affirmance rate appears largely attributable to the high degree of deference the Federal Circuit affords the PTAB's factual findings underlying its patentability determinations.[30]

And perhaps not surprisingly given the high value of the products involved, nearly 83%,or 69 out of 83, of IPR FWDs pertaining to biologics-related patent challenges have been appealed to the Federal Circuit, though, as noted above, the vast majority that have been decided were affirmed.

Focusing on the decisions since our last article, each of the 12 affirmances involved patents relating either to Teva Pharmaceutical Industries Ltd.'s Ajovy[31] or drug delivery patents asserted in copending litigation against Moderna Inc.'s Spikevax,[32] while the one reversal pertained to a protein folding patent that Amgen Inc. had asserted against Neulasta and Neupogen biosimilars in copending litigation.[33]

Biologics-Related PGRs

PGR challenges to biologics-related patents are far less common than IPR challenges, with IPR challenges outnumbering PGR challenges by a ratio of more than 10 to 1.[34]

Not a single biologics-related PGR petition was filed from the inception of the procedure on Sept. 16, 2012, through 2016, with only two filed in 2017, one in 2018, five in 2019 and two in 2020.

But in 2021 we witnessed a relatively substantial uptick with nine biologics-related PGR challenges filed, though afterward only four challenges were filed in 2022, and just one challenge has been filed so far this year.

Overall, 24 biologics-related PGRs have been filed since the inception of the procedure. Because of the limited number of PGR petitions filed as of April 27, any conclusions that may be drawn from the existing data must be viewed with caution.

The reluctance of the biopharma industry to file PGR petitions relative to IPR petitions is likely attributable to the potentially far greater estoppel impact arising from PGR proceedings on district court

litigations involving the same patent.[35]

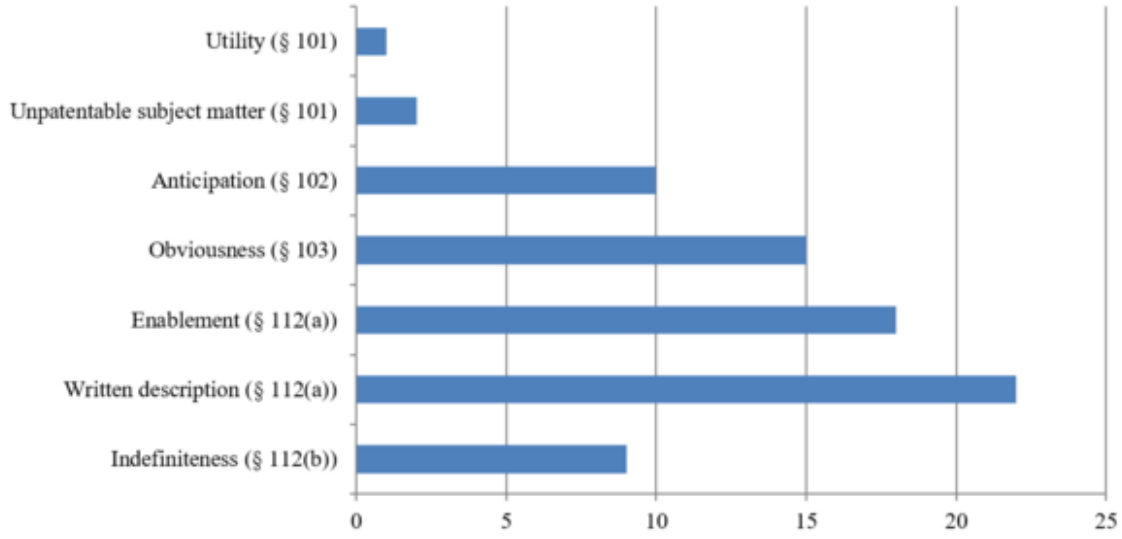
Nonetheless, the U.S. Supreme Court's recent decision in Amgen v. Sanofi, which affirmed the Federal Circuit's determination that certain functional genus claims covering monoclonal antibodies were invalid for lack of enablement,[36] may temper that reluctance and lead to an increase in filings of PGR petitions.

Looking at the 24 PGR petitions by patent type, 11 petitions, or 46%, challenged composition-of-matter patents, nine petitions, or 36%, challenged method-of-treatment patents, one petition, or 4%, challenged a method-of-manufacturing patent, and three petitions, or 12%, challenged formulation patents.

Turning to the statutory grounds for those challenges, the data indicate that written description, with 22 out of 24 petitions, and enablement, with 18 out of 24 petitions, 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.[37]

The frequency of statutory grounds alleged in the 24 PGR petitions is presented below in Figure 8:

Figure 8: Frequency of Statutory Grounds Alleged in PGRs Filed Through April 27, 2023



And given the Supreme Court's Amgen v. Sanofi decision, we expect enablement to continue serving as a lead statutory ground for challenging biologics-related patents by PGR for the foreseeable future.

With respect to the resolution of the 24 PGRs as of April 27, 21 have reached the institution stage, with the PTAB instituting nine, or 43%, and denying institution of 12, or 57%.[38]

The PGR institution rate of 43% is lower than the IPR institution rate of 62%, which is somewhat counterintuitive in view of the availability of additional statutory grounds to challenge patent claims in PGR proceedings.

Of the nine instituted petitions, all challenged patent claims were held unpatentable in five FWDs, one petition was resolved by settlement and three petitions remain pending. Of the five FWDs, there is one appeal pending before the Federal Circuit, while the remaining four were not appealed.

Conclusion

With 280 IPR petitions filed over the last 10 ½ years, we can provide a robust picture of statistical trends in biologics-related IPRs.

We observed that the lion's share of petitions involve challenges to method-of-treatment patents, at 45%, with many fewer challenges to composition-of-matter patents, at 23%, method-of-manufacturing patents, at 21% and formulation patents, at 11%.

The overall institution rate for biologics-related IPR petitions tends to favor challengers, with the PTAB granting 62% of petitions and denying 38%. Institution rates were over 70% for composition-of-matter patents, about 60% for method-of-treatment and method-of-manufacturing patents, and 50% for formulation patents.

For the 83 instituted IPRs resolved by an FWD, petitioners achieved considerable success, with roughly 60% 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 and formulation patents, with about 70% of FWDs holding all claims unpatentable, compared to about 50% of FWDs holding all claims unpatentable for method-of-manufacturing and composition-of-matter patents.

Nearly 85%, or 69 out of 83, of biologics-related FWDs were appealed, with the Federal Circuit affirming in 86% of cases. As for PGRs, the biopharma industry has been willing to use them in a very limited fashion, with only 24 filed since the inception of the procedure, though we expect that willingness to increase in view of the Amgen v. Sanofi decision.

In sum, the data suggests 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.

We expect the biopharma industry to continue employing both procedures as market conditions and product launches warrant.

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Steptoe associate Darpan Patel and law clerk Yun Zhang contributed to this article. Former summer associate Justin Rosinski and former associate Richard Praseuth also contributed to this article.

[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 and 21 CFR § 600.3, or involved manufacturing or treating a disease with such compositions or formulations. We excluded petitions involving diagnostic patents.

[2] Our conclusions here confirm those set forth in prior articles analyzing trends in biologics-related IPRs and PGRs. See 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] Following publication of our most recent article, we reevaluated our categorization of certain petitions based upon discovery of new information and clarification of our definition of a biologics-related petition. Accordingly, we updated our data set to remove 14 IPRs, add 10 IPRs, and add 7 PGRs.

[4] Likely reasons for the biopharma industry's initial slow embrace of the IPR procedure included an historical reluctance by that industry to employ post-grant procedures, a general unfamiliarity with the new IPR procedure, and an insufficient development of biosimilar programs, such that the need to clear a path for a product was not yet sufficiently immediate. See Molenda & Praseuth, supra, at 3.

[5] That rise in filings is likely explained by various companies having advanced their biosimilar programs to the point where IPR-based challenges would play a key role in bringing their products to market. See Molenda & Praseuth, supra, at 3.

[6] The spike in 2017 appears to be correlated to biosimilar applicants clearing the path for biosimilars of Humira®, Rituxan®, Herceptin®, and Avastin®, along with innovators clearing the path for their biologics, including Dupixent® and a variety of vaccines. See Rosinski et al., supra, at 3-4 & nn. 7-12.

[7] See Mylan Pharms. Inc. v. Regeneron Pharms. Inc., IPR2022-01225 (filed July 1, 2022, challenging claims of U.S. Patent No. 10,130,681); IPR2022-01226 (filed July 1, 2022, challenging claims of U.S. Patent No. 10,888,601); IPR2023-00099 (filed Oct. 28, 2022, challenging claims of U.S. Patent No. 10,857,205); Celltrion, Inc. v. Regeneron Pharms. Inc., IPR2022-00257 (filed Dec. 9, 2021, challenging claims of U.S. Patent No. 9,669,069); IPR2022-00258 (filed Dec. 9, 2021, challenging claims of U.S. Patent No. 9,254,338); IPR2023-00462 (filed Jan. 17, 2023, challenging claims of U.S. Patent No. 10,464,992); IPR2023-00533 (filed Feb. 10, 2023, challenging claims of U.S. Patent No. 10,888,601); IPR2023-00532 (filed Feb. 10, 2023, challenging claims of U.S. Patent No. 10,130,681); IPR2023-00620 (filed Feb. 28, 2023, challenging claims of U.S. Patent No. 10,406,226); Apotex Inc. v. Regeneron Pharms. Inc., IPR2022-00298 (filed Dec. 9, 2021, challenging claims of U.S. Patent No. 9,254,338); IPR2022-0301 (filed Dec. 9, 2021, challenging claims of U.S. Patent No. 9,669,069); IPR2022-01524 (filed Sept. 9, 2022, challenging claims of U.S. Patent No. 11,253,572); Samsung Bioepis Co. v. Regeneron Pharms. Inc., IPR2023-00442 (filed Jan. 6, 2023, challenging claims of U.S. Patent No. 10,130,681); IPR2023-00566 (filed Feb. 10, 2023, challenging claims of U.S. Patent No. 10,888,601); IPR2023-00739 (filed Mar. 26, 2023, challenging claims of U.S. Patent No. 10,888,601); IPR2023-00884 (filed Apr. 27, 2023, challenging claims of U.S. Patent No. 11,253,572).

[8] Fresenius Kabi USA LLC v. Chugai Seiyaku Kabushiki Kaisha, IPR2021-01024 (filed June 28, 2021, challenging U.S. Patent No. 7,521,052); IPR2021-01025 (filed June 28, 2021, challenging U.S. Patent No. 10,744,201), IPR2021-01288 (filed Aug. 18, 2021, challenging claims of U.S. Patent No. 8,580,264); IPR2021-01336 (filed Aug. 18, 2021, challenging claims of U.S. Patent No. 10,874,677); IPR2021-01542 (filed Sept. 24, 2021, challenging U.S. Patent No. 8,580,264); IPR2022-00201 (filed Nov. 24, 2021, challenging U.S. Patent No. 9,750,752); IPR2022-01065 (filed June 7, 2022, challenging U.S. Patent No. 10,231,981); Celltrion Inc. v. Chugai Seiyaku Kabushiki Kaisha, IPR2022-00578 (filed Feb. 21, 2022, challenging U.S. Patent No. 8,580,264); IPR2022-00579 (filed Feb. 21, 2022, challenging U.S. Patent No. 10,874,677).

[9] Fresenius, Paper No. 74, IPR2021-01024; Paper No. 74, IPR2021-01288; Paper No. 14, IPR2022-01065

(granting joint motions to terminate IPR proceedings due to settlement). Pfizer recently achieved a similar outcome when it asserted an IPR challenge against a patent covering Amgen's Neulasta® in Pfizer Inc. v. Amgen Inc., IPR2021-00528 (filed Feb 10, 2021, challenging U.S. Patent No. 8,273,707). Specifically, that challenge led to a settlement of both the IPR and co-pending district court litigation. See Jasmin Jackson, "Amgen Agrees To End Neulasta IP Suit Against Pfizer, Hospira," Law360 (Mar. 21, 2022), available at https://www.law360.com/articles/1475615/amgen-agrees-to-end-neulasta-ip-suit-against-pfizer-hospira.

[10] JSR Corp. v. Cytiva BioProcess R&D AB, IPR2022-00036 & IPR2022-00043 (both filed Oct. 12, 2021, challenging U.S. Patent No. 10,213,765); IPR2022-00041 & IPR2022-00044 (both filed Oct. 12, 2021, challenging U.S. Patent No. 10,343,142); IPR2022-00042 & IPR2022-00045 (both filed Oct. 12, 2021, challenging U.S. Patent No. 10,875,007).

[11] Cellink AB v. Organovo Inc., IPR2021-01049 (filed June 7, 2021, challenging U.S. Patent No. 9,149,952); IPR2021-01050 (filed June 7, 2021, challenging U.S. Patent No. 9,855,369); BICO Group AB v. Organovo Inc., IPR2021-01543 (filed Sept. 20, 2021, challenging U.S. Patent No. 9,315,043); BICO Group AB v. MUSC Found. Rsch. Dev., IPR2021-01544 (filed Sept. 21, 2021, challenging U.S. Patent No. 9,752,116).

[12] In our previous articles we characterized patents based on the predominant claim type (composition-of-matter, formulation, method-of-manufacturing, or method-of-treatment), even though some of the challenged patents contain more than one claim type. We have continued to follow that approach here.

[13] Examples of challenges to method-of-treatment patents include most of the recent challenges to patents covering Eylea® and Actemra®. See supra, nn. 8-9.

[14] See Molenda & Praseuth, supra, at 2.

[15] See, e.g., Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021); AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc., 759 F.3d 1285 (Fed. Cir. 2014).

[16] See, e.g., Amgen Inc. v. Sanofi, 598 U. S. ____ (2023).

[17] See Molenda & Praseuth, supra, at 3 & n.7.

[18] A recent challenge to a composition of matter patent covering a blockbuster drug is Dana-Farber Cancer Inst. Inc. v. E.R. Squibb & Sons LLC, IPR2023-00501 (filed Feb. 6, 2023, challenging claims of U.S. Patent No. 8,008,449), relating to Opdivo®.

[19] See Molenda & Praseuth, supra, at 4.

[20] Spectrum Sols. LLC v. DNA Genotek Inc., IPR2022-00774 (filed Mar. 28, 2022, challenging U.S. Patent No. 10,000,795).

[21] Wuhan Healthgen Biotech. Corp. v. Ventria Bioscience Inc., IPR2022-00407 (filed Jan. 7, 2022, challenging claims of U.S. Patent No. 8,609,416); IPR2022-00712 (filed Mar. 17, 2022, challenging claims of U.S. Patent No. 10,618,951).

[22] See supra note 11.

[23] See supra note 12.

[24] Celltrion, Inc. v. Regeneron Pharms. Inc., IPR2023-00462 (filed Jan. 17, 2023, challenging claims of U.S. Patent No. 10,464,992).

[25] Fresenius Kabi USA LLC v. Chugai Seiyaku Kabushiki Kaisha, IPR2021-01336 (filed Aug. 18, 2021, challenging claims of U.S. Patent No. 10,874,677); Celltrion Inc. v. Chugai Seiyaku Kabushiki Kaisha, IPR2022-00579 (filed Feb. 21, 2022, challenging claims of same patent).

[26] Our analysis of overall institution rates and institution rates for specific patent types does not include the 20 of 280 petitions that were awaiting an institution decision as of April 27, 2023, as well as the 31 of 280 petitions that had settled prior to the PTAB's institution decision, leaving 229.

[27] One commenter noted a recent rise in institution rates and attributed that rise to a change in PTAB policy promulgated in June 2022 by PTO Director Kathi Vidal to limit discretionary denials of institution. Inge A. Osman et al, The PTAB Pendulum Swings Back to Petitioners, Latham & Watkins Client Alert (Nov. 15, 2022), available at https://www.lw.com/admin/upload/SiteAttachments/Alert-3032.pdf.

[28] Of those 73 appeals, 69 (94%) were from FWDs, including 45 appeals (62%) from FWDs in which all claims were held unpatentable, 20 appeals (27%) from FWDs in which no claims were held unpatentable, 4 appeals (5%) from FWDs in which some but not all claims were held unpatentable. Of the remaining 4 appeals, 2 (3%) were from denials of institution and 2 (3%) were from denials of pre-institution stage dismissals on sovereign immunity grounds. By patent type, 42 appeals (58%) involved method-of-treatment patents, 16 appeals (22%) involved composition-of-matter of patents, 6 appeals (8%) involved method-of-manufacturing patents, and 9 appeals (12%) involved formulation patents.

[29] This affirmance rate is 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 March 2023, Finnegan at the PTAB Blog (May 1, 2023), available at https://www.finnegan.com/en/insights/blogs/at-the-ptab-blog/federal-circuit-ptab-appeal-statistics-for-march-2023.html (reporting that the Federal Circuit affirmed IPR decisions on every issue at a rate of 73%). 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, but rather, each case's subsequent history: four cases settled, one decision was appealed again and then reversed, and one case remains pending.

[30] 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).

[31] Teva Pharms. Int'l GmbH v. Eli Lilly and Co., 8 F.4th 1349 (Fed. Cir. 2021); Eli Lilly and Co. v. Teva Pharms. Int'l GmbH, 8 F.4th 1331 (Fed. Cir. 2021); Teva Pharms. Int'l GmbH v. Eli Lilly and Co., 856 F. App'x 312 (Fed. Cir. 2021).

[32] Arbutus Biopharma Corp. v. ModernaTx Inc., 65 F.4th 656 (Fed. Cir. 2023); ModernaTx Inc. v. Arbutus Biopharma Corp., 18 F.4th 1352 (Fed. Cir. 2021); Moderna Tx, Inc. v. Arbutus Biopharma Corp., 18 F.4th 1364 (Fed. Cir. 2021).

[33] Amgen Inc. v. Vidal, No. 2019-2171, 2022 WL 1112817 (Fed. Cir. Apr. 14, 2022).

[34] 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 of 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).

[35] As is the case with IPR estoppel, PGR estoppel applies to "any ground that the petitioner raised or reasonably could have raised during that [review proceeding]." Compare 35 U.S.C. § 315(e)(2) (IPR) with U.S.C. § 325(e)(2) (PGR). But the reach of PGR estoppel is inherently far greater, because it extends to all statutory grounds available to assert for invalidity. Compare Michael Siem et al., Patent Strategy Considerations After Caltech Estoppel Ruling, Law360 (April 15, 2022), available at https://www.law360.com/articles/1482119 (IPR estoppel) with Scott McKeown, PGR's Scary Estoppel Footprint, Ropes & Gray Patents Post Grant (March 10, 2022), available at https://www.patentspostgrant.com/pgrs-scary-estoppel-footprint/ (PGR estoppel).

[36] Amgen, 598 U. S. ____.

[37] See, e.g., Mark A. Lemley and 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).

[38] Of the remaining petitions that did not reach the institution stage, one was terminated pre-institution, while two remain pending.