A Survey of PGR Outcomes

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INTRODUCTION

Inter Partes reviews (IPRs) and post grant reviews (PGRs) are procedures for challenging the validity of patents at the U.S. Patent and Trademark Office (PTO). IPRs and PGRs went into effect as a result of the America Invents Act (AIA) on September 15, 2012, and were intended to replace *inter partes* reexamination.

In the nine years since their inception, hundreds of PGRs and thousands of IPRs have been filed. When the procedures were initiated, institution and invalidation rates were high, leading Chief Judge Rader to call the PTAB "death squads" for patents. Much has changed since then with institution rates falling, claim construction standards changing (from the broadest reasonable interpretation to the *Phillips v. AWH Corp.* standard used in federal courts), an increase in allowance of motions to amend, and an increase in discretionary denials based on parallel litigations.

While most of the focus on post grant proceedings at the PTAB has been on IPRs, PGRs are increasingly being filed. Petitioners considering post grant reviews have a wealth of data from the large number of IPR decisions to examine statistical trends. The same is not true for PGRs given the fewer number of PGRs filed to date.

To address this, we analyzed PGR outcomes for the nine years since their inception through December 31, 2021 and compared them to IPR outcomes and 35 U.S.C. § 112 challenge outcomes in district court litigations. With a focus on pharmaceutical and biotechnology patents, we analyzed PGR outcomes for patents on small molecule drugs listed in the FDA's "Orange Book," biologic drugs listed in the Center for Drug Evaluation and Research (CDER) "Purple Book," and patents falling under the PTO's Tech Center 1600 (TC 1600), which includes patents for biotechnology, chemistry, small molecule drugs, and a larger set of biologics that also includes drugs regulated by the Center for Biologics Evaluation and Research (CBER) such as vaccines.

DIFFERENCES BETWEEN IPRs AND PGRs

IPRs and PGRs differ in a number of significant ways. IPRs are available for any issued patent, while PGRs are only available for patent applications filed after March 16, 2013. PGRs must be filed within nine months of patent grant or reissue, where IPRs can be filed, for first-to-file patents, the later of nine months after patent grant or reissue, or the date any instituted PGR is terminated. For first-to-invent patents these IPR deadlines do not apply and the patents can be challenged as soon as they are granted or reissued. The constraints on PGR filings may, in part, explain why there have been fewer PGRs filed compared to IPRs.

In IPRs, invalidity challenges are limited to 35 U.S.C. §§ 102 and 103 based on patents and printed publications, whereas in PGRs, the scope of invalidity challenges is much broader and can include challenges under §§ 101, 102, 103, 112, and for double patenting. However, the broader scope of invalidity challenges available in PGRs poses additional risks of a broader scope of estoppel in PGRs compared to IPRs.[1]

[1] Petitioners are estopped in district court and the International Trade Commission (ITC) from raising grounds and prior art that were raised or could reasonably have been raised during post grant proceedings. *GREE, Inc. v. Supercell Oy*, Case No. 2:19-cv-00071, Dkt. No. 81 (EDTX Oct. 30, 2019).

PGR AND IPR FILINGS OVER TIME

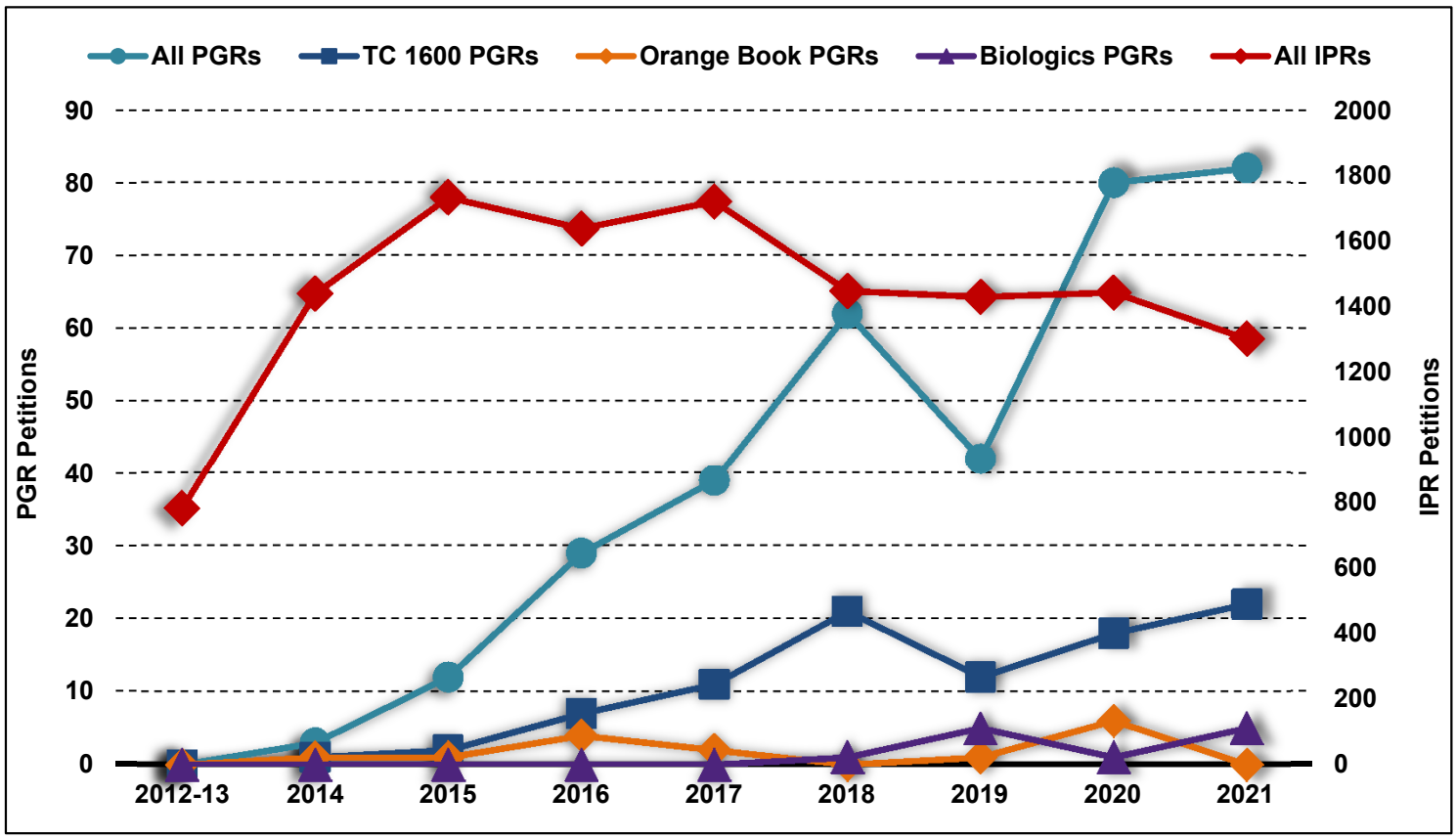

Figure 1: PGR and IPR filings (2012 – 2021)

Figure 1 shows the number of PGR and IPR petitions filed since their inception in 2012 through December 31, 2021. For our analysis, we reviewed PGR filings for all patent technologies (teal line) as well as the subsets of PGRs filed on Orange Book-listed patents (orange line), CDER-listed biologic drug patents ("Biologics") (purple line), and TC 1600 patents (blue line). PGR filings have risen steadily over time and were the highest ever in 2021. In comparison, IPR filings (red line) were highest between 2015 and 2017, followed by a decrease in 2018 that has continued through 2021.

While the total number of biologic drug PGR filings to date is still low compared to the number of biologic drug IPRs (N=10 vs. N=162, respectively), it is likely that biologic drug PGR filings will continue to increase over time, particularly given the increased number of biosimilars being developed based on reference products that were FDA approved in recent years. The first wave of biosimilars referenced biologic drugs approved many years ago (*e.g.* Humira® (adalimumab) approved in 2002; Remicade® (infliximab) approved in 1998; Neupogen® (filgrastim) approved in 1991). Since PGRs can only be filed within the first nine months of patent issuance, few reference products for the first wave of biosimilars had patents that issued recently enough to be available for PGRs. As a result, to date most of the PGRs on biologic drug patents have not been filed by biosimilar manufacturers but instead by entities with competing products directed to similar biologic targets. This may change over time as biosimilars to more recently approved reference products become available.

In addition to the time constraints for filing PGRs previously discussed, another reason PGRs have been filed at a much lower rate than IPRs is likely because the broader scope of invalidity challenges available in a PGR creates a far greater risk of a broader scope of estoppel, which is a formidable issue for petitioners considering whether to file a PGR.

PGR INSTITUTION RATES BY TECHNOLOGY

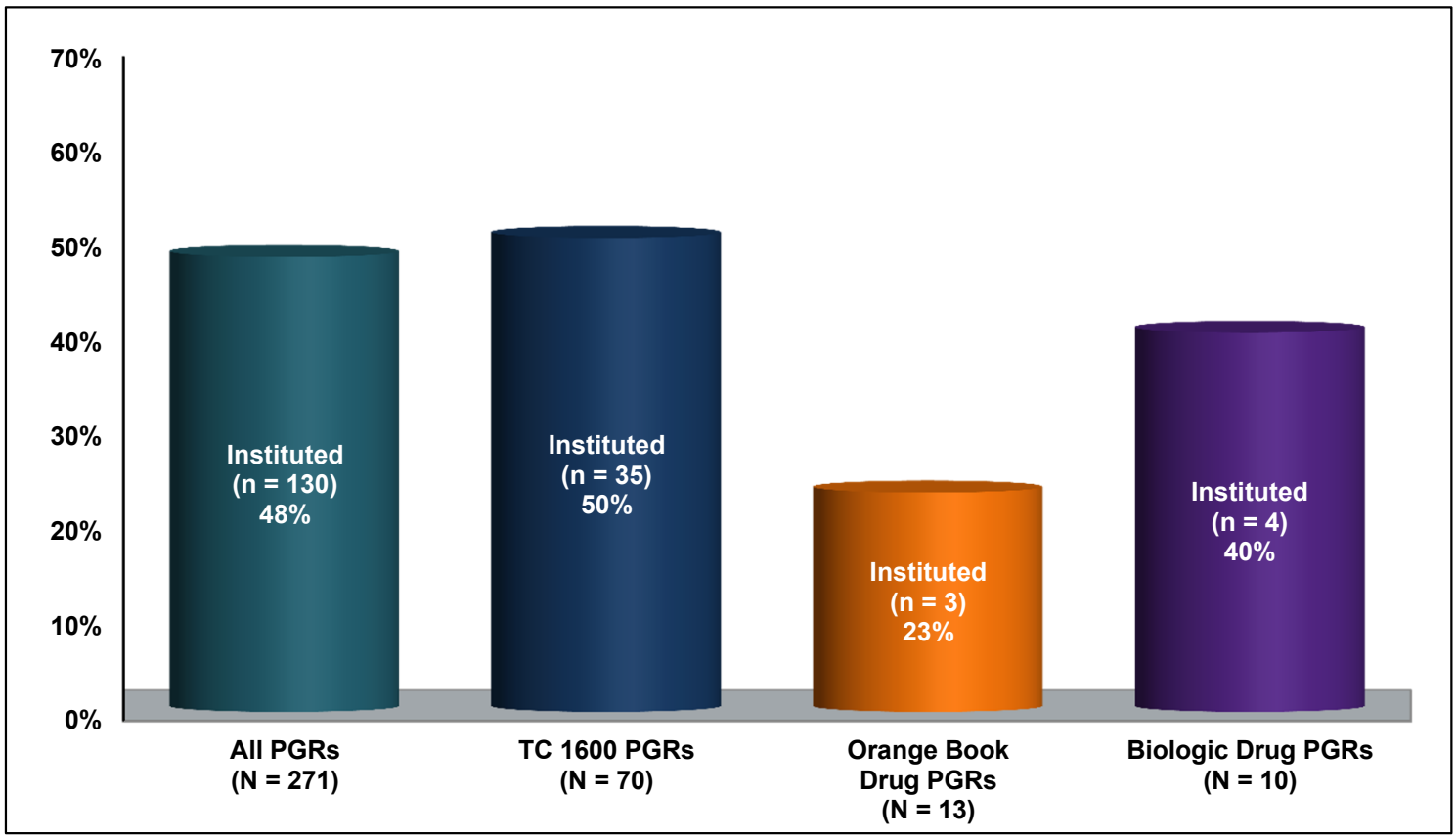

Figure 2: PGR institution rates by technology

Figure 2 shows PGR institution rates by technology. Within this relatively small data set, PGR institution rates varied, with TC 1600 patent challenges being instituted at a similar rate compared to that for all PGR institutions (50%, n=35 of 70 and 48%, n=130 of 271, respectively), while Orange Book-listed drug and biologic drug patent challenges were instituted less frequently (23%, n=3 of 13 and 40%, n=4 of 10, respectively). While the data available is still limited (N=23 for Orange Book and biologic drug PGRs), we will continue to monitor PGR decisions on those patents to determine whether this trend continues.

About 14% of PGRs terminate prior to institution (n=44 of 315, data not shown). This is consistent across various technologies with about 13% (n=2 of 15) of Orange Book drug PGRs and 9% (n=1 of 11) of biologic drug PGRs terminating prior to institution (data not shown).

PGR AND IPR INSTITUTION RATES

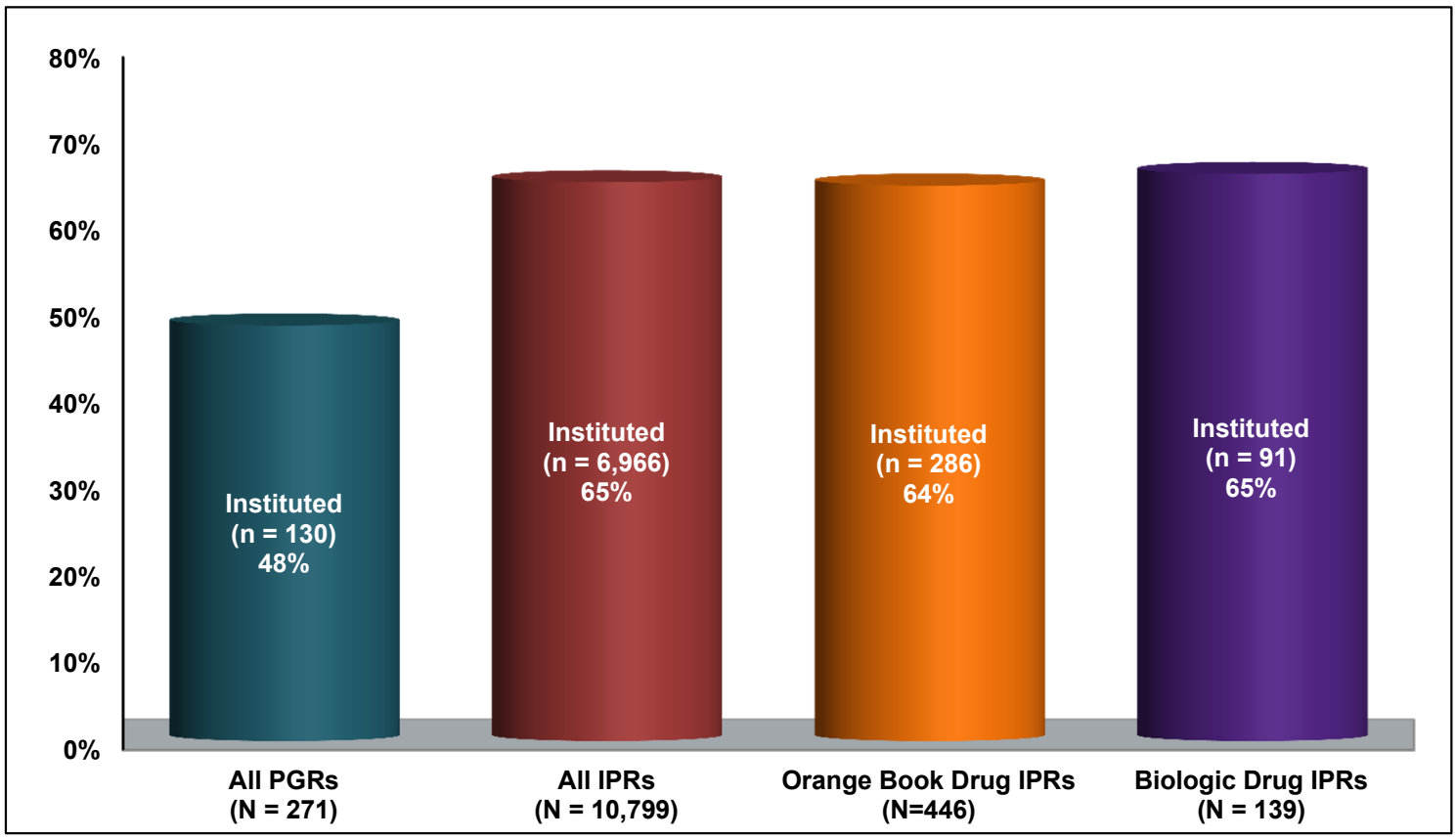

Figure 3: PGR and IPR institution rates[2]

Figure 3 shows institution rates for PGRs compared to IPRs for all technologies as well as Orange Book and biologic drug IPRs. It is noteworthy that compared to the 48% institution rate for PGRs (n=130 of 271), IPRs have been instituted at a significantly higher rate (65%, n=6,966 of 10,799). This higher rate is also seen for both Orange Book and biologic drug IPRs (64%, n=286 of 446 and 65%, n=91 of 139 respectively).

If current trends continue, a possible reason why PGRs are instituted at lower rates compared to IPRs may reflect the more limited timeframe for which a PGR is available to challenge patents, *i.e.*, within 9-months after patent issuance, which presents additional hurdles to petitioners in developing an evidentiary record, compared to in an IPR which does not have such time limitations. This time limitation is impactful given that in a PGR there are many more possible invalidity challenges available to a petitioner (*e.g.*, §§ 101, 102, 103, 112 and double-patenting) compared to only §§ 102 and 103 in an IPR. The broad scope of PGR invalidity challenges imposes additional burdens on PGR petitioners in terms of resources that are required to fully develop the evidentiary record necessary to meet the institution requirements (*e.g.*, a much broader scope of prior art needs to be collected and reviewed to show the state of the art for written description and enablement challenges and an increased demand for expert testimony). Petitioners must consider every challenge type even if they are not all ultimately raised in the petition because estoppel can attach to grounds that reasonably could have been raised in a PGR.

[2] IPR institution rates are based on PTO data available at: https://www.uspto.gov/patents/ptab/statistics/aia-trial-statistics-archive.

PGR AND IPR INSTITUTION RATES OVER TIME

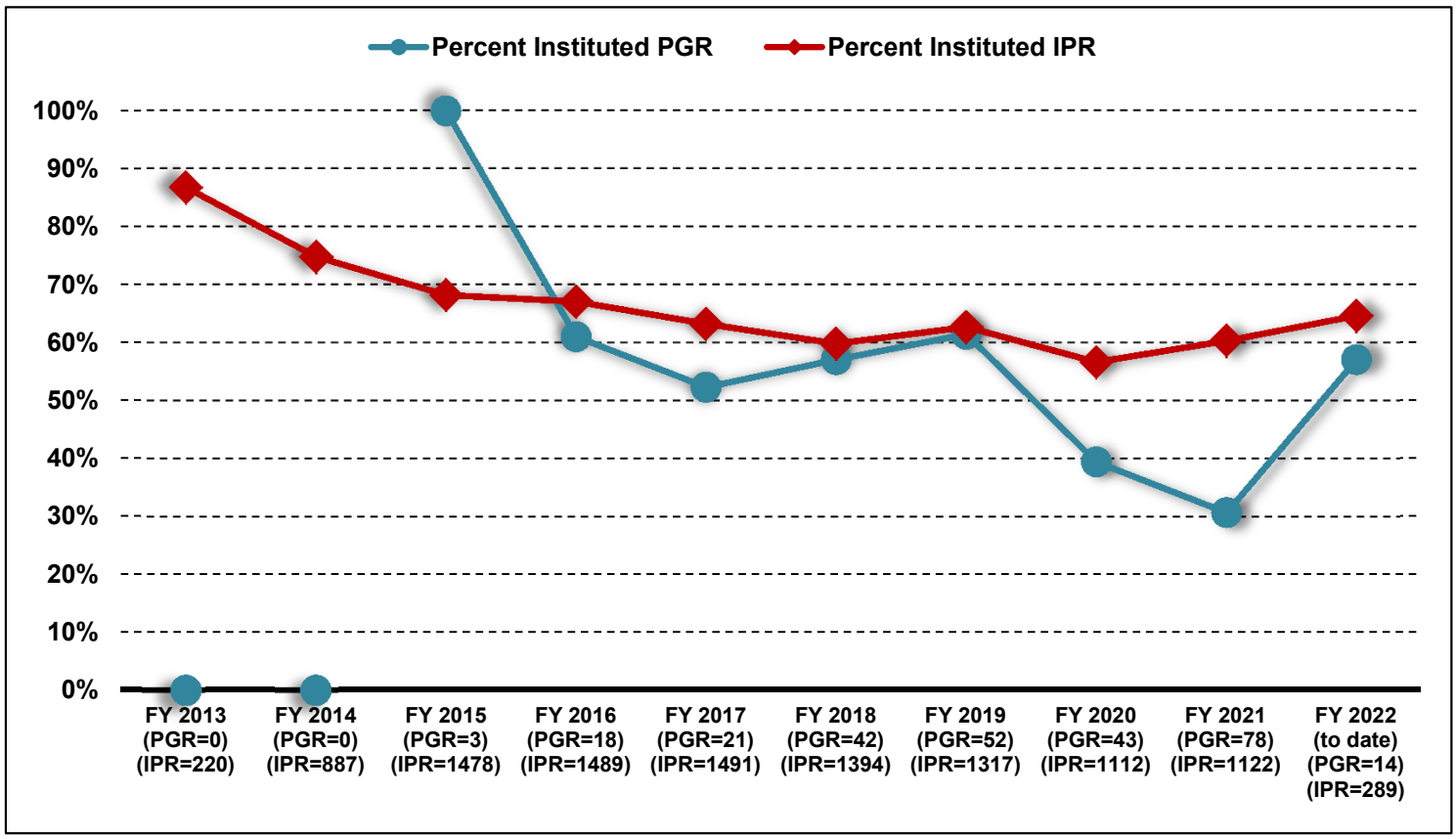

Figure 4: PGR and IPR institution rates over time

Figure 4 shows PGR and IPR institution rates over time. PGR institution rates (teal line) have trended lower since their inception, with FY 2021 having the lowest institution rate with only 31% (n=24 of 78) of petitions being instituted. Thus far in FY 2022, PGR institution rates are at 57% (n=8 of 14), but it is too early in the fiscal year to determine whether this represents an upward trend.

The decrease in PGR institution rates in FY 2020 and FY 2021 is significant in comparison to IPRs (red line), which have decreased since their inception but remain at about 60% instituted, nearly double that of PGRs in the last full fiscal year. If this trend continues, one possibility for this difference could be the differing ways in which IPRs and PGRs are used to challenge different collections/technologies of patents.

BASES FOR PGR DENIAL OVER TIME

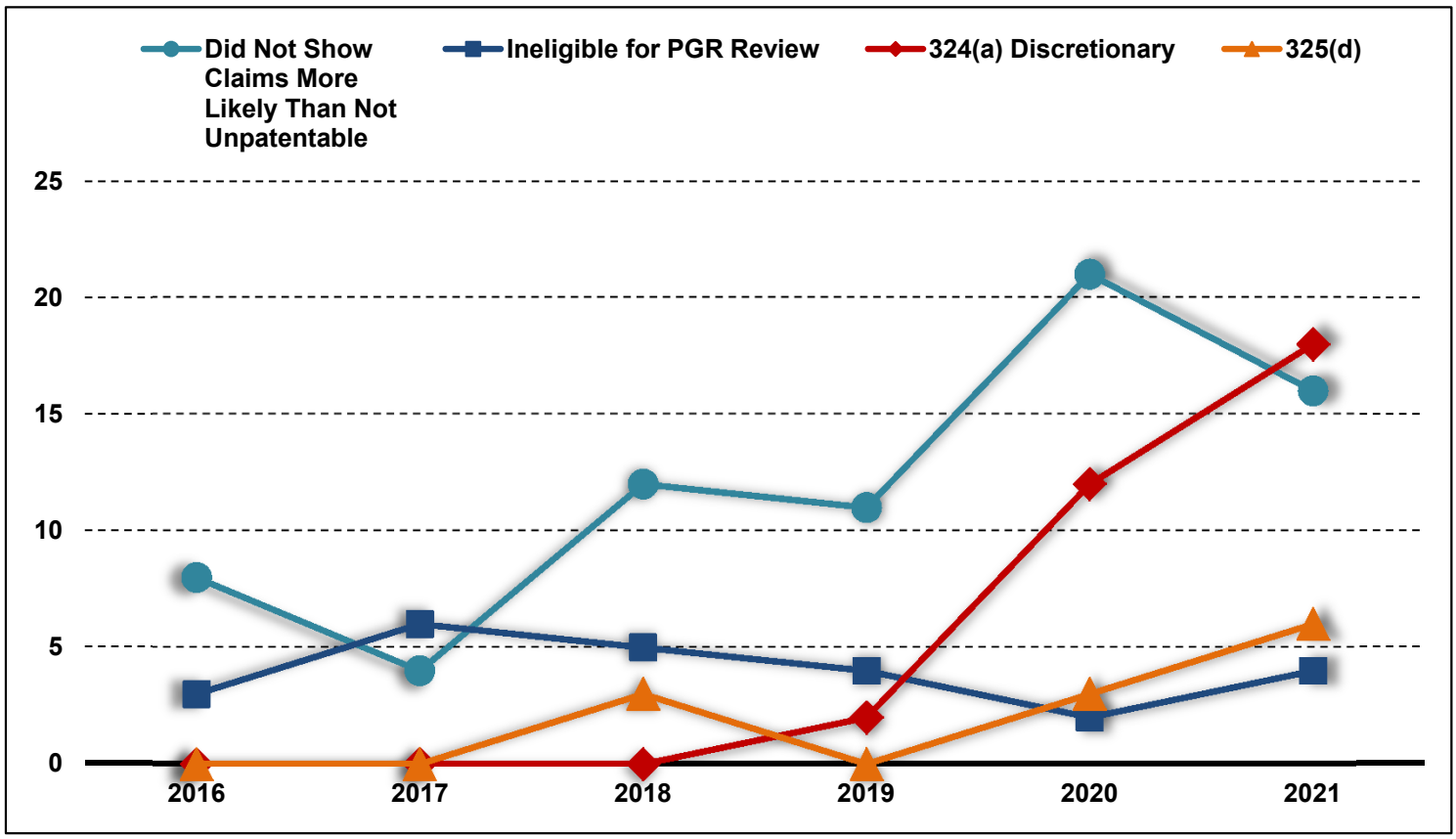

Figure 5: Bases for PGR denial over time

Figure 5 shows the bases for PGR denials over time. The PTAB has increasingly denied PGR (and IPR) institutions for procedural reasons. In 2021, procedural denials were the most frequent reason for PGR institution denials.

The increase in the use of procedural denials under 324(a) is largely the result of changes in PTAB procedures beginning in 2019 related to its 2018 *NHK* v. *Intri-Plex Technologies* decision, designated as precedential in May 2019,[3] and the *Apple v. Fintiv*[4] decision designated as precedential in May 2020, the latter in which the PTAB elaborated on *NHK*, providing a list of factors to be weighed in determining whether to institute an IPR where there is a parallel proceeding in district court or in the International Trade Commission. In *Fintiv*, applying these factors, the PTAB affirmed discretionary denial where a parallel district court litigation was at an advanced stage.

The *NHK-Fintiv* factors have been controversial. While cases challenging them in the Supreme Court were denied certiorari this year,[5] their fate remains unclear as the PTO has solicited public comments on the use of the *NHK-Fintiv* factors, and Senator Leahy has sought to eliminate their use through a bill, the "Restoring the America Invents Act," introduced in the Senate in September 2021. Changes to the ability of the PTAB to use procedural denials based on *NHK-Fintiv* factors will likely affect the rate of PGR institutions going forward.

[3] *NHK Spring Co. v. Intri-Plex Technologies, Inc.*, No. IPR2018-00752, 2018 WL 4373643 (P.T.A.B. Sept. 12, 2018).

[4] *Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, 2020 WL 2126495 (P.T.A.B. Mar. 20, 2020).

[5] *See Mylan Laboratories Ltd. v. Janssen Pharmaceutica, N.V.*, Supreme Court Case No. 21-202 (cert denied January 18, 2022); *Apple Inc. v. Optis Cellular Technology, LLC*, Supreme Court Case No. 21-118 (cert denied January 18, 2022).

PGR INSTITUTION RATES BY INVALIDITY CHALLENGE TYPE

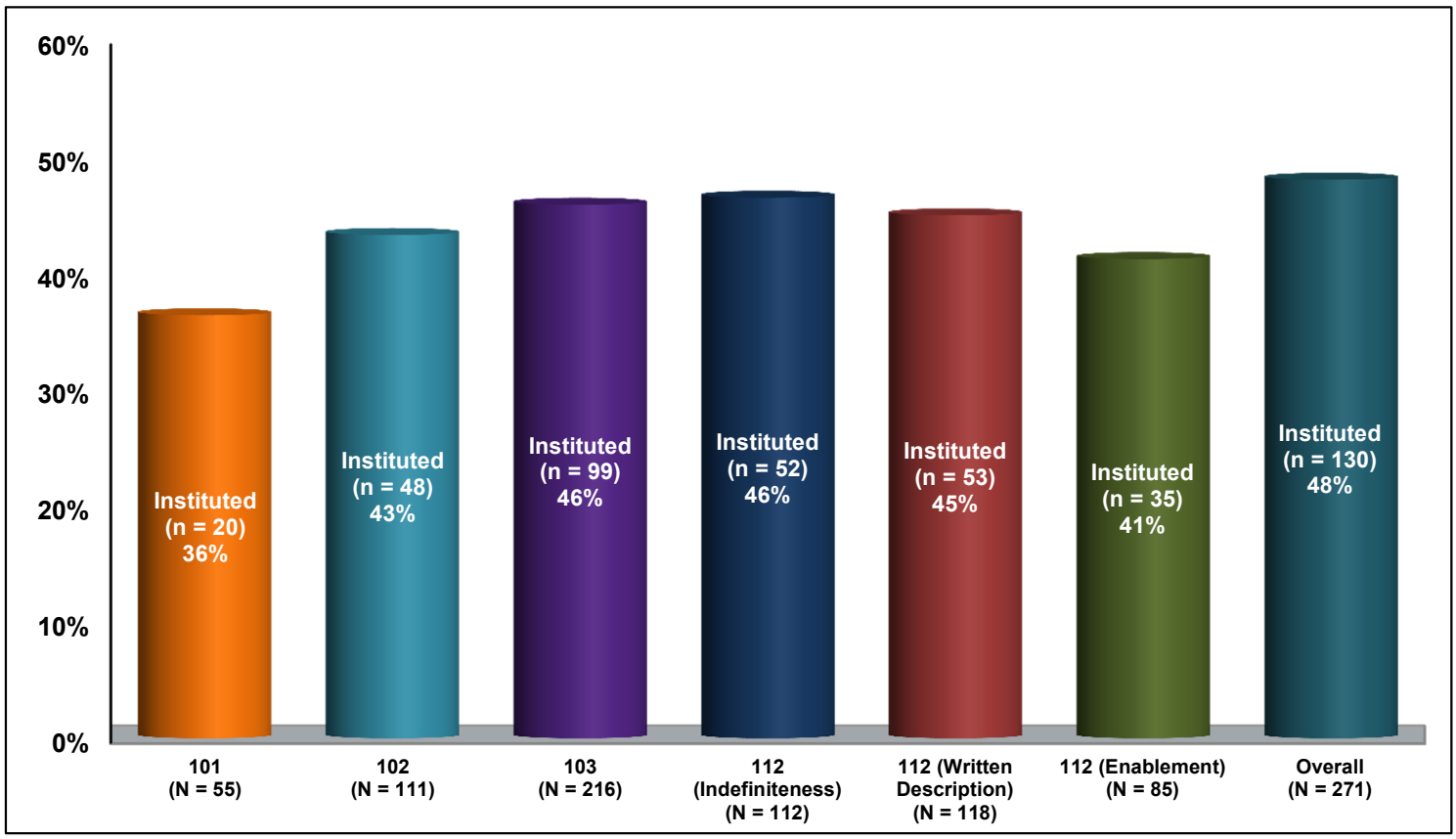

Figure 6: PGR institution rates by invalidity challenge type[6]

Figure 6 shows PGR institution rates by invalidity challenge type under §§ 101, 102, 103, and 112 (indefiniteness, written description, and enablement). Where there were multiple challenge types in a petition each was reviewed separately. Infrequently raised invalidity challenges such as improper narrowing of dependent claims, ornamentality and double-patenting were not included in our analysis due to the limited data available for those challenges.

Invalidity challenges under § 103 were the most frequent PGR challenge (challenged in about 80% of all PGR petitions), with challenges based on § 102, § 112 indefiniteness, and § 112 written description being challenged about half as often as § 103.

PGR institution rates ranged from 41-46% for invalidity challenges based on §§ 102 (n=48 of 111), 103 (n=99 of 216), 112 indefiniteness (n=52 of 112), written description (n=53 of 118), and enablement (n=35 of 85). Institution rates for § 101 challenges were slightly lower at 36% (n=20 of 55).

It appears that patent challengers are using PGRs to take advantage of invalidity challenges that are not available in IPRs since only 25% of PGR petitions contained challenges based solely on §§ 102 and/or 103, which are challenges that are also available in IPRs (data not shown).

[6] Our data set includes challenge types in all PGR petitions reaching an institution decision. Those that were terminated prior to institution and those awaiting an institution decision have not been included.

PGR AND IPR FINAL WRITTEN DECISION OUTCOMES

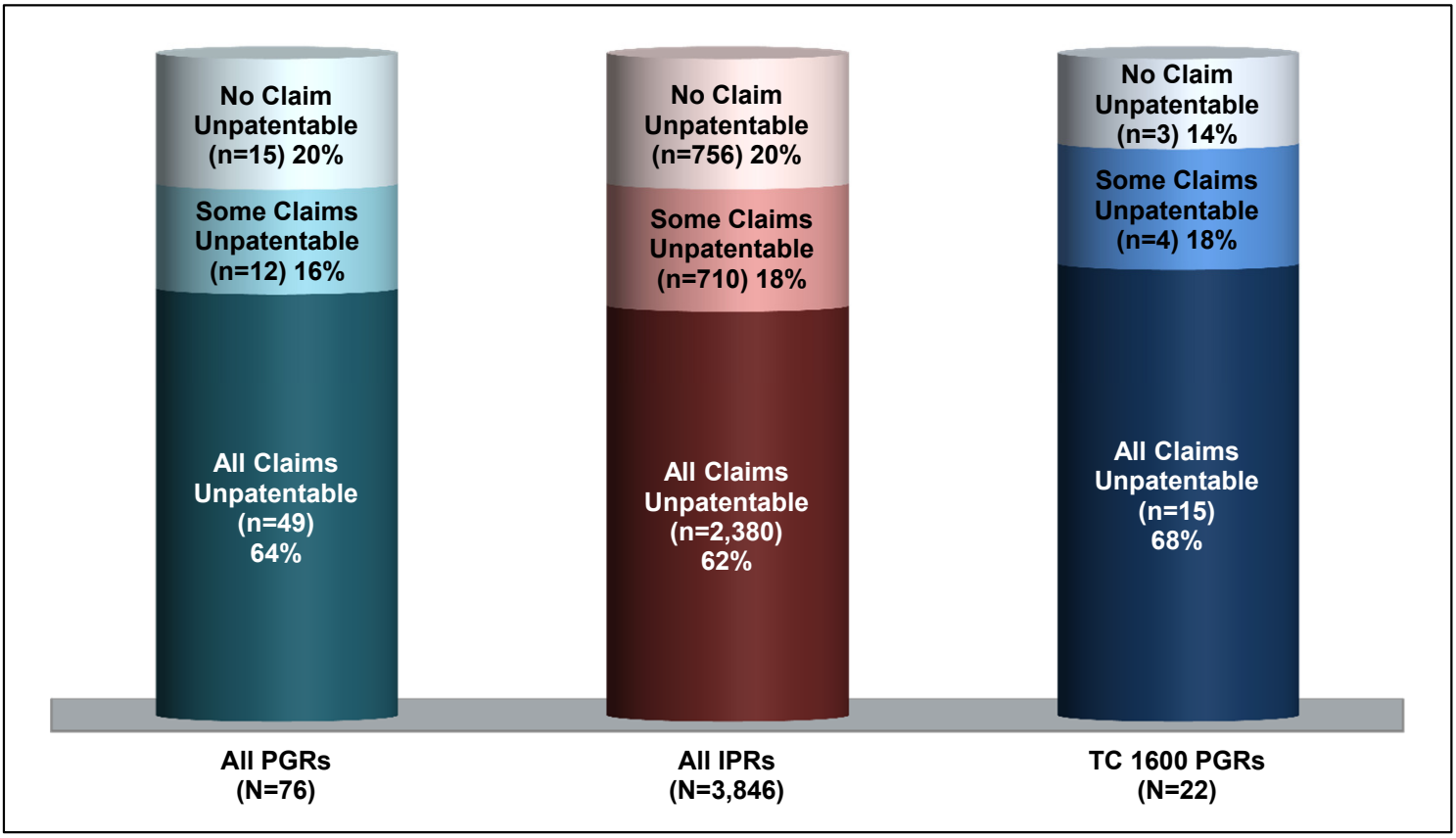

Figure 7: PGR and IPR Final Written Decision outcomes

Figure 7 shows Final Written Decision (FWD) outcomes for PGRs (N=76) and IPRs (N=3,846).[7] We also evaluated FWD outcomes for TC 1600 PGRs (N=22). The rate for FWD invalidation of all claims is similar for PGRs and IPRs (64%, n=49 of 76 and 62%, n=2,380 of 3,846, respectively), and is also similar for TC 1600 patents (68%, n=15 of 22), suggesting that invalidity outcomes for biotechnology patents are similar to that for other technologies, although the data set for TC 1600 is still small (N=22). The outcome of some or no claims being found unpatentable is also similar in PGRs (36%) and IPRs (38%). A similar outcome of 32% is found in TC 1600 patents, although once again the data set is small. This suggests that at the FWD stage claim survival rates are similar for PGRs and IPRs.

As of this writing there have been too few PGR FWDs for Orange Book-listed and biologic drug patents to determine any trends regarding FWD outcomes for these patents.

[7] IPR final written decision outcomes are based on PTO data available at: https://www.uspto.gov/patents/ptab/statistics/aia-trial-statistics-archive.

PGR FWD OUTCOMES BY INVALIDITY CHALLENGE TYPE

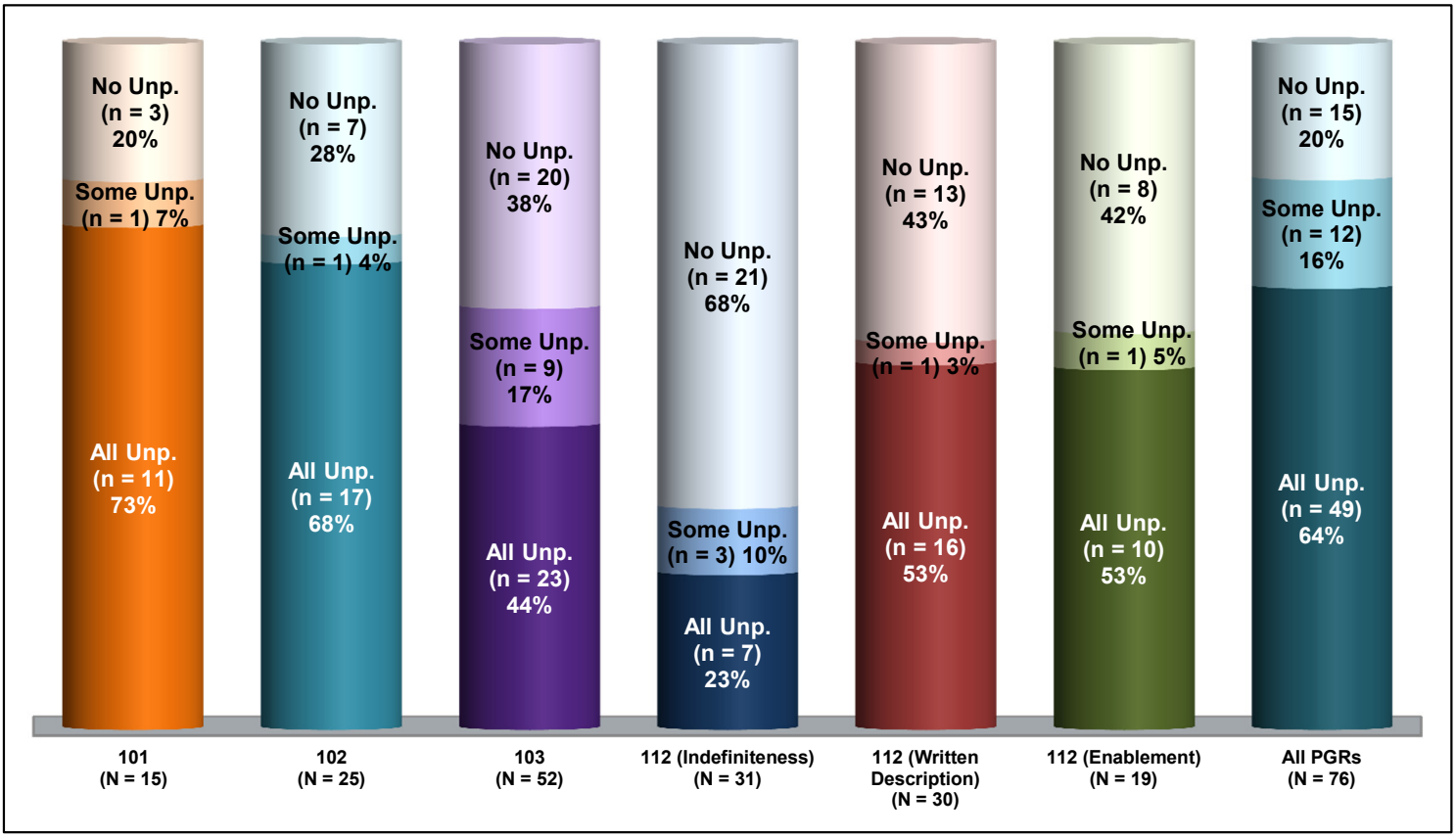

Figure 8: PGR FWD outcomes by invalidity challenge type

Figure 8 shows PGR FWD outcomes by invalidity challenge type under §§ 101, 102, 103, and 112 (indefiniteness, written description, and enablement). Where there were multiple challenge types in a petition each was reviewed separately. Infrequently raised challenges such as improper narrowing of dependent claims, ornamentality and double-patenting were not included in this analysis due to the limited data available for those challenges. Because claims are often challenged under multiple grounds, they are sometimes found not unpatentable under one ground but are invalidated under another ground.

There is considerable variability in PGR FWD outcomes when analyzed by invalidity challenge type. Invalidity challenges based on §§ 101 (N=15), 102 (N=25) and 112 written description (N=30) and enablement (N=19) were the most successful with 53-73% success in invalidating all challenged claims. Patent challengers were least successful at invalidating all claims under §§ 112 indefiniteness (23%) and 103 (44%).

Figure 8 also shows data for outcomes on some and no unpatentable claims for each of the invalidity challenge types. While the data sets for many of the challenge types are still very small and it is difficult to determine if trends exist in those categories, it appears that split decisions of some claims being unpatentable and some not unpatentable are rare for challenge types other than under § 103. Where FWDs finding some claims unpatentable for § 103 are similar in frequency to PGR outcomes as a whole (17%, n=9 of 52 and 16%, n=12 of 76, respectively), other challenge types have findings of some claims patentable 10% or less of the time. Because the data sets are small, we continue to monitor them for trends.

PGR OVERALL OUTCOMES BY INVALIDITY CHALLENGE TYPE

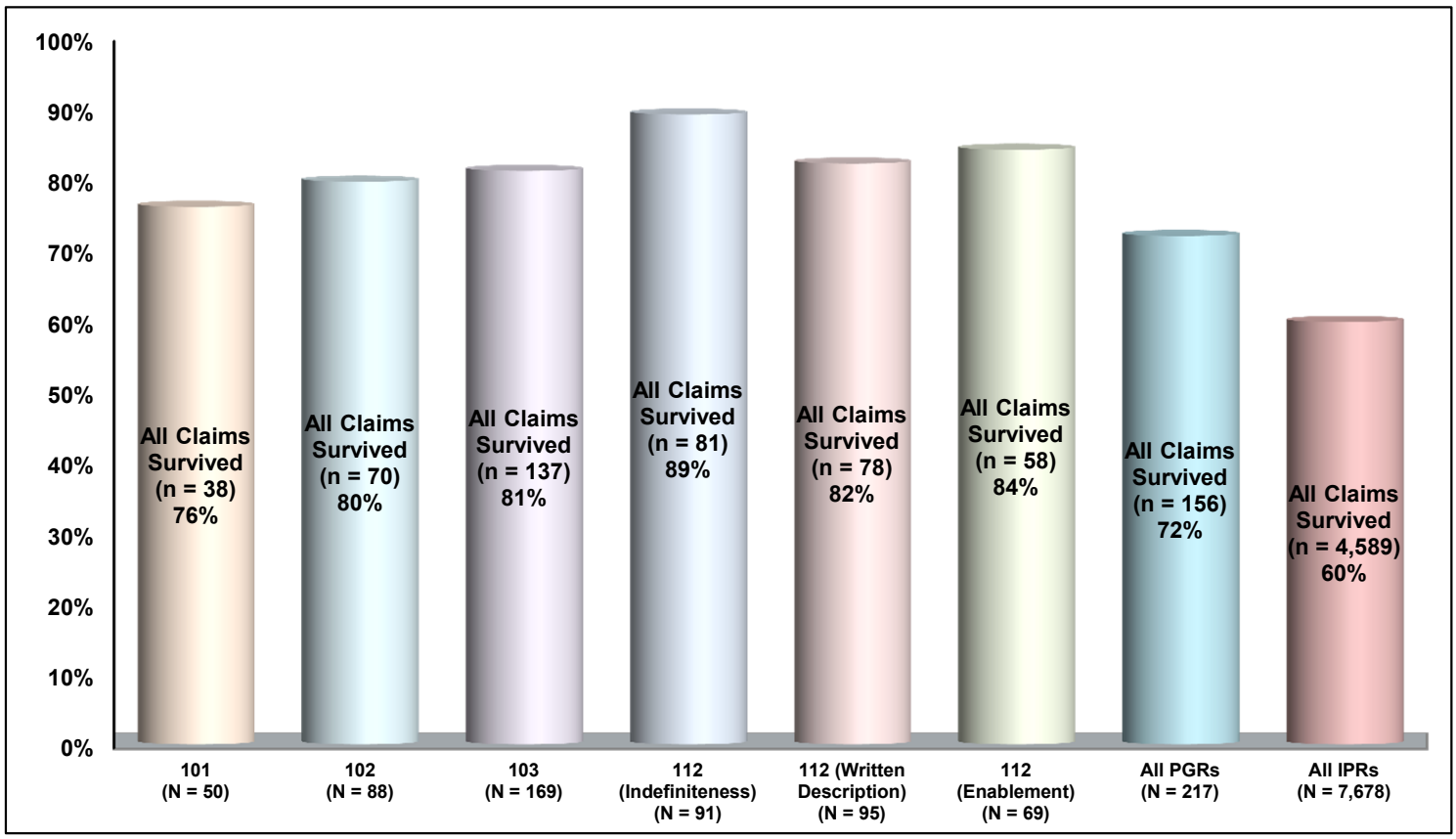

Figure 9: PGR overall outcomes by invalidity challenge type

Figure 9 shows PGR overall outcomes by invalidity challenge type. Where there were multiple challenge types in a petition each was reviewed separately. Infrequently raised challenges such as improper narrowing of dependent claims, ornamentality and double-patenting were not included in our analysis due to the limited data available for those challenges. As previously noted, because claims are often challenged under multiple grounds, they are sometimes found not unpatentable under one ground but are invalidated under another ground.

In contrast to our analysis in Figure 8, which considers only FWDs, Figure 9 considers outcomes in both Decisions Not to Institute (DNIs) and FWDs. Considering both DNIs and FWDs, 72% of PGR challenges resulted in no claims being found unpatentable (n=156 of 217) compared to 60% for IPR challenges (n=4,589 of 7,678). The >70% claim survival rate is consistent across PGR invalidity challenge types. Accordingly, patent owners have a higher success rate for survival of all claims in a PGR compared to an IPR. As shown above in Figure 7, while the FWD outcomes for PGRs invalidated claims at a higher rate than for IPRs, the IPR institution rate is considerably higher than for PGRs (65% IPRs, n=6,966 of 10,799; 48% PGRs, n=130 of 271, shown above in Figure 3), resulting in IPRs overall being less favorable to patent owners compared to PGRs.

PGR AND DISTRICT COURT OUTCOMES BY § 112 CHALLENGE TYPE

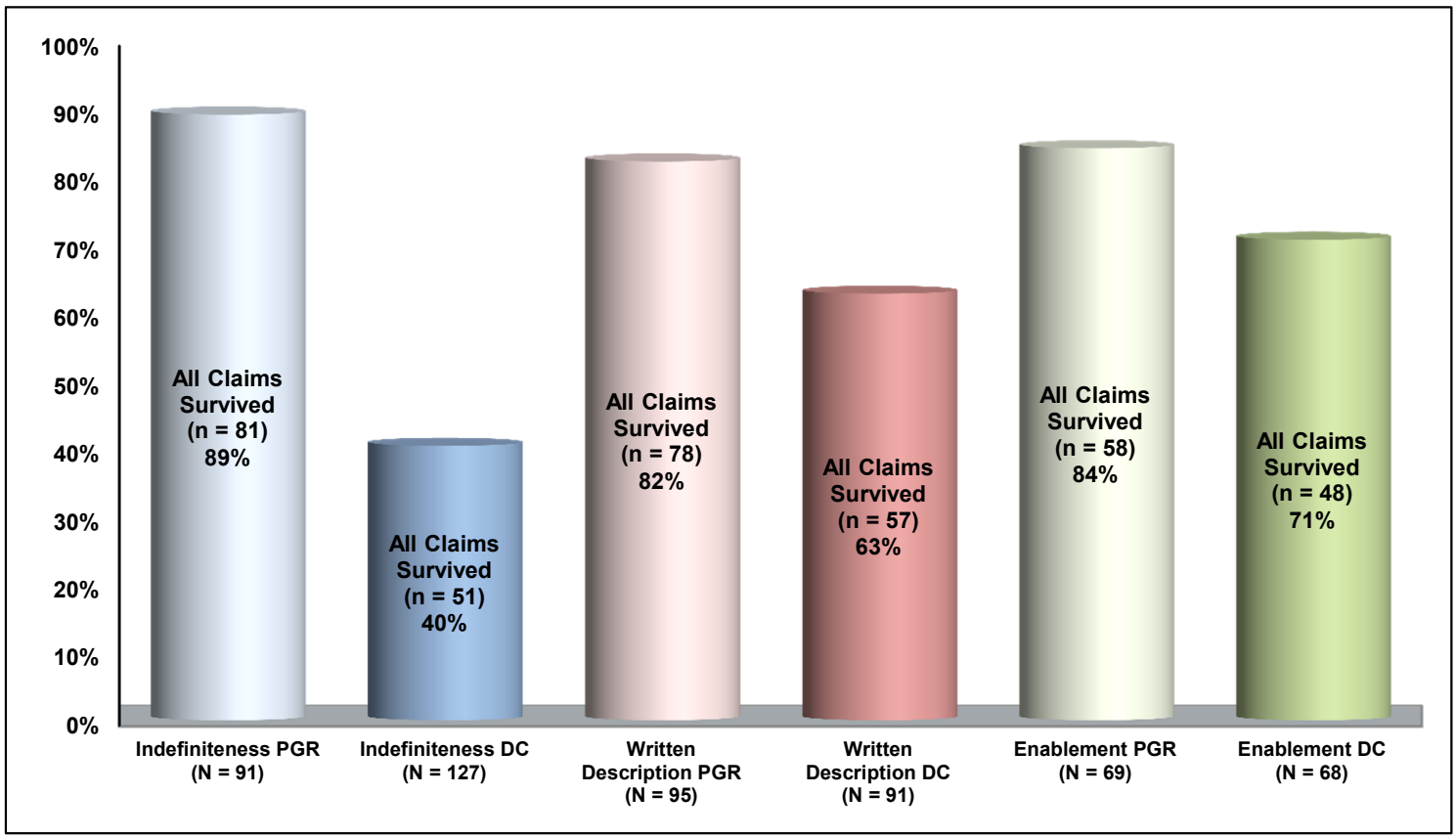

Figure 10: PGR and district court outcomes by § 112 challenge type

Since § 112 invalidity challenges are available in PGRs, we compared PGR § 112 challenge outcomes for indefiniteness, written description and enablement to those challenges in district court (DC) litigations. For this analysis we reviewed district court litigation summary judgment and trial outcomes from January 1, 2015 through December 31, 2021, as this time frame includes essentially all PGR filings. As previously noted, because claims are often challenged under multiple grounds, they are sometimes found not unpatentable under one ground but are invalidated under another ground. Our analysis looks at the outcome of each challenge individually.[8]

As shown in Figure 10, claims have a higher rate of survival (*i.e.*, no claims unpatentable, considering both DNIs and FWDs) from § 112 challenges at the PTAB compared to in district court. This is most apparent for challenges based on indefiniteness (89% PGR survival, n=81 of 91; 40% DC survival, n=51 of 127) and written description (82% PGR survival, n=78 of 95; 63% DC survival, n=57 of 91). The difference between claim survival in the two venues for challenges based on enablement is slightly less pronounced (84% PGR survival, n=58 of 69; 71% DC survival, n=48 of 68). From the data available as of this writing, which includes 172 PGR outcomes and 134 DC cases with decisions on indefiniteness, written description and enablement challenges, patent challengers have a higher success rate at invalidating claims under § 112 in district court compared to the PTAB. The higher rate of claim survival for a § 112 challenge in district court compared to a PGR is despite the lower burden of proof required to invalidate claims at the PTAB compared to district court (preponderance of the evidence vs. clear and convincing evidence, respectively).

[8] Ns listed for district court litigations are the number of patents with a district court decision (summary judgment or trial) for that particular challenge type.

LESSONS LEARNED

Our website, Venable Fitzpatrick's ***BiologicsHQ*** (https://www.biologicshq.com), provides regularly updated information regarding Purple Book and biosimilar-related drug patents as a resource for practitioners in the Life Sciences. Our database includes, *inter alia*, PTAB post grant proceedings and district court litigations. While both IPRs and PGRs have been available for over 9 years, to date there have been far fewer PGR decisions compared to IPRs. The purpose of this article is to provide the results of our survey of PGR decisions, with an emphasis on life sciences patents.

As of this writing there have been very few life sciences PGRs, with only 23 PGR petitions reaching an institution decision for Orange Book and biologic drug patents, so it is not possible to derive meaningful trends for PGR outcomes on these patents.

However, information derived from TC 1600 patent PGRs (N=70), which includes biotechnology patents, Orange Book-listed patents, CDER and CBER-regulated biologic patents, demonstrates that they are being instituted at about the same rate as PGRs as a whole, *i.e.*, in about 50% of challenges (n=35 of 70), but at a lower rate than for all IPRs, which are instituted in about two-thirds of challenges (n=6,966 of 10,799). Of the 22 TC 1600 PGRs that have reached a FWD as of this writing, about two-thirds of those decisions resulted in all claims being found unpatentable, which is similar to the 64% invalidation rate in all PGRs and 62% invalidation rate in all IPRs (n=49 of 76 and n=2,380 of 3,846, respectively).

Comparing all PGR outcomes to all IPR outcomes, patent owners have fared better in PGR challenges than IPRs. Much of this difference is attributed to lower institution rates in PGRs compared to IPRs. If this trend continues, it may partially reflect the increased challenges of developing an evidentiary record for the much broader scope of invalidity challenges in a PGR within a more limited timeframe in which to file a PGR challenge (9 months after patent issuance).

It is noteworthy that patent owners have fared better against § 112 challenges in PGRs compared to § 112 challenges in district court. This seems counter-intuitive given the lower burden of proof for invalidating claims at the PTAB compared to in district court. It will be interesting to see of this trend continues.

The much smaller number of PGR challenges generally, and to biologic patents specifically, than was originally anticipated is likely a result of the much greater risk of a broad scope of estoppel in PGRs compared to IPRs. Appellate issues may also be a factor. The Federal Circuit has given great deference to PTAB decisions and the availability of an appeal is not guaranteed for PTAB proceedings. Whereas challengers at the PTAB do not require standing, the Federal Circuit has determined that an appeal of a PTAB decision by a patent challenger does have a standing requirement.[9] Therefore, patent challengers considering whether to instigate a post grant proceeding in the PTAB must consider that they may be denied the ability to appeal an adverse decision. In the biosimilars context, this may be a particular concern for PGRs, given that they need to be filed within 9 months of patent grant, which may be too early in biosimilar product development to confer appellate standing.

[9] *See e.g. ModernaTX, Inc. v. Arbutus Biopharma Corp.*, 2021 U.S. App. LEXIS 35471, 2021 U.S.P.Q.2D (BNA) 1176 (Fed. Cir. 2021); *Apple Inc. v. Qualcomm Inc.*, 992 F.3d 1378 (Fed. Cir. 2021); *Momenta Pharms., Inc. v. Bristol-Myers Squibb Co.*, 915 F.3d 764 (Fed. Cir. 2019); *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168 (Fed. Cir. 2017); *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258 (Fed. Cir. 2014).