August 2024

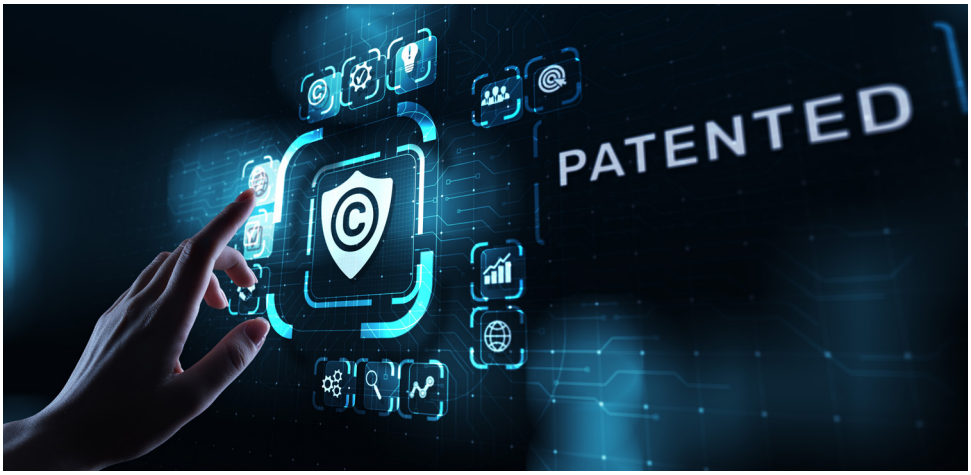
WILSON SONSINI

THE PTAB REVIEW

This issue of *The PTAB Review* begins by providing an analysis of how institution decisions consider declaration testimony submitted by a patent owner. Next, it summarizes proposed rulemaking from the United States Patent and Trademark Office (USPTO) about practices at the Patent Trial and Appeal Board (PTAB), including discretionary denial of institution. Third, it summarizes a USPTO decision providing guidance for patenting antibodies using means-plus-function claims. Finally, it reviews a recent precedential Federal Circuit decision cautioning against an overly rigid approach to obviousness.

Patent Owner Pre-Institution Testimony: A Review

Expert witness testimony is frequently used by petitioners and patent owners in PTAB cases. It can be used to help the PTAB better understand the evidence or to assist in determining a fact in dispute.[1] It is standard practice for petitioners to include an expert witness declaration supporting their petition challenging a patent. Such testimony may support petitioners' arguments about the interpretation



of prior art references, motivation to combine references, and reasonable expectations of success. Absent expert testimony, mere attorney argument "cannot take the place of evidence lacking in the record."[2]

Though patent owners commonly submit expert witness testimony after institution, doing so before institution (e.g., when filing the Patent Owner Preliminary Response (POPR)) is less common. Patent owners sometimes avoid pre-institution declarations, reasoning that a battle of the experts over factual issues is an invitation for the PTAB to institute. However, others may reason that pre-institution expert testimony gives their counterarguments more weight than mere attorney argument. A review of institution decisions from 2018-2024 indicated about 40 percent of POPRs are accompanied by expert witness testimony, and that the percentage remained fairly consistent year over year.[3]

To illustrate the impact of patent owner pre-institution testimony, we conducted a review of over 750 institution decisions for PTAB cases filed after January 1, 2023, and identified scenarios where the patent

[1] Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019), 34; Fed. R. Evid. 702(a).

[2] *Garrett M. Salpeter v. ARP Manufacturing, LLC*, IPR2019-01382, Paper 13 (Dec. 27, 2019), 12.

[3] Anthony Sotelo, Amanda Antons, and Katherine Helm, *Does Expert Testimony Aid Preliminary IPR Responses?*, Law360 (May 9, 2024), https://www.law360.com/ip/articles/1834684/does-expert-testimony-aid-preliminary-ipr-responses-.

In This Issue

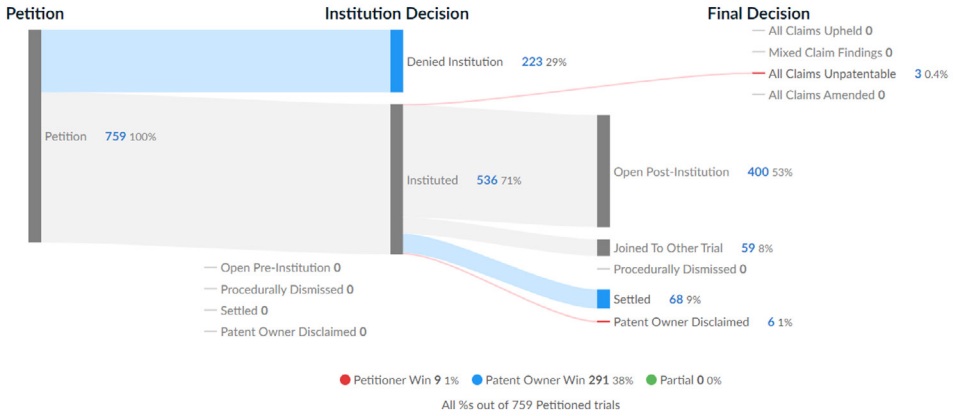
(Continued on page 2)

Patent Owner Pre-Institution Testimony: A Review *(continued from page 1)*

owner submitted a pre-institution expert witness declaration.

A Look at the Numbers

We identified petitions filed after January 1, 2023, using Lex Machina.[4] Of 759 petitions that had already resulted in a decision on institution, 71 percent were instituted, and institution was denied in 29 percent of cases.



Based on a review of these cases, patent owners had filed a pre-institution expert declaration in 37 percent of the cases where the PTAB later denied institution but only in 26 percent of cases where the PTAB later granted institution. Though these raw percentages may suggest that filing a pre-institution expert witness declaration provides a patent owner with some additional advantage, a case-by-case evaluation provides additional insight about how to best use pre-institution declaration testimony to support preliminary response arguments, and how petitioners can best respond to it.

When Should a Patent Owner Include Pre-Institution Expert Testimony?

A pre-institution expert declaration will often benefit a patent owner less in some circumstances than others. For example, if the thrust of the patent owner's argument is that institution should be denied due to a statutory time bar, parallel proceedings challenging the patent, or a lack of showing that each element of the claims is anticipated or obvious, then a pre-institution expert may be of little help: the record itself should be sufficient to rebut the challenge.

When the patent owner introduces testimonial evidence, the PTAB historically viewed any issues of material fact created by conflicts with the petitioner's expert's testimony "in the light most favorable to the petitioner" in deciding whether to institute.[5] But in December 2020, the USPTO amended its rules to remove this presumption, instead mandating that the patent owner's pre-institution evidence would be considered "as part of the totality of the evidence."[6]

While PTAB panels are no longer required to consider a patent owner's expert's testimony in a light most favorable to the petitioner, they may differ in how they approach factual disputes raised by pre-institution expert testimony. For example, some panels have stated that where "[t]he parties' evidence, particularly the declarants' testimony, presents a battle of the experts" then they believe those issues "would be best addressed during a trial" thus leading to institution.[7] In such cases, institution affords "the opportunity to cross-examine [the witnesses] during the course of the trial" to more fully address factual contentions.[8] Even where a patent owner's expert witness' testimony "may have merit, [if] those arguments raise a genuine issue of material fact" then the PTAB may "decline to resolve" those issues "on the current record" without instituting a full trial.[9]

In contrast, another panel denied institution notwithstanding the petitioner's argument that patent owner's expert witness testimony had not yet been cross-examined.[10] The panel stated that the "Petitioner argues that it has not yet had an opportunity to test or vet Patent Owner's evidence, but that does not prevent us from considering that evidence at this stage."[11] The panel indicated that they would consider such evidence and give it "appropriate weight despite the fact that Petitioner had not yet had a chance

---

[4] https://law.lexmachina.com/.
[5] *Fujitsu Network Communications, Inc. v. Core Optical Technologies, LLC*, IPR2016-01618, Paper 13 (Jan. 31, 2017), at 11 (citing 37 C.F.R. §42.108(c)).
[6] 85 Fed. Reg. 79120, 79122 (2020).
[7] *Xilinx Asia Pacific Pte. Ltd. v. Analog Devices, Inc.*, IPR2020-01219, Paper 9 (Jan. 25, 2021), at 15-16.
[8] *Id.*
[9] *Novartis Gene Therapies, Inc. v. Genzyme Corp.*, IPR2023-01044, Paper 10 (Jan. 9, 2024), at 31 (citing 37 C.F.R. §42.108(c)).
[10] *Roofr Inc. v. Pictometry International Corp.*, IPR2023-00437, Paper 14 (Aug. 1, 2023).
[11] *Id.* at 13.

(Continued on page 3)

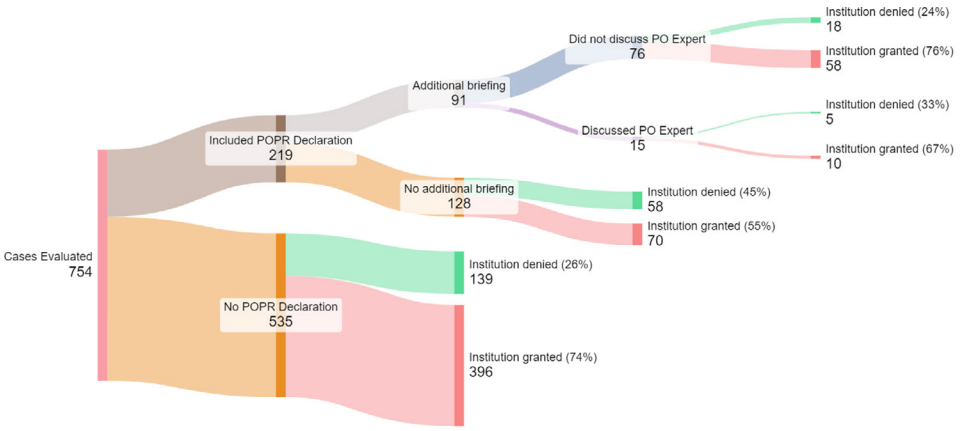
Patent Owner Pre-Institution Testimony: A Review *(continued from page 2)*

to cross examine these witnesses."[12] They explained that "[a]t this stage in the proceeding, it is Petitioner's burden to establish that it has a reasonable likelihood of succeeding despite the arguments and evidence adduced by Patent Owner."[13] Accordingly, a particular panel might give significant weight to a patent owner's pre-institution expert declaration despite the petitioner's inability to subject that testimony to cross-examination.

Patent owners also should be aware that the introduction of a pre-institution declaration may lead to additional briefing, providing the petitioner with an opportunity to address the introduced testimonial evidence.[14] Even when additional briefing is not authorized, disputed factual issues raised by a patent owner's expert declaration does not necessarily mean that the case will not be instituted. An example of this arose in *SNF S.A. v. Chevron U.S.A.*, where the patent owner's expert argued the petitioner's expert erred in reproducing examples from the literature.[15] The petitioner sought additional briefing to reply to the patent owner's expert testimony. Although the PTAB stated there was no good cause established for additional briefing, the case was instituted and proceeded to trial, allowing for cross-examination and further development of the record.[16] In summary, the result from a patent owner's submission of pre-institution expert witness testimony may be unpredictable.

What Should a Petitioner Do When Encountering a Patent Owner Pre-Institution Declaration?

From a patent challenger's perspective, the question arises: what should one do when the patent owner includes an expert witness declaration with its preliminary response? To answer this question, we evaluated the institution rates of cases where additional pre-institution briefing addressed arguments raised in the POPR.[17] Of the PTAB cases reviewed where an expert witness declaration was included with the POPR, less than half (42 percent) included additional pre-institution briefing from petitioners, and the majority of the granted briefs were limited by the PTAB to address discretionary denial arguments or unexpected claim construction arguments. Our analysis showed that where pre-institution briefing was granted, the vast majority (84 percent) of petitioners did not address the patent owner's expert witness testimony. Institution rates were comparable to typical institution rates (65-70 percent instituted)[18] regardless of whether no POPR declaration was filed (74 percent instituted), additional briefing was filed that did not discuss expert testimony (76 percent instituted), or additional briefing was filed that addressed the declaration testimony (67 percent instituted). In contrast, the institution rate fell to 55 percent in cases where the patent owner included a pre-institution declaration, but no additional briefing was authorized. This data thus suggests there is an advantage to the patent owner when filing pre-institution testimony if no additional briefing is authorized.



Of particular interest are cases where the petitioner not only requested additional pre-institution briefing but also used that briefing to address the patent owner's expert's testimony. With a small

[12] *Id.*
[13] *Id.* at 13-14 (citing 35 U.S.C. §314).
[14] *See, e.g., Manufacturing Resources International, Inc. v. Samsung Electronics Co., Ltd.*, IPR2023-01203, Paper 11 (Feb. 7, 2024), at 2.
[15] IPR2022-01534, Paper 11 (Mar. 14, 2023).
[16] *Id.*; *see also* IPR2022-01534, Paper 12 (April 19, 2023).
[17] Excluded from this data set is one outlier case (*Chongqing Yanmei Tech. Co. v. Terves LLC*, IPR2023-00521).
[18] United States Patent and Trademark Office, PTAB Trial Statistics FY22 End of Year Outcome Roundup IPR, PGR: Patent Trial and Appeal Board Fiscal year 2022, *available at* https://www.uspto.gov/sites/default/files/documents/ptab_aia_fy2022_roundup.pdf.

(Continued on page 4)

Patent Owner Pre-Institution Testimony: A Review *(continued from page 3)*

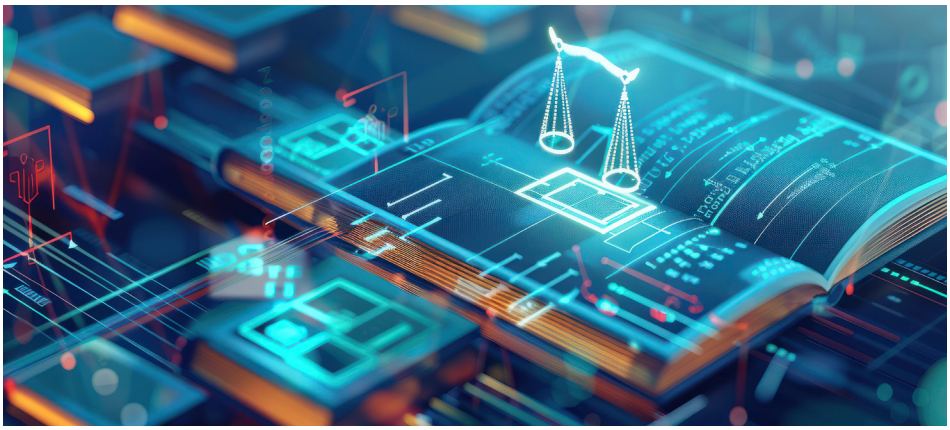
sample size of 15 instances, any attempt to elucidate a trend may be unreliable. Instead, a brief review of each case—and what the PTAB found to be most compelling—is instructive. Institution was ultimately denied in five cases where the petitioner was authorized to file additional pre-institution briefing and that briefing discussed the POPR expert testimony. In four of the five cases, the panels denied institution on the basis that the petition failed to demonstrate all elements of the claim were disclosed in the asserted prior art. In the fifth case, the panel denied institution because it was unable to conduct the required prior-art analysis due to an insufficiently clear claim construction. Thus, in each of the cases where institution was denied, the panels concluded there were apparent underlying flaws with the case-in-chief, and the PTAB did not need to rely on the patent owner's expert to deny institution. In these situations, there was never an opportunity for a battle of the experts.

Practice Considerations

Our analysis of recent PTAB institution decisions illustrates there is no universal advantage or disadvantage to a patent owner filing pre-institution expert testimony. When deciding whether to submit an expert witness declaration in support of pre-institution arguments, a patent owner should evaluate the merits with a holistic approach. Expert witness testimony may be most successful where there are clear flaws in the petitioner's case-in-chief. Patent owners should ensure that any expert witness testimony they provide at the pre-institution stage is supported by the record to minimize the risk of an unsupported battle of the experts, which in turn may increase the likelihood of institution.

Petitioners encountering pre-institution expert testimony should evaluate the case as a whole and request authorization for additional pre-institution briefing to address inconsistent or unsupported statements by the patent owner's expert. Petitioners are frequently successful at rebutting patent owner pre-institution expert testimony and achieving institution when the case-in-chief is otherwise solid.

USPTO Proposes Rules for Discretionary Denial of Institution and Requiring Pre-Institution Filing of Settlement Agreements



This year, the USPTO has issued a flurry of notices proposing rules, many affecting PTAB trial practice. The PTAB rules have covered increasing inclusiveness of attorneys in PTAB trials,[19] modifying fees,[20] and codifying Director review of PTAB decisions.[21] Recently, the USPTO proposed rulemaking that would codify discretionary institution denial practice and a requirement for pre-institution filing of settlement agreements.[22]

Discretionary Denial

The Director may deny institution of an *inter partes* review (IPR) or post-grant review (PGR).[23] The USPTO has evolved several discretionary bases for such denials, including parallel litigation,[24] parallel petitions challenging the same patent,[25] and serial petitions challenging the same patent.[26] The proposed

[19] 89 Fed. Reg. 13017 (Feb. 2024).
[20] 89 Fed. Reg. 23226 (Apr. 2024).
[21] 89 Fed. Reg. 26807 (Apr. 2024).
[22] 89 Fed. Reg. 28693 (Apr. 2024).
[23] 35 U.S.C. §§314(a) or 324(a), respectively.
[24] *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, 5-6 (2020) (precedential).
[25] Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019), 59-60 & n.3.
[26] *General Plastic Indus. Co. v. Canon K.K.*, IPR2016-01357, Paper 19, 15-16 (2017) (precedential).

(Continued on page 5)

USPTO Proposes Rules for Discretionary Denial of Institution . . . *(continued from page 4)*

rulemaking addresses parallel and serial petitions. The proposed rules would largely codify existing practices but would also provide clarity into when the parallel or serial petition considerations apply. The rules would define a "parallel petition" as another petition from the same petitioner challenging the same patent before thePOPR is due in the first case.[27] A "serial petition" would be another petition challenging overlapping claims from the same or related petitioner and filed after the POPR is due in the first case.[28] Hence, the POPR due date will become a bright line determining how the later petition will be treated.

Parallel petitions would require a statement providing good cause for why the second petition is needed.[29] The proposed rule offers nine considerations for evaluating the statement, including the number of claims and complexity of the technology.[30] As for serial petitions, although the notice proposes to codify the existing analysis, it eliminates factors addressing the PTAB's resources and decisional capacity as considerations the parties need to address, although the PTAB may still consider them in denying institution.[31]

Beyond parallel or serial petition considerations, the Director may also deny IPR or PGR institution (and reexamination) under a statute[32] that discourages reconsidering prior art and arguments considered in an earlier USPTO proceeding. The PTAB had already adopted a framework for analyzing this statutory consideration by determining whether the art and arguments are substantially the same and, if so, determining whether the earlier consideration erred.[33] With the proposed rulemaking, even if not all of the grounds or claims have been previously considered, the PTAB might nevertheless deny institution if the overlap "implicated" the statutory concern.[34] However, the PTAB would not deny institution based on art of record that was not "meaningfully addressed" previously by the Office.[35]

The proposed rules would also implement a briefing schedule to address certain discretionary denial issues, as opposed to the current practice which largely depends on obtaining briefing authorization on a case-by-case basis (although such briefing is typically granted). A patent owner would be able to challenge serial petitions (and petitions with previously considered art or arguments), but not the parallel petitions, with a request for discretionary denial of up to 10 pages filed no later than two months after the PTAB has docketed the petition.[36] The petitioner's opposition of up to 10 pages would be due concurrent with the POPR.[37] The patent owner's reply addressing discretionary denial would be due two weeks after the POPR.[38]

For joinder petitions, the PTAB will treat the parallel-petition and same art/argument concerns as having been resolved with the first petition and will not consider discretionary denial on these bases.[39]

Pre-Institution Settlement Agreement

By statute, parties settling an IPR or PGR trial must file a written settlement agreement.[40] The PTAB has evolved a practice of requiring filing of such agreements before institution as well. The notice of proposed rulemaking explains that most settlements occur before institution.[41] The USPTO notice cites administration policy as an additional reason to extend the statutory requirement to pre-institution settlements. Because the PTAB is already enforcing such filings, this codification will likely have little impact.

Conclusion

If these practices are codified in rules, their application should ultimately be more stable and predictable because future Directors would have to go through rulemaking—including notice well in advance of adoption—to change them.

---

[27] 89 Fed. Reg. at 28703, proposed 37 C.F.R. §42.2.
[28] *Ibid*.
[29] *E.g.*, *id*. at 28704, proposed 37 C.F.R. §42.108(d).
[30] *Ibid*.
[31] 89 Fed. Reg. at 28699.
[32] 35 U.S.C. §325(d).
[33] *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, 8-9 (2020) (precedential).
[34] *E.g.*, 89 Fed. Reg. at 28705, proposed 37 C.F.R. §42.108(f).
[35] *E.g.*, *id.* at 28705, proposed 37 C.F.R. §42.108(f).
[36] *E.g.*, *id*. at 28704, proposed 37 C.F.R. §42.107(b).
[37] *Id.* at 28696.
[38] *Id.*
[39] *E.g.*, 89 Fed. Reg. at 28704, proposed 37 C.F.R. §42.108(c)(2).
[40] 35 U.S.C. §§317(b) and 327(b).
[41] 89 Fed. Reg. at 28697.

USPTO Decides Written Description Support for Means-Plus-Function Antibody Claims Does Not Require Specification Disclosure of All Equivalents

On May 21, 2024, the Appeal Review Panel (ARP) of the PTAB (constituted by the USPTO Director, Commissioner for Patents, and PTAB Chief Administrative Patent Judge) issued a decision in *Ex parte Chamberlain*[42] determining that means-plus-function claims may be used to claim a disclosed antibody and its equivalents regardless of whether the specification discloses the equivalent antibodies. In the process, the USPTO provided patentees with a roadmap for antibody claims that extend more broadly than the individually disclosed antibodies.

Our frequent readers will recall that antibody claims have been a topic of great interest recently. Last year, the U.S. Supreme Court famously held a set of claims reciting a genus of antibodies by their ability to bind to a target molecule was invalid under 35 U.S.C. § 112 even though the specification disclosed 20 antibody sequences falling within the genus.[43] Responding to the difficulty of claiming the entire genus based on disclosure of a non-representative selection of species, some scholars advocated using means-plus-function claims to obtain greater assurance of validity under Section 112 while leaving some room to dispute claim breadth in the form of "equivalents" of the disclosed structures.[44] Such efforts met a temporary roadblock when the PTAB held means-plus-function antibody claims invalid under Section 112 for failing to disclose the structures of the equivalents of the disclosed antibodies.[45]

The USPTO subsequently asked the Federal Circuit to vacate and remand that decision to allow the USPTO to more "clearly and thoroughly" express its views on the subject.[46] The product of that remand clarifies that means-plus-function claims are not invalid under Section 112 for failing to disclose the equivalents of the disclosed antibodies, providing new life to this strategy for functionally claiming a genus of antibodies.

The claims at issue in *Chamberlain* were directed to methods of treating a patient by administering an antibody that 1) binds human C5 protein; and 2) has two specific mutations to the human Fc domain that increased the in vivo half-life of the antibody as compared to the unsubstituted antibody.[47] The ARP first evaluated claims reciting "administering an anti-C5 antibody" with the recited mutations and subsequently evaluated similar claims that phrased the antibody limitations as "means for binding human C5 protein."[48]

Regarding the claimed anti-C5 antibodies, the ARP explained that the claims' use of functional language for an entire genus required disclosure of a representative number of species of sufficient variety to reflect the variation within the genus and to demonstrate the inventor was in possession of the necessary common attributes or features possessed by the members of the genus.[49] The specification's reference to "anti-complement (C5) antibodies such as

5G1.1" was insufficient to provide written description support for the broad genus of anti-C5 antibodies (having various specificities and epitopes).[50] The ARP explained that the claims encompassed a "vast repertoire of antibodies" but were unrestricted by variable region structure, epitope, function, or mechanism of action in treatment.[51]

Furthermore, the ARP concluded the specification lacked adequate structure-function relationship information to visualize or recognize members of the genus because it failed to disclose how much variation is permissible for the antibody to both bind C5 and treat the patient, failed to identify the amino acid sequence that enables it to do so, and left the ordinary artisan unable to distinguish which Fc-substituted anti-C5 antibodies would fall with the

[42] *Ex parte Chamberlain*, Appeal No. 2022-001944 (Appeal Review Panel May 21, 2024).
[43] *Amgen v. Sanofi*, 598 U.S. 594 (2023).
[44] *E.g.*, Mark A. Lemley & Jacob S. Sherkow, *The Antibody Patent Paradox*, 132 YALE L.J. 994 (2023).
[45] *Ex parte Chamberlain*, Appeal No. 2022-001944, at 35.
[46] *In re Xencor, Inc.*, Appeal No. 2023-2048 (Fed. Cir. Nov. 27, 2023), Paper 32.
[47] *Ex parte Chamberlain*, Appeal No. 2022-001944, at 3-4.
[48] *Id.*
[49] *Id.* at 18-19.
[50] *Id.* at 22.
[51] *Id.* at 22.

(Continued on page 7)

USPTO Decides Written Description Support for Means-Plus-Function . . . *(continued from page 6)*

claim scope by treating the patient and which would not.[52] Because there was no description in the specification that permitted an ordinary artisan to distinguish which members of the genus can be used to treat patients and which cannot, the ARP concluded the claimed anti-C5 antibodies were not sufficiently well-known in the art to make it unnecessary for the specification to disclose representative species or the required structure-activity relationship.[53]

Regarding the treating limitation, the ARP concluded the claims again lacked written description support because the specification did not describe in sufficient detail what patients with what diseases or conditions can be successfully treated with the claimed Fc-substituted anti-C5 antibody.[54] Though the specification listed three classes of diseases/conditions that might benefit from administration of various antibodies with an Fc modification, it failed to demonstrate that these diseases are representative of all claimed diseases.[55]

For the means-plus-function claim, the ARP concluded that the 5G1.1 antibody was the corresponding structure for the claimed means, that there was adequate written description support for the claim, and the claim was not indefinite, but that the claim lacked written description support for the full breadth of treating a patient.[56] The specification did not need to disclose the sequence of 5G1.1 because the patent owner demonstrated that 5G1.1 referenced a sequence that was already known in the art.[57] The ARP concluded that disclosure of equivalents is not necessary to satisfy the written description or indefiniteness requirements for a means-plus-function claim term.[58]

The *Chamberlain* decision affords patentees an opportunity to claim the antibodies they have specifically disclosed as part of their invention as well as undisclosed equivalents thereof. Under the guidance provided in *Chamberlain*, means-plus-function antibody claims are most likely to be valid when limited to a specific disease condition for which the specification provides a working example. This arguably provides a path for patentees to secure at least somewhat broader antibody protection while deferring adjudication of which antibodies are equivalent (and thereby infringing) for a later day. At the same time, *Chamberlain* underscores that the USPTO is not amenable to granting or upholding broad, functionally-defined antibody genus claims absent a showing that the specification discloses a representative number of species or a structure-activity relationship for using the genus to treat the claimed indication.

[52] *Id.* at 22-23.
[53] *Id.* at 23-25.
[54] *Id.* at 25-26.
[55] *Id.* at 26-27, 38.
[56] *Id.* at 28-29.
[57] *Id.* at 33-34.
[58] *Id.* at 35-37.

Federal Circuit Vacates District Court for Overly Rigid Approach to Obviousness of Drug Dosing Regimen Under *KSR*

In its 2007 decision *KSR International Co. v. Teleflex Inc.*, the Supreme Court emphasized that an expansive and flexible approach to the obviousness analysis must be applied by courts when assessing the validity of a claimed invention.[59] To this end, the Supreme Court cautioned against analyses that required explicit teachings from the prior art without due consideration to the ordinary creativity of the person of ordinary skill (POSA).[60] In *Janssen Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.*, the Federal Circuit reiterated the principles outlined in *KSR* when vacating a district court's determination of non-obviousness of claims directed to dosing regimens of a known drug.[61]

Janssen involved the validity of claims of U.S. Patent No. 9,439,906 (the "'906 patent"), which covers the administration of Janssen's Invega

[59] 550 U.S. 398, 415 (2007).
[60] *Id.* at 401-02.
[61] 97 F.4th 915 (Fed. Cir. 2024).

(Continued on page 8)

Federal Circuit Vacates District Court for Overly Rigid Approach . . . *(continued from page 7)*

Sustenna, an extended-release intramuscular injectable of paliperidone palmitate, a drug indicated for the treatment of schizophrenia in adults.[62] More specifically, the claims recite the intramuscular injection of certain dosage amounts of paliperidone palmitate to a psychiatric patient (with or without renal impartment) at specific locations and on certain days during the course of treatment.[63] At the time of the '906 patent's priority date, the administration of paliperidone palmitate, including the recommended dosing and intramuscular injection, was well known to POSAs for the effective treatment of schizophrenia.[64]

Patent Owner Janssen sued Teva for infringement of the '906 patent after Teva filed an Abbreviated New Drug Application (ANDA) seeking U.S. Food and Drug Administration (FDA) approval to sell a generic version of Invega Sustenna.[65] Before the district court, Teva argued that the '906 patent claims were obvious over three primary references, including a clinical study protocol ("the '548 protocol").[66] The '548 protocol described a protocol for a Janssen-sponsored Phase III clinical trial designed to study the effectiveness and safety of a fixed-dosage regimen of intramuscularly-injected paliperidone for the treatment of schizophrenia.[67]

The clinical trial described by the '548 protocol yielded insufficient results to obtain FDA approval and was ultimately considered a failure by Janssen.[68] These results, however, were unknown to the POSA by the '906 patent's priority date.[69] Despite this, in concluding that Teva had failed to carry its burden in proving the obviousness of the claims, "the import of these unknown results influenced the district court's view about what the claims require, what a POSA would need to know before she was motivated to modify the '538 protocol, and what results would be unexpected."[70]

Teva raised three issues regarding obviousness on appeal: 1) whether the district court "required a showing of obviousness that was incongruent with the scope of the claims"; 2) "whether the court analyzed the prior art with a degree of rigidity foreclosed by *KSR*"; and 3) whether the court properly analyzed secondary considerations.[71]

For the first issue, Teva asserted the district court required Teva to show that "it would have been obvious to use the recited dosing regimens for the general population of patients—i.e., a generalized dosing regimen."[72] According to the district court, because the prior art did not demonstrate population-wide safety and efficacy, and thus did not teach a generalized dosing regimen, the '906 patent claims were non-obvious over that art.[73] Because the claims merely recite administering paliperidone to "*a* psychiatric patient," however, the Federal Circuit concluded that "[n]othing in the claims requires that the regimen be used for—let alone be ideal for—the patient population generally or a certain percentage of the patient population."[74] That is, administration of the dosing regimen to one patient would

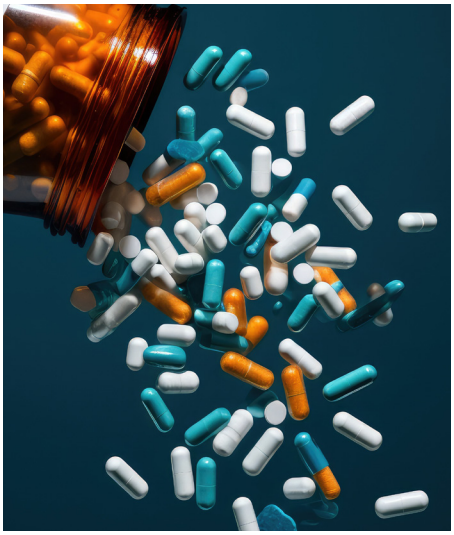
[62] *Id.* at 918.
[63] *Id.* at 918-20.
[64] *Id.* at 920-22.
[65] *Id.* at 918.
[66] *Id.* at 922.
[67] *Id.*
[68] *Id.* at 922-23.
[69] *Id.* at 922.
[70] *Id.*
[71] *Id.* at 924.
[72] *Id.* at 925.
[73] *Id.*
[74] *Id.* at 926.

(Continued on page 9)

Federal Circuit Vacates District Court for Overly Rigid Approach . . . *(continued from page 8)*

satisfy the claims. The Federal Circuit identified several aspects of the district court's obviousness analysis where it required the prior art to demonstrate the use of the claimed dosing regimens for a generalized population, including the district court's "conflating Janssen's purported difficulties in generating data to gain [FDA] approval for a 'universal' or 'generalized' dosing regimen with the scope of the *claims* themselves" and the undue weight given to the difficulties encountered by Janssen during the FDA approval process.[75] Thus, as *KSR* had counseled, "[b]ecause what matters is the objective reach of the claim," the Federal Circuit found that the district court had erred "to the extent it effectively defined its obviousness inquiry as one concerning the 'generalized' suitability of the dosing regimens."[76]

For the second issue, Teva argued that the district court's analysis was impermissibly rigid and did not comport with *KSR*.[77] Agreeing with Teva, the Federal Circuit found error in several respects in the district court's "siloed and inflexible approach" that "seem[ed] to tackle the express statements of each reference one-by-one" without "giving the needed weight to the perspective of a POSA capable of deducing what references fairly suggest or employing ordinary creativity."[78] The Federal Circuit focused on the district court's assessment of the '548 protocol, where the court had found that a POSA would not have been motivated to modify the '548 protocol because the protocol contained no safety or efficacy data.[79] In other words, according to the district court's analysis, if a prior art reference does not contain safety and efficacy data, there would be no reason to combine it with other prior art references.[80] The Federal Circuit found this to be error because, "[w]hatever role safety and efficacy data may play in assessing the strength of a motivation or a lack of motivation to



combine . . ., absence of such safety and efficacy data in the '548 Protocol cannot justify simply discarding that prior art particularly where, as here, the claims do not have any safety and efficacy requirement."[81]

The Federal Circuit also found the district court erred by "fail[ing] to consider what the '548 protocol would fairly suggest to a POSA."[82] For instance, the court did not consider evidence establishing how a POSA would have viewed the Phase III status of the '548 protocol or evidence showing that paliperidone was already on the market and prescribed to patients with schizophrenia.[83] While "obtaining specific results or outcomes in a population of patients could have been one motivation for modifying the protocol," which apparently motivated Janssen, "the motivation analysis does not look only to the data the patentee found significant" (i.e., the results of the '548 protocol's clinical study).[84]

For similar reasons, the Federal Circuit rejected the district court's finding that motivation was undermined by the POSA being unaware of the '548 protocol's ultimate failure. The Federal Circuit found that "the '548 protocol did not need to hold itself out as flawed for a POSA to alter it."[85] Identifying a recognized problem or need in the prior art is one way to demonstrate obviousness, not the only way.[86] The district court additionally erred by requiring Teva to prove that a POSA would have been motivated to administer the drug at the claimed muscular site (i.e., deltoid muscle) to the exclusion of other possible sites (e.g., gluteal muscle).[87] As the Federal Circuit held, "[a] POSA can be motivated to do more than one thing" and Teva was not required "to show that a POSA would be

---

[75] *Id.* at 926-27 (emphasis original).
[76] *Id.* at 926 (alteration and internal quotations omitted).
[77] *Id.* at 927-28.
[78] *Id.* at 928.
[79] *Id.*
[80] *Id.*
[81] *Id.* at 928-29.
[82] *Id.* at 929.
[83] *Id.*
[84] *Id.*
[85] *Id.*
[86] *Id.* at 929-30.
[87] *Id.* at 930.

(Continued on page 10)

Federal Circuit Vacates District Court for Overly Rigid Approach . . . *(continued from page 9)*

singularly motivated to use the deltoid injection site."[88] The district court erred by narrowly focusing on the express dosage amounts disclosed in the '548 protocol and rejecting relevant evidence concerning similar injectable drugs to the exclusion of the inferences that a POSA would have made in view of the prior art.[89]

In sum, the Federal Circuit found that the district court's obviousness analysis "ran afoul of *KSR*'s basic mandate in a number of ways" by failing to "consider the 'interrelated teachings of multiple' references, 'the background knowledge possessed by a person having ordinary skill in the art,' or 'the inferences and creative steps that a person of ordinary skill in the art would employ.'"[90] "Instead, the court sought an explicit indication in the '548 protocol that an improvement was required—at times also suggesting that it was searching for an indication that the claims captured *the* singular way the protocol would be modified."[91]

Lastly, for the third issue, the Federal Circuit addressed the district court's analysis of Janssen's evidence of secondary considerations. First, the Federal Circuit addressed the district court's analysis of unexpected results where it had compared the claims to "the conventional wisdom" that dosing with antipsychotics should "start low and go slow," which was contrary to the claims that used "high, rather than low, loading doses to initiate treatment."[92] The Federal Circuit found this comparison, which involved medications with active ingredients other than paliperidone, to be improper because it was not "a comparison of the closest prior art."[93] The '548 protocol, as the closest prior art, disclosed the claimed starting dose—"[t]here is simply nothing unexpected about starting with a dose of the paliperidone palmitate LAI [long acting injectable] that was already disclosed simply because other medications were dosed differently."[94]

The Federal Circuit also disagreed with the district court's finding of unexpected results compared to the '548 protocol itself because "the court did not use the required reference point for evaluating unexpectedness."[95] "The question was whether, as of the priority date, using the claimed dosing regimens yielded unexpected results when compared with a POSA's expectations based on the state of the prior art."[96] For this reason, the Federal Circuit found inappropriate the district court's comparison between Janssen's expectations of the '548 protocol results and its disappointment in those results because it was unclear how the study's failures related to the claims, rather than how the clinical trial was conducted.[97] The Federal Circuit also found improper the district court's comparison between the results of the '548 protocol's clinical trial and the results of the marketed drug because the POSA would have been unaware of those results, making it irrelevant to the POSA's expectations.[98]

Finally, the Federal Circuit addressed the district court's analysis of long-felt need and commercial success and whether it improperly disregarded the impact of blocking patents.[99] The Federal Circuit found that the court's assessment of the impact of the blocking patents "should have focused on the blocked space that related to Invega Sustenna because that is what Janssen contended was commercially successful and filling an unmet need," rather than whether it was possible to practice the claims without infringing by dosing a different formulation of paliperidone (i.e., not Invega Sustenna).[100] The Federal Circuit also found the court's reliance on the existence of the safe harbor provision alone to be in error because "[t]he ability to avoid infringement liability for conduct related to preparing FDA submissions does not end the inquiry into the potential deterrence associated with the risk of market entry preclusion once those submissions are complete."[101]

In summary, this decision provides a strong reminder of the importance of avoiding an overly rigid approach to the obviousness analysis in order to survive appellate review.

---

[88] *Id.*
[89] *Id.* at 930-31.
[90] *Id.* at 931.
[91] *Id.* (emphasis original).
[92] *Id.* at 933-34.
[93] *Id.* at 934.
[94] *Id.*
[95] *Id.*
[96] *Id.*
[97] *Id.*
[98] *Id.* at 934-35.
[99] *Id.* at 935.
[100] *Id.* at 936.
[101] *Id.*

About Our Post-Grant Practice

The professionals in Wilson Sonsini Goodrich & Rosati's post-grant practice are uniquely suited to navigate the complex trial proceedings at the United States Patent and Trademark Office (USPTO). We have extensive experience before the PTAB, representing clients in numerous new trial proceedings and in countless reexaminations and patent interference trials. Our practice includes professionals with decades of experience at the PTAB, including former USPTO personnel. Our core team leverages firmwide intellectual property expertise to provide comprehensive IP solutions for clients that cover strategy, prosecution, licensing, enforcement, and defense.

For more information, please contact:

Michael Rosato
206.883.2529
mrosato@wsgr.com

Matt Argenti
650.354.4154
margenti@wsgr.com

Richard Torczon
202.973.8811
rtorczon@wsgr.com

Jad Mills
206.883.2554
jmills@wsgr.com

WILSON SONSINI

650 Page Mill Road, Palo Alto, California 94304-1050 | Phone 650-493-9300 | Fax 650-493-6811 | www.wsgr.com

Wilson Sonsini has 19 offices in technology and business hubs worldwide. For more information, visit wsgr.com/offices.

For more information on the current venture capital climate, please contact any member of Wilson Sonsini Goodrich & Rosati's emerging companies practice. To learn more about Wilson Sonsini's full suite of services for entrepreneurs and early-stage companies, please visit the emerging companies section of wsgr.com.