May 2023

WILSON SONSINI

THE PTAB REVIEW

This issue of *The PTAB Review* begins by summarizing several Patent Trial and Appeal Board (PTAB) policy questions the U.S. Patent and Trademark Office (USPTO) has raised in an advance notice of proposed rulemaking. Readers should follow this rulemaking, which could significantly affect both petitioners and patent owners. Concerned readers may wish to weigh in on one or more of the proposals that are under consideration.

Next, we examine two recent appellate decisions. One is a Federal Circuit decision addressing the scope of *inter partes* review (IPR) estoppel and the allocation of the burden of proving whether IPR estoppel applies in a given circumstance. The second is a Federal Circuit decision addressing the requirement for showing written description support of a negative claim limitation, on which the U.S. Supreme Court recently denied review.

Then, we examine several decisions addressing the requirement when proving obviousness to establish a rationale that would cause a person of ordinary skill in the art to combine prior art elements in a manner that satisfies the challenged claim as a whole. We discuss the difference between a challenger merely establishing that a modification could have been made and a challenger establishing that a modification would have been made (even if other more desirable alternatives were known).

Finally, we briefly summarize the Supreme Court's May 18, 2023 decision addressing enablement of antibody genus claims in *Amgen Inc. v. Sanofi*.

In This Issue

USPTO Advance Notice of Proposed Rulemaking

Regular readers of *The PTAB Review* are well aware of various efforts to fine-tune how and when someone may request a PTAB trial. In addition to statutory bases for denial of institution (i.e., weak merits or duplicative challenges (35 U.S.C. §325(d))), the USPTO in recent years introduced additional discretionary bases for denial of institution related to parallel litigation (*Fintiv*), serial challenges to the same patent at the PTAB (*General Plastic*), and simultaneous petitions against the same patent. These initiatives were introduced via precedential PTAB decisions or practice guide updates and, as discussed in 2021, resulted in a significant number of denials of institution. Director Kathi Vidal subsequently issued additional guidance regarding discretionary denial with the goal of providing greater predictability to stakeholders, as discussed in October 2022. In March 2023, the Federal Circuit upheld the authority of the Director to establish discretionary bases for denial of institution but revived claims that the Director was required by the Administrative Procedures Act to do so via notice-and-comment rulemaking rather than by designating PTAB decisions precedential.[1] On April 21,

2023, the USPTO issued an advanced notice of proposed rulemaking considering discretionary institution practices, among others. The proposals under consideration are significant, far reaching, and of interest to potential petitioners and patent owners. A summary of the proposals is provided below. The USPTO has requested feedback on these proposals, which is due by June 20, 2023.

Discretionary Denial

The USPTO proposes to adopt by regulation certain existing and new discretionary denial practices. The USPTO seeks to provide clear rules about discretionary denial and also to emphasize the PTAB's ability to deny

[1] *Apple Inc. v. Vidal*, 2022-1249 (Fed. Cir. Mar. 13, 2023).

(Continued on page 2)

USPTO Advance Notice of Proposed Rulemaking *(continued from page 1)*

institution as a sanction or in response to improper conduct. The USPTO also proposes that the parties address discretionary denial issues in a separate paper to preserve petition word count for the merits. The patent owner would file a 10-page request for discretionary denial prior to the deadline for the preliminary response. The petitioner could then file a 10-page opposition and the patent owner a five-page reply. The USPTO additionally proposes that the PTAB be authorized to raise discretionary denial issues *sua sponte*. The USPTO is considering requiring the patent owner to disclose information about entities having a substantial relationship with the patent owner as a condition of requesting discretionary denial.

(i) New Bases for Discretionary Denial

New categories of discretionary denial proposed by the USPTO include restricting petitions filed by for-profit entities having no apparent reason to challenge the claims. The identified goal of the proposal is to curb abusive filings where the petitioner is in essence seeking to shield the actual real parties in interest and privies from statutory estoppel. The proposal would be to deny institution where the petition is filed by an entity that 1) is for-profit; 2) has not been sued for infringement or threatened with infringement sufficient to create declaratory judgment standing; and 3) is not or could not be alleged to be practicing in the field of the challenged patent with a product or service that is on the market or intended to be marketed. Rather than narrowly tailoring its rules to prohibit abusive conduct, this proposal may essentially require a petitioner who is not already accused of infringement to identify a potentially infringing product in order to petition the PTAB for review. This would represent a significant expansion of discretionary denial as compared to current practice.

Another proposal under consideration is to deny institution if the patent owner provides the petitioner with a covenant not to sue for the subject patent. This would essentially provide a patent owner with an off-ramp from America Invents Act (AIA) review.

Still another proposal under consideration is to deny institution where the patent owner lacks funding to defend challenges to the patent but has sought to bring the invention to market. The USPTO proposes to use micro or small entity status at patent issuance and preceding year gross income metrics as the criteria for establishing funding status. The USPTO proposes imposing disclosure requirements to determine whether an allegedly under-resourced patent owner has financial relationships with well-resourced private or government interests.

Still another proposal under consideration is to deny institution where a district court, PTAB trial, or reexamination proceeding has already finally adjudicated the claims favorably to the patent owner, unless a petitioner who would have standing to challenge the patent in district court demonstrates the petition has compelling merits.

(ii) Compelling Merits Safe Harbor

The USPTO proposes that a challenge that presents compelling merits will be allowed to proceed at the PTAB even where the petition otherwise would be subject to discretionary denial. The compelling merits standard would be satisfied when the evidence of record at institution leaves the PTAB with a firm belief or conviction that it is highly likely to lead to a conclusion that a claim is unpatentable by a preponderance of evidence. This is a higher bar than the statutory standards for institution of IPRs and PGRs. The USPTO proposes not reaching a compelling-merits determination until all other discretionary-denial factors favor discretionary denial.

The USPTO also requests comments on how a compelling-merits analysis should proceed if the patent owner raises a factual question that cannot be resolved at institution (such as secondary considerations of nonobviousness), including whether the PTAB should review the record in the light most favorable to and draw all reasonable inferences in favor of the patent owner.

(iii) Duplicative Challenges (35 U.S.C. §325(d))

Regarding discretionary denial of duplicative challenges under 35 U.S.C. §325(d), the USPTO proposes to adopt by regulation the existing *Advanced Bionics*[2] framework with certain modifications. In particular, the USPTO proposes that an examiner notation indicating consideration of a reference but without discussion of it (e.g., considered on an Information Disclosure Statement or Examiner Search Results) would not qualify as a basis for discretionary denial. The USPTO proposes relying on prosecution history from related applications with substantially similar claims for discretionary denial. The USPTO proposes that different publications of the same document (U.S. national stage filing vs. Patent Cooperation Treaty application) and nonpatent literature teaching the same claim limitation in the same way be considered substantially the same art for purposes of

[2] *Advanced Bionics, LLC v. Med-El Elektromedizinische Gerate GMBH*, IPR2019-01469, Paper 6 (Feb. 13, 2020) (precedential).

(Continued on page 3)

USPTO Advance Notice of Proposed Rulemaking *(continued from page 2)*

discretionary denial. The USPTO proposes that the burden be placed upon the patent owner to show the same or substantially the same art or arguments were previously considered, whereupon the petitioner must show material error by the USPTO to justify institution.

(iv) Parallel District Court Litigation

Regarding discretionary denial based on parallel litigation, the USPTO proposes to adopt by regulation the existing *Fintiv* framework with modifications. The USPTO proposes that PGR proceedings, which have strict time limits on which patents are eligible and result in broad estoppel, be exempted from *Fintiv* denial. The USPTO proposes a clear, predictable denial of institution for IPR challenges to patents subject to co-pending district court litigation involving at least one of the same claims and an expected trial date that precedes the projected issuance of the final written decision unless a safe harbor applies. The USPTO proposes a safe harbor will apply when 1) the petition is filed within six months of the petitioner being served with an infringement complaint; 2) the district court litigation has already been stayed pending the PTAB's final written decision; or 3) the petition presents compelling merits. The USPTO also proposes a safe harbor will apply when a petitioner files a *Sotera* stipulation agreeing not to pursue potentially overlapping grounds in district court regarding the claims challenged in the petition. The USPTO seeks comments about whether this safe harbor should be withdrawn and a *Sotera* stipulation should instead be made a necessary but not sufficient basis for institution.

(v) Serial Petitions

The USPTO proposes a predictable rule granting discretionary denial when the same petitioner or someone with a significant relationship to that petitioner files a second petition challenging at least one of the same claims after a preliminary response is filed or was due, unless the earlier petition was resolved for reasons not materially related to the merits or exceptional circumstances are shown. Exceptional circumstances would include that the claims have been amended, the petitioner could not reasonably have known of or found the art asserted in the serial petition, or the petition raises new statutory grounds not raised in the prior petition with a justifiable explanation for why it was not previously raised. The USPTO also requests comments on whether it should deny institution of any serial petition regardless of any relationship to the first petitioner, which would be a significant expansion of discretionary denial practice.

Even when a subsequent petitioner is neither a privy nor a real party in interest to the first petition, the PTAB has denied institution of a serial petition where the petitioners shared both a licensor-licensee relationship and were co-defendants in district court litigation. The PTAB also has denied institution where the petitioner was previously a joinder petitioner challenging the same claims. The USPTO proposes a "substantial relationship" test between entities to determine whether to apply discretionary denial of institution. Substantial relationships would include real parties in interest, privies, as well as the license/co-defendant and joinder petitioner relationships discussed above. In addition, the USPTO is considering whether to find a substantial relationship when a petitioner is a member of an organization or where entities pool resources to challenge a patent. This would significantly expand the scope of discretionary denial practice. The USPTO also proposes a significant expansion of disclosure obligations as compared to existing practice to enforce its substantial relationship test.

(vi) Multiple Simultaneous Petitions

The USPTO proposes to adopt existing guidelines prohibiting a petitioner from filing multiple simultaneous petitions against the same patent except where good cause is shown. The USPTO proposes to permit a petitioner to pay additional fees for a higher word count (e.g., 50 percent increase for 50 percent higher word count) for the petition and all subsequent merits briefing. This would provide a cost savings as compared to filing multiple petitions against the same patent and reduce the risk of IPR estoppel from one case impacting another in unintended ways.

Miscellaneous Procedural Modifications

The USPTO proposes to require true copies of all settlement agreements to be filed for pre-institution settlements as well as post-institution settlements. While the current statute only requires such disclosure for a termination after institution, this regulation would adopt current the PTAB's practice of applying the requirement to pre-institution settlements.

Conclusion

The USPTO's advanced notice of proposed rulemaking provides an important opportunity for stakeholders to provide feedback on a host of critical issues for the PTAB. The effects of these proposals are far reaching, with the potential to significantly shift the balance of power between patent owners and petitioners before the PTAB. Members of Wilson Sonsini's post-grant review practice stand ready to answer your questions about how these proposals may impact you and your industry.

Federal Circuit Establishes "Skilled Searcher" Standard and Burden of Proof for IPR Estoppel

In *Ironburg Inventions Ltd. v. Valve Corp.*[3] the Federal Circuit clarified the scope of estoppel and the burden of proof for applying estoppel following an IPR. By statute, when an IPR results in a final written decision, petitioners—and their privies and real parties in interest—are estopped from requesting or maintaining USPTO proceedings against challenged claims "on any ground that the petitioner raised or reasonably could have raised" during that IPR.[4] A similar estoppel applies in civil actions and International Trade Commission (ITC) proceedings.[5] Previous Federal Circuit decisions have held that IPR estoppel precludes the use of art that reasonably could have been raised in the petition regardless of whether it could have been addressed in the final written decision,[6] and takes immediate effect upon issuance of the final written decision even against pending IPRs based on simultaneously filed petitions.[7] *Ironburg* further defines the contours of IPR estoppel by 1) setting forth the standard for determining whether petitioners "reasonably could have raised" a ground and 2) placing the burden of proof on patent owners.[8]

Case Background

After Ironburg sued Valve for infringement of a videogame-controller patent, Valve filed an IPR petition presenting multiple grounds of unpatentability, each of which challenged a different subset of the claims.[9] The PTAB instituted trial on some, but not all grounds,[10] which was permitted before the U.S. Supreme Court's decision in *SAS Inst., Inc. v. Iancu*.[11] The PTAB ultimately canceled all claims in the instituted grounds, though other claims challenged only in the non-instituted grounds survived.[12] Valve did not seek remand following *SAS* to allow the PTAB to consider the non-instituted grounds.[13]

In district court, Valve presented four art-based grounds of invalidity, including the non-instituted grounds from the IPR and additional grounds that had not been included in its IPR petition ("non-petitioned grounds").[14] The district court found that IPR estoppel arose from the art asserted in both types of grounds, evaluating whether Valve "reasonably could have raised" the grounds under the "skilled searcher" standard that had previously been used by several other district courts.[15]

IPR Estoppel Holdings

The Federal Circuit quickly dispensed with Valve's argument that it could not have reasonably raised the non-instituted grounds, citing an intervening Federal Circuit decision addressing a similar issue. In that case, the Federal Circuit held that IPR estoppel arises from all art raised in the petition, even when grounds raising that art were not instituted under the now defunct partial-institution framework.[16]

Turning to Valve's argument that it could not have reasonably raised the non-petitioned grounds, the Federal Circuit began by adopting the "skilled searcher" standard that was proposed by both parties on appeal.[17] Under this standard, grounds that a petitioner "reasonably could have raised" are those that "a

[3] 64 F.4th 1274 (Fed. Cir. 2023).
[4] 35 U.S.C. §315(e)(1).
[5] 35 U.S.C. §315(e)(2).
[6] *California Inst. of Tech. v. Broadcom Ltd.*, 25 F.4th 976 (Fed. Cir. 2022).
[7] *Intuitive Surgical, Inc. v. Ethicon LLC*, 25 F.4th 1035 (Fed. Cir. 2022).
[8] *Ironburg*, 64 F.4th at 1297-99.
[9] IPR2016-00948, Paper 1.
[10] IPR2016-00948, Paper 10.
[11] 584 U.S. __, 138 S. Ct. 1348 (2018).
[12] IPR2016-00948, Paper 44.
[13] *Ironburg*, 64 F.4th at 1283.
[14] *Id.* at 1296.
[15] *Id.*
[16] *Id.* at 1297 (citing *Click-to-Call Techs. LP v. Ingenio, Inc.*, 45 F.4th 1363, 1370 (Fed. Cir. 2022)).
[17] *Ironburg*, 64 F.4th at 1297-98.

(Continued on page 5)

Federal Circuit Establishes "Skilled Searcher" Standard and Burden . . . *(continued from page 4)*

skilled searcher conducting a diligent search reasonably could have been expected to discover."[18]

Despite agreeing with the standard applied by the district court, the Federal Circuit nevertheless vacated and remanded this portion of its decision because the district court had placed the burden of proof on Valve, the patent challenger.[19] The panel noted that various district courts have allocated this burden differently, and it resolved this split by holding that *patent owners* bear the burden of proving that a skilled searcher conducting a diligent search would have reasonably identified the relevant ground.[20] This burden allocation, the panel reasoned, is consistent with the general practice for affirmative defenses.[21] The panel recognized that district courts may encounter attorney-client privilege issues if a patent challenger seeks to protect the details of its search efforts, but it noted that courts are equipped to resolve privilege disputes and emphasized that the relevant inquiry is what a skilled searcher "*would* find through reasonable diligence and not what an actual researcher in fact *did* find."[22]

Lessons from the Decision

This decision has several strategic implications for petitioners and patent owners. First, it provides a clear statement of the standard that parties must address in disputes over whether a petitioner "reasonably could have raised" a ground. In placing the burden of proof on patent owners, the decision also clarifies the battle lines for estoppel disputes: patent owners must be prepared to come forward with sufficient evidence to meet their burden, while patent challengers have the option of taking a more defensive posture and framing the issue in terms of the patent's owner failure of proof.

The decision also hints at what tactics and evidence may or may not be successful. The panel appeared skeptical that patent challengers can defeat plausible estoppel arguments by asserting privilege to block production of their search results. The panel's explanation that courts can resolve such privilege issues and "factor such resolution" into their findings[23] highlights several risks of this approach. For example, to the extent search results are covered by work-product protections rather than attorney-client privilege, such protections may be defeated by a showing of necessity. Even if work-product or attorney-client privilege assertions are upheld, the court's ability to "factor such resolution" into its findings suggests the possibility of an adverse inference.

The Federal Circuit's emphasis that the relevant inquiry is what a searcher *would* have reasonably found (not what an actual searcher *did* find) also has several implications. While patent owners can show that their own post-hoc searches identified a given reference, as Valve did here,[24] they should consider presenting additional types of evidence. The panel states that, if patents owners present the results of their own search, they must show that the search was "only 'reasonably' diligent and did not involve extraordinary measures."[25] The panel similarly notes that searches "employ[ing] 'scorched earth' tactics to find the references … may be irrelevant."[26] Even if a patent owner's post-hoc search did not employ "scorched earth" tactics, the patent challenger may argue that the search was reverse engineered to identify a reference.

Given these potential rebuttals, patent owners should consider presenting additional evidence that a reasonably diligent search would have identified the relevant references. For example, patent owners might present evidence that references were indexed in a common prior-art database and would have been included in results based on reasonable search parameters. In contrast, patent challengers should emphasize the lack of availability of the reference in standard databases. Patent challengers may also wish to document their original search strategy to provide ammunition for countering such evidence. If patent challengers present their own search results, patent owners should emphasize the deficiencies of the search as compared to a reasonably diligent search by a skilled searcher. Moreover, given the possibility that search results may be discoverable in an estoppel dispute, patent challengers should be prepared for the possibility that estoppel will apply to all identified references. *Ironburg* thus reinforces the need to carefully consider the mechanics of IPR estoppel as early as possible when developing a litigation strategy.

---

[18] *Id.* at 1298.
[19] *Id.*
[20] *Id.* at 1299-30.
[21] *Id.* at 1299.
[22] *Id.*
[23] *Id.*
[24] *Id.* at 1298.
[25] *Id.* at 1298-99.
[26] *Id.* at 1299.

Update on Written Description for Negative Limitations

The Supreme Court denied *certiorari* recently in a case involving a Novartis patent on administrating fingolimod, a drug useful for treating relapsing-remitting multiple sclerosis.[27] The Federal Circuit's decision had raised questions about written description for negative limitations as well as questions about the interplay between rehearing requests and changes in panel composition. A Federal Circuit panel had originally affirmed (in a 2-1 vote) a district court decision that the written description supported a negative limitation that precluded a "loading dose" prior to recited administration of fingolimod, despite there being no discussion of loading doses in the specification. This decision was reversed on panel rehearing, but only after one of the panel members was replaced due to retirement. In its petition for *certiorari*, Novartis had challenged both the propriety of granting rehearing based on a change to panel membership as well as the panel's application of the written description requirement to the negative limitation in the case at issue. The Supreme Court's denial of *certiorari* leaves the Federal Circuit decision in place and spells the end of Novartis's patent.

[27] *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013 (Fed. Cir. 2022), *cert. denied sub nom. Novartis Pharms. Corp. v. HEC Pharm Co.*, _ S. Ct. __, 91 U.S.L.W. 3261 (Apr. 17, 2023).

Could Have, Would Have; Rationale to Combine in a *KSR* World

In March 2023, the Federal Circuit issued two precedential obviousness decisions that reached opposite conclusions on motivation. In *Intel*,[28] the court reversed a PTAB decision of nonobviousness because the PTAB had erroneously rejected a general motivation to combine. By contrast, in *Philip Morris*,[29] the court affirmed nonobviousness at least in part because the primary reference considered its solution to be better. The Supreme Court explained in *KSR*[30] that "a predictable variation" is likely obvious and that "any need or problem known in the field and addressed by the patent can provide a reason for combining the elements in the manner claimed." While *KSR* provides support for accepting a general motivation and finding predictable variations obvious, a tension may exist in some Federal Circuit decisions that hold that showing an artisan *could* make a modification or combination to create an operative device or method is insufficient to demonstrate obviousness absent a demonstration of superiority over the existing prior art embodiment.

In *Intel*, the PTAB had rejected Intel's argument that a known technique for solving the same problem was sufficient reason for the combination; instead, Intel was faulted for failing to show the combination would result in an improvement. The Federal Circuit reversed, citing *KSR* and explaining "It's enough for Intel to show that there was a known problem of cache coherency in the art, that Bauman's secondary cache helped address that issue, and that combining the teachings of Kabemoto and Bauman wasn't beyond the skill of an ordinary artisan." The court expressly rejected the PTAB's heightened motivation test, explaining "universal motivations known in a particular field to improve technology provide a motivation to combine prior art references *even absent any hint of suggestion* in the references themselves."[31]

In the second case, Philip Morris contended among other arguments that the placement of a heating element in an electronic cigarette was a mere design choice. The court concluded the ITC's contrary finding was proper. Philip Morris also contended that the ITC erred in relying on the reference's stated advantages for its placement of the heating element, implicitly treating the preference as a teaching away from the otherwise obvious modification. The court explained that the ITC never called the reference's preference a teaching away, but nevertheless upheld the ITC's decision that an artisan would not have modified the reference. The Federal Circuit affirmed the ITC on several bases, so the affirmance did not turn solely on the ITC's finding regarding the

[28] *Intel Corp. v. PACT XXP Schweiz AG*, No. 2022-1037 (Fed. Cir. Mar. 13, 2023).
[29] *Philip Morris Products S.A. v. International Trade Comm'n*, No. 2022-1227 (Fed. Cir. Mar. 31, 2023).
[30] *KSR International v. Teleflex Inc.*, 550 U.S. 398, 420 (2007).
[31] *Intel*, slip op. at 11 (original emphasis, cleaned up), *citing Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 797-99 (Fed. Cir. 2021).

(Continued on page 7)

Could Have, Would Have; Rationale to Combine in a *KSR* World *(continued from page 6)*

reference's preferred implementation.[32] Hence, its discussion of whether the reference's preference undercut motivation even absent a teaching away could be viewed as dicta.[33]

The Federal Circuit has elsewhere held that "obviousness concerns whether a skilled artisan not *only could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention."[34] Yet, the court has also recognized this could-would distinction can be in tension with *KSR*.[35] The PTAB and the Federal Circuit tend to invoke this distinction when the record includes some cost-benefit tradeoff for the modification. A teaching in the art away from the modification has long been an acceptable basis for holding a claimed invention is not obvious.[36] Under Federal Circuit precedent, however, proving a teaching away is very difficult, requiring a clear discouragement.[37] Until the tension among *KSR*, the could-would distinction, and the heightened requirement for showing a teaching away is resolved, parties will have to navigate this uncertainty when arguing motivation before the PTAB.

[32] Indeed, the author of *Intel* was on the *Philip Morris* panel and joined the decision.
[33] Slip op. at 29 ("Morgan itself provides strong evidence against a conclusion that it would have been obvious to replace the circumferential heaters with a centered heater.").
[34] *E.g.*, *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (original emphasis).
[35] *Auris Health, Inc. v. Intuitive Surg. Ops.*, 32 F.4th 1154, 1158-59 (Fed. Cir. 2022).
[36] *KSR*, 550 U.S. at 416 ("The Court relied upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious."), *discussing United States* v. *Adams*, 383 U.S. 39, 51-52 (1966).
[37] *E.g.*, *Syntex (USA) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1380 (Fed. Cir. 2005) ("Under the proper legal standard, a reference will teach away when it suggests that the developments flowing from its disclosures are unlikely to produce the objective of the applicant's invention.").

Supreme Court Affirms Lack of Enablement of Antibody Genus Claims in *Amgen, Inc. v. Sanofi*

Enablement issues arise in America Invents Act trials as a substantive basis for challenge in PGRs and when a priority claim must be evaluated for a prior art challenge in IPRs. In a unanimous decision issued on May 18, 2023, the Supreme Court affirmed the Federal Circuit's enablement ruling about antibody genus claims in *Amgen, Inc. v. Sanofi* (21-757).[38] The claims related to antibodies used to reduce LDL cholesterol by binding the naturally occurring PCSK9 protein and blocking it from impairing natural processes for removing LDL cholesterol from the blood. Each of Amgen and Sanofi own a patent for their own anti-PCSK9 antibodies, which are sold respectively as Repatha and Praluent. But Amgen's claims at issue were broader, encompassing any antibody that performs the blocking function by binding a set of specific amino acids on PCSK9. Amgen's specification identified primary sequences for 26 antibodies, three-dimensional structures for two of them (Repatha and one other), and it described two methods known in the art to make new antibodies and methods to test whether they bind and block PCSK9.

After the jury recommended finding the claims enabled, the district court concluded that the claims were not enabled as a matter of law. The Federal Circuit affirmed.[39] The unanimous Opinion of the Court, authored by Justice Neil Gorsuch, affirmed the judgement. Relying on its own precedents, the Court explained:

> "If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable.
>
> That is not to say a specification always must describe with particularity how to make and use every single embodiment within a claimed class. For instance, it may suffice to give an example (or a few examples) if the specification also discloses some general quality running through the class that gives

[38] Wilson Sonsini attorneys served as counsel for an *amicus curiae* brief in support of respondents: https://www.supremecourt.gov/DocketPDF/21/21-757/254592/20230213142636797_Amicus%20Br.%20ISO%20Respondents%20-%202023.02.13.pdf.
[39] 987 F.3d 1080 (Fed. Cir. 2021).

(Continued on page 8)

Supreme Court Affirms Lack of Enablement of Antibody Genus Claims . . . *(continued from page 7)*

it a peculiar fitness for the particular purpose."[40]

The Court stated that a specification requiring the artisan to engage in "a reasonable amount of experimentation to make and use a patented invention" may still be enabled, and that what is reasonable "will depend on the nature of the invention and the underlying art."[41] The Court observed that Amgen likely had enabled the 26 antibodies it disclosed, but agreed with the lower courts that Amgen's claims "sweep much broader than those 26 antibodies" and "failed to enable all that it has claimed, even allowing for a reasonable degree of experimentation."[42] The Court agreed with the lower courts that Amgen's disclosures of two ways to find additional claimed antibodies "amount to little more than two research assignments," involving "trial-and-error" without identifying "a quality common to every functional embodiment."[43] The Court cautioned that "enablement is not measured against the cumulative time and effort it takes to make every embodiment within a claim" and that there is no higher enablement bar for functionally-defined genera claims, but concluded that the Federal Circuit's judgment turned on no such rule.[44]

Though it purports to break no new ground, this decision is likely to be cited frequently at the PTAB as well as in district court when enablement is litigated, especially in cases involving a functionally-defined genus.

---

[40] Slip op. at 13 (internal citations and quotations omitted).
[41] Slip op. at 15.
[42] Slip op. at 15.
[43] Slip op. at 16-17.
[44] Slip op. at 18.

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.