UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DAIICHI SANKYO, INC. AND
ASTRAZENECA PHARMACEUTICALS, LP
Petitioners

v.

SEAGEN INC.
Patent Owner

Case PGR2021-00030

U.S. Patent No. 10,808,039

PETITIONERS' REQUEST FOR REHEARING UNDER 37 C.F.R. § 42.71(d)

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Rules

Other Authorities

I. STATEMENT OF THE PRECISE RELIEF REQUESTED

Daiichi Sankyo, Inc. ("Daiichi Sankyo US") and AstraZeneca Pharmaceuticals, LP ("AstraZeneca US") (collectively, "Petitioners") request rehearing—by a Precedential Opinion Panel if needed—of the Board's decision to de-institute this proceeding based solely on an intervening, non-final development in a parallel district court litigation. The Board's decision is squarely contrary to Director Vidal's recent guidance on the application of *Fintiv*[1] and—if left uncorrected—risks destabilizing the Board's discretionary-denial jurisprudence.[2] The Board instituted review after expressly finding that Petitioners demonstrated "strong merits" in their challenge that the claims under review lack enablement. Paper 17 at 3. In fact, Petitioners' enablement challenge was strong enough to warrant institution even though a parallel jury trial on the same claims was ongoing

[1] Katherine K. Vidal, *Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation* (P.T.O. June 21, 2022).

[2] The Director should review—and correct—the Board's decision to ensure uniform application of the standards set forth in her *Fintiv* guidance either through participation in the concurrently requested Precedential Opinion Panel or via Director Review. While the Patent Office does not accept requests for Director review of decisions on institution, the Director can grant such review *sua sponte*.

and the jury was imminently poised to render its own verdict on enablement.

Three months later, the Board panel reversed course and de-instituted the proceeding. The panel acknowledged again that Petitioners' enablement challenge "present[ed] 'strong merits.'" Paper 31 at 6 (quoting Paper 17 at 3). The Board opined, however, that because a jury in the parallel case "has determined that the claims do not lack enablement," Petitioners' challenge could not amount to a "'compelling unpatentability challenge' on the lack-of-enablement" under the standard of Director Vidal's *Fintiv* guidance. *Id.* at 6 (quoting Vidal Mem. 4-5). But, the Board panel's deference to an intervening jury verdict actually is antithetical to Director Vidal's guidance.

The guidance requires *the Board* to determine whether a petition presents a "compelling unpatentability challenge." Vidal Mem. at 4-5. If it does, "that determination alone" precludes a discretionary denial of institution, irrespective of *Fintiv*'s other factors (including any developments in the district court). *Id.* at 5. By discounting its finding of "strong merits" solely based on a parallel jury verdict, the panel impermissibly abdicated its fact-finding duty, instead deferring to a district court jury on whether review is warranted, and violated the very guidance on which it purported to rely.

Unless the panel's erroneous approach is corrected, the application of Director Vidal's guidance risks rendering *Fintiv*'s application utterly unpredictable. Once

the Board determines that a PGR should be instituted despite parallel district court litigation, it cannot be that the Board can then change its decision with every new development in the district court. A jury verdict is not a final word on the patentability question in an infringement litigation; such a verdict is always subject to post-trial motions and to subsequent appellate review, and is often set aside. The entire point of instituting in the face of an imminent jury verdict was for the Board to consider the merits; that rationale cannot change once the jury actually renders that verdict. Indeed, if the Board is to defer to imminent jury verdicts, there is little reason to institute in the first place: the jury will eventually render a verdict in most cases, as expected.

Nor can the "compelling evidence test" set forth in Director Vidal's guidance require that a jury—applying the clear-and-convincing-evidence standard—agree with the patentability challenge. Requiring such a high threshold would be deeply inconsistent with the guidance's teaching that the "compelling evidence test" is met where the Board finds "strong evidence on the merits." Vidal Mem. 5 n.6 (citing prior Board decisions).

Rehearing is warranted for additional reasons. The de-institution decision failed to weigh properly several of the *Fintiv* factors—including the strength of Petitioners' written description argument (which was separate from Petitioners' strong enablement challenge) and the fact that the parallel district court proceedings

have not advanced materially since the Board's prior decision instituting trial. The interests of efficiency and integrity of the patent system also support institution. The Patent Owner disclaimed the subject matter of Claim 8 and took an adverse judgment, yet the identical disclaimed subject matter still set forth as one of two options in non-disclaimed Claims 1-5 would otherwise avoid post-grant review if institution is not granted. Paper 31 at 7. The Board should not countenance such manipulation of the PGR process.

This case is a prime example of the inconsistent and unpredictable application of *Fintiv* that has been subject of persistent criticism, and which Director Vidal's guidance sought to remedy. The changing decisions in this one case makes this unpredictability worse, not better. Under the Board's normal timelines, the trial in this proceeding should have been instituted well over a year ago, with the Board issuing a final decision by now. Given the cumulative delay in consideration of this post-grant review, as well as the ongoing post-trial briefing and presumptive appellate proceedings in the parallel infringement litigation, Petitioners respectfully request expedited review of this rehearing request.

II. LEGAL STANDARD

"A party dissatisfied with a decision may file a single request for rehearing," "identify[ing] all matters the party believes the Board misapprehended or overlooked." 37 C.F.R. § 42.71(d).

III. BACKGROUND

On October, 20, 2020, the Patent Office issued U.S. Patent No. 10,808,039 ("the '039 patent") to Seattle Genetics, Inc., now known as Seagen, Inc. ("Patent Owner"). At 12:02 am Eastern Time the same day, Patent Owner sued Daiichi Sankyo Company, Limited (Daiichi Sankyo US's foreign parent company) for infringement in the Eastern District of Texas. Two months later (on December 23, 2020), Petitioners filed this proceeding (PGR2021-00030), seeking review of Claims 1-5 and 9-10 of the '039 patent. On January 6, 2021, Patent Owner served infringement contentions asserting all 10 claims of the '039 patent. Given these allegations about Claims 6-8, Petitioners promptly filed a second petition (PGR2021-00042), challenging Claims 6-8 as well.

The Board denied institution of both proceedings under *Fintiv* on June 24, 2021. The Board acknowledged that the merits of Petitioners' enablement challenge weighed in favor of institution. Paper 11 at 19. Nevertheless, the Board opined that, because a parallel district court trial was scheduled nearly four months before the projected statutory deadline for the Board's final decision, institution would not represent an efficient use of the Board's resources. *Id.* at 14-15, 20. Shortly thereafter, having defeated institution, Patent Owner withdrew its infringement assertions regarding Claims 6-8 from its lawsuit. *See* Paper 12 at 4.

Petitioners sought rehearing in both proceedings. The Board considered

Petitioners' requests for over eight months. On April 7, 2022—on the eve of the district court jury deliberation—the Board granted rehearing and instituted both PGRs. The Board noted specifically the "strong merits" of Petitioners' "argument that the claims lack enablement" as a reason to institute trial. Paper 17 at 3. The Board also acknowledged that the claims challenged in PGR2021-00042 were no longer asserted in the parallel litigation, and that both PGRs "involve essentially identical issues," thereby warranting institution of both proceedings. *Id.* at 6-7.

After institution, Patent Owner disclaimed Claims 6-8 and requested adverse judgment as to those claims in PGR2021-00042. Patent Owner then sought rehearing in this proceeding (PGR2021-00030). Patent Owner argued that, following the disclaimer, there were no longer any claims before the Board that were not at issue in the district court litigation. Paper 20 at 4. Patent Owner also argued that, under *Fintiv*, institution was unwarranted because the district court jury had rejected the non-enablement defense as to the claims at issue. *Id.* at 9.

On July 15, 2022, well into the course of this proceeding, the Board granted Patent Owner's rehearing request and again denied institution. The Board justified its reversal by the "changed circumstances" of Patent Owner's disclaimer of Claims 6-8 and "a jury verdict not finding invalidity of the challenged claims." Paper 31 at 7. The Board acknowledged its prior finding that Petitioners' enablement challenge "present[s] 'strong merits,'" but opined that, because "a jury has

determined that the claims do not lack enablement," that challenge does not rise to the level of "'a compelling unpatentability challenge' on the lack-of-enablement." *Id.* at 6 (quoting Paper 17 at 3 and Vidal Mem. 4-5).

Ten days later, on July 25, 2022, the Board entered adverse judgment in PGR2021-00042.

IV. STATEMENT OF REASONS FOR RELIEF REQUESTED

A. The Board's Deference to a Jury's Invalidity Finding Contravenes the Vidal Memorandum

The Board's de-institution decision subverts Director Vidal's recent guidance regarding proper application of *Fintiv*. The Vidal Memorandum unequivocally instructs that "the PTAB will not deny institution based on *Fintiv* if there is compelling evidence of unpatentability." Vidal Mem. 4-5. "Compelling, meritorious challenges," the memorandum explained, "are those in which the evidence, if unrebutted in trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence." *Id.* at 4. "[T]hat determination alone" precludes a discretionary denial of institution, irrespective of *Fintiv*'s other factors. *Id.* at 5.

The de-institution decision departed from Director Vidal's guidance—and from the Board's obligations as an independent factfinder—when it reasoned that Petitioners' "strong" enablement challenge was less than compelling merely because a jury in the parallel infringement litigation did not find lack of enablement. The

Vidal Memorandum requires *the Board* to determine whether a petition presents a "compelling unpatentability challenge." *Id.* at 4-5. A Board panel may not substitute a decision rendered by a different factfinder in a parallel infringement proceeding for its own, especially when the other decision is rendered in the face of a presumption of validity, and under a clear and convincing evidentiary standard that is qualitatively different from the preponderance of the evidence standard applied by the Board. By discounting its own prior finding of "strong merits"—a finding that the Board expressly acknowledged—the Board abdicated its fact-finding responsibility and effectively deferred to conclusions reached *by a different factfinder* in a parallel infringement litigation in deciding whether to institute review.

The Board panel's approach risks rendering the application of *Fintiv* utterly unpredictable. A jury verdict is not a final word on the patentability question; it is always subject to post-trial motions and to appellate review. In fact, it is not unusual for the Federal Circuit to overturn a jury's enablement verdicts. *See, e.g.*, *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021) (finding lack of enablement despite two separate juries returning verdicts finding that lack of enablement was not proven). The "compelling evidence test" cannot be made to depend on the specific factual jury finding rendered in another proceeding. A system where the compelling evidence test—and the Board's resulting decision whether to institute trial—fluctuates based on a non-final development in a parallel proceeding

will invariably result in unpredictable decision-making. Under the Board panel's logic, it would have to grant institution again if the district court on post-trial motions (or the Federal Circuit on appeal) sets aside the jury's enablement verdict. The aim of Director Vidal's guidance was to insulate the Board's decision-making from the back-and-forth of a parallel infringement case where petitioner has presented "a compelling unpatentability challenge." The panel's approach, by contrast, would tie the Board's institution decision even closer to the vagaries of district court litigation.

Nor is there a way to reconcile the Board's de-institution decision with its prior decision to institute trial. The Board's institution decision was issued on the eve of the jury's verdict. If the strength of Petitioners' enablement challenge was sufficient to warrant institution then, those merits must be "compelling" enough to warrant institution now. The Board's decision to deny institution cannot be reconciled with the proper application of *Fintiv*, as explained in the Vidal Memorandum, or with the analysis in the Board's institution decision.

B. The Board's Treatment of the "Compelling Evidence of Unpatentability" Standard Contravenes the Vidal Memorandum

The de-institution decision also ignores Director Vidal's guidance as to what constitutes a "compelling evidence of unpatentability." The Vidal Memorandum explains that "[t]he compelling evidence test affirms the PTAB's current approach of declining to deny institution under *Fintiv* where the evidence of record so far in

the case would plainly lead to a conclusion that one or more claims are unpatentable." Vidal Mem. at 5 n.6. The memorandum then cites, as illustrative examples, the Board's prior decisions that declined to deny institution under *Fintiv* because of "strong evidence on the merits," "particularly strong evidence on the merits," and "'very strong' evidence on the merits." *Id.* (citing prior Board decisions). Consistent with this guidance, Members of the Board have publicly represented to the Board's practitioners and the general public that the Vidal Memorandum's approach is "[c]onsistent with PTAB's current approach on institution in view of strong evidence on the merits even when other factors weigh in favor of discretionary denial." Michael Tierney, Michael Kim, and Justin Busch, *Patent Trial and Appeal Board Boardside Chat* (P.T.O. July 7, 2022) at 14, *available at* https://www.uspto.gov/sites/default/files/documents/PTABBoardsideChatDiscretionaryDenialsJuly2022.pdf.

The Board expressly acknowledged that Petitioners' PGR petition "present[s] '*strong merits*'" on its enablement challenge, but nevertheless concluded that it "does not 'present[] a *compelling* unpatentability challenge' on the lack-of-enablement issue." Paper 31 at 6 (citations omitted) (emphasis added). This reasoning is directly contrary to the Vidal Memorandum's explanation that the "compelling evidence test" is met where the Board finds "strong evidence on the merits." Vidal Mem. 5 n.6 (citing *Illumina*, IPR2020-00988, Paper 20 (PTAB

Dec. 8, 2020)). By drawing an artificial—and unsupported—distinction between "strong" and "compelling" evidence of unpatentability, the Board erred in applying Director Vidal's guidance on *Fintiv*. The "strong merits" of Petitioners' enablement challenge—which the Board has consistently found, Paper 11 at 19; Paper 17 at 3; Paper 31 at 6—preclude application of *Fintiv* and mandate institution.

Even if the "compelling evidence test" differs in some way from the "strong evidence" standard, it cannot mean the clear-and-convincing evidence standard that a district court jury applies when considering validity. Such a high threshold would be squarely contrary to the PGR statute, which directs the Board to apply the preponderance-of-the-evidence standard when considering unpatentability. 35 U.S.C. § 326(e). Yet the Board, by deferring to a jury verdict when analyzing whether Petitioners' enablement challenge met the "compelling evidence" test, effectively required them to satisfy the clear-and-convincing standard. Rehearing is necessary to clarify that, at a minimum, the "compelling evidence" standard is not the same as the clear-and-convincing standard. Rather, as Director Vidal's guidance instructed, that standard should be viewed through the prism of the Board's prior case law that regularly instituted trial where petitioner's unpatentability challenge presented "strong merits."

The Board's decision to deny institution also overlooked the import of its prior institution decision in light of the fact that this is a PGR proceeding. The statutory

institution standard for a PGR requires the Board to "determine[] that the information presented in the petition . . . , if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 35 U.S.C. § 324(a). The Vidal Memorandum's standard for a "compelling unpatentability challenge" tracks this standard: "Compelling, meritorious challenges are those in which the evidence, if unrebutted in trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence." Vidal Mem. 4. The Board's prior decision, which instituted trial, found that the PGR institution standard had been met: "Petitioner has shown that it is more likely than not that at least one of the claims challenged in the Petition is unpatentable." Paper 17 at 3. Given the Board's prior finding that the institution standard had been met and its finding of "strong merits," the "compelling evidence test" was necessarily met.

Moreover, Petitioners' other grounds of unpatentability also satisfy the "compelling evidence test." For instance, in addressing Petitioners' written description challenge, the Board previously observed that it was "skeptical that the Specification" provided the necessary support, and urged Patent Owner to "introduce evidence to the contrary at trial." Paper 17 at 35. By the Board's own account, Petitioners' written description challenge also qualifies as a "compelling unpatentability challenge." The Board's failure in its de-institution decision to even

consider the merits of this ground of unpatentability and whether it warrants institution is another reason for rehearing.

C. The Board Failed To Conduct a Proper *Fintiv* Analysis

The Board also erred in failing to conduct a complete and proper *Fintiv* analysis. *First*, the Board failed to consider the strength of Petitioners' written description argument when determining whether their PGR petition presented a "compelling unpatentability challenge"—one that warranted institution irrespective of the remaining *Fintiv* factors. *Supra* at 12. In its prior institution decision, the Board had expressed skepticism that the '039 patent's inventors in fact invented ADCs where the drug moiety can encompass all drug moieties. Paper 17 at 35. Yet the Board overlooked Petitioners' written description argument when considering the merits of their unpatentability challenge. The "compelling unpatentability challenge" standard requires a holistic assessment of the unpatentability grounds presented in a petition; the Board's failure to do so warrants rehearing.

Second, the Board failed to consider the parties' efforts in this proceeding, as compared to the efforts invested in the parallel district court litigation. Here, Patent Owner already deposed Petitioners' expert, *see* Paper 28, and filed its Patent Owner's Response, *see* Paper 29. This proceeding was thus already well underway when the Board reversed course and de-instituted. This considerable investment of resources stands in marked contrast to the situation three months ago, when the

Board instituted review. At that point, no proceedings had occurred beyond the filing of Patent Owner's preliminary response. By contrast, the parallel district court proceeding has not advanced materially between April 7, 2022 (when the Board instituted review) and July 15, 2022 (when the Board de-instituted).[3]

Third, the Board overlooked the fact that the de-institution decision sanctions manipulation of the PGR process. As the Board observed, its de-institution was motivated to a significant extent by Patent Owner's disclaimer of Claims 6-8 of the '039 patent and subsequent request for adverse judgment in PGR2021-00042. Paper 31 at 7. This should have been a factor *favoring* institution. Claims 1-5 (*i.e.*, claims at issue in this proceeding) cover the identical subject matter of Claim 8 (disclaimed by Patent Owner) because of their Markush-group format.[4] The Board denial of

[3] On June 28, 2022, the district court held a bench trial on whether the '039 patent should be unenforceable under the doctrine of prosecution laches, and issued an opinion rejecting that argument on July 15, 2022. The issue of prosecution laches was unrelated to the unpatentability issues in this PGR proceeding.

[4] Claims 1-5 have the Markush-type limitation "wherein the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody-drug conjugate or an intracellular metabolite of the antibody-drug conjugate." Ex. 1001 (332:7-40).

institution wrongly operates to insulate those claims from review.

The statutory goal of the PGR regime—as well as the integrity of the patent system—mandate a prompt review of patents that never should have issued. Here, by denying institution the Board permits Patent Owner unilaterally to "change[] circumstances" *after* institution through selective disclaimer and adverse judgment of narrower Claims 6-8 to shield necessarily broader Claims 1-5 from post-grant review. Paper 31 at 7. As Director Vidal's guidance emphasized, the Board's discretionary denial authority should be exercised to prevent "abuse." Vidal Mem. 4. Here, prevention of abuse counsels maintenance of the PGR proceedings, especially given the strength of Petitioners' unpatentability challenge.

D. Extension of *NHK Spring*/*Fintiv* to PGR Proceedings Is Improper

Petitioners continue to maintain that the Board's extension of *Fintiv* to PGRs ignores important differences between IPRs and PGRs and undermines congressional objective in establishing the PGR scheme. *See* Paper 12 at 4-11.

V. CONCLUSION

The Board should reconsider its de-institution decision and institute review.

Dependent Claim 8 is otherwise identical but limited to one of the two options: "wherein the drug moiety is intracellularly cleaved in a patient from an intracellular metabolite of the antibody-drug conjugate." Ex. 1001 (332:59-62).

Respectfully submitted,

Dated: August 4, 2022

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CERTIFICATE OF SERVICE

I hereby certify that on August 4, 2022, I caused a true and correct copy of the foregoing Petitioners' Request for Rehearing Under 37 C.F.R. § 42.71(d) to be served electronically on counsel for Patent Owner at the following addresses:

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