

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DAIICHI SANKYO, INC. and
ASTRAZENECA PHARMACEUTICALS, LP,
Petitioner,

v.

SEAGEN INC.,
Patent Owner.

PGR2021-00030
Patent 10,808,039 B2

Before ERICA A. FRANKLIN, SHERIDAN K. SNEDDEN, and
CHRISTOPHER M. KAISER, *Administrative Patent Judges*.

PER CURIAM.

DECISION
Granting Petitioner's Request on Rehearing
37 C.F.R. § 42.71(d)
Granting Institution of Post-Grant Review
35 U.S.C. § 324

I. INTRODUCTION

A. Status of the Proceeding

Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals, LP (collectively, “Petitioner”) filed a Petition requesting a post-grant review of claims 1–5, 9, and 10 of U.S. Patent No. 10,808,039 B2 (Ex. 1001, “the ’039 patent”). Paper 1 (“Pet.”). Seagen Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”). Petitioner filed a Reply to Patent Owner’s Preliminary Response. Paper 8 (“Reply”). Patent Owner filed a Sur-reply to Petitioner’s Reply. Paper 9 (“Sur-reply”).

Initially, we exercised our discretion to deny institution under 35 U.S.C. § 324(a) in view of the scheduled trial date of a parallel district court proceeding being nearly four months before our projected statutory deadline for issuing a final written decision, and other *Fintiv*¹ factors. Paper 11 (“First Denial Decision” or “First Denial Dec.”). Petitioner filed a request for rehearing. Paper 12 (“First Reh’g Req.” or “First Rehearing Request”). Concurrently therewith, Petitioner requested that the Board’s Precedential Opinion Panel (“POP”) reconsider the First Denial Decision. Paper 13; Ex. 3001 (“First POP Request”). POP declined to review the issue raised in the First POP Request. Paper 16. Upon consideration, we granted the First Request for Rehearing and instituted post-grant review. Paper 17 (“Institution Decision” or “Inst. Dec.”).

¹ *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) (“*Fintiv* Order”).

Thereafter, Patent Owner filed a request for rehearing in light of changed circumstances in the parallel district court proceeding and additionally in the related proceeding PGR2021-00042. Paper 20 (“Second Reh’g Req.” or “Second Rehearing Request”). Petitioner filed a Response (Paper 24) and Patent Owner filed a Reply (Paper 26). In light of the changed circumstances in the parallel district court proceeding, we granted the Second Rehearing Request and exercised our discretion to deny institution. Paper 31 (“Second Denial Decision” or “Second Denial Dec.”).

Subsequently, Petitioner filed a request for rehearing,² arguing that our Second Denial Decision did not accord with the guidance provided by the Director in a Guidance Memorandum³ regarding discretionary denials in light of parallel district court proceedings. Paper 32 (“Third Reh’g Req.” or “Third Rehearing Request”). As with the First Rehearing Request, the Third

² This request for rehearing is Petitioner’s second rehearing request regarding our institution determination, and the third rehearing request overall. Our rules provide for only a single rehearing request in the absence of authorization from the Board. 37 C.F.R. § 42.71(d) (“A party dissatisfied with a decision may file a single request for rehearing without prior authorization from the Board.”). It might be argued that Petitioner’s latest rehearing request is not permitted by Rule 42.71(d) because Petitioner did not seek authorization before filing it. To the extent this is the case, we treat POP’s directive that we consider the rehearing request as providing the necessary authorization.

³ *Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation* (June 21, 2022), available at https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf (“Guidance Memo”).

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Rehearing Request was accompanied by a request that POP conduct the requested rehearing. Paper 33; Ex. 3005 (“Second POP Request”). On February 7, 2023, POP denied the request for POP review but provided instructions for us to follow during our consideration of the Third Rehearing Request. Paper 35.

As discussed further below, we grant Petitioner’s Request for Rehearing and institute trial.

B. Instructions from POP

In its February 7, 2023 Order, POP provided instructions for our consideration of the Third Rehearing Request. Paper 35, 4. Specifically, the Order states that, “when considering the submitted rehearing request, in determining whether to exercise discretion to deny institution under the Guidance Memo, . . . the original Board panel shall exercise its own judgement [sic] as to whether the merits of the Petition are ‘compelling,’ as clarified” therein. *Id.* In addition, POP ordered that we make this determination “within two weeks.” *Id.*

II. DISCRETIONARY DENIAL OF INSTITUTION
AND REQUEST FOR REHEARING

Institution of post-grant review is discretionary. *See* 35 U.S.C. § 324(a) (no mandate to institute review); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) (“[T]he agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.”). The Board’s precedential *NHK* decision explains that the Board may consider the

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advanced state of a related district court proceeding, among other considerations, as a “factor that weighs in favor of denying the Petition under § 314(a).” *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 at 20 (PTAB Sept. 12, 2018) (precedential). The Board’s precedential *Fintiv* Order identifies several factors to be considered in analyzing whether the circumstances of a parallel district court proceeding warrant discretionary denial under *NHK*, with the goal of balancing efficiency, fairness, and patent quality. *Fintiv* Order 5–6. These factors are the following: 1) whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted; 2) proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision; 3) investment in the parallel proceeding by the court and parties; 4) overlap between issues raised in the petition and in the parallel proceeding; 5) whether the petitioner and the defendant in the parallel proceeding are the same party; and 6) other circumstances and considerations that impact the Board’s exercise of discretion, including the merits. *Id.* *NHK* and the *Fintiv* Order apply “to all proceedings pending before the Office,” including post-grant review proceedings such as the present matter. Guidance Memo 9.

In our Institution Decision, we granted Petitioner’s Request for Rehearing and instituted post-grant review in light of the fact that claims 6–8 of the ’039 patent, challenged in PGR2021-00042, were dropped from the related district court litigation and further upon consideration that proceeding to trial before the Board in each of PGR2021-00030 and PGR2021-00042 would involve review of practically the same issues,

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thereby raising concerns of inefficiency, duplicative efforts, and conflicting results if the Board were to institute trial in one proceeding but not the other. Inst. Dec. 6–7.

In the Second Rehearing Request, Patent Owner informed us that it had since disclaimed claims 6–8 of the '039 patent. Second Reh'g Req. 4 (citing Ex. 2041). Patent Owner additionally entered a request for adverse judgment in PGR2021-00042 citing its disclaimer under 35 U.S.C. § 253(a) and 37 C.F.R. § 1.321(a), disclaiming the entire patent term for claims 6–8 in the '039 patent from grant through expiration. PGR2021-00042, Paper 24. We entered adverse judgment and terminated that proceeding. PGR2021-00042, Paper 25.

Regarding claims 1–5, 9, and 10 challenged in this proceeding, Patent Owner informed us that

after a full trial on the merits of claim[s] 1–5, 9, and 10, a jury rejected Petitioner's enablement defense, as well as Petitioner's other invalidity defenses. The jury heard testimony from fact and expert witnesses for both parties, including Seagen's expert witness (Dr. Carolyn Bertozzi), from whom the Board has not yet heard. The jury found that Defendants had failed to prove that the asserted claims are invalid, and that Seagen had successfully proven Defendants infringed the asserted claims. Defendants' defenses of written description, enablement, and anticipation were the same as the grounds in the Petition. Thus, a jury has already determined that Petitioner's invalidity arguments, including its lack of enablement argument, lack merit.

Second Reh’g Req. 5 (emphasis omitted). In view of the above changed circumstances, Patent Owner contended that the *Fintiv* factors strongly favored denial. *Id.* at 9.

Petitioner responded with its contention that there was not yet a final determination regarding invalidity by the district court and that “the equitable issue of prosecution laches remain[ed] pending in the district court.” Response 3. Petitioner also contended that numerous post-trial proceedings remained at the district court with respect to equitable issues and post-trial motions. *Id.* at 3–4. On considering those arguments, we agreed with Patent Owner that a rehearing of our prior institution decision was appropriate due to the changed circumstances of: (1) the statutory disclaimer of claims 6–8 of the ’039 patent, (2) Patent Owner’s request for adverse judgment of related proceeding PGR2021-00042, and (3) the additional investment in the parallel proceeding by the district court and the parties, including the completion of a jury trial that resulted in a jury verdict not finding invalidity of the challenged claims. We further agreed with Patent Owner that “[c]ontinuing with this proceeding would result in duplicative efforts and potentially conflicting results between the district court and the Board.” Second Reh’g Req. 9. Based on “the combination of these changed circumstances, rather than any one of them individually,” we granted the Second Rehearing Request and exercised our discretion to deny institution. Second Denial Dec. 6–7. In reaching that decision, we determined that “the record as it [stood at the time did] not ‘present[] a compelling unpatentability challenge’ on the lack-of-enablement issue.” *Id.*

at 6 (quoting Guidance Memo 4–5) (second alteration in original). We said that, in light of the fact that “[t]he district court already ha[d] substantially completed its review of the enablement issue, and [that] a jury ha[d] determined that the claims [did] not lack enablement,” we could not “conclude that Petitioner’s enablement case [was] compelling.” *Id.*

The Third Rehearing Request argues, among other things, that, in light of the Guidance Memo, we should not have considered the parallel proceeding in determining whether a compelling unpatentability challenge had been presented. Third Reh’g Req. 7–9. By improperly considering the parallel proceeding, the Third Rehearing Request argues that we acted inconsistently with the Guidance Memo. *Id.* at 9–13. On reconsideration of the record, and with the clarification provided by POP, Paper 35, 3, as part of our *Fintiv* analysis, we agree that our determination on the compelling-challenge issue was in error.

The Guidance Memo defines “[c]ompelling, meritorious challenges” as “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.” Guidance Memo 4. The phrase “plainly lead to a conclusion that one or more claims are unpatentable” was further clarified in the Director’s precedential decision in *OpenSky Industries, LLC v. VLSI Technology, LLC*, as only satisfied when “it is highly likely that the petitioner would prevail with respect to at least one challenged claim.” IPR2021-01064, Paper 102 at 49–50 (PTAB Oct. 3, 2022) (Decision by the Director) (precedential). Thus, a compelling challenge is one “in which the

evidence, if unrebutted in trial, would” render it “highly likely that the petitioner would” show “that one or more claims are unpatentable by a preponderance of the evidence.” *Id.*; Guidance Memo 4.

The precise bounds of a “highly likely” case as opposed to a mere “likely” one, are not entirely clear, and this case likely falls somewhere near that boundary. We note first that the standard for instituting trial in a post-grant review requires a showing 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). We previously held that this standard had been met in the present case. Inst. Dec. 3. In particular, we determined that Petitioner had made the necessary “threshold showing” as to its arguments that (1) “the claimed subject matter [was] not enabled for the full scope as claimed,” and (2) “Ogitani anticipates at least one of the challenged claims.” *Id.* at 26, 40. Moreover, “[w]e previously described ‘Petitioner’s argument that the claims lack enablement’ as presenting ‘strong merits.’” Second Denial Dec. 6 (quoting Inst. Dec. 3).

We are not persuaded that our earlier description of the merits of Petitioner’s enablement ground as “strong” was in error. As noted in our Institution Decision, the challenged claims recite antibody-drug conjugates that include “a drug moiety,” with no further limitation of the drug moiety to specific moieties, such as dolastatin/auristatin derivatives. Inst. Dec. 14–15 (quoting Ex. 1001, 331:36–332:40). On the record available at the time of the Institution Decision, “we [were] persuaded . . . that the Specification

does not enable the full scope of the claims” because it “focuses on dolastatin/auristatin derivatives and does not describe novel [antibody-drug conjugates] having non-dolastatin/auristatin derivative drug moieties,” with every single “embodiment, example, figure, and assay disclosed in the Specification appear[ing] to use a drug moiety that is a dolastatin/auristatin derivative.” *Id.* at 25–26 (citing Ex. 1001, at code (57), 4:22–29, 50:56–52:30, 71:19–22, 131:23–48, Figs. 1–19, Examples 2–16). Although we acknowledge the possibility that the entirety of the evidence adduced at trial might lead us to a different conclusion, the record at the time of institution showed a mismatch between the scope of the challenged claims and the scope of the subject matter enabled by the Specification of the ’039 patent. Petitioner’s showing of that mismatch on the preliminary record was significantly more than the mere more-likely-than-not showing sufficient to warrant institution of trial.

Together,⁴ we believe that the two determinations we have made previously—that Petitioner has shown it is more likely than not that at least

⁴ To be clear, we hold that the specific facts of this proceeding are sufficient to place this case within the realm of cases where compelling evidence of unpatentability has been shown. We do not hold (1) that merely meeting the post-grant review institution standard is sufficient to show compelling evidence of unpatentability, (2) that merely showing “strong” merits is always sufficient to show compelling evidence of unpatentability, or even (3) that a combination of meeting the post-grant review institution standard and showing “strong” merits would be sufficient to show compelling evidence of unpatentability in cases that present facts different from those of the present case.

one claim is unpatentable and that one of Petitioner’s challenges presents strong merits—are sufficient to show that the likelihood of Petitioner’s success at trial falls within the uncertain bounds of “highly likely.”⁵

Accordingly, we determine that the Petition “presents compelling evidence of unpatentability” as that phrase is defined in the Guidance Memo and the *OpenSky* decision. For this reason, we erred by “discretionarily deny[ing] institution in view of [the] parallel district court [proceeding].” Guidance Memo 2. We grant Petitioner’s request for rehearing and do not exercise discretion to deny institution.

We acknowledge that instituting review in this proceeding when the district court already has reached its result requires the parties to duplicate the efforts they have put into the district court proceeding and requires us to duplicate the efforts of the district court and its jury. We are not insensitive to the fact that such a situation “can increase, rather than limit, litigation costs,” contrary to what “Congress designed the America Invents Act (AIA)

⁵ Our determination that Petitioner is “highly likely” to succeed in proving at least one claim unpatentable on at least one ground should not be understood to mean that we have prejudged the outcome of the trial. In particular, under *OpenSky* and the Guidance Memo, a compelling challenge is one “in which the evidence, if unrebutted in trial, would” render it “highly likely that the petitioner would” show “that one or more claims are unpatentable by a preponderance of the evidence.” *OpenSky*, IPR2021-01064, Paper 102 at 49–50; Guidance Memo 4. Thus, in making our compelling-challenge determination, we are not permitted to consider any rebuttal evidence that has been entered, let alone any rebuttal evidence that may be entered during the trial. Our final determination will not be so limited and will be made based upon the full arguments and evidence developed during the trial.

post-grant proceedings” to accomplish. Guidance Memo 1. But the Guidance Memo is unequivocal: “the PTAB will not rely on the *Fintiv* factors to discretionarily deny institution in view of parallel district court litigation where a petition presents compelling evidence of unpatentability.” *Id.* at 2. In the absence of such discretionary denial, we institute trial for the reasons discussed in the Institution Decision. Inst. Dec. 16–41.

III. CONCLUSION

For the reasons discussed above, we grant Petitioner’s request for rehearing, do not exercise discretion to deny institution, and institute trial for the reasons discussed here and in our earlier Institution Decision. We will issue a scheduling order for this proceeding shortly.

Our findings and conclusions discussed herein are based on a preliminary record. We will make a final determination on the patentability of the challenged claims, as necessary and applying the preponderance of the evidence standard, based on a fully developed record through trial. Any argument not raised in a timely Patent Owner Response to the Petition, or as permitted in another manner during trial, shall be deemed waived even if asserted in the Preliminary Response. *See In re NuVasive, Inc.*, 842 F.3d 1376, 1380–81 (Fed. Cir. 2016) (holding Patent Owner waived an argument addressed in the Preliminary Response by not raising the same argument in the Patent Owner Response). In addition, nothing in this Decision authorizes Petitioner to supplement information advanced in the Petition in a manner not permitted by the Board’s Rules.

IV. ORDER

Accordingly, it is

ORDERED that Petitioner's Third Rehearing Request is *granted*;

FURTHER ORDERED that pursuant to 35 U.S.C. § 324(a), a post-grant review is instituted as to claims 1–5, 9, and 10 of the '039 patent; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 324(d) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; the trial will commence on the entry date of this decision.

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