

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 PGR2021-00042

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

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

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I. STATEMENT OF THE PRECISE RELIEF REQUESTED

Petitioners Daiichi Sankyo, Inc. (“Daiichi Sankyo US”) and AstraZeneca Pharmaceuticals, LP (“AstraZeneca US”) respectfully request rehearing of the Decision Denying Institution of Post-Grant Review (Paper 12, “Decision” or “Dec.”). Invoking *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 (P.T.A.B. Sept. 12, 2018), and *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020), the Decision denied institution under 35 U.S.C. § 324(a), because of a parallel district court proceeding. (Dec. at 11.) The Board did so despite acknowledging the strength of the Petition’s patentability challenges and that it was filed “diligently and without much delay.” (Dec. at 16, 19.)

The Board should grant reconsideration. *First*, rehearing is warranted because of a material change in circumstances. Subsequent to the Decision, Patent Owner dropped claims 6-8 of the patent-at-issue, i.e., U.S. Patent No. 10,808,039 (“the ’039 patent”)—the claims at issue in this PGR—from its infringement suit. As a result, *Fintiv* is thus no longer applicable to that proceeding and cannot preclude institution. By its terms, *Fintiv* applies only when the same invalidity challenges are present both before the Board and in a parallel infringement litigation. By dropping all the claims at issue in this petition from its infringement complaint, Patent Owner eliminated the danger of duplicative efforts or inconsistent results between the two tribunals.

Second, the Board (by a Precedential Opinion Panel (“POP”) if necessary) should reject the Decision’s extension of *NHK Spring* and *Fintiv* to PGR proceedings. Such extension contravenes the PGR statutory scheme and congressional intent, ignores the Patent Office’s different statutory mandates for PGRs and IPRs, and significantly curtails the availability of PGRs as a mechanism for challenging patentability.

Third, even were *Fintiv* applicable in the PGR context, rehearing is warranted. The Decision fails to weigh properly several of the *Fintiv* factors, such as the lack of substantial investment in parallel litigation and Petitioners’ prompt filing of their petition, and misapprehends others, including by assuming incorrectly that both real parties-in-interest were defendants in the parallel district court litigation.

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). New fact or circumstances arising since the initial decision on institution may provide a basis for institution on rehearing. *See, e.g., Sand Revolution II, LLC v. Cont’l Intermodal Grp. - Trucking LLC*, IPR2019-01393, Paper 24 at 2-3 (P.T.A.B. June 16, 2020) (informative) (granting institution on rehearing “in light of new evidence of record”).

III. BACKGROUND

At 12:02 am Eastern time on the day the patent issued, Patent Owner filed its infringement suit in the Eastern District of Texas, which it later used to convince the Board to deny institution here. Patent Owner's complaint did not specify all the asserted claims, and named only Daiichi Sankyo Company, Limited ("Daiichi Sankyo Japan") (not Petitioners) as a defendant. Petitioners and Daiichi Sankyo Japan filed a separate suit seeking a declaratory judgment of noninfringement of the '039 patent, and then Petitioners filed PGR2021-00030, challenging patentability of claims 1-5, 9, and 10.

On January 6, 2021, Patent Owner served infringement contentions asserting claims 1-10. Given these allegations regarding claims 6-8, Petitioners filed the Petition, seeking cancellation of those claims too. Patent Owner characterized this second petition as "address[ing] dependent claims based on the same prior art and unpatentability arguments" as the first petition, and "necessarily invok[ing] a challenge" to independent claim 1 (at issue in PGR2021-00030). Paper 8 at 32, 33.

The Board denied institution of PGR2021-00030 and -00042 based on the current state of the parallel district court litigation. Shortly thereafter, Patent Owner notified Petitioners that it has dropped claims 6-8 from its infringement suit. *See* Joint Status Report, *Daiichi Sankyo, Inc. v. Seagen Inc.*, No. 20-cv-

01524-LPS (D. Del. July 21, 2021), ECF No. 37, at 1-2 (“[O]n July 16, Seagen dropped from the Texas case Claims 6-8 of the ’039 patent.”).

IV. STATEMENT OF REASONS FOR RELIEF REQUESTED

A. A Material Change in Circumstances Requires Rehearing and Institution

A material change in circumstances requires rehearing and institution of PGR. Subsequent to the Decision, the Patent Owner dropped claims 6-8 of the ’039 patent from its infringement suit. *See supra* p. 3. As a result, *Fintiv* is no longer applicable to this proceeding and cannot preclude institution. By its terms, *Fintiv* applies only when “the same invalidity challenges” are present both in a petition pending before the Board and in a parallel district court litigation. IPR2020-00019, Paper 11 at 2 (citing *NHK Spring*, Paper 8). Now that Patent Owner dropped all the claims challenged in this petition from its infringement suit, the district court will have no occasion to consider any invalidity challenges to those claims. As a result, there is no danger of “inefficiency, duplication of effort, [or] the risk of inconsistent results” (Dec. at 11) as to claims 6-8 of the ’039 patent.

The Board has granted rehearing in light of changed circumstances, *see Sand Revolution*, IPR2019-01393, Paper 24 at 2-3, and should do the same here. Doing otherwise would encourage manipulation where patent owners would strategically allege infringement of challenged claims in the parallel district court litigation, use

that fact to obtain institution denial, and then drop those claims from the district court case. The Board should not countenance such gamesmanship.

Patent Owner may argue that the patentability grounds and arguments related to claims 6-8 are similar to those related to claims 1-5, 9, and 10 (which remain pending before the district court). *See* Paper 8 at 32, 33. But it would be a drastic—and unwarranted—extension of *Fintiv* to permit denial of institution where the parallel district court proceedings *will not* determine the patentability of the challenged claims. If necessary, the Board should set this rehearing before the POP in order to clarify that *Fintiv* does not apply under these circumstances.

B. The Board Should Reconsider Extension of *NHK Spring* and *Fintiv* to PGR Proceedings

The Board should reconsider the panel’s Decision extending to PGR proceedings *NHK Spring* and *Fintiv*, which concern institution of IPR proceedings filed by companies sued in district courts. This extension ignores important differences between IPR and PGR proceedings and undermines the explicit congressional objective to provide a “new, but time-limited, post-grant review procedure” that “enable[s] early challenges to patents.” H.R. Rep. No. 112-98, pt. 1, at 47-48 (2011). At a minimum, the Board should adjust *Fintiv*’s analysis to

take account of the unique features of the PGR scheme and the overall congressional objective of creating a system for early post-grant validity review.¹

The Decision acknowledged that *NHK Spring* and *Fintiv* arose in the context of IPR proceedings, and that “there are differences between *inter partes* review and post-grant review.” (Dec. at 11.) It also recognized the critical difference—that “the window for filing a petition for post-grant review is open only for nine months from the date of issuance,” and that Congress designed the PGR regime with “[t]he intent ... to enable early challenges to patents.” (Dec. at 11-12 (citations omitted).) The Decision nevertheless proceeded to apply the *NHK Spring/Fintiv* rule to the PGRs based on a perceived similarity between the statutory provisions authorizing institution of IPR and PGR review, 35 U.S.C. § 314(a) and § 324(a), and its assertion that “the overall policy justifications associated with the exercise of discretion—inefficiency, duplication of effort, and the risk of inconsistent results—apply to post-grant review proceedings” as well. (*Id.* at 11.)

In reaching this conclusion, the Decision’s analysis downplays—or ignores altogether—the critical features of the PGR statutory scheme. Congress designed the PGR process as “a new, *early-stage* process for challenging patent validity.”

¹ Any curtailment of *Fintiv*-based discretion to IPRs in *Apple Inc. v. Iancu*, No. 20-cv-06128 (N.D. Cal. filed Aug. 31, 2020), should also apply here.

H.R. Rep. No. 112-98, pt. 1, at 48 (emphasis added). Congress accordingly prescribed a strict deadline for seeking PGR review, providing that “[a] petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent or of the issuance of a reissue patent.” 35 U.S.C. § 321(c). Congress did so in order to incentivize “*early challenges* to patents,” and it believed that “[t]his new, *but time-limited*, post-grant review procedure will provide a meaningful opportunity to improve patent quality and restore confidence in the presumption of validity that comes with issued patents in court.” H.R. Rep. No. 112-98, pt. 1, at 47-48 (emphasis added). By setting forth strict time limits both with respect to the filing and adjudication of PGRs, Congress explicitly promulgated a statutory pathway to ensure review of patents “early in their life, *before* they disrupt an entire industry or result in expensive litigation.” 157 Cong. Rec. S1326 (daily ed. Mar. 7, 2011) (statement of Sen. Sessions) (emphasis added). Section 321(c), thus, reflects Congress’s considered judgment that a PGR petition is timely filed within 9 months of the patent’s grant or issuance. That express timing requirement—notably absent for IPRs—precludes the imposition of a separate, non-statutory timing requirement based on the progress of a parallel district court proceeding. The Board cannot exercise its discretion in a way that contradicts congressional mandate.

The strict filings deadline in the PGR scheme is in marked contrast to the IPR regime. There, review *may not* be requested until the later of “the date that is 9 months after the grant of a patent” or the termination of any post-grant review. 35 U.S.C. § 311(c)(1)-(2). Moreover, while the IPR statute provides a one-year safe harbor within which a party served with an infringement complaint may petition for review, *see* 35 U.S.C. § 315(b), it contains no temporal deadline for seeking IPR review. Unlike in PGRs, review may be requested, and institution granted, long after the patent had issued, and after litigation of the patent in district court commences. Even if the *Fintiv* rationale could justify denial of institution in some IPRs because of advanced parallel district-court proceedings, that logic does not apply in the PGR context, where the entire process was designed to incentivize *early* challenges to newly issued patents before those patents are litigated in expensive district court actions.

An IPR petition is often filed in response to an infringement complaint, *see* 35 U.S.C. § 315(b), in order to obtain the benefit of the Board’s comparative patent expertise and rapid adjudication. In such a situation, as the Board has noted, there may be concerns about “inefficiency, duplication of efforts, and the risk of inconsistent results” between the district court and the Patent Office (Dec. at 11), which *Fintiv* seeks to avoid. A PGR petition, by contrast, is meant to serve as a check on whether *the Patent Office* has acted correctly in issuing the patent in the

first place. *See supra* pp. 5-7. That makes it particularly inappropriate for the Patent Office to abdicate its statutory responsibility to take a second look at the newly issued patent on a basis that is found nowhere in the statute.

Denying institution because of a parallel proceeding risks curtailing PGRs as a forum for challenging questionable patents, in direct contravention of congressional intent. This case is a telling example. The Decision acknowledged that Petitioners “acted diligently and without much delay” by filing their PGR Petition “approximately two weeks after Patent Owner first alleged infringement” of claims 6-8. (Dec. at 16 (citations omitted).) The Decision nevertheless viewed Petitioners’ prompt filing as “not weigh[ing] for or against” institution. (Dec. at 17.) This mistaken approach flies in the face of congressional intent to “enable early challenges to patents.” H.R. Rep. No. 112-98, pt. 1, at 47-48.

As another Board panel observed, when granting institution of a petition filed “a little more than three months” after patent issuance, “[g]iven the prompt filing of th[e] petition, denying Petitioner the opportunity to seek post-grant review under these circumstances would *effectively deny them the opportunity to ever seek post-grant review.*” *Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, PGR2019-00048, Paper 19 at 11 n.7 (P.T.A.B. Nov. 20, 2019) (emphasis added). The Decision cited the *Teva* decision as an example where the Board has previously considered discretionary denial of institution in the PGR context (*see*

Dec. at 11), but its analysis cannot be reconciled with the reasoning of the *Teva* panel in instituting review notwithstanding a parallel court proceeding. Rehearing in this circumstance is appropriate to restore consistency to the Board's precedents.

Other features of the PGR scheme further militate against the mechanical application of *Fintiv*'s IPR-centric analysis to PGRs. In the IPR statute, Congress limited the grounds of patentability challenges to challenges under sections 102 and 103 based on patents and printed publications. *See* 35 U.S.C. § 311(b). In PGRs, by contrast, a patent may be challenged on any ground related to invalidity under section 282, and the challenge does not have to rely on prior art references. *See* 35 U.S.C. § 321(b). As a result, the statutory estoppel from a PGR proceeding is also broader than the statutory estoppel from an IPR proceeding. *See* 35 U.S.C. § 325(e)(2) (providing for estoppel "in a civil action" with respect to "any ground that the petitioner raised or reasonably could have raised during th[e] post-grant review"). The broader scope of review and of the resulting estoppel provided under the PGR statute indicates that Congress did not intend for the Board to deny institution merely based on a parallel court proceeding, especially since Congress designed PGRs to "provid[e] quick and cost effective *alternatives* to litigation." H.R. Rep. No. 112-98, pt. 1, at 48 (emphasis added). By denying institution of a timely (and promptly) filed PGR petition, the Board frustrates Congressional purpose.

The Board's application of *Fintiv* is particularly concerning given that neither Petitioner is a party to the parallel district court action. The Board dismissed this fact on the rationale that the real parties-in-interest in the PGR proceeding were parties to the infringement litigation. (Dec. at 19.) That premise, however, was incorrect. AstraZeneca UK Limited, the real party-in-interest affiliated with Petitioner AstraZeneca US, is *not* a party to the district court litigation. Congress intended for parties like AstraZeneca to assist the Patent Office in maintaining patent quality by filing prompt challenges to patents that should not have been issued in the first place. Denying institution of petitions filed by entities like AstraZeneca because of litigation filed against *other parties* contravenes congressional intent in devising the PGR regime.²

The Board should reconsider, and reject, the extension of the *Fintiv* framework to the PGRs. Discretionary denial of a timely-filed PGR petition based on a parallel district court proceeding ignores the unique features of the PGR scheme and flouts congressional objective. At the very least, the Board should treat prompt filing of a PGR petition as the overriding factor in its section 324(a)

² Since the Board's denial of institution, AstraZeneca US and AstraZeneca UK Limited have sought to intervene in the district court litigation, but they were not parties at the time of the Decision.

analysis—one that can be outweighed only by the evidence of some manifest unfairness to the patent owner. *See Teva*, PGR2019-00048, Paper 19 at 11 (instituting trial where petition “promptly” sought review and patent owner did not claim that petitioner obtained any “tactical advantage” from the petition’s timing).

C. Even if the Board May Discretionarily Deny PGRs Under *NHK Spring* or *Fintiv*, It Erred by Denying Institution in This Case

Even under *NHK Spring* or *Fintiv*, the Board erred in denying institution. The Decision misapprehended several relevant factors, leading it to exercise its discretion incorrectly.

1. The Decision refused to “infer” whether the district court would grant a stay should the Board institute review. (Dec. at 14.) Petitioners presented statistics showing that the district court has historically stayed its proceedings where the Board instituted review. *See* Paper 9 at 1. The Decision rejected that evidence on the premise that it concerned “actions taken in different cases with different facts.” (Dec. at 14.) This reasoning—which would refuse *any* statistical evidence based on past decisions and trends—creates the “chicken-and-egg” problem. Prior to institution, stay requests may be speculative, and most courts are reluctant to grant them. Properly applied, *Fintiv* accounts for a court’s willingness to consider future stay requests, should the Board institute review. The Board should consider evidence “suggest[ing] the district court may be willing to avoid

duplicative efforts and await the PTAB’s final resolution of the patentability issues raised in the petition before proceeding with the parallel litigation.” *Fintiv*, IPR2020-00019, Paper 11 at 7; *see also Medtronic, Inc. v. Teleflex Innovations S.A.R.L.*, IPR2020-00134, Paper 20 at 9-10 (P.T.A.B. June 26, 2020) (considering “the district court’s prior history of granting stays pending resolution of related IPRs”). The Board should have credited Petitioners’ evidence showing that the district court would likely stay its proceedings upon PGR institution, especially since PGRs provide for even greater potential trial simplification than IPRs. *Supra* p. 12.

2. The Decision observed that the scheduled trial date in the district court litigation would occur less than four months before the deadline for the Final Written Decision. (Dec. at 15.) But the Decision erred in concluding that this time difference weighed against institution. Given the average speed with which courts in the Eastern District of Texas schedule cases for trial, this short difference only demonstrates how promptly the petition was filed. Under the Board’s rationale, if the supposed trial date (which may yet be postponed) precedes the Board’s anticipated final decision date, the Board can deny institution. This reasoning incentivizes forum shopping by bringing patent infringement suits in districts with expedited trial schedules.

3. The Decision observed correctly that “the level of investment by the

parties and the court is not substantial.” (Dec. at 15.) The Decision then concluded, however, that this factor “does not weigh for or against” institution. (Dec. at 17.)

Fintiv instructs that “[i]f, at the time of the institution decision, the district court has not issued orders related to the patent at issue in the petition, this fact weighs *against* exercising discretion to deny institution under *NHK Spring*.” IPR2020-00019, Paper 11 at 10 (emphasis added). After the Decision correctly found that the investment in the district court proceedings was “not substantial,” *Fintiv* compelled a conclusion that this factor weighs in favor of institution.

Fintiv also places special importance on whether “the petitioner filed the petition expeditiously, such as promptly after becoming aware of the claims being asserted,” and instructs that “this fact has weighed against exercising the authority to deny institution.” IPR2020-00019, Paper 11 at 11. Here, Petitioners moved with great speed, filing their Petition *two months* after the ’039 patent’s issuance. The Decision itself found that Petitioners “acted diligently and without much delay.” (Dec. at 16.) In view of this finding, the Board could not conclude that this factor “does not weigh for or against” institution. Under *Fintiv*, the Board was required to accord this finding special weight in favor of institution, especially given the PGR statute’s goal to enable *early* validity challenges.

4. In analyzing the fourth *Fintiv* factor, the Board concluded it was

“unable to determine if there is significant overlap in the issues addressed in the Texas Litigation and Petitioner’s arguments.” (Dec. at 17.) This finding should have weighed *in favor* of institution, not against it. In any event, the potential for overlap is precisely why Congress created the PGR scheme, so that the validity of a newly issued patent could be determine in specialized agency proceedings, thereby reducing litigation costs.

5. As noted above (*supra* p. 11), in analyzing the fifth *Fintiv* factor, the Board erred in finding that both real-parties-in-interest were parties to the district court litigation: only one was. The Board needs to re-weigh this factor.

6. In weighing the final *Fintiv* factor, the Board rejected Patent Owner’s suggestion that “the merits are substantively weak,” and acknowledged the Petition’s potential merits. (Dec. at 19.) The Board concluded, however, that this factor did not “outweigh the other *Fintiv* factors.” (*Id.*)

As shown above, the Board misapprehended how various factors weighed in the decision not to institute the Petition. Properly weighed, the petition’s merit, combined with the factors discussed above, weigh in favor of institution.

V. CONCLUSION

The Board should reconsider its Decision and institute review.

Respectfully submitted,

Dated: July 26, 2021

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CERTIFICATE OF SERVICE

I hereby certify that on July 26, 2021, I caused a true and correct copy of the foregoing Petitioner's 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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