IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
Alexandria Division

DAIICHI SANKYO, INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	1:21-cv-899 (LMB/JFA)
	)	
KATHERINE K. VIDAL, Director of the United States Patent and Trademark Office, et al.,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

In this civil action, plaintiffs Daiichi Sankyo, Inc. ("Daiichi Sankyo") and AstraZeneca Pharmaceuticals, LP ("AstraZeneca") (collectively, "plaintiffs") challenge the Fintiv instructions, a set of non-exclusive factors adopted by the United States Patent and Trademark Office ("PTO") and its Director ("Director") (collectively, "defendants") to aid in deciding whether to institute post-grant review of a recently issued patent when parallel litigation involving the same patent is ongoing in a federal district court. Before the Court are defendants' Motion to Dismiss for Lack of Jurisdiction [Dkt. No. 15] and Motion to Dismiss for Failure to State a Claim [Dkt. No. 16]. For the reasons that follow, the Motion to Dismiss for Lack of Jurisdiction will be granted, the Motion to Dismiss for Failure to State a Claim will be denied as moot, and this civil action will be dismissed without prejudice.

I. BACKGROUND

A. Statutory and Regulatory Background

1. Post-Grant Review

An inventor or other interested party has long been able to challenge the validity of existing patent claims in federal court. SAS Inst., Inc. v. Iancu, 138 S. Ct. 1348, 1353 (2018).

To provide an alternative to the costly, protracted litigation often involved in challenging patents in federal court, Congress enacted various administrative procedures for obtaining review of an existing patent by the PTO. See id. (discussing the development of the PTO's administrative remedies); Cuozzo Speed Techs., LLC v. Lee, 579 U.S. 261, 267 (2016). These remedies include two adversarial, adjudicatory proceedings known as inter partes review, 35 U.S.C. § 311, et seq., and post-grant review, 35 U.S.C. § 321, et seq., which Congress created as part of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011). Post-grant review is the focus of this civil action.

Compared to inter partes review, which applies to patents that have been issued for some time, post-grant review was designed to "enable early challenges to patents, while still protecting the rights of inventors and patent owners against new patent challenges unbounded in time and scope," and was intended to "make the patent system more efficient" by providing a "meaningful opportunity to improve patent quality and restore confidence in the presumption of validity[.]" H.R. Rep. No. 112-98, at 47-48 (2011). Accordingly, a party seeking to challenge a patent via post-grant review must file a petition for post-grant review within nine months of the patent's issuance. 35 U.S.C. § 321(c). By contrast, a petition for inter partes review cannot be filed until at least nine months after a patent is granted. Id. § 311(c). Post-grant review also permits broad challenges to a patent on almost any basis of unpatentability, id. § 321(b), whereas inter partes review is limited to challenges on the basis of prior art, id. § 311(b).

The Patent Trial and Appeal Board ("the Board"), an executive adjudicatory body within the PTO, is responsible for conducting both post-grant and inter partes review. The Board sits in three-member panels designated by the Director, and panel members are drawn from the Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks,

and more than 200 administrative patent judges ("APJs").[1] 35 U.S.C. § 6(a),(c); see United States v. Arthrex, Inc., 141 S. Ct. 1970, 1977 (2021).

Post-grant and inter partes review are advantageous over district court litigation because they are conducted by Board panels of APJs who have relevant subject matter expertise for adjudicating complex scientific disputes compared to federal judges or lay jurors. And, whereas a patent challenger in federal court must prove patent invalidity by clear and convincing evidence, see Microsoft Corp. v. i4i Ltd. Partnership, 564 U.S. 91, 102 (2011), the challenger in post-grant or inter partes review is required to prove unpatentability only by a preponderance of the evidence. 35 U.S.C. §§ 316(e), 326(e),

Like inter partes review, post-grant review begins with a petition filed by the party challenging the validity of a patent. Id. §§ 311(a), 321(a). After the petition is filed, the patent owner has three months in which to file a preliminary response. 37 C.F.R. §§ 42.107, 42.207. The Director then has three months in which to determine whether to institute review. 35 U.S.C. §§ 314(b), 324(c). The Director has delegated her authority to determine whether to institute review to the Board, see 37 C.F.R. §§ 42.4(a), 42.108, 42.208, and it is the Board's process of deciding whether to institute post-grant review that plaintiffs seek to challenge in this civil action.

Although the Director (and, by delegation, the Board) has the discretion to institute post-grant review, the threshold for institution is a finding by the Director that "it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable" or that the "petition raises a novel or unsettled legal question that is important to other patents or patent applications."

[1] APJs are appointed by the Secretary of Commerce, in consultation with the Director, and are required to be "persons of competent legal knowledge and scientific ability." 35 U.S.C. § 6(a).

35 U.S.C. § 324(a)-(b). A petition must also satisfy several other filing requirements. See id. §§ 321-322. Even if these prerequisites are met, the Director is not required to institute review and retains the discretion to deny a petition. See Cuozzo, 579 U.S. at 273.

In certain cases, the AIA dictates whether post-grant review can be instituted if there are ongoing administrative proceedings or parallel civil actions involving the same patent. Specifically, if the petitioner has previously filed a civil action in federal court challenging the validity of a patent claim before filing a petition for post-grant review of that patent, review "may not be instituted[.]" 35 U.S.C. § 325(a)(1). If the challenger has petitioned for post-grant review and subsequently files a civil action in federal court challenging the validity of a patent, the civil action must be stayed.[2] Id. § 325(a)(2). In other words, a challenger can use either post-grant review or a civil suit in federal court to seek review of a patent's validity but not both at the same time; however, filing a counterclaim in federal court that challenges the validity of a patent claim—for example, as a defense to a patent infringement suit—does not preclude the challenger from filing a simultaneous petition for post-grant review. Id. § 325(a)(3).

The AIA also explicitly authorizes the Director to determine how to manage concurrent "proceeding[s] or matter[s] involving the patent" that are before the PTO, including "providing for the stay, transfer, consolidation, or termination of any such matter or proceeding." Id. § 325(d). Other than these considerations, the AIA neither requires nor prohibits the Director from considering parallel proceedings, whether before the PTO or in federal court, in her decision whether to institute post-grant review. As relevant here, the statute is silent as to

[2] The stay may be lifted if "the patent owner moves the court to lift the stay," "the patent owner files a civil action or counterclaim" alleging infringement of the patent, or the challenger "moves the court to dismiss the civil action." Id. § 325(a)(2).

situations in which a party challenges patent validity as a defense to an infringement action in district court and also seeks post-grant review by the PTO.

Once the Director determines whether to institute post-grant review, her decision is "final and nonappealable," id. § 324(e); however, a dissatisfied party is permitted to "request rehearing on a decision by the Board," which is reviewed for an abuse of discretion. 37 C.F.R. § 42.71.

If post-grant review is instituted, the Board conducts a trial on the merits and must issue a final written decision, generally within one year, confirming or rejecting patentability of the claim or claims at issue, 35 U.S.C. §§ 326(a)(11), 328(a). Once this process begins, the petitioner is estopped from asserting in a civil action or administrative proceeding the invalidity of the same patent on "any ground that . . . [was] raised or reasonably could have [been] raised" during the Board's review. Id. § 325(e). A party who is dissatisfied with the Board's final written decision on patentability is permitted to appeal the decision to the United States Court of Appeals for the Federal Circuit. Id. § 329. The party may also seek rehearing of the decision by the Board. 37 C.F.R. § 42.71(d).

2. Director Review of Board Decisions

Although the AIA authorizes only the Board to grant a rehearing of its decision, 35 U.S.C. § 6(c), the PTO has established an interim process in which any party to a proceeding may request that the Director review a Board decision. See Interim Process for Director Review, United States Patent and Trademark Office, https://www.uspto.gov/patents/patent-trial-and-appeal-board/interim-process-director-review (last updated Sept. 22, 2022). The PTO created this interim Director review process in response to the Supreme Court's decision in United States v. Arthrex, 141 S. Ct. 1970 (2021), which found that the "unreviewable authority wielded by APJs," who were removable by the Director only for cause, in inter partes review is "incompatible with their appointment by the Secretary to an inferior office." Id. at 1985. Even

though the Director "possesse[d] powers of 'administrative oversight'" over APJs, the Court found that the Board's final patentability decisions were effectively insulated from the Director because "[t]he only possibility of review" was a petition for rehearing by the Board, but the AIA did not permit the Director to grant rehearing. Id. at 1980-81. Because APJs had "significant authority" in inter partes review to issue decisions that were binding on the Executive Branch but the AIA "insulat[ed] their decisions from review and their offices from removal" by the Director, the Supreme Court concluded that the structure of inter partes review ran afoul of the Appointments Clause. Id. at 1986.

In response to Arthrex, the PTO implemented an interim process for Director review of the Board's final written decisions in inter partes and post-grant review (the "Arthrex interim process"[3]). See supra Interim Process for Director Review. Pursuant to that process, a party seeking review of the Board's final written decision may request either Director review or rehearing by the original Board panel, but not both. Id. Although Director review is available for a Board decision resulting from a granted request for rehearing, there is no Director review of a Board decision denying a request for rehearing. Id. Director review is also unavailable for Board decisions on whether to institute review in the first instance. Id. Even though a party may not request Director review of an institution decision, the Director retains "the authority to review such decisions sua sponte after issuance (at the Director's discretion)." Id.

3. Precedential Opinions

When the Board renders a decision, including on whether to institute either inter partes or post-grant review, ordinarily the decision is not binding in any other case other than the one in

[3] Plaintiffs call the PTO's interim Director review process the "Arthrex Rule," [Dkt. No. 5] ¶ 1, but that label misleading because the review process is not a rule.

which it was issued, see Patent Trial and Appeal Board, Standard Operating Procedure 2 (Revision 10), at 3 (Sept. 20, 2018); however, under the AIA, the Director has "an interest in creating binding norms for fair and efficient Board proceedings, and for establishing consistency across decision makers," id. at 2. Accordingly, under Standard Operating Procedure 2,[4] the PTO created a Precedential Opinion Panel to "decide issues of exceptional importance" and "establish binding agency authority concerning major policy or procedural issues[.]" Id. at 1, 3. Members of the Precedential Opinion Panel are selected by the Director but, by default, the panel consists of the Director, the Commissioner for Patents, and the Chief Administrative Patent Judge. Id. at 4. Standard Operating Procedure 2 establishes a process for Precedential Opinion Panel review of Board decisions, as well as a mechanism by which Board decisions may be designated as precedential.

The Precedential Opinion Panel may rehear Board decisions to address "issues of exceptional importance" or "issues of broad applicability to the Board." Id. at 3-4. The Precedential Opinion Panel may also sua sponte rehear a decision, and any party to a proceeding may request panel review of a particular Board decision. Id. at 5-6. Recommendations for review are first evaluated by a Screening Committee, which is comprised of Precedential Opinion Panel members or their designees. Id. at 6-7. The Screening Committee then makes a recommendation to the Director, who may convene the Precedential Opinion Panel to decide whether to grant review, and if review is granted, to render a decision in the case. Id. When the Precedential Opinion Panel issues a decision, it may be designated as precedential with the Director's approval, in which case the decision is "binding Board authority in subsequent matters

[4] Standard Operating Procedures "set forth internal norms for the administration" of the Board and provide that they "do[] not create any legally-enforceable rights." Id. at 2.

involving similar facts or issues." Id. at 8, 11. Alternatively, the decision may be designated as informative, meaning that it "set[s] forth Board norms that should be followed in most cases" although it is not binding authority. Id. Otherwise, a decision is routine, in which case it is nonprecedential. Id. at 8. If a request for Precedential Opinion Panel review is denied, a party does not have a right to "further review." Id. at 6.

Standard Operating Procedure 2 also establishes a separate process by which routine Board decisions may be designated as precedential or informative. Any person may nominate a Board decision for designation as precedential or informative. Id. at 9. The Screening Committee reviews nominated decisions and can recommend a decision for further review by an Executive Judges Committee consisting of five of the most senior APJs. Id. at 9-10. The Executive Judges Committee then submits its recommendation to the Director, who makes the final decision on designation. Id. 10-11. Standard Operating Procedure 2 makes clear that no Board or Precedential Opinion Panel decision may be designated as precedential without the Director's approval, and the Director retains full discretion to designate or de-designate decisions. Id. at 1, 8, 11.

4. The Fintiv Instructions

Two Board decisions that have been designated as precedential—NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc., No. IPR2018-00752, Paper 8, at 20 (P.T.A.B. Sept. 12, 2018) ("NHK"), and Apple Inc. v. Fintiv, Inc., No. IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) ("Fintiv")—are at the heart of plaintiffs' claims in this civil action. These two decisions articulate a set of factors, known as the Fintiv instructions,[5] for determining whether to institute

[5] Plaintiffs refer to the two decisions collectively as the "NHK-Fintiv rule," see [Dkt. No. 5] ¶ 1, whereas the PTO refers to them as the "Fintiv factors," see [Dkt. No. 44-2] at 2, and the Federal Circuit calls them the "Fintiv instructions," see Apple Inc. v. Vidal, 63 F.4th 1, 9 (Fed. Cir. 2023). Based on the Court's understanding of the content of and the way that NHK and Fintiv

review when there is ongoing parallel litigation in federal court involving the same patent. Although both decisions concerned petitions for inter partes review, the Board has applied the Fintiv instructions to petitions for post-grant review.

In NHK, the Board exercised its discretion to deny institution of inter partes review, citing the "advanced state" of a parallel district court proceeding as a factor weighing in favor of denying the petition under 35 U.S.C. § 314(a). No. IPR2018-00752, Paper 8, at 20 (P.T.A.B. Sep. 12, 2018).[6] Specifically, the Board was concerned that instituting review would be an "inefficient use of Board resources," because trial had been set in the district court for March 25, 2019, whereas inter partes review would not conclude until September 2019, and the petitioner was asserting the "same prior art and arguments" in the district court proceeding as were in its inter partes review petition. Id. at 20. The Board concluded that instituting review would "not be consistent" with the AIA's objective of providing "an effective and efficient alternative to district court litigation." Id. (quoting Gen. Plastic Indus. Co., Ltd. v. Canon Kabushiki Kaisha, No. IPR 2016-01357, Paper 19, at 16-17 (P.T.A.B. Sept. 6, 2017)). On May 7, 2019, the Director designated NHK as precedential.

In Fintiv, the Board refined its framework for analyzing the impact of parallel district court litigation when deciding whether to institute inter partes review by articulating six factors that should be weighed as part of a "balanced assessment of all relevant circumstances in the case":

> 1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;

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operate in practice, "Fintiv instructions" is the most accurate description and will be used throughout this Memorandum Opinion.

[6] The Board also concluded that denying inter partes review was warranted under 35 U.S.C. § 325(d), which authorizes the Board to consider whether "the same or substantially the same prior art or arguments previously were presented" to the PTO. Id. at 18.

> 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 the parties;
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> 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 that impact the Board's exercise of discretion, including the merits.

No. IPR2020-00019, Paper 11, at 5-6 (P.T.A.B. Mar. 20, 2020). The Board observed that these factors "relate to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding," and explained that some factors may be more or less relevant depending on the petition. Id. at 6. The Board also remarked that "[o]ther facts and circumstances," including those unrelated to parallel proceedings, might bear on its discretion to grant or deny a petition. Id. at 16.[7] On May 5, 2020, the Director designated the Fintiv decision as precedential.

The Board has since applied the Fintiv instructions to petitions for post-grant review. None of these post-grant review decisions have been designated as precedential. See, e.g., Supercell Oy v. Gree, Inc., No. PGR2020-00034, Paper 13 (P.T.A.B. Sept. 3, 2020); Apple Inc. v. Pinn, Inc., No. PGR2020-00066, Paper 16 (P.T.A.B. Dec. 8, 2020); Apple Inc. v. Pinn, Inc., No. PGR2020-00073, Paper 15 (P.T.A.B. Dec. 8, 2020); Daiichi Sankyo, Inc. v. Seagen Inc., No.

[7] The Board did not decide whether to grant Apple's petition for review. Instead, it ordered the parties to submit supplemental briefing on the six factors outlined in its decision. Id. After the supplemental briefing was filed, the Board ultimately denied review because "instituting a trial would be an inefficient use of Board resources" and the Board's "preliminary assessment of the merits of some challenges presented in the [p]etition" had revealed "some weaknesses." Apple Inc. v. Fintiv, Inc., No. IPR2020-00019, Paper 15, at 17 (P.T.A.B. May 13, 2020).

PGR-2021-00030, Paper 11 (P.T.A.B. June 24, 2021); Daiichi Sankyo, Inc. v. Seagen Inc., No. PGR-2021-00042, Paper 12 (P.T.A.B. June 24, 2021).

B. Factual and Procedural Background

Plaintiffs, Daiichi Sankyo and AstraZeneca, are corporations "in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to treat serious diseases, including cancer." [Dkt. No. 5] ¶ 9. Non-party Seagen, Inc. ("Seagen") is the owner of United States Patent No. 10,808,039 ("the '039 Patent"), titled "Monomethylvaline compounds capable of conjugation to ligands," which was issued on October 20, 2020, and which plaintiffs have sought to challenge through post-grant review. Id. ¶¶ 9, 53.

The same day Seagen received its patent, it filed suit against Daiichi Sankyo Company, Limited ("DSC"), Daiichi Sankyo's overseas parent company, in the Eastern District of Texas, alleging that DSC's Enhertu product infringed the '039 Patent. Id. ¶ 51; see Complaint, Seagen, Inc. v. Daiichi Sankyo Co., Ltd., No. 2:20-cv-337-JRG (E.D. Tx. Oct. 19, 2020). DSC asserted invalidity of the '039 Patent as a defense. Seagen did not name either plaintiff as a party.[8] On November 13, 2020, plaintiffs and DSC filed suit against Seagen in the District of Delaware seeking a declaratory judgment of noninfringement of the '039 Patent. [Dkt. No. 5] ¶ 52; see Complaint, Daiichi Sankyo, Inc. v. Seagen Inc., No. 1:20-cv-1524-GBW (D. Del. Nov. 13, 2020). That action has been stayed since April 28, 2021, pending the outcome of Seagen's infringement suit in the Eastern District of Texas, the post-grant review proceedings, and this civil action.

[8] On July 28, 2021, AstraZeneca, along with AstraZeneca UK Limited, intervened in the infringement suit and joined DSC's invalidity contentions. See AstraZeneca's Answer to Plaintiff's Complaint, Seagen, Inc. v. Daiichi Sankyo Co., Ltd., No. 2:20-cv-337-JRG (E.D. Tx. July 29, 2021).

1. Plaintiffs' Post-Grant Review Petitions

On December 23, 2020, and January 22, 2021, plaintiffs filed two petitions which together requested post-grant review of all claims of the '039 Patent. [Dkt. No. 5] ¶ 53. The first petition, docketed as PGR2021-00030, covered claims 1-5, 9 and 10 of the '039 Patent ("the 00030 Petition"). Id. The second petition, docketed as PGR2021-00042, covered claims 6-8 of the '039 Patent ("the 00042 Petition"). Id.

On June 24, 2021, applying the Fintiv instructions to plaintiffs' petitions, the Board declined to institute review as to both petitions. Id. ¶ 54; [Dkt. No. 5-4] (Daiichi Sankyo, Inc. v. Seagen, Inc., No. PGR-2021-00030, Paper 11 (P.T.A.B. June 24, 2021)); [Dkt. No. 5-5] (Daiichi Sankyo, Inc. v. Seagen, Inc., No. PGR-2021-00042, Paper 12 (P.T.A.B. June 24, 2021)). It applied the Fintiv instructions because "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[.]" [Dkt. No. 5-4] at 11; [Dkt. No. 5-5] at 11. The Board observed that "there may be merit to Petitioner's scope of enablement challenges," but did not "find that the merits outweigh the other Fintiv factors favoring exercising [its] discretion to deny institution." [Dkt. No. 5-4] at 19-20; [Dkt. No. 5-5] at 19-20.

Less than a month later, on July 16, 2021, Seagen dropped claims 6-8, which were the only claims at issue in plaintiffs' 00042 Petition, from its infringement suit in the Eastern District of Texas. [Dkt. No. 5] ¶ 56. On July 26, 2021, plaintiffs requested that the Board rehear its decisions denying post-grant review as to both the 00030 Petition and the 00042 Petition. Id. ¶ 57. Plaintiffs also applied for Precedential Opinion Panel review, asserting that the denial of post-grant review raised "precedent-setting questions of exceptional importance." Id. ¶ 58; [Dkt. No. 5-6] at 1. Specifically, plaintiffs argued that the Precedential Opinion Panel "should reject the extension of NHK Spring and Fintiv to [post-grant review] proceedings," because "[s]uch

extension contravenes the [post-grant review] statutory scheme and congressional intent, ignores different statutory mandates of the Patent Office, and significantly curtails the availability of [post-grant review] as a mechanism for challenging patentability." [Dkt. No. 5-6] at 1; [Dkt. No. 5] ¶ 59. Plaintiffs also requested that the Precedential Opinion Panel "clarify that NHK Spring and Fintiv do not apply when the patent claims challenged in Board proceedings are not at issue in the parallel district court proceedings," such as when the patent owner drops claims challenged in a petition from its infringement action, as Seagen did with claims 6-8. Id. ¶ 60; [Dkt. No. 5-6] at 2.

On September 17, 2021, the Precedential Opinion Panel denied plaintiffs' requests for review. [Dkt. No. 5] ¶ 61; [Dkt. Nos. 5-7, 5-8]. Plaintiffs' requests for rehearing by the original Board panel remained pending when they initiated this civil action. [Dkt. No. 5] ¶ 62.

2. This Civil Action

On August 5, 2021, plaintiffs filed a six-count Complaint, which they amended on September 23, 2021 following the denial of Precedential Opinion Panel review. The first three counts of the Amended Complaint challenge the Fintiv instructions and their extension to post-grant review under the Administrative Procedure Act ("APA"). [Dkt. No. 5]. Specifically, the Amended Complaint alleges that the Fintiv instructions, as applied to post-grant review, are "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" (Count I), id. ¶¶ 68-79, are "arbitrary, capricious, and not in accordance with law" (Count II), id. ¶¶ 80-86, and were impermissibly promulgated as a "binding substantive rule without notice and comment" (Count III), id. ¶¶ 87-89.

Count IV challenges the denial of Precedential Opinion Panel review of the 00030 and 00042 Petitions, alleging that the denials were "arbitrary, capricious, an abuse of discretion, in excess of authority, and not in accordance with law." Id. ¶¶ 90-98. Count V challenges the

Arthrex interim process, alleging it is "arbitrary, capricious, an abuse of discretion, in excess of authority, and not in accordance with law, insofar as it does not provide for Director review of the Board's decisions denying [post-grant review] institution." Id. ¶¶ 99-104. Count VI seeks a declaration that the Fintiv instructions, the decisions denying plaintiffs' request for Precedential Panel Opinion review, and the Arthrex interim review process, are invalid, unenforceable, and must be set aside. Id. ¶¶ 105-12. The Complaint also seeks a permanent injunction prohibiting the PTO from relying on the Fintiv instructions to deny institution of post-grant review, an order requiring the PTO to create a process for Director review of Board decisions denying institution, including as to the 00030 and 00042 Petitions, and reinstatement of plaintiffs' requests for Precedential Panel Opinion review. Id. at 31-32.

On November 24, 2021, the Director filed a Motion to Dismiss for Lack of Jurisdiction [Dkt. No. 15] and a Motion to Dismiss for Failure to State a Claim [Dkt. No. 16], which are fully briefed and for which oral argument has been held.[9]

3. Subsequent Developments

Since the motions were filed, much has changed in both the administrative proceedings before the Board and the infringement suit in the Eastern District of Texas. On April 7, 2022, three days after trial began in Seagen's infringement suit in the Eastern District of Texas, the Board granted plaintiffs' rehearing requests and instituted post-grant review as to all claims of the '039 Patent. [Dkt. No. 39]. The Board instituted review as to the 00042 Petition, which concerned claims 6-8 of the '039 Patent, because "the claims challenged in the Petition are no longer asserted in the Texas Litigation" that had served as the basis for the Board exercising its

[9] Plaintiffs filed a Motion for Summary Judgment on January 6, 2022, [Dkt. No. 26], which the Court has stayed pending resolution of the Motions to Dismiss.

discretion to deny review, [Dkt. No. 39-2] (Daiichi Sankyo, Inc. v. Seagen, Inc., No. PGR-2021-00042, Paper 18 (P.T.A.B. Apr. 7, 2022)) at 7, and the petition established that "it is more likely than not that [p]etitioner would prevail in showing that at least one claim of the '039 Patent is unpatentable," id. at 41. The Board also instituted review as to the 00030 Petition, which concerned claims 1-5, 9 and 10 of the '039 Patent, finding that the argument that the challenged claims lack enablement had "strong merits," [Dkt. No. 39-1] (Daiichi Sankyo, Inc. v. Seagen, Inc., No. PGR-2021-00030, Paper 17 (P.T.A.B. Apr. 7, 2022)) at 3, and involved "essentially identical issues" as the 00042 Petition, such that "considerations of efficiency . . . strongly weigh in favor of also instituting trial," id. at 6-7.

On April 8, 2022, the jury returned its verdict in the infringement suit in the Eastern District of Texas, finding that DSC had willfully infringed at least one of claims 1-5, 9 and 10 of the '039 Patent. See Verdict Form, Seagen, Inc. v. Daiichi Sankyo Co., Ltd., No. 2:20-cv-337-JRG (E.D. Tx. Apr. 8, 2022). The jury also found that none of the patent claims was invalid. Id.

On April 20, 2022, Seagen disclaimed claims 6-8 of the '039 Patent. [Dkt. No. 41-1] at 3. The next day, Seagen requested that post-grant review of claims 6-8 in the 00042 Petition be terminated because there were no longer any recognized claims at issue in that proceeding. Id. Seagen also sought rehearing of the Board's decision to institute post-grant review of the 00030 Petition. Id. On May 11, 2022, Seagen requested an adverse judgment against itself in the post-grant review proceeding involving claims 6-8. [Dkt. No. 44-3].

On June 21, 2022, the Director, having received hundreds of responses to a request for comments about the Fintiv instructions, issued a memorandum—the "Vidal Memorandum"—to provide clarification about "the [Board's] current application of Fintiv to discretionary institution when there is parallel litigation." [Dkt. No. 44-2] at 2. The Vidal Memorandum provided that

the Board "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," that is, "challenges . . . in which the evidence, if unrebutted at trial [before the Board], would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence." Id. at 2-4. The Director explained that "[t]his clarification strikes a balance among the competing concerns of avoiding potentially conflicting outcomes, avoiding overburdening patent owners, and strengthening the patent system by eliminating patents that are not robust and reliable." Id. at 5. The Vidal Memorandum also affirmed that the Fintiv instructions apply not only to inter partes review but also to post-grant review. See id. at 3-4.

On July 15, 2022, the Board granted Seagen's rehearing request and de-instituted post-grant review as to the 00030 Petition, reasoning that that a rehearing was appropriate due to Seagen's disclaimer of claims 6-8 of the '039 Patent, its request for adverse judgment as to the 00042 Petition, and the "additional investment in the parallel proceeding by the district court and the parties," including the jury's determination that claims 1-5, 9 and 10 did not lack enablement. [Dkt. No. 44-1] (Daiichi Sankyo, Inc. v. Seagen, Inc., No. PGR-2021-00030, Paper 31 (P.T.A.B. July 15, 2022)) at 7. Although the Board acknowledged its earlier finding that the 00030 Petition presented "strong merits" of unpatentability, id. at 4, it explained that it could not "conclude that [p]etitioner's enablement case is compelling" because the district court in the parallel infringement suit had "substantially completed its review of the enablement issue" and the jury's verdict confirmed the patent's validity, id. at 6. The Board further agreed with Seagen that continuing with post-grant review would "result in duplicative efforts and potentially conflicting

results between the district court and the Board." Id. at 7.[10] On August 4, 2022, plaintiffs filed a request for rehearing of the Board's decision to de-institute post-grant review of the 00030 Petition as well as a request for Precedential Opinion Panel review of that decision. [Dkt. No. 47]. Throughout these developments before the PTO, this civil action was stayed.

On February 7, 2023, based on the Vidal Memorandum, the Precedential Opinion Panel entered an order instructing the Board to evaluate whether the merits of the 00030 Petition were "compelling" before denying institution under Fintiv. Daiichi Sankyo, Inc. v. Seagen, Inc., No. PGR-2021-00030, Paper 35 (P.T.A.B. Feb. 7, 2023). In its order, the Precedential Opinion Panel observed that it was "unclear . . . whether the panel made a proper determination" as to whether to institute post-grant review because it "appears to have concluded that the Petition could not present compelling evidence of unpatentability in view of the jury verdict alone." Id. at 3. Finding that the Board was "best positioned, in the first instance" to evaluate the merits of the 00030 Petition, the Precedential Opinion Panel denied plaintiffs' request that it review the Board's decision, instead directing the Board to "exercise its own judgment as to whether the merits of the Petition are 'compelling' . . . within two weeks." Id. at 4.

On February 14, 2023, after conducting that review, the Board reversed its earlier decision and instituted post-grant review of claims 1-5, 9 and 10 of the '039 Patent, finding that the petition "present[ed] compelling evidence of unpatentability" and that it had erred in discretionarily denying post-grant review based on the Fintiv instructions. [Dkt. No. 50-1] (Daiichi Sankyo, Inc. v. Seagen, Inc., No. PGR-2021-00030, Paper 36 (P.T.A.B. Feb. 14, 2023)) at 12. The Board "acknowledge[d] that instituting review in this proceeding when the district

[10] On July 25, 2022, the Board granted Seagen's request for adverse judgment as to the 00042 Petition and entered an adverse judgment against Seagen. [Dkt. No. 46-1] (Daiichi Sankyo, Inc. v. Seagen, Inc., No. PGR-2021-00042, Paper 25 (P.T.A.B. July 25, 2022)).

court already has reached its result requires the parties to duplicate the efforts they have put into the district court proceeding and requires [the Board] to duplicate the efforts of the district court and its jury," id. at 11, but concluded that the Vidal Memorandum was "unequivocal" that a discretionary denial was not appropriate given the strength of the unpatentability challenge, id. at 12. As of July 10, 2023, the Board has not rendered a substantive decision on the validity of the '039 patent.[11]

II. DISCUSSION

The Director has raised numerous grounds for dismissing the Amended Complaint in her motions to dismiss—including that plaintiffs lack standing, their claims are not ripe, the Fintiv instructions are neither reviewable final agency action under the APA nor subject to notice-and-comment rulemaking, the Precedential Opinion Panel's decisions are not reviewable final agency action, and the Arthrex interim process does not violate the Appointments Clause—but many of these issues do not require resolution in light of the changes that have occurred in the administrative proceedings before the Board. As will be discussed below, because plaintiffs have obtained post-grant review of the '039 patent and have not demonstrated a sufficiently imminent threat of future injury, all of their claims have become moot and, as such, they lack standing to continue to press their claims. Moreover, plaintiffs' challenge to the substance of the Fintiv instructions is unreviewable. Accordingly, the Motion to Dismiss for Lack of Jurisdiction will be granted, and the Motion to Dismiss for Failure to State a Claim will be denied as moot.

[11] The parties have filed supplemental briefing addressing all of these developments. See [Dkt. Nos. 41, 44, 46, 47, 54, 55].

A. Standard of Review

Fed. R. Civ. P. 12(b)(1) requires that a civil action be dismissed when the court lacks subject matter jurisdiction over the dispute. A "defendant may challenge subject-matter jurisdiction in one of two ways: facially or factually." Beck v. McDonald, 848 F.3d 262, 270 (4th Cir. 2017). A facial challenge contends that "a complaint simply fails to allege facts upon which subject matter jurisdiction can be based," and in evaluating such a challenge, "the facts alleged in the complaint are taken as true." Id. (quoting Kerns v. United States, 585 F.3d 187, 192 (4th Cir. 2009)). By contrast, a factual challenge contends that "the jurisdictional allegations of the complaint [are] not true," and a court is permitted to "go beyond the allegations of the complaint and in an evidentiary hearing determine if there are facts to support the jurisdictional allegations." Id. (quoting Kerns, 585 F.3d at 192). In either case, the plaintiff bears the burden of proving that subject matter jurisdiction exists. Id.

The justiciability doctrines of standing and mootness are implicated in this dispute, and because the issues are intertwined, they will be examined together. Article III of the Constitution confers jurisdiction on federal courts only over "cases" and "controversies." The doctrine of standing is "rooted in the traditional understanding of a case or controversy," and it "serves to prevent the judicial process from being used to usurp the powers of the political branches and confines the federal courts to a properly judicial role." Spokeo, Inc. v. Robins, 578 U.S. 330, 338 (2016) (internal citations omitted). To establish standing, a plaintiff must show "(i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." TransUnion LLC v. Ramirez, 141 S. Ct. 2190, 2203 (2021) (citing Lujan v. Defs. of Wildlife, 504 U.S. 555, 560-61 (1992)). When a plaintiff seeks injunctive or declaratory relief, the injury-in-fact requirement for prospective relief can be satisfied "either by

demonstrating 'a sufficiently imminent injury in fact' or by demonstrating 'an ongoing injury[.]'" Garey v. James S. Farrin, P.C., 35 F.4th 917, 922 (4th Cir. 2022) (quoting Deal v. Mercer Cnty. Bd. of Educ., 911 F.3d 183, 189 (4th Cir. 2018)). "An allegation of future injury may suffice if the threatened injury is 'certainly impending,' or there is a 'substantial risk that the harm will occur.'" Susan B. Anthony List v. Dreihaus, 573 U.S. 149, 158 (2014) (quoting Clapper v. Amnesty Int'l USA, 568 U.S. 398, 414 n.5 (2013)). In short, to have standing, a plaintiff must have a "personal stake" in the case—to be able to "sufficiently answer," "What's it to you?" TransUnion, 141 S. Ct. at 2203.

Mootness is closely related to standing and "has been described as the doctrine of standing set in a time frame: The requisite personal interest that must exist at the commencement of the litigation (standing) must continue throughout its existence (mootness)." Lebron v. Rumsfeld, 670 F.3d 540, 561-62 (4th Cir. 2012) (quoting Arizonans for Off. Eng. v. Arizona, 520 U.S. 43, 68 n.22 (1997)). A claim becomes moot "when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome." Long v. Pekoske, 38 F.4th 417, 422-23 (4th Cir. 2022) (quoting Already, LLC v. Nike, Inc., 568 U.S. 85, 91 (2013)). "If intervening factual or legal events effectively dispel the case or controversy during pendency of the suit, the federal courts are powerless to decide the questions presented." Ross v. Reed, 719 F.2d 689, 693-94 (4th Cir. 1983).

Because the requirements of standing and mootness "apply independently to each form of relief sought," Carter v. Fleming, 879 F.3d 132, 137 (4th Cir. 2018) (internal quotations omitted), a court must be satisfied that a plaintiff has satisfied both standing and mootness requirements for each asserted claim. See Town of Chester v. Laroe Ests., Inc., 581 U.S. 433, 439 (2017).

B. The Fintiv Instructions (Counts I, II, and III)

Counts I, II, and III of the Amended Complaint challenge the Fintiv instructions and their extension to post-grant review, with Counts I and II mounting a substantive challenge under the APA and Count III challenging the instructions on procedural grounds based on the PTO's failure to promulgate them through notice-and-comment rulemaking. Although plaintiffs maintain that they are challenging the Fintiv instructions as final agency action "separate and apart from" how they applied to their specific petitions, see [Dkt. No. 5] ¶ 70; [Dkt. No. 25] at 11 ("Plaintiffs challenge the [Fintiv instructions] . . . generally—not merely as applied to two particular [post-grant review] denials."); [Dkt. No. 54] at 4, they also rely on the application of the Fintiv instructions to the 00030 Petition to "illustrate[] the injury" they allege is caused by the instructions, id. at 6. Accordingly, the justiciability of plaintiffs' challenge to the Fintiv instructions both generally and as-applied to their specific post-grant review petitions must be considered.

1. Standing and Mootness

The Director argues that because the Board granted an adverse judgment against Seagen as to the 00042 Petition and instituted post-grant review as to the 00030 Petition, plaintiffs do not have standing to challenge the Fintiv instructions. The Court agrees that to the extent plaintiffs' claims relate to the 00042 and 00030 Petitions, they do not state an ongoing, actual controversy. Throughout this civil action, plaintiffs' theory of injury has been that they continue to be harmed by the Fintiv instructions which "[d]eprive[] [them] of the possibility of realizing [the] benefits of the statutory [post-grant review] process," [Dkt. No. 25] at 10; however, Seagen has disclaimed all patent claims at issue in the 00042 Petition, rendering that petition moot. As for the 00030 Petition, even if diminution of the opportunity to obtain the benefits of post-grant review constituted a concrete injury, plaintiffs have actually, albeit belatedly, obtained the

opportunity to have post-grant review of the patent claims at issue in the 00030 Petition. Post-grant review having been instituted, the requested relief—setting aside the Fintiv instructions and enjoining defendants from relying on the instructions to deny review—would have no effect on the 00030 Petition because there is no longer any occasion for the Board to rely on the instructions. See Norfolk S. Ry Co. v. City of Alexandria, 608 F.3d 150, 161 (4th Cir. 2010) (finding a case moot when the court's ruling "could not have any practical effect on the outcome of this case"). In this case, application of the Fintiv instructions, as clarified by the Vidal Memorandum, resulted in plaintiffs obtaining the benefits of post-grant review, which is what they ultimately sought. Accordingly, the Court is unable to "grant any effectual relief" as to either petition. Long, 38 F.4th at 423 (quoting Williams v. Ozmint, 716 F.3d 801, 809 (4th Cir. 2013)). As the Supreme Court has explained, there is "no precedent for the proposition that when a plaintiff has sued to challenge the lawfulness of certain action or threatened action but has settled that suit, he retains standing to challenge the basis for that action (here, the regulation in the abstract), apart from any concrete application that threatens imminent harm to his interests." Summers v. Earth Island Institute, 555 U.S. 488, 494 (2009).

Plaintiffs contend that they have suffered a legally cognizable injury from the Board's "unreasonable and unlawful delay" in instituting post-grant review and that, but for the Fintiv instructions, the Board would have instituted review upon initial consideration of their petition which was filed on December 23, 2020. [Dkt. No. 54] at 6-7. Plaintiffs maintain that under the timelines prescribed by the AIA, they would have received a final decision on patentability by June 2022 or, at the latest, December 2022. See id.; 35 U.S.C. §§ 324(c), 326(a)(11). Plaintiffs further argue that had the Board timely instituted review, "it is highly likely that the Board would have ruled the '039 patent invalid, thereby eliminating Seagen's cause of action in the parallel

infringement litigation"; however, due to the delay, they have been "forced . . . to litigate in district court for additional months, expending considerable resources," and these "costs of continued infringement litigation" constitute a concrete injury.[12] [Dkt. No. 54] at 7-8.

The Court recognizes that post-grant review was designed to provide a quick, early, and efficient administrative process by which patents could be challenged within nine months of their issuance, see [Dkt. No. 5] ¶¶ 24-25, 72-74,[13] and that the Board's repeated changes in position in denying review on June 24, 2021, instituting review on April 7, 2022, de-instituting review on July 15, 2022, and finally re-instituting review on February 14, 2023 caused significant delay and uncertainty for plaintiffs. Nevertheless, that delay and any resulting financial expenditures are not redressable by this Court because post-grant review has been instituted, and the declaratory and injunctive relief requested in the Amended Complaint would have no effect on the past delay and litigation costs incurred by plaintiffs. See Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 107-09 (1998) ("Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court[.]"); S. Walk at Broadlands Homeowner's Ass'n, Inc. v. OpenBand at Broadlands, LLC, 713 F.3d 175, 183 (4th Cir. 2013). Plaintiffs point to Nine Iraqi Allies Under Serious Threat Because of Their Faithful Service to the United States v. Kerry, 168 F. Supp. 3d 268, 281-82 (D.D.C. 2016), to support their position that the unreasonable delay in

[12] The jury verdict of validity, returned on April 8, 2022, would still have occurred before the Board's decision on validity based on the timeline proffered by defendants.

[13] See H.R. Rep. No. 112-98, at 48 (2011) (explaining that post-grant review was "intended to remove current disincentives to current administrative processes," to provide "quick and cost effective alternatives to litigation," and to "improve patent quality" and "make the patent system more efficient"); 157 Cong. Rec. S5319 (daily ed. Sept. 6, 2011) (statement of Sen. Kyl) ("By allowing post-grant review of patents . . . the bill creates an inexpensive substitute for district court litigation and allows key issues to be addressed by experts in the field."); 157 Cong. Rec. S1326 (daily ed. Mar. 7, 2011) (statement of Sen. Sessions) (stating that post-grant review "will allow invalid patents that were mistakenly issued by the PTO to be fixed early in their life, before they disrupt an entire industry or result in expensive litigation").

considering their petitions for review is a cognizable injury. To the contrary, that case supports the conclusion that plaintiffs' claims are moot: the district court found that as to the plaintiffs whose special immigrant visa applications had been granted, their claims based on the delay in processing those visas were moot and they had no standing to litigate the case. Id. at 283.

Plaintiffs next contend that their case falls within an exception to mootness for wrongs "capable of repetition yet evading review," arguing that "if the PTO could moot any APA challenge to the [Fintiv instructions] by selectively re-instituting [post-grant] review (irrespective of how late in the process), that would impermissibly frustrate review." [Dkt. No. 54] at 5. They point out that the Board changed its institution decision on the 00030 Petition three times and assert that the dismissal of their claims in this litigation as moot "would effectively license the Board's dilatory re-institution of [post-grant] review as a mechanism to avoid judicial scrutiny of its rules governing institution in instances of parallel district court proceedings." Id. That argument ignores the impact of the Vidal Memorandum, which changed how Fintiv is applied by directing the Board not to deny institution of review when parallel district court litigation is in process if the petition presents "compelling evidence of unpatentability." [Dkt. No. 44-2] at 2.

In any case, the exception to mootness for wrongs "capable of repetition yet evading review" is a "narrow exception . . . limited to the 'exceptional situation'" when "(1) the challenged action is in its duration too short to be fully litigated prior to cessation or expiration; and (2) there is a reasonable expectation that the same complaining party will be subject to the same action again." Williams, 716 F.3d at 810 (first quoting City of Los Angeles v. Lyons, 461 U.S. 95, 109 (1983), then quoting Lux v. Judd, 651 F.3d 396, 401 (4th Cir. 2011)). To satisfy the second requirement, there must be a "'reasonable expectation' or a 'demonstrated probability,'" not a "mere physical or theoretical possibility," that the "same controversy will

recur involving the same complaining party." Murphy v. Hunt, 455 U.S. 478, 482 (1982) (quoting Weinstein v. Bradford, 423 U.S. 147, 149 (1975) (per curiam)).

Plaintiffs have not shown that the second requirement is met. Although the Board reversed course three times, it has concluded that a discretionary denial under Fintiv is not warranted because of the compelling merits of the 00030 Petition. [Dkt. No. 50-1] at 11. Seagen has not petitioned for rehearing of the Board's decision to institute post-grant review, and the time to do so has expired. See 37 C.F.R. § 42.71(d). Moreover, briefing on the petition is complete, and oral argument, if requested by either party, will be held on August 24, 2023. See Daiichi Sankyo, Inc. v. Seagen, Inc., No. PGR-2021-00030, Paper 42 (P.T.A.B. May 8, 2023). In light of these developments, there is no reasonable expectation that the Fintiv instructions will once again be applied to the 00030 Petition to deny institution of post-grant review.

Turning next to plaintiffs' asserted "challenge . . . to the overall rule, not to any specific institution decision," [Dkt. No. 54] at 4, the Court finds that plaintiffs have not established a sufficient risk of future injury to pursue prospective declaratory and injunctive relief as to the Fintiv instructions. To satisfy the imminence requirement of an injury-in-fact, the Supreme Court has made clear that the threatened injury cannot be "too speculative," "'must be certainly impending to constitute injury in fact,' and . . . '[a]llegations of possible future injury' are not sufficient." Clapper, 568 U.S. at 409 (emphasis in original) (first quoting Lujan, 504 U.S. at 565 n.2, then quoting Whitmore v. Arkansas, 495 U.S. 149, 158 (1990)); see Lyons, 461 U.S. at 105, 110; Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc., 528 U.S. 167, 190 (2000); Susan B. Anthony List, 573 U.S. at 158; Ramirez, 141 S. Ct. at 2210.

Plaintiffs assert that they face an ongoing and future threat of harm from the Fintiv instructions because they are "pioneering biopharmaceutical companies" that "require a robust

protection of their patent rights in revolutionary biopharmaceutical products." [Dkt. No. 54] at 4. They maintain that because the Fintiv instructions are binding and must be applied by the Board when considering whether to institute post-grant review when there is parallel district court litigation, Fintiv "continues to deny [p]laintiffs the benefits and protections of the [post-grant review] process," and when they "next face an infringement suit directed at one of their innovative products based on a dubious new patent, they want to have full access to the statutory [post-grant review] process to counter that infringement challenge and to protect their intellectual property." Id. at 4.

To support their imminent injury argument, plaintiffs rely on a recent decision of the Federal Circuit in Apple Inc. v. Vidal, 63 F.4th 1 (Fed. Cir. 2023), which concerned a similar challenge to the Fintiv instructions in the context of inter partes review. In that case, the plaintiffs—Apple Inc. ("Apple"), Cisco Systems, Inc., Google LLC, Intel Corporation, Edwards Lifesciences Corp., and Edwards Lifesciences LLC—challenged the Fintiv instructions under the APA as being in excess of the Director's statutory authority by reducing the availability of inter partes review and authorizing discretionary denials that are contrary to the AIA, as arbitrary and capricious, and as procedurally invalid because the instructions were not adopted through notice-and-comment rulemaking. The Federal Circuit held that the statutory authority and arbitrary-and-capricious challenges to the Fintiv instructions were unreviewable, id. at 13, but that the procedural challenge was reviewable and "at least Apple has standing to press it," id. at 14.

Although neither Apple nor any of the other plaintiffs identified specific inter partes review petitions that were likely to be denied in the future due to Fintiv, the Federal Circuit found that Apple was "non-speculatively threatened with harm to a legally protected interest

from the challenged instructions," id. at 16, pointing to two paragraphs in the Apple complaint, which alleged:

> 23. Apple is an American success story and developer of iconic consumer devices and software that have transformed the American economy. With more than 90,000 employees in the United States, Apple is one of the country's largest employers in the high-technology business sector. Overall, Apple supports 2.4 million jobs in all 50 states. Last year, Apple spent over $60 billion with more than 9,000 domestic suppliers across the country, including at manufacturing locations in 36 states. Apple invests billions of dollars annually in U.S. research and development, and it owns more than 22,000 U.S. patents that protect that investment. . . .
>
> 28. Each Plaintiff's success in developing transformative, cutting-edge technologies depends on a patent system that provides strong legal protections for meritorious patents while ensuring that weak patents cannot be exploited in litigation to inhibit innovation.

Amended Complaint, Apple Inc. v. Vidal, No. 5:20-cv-6128-EJD (N.D. Cal. Nov. 9, 2020).

The Federal Circuit found that such "brief elaboration" of harm was "enough in this case," reasoning that:

> We may take judicial notice that Apple is a repeat player, in the relevant respect, on a very large scale. On a regular basis, for many years, it has been sued for infringement (giving it a concrete stake) and then petitioned for an [inter partes review] of patent claims at issue in that suit. Some of the petitions have been denied—for Apple, at least in Fintiv itself—based on the institution instructions at issue.
>
> Given that history, it is far from speculative that this sequence will be repeated in the future, considering Apple's size and use of a wide variety of technologies and the realistically perceived advantages of the [inter partes review] process, including the applicability of a lighter burden of persuasion to prevail in challenging a patent claim than the burden applicable in district court. . . . It is not unduly conjectural, but "the predictable effect" of the instructions, Department of Commerce, 139 S. Ct. at 2566, that the challenged instructions, which are plausibly alleged to cause more denials of institution than might otherwise occur, will continue causing harm in the form of denial of the benefits of [inter partes review] linked to the concrete interest possessed by an infringement defendant—even though Apple cannot specify in advance individual [inter partes review] requests (filed with an infringement suit pending) that will be denied.

Apple, 63 F.4th at 16-17.

Plaintiffs argue that they are like Apple and have standing to prospectively challenge the Fintiv instructions because of the "nature of [their] biopharmaceutical business" and their "history" of having post-grant review petitions denied, and if they are sued for infringement based on a "newly issued patent of dubious quality," they will seek to challenge the validity of the patent claims in post-grant review. [Dkt. No. 55] at 3-4.

The Court declines to extend the Federal Circuit's decision in Apple to this case because its holding as to standing, in large part, relied on taking judicial notice of "Apple's size and use of a wide variety of technologies" and its status as a "repeat player . . . on a very large scale" in being sued for infringement, petitioning for inter partes review of the asserted patent claims, and then having their petitions for review denied pursuant to the Fintiv instructions. Apple, 63 F.4th at 16-17. The Federal Circuit's reasoning presents Apple as a sui generis plaintiff.

By contrast, although AstraZeneca is a major global biopharmaceutical company, plaintiffs have not adequately alleged that either it or Daiichi Sankyo have the same size, scale, or extensive history as Apple. Moreover, there are no facts in this record that show, or from which the Court can take judicial notice, that plaintiffs are "repeat players" like Apple in being sued for infringement, filing for post-grant review, and having petitions for review denied based on the Fintiv instructions to support finding a "substantial risk" that plaintiffs will he harmed in the future because of the instructions. Susan B Anthony List, 573 U.S. at 158. As the Director correctly points out, aside from the '039 patent at issue in this case for which post-grant review has been instituted, plaintiffs have not identified a single instance in which they were sued for patent infringement, subsequently sought post-

grant review based on the claims asserted in that suit, and were denied review based on the Fintiv instructions.[14]

On this record, neither plaintiff has shown that there is a "real and immediate threat of repeated injury," Outdoor Amusement Bus. Ass'n, Inc. v. Dep't of Homeland Sec., 983 F.3d 671, 680 (4th Cir. 2020), from any future application of the Fintiv instructions. Whether or not they will at some point in the future sustain injury in the form of denial of the benefits of post-grant review depends on them (1) being sued by a third-party for patent infringement, (2) based on a patent issued within the last nine months that is eligible for post-grant review, (3) requesting post-grant review of the claims asserted in that suit, and (4) ultimately being denied post-grant review based on the Fintiv instructions and their failure to make out a compelling claim of unpatentability. As such, plaintiffs' theory of harm rests on a "highly attenuated chain of possibilities" that "does not satisfy the requirement that threatened injury must be certainly impending." Clapper, 568 U.S. at 410. Without more concrete, specific evidence of when or to what extent they might face the risk of being sued for infringement and then seek to use post-grant review,[15] plaintiffs provide only an inadequate "some day" risk of future harm. Lujan, 504 U.S. at 564.

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[14] It is notable that the Apple complaint identified five requests for inter partes review filed by Apple, including Fintiv itself, in which the Board applied the Fintiv instructions to deny review. See Amended Complaint, ¶¶ 59, 61, Apple Inc. v. Vidal, No. 5:20-cv-6128-EJD (N.D. Cal. Nov. 9, 2020).

[15] Plaintiffs maintain that they are collaborating on a pipeline product related to Enhertu, "which may be [the] subject of infringement accusations," and Seagen has "already tried to accuse" them of infringement, but this potential source of future injury is of no help because it concerns the same '039 patent. [Dkt. No. 55] at 3-4. As discussed, plaintiffs have obtained post-grant review of the '039 patent and the Board has determined that there are compelling unpatentability arguments, such that any risk of future injury from application of the Fintiv instructions is moot. Plaintiffs add that their pipeline products could be the "subject of infringement accusations" on the basis of "other questionable patents," id. at 3, but this claim is vague, lacks support, and is therefore insufficient to establish a non-speculative threat of future injury.

In sum, plaintiffs have not shown the risk that they might suffer harm in the form of the diminution of the opportunity to obtain the benefits of post-grant review is "sufficiently imminent and substantial," Ramirez, 141 S. Ct. at 2210, or "certainly impending," Susan B. Anthony List, 573 U.S. at 158, to have standing to press their claims that the Fintiv instructions are contrary to law, arbitrary or capricious, or procedurally invalid, and they cannot rely on past or ongoing injury based on the '039 patent because that issue is moot. For these reasons, Counts I, II, and III of the Amended Complaint are not justiciable and must be dismissed.

2. Reviewability

The Court also lacks jurisdiction over Counts I and II because 35 U.S.C. § 324(e), which provides that "[t]he determination by the Director whether to institute a post-grant review . . . shall be final and nonappealable," precludes judicial review of plaintiffs' substantive challenges to the Fintiv instructions.

Judicial review under the APA is excluded where "statutes preclude judicial review" of the challenged agency action. 5 U.S.C. § 701(a). Although there is a "strong presumption" in favor of judicial review of agency action, Bowen v. Michigan Acad. of Fam. Physicians, 476 U.S. 667, 670 (1986), that presumption "may be overcome by specific language or specific legislative history" or "inferences of intent drawn from the statutory scheme as a whole," Block v. Cmty. Nutrition Inst., 467 U.S. 340, 349 (1984).

In Apple Inc. v. Vidal, the Federal Circuit held that plaintiffs' challenges to the content of the Director's instructions in Fintiv were unreviewable under 35 U.S.C. § 314(d), which provides that "[t]he determination by the Director whether to institute an inter partes review . . . shall be final and nonappealable." 63 F.4th at 11-14. The Federal Circuit based its decision on the Supreme Court's decisions in Cuozzo Speed

Technologies, LLC v. Lee, 579 U.S. 261 (2016), SAS Institute v. Iancu, 138 S. Ct. 1348 (2018), and Thryv, Inc. v. Click-to-Call Technologies, 140 S. Ct. 1367 (2020), all of which interpreted § 314(d). In Cuozzo, the Supreme Court held that § 314(d)'s bar on appealing institution decisions "applies where the grounds for attacking the decision to institute inter partes review consist of questions that are closely tied to the application and interpretation of statutes related to the Patent Office's decision to initiate inter partes review."[16] 579 U.S. at 274-75; see Thryv, 140 S. Ct. at 1373 (reasoning that an appeal that "challenges not the manner in which the agency's review 'proceeds' once instituted, but whether the agency should have instituted review at all" was barred by § 314(d)). Based on Cuozzo, SAS Institute, and Thryv, the Federal Circuit held in Apple that the statutory and arbitrary-and-capricious challenges to the Fintiv instructions were rendered unreviewable by § 314(d) because they "have institution as their direct, immediate, express subject" and "focus directly and expressly on institution standards, nothing else." 63 F.4th at 12.

Plaintiffs argue that the Federal Circuit's reviewability decision in Apple does not apply to their claims because their challenge as to whether the PTO erred in extending the Fintiv instructions to post-grant review "is different from the arbitrary and capricious challenge at issue in Apple." [Dkt. No. 55] at 1. Plaintiffs' argument is unpersuasive. Section 324(e) contains a no-appeal provision for post-grant review that is identical to the bar in § 314(d). See SightSound Techs., LLC v. Apple Inc., 809 F.3d 1307, 1313 (Fed.

[16] The Supreme Court did not decide what effect § 314(d) would have on "appeals that implicate constitutional questions, that depend on other less closely related statutes, or that present other questions of interpretation that reach, in terms of scope and impact, well beyond 'this section,'" and explained that its interpretation did not "enable the agency to act outside its statutory limits," which would be reviewable through an appeal of the Board's final written decision under § 319 and pursuant to the APA. Cuozzo, 579 U.S. at 275; see SAS Inst., 138 S. Ct. at 1359.

Cir. 2015) (describing § 314(d) as "mirror[ing] the bar on appeal in § 324(e)"). When the Federal Circuit has considered whether a challenge to an institution decision was prohibited by § 324(e), it has analyzed the issue under Thryv, 140 S. Ct. 1367, which interpreted the no-appeal provision in § 314(d). See SIPCO, LLC v. Emerson Electric Co., 980 F.3d 865, 869-70 (Fed. Cir. 2020). This Court finds no meritorious distinction between § 314(d) and § 324(e), nor have plaintiffs provided a basis for interpreting these sections differently. Accordingly, consistent with Cuozzo and Thryv, § 324(e) bars judicial review of claims that are "closely tied," Cuozzo, 579 U.S. at 275, or "closely related," Thryv, 140 S. Ct. at 1370, to the Board's decision whether to institute post-grant review.

Like the Apple plaintiffs' challenge to the Fintiv instructions, plaintiffs' challenge is essentially a dispute about the content of the Director's institution instructions to the Board. The Amended Complaint alleges that the Fintiv instructions are in excess of statutory authority because the AIA does not authorize the Board to deny post-grant review when there is parallel district court litigation. [Dkt. No. 5] ¶ 71. Plaintiffs assert that the strict nine-month time period for filing a petition for post-grant review and the congressional objective that post-grant review incentivize early challenges to patents would be "thwarted" if the Board were permitted to deny petitions on non-statutory grounds such as parallel infringement actions in district court. Id. ¶¶ 72-73. Plaintiffs further contend that other "features" of post-grant review differentiate it from inter partes review, such as the ability to raise more grounds for patent invalidity, and these differences make it erroneous to extend Fintiv to post-grant review. Id. ¶ 75. Along these lines, the Amended Complaint alleges that the Board's failure to "adequately consider the

differences" between post-grant review and inter partes review rendered the extension of the Fintiv instructions to post-grant review arbitrary and capricious. Id. ¶¶ 78, 83. Finally, plaintiffs assert that the Fintiv instructions are arbitrary and capricious because they require the Board to "engage in substantial speculation as to the likely course of the parallel district court proceeding" and its "factors are vague and malleable." Id. ¶ 84.

Contrary to plaintiffs' assertion that Counts I and II are "different" from the challenges at issue in Apple, these claims "have institution as their direct, immediate, express subject," Apple, 63 F.4th at 12, because they concern the standards and criteria under which the Director exercises her "unreviewable discretion" to institute post-grant review. Arthrex, 141 S. Ct. at 1977; see Apple Inc. v. Iancu, 2021 WL 5232241, at *6 (N.D. Cal. Nov. 10, 2021) ("To inquire into the lawfulness of the [Fintiv instructions], the Court would have to analyze 'questions that are closely tied to the application and interpretation of statutes related to the [Director's] decision to initiate inter partes review.'" (quoting Cuozzo, 579 U.S. at 275-76)). Accordingly, based on the Federal Circuit's reasoning in Apple, Counts I and II fall within § 324(e)'s bar on reviewability.

In a final attempt to circumvent § 324(e) and Cuozzo, plaintiffs argue that they are not challenging a "particular decision whether to institute [post-grant review]" but instead are "challenging as unlawful the rule by which the PTO makes such decisions," such that § 324(e) does not apply. [Dkt. No. 25] at 16-17. In this case, that is a distinction without a difference. As the Director points out, plaintiffs' efforts to characterize their claims as general challenges to the Fintiv instructions and not a particular institution decision amount to "little more than an attempted end-run around the nonappealability of the institution decision" under § 324(e). [Dkt. No. 17] at 16. The Fintiv instructions are

essentially the Director's policy for how to determine whether to grant a petition for post-grant review of a patent when there is parallel district court litigation involving the same patent. That the Fintiv instructions are generally applicable to all institution decisions (with a parallel infringement suit pending) does not make the instructions reviewable, as "[t]he Supreme Court has rejected the notion that 'if the agency gives a reviewable reason for otherwise unreviewable action, the action becomes reviewable.'" Apple, 63 F.4th at 13 (quoting Interstate Com. Comm'n v. Brotherhood of Locomotive Eng'rs, 482 U.S. 270, 283 (1987)); see Saint Regis Mohawk Tribe v. Mylan Pharms. Inc., 896 F.3d 1322, 1327 (Fed. Cir. 2018) ("If the Director decides not to institute, for whatever reason, there is no review. In making this decision, the Director has complete discretion to decide not to institute review.").

Indeed, in Apple, the Federal Circuit rejected the distinction between a "petition-specific challenge" like those in Thryv and Cuozzo and the Apple plaintiffs' "challenge to the Director's instructions to the Board, as delegatee, regarding how to exercise the Director's institution discretion," concluding that § 314(d) "encompass[ed] preclusion of review of the content-focused challenges to the instructions[.]" Apple, 63 F.4th at 13. The Federal Circuit's conclusion "rest[ed] on . . . the inevitability and congressional expectation of the Director's delegation of the institution decision, given the large number of institution decisions the Director would otherwise have to make personally, in highly technical matters involving significant records, while fulfilling many other responsibilities." Id. at 13. The Federal Circuit explained that because of "the need for delegation" and the Director's "political responsibility" over Board proceedings, "the Director must be able to give guidance in the form of instructions . . . about how to make

the institution determinations on her behalf" to ensure they are "made in accordance with the policy choices about institution" that she would otherwise make on her own if she personally made the decisions. Id.; see Ethicon Endo-Surgery, Inc. v. Covidien LP, 812 F.3d 1023, 1033 (Fed. Cir. 2016) (holding that "as a matter of inherent authority and general rulemaking authority, the Director ha[s] authority to delegate the institution decision to the Board"). The Federal Circuit observed that if the Director "personally made an institution decision" based on the Fintiv factors, her decision would be unreviewable under § 314(d), and therefore, for the inter partes system to function, "the same conclusion must follow" that the Director's instructions to the Board in delegation of her authority are unreviewable. Apple, 63 F.4th at 13.

The same reasoning applies to the PTO's extension of the Fintiv instructions to post-grant review. The decision whether to institute post-grant review is "committed 'to the Director's unreviewable discretion,'" In re Palo Alto Networks, 44 F.4th at 1373 (quoting Arthrex, 141 S. Ct. at 1977), and the exercise of that discretion includes how to manage Board proceedings in view of parallel district court litigation, see Apple, 63 F.4th at 8. As the Federal Circuit has observed, "[b]eing sued for infringement provides a defendant a distinct motivation to seek cancellation . . . of patent claims asserted against it in court," which would be through post-grant review in the case of a newly issued patent, but the existence of parallel proceedings addressing similar issues of patent invalidity "raises self-evident issues of efficiency and interbranch relations." Id. Because the AIA does not prescribe how the Director is to address "such an overlapping pending court case," "Congress generally left the two branches to exercise their available discretion to

address such issues."[17] Apple, 63 F.4th at 8. The Director must be able to issue instructions to the Board about how to consider those issues on her behalf because the "short time frame to decide whether to institute" post-grant review means that she herself cannot review every petition. Ethicon, 812 F.3d at 1031-32.

The Director has provided this direction through the Fintiv instructions, as clarified through subsequent guidance. The instructions appropriately direct the Board to consider a non-exhaustive set of factors that balance concerns about inefficiencies, duplication of resources, and the risk of inconsistent results against the strength of the petition's unpatentability arguments and the need to eliminate weak patents, allowing the Board to make an institution decision on the Director's behalf that accords with the circumstances of a particular petition and the parallel litigation. Moreover, the Vidal Memorandum now clarifies that the Board must also consider the merits of a petition and cannot deny a petition under Fintiv if the petition presents "compelling evidence of unpatentability," [Dkt. No. 44-2] at 2, which tempers much of the concerns raised by plaintiffs.

In sum, the challenges in Counts I and II to the Fintiv instructions which "directly govern institution," Apple, 63 F.4th at 12, are unreviewable pursuant to 35 U.S.C. § 324(e). For all of the aforementioned reasons, defendants' Motion to Dismiss for Lack of Jurisdiction will be granted as to Counts I, II, and III of the Amended Complaint.

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[17] A mandatory stay of a civil action until resolution of a pending request for post-grant review in many cases would best serve concerns about efficiency and judicial economy, but Congress has not enacted a provision to that effect, although it could have done so. Cf. In re Princo Corp., 486 F.3d 1365, 1368 (Fed. Cir. 2007) (observing that 28 U.S.C. § 1659(a), which provides that a "district court shall stay . . . proceedings in the civil action with respect to any claim that involves the same issues involved in the same proceeding" before the International Trade Commission, was enacted "to prevent infringement proceedings from occurring in two forums at the same time" (internal quotations omitted)).

C. Denial of Precedential Opinion Panel Review (Count IV)

In Count IV of the Amended Complaint, plaintiffs challenge the Precedential Opinion Panel's failure to review the Board's denial of post-grant review as to their petitions. See [Dkt. No. 5] ¶¶ 94-96; [Dkt. No. 25] at 13 (acknowledging that Count IV is "specific to [p]laintiffs' [post-grant review] petitions"). Count IV seeks declaratory and injunctive relief setting aside the Precedential Opinion Panel's denials and reinstating their requests for review by the panel. [Dkt. No. 5] at 32.

Since the Amended Complaint was filed, Count IV has become moot because the Board has revised its institution decision for the 00030 Petition in response to the February 7, 2023 order of the Precedential Opinion Panel. That order instructed the Board to re-evaluate the merits of the 00030 Petition, which led the Board to institute review of claims 1-5, 9 and 10 of the '039 patent after finding that it had erred in denying post-grant review. Accordingly, there is no longer any "effective relief available in federal court that [plaintiffs] ha[ve] not already received" as to the denial of Precedential Opinion Panel review. SAS Inst., Inc. v. World Programming Ltd., 874 F.3d 370, 389 (4th Cir. 2017). As for the 00042 Petition, for the reasons explained above, any claims based on that petition are moot because an adverse judgment has been entered against Seagen. Therefore, defendants' Motion to Dismiss for Lack of Jurisdiction will be granted as to Count IV of the Amended Complaint.

D. The Arthrex Interim Process (Count V)

Count V of the Amended Complaint alleges that the PTO's Arthrex interim process runs afoul of the Appointments Clause because it does not provide for Director review of the Board's institution decisions. [Dkt. No. 5] ¶¶ 102-03. The Amended Complaint also asserts that plaintiffs were subjected to arbitrary and capricious treatment because they

were not provided with the opportunity to seek Director review. Id. ¶ 104. Plaintiffs seek a declaration and an injunction ordering the Director to provide a process for reviewing the Board's institution denials.

Plaintiffs' as-applied challenge to the Arthrex interim process is moot because post-grant review has been instituted as to the'039 patent and therefore there is no longer any occasion for them to seek Director review of the Board's institution decision. As for their facial challenge to the lack of Director review of institution decisions, plaintiffs lack standing to press that claim for reasons previously explained. Specifically, they have not established that any injury from the diminution of the opportunity to obtain post-grant review is "certainly impending" or that there is a "substantial risk that the harm will occur." Susan B. Anthony List, 573 U.S. at 158. Whether plaintiffs will face harm from the denial of Director review is speculative, attenuated, and inchoate, because any future injury rests upon the same chain of events—that plaintiffs will seek post-grant review when parallel litigation involving the same patent claims is ongoing, be denied review, and then seek Director review of that denial.

In sum, plaintiffs' as-applied challenge to the Arthrex interim process is moot and they lack standing to challenge it on its face. Therefore, defendants' Motion to Dismiss for Lack of Jurisdiction will be granted as to Count V of the Amended Complaint.[18] Finally,

[18] In In re: Palo Alto Networks, Inc., 44 F.4th 1369 (Fed. Cir. 2022), the Federal Circuit held that the Director's refusal to accept requests for review of Board decisions denying institution of inter partes and post-grant review does not violate the Appointments Clause. The court explained that such a challenge differs "fundamentally" from the challenge in Arthrex because "there is no structural impediment to the Director's authority to review institution decisions either by statute or by regulation," as "[i]nstitution decisions are, by statute, the Director's to make and are only made by the Board as a matter of delegated authority." Id. at 1375. Even when the Director delegates to the Board the authority to determine whether to institute review, she "plainly has the authority to revoke the delegation or to exercise her review authority in individual cases despite

because Counts I to V of the Amended Complaint will be dismissed for lack of subject matter jurisdiction, Count VI, which seeks a declaratory judgment based on those claims and is not an independent cause of action, will also be dismissed.

III. CONCLUSION

For the reasons stated above and by an Order to be issued with this Memorandum Opinion, defendants' Motion to Dismiss for Lack of Jurisdiction [Dkt. No. 15] will be granted and their Motion to Dismiss for Failure to State a Claim [Dkt. No. 16] will be denied as moot.

Entered this 11th day of July, 2023.

Alexandria, Virginia

/s/
Leonie M. Brinkema
United States District Judge

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the delegation." Id. The Appointments Clause only requires that a Presidentially-appointed, Senate-confirmed officer have review authority, but it does not preclude such an officer from delegating her authority to other agency officers, and therefore there is no constitutional infirmity in the Director's review policy. Id. at 1375-77.