IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

DAIICHI SANKYO, INC. and ASTRAZENECA PHARMACEUTICALS, LP Plaintiffs, v. ANDREW HIRSHFELD, in his official capacity as Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and UNITED STATES PATENT AND TRADEMARK OFFICE, Defendants.	Civil Action No. 1:21-cv-00899

COMPLAINT

Daiichi Sankyo, Inc. ("Daiichi Sankyo") and AstraZeneca Pharmaceuticals, LP ("AstraZeneca" and, together with Daiichi Sankyo, "Plaintiffs"), by their undersigned counsel, hereby file this Complaint against Andrew Hirshfeld, in his official capacity as senior official Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office ("the Director"), and the United States Patent and Trademark Office's ("the PTO" and, together with the Director, "Defendants"), and allege as follows:

NATURE OF THE ACTION

1. This is a civil action seeking judicial review under the Administrative Procedure Act, 5 U.S.C. §§ 701-06, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, of two agency actions undertaken by the PTO:

(i) the rule adopted by the Director to govern the PTO's consideration of *inter partes* review ("IPR") petitions where parallel patent infringement litigation is pending (hereinafter, "the *NHK-Fintiv* rule"), insofar as that rule authorizes the Patent Trial and Appeal Board ("the Board") to deny institution of post-grant review ("PGR") proceedings; and

(ii) the process adopted by the Director for review of the Board's decisions (hereinafter, "the *Arthrex* rule"), insofar as that rule does not provide for Director review of the decisions denying institution.

2. In the *NHK-Fintiv* rule, the Director instructed the Board that it may deny an IPR petition based on a balancing of discretionary factors (found nowhere in the applicable statute) related to a parallel infringement litigation pending before a federal district court. In several Board decisions (including those denying institution of Plaintiff's petitions), the PTO extended that rule to PGR proceedings. That extension is inconsistent with the PGR statutory scheme and congressional intent, leads to inconsistent agency decision-making, and significantly curtails the availability of PGRs as an alternative forum for challenging patent validity, thereby undermining PGR's critical role in protecting a strong patent system. The *NHK-Fintiv* rule is therefore arbitrary, capricious, an abuse of discretion, in excess of authority, and not in accordance with law. The *NHK-Fintiv* rule is also procedurally invalid because it was not adopted through

notice-and-comment rulemaking, but instead promulgated through an internal process established by the Director that provides no opportunity for, or consideration of, public input.

3. In the *Arthrex* rule, the Director promulgated an interim process for implementing the Supreme Court's decision in *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021), which held that, in order to comply with the requirements of the Appointments Clause, the Director must have the ability to review and rehear the Board's decisions. The *Arthrex* rule permits the Director to review and reheard the Board's decisions either sua sponte or upon a request by a party to the Board proceeding. The PTO, however, limited this review process to the Board's final written decisions, and refused to extend it to decisions denying institution, even though such decisions are final agency actions. The *Arthrex* rule's failure to provide for Director review of the Board's institution decisions is contrary to the Supreme Court's guidance in *Arthrex*, and is therefore in excess of the PTO's statutory authority and not in accordance with law.

4. Plaintiffs filed two PGR petitions with the PTO seeking review of various claims of a patent held by Seagen Inc. ("Seagen"). A panel of the Board, acting on the designation of the Director, declined to institute review based on pending parallel patent infringement litigation between Seagen and Daiichi Sankyo's parent company. The Board based its decision on the *NHK-Fintiv* rule, which it applied to Plaintiffs' PGR petitions. Plaintiffs timely requested rehearing of the decisions denying institution. Plaintiffs also requested, pursuant to the procedures established by the Director, that the Board's Precedential Opinion Panel conduct review of the panel's decisions because they contravene the PGR statute and involve an issue of exceptional importance. Because of the *Arthrex* rule, however, Plaintiffs were unable to request Director review of the Board's decisions denying institution.

5. This Court should set both the *NHK-Fintiv* rule and the *Arthrex* rule aside as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The Court should also set aside the *NHK-Fintiv* rule as undertaken "without observance of procedure required by law." *Id.* § 706(2)(D).

PARTIES

6. Daiichi Sankyo is a corporation organized under the laws of the State of Delaware, with its principal place of business in Baking Ridge, New Jersey.

7. AstraZeneca is a limited partnership organized and existing under the laws of the State of Delaware, with its corporate headquarters in Wilmington, Delaware.

8. Both Daiichi Sankyo and AstraZeneca are in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to treat serious diseases, including cancer. Daiichi Sankyo and AstraZeneca requested institution of two PGR proceedings (PGR2021-00030 and PGR2021-00042) against U.S. Patent No. 10,808,039 ("the '039 patent") held by Seagen, challenging it as unpatentable.

9. Andrew Hirshfeld is a senior official Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the PTO, having his primary place of business in Alexandria, Virginia. The Director is being sued in his official capacity.

10. The PTO is a United States government administrative agency within the Department of Commerce, having its principal place of business in Alexandria, Virginia.

JURISDICTION AND VENUE

11. This action arises under the United States Patent Act, 35 U.S.C. §§ 1 *et seq.*, the Administrative Procedure Act, 5 U.S.C. §§ 701-06, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

12. This Court has federal question jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under federal law.

13. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e) and 5 U.S.C. § 703 because the PTO is located in the Eastern District of Virginia and Defendants committed acts that created Plaintiffs' cause of action in the Eastern District of Virginia.

14. Both the *NHK-Fintiv* rule and the *Arthrex* rule are final agency actions subject to judicial review under 5 U.S.C. § 704.

LEGAL FRAMEWORK

I. The PGR Statutory Scheme and Its Advantages over Infringement Litigation.

15. The U.S. patent laws have historically provided both administrative and judicial paths for challenging the validity of patent claims after a patent had issued. By the 2010s, however, there was "a growing sense that questionable patents [we]re too easily obtained" and "too difficult to challenge." H.R. Rep. No. 112-98, pt. 1, at 39 (2011) (footnote omitted). At the same time, "the courts [we]re constrained" in their ability to "move[] in the direction of improving patent quality and making the determination of patent validity more efficient." *Id.*

16. Congress responded by enacting the Leahy-Smith America Invents Act (the "AIA"), Public Law No. 112-29, 125 Stat. 284 (2011). The AIA sought to "improv[e] patent quality and provid[e] a more efficient system for challenging patents that should not have

issued," while "reducing unwarranted litigation costs and inconsistent damage awards." H.R. Rep. No. 112-98, pt. 1, at 39-40.

17. As part of this effort, the AIA "create[d] a new post-grant opposition procedure" through which a party can request the PTO to reconsider and cancel an issued patent claim. *Id.* at 47-48. Any person other than the patent owner can file a petition for PGR, 35 U.S.C. § 321(a), and request cancellation of "1 or more claims of a patent" on any ground related to invalidity under section 282(b), *id.* § 321(b).

18. Importantly, Congress prescribed a strict time limit for seeking PGR. A PGR petition must be filed within "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 set this time limit in order "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." H.R. Rep. No. 112-98, pt. 1, at 47-48. Congress 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." *Id.* at 48.

19. The Director decides whether to institute a PGR, and he may do so provided "that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 35 U.S.C. § 324(a). The Director has delegated his authority to the Board—an adjudicatory body within the PTO that conducts PGRs, as well as other patent review proceedings under the AIA. *See* 37 C.F.R. §§ 42.4(a), 42.208(c). "The Board institutes the trial on behalf of the Director." *Id.* § 42.4(a).

20. The Board consists of "[t]he Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative patent judges." 35 U.S.C.

§ 6(a). In any given PGR proceeding, the Board makes institution decisions in panels composed of at least three members of the Board. *Id.* § 6(c). The administrative patent judges are appointed by the Secretary of Commerce in consultation with the Director. *Id.* § 6(a).

21. Once a PGR is instituted, the Board, sitting as a three-judge panel, examines the challenged patent's validity. *See* 35 U.S.C. §§ 6, 326(c). The AIA provides a challenger with broader participation rights in the proceeding. Upon the proceeding's conclusion, the Board issues a final written decision determining the patentability of the challenged claims. *Id.* § 328(a). Once the Board's decision becomes final (upon appeal to the United States Court of Appeals for the Federal Circuit or expiration of the time to appeal), the Director must "issue and publish a certificate" that cancels patent claims "finally determined to be unpatentable," confirms patent claims "determined to be patentable," and incorporates into the patent "any new or amended claim determined to be patentable." *Id.* § 328(b).

22. The AIA provides that "[t]he Director shall prescribe regulations . . . establishing and governing a post-grant review." *Id.* § 326(a)(4). Pursuant to the statutory direction, the PTO promulgated regulations governing the conduct of post-grant review. *See* United States Patent and Trademark Office, *Changes to Implement Inter Partes Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents*, 77 Fed. Reg. 48,680 (Aug. 14, 2012).

23. Several features of PGRs make them advantageous compared to district court litigation for determining whether an issued patent's claims are patentable. PGRs are conducted by the Board's Administrative Patent Judges, who must be "persons of competent legal knowledge and scientific ability." 35 U.S.C. § 6(a), (c). In contrast, patent validity disputes in the district court are typically resolved by lay jurors who need not have any specialized technical

expertise. Moreover, the standard of proof in a PGR proceeding is lower than in district court litigation. A PGR petitioner need only demonstrate that the challenged claims are unpatentable by a preponderance of the evidence, *see* 35 U.S.C. § 326(e)—a lower burden than the presumption of validity applied in district court litigation, *see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007).

24. PGR is designed to be more streamlined and efficient than district court litigation. The scope of discovery in PGR proceedings is more limited than in civil litigation. *See* 35 U.S.C. § 326(a)(5); 35 C.F.R. § 42.51. The AIA also sets time limits for the Director's decision to institute review and for the issuance of a final written decision. The Director must decide whether to institute review within three months after receiving the patent owner's preliminary response to the PGR petition (or the expiration of the period for the preliminary response), *see* 35 U.S.C. § 324(c), and the Board must issue its final written decision within a year from institution (though the Director may extend this deadline by "not more than 6 months" for good cause), *see id.* § 326(a)(11).

25. Given Congress' design of PGRs as an efficient "early-stage process for challenging patent validity," H.R. Rep. No. 112-98, pt. 1, at 48, the AIA provides that PGR may proceed in parallel with district court litigation where the validity of the same patent claims is at issue. While the AIA forecloses PGR if the petitioner has previously "filed a civil action challenging the validity of a claim of the patent," 35 U.S.C. § 325(a)(1), it expressly permits a petitioner—such as a defendant accused of patent infringement—to assert invalidity arguments in a counterclaim without forgoing PGR review, *id.* § 325(a)(3).

26. Apart from the prohibition in section 325(a)(1) on filing a PGR petition after filing a suit challenging patent validity, no provision of the AIA requires (or even permits) the

Director to deny institution of a PGR petition based on pending district court litigation involving the same patent claims.

II. The PTO's Process for Designating the Board Decisions as Precedential.

27. The PTO has established the Standard Operating Procedures ("SOPs") for the Board, designed to "increase[e] transparency, predictability, and reliability across the USPTO." United States Patent and Trademark Office, *Revisions to Standard Operating Procedures: Paneling and Precedential Decisions*, https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/procedures/revisions-standard-operating. The Board's SOP 2 prescribes a procedure for designating select Board decisions as "binding Board authority." Ex. A (United States Patent and Trademark Office, Patent Trial and Appeal Board, *STANDARD OPERATING PROCEDURE 2 (REVISION 10)* (Sept. 20, 2018), https://www.uspto.gov/sites/default/files/documents/SOP2%20R10%20FINAL.pdf) § III.D, at 11.

28. A typical Board decision "is, by default, a routine decision" that has no precedential force in future cases. *Id.* § I.B, at 3. A routine decision "is binding in the case in which it is made . . . but it is not otherwise binding authority." *Id.*

29. SOP 2, however, "provides a mechanism for highlighting certain Board decisions by designating them as precedential or informative." *Id.* "A precedential decision is binding Board authority in subsequent matters involving similar facts or issues." *Id.* § III.D, at 11. An informative decision "set[s] forth Board norms that should be followed in most cases, absent justification, although an informative decision is not binding authority on the Board." *Id.*

30. Under SOP 2, the Director decides whether to designate a Board decision as precedential. *Id.* § III.C, at 10-11. The Director does so based on a recommendation from the

Executive Judges Committee of the Board (composed of five most senior Administrative Patent Judges, *see id.* § III.B, at 10), and may consult with other PTO officials before making his decision. *Id.* § III.C, at 10-11.

31. Although members of the public may nominate a Board decision for designation as precedential, *id.* § III.A, at 9, SOP 2 does not provide for public notice that the PTO is considering designating a particular decision as precedential, nor allow for public comment. *Id.* § III, at 8-11.

III. The PTO's Precedential Opinion Panel Review Process.

32. SOP 2 also created the Precedential Opinion Panel review process. *See* SOP 2 § II, at 3-8. The Precedential Opinion Panel by default consists of the Director, the Commissioner for Patents, and the Board's Chief Judge. *See id.* § II.B, at 4. The Director may replace the default members of the Precedential Opinion Panel with the Deputy Director, the Deputy Chief Judge, or an Operational Vice Chief Judge, and the primary members of the Precedential Opinion Panel may delegate their authority to the same three officials for reasons such as conflict of interest or availability. *Id.* at 4-5.

33. The purpose of the Precedential Opinion Panel is "to establish binding agency authority concerning major policy or procedural issues, or other issues of exceptional importance in the limited situations where it is appropriate to create such binding agency authority through adjudication before the Board." *Id.* § II.A, at 3. To accomplish this objective, the Precedential Opinion Panel is authorized to consider proceedings before the Board that involve "important issues regarding statutes, rules, and regulations; important issues regarding binding or precedential case law; or issues of broad applicability to the Board." *Id.* at 3. The Precedential Opinion Panel "also may be used to resolve conflicts between Board decisions, to promote

certainty and consistency, or to rehear any case it determines warrants the Panel's attention." *Id.* at 4.

34. Any party to a proceeding before the Board may request "Precedential Opinion Panel review of a particular Board decision in that proceeding." *Id.* § II.C, at 5. The request must contain one of the following certifications: (*i*) that the Board panel decision is contrary to specific "decision(s) of the Supreme Court of the United States, the United States Court of Appeals for the Federal Circuit, or the precedent(s) of the Board"; or (*ii*) that the Board panel decision is contrary to specific "constitutional provision, statute, or regulation"; or (*iii*) that "this case requires an answer to one or more precedent-setting questions of exceptional importance." *Id.* at 5-6.

35. The Director has authority to convene a Precedential Review Panel based on a party's request. *Id.* at 5; *see also id.* § II.D, at 7. "There is no right to further review of a recommendation for Precedential Opinion Panel Review that is not granted." *Id.* § II.C, at 6.

36. If the Precedential Opinion Panel designates its decision as precedential, such decision "is binding Board authority in subsequent matters involving similar facts or issues." *Id.* § III.D, at 11; *see also id.* § II.E, at 8. The Precedential Opinion Panel can also designate its decision as informative. An informative decision is not binding Board authority but "set[s] forth Board norms that should be followed in most cases, absent justification." *Id.* § III.D, at 11; *see also id.* § II.E, at 8.

FACTUAL BACKGROUND

I. The *NHK-Fintiv* Rule.

37. The AIA specifies several requirements that must be met for the Director to institute PGR. *See, e.g.*, 35 U.S.C. §§ 321(c), 322(a)(1)-(5), 325(a)(1)-(2). For instance, a PGR petition must 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." *Id.* § 321(c). The Director also "may not" institute PGR "unless the Director determines" that the PGR petition "would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." *Id.* § 324(a).

38. The AIA enumerates certain discretionary grounds on which the Director may decline to institute PGR. For example, "the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the [Patent] Office." 35 U.S.C. § 325(d).

39. In two decisions, the PTO articulated an additional standard under which the Board may decline to institute review of a timely filed petition based on the pendency of parallel district court litigation over the validity of the same patent claims—even if the other statutory preconditions have been met. Both decisions concerned IPR (not PGR) petitions.

40. In *NHK Spring Co. v. Intri-Plex Technologies, Inc.*, IPR2018-00752, Paper 8 (P.T.A.B. Sept. 12, 2018) (attached as Ex. B), the Board held that the advanced state of a parallel district court action involving similar invalidity disputes as an IPR petition can serve as a ground for denying an otherwise timely and meritorious petition because "instituting a trial under [such] circumstances . . . would be an inefficient use of Board resources." *NHK*, Paper 8 at 19-20. The Board reasoned that because a pending infringement lawsuit involving "the same prior art and

arguments" as the IPR petition was "nearing its final stages," with trial "set to begin" about six months before the IPR would end, IPR "would not be consistent with an objective of the AIA . . . to provide an effective and efficient alternative to district court litigation." *Id.* at 20 (internal quotation marks omitted).

41. In *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (attached as Ex. C), the Board reaffirmed *NHK*, and set forth several factors for determining whether to institute IPR when parallel litigation is pending "as part of a balanced assessment of all relevant circumstances of the case, including the merits." *Fintiv*, Paper 11 at 5 (internal quotation marks omitted). The Board enumerated six such factors:

> 1. whether the court granted a stay or evidence exists that one may be granted if [an IPR] proceeding is instituted;
>
> 2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
>
> 3. investment in the parallel proceeding by the court and 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.

Fintiv, Paper 11 at 5-6.

42. Although the Board offered general guidance on how it might apply some of these factors, the *Fintiv* decision did not clearly "instruct [the Board] how to weigh the factors." *Cisco*

Sys., Inc. v. Ramot at Tel Aviv Univ. Ltd., IPR2020-00122, 2020 WL 2511246, at *5 (P.T.A.B. May 15, 2020) (Crumbley, Administrative Patent Judge ("APJ"), dissenting).

43. The Director designated *NHK* as precedential on May 7, 2019. Ex. B at 1.

44. The Director designated *Fintiv* as precedential on May 5, 2020. Ex. C at 1.

45. Because these decisions are designated as precedential, the Board is required to apply them in future institution decisions regarding petitions that challenge patent claims that are also the subject of pending infringement litigation. These decisions therefore constitute a rule—the *NHK-Fintiv* rule—within the meaning of the Administrative Procedure Act ("APA") because they are "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). The *NHK-Fintiv* rule "alter[s] the rights or interests of parties" by defining circumstances under which the Board may deny institution. *JEM Broad. Co. v. FCC*, 22 F.3d 320, 326 (D.C. Cir. 1994).

46. The Director adopted the *NHK-Fintiv* rule without notice-and-comment rulemaking.

47. Having been established as a binding rule through the designation of the *NHK* and *Fintiv* decisions as precedential, the *NHK-Fintiv* rule constitutes final agency action.

48. The Board has since applied the *NHK-Fintiv* rule to PGR proceedings,[1] including PGR petitions filed by Plaintiffs. *See, e.g.*, *Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, PGR2019-00048, Paper 19 (P.T.A.B. Nov. 20, 2019); *Supercell Oy v. Gree, Inc.*, PGR2020-00034, Paper 13 (P.T.A.B. Sept. 3, 2020); *Apple Inc. v. Pinn, Inc.*, PGR2020-00066, Paper 16 (P.T.A.B. Dec. 8, 2020); *Apple Inc. v. Pinn, Inc.*, PGR2020-00073, Paper 15 (P.T.A.B. Dec. 8,

[1] The *NHK-Fintiv* rule is being challenged before another court as well. *Apple Inc. v. Iancu*, No. 20-cv-06128 (N.D. Cal. filed Aug. 31, 2020).

2020); *Daiichi Sankyo, Inc. v. Seagen Inc.*, PGR-2021-00030, Paper 11 (P.T.A.B. June 24, 2021); *Daiichi Sankyo, Inc. v. Seagen Inc.*, PGR-2021-00042, Paper 12 (P.T.A.B. June 24, 2021).

49. The Board's decisions applying the *NHK-Fintiv* rule to PGR proceedings have been inconsistent and unpredictable, leading to arbitrary denials of PGR institution. For example, the Board denied Plaintiffs' petitions even though it acknowledged that Plaintiffs "acted diligently and without much delay" by filing their first PGR petition "two months after the issuance of the '039 Patent" and their second petition "two weeks after Patent Owner first alleged infringement of [the challenged] claims." Ex. D (*Daiichi Sankyo, Inc. v. Seagen Inc.*, PGR2021-00030, Paper 11 (P.T.A.B. June 24, 2021)) at 16 (citation omitted); Ex. E (*Daiichi Sankyo, Inc. v. Seagen Inc.*, PGR2021-00042, Paper 12 (P.T.A.B. June 24, 2021)) at 16 (citation omitted). In contrast, the Board, applying the *NHK-Fintiv* rule, instituted review in other PGR proceedings where a petition was filed much later. *See, e.g.*, *Cast Lighting, LLC v. Wangs Alliance Corp.*, PGR2021-00012, Paper 12 at 10, 37-38 (P.T.A.B. June 7, 2021) (PGR petition filed 274 days after patent issuance); *see also Philip Morris Prods., S.A. v. RAI Strategic Holdings, Inc.*, PGR2020-00071, Paper 11 at 19, 33 (P.T.A.B. Jan. 13, 2021) (PGR petition filed 207 days after patent issuance).

II. Plaintiffs' Petitions Requesting PGR and the Board's Decisions Denying Institution.

50. On October 20, 2020, Seagen, the alleged owner of the '039 patent, filed a lawsuit asserting that patent against Daiichi Sankyo's overseas parent, Daiichi Sankyo Company, Limited ("DSC"), in the U.S. District Court for the Eastern District of Texas. In that action, Seagen did not name either Daiichi Sankyo or AstraZeneca as a party.

51. On November 13, 2020, Plaintiffs and DSC filed a lawsuit against Seagen seeking a declaratory judgment of noninfringement of the '039 patent in the U.S. District Court for the District of Delaware. This action has been stayed since April 28, 2021, pending determinations in the Eastern District of Texas.

52. On December 23, 2020, and January 22, 2021, Plaintiffs filed PGR petitions requesting review of all claims in a patent held by Seagen. The Board docketed those petitions as PGR2021-00030 (as to Claims 1-5, 9-10) and PGR2021-00042 (as to Claims 6-8).

53. On June 24, 2021, a panel of the Board, acting on the designation of the Director, declined to institute review of Plaintiffs' petitions. *See* Ex. D (*Daiichi Sankyo, Inc. v. Seagen Inc.*, PGR-2021-00030, Paper 11 (P.T.A.B. June 24, 2021)); Ex. E (*Daiichi Sankyo, Inc. v. Seagen Inc.*, PGR-2021-00042, Paper 12 (P.T.A.B. June 24, 2021)). The Board 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." Ex. D at 11; Ex. E at 11. The Board nevertheless applied the *NHK Spring*/*Fintiv* rule to the Plaintiffs' petitions for PGR 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. Ex. D at 11 (citing Board decisions); Ex. E at 11 (same).

54. The Board's decisions denying Plaintiff's PGR petitions illustrate the problems with applying the *NHK-Fintiv* rules to PGR proceedings. For instance, the Board applied *Fintiv* even though neither Daiichi Sankyo nor AstraZeneca was a party to the district court litigation. The Board dismissed this fact on the rationale that the real parties in interest in the PGR

proceedings were parties to the infringement litigation. *See* Ex. D at 18-19; Ex. E at 18-19. That premise, however, was incorrect. AstraZeneca UK Limited, the real-party-in-interest affiliated with petitioner AstraZeneca, was *not* a party to the district court litigation.

55. Plaintiffs timely requested rehearing of the decisions denying institution. Plaintiffs also requested, pursuant to SOP 2, that the Precedential Opinion Panel conduct review of the panel's decisions because they contravene the PGR statute and involve an issue of exceptional importance.

56. Plaintiffs are currently awaiting a decision by the Board on whether the Board will rehear the decisions denying institution. Plaintiffs will continue to be harmed by the application of the *NHK-Fintiv* rule to PGR proceedings because the Board will be required to apply that rule on rehearing.

III. The *Arthrex* Rule.

57. On June 21, 2021, the Supreme Court issued its decision in *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021). The Court held that "the unreviewable authority wielded by APJs during inter partes review is incompatible with their appointment by the Secretary [of Commerce] to an inferior office." *Arthrex*, 141 S. Ct. at 1985. The Board panel "lacked the power under the Constitution" to issue a final agency decision for the PTO because the Appointments Clause required "an adequate opportunity for review by a principal officer." *Id.* at 1987-88. As a remedy, the Court invalidated 35 U.S.C. § 6(c)—a statutory provision that provides for rehearing by a panel of at least three Board members—"to the extent that its requirements prevent the Director from reviewing final decisions rendered by APJs," and ordered a remand to the Director "for him to decide whether to rehear the petition" and issue his own decision on behalf of the Board. *Id.* at 1987.

58. On June 29, 2021, the PTO promulgated an interim review process implementing the Supreme Court's *Arthrex* decision. *See* Ex. F (United States Patent and Trademark Office, Patent Trial and Appeal Board, *USPTO Implementation of an Interim Director Review Process Following* Arthrex (June 29, 2021), https://www.uspto.gov/patents/patent-trial-and-appeal-board/procedures/uspto-implementation-interim-director-review); *see also* Ex. G (United States Patent and Trademark Office, Patent Trial and Appeal Board, *Arthrex Q&As* (originally June 29, 2021; updated July 20, 2021), https://www.uspto.gov/patents/patent-trial-and-appeal-board/procedures/arthrex-qas).

59. The PTO's process—the *Arthrex* rule—provided for Director review of the Board's final written decisions in PGRs, but did not provide for Director review of the Board's decisions denying PGR institution, even though those decisions represent the agency's final action on those petitions.

60. On July 1, 2021, Defendant Hirshfeld reaffirmed during a public "PTAB Boardside Chat" webinar that the *Arthrex* rule was limited to review of the Board's final written decisions and will not provide for Director review of the Board's decisions denying PGR institution.

61. Under the *Arthrex* rule, Plaintiffs have been unable to request Director review of the Board's decisions denying institution of their PGR petitions.

COUNT I—ADMINISTRATIVE PROCEDURE ACT
(The *NHK-Fintiv* Rule Is in Excess of Statutory Jurisdiction and Authority)

62. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 61 above.

63. Section 706 of the Administrative Procedure Act authorizes courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

64. Plaintiffs challenge the *NHK-Fintiv* rule, which is a final agency action separate and apart from the proceedings on Plaintiffs' PGR petitions pending before the Board.

65. The AIA does not authorize the Director to deny PGR petitions based on perceived overlap with pending infringement litigation involving the same patent claims. In establishing the PGR process, Congress chose a precise statutory scheme. While Congress was well aware of the possibility of parallel validity proceedings, *see* AIA § 18(b)(1) (codifying a petitioner's ability to seek a stay of the district court in view of a pending CBM review), it did not authorize the Director to deny a PGR simply because of events in a parallel district court proceeding. Congress only authorized the Board to stay or terminate a pending PGR in view of other proceedings *before the Patent Office*. *See* 35 U.S.C. §§ 315(d), 325(d). By not authorizing any similar power, much less denial of institution, in light of a parallel district court action, Congress indicated the withholding of such powers.

66. Even if the *NHK-Fintiv* rule had some applicability in the IPR context, the Board's extension of that rule to PGR petitions 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." H.R. Rep. No. 112-98, pt. 1, at 48. 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 48. Section 321(c), thus, reflects Congress' considered judgment that a PGR petition is timely if filed within 9 months of the patent's grant or issuance. This statutory deadline would be meaningless, and congressional objective would be thwarted, if the Board can deny timely-filed petitions on non-statutory grounds. The Board cannot exercise its discretion to deny institution in a way that contradicts the statutory design.

67. The strict filing 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 cut-off deadline for seeking IPR review. Unlike in PGRs, review may be requested, and institution granted, long after the patent had issued. Even if the *NHK-Fintiv* rule could justify denial of institution in some IPRs because of advanced parallel district-court proceedings, that logic has no place in the PGR context, where the entire process was designed to incentivize early challenges to newly issued (or reissued) patents. 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, there may be concerns about inefficiency, duplication of efforts, and the risk of inconsistent results between the district court and the PTO, 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. 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 the basis that is found nowhere in the statute.

68. Denying institution because of a parallel proceeding risks curtailing PGRs as a forum for challenging questionable patents, in direct contravention of congressional intent. The Board's denial of Plaintiffs' PGR petitions is a telling example. The Board acknowledged that Plaintiffs "acted diligently and without much delay" by filing their first PGR petition "two months after the issuance of the '039 Patent" and their second petition "two weeks after Patent Owner first alleged infringement of [the challenged] claims." Ex. D at 16 (citation omitted); Ex. E at 16 (citation omitted). The Board nevertheless viewed Plaintiffs' prompt filing as "not weigh[ing] for or against" institution. Ex. D at 17; Ex. E at 17. This erroneous 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. Denying PGR under these circumstances "would effectively deny [Plaintiffs] the opportunity *to ever seek post-grant review*." *Teva Pharms.*, PGR2019-00048, Paper 19 at 11 n.7 (emphasis added).

69. Other features of the PGR scheme confirm that the *NHK-Fintiv* rule may not be extended 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 grounds related to invalidity under section 282(b), and the challenge does not have to rely on prior art references. *See* 35 U.S.C. § 321(b).

70. 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").

71. The broader scope of review and of the resulting estoppel provided under the PGR statute is a further indication that Congress did not intend for the Board to deny institution merely based on events in a parallel district court proceeding (to the extent that should even be considered in any context). Congress envisioned that the PGR process would "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.

72. In extending the *NHK-Fintiv* rule to PGRs, the Board did not adequately consider these importance differences between IPR and PGR proceedings, and between the IPR and PGR statutory schemes. To the extent the Board considered some of these differences, it failed to adequately explain its reasoning for extending the *NHK-Fintiv* rule to PGRs, and its decision to do so is inconsistent with the applicable statute. The decision is thus arbitrary and capricious.

73. The *NHK-Fintiv* rule, as applied to PGRs, is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" because it violates the AIA and the Director exceeded his statutory authority in adopting it. 5 U.S.C. § 706(2)(C).

COUNT II—ADMINISTRATIVE PROCEDURE ACT
(The *NHK-Fintiv* Rule Is Arbitrary and Capricious and Not in Accordance with Law)

74. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 73 above.

75. Section 706 of the Administrative Procedure Act authorizes courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

76. For reasons alleged in Count I, the *NHK-Fintiv* rule, as applied to PGRs, is arbitrary, capricious, and not in accordance with law because it violates the AIA and the Director exceeded his statutory authority in adopting it.

77. For reasons alleged in Count I, the *NHK-Fintiv* rule, as applied to PGRs, is also arbitrary, capricious, and not in accordance with law. Specifically, the Board did not adequately consider the differences between the IPR and PGR statutory schemes, and failed to adequately explain its reasoning for extending the *NHK-Fintiv* rule to PGR proceedings.

78. Additionally, the *NHK-Fintiv* rule is arbitrary, capricious, and an abuse of discretion because it requires the Board to engage in substantial speculation as to the likely course of the parallel district court proceeding and because its factors are vague and malleable. As a result, the rule produces irrational, unpredictable, and unfair outcomes, treating similarly situated PGR petitioners differently and depriving some patent infringement defendants of a speedy, efficient, and specialized forum for invalidating the patent at issue.

79. In PGR petitions filed by Plaintiffs, for instance, the Board denied institution even though neither Daiichi Sankyo nor AstraZeneca was a party to the district court litigation. The Board reasoned that the real parties in interest in the PGR proceedings were parties to the infringement litigation, *see* Ex. D at 19; Ex. E at 19, but that was incorrect. AstraZeneca UK Limited, the real-party-in-interest affiliated with petitioner AstraZeneca, was *not* a party to the district court litigation. Congress intended for parties like AstraZeneca to assist the PTO in

maintaining patent quality by filing prompt challenges to patents that should not have been issued in the first place. Denying institution on these facts contravenes congressional intent in devising the PGR regime.[2]

80. The *NHK-Fintiv* rule as extended to PGR proceedings is arbitrary, capricious, and an abuse of discretion because the Board did not adequately consider the differences between the IPR and PGR statutory schemes, and because the *NHK-Fintiv* rule will not achieve its stated purpose of promoting administrative efficiency.

COUNT III—ADMINISTRATIVE PROCEDURE ACT
(The *NHK-Fintiv* Rule Is Undertaken Without Observance of Procedure Required by Law)

81. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 80 above.

82. Section 706 of the Administrative Procedure Act authorizes courts to "hold unlawful and set aside agency action, findings, and conclusions" undertaken "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

83. The Director promulgated the *NHK-Fintiv* rule as a binding substantive rule without notice and comment in violation of the APA. Even if the *NHK-Fintiv* rule were not contrary to law, the Director could not adopt such a rule without notice-and-comment rulemaking. *See* 5 U.S.C. § 553; 35 U.S.C. §§ 2(b)(2), 326(a).

COUNT IV—ADMINISTRATIVE PROCEDURE ACT
(The *Arthrex* Rule Is Arbitrary and Capricious in Excess of Authority, and Not in Accordance with Law)

84. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 83 above.

[2] Since the Board's denial of institution, AstraZeneca has intervened in the district court litigation, but it was not a party at the time of that denial.

85. Section 706 of the Administrative Procedure Act authorizes courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

86. The *Arthrex* rule is a final agency action that 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 PGR institution.

87. As the Supreme Court held, the Board panels composed of APJs "lack[] the power under the Constitution" to issue final agency decisions for the PTO because the Appointments Clause required "an adequate opportunity for review by a principal officer." *Arthrex*, 141 S. Ct. at 1987-88. The Director, as the PTO's only principal officer within the meaning of the Appointments Clause must have the opportunity to decide whether to review and rehear the Board's decisions before they become the agency's final decisions.

88. The Board's decisions denying PGR institution represent the agency's final action with respect to those petitions. To the extent the *Arthrex* rule does not permit Director review of the Board's institution decisions, it is contrary to the binding Supreme Court precedent, and is therefore "not in accordance with law" and "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

89. In addition, by not providing Plaintiffs with the opportunity to seek Director review of the Board's decisions denying institution of their PGR petitions, the *Arthrex* rule subjected Plaintiffs to arbitrary and capricious treatment. 5 U.S.C. § 706(2)(A).

COUNT V—DECLARATORY JUDGMENT ACT
(Declaration of Plaintiffs' Rights)

90. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 89 above.

91. The Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, provides that, "[i]n a case of actual controversy within its jurisdiction," a federal court "may declare the rights and other legal relations of any interested party seeking such declaration."

92. Defendants' denial of their PGR petitions under the *NHK-Fintiv* rule and denial of their right to seek Director review of that denial under the *Arthrex* rule was unauthorized, in excess of authority, and unlawful.

93. Plaintiffs have been harmed, and continue to be harmed, by the *NHK-Fintiv* rule and the *Arthrex* rule.

94. For the foregoing reasons, an actual and justiciable case or controversy exists between Plaintiffs on one side and the PTO and the Director on the other.

95. Plaintiffs are entitled to judgment declaring that the *NHK-Fintiv* rule, as applied to PGRs, and the *Arthrex* rule, insofar as it prevents Director review of the Board's denials of institution, is void, invalid, and unenforceable.

PRAYER FOR RELIEF

Wherefore, Plaintiffs respectfully requests that this Court enter the following relief:

1. Declare, adjudge, and decree that the *NHK-Fintiv* rule is arbitrary, capricious, in excess of statutory authority, and contrary to law, and must be set aside;
2. Declare, adjudge, and decree that the *Arthrex* rule is arbitrary, capricious, in excess of statutory authority, and contrary to law, and must be set aside;
3. Permanently enjoin Defendants, and their officers, agents, employees, assigns, and all persons acting in concert or participating with them, from relying on the

NHK-Fintiv rule or the non-statutory factors it incorporates to deny institution of PGRs;

4. Order Defendants to provide for a process enabling Director review of the Board's decisions denying PGR institutions, including in PGR2021-00030 and PGR2021-00042;

5. Award Plaintiffs their costs and attorney's fees and expenses as allowed by law; and

6. Award such other relief as this Court deems just and proper.

Dated: August 5, 2021

Respectfully submitted,

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