

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SEAGEN INC.
Patent Owner.

Case No. PGR2021-00030
Patent 10,808,039

**PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW OF THE
FINAL WRITTEN DECISION (PAPER 57)**

Patent Owner Seagen Inc. (“Seagen”) respectfully requests director review of the Board’s Final Written Decision determining that U.S. Patent 10,808,039 (“the ’039 patent”) is eligible for PGR.

The ’039 patent claims priority to a parent application filed in 2004—nearly eight years before the effective date of the AIA—and *none* of the subsequent continuation applications in the family introduced new matter. Indeed, for this very reason, the Examiner assigned the ’039 patent pre-AIA status during prosecution, and determined that the claims were patentable based on the pre-AIA patent statute. The Panel’s finding that the ’039 patent nonetheless could be challenged in PGR—under post-AIA legal standards—invites inefficiency and wasteful proceedings. The Board’s Final Written Decision should be vacated, and the Petition should be dismissed. Director Review is particularly appropriate in this case because the Panel decision confirms an inconsistency within the Board in the determination of PGR eligibility for transition applications like the ’039 patent. This critical jurisdictional issue should be reviewed by the Director to ensure uniformity and predictability for patentees and patent challengers by clarifying that pre-AIA patents are not subject to PGR.

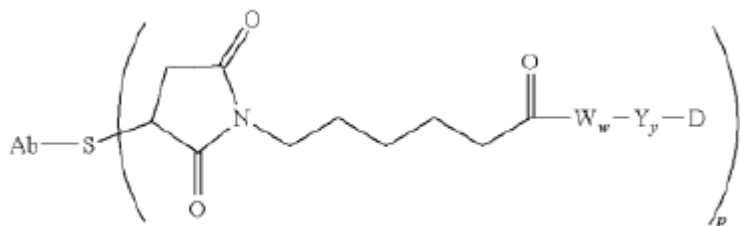
As a threshold matter, a patent is only eligible for PGR if the challenged claims do not have an effective filing date prior to the institution of the AIA. During prosecution, the ’039 patent was found to have priority to a pre-AIA application.

Moreover, the legislative history of the AIA confirms that patents like the '039 patent, which issued from a chain of applications that added no new matter after the AIA, were never meant to be subject to PGR. Yet, the Panel ruled differently, cancelling the challenged claims in a proceeding that it had never jurisdiction to hear. The Panel's failure to credit the Examiner's determination of pre-AIA status was legal error that merits vacatur and dismissal.

In addition, the Panel's decision frustrates important policy objectives. Under this Panel's analysis, the threshold jurisdictional inquiry and the ultimate merits of patentability rise and fall together, which, if allowed to stand, would result in PGR proceedings that end in a finding that the challenged claims were never eligible for PGR in the first place. This does not just invite waste, it guarantees it, and such a regime is not in keeping with Congress's intent. For these reasons, Seagen respectfully requests that the Director vacate the Final Written Decision.

I. BACKGROUND OF THE CASE

This case concerns antibody-drug conjugates, referred to as "ADCs." (*See* Final Written Decision at 4–5.) Claim 1 of the '039 patent is directed towards ADCs having the formula:



wherein “Ab is an antibody, S is sulfur, each —W_w— unit is a tetrapeptide” having a specified formula; “Y is a spacer unit, y is 0, 1, or 2, D is a drug moiety, and p ranges from 1 to about 2, wherein the S is a sulfur atom on a cysteine residue of the antibody, and wherein the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody-drug conjugate on an intracellular metabolite of the antibody-drug conjugate.” (*Id.* at 8–9 (quoting Ex. 1001, 331:35–66, 332:35–40).) The ’039 patent claims priority to seven substantively identical continuation applications, including non-provisional Application No. 10/983,340, filed November 5, 2004. (*See* Paper No. 29, “PO Response,” at 75–76; Final Written Decision at 20–21.)

Petitioners Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals, L.P. (collectively, “Petitioners”) challenged the claims on grounds of inadequate written description and enablement under § 112(a); for failing to set forth the subject matter of the invention under § 112(b); and for anticipation under § 102. On January 16, 2024, the Board issued its Final Decision, finding that Petitioners had demonstrated that Challenged Claims 1–5, 9 and 10 of the ’039 patent are unpatentable. (Final Written Decision at 29, 40, 79, 83.) The Board found that the ’039 patent was not entitled to the November 4, 2004 priority date of its oldest non-provisional parent application. (*Id.* at 14–29.)

Prior to institution, Seagen argued that the Board lacked jurisdiction because

the '039 patent was a pre-AIA application not subject to PGR. (Paper 7 at 64–69.) In its institution decision, the Board found that Petitioners were likely to demonstrate that the challenged claims “lack[] enablement in all of the applications from which they claim priority.” (Paper 17 at 10.) Post-institution, Seagen’s Response and Sur-Reply renewed and reiterated its argument that the '039 was not eligible for PGR. (see Paper 29 at 80–82, Paper 47 at 24.) Although the Board has recognized that a Patent Owner may raise jurisdictional challenges after PGR has been instituted, *Inguran, LLC v. Premium Genetics (UK) Ltd.*, No. PGR2015-00017, Paper 8 at 12, the Panel did not address PGR eligibility in its Final Written Decision.

II. LEGAL STANDARD

A. Director Review of Important Issues of Law or Policy and Erroneous Conclusions of Law Is Proper.

The Board’s Revised Interim Director Review Process permits Director Review of a final written decision when the request presents “(a) an abuse of discretion, (b) important issues of law or policy, (c) erroneous findings of material fact, or (d) erroneous conclusions of law.” Revised Interim Director Review Process (5)(A)-(A)(ii)(c)(1).¹ If Director Review is granted, the panel’s errors will be reviewed de novo by the Director, or a Delegated Rehearing Panel. *Id.* at (5)(A)(iii).

¹ <https://www.uspto.gov/patents/ptab/decisions/revised-interim-director-review-process>.

B. Pre-AIA Applications Are Not Eligible for PGR.

The AIA was enacted on September 16, 2011 and by its express language applies to patents and patent applications having at least one claim with an effective filing date after March 16, 2013. AIA § 3(n)(1). That is, as the statute sets forth, and as the Board has repeatedly recognized, the AIA authorizes PGR only for post-AIA patents. *See, e.g., Rockwool Int'l A/S v. Knauf Insulation, Inc.*, No. PGR2022-00022, Paper 10 at 4–5 (P.T.A.B. July 6, 2022); *SweeGen Inc. v. PureCircle USA Inc.*, No. PGR2020-00070, Paper 14 at 8–10 (P.T.A.B. Jan. 19, 2021).

III. ARGUMENT

Director Review should be granted because the Board reached an erroneous conclusion of law in failing to consider the Examiner's determination during prosecution that the '039 patent is a pre-AIA patent ineligible for post-grant review, and because this Request presents important issues of law or policy. The Board's Final Written Decision ensures a split among panels of the Patent Trial and Appeal Board on this threshold jurisdictional question, and Director Review is needed to resolve it. Specifically, the Director should find that transition applications like the '039 patent are not PGR-eligible, as the Board's determination conflicts both with the legislative history of the AIA and runs contrary to its public policy objectives. To ensure predictability and efficiency, and eliminate wasteful proceedings, the Director should clarify that patent applications that claim priority to pre-AIA

applications and that were examined under the pre-AIA patent statute are not eligible for PGR, as Congress expressly intended. Moreover, the Panel’s failure to address Seagen’s arguments concerning jurisdiction in its Final Written Decision (*see* PO Response at 81–82) further merits dismissal, or, at the least, remand.

A. Transition Applications Are Only Eligible for PGR If They Do Not Claim Priority to a Pre-AIA Application.

To meet its burden to show that a challenged patent is eligible for post-grant review, a petitioner “has the burden to show that the patent is subject to the first-inventor-to-file provisions of the AIA.” *US Endodontics, LLC v. Gold Standard Instruments, LLC*, No. PGR2015-00019, Paper 17 at 11–12 (P.T.A.B. Jan. 29, 2016); *Inguran*, No. PGR2015-00017, Paper 8 at 8 (“[T]he petitioner bears the burden of setting forth grounds for standing for post-grant review.”); 37 C.F.R. § 42.204(a) (petitioner must “certify that the patent for which review is sought is available for post-grant review”).

If an application is filed after March 16, 2013, and claims the benefit of an application filed prior to March 16, 2013, the application is considered to be a “transition application” for purposes of the AIA. *See* MPEP § 210; AIA § 3(n)(1). The patent that results from such an application is eligible for PGR only if the effective filing date for the patent claims is after March 16, 2013. *See* AIA § 3(n)(1); *see also Merck Sharp & Dohme Corp. v. Wyeth LLC*, No. PGR2017-00016 and No. PGR2017-00017, Paper 9 at 6–7 (P.T.A.B. Oct. 20, 2017). And, as a matter of law,

a patent claim is entitled to an effective filing date of an earlier application “so long as the disclosure in the earlier application meets the requirements of 35 U.S.C. § 112, ¶ 1, including the written description requirement, with respect to that claim.” *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326 (Fed. Cir. 2008).

The '039 patent issued from a series of seven substantively identical continuation applications, the first of which was filed on November 5, 2004. (PO Response at 75–76, 80–82.) None of the applications filed after March 16, 2013, including the one that resulted in the '039 patent, U.S. Pat. App. No. 16/507,839, introduced any new matter not already present in the pre-AIA applications. Thus, the '039 patent cannot rely on any post-AIA matter for written description support. Recognizing this, the Examiner assigned the application pre-AIA status, and determined it was patentable—including determining that the claims were supported and enabled by the written description as required by 35 U.S.C. § 112—under pre-AIA law. (PO Response at 80–81.)

Given these facts, the '039 patent, which was examined and issued under pre-AIA law, does not fall under the first-to-file rules of the AIA, and is not eligible for PGR. The Panel erred by finding otherwise.

B. The Panel’s Failure to Consider the Examiner’s Determination Was Contrary to Law, and Creates Inconsistency Within the Board.

The prosecution history here confirms that the '039 patent issued from a pre-AIA application and thus is not eligible for PGR. Specifically, the Examiner

reviewed the application that issued as the '039 patent under the pre-AIA first-to-invent provisions, by (1) indicating “No” in the AIA status box of all Office Actions; (2) providing a “Notice of Pre-AIA or AIA Status” indicating that the “application is being examined under the Pre-AIA first to invent provisions”; and (3) applying pre-AIA versions of the patent statute during prosecution. (PO Response at 80–81.) This was consistent with the Manual of Patent Examining Procedure, which states that a transition applicant need not provide a post-AIA statement if “[t]he nonprovisional application discloses *only subject matter also disclosed* in a priority or domestic benefit application filed prior to March 16, 2013.” (M.P.E.P. § 210(III)(A) (emphasis added).)

As prior Board decisions have recognized, an Examiner’s determination of eligibility during prosecution is relevant to a determination of eligibility for PGR. *See Mylan Pharms. Inc. v. Yeda Rsch. & Dev. Co.*, No. PGR2016-00010, Paper 9 at 6–7 (P.T.A.B. Aug. 15, 2016); *Merck*, No. PGR2017-00016 and No. PGR2017-00017, Paper 9 at 14–15. *Mylan* is particularly instructive: there, the Board deferred to the Examiner’s analysis of the challenged patent under the pre-AIA first-to-invent framework, refusing to even reach the Petitioner’s challenge that the challenged patent did not properly claim priority to a pre-AIA application.

Specifically, the *Mylan* Panel “agree[d] with Patent Owner that the issue of whether the [challenged] patent is a first-inventor-to-file patent,” and thus ineligible

for PGR, “*was addressed by the Examiner during prosecution*, as stated in” its notice that “[t]he present application is being Examiner [sic] under the pre-AIA first to invent provisions.” PGR2016-00010, Paper 9 at 7 (emphasis added). Likewise, in *Merck*, the Board noted that the challenged patent “was assigned pre-AIA status and examined under pre-AIA first-to-invent provisions,” and recognized that the “Examiner’s acknowledgment during prosecution that a patent application is entitled to a pre-AIA priority date may be a factor supporting a finding that the patent is ineligible for post grant review.” PGR2017-00017, Paper 9 at 14–15.² Ignoring this persuasive authority, which Seagen raised below (PO Response at 80–81), the Board failed to address, much less credit, the Examiner’s finding that the ’039 is a pre-AIA application ineligible for PGR.

Patent Owner is aware of other proceedings that have reached a conflicting outcome: in *Inguran* (which preceded both *Merck* and *Mylan*), the panel instituted PGR notwithstanding the challenged patent’s claim of priority to a pre-AIA application. See PGR2015-00017, Paper 8 at 11–12. Similarly, in *Collegium Pharm., Inc. v. Purdue Pharm. L.P.*, the panel cited *Merck* and *Mylan* and “recognize[d] that pre-AIA status designations during prosecution may be considered,” but held that such determinations are “not conclusive” to PGR

² The *Merck* panel declined to reach the argument raised here: that “only patents that claim ‘new’ subject matter, added by amendment on or after March 16, 2013, are eligible for post grant review.” PGR2017-00017, Paper 9 at 15.

eligibility. PGR2018-00048, Paper 18, at 11-12.

The need for a single standard to be applied by all panels of the Board—including the weight to be given to an Examiner’s determination of pre-AIA status—presents a compelling basis for Director Review. Absent direction from the Director, inconsistent determinations of the threshold question of justiciability are guaranteed to continue. The Director should take this opportunity to affirm that the analysis in the *Merck* and *Mylan* decisions is authoritative—and that patents examined under the pre-AIA framework should not be found eligible for PGR.

The Panel’s contrary approach in this case and in *Inguran* and *Collegium* frustrates the efficient prosecution of patents. It adds considerable unpredictability if patentees can no longer rely on the finding of the U.S. Patent and Trademark Office during prosecution that patent claims are subject to the pre-AIA first-to-invent provisions, only to have an entirely different legal standard applied to those same claims years later in PGR. Effectively, the Panel’s determination here requires patentees like Seagen to satisfy *both* the pre- and post-AIA standards for patenting in order to secure and maintain their patents, an unfair and heightened burden that was never contemplated by Congress. The Director should vacate the Panel’s Final Written Decision and resolve this split among panels.

C. Confirming the *Mylan* and *Merck* Approach Is Consistent With the Legislative History of the AIA.

The legislative record of the AIA further confirms that any dispute about

whether transition applications are eligible for PGR should be resolved in favor of the Patent Owner. The AIA was enacted to “establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs.” 157 CONG. REC. S1361 (daily ed. Mar. 8, 2011) (Ex. 2035). Consistent with that goal, the legislative history of the AIA specifies that “continuations of first-to-invent [pre-AIA] applications *that do not introduce new matter* will remain subject to first-to-invent [pre-AIA] rules.” *See id.* at S1373 (emphasis added). The applicant was allowed to either “choose to pull the whole invention into the first-to-file universe by including the new disclosure in a continuation of his pending first-to-invent application, or he can choose to keep the pending application in the first-to-file world by filing the new disclosure as a separate invention.” *Id.*

The inventors of the '039 patent added no new matter to their pre-AIA applications when filing each continuation in the family that ultimately issued the '039 patent. In so doing, they understood and expected that they would keep their invention within the first-to-invent “universe,” *see id.*, including insulation from PGR. The Director should grant Review, and issue guidance consistent with Congress’s clear intent to ensure that pre-AIA patents like the '039 patent are not “pull[ed] ... into the first-to-file universe.” *Id.*

D. The Panel's Determination Guarantees Inefficiency and Waste, and Unduly Burdens the Patent System.

The AIA was intended to provide “increased predictability, certainty, and transparency.” (PO Response at 81–82 (citing 157 CONG. REC. S1179 (daily ed. Mar. 3, 2011).) Beyond that, Congress sought through the AIA to “limit unnecessary and counterproductive litigation costs.” H.R. Rep. 112-98 at 40 (June 1, 2011). The Panel’s Final Written Decision frustrates these important policy considerations. Importantly, in cases like this one, the threshold question of PGR eligibility is part and parcel with an ultimate determination on the merits: where the written description in the priority application is identical to the written description of the challenged patent (because no new matter was added after the AIA’s effective date), questions of PGR eligibility and patentability under § 112 rise and fall together. *See, e.g., Team Worldwide Corp. v. Intex Recreation Corp.*, No. 2020-1975, 2021 WL 4130634, at *4 (Fed. Cir. Sept. 9, 2021) (treating “the issue of eligibility for post-grant review as rising or falling with the § 112(b) issues”).

In such cases, if PGR is instituted, the parties (and the Board) may incur significant time and energy only to reach a Final Written Decision in which the challenged claims are deemed ineligible for PGR *ab initio*. Moreover, those same parties may all the while be conducting district court litigation in which it is unclear which defenses, if any, will be estopped based on the outcome of the concurrent

PGR proceedings. Patentees thus face a no-win situation in cases like this: if the Final Written Decision finds the challenged patent eligible for PGR, then its claims will inevitably be cancelled. However, if the Final Written Decision finds the challenged patent *ineligible* for PGR as having priority to a pre-AIA application, then the Petition should never have been instituted in the first place. This posture incentivizes petitioners to file improper PGR petitions against pre-AIA patents, challenging priority through the vehicle of a written description argument, because if instituted, the § 112 issues—unavailable in IPR against the patent—would not be resolved until the Final Written Decision. Such ambiguity, unpredictability, and inefficiency is not what Congress intended, and is not in keeping with the legislative history of the AIA.

This very situation arose in *Inguran*, where the patentee disputed that the challenged transition patent was eligible for PGR, based in part on the Examiner’s determination of pre-AIA status. PGR2015-0017, Paper 8 at 11-12. Rather than addressing the fundamental unfairness of forcing a patent that issued from a pre-AIA application into post-AIA PGR proceedings, however, the Board punted on the issue, observing that “standing issues may still be raised during trial” or in the patent owner response. *Id.* (quotation omitted). But that does not solve the problem—and notably, as here, the *Inguran* panel issued a Final Written Decision finding the challenged claims unpatentable without again addressing the threshold jurisdictional

question. PGR2015-0017, Paper 22.

Similarly, in *Collegium*, the Panel acknowledged that the Board may consider an Examiner's finding of pre-AIA status in determining whether a challenged patent is eligible for PGR, but held that such a finding was neither "conclusive" nor "dispositive." PGR2018-00048, Paper 18, at 11-12. Such a standard only invites further confusion as to the appropriate level of deference that should be afforded to the Examiner's finding, and perpetuates the risk of costly, resource-intensive battles over patents that will only later be deemed ineligible for PGR.

In short, even if patentees *can* raise standing issues after institution, they should not be *required* to do so, especially where the jurisdictional and merits issues are inseparable. That concern is particularly apparent in cases like this proceeding, where Seagen raised an eligibility challenge after PGR was instituted, but the Board failed to address it in the Final Written Decision, depriving Seagen its opportunity to be heard on the issue.

IV. CONCLUSION

For the reasons described above, Seagen respectfully requests that the Director grant Review, vacate the Final Written Decision, and find that the '039 patent is not eligible for post-grant review.

Dated: February 14, 2024

Respectfully submitted,

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Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached PATENT OWNER'S REQUEST FOR REHEARING BY THE DIRECTOR OF THE FINAL WRITTEN DECISION was served as of the below date via email on the Petitioner at the following correspondence address:

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