UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME LLC,
Petitioner

v.

THE JOHNS HOPKINS UNIVERSITY,
Patent Owner

Case IPR2024-00240
Patent 11,591,393 B2

PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW

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I. INTRODUCTION

The AIA contains a declaratory judgment (DJ) loophole that allows petitioners like Merck to take multiple bites at the invalidity apple. The DJ loophole has been used by petitioners to force patent owners like Johns Hopkins University (JHU) to defend their patents in both district court and the PTAB. Indeed, pundits have ***encouraged*** petitioners to use this loophole to litigate validity in district court while keeping ***intact*** their ability to challenge patentability at the PTAB. Regarding the loophole, one court observed that a petitioner could fully litigate validity of a patent in the district court, lose, and then seek a do-over at the PTAB "while being subject to no estoppel or time limit whatsoever."[1] The DJ loophole violates the spirit, if not the letter, of the AIA and undermines Congress's intent to provide the PTAB as an ***alternative*** forum to district courts.

The DJ loophole works as follows. *First*, a petitioner files a civil action in district court requesting a declaratory judgment of non-infringement, ***but not invalidity***, of a patent. Alleging only non-infringement avoids the estoppel limitation of 35 U.S.C. §315(a)(1), which prohibits institution of an *inter partes* review after the petitioner (or real party in interest) files a civil action challenging the validity of a claim of the patent. *Second*, after the patent owner answers the complaint and

[1] *Epic Games, Inc. v. Acceleration Bay LLC*, No. 4:19-cv-04133-YGR, 2020 WL 1557436, at *3 (N.D. Cal. Apr. 1, 2020).

counterclaims for infringement of the patent—a compulsory counterclaim ***required*** under Federal Rule of Civil Procedure 13—the petitioner files a counterclaim-in-reply of ***invalidity*** in the district court. *Third*, after the case is underway in the district court, the petitioner strategically times filing a petition challenging the patent at the PTAB. The petitioner is not estopped under §315(a)(1), and the patent owner—like JHU here—is left to defend its patent in multiple forums.

The facts of this case provide the Director a perfect vehicle to prevent exploitation of the DJ loophole. The patent-at-issue here, the '393 Patent, is the first of nine JHU patents that Merck challenged in both district court (via a declaratory judgment action) and the PTAB (via multiple petitions).[2] JHU's patents teach a method of treating cancer patients using pembrolizumab, a PD-1 checkpoint inhibitor that Merck markets under the brand-name Keytruda®. JHU unexpectedly found that pembrolizumab could be used to successfully treat a cancer tumor ***when*** and ***because*** that tumor has a particular genetic biomarker: microsatellite instability (MSI-H). JHU's breakthrough was hailed by the scientific community—including ***FDA*** and ***Merck itself***—as a paradigm shift in cancer therapy. With JHU's help, Merck obtained the first ever FDA approval for a tumor-agnostic cancer treatment: a treatment performed ***in response to*** the presence of a genetic biomarker, not the type of tissue where the cancer is found.

[2] IPR2024-00240, -622, -623, -624, -625, -647, -648, -649, and -650.

When JHU sought patents on its methods of treatment and the first of those applications published, Merck reached out to JHU to initiate licensing negotiations. Merck ultimately declined a license at that time. When the first patent later issued, JHU reached out to Merck and, after multiple discussions with JHU, Merck again declined a license. Instead, to gain leverage, Merck exploited the DJ loophole. In 2022—***five years*** after it first learned of JHU's patent applications and over a year and a half after the first patent issued—Merck filed a DJ action alleging ***non-infringement*** of JHU's patents. Merck purposefully omitted any claim of ***invalidity*** in its DJ action to avoid estoppel under §315(a)(1).

Then, Merck waited for nine months until the window for filing a PGR petition closed and the district court proceedings were well underway. ***Two days*** after the nine-month PGR window closed, Merck filed an IPR challenging the claims of the '393 Patent. By filing an IPR rather than a PGR, Merck not only avoided estoppel under §315(a)(1), but also the broad estoppel inherent in PGR challenges under 35 U.S.C. §325(e)(2). But Merck was not done. Merck then waited four more months—until just before JHU's POPR was due—to file IPR petitions on JHU's ***eight*** other patents, seven of which were PGR-eligible well after Merck filed its DJ action. Indeed, the PGR window for the last patent expired less than a month before Merck's *en masse* IPR filings. Unsurprisingly, Merck did ***not*** file any *Sotera* stipulations with its petitions for IPR—ensuring duplication of efforts between the

parties, the PTAB, and the district court. Merck's actions during this time—forcing JHU to litigate in two forums—led to ***over 4,000 attorney hours***, equating to millions of dollars, expended on behalf of JHU in district court alone.

To add insult to injury, Merck's Petitions asserted anticipation by the same clinical study announcement (the MSI-H Study Record or "MSR") that JHU overcame during prosecution of the '393 Patent's parent application. JHU had amended its claims during prosecution to recite that treatment occurred ***in response to*** determining a patient's tumor is MSI-H positive. The Examiner allowed the claims because the prior art did not "treat the patient ***based on*** a determination of" MSI-H. POPR, 36-37.

But the Board instituted each of Merck's Petitions and, in the Final Written Decision for the '393 Patent, the Board determined that all claims were unpatentable over the MSR, regardless of the "in response to" limitation. JHU has no reason to believe that the Board will decide differently for JHU's remaining patents. In fact, the Board gave JHU only ***eleven minutes*** per patent to defend itself during oral hearings.[3] Recognizing this inherent unfairness, JHU requested that the Board cancel the upcoming hearings.

The Director should prevent the gamesmanship Merck exhibited here by

[3] *See, e.g.*, IPR2024-00622, Paper 56 (allotting JHU 45 minutes for four patents); IPR2024-00647, Paper 47 (same).

rectifying Merck's exploitation of the DJ loophole and failure to file PGRs even though it had notice and opportunity to do so. Although Merck's playbook does not run afoul of the AIA's literal language, it "cannot be reconciled with the clear congressional intent that the IPR serve as a 'substitute' for district court litigation[.]" *Epic Games*, 2020 WL 1557436, at *3. JHU respectfully requests the Director grant Director Review, vacate the Final Written Decision in IPR2024-00240, and terminate all nine proceedings.

II. STANDARD FOR REVIEW

The Director "may review final PTAB decisions and…issue decisions…on behalf of the Board." *United States v. Arthrex, Inc.*, 594 U.S. 1, 25 (2021). Requests for Director Review of a Board's Final Written Decision are limited to decisions presenting (a) an abuse of discretion, (b) important issues of law or policy, (c) erroneous findings of material fact, or (d) erroneous conclusions of law.

III. ARGUMENT

This case presents an important issue of policy. One of Congress's goals in implementing the AIA was to provide post-grant proceedings as a faster and less expensive ***alternative*** to district court proceedings. But the DJ loophole frustrates this goal by allowing a petitioner to initiate a civil action concerning a patent in district court, but also later file a petition seeking IPR. Merck's playbook is especially egregious here because, in addition to exploiting the DJ loophole, Merck

also ensured its ability to continue challenging the validity of JHU's patents in district court by strategically filing IPRs instead of PGRs, and by not filing *Sotera* stipulations in the PTAB.

A. Merck's Playbook Frustrates Congress's Intent for IPRs to be an Alternative to District Court Litigation

Congress intended for AIA proceedings to be "quick and cost effective alternatives to litigation." H.R. Rep. No. 112-98, pt. 1, at 48 (2011). But Congress also recognized "the importance of quiet title to patent owners to ensure continued investment resources." *Id.* In an attempt to balance these concerns, Congress devised twin provisions forcing a patent challenger to choose between forums: ***either*** district court (by filing a DJ civil action) ***or*** the PTAB (by filing a petition within one year of being served with a complaint alleging infringement). These twin provisions were designed to "prevent an accused infringer from using the IPR mechanism as a 'second bite at the apple' after challenging the validity of a patent in a district court." *Epic Games*, 2020 WL 1557436, at *1.[4] Under §315(a)(1), a petitioner (or real party in interest) that files a civil action challenging the validity of a patent claim is barred from later challenging that claim at the PTAB. And, under §315(b), a petitioner served with a complaint alleging infringement is barred from filing a petition more than one year later.

[4] Section 315(a)(2) also requires a stay of a civil action if the petitioner files a civil action on or after the date it files a petition for IPR.

As the *Epic Games* court recognized, however, these provisions do not address counterclaims-in-reply—like those Merck filed in district court in reply to JHU's compulsory counterclaim of infringement. *Id.* In *Epic Games*, patent owner asked the district court to strike the DJ plaintiff's counterclaim in reply as "an end-run around rules governing availability of *inter partes* review." *Id.* The court was sympathetic to patent owner's plight, but nonetheless denied the motion to strike as futile. *Id.*, at *4. In doing so, however, the court "recognize[d] the apparent loophole left by the statutory scheme governing IPR availability." *Id.*, at *3. "Unlike a patent infringement defendant (which cannot bring an IPR more than one year after being sued) or a declaratory judgment plaintiff seeking a judgment of invalidity (which cannot seek an IPR at all)," the court explained, "a declaratory judgment counterclaimant faces no apparent restrictions on seeking an IPR." *Id.*

Since the *Epic Games* decision, commentators have lauded the DJ loophole as a way for an infringer to "conceivably have its cake and eat it too when it comes to an invalidity challenge." Merlott, COURT ALLOWS ACCUSED INFRINGER'S HAVE-CAKE, EAT-CAKE PATENT INVALIDITY STRATEGY (Apr. 16, 2020)[5]; *see also* Weil, DUE TO "APPARENT LOOPHOLE" IN STATUTORY FRAMEWORK, DISTRICT COURT PERMITS INVALIDITY CHALLENGE THAT DOES NOT FORECLOSE LATER IPR (Apr. 15,

[5] Available at https://www.ptablitigationblog.com/court-allows-accused-infringers-have-cake-eat-cake-patent-invalidity-strategy.

2020)[6] ("Practice Tip: Potential infringers who wish to litigate validity in district court—while keeping intact their ability to challenge patentability at the PTAB—should consider seeking first a declaratory judgment of non-infringement.").

Panels of the Board have similarly declined to prevent petitioners from benefitting from both the district court and the PTAB. In one example, a panel held that counterclaims-in-reply are not subject to the bar under §315(a)(1) because they are not "civil actions" challenging validity. *See Canfield Scientific, Inc. v. Melanoscan, LLC*, IPR2017-02125, Paper 15 at 3-7 (PTAB Mar. 30, 2018). While acknowledging that policy arguments for treating counterclaims-in-reply as civil actions "have some merit," the panel determined that policy considerations could not override the statute's plain language. *Id.* at 7; *see also Ariosa Diagnostics v. Isis Innovation Ltd.*, IPR2012-00022, Paper 20 at 7 (PTAB Feb. 12, 2013) (holding "[a] civil action for a declaratory judgment of non-infringement is not a civil action challenging the validity of a patent" and does not bar petitioner from seeking IPR).

But the Director has not been so constrained.

B. The Director Should Prevent Exploitation of the DJ Loophole

Unlike panels of the Board, the Director may rectify the gamesmanship that Merck exhibited here by preventing exploitation of the DJ loophole and encouraging

[6] Available at https://www.akingump.com/en/insights/blogs/ip-newsflash/due-to-apparent-loophole-in-statutory-framework-district-court-permits-invalidity-challenge-that-does-not-foreclose-later-ipr.

early filing of PGRs. The AIA created IPR as a "review process [that] allows a third party to ask the U.S. Patent and Trademark Office to reexamine the claims in an already-issued patent and to cancel any claim that the agency finds to be unpatentable in light of prior art." *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 265 (2016). But the AIA contains "no mandate to institute review[.]" *Id.* at 273. Rather, the Supreme Court has stated that the Director has broad, "unreviewable discretion" to deny a petition for IPR even where a petition otherwise satisfies the institution standard under 35 U.S.C. §314(a). *Arthrex*, 594 U.S. at 8-9; *see also Apple Inc. v. Vidal*, 63 F.4th 1, 8 (Fed. Cir. 2023) (noting that Congress "recognized the likelihood of parallel pending proceedings in the PTO and in the courts," but left up to the Director how "to address such an overlapping pending court case in exercising the discretion whether to institute an IPR").

Historically, the Director delegated her discretionary authority to deny institution to the Board. 37 C.F.R. § 42.4(a). But today, the Director issues decisions on discretion herself, in consultation with at least three PTAB judges. INTERIM PROCESS FOR PTAB WORKLOAD MANAGEMENT (Mar. 26, 2025). Regardless of whether her discretion authority is delegated or not, the Director retains ultimate authority over institution, and "any institution decision made by the Board as delegatee of the Director is subject to reversal by the Director." *Apple*, 63 F.4th at 7.

By statute, the Director provides guidance about how she will apply her

discretion because she is "responsible for providing policy direction and management supervision for the Office." 35 U.S.C. §3(a)(2); *see also Apple*, 63 F.4th at 13 (holding that the Director has ultimate "political responsibility of determining which cases should proceed" (quotation omitted)). The Federal Circuit has further explained that policy guidance from the Director "is crucial for ensuring that [institution] determinations will overwhelmingly be made in accordance with the policy choices about institution [the Director] would follow if she were making the determinations herself." *Id.*

The Director should rectify Merck's exploitation of the DJ loophole and failure to file PGRs by vacating the Final Written Decision and terminating these cases. There are ample reasons for the Director to do so here, including judicial economy, the integrity of the patent system, and basic fairness. Merck chose to sue JHU, not the other way around. Merck strategically manipulated the process to challenge JHU's claims in both district court and the PTAB. And Merck caused JHU to incur over 4,000 attorney hours in district court, including fully briefing claim construction, and still more hours to defend itself at the PTAB.

Rectifying Merck's gamesmanship would also maintain consistency with Congress's intent to prevent duplication, streamline the process of challenging patent validity, and reduce costs. The language of §315(a)(3) does not counsel otherwise. Section 315(a)(3) seeks to protect the IPR rights of an accused infringer

sued for infringement in a venue it did not choose. In the case of the DJ loophole, however, it is the petitioner (***not*** the patent owner) who chooses the venue by commencing the "civil action." Accordingly, only a patent challenger who files a civil action ***on the same day or after*** it files a petition for IPR should be "presumptively entitled to his choice of venue" under §315(a)(2). 157 Cong. Rec. S5429 (daily ed Sept. 8, 2011); *see also id.* (stating, "The final bill will still bar seeking IPR or PGR after a declaratory-judgment action has been filed, but will allow a declaratory-judgment action to be filed on the same day or after the petition for IPR or PGR was filed."). Otherwise, the petitioner can have its cake (ability to choose venue) and eat it too (ability to file a petition for IPR ***after*** it challenges validity of the patent claims).

C. Merck's Gamesmanship Justifies Vacating the Final Written Decision and Terminating All Proceedings Between Merck and JHU

Merck chose to sue JHU in district court and should be held to that choice. Merck has undoubtedly exploited the DJ loophole, including by taking inconsistent positions before the PTAB and district court, and by making material misrepresentations to stymie JHU's efforts to obtain discovery on commercial success. "[T]he Office may consider unfair dealings as a factor when determining whether to exercise discretion to deny institution," *Tessell, Inc. v. Nutanix, Inc.*, IPR2025-00322, Paper 14 at 2 (Stewart June 12, 2025), and should do so here.

1. After Multiple Rounds of Licensing Negotiations Over Five Years, Merck Chose District Court

JHU—not Merck—came up with and tested the hypothesis that MSI-H might be a tissue-agnostic biomarker for pembrolizumab (Keytruda®). While Merck provided its drug, it otherwise initially declined to fund JHU's clinical trial. After JHU's trial succeeded, Merck—with JHU's help and using JHU's clinical trial data—secured FDA approval for a tissue-agnostic indication for Keytruda® in 2017. Merck approached JHU about licensing JHU's pending patent applications, including the parent of the '393 Patent.[7] Answer, ¶¶125-29. Discussions continued in 2019 and 2020. *Id*., ¶¶141-43. After the parent patent issued in 2021, negotiations resumed, and JHU provided a proposed license at Merck's request. *Id*., ¶¶144-47. In June 2021, Merck notified JHU it would not take a license. *Id*., ¶¶148-49.

Then, over a year later, Merck exploited the DJ loophole. Merck filed a DJ action alleging non-infringement (but not invalidity) of four JHU patents. *Id.*, ¶129; Complaint[8], ¶¶55-77. Only after JHU counterclaimed for infringement of all nine patents presently before the Board did Merck file its counterclaims in reply alleging invalidity.[9] *Id.*, Merck Answer and Counterclaims, ¶¶7-52. Merck not only alleged

[7] *Merck Sharp & Dohme LLC v. The Johns Hopkins University*, No. 1-22-cv-03059-JRR, D.I. 40 (D. Md. May 22, 2023) ("Answer").
[8] *Merck*, No. 1-22-cv-03059-JRR, D.I. 1 (D. Md. Nov. 29, 2022) ("Complaint").
[9] *Merck*, No. 1-22-cv-03059-JRR, D.I. 46 (D. Md. June 22, 2023) ("Merck Answer and Counterclaims").

anticipation and obviousness based on the same art as here (mainly, the MSR), but also invalidity under §§101 and 112. POPR, 64-65 (citing EX2031). Merck then dragged its feet throughout discovery—resisting document production and delaying scheduling depositions—in a clear effort to ameliorate *Fintiv* concerns at the PTAB, increase litigation costs, and support its subsequent district-court stay request.[10]

2. Merck's Continued Its Gamesmanship by Filing IPRs Rather Than PGRs

The '393 Patent issued on February 28, 2023. Merck waited until November 30, 2023—just ***two days*** after the 9-month window to file a PGR closed—to file an IPR Petition. This decision was intentional. *See* Paper 8, 1 n.1 (Merck admitting it did not file IPRs sooner because "some [of the nine patents] were not even IPR eligible until 2024"). Merck sought to minimize the estoppel impact of the IPRs and maximize inefficiency of litigating in two forums by refusing to file *Sotera* stipulations. POPR, 60. So even if Merck were eventually estopped under §315(e)(2), it would not be estopped from maintaining its invalidity arguments under §§101 and 112.

Next, Merck waited again—this time waiting over three months to file petitions challenging the ***other eight patents*** asserted in district court, filing four of them the day before JHU's POPR was due, and one month after the last PGR

[10] *See Merck*, No. 1-22-cv-03059-JRR, D.I. 126 (D. Md. June 29, 2024) ("Stay Order") at 5.

deadline. Once the Board instituted the first IPR, Merck ran to the district court and requested a stay. While granting the stay, even the district court acknowledged Merck's gamesmanship, noting that "the court appreciates JHU's irritation about what it views as unsportsmanlike conduct (to put it mildly)." Stay Order, 5.

Meanwhile, in the IPR, when JHU sought discovery of Merck's IQVIA sales data by cancer type to support its commercial success analysis, Merck falsely and repeatedly represented it had no such data, including on a conference call with the Board. *See* POR, 88-89 n. 12; Paper 30, 1 (Merck alleging JHU requests "documents that JHU knows Merck does not have"), 5 ("Merck does not possess the discovery sought…Merck does not obtain such documents from third-parties"). Merck had made that same representation in district court.[11] *Id*., 1 (Merck alleging JHU's request "reveals that its motion is a litigation tactic designed to…harass Merck with essentially the same failed dispute that JHU raised" in district court); *see also* Paper 32, 6 ("[I]t appears that JHU attempted to obtain these same documents from Merck in the related litigation…and the shift by Merck to this forum may have contributed to the delay in resolution of this issue."). Tellingly, less than 24 hours after the Board ordered Merck to either produce the data or "produce a sworn affidavit prepared by a Merck executive-level employee" to attest to the lack of the data, (Paper 32, 9),

[11] *See Merck*, No. 1-22-cv-03059-JRR, D.I. 111 (D. Md. June 11, 2024) ("Merck is not currently aware of the existence of any sales data from a third-party, such as IQVIA, that reports Keytruda® sales by indication/cancer type.").

Merck conceded "[t]hat data is IQVIA claims data," was in Merck's possession (as it had been all along) and would produce it, POR, 88-89 n.12. Deterring such conduct before the district court and the PTAB is yet another reason to eliminate the DJ loophole.

Merck also took inconsistent positions before the district court and PTAB on the key claim term "in response to." POR, 9-10. In district court, Merck agreed that "in response to" required a causal relationship between "determining" a patient was MSI-H and "treating" that patient with Keytruda® and proposed the narrow construction "as the reaction ***specifically to***." *Id*. (citing EX2160, 24) (emphasis added). Before the PTAB, however, Merck argued that same construction amounted to a "particularly improper" "attempt to insert [a] negative limitation[.]" Reply, 9. Merck's exploitation of these contradictory positions—on one hand to avoid infringement and the other to undermine validity—further supports vacating the FWD. *See Cambridge Mobile Telematics, Inc. v. Sfara Inc.*, IPR2024-00952, Paper 12 at 6-9 (PTAB Dec. 13, 2024) (informative) (denying institution where petitioner failed to explain its differing claim construction positions).

IV. CONCLUSION AND RELIEF REQUESTED

JHU respectfully requests that the Director grant Director Review, vacate the Board's Final Written Decision, dismiss the Petition, and terminate all proceedings between Merck and JHU.

Respectfully submitted,

Date: June 26, 2025

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR § 42.6(e)(4), the undersigned certifies that on June 26, 2025, a complete and entire copy of this Patent Owners Request for Director Review was provided via email to the Petitioner by serving the correspondence address of record as follows:

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