

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**
(Northern Division)

MERCK SHARP & DOHME LLC,

Plaintiff,

v.

THE JOHNS HOPKINS UNIVERSITY,

Defendant.

Civil Action No. JRR-22-3059

**PLAINTIFF MERCK SHARP & DOHME LLC'S
MEMORANDUM IN SUPPORT OF ITS MOTION TO STAY
PENDING THE U.S. PATENT OFFICE'S *INTER PARTES* REVIEW PROCEEDING**

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I. INTRODUCTION

The U.S. Patent Office just issued a decision that warrants an immediate stay of all deadlines and proceedings in this District Court action. Specifically, on June 13, 2024, a specialized tribunal within the U.S. Patent Office entrusted to review whether patents should have been granted—the Patent Trial and Appeal Board (“PTAB”)—publicly docketed its decision instituting *inter partes* review (“IPR”) of Defendant JHU’s ’393 patent, a core patent at issue in this action.¹ The remaining patents involved in this action are also subject to IPR petitions for review. The PTAB issued its decision based on competing presentations of evidence by the Parties. After careful review of the JHU patent and the prior art, the PTAB found that the evidence of record showed that “the Examiner erred,” and that there was “compelling evidence of unpatentability,” implicating “the interest of efficiency and integrity in the overall patent system.”²

The IPR will consist of depositions, further briefing, and an oral hearing before the expert judges of the PTAB, all of which are scheduled to take place and be completed within the next 12 months.³ The PTAB’s final determination as to whether to cancel JHU’s patent will be made by its statutory deadline of June 13, 2025.⁴ As such, the PTAB’s institution decision materially changes the litigation landscape of the Parties for this matter, counseling decisively in favor of a stay in this Court to promote efficiency.

In fact, when JHU was trying to convince the PTAB not to review its patent, JHU argued

¹ The PTAB’s Institution Decision for IPR2024-00240 as to U.S. Patent No. 11,591,393 (the “’393 patent”) is attached to this memorandum as Ex. A-1.

² Ex. A-1 at 29, 33.

³ Ex. A-2 at 11.

⁴ 35 U.S.C. § 316(a)(11); *see also* 37 C.F.R. § 42.100.

that “litigating substantially overlapping patent issues in two forums is *inefficient and burdens the [PTAB], the District Court, and the Parties*”⁵ and that, if the PTAB institutes an IPR as it did, “the Parties, the District Court and the [PTAB] will be addressing the same issues, *duplicating effort and risking inconsistent outcomes for no reason.*”⁶ But the PTAB determined that Merck’s showing of unpatentability was “compelling,” and warranted taking jurisdiction over the review of JHU’s patent. As a result, JHU should not be credibility heard if it now disagrees that it would be inefficient and place unnecessary burden on the District Court and the Parties for this District Court action to continue in parallel with the IPR.

The District Court action is complex because it arose from a breach of contract action with counterclaims of patent infringement. It involves, among other things, detailed intricacies of pharmaceutical industry practices along with technical issues specific to immunotherapy cancer treatments with chemical compounds in a class of drugs called PD-1 inhibitors. That factual backdrop is further complicated by the overlapping patent issues of invalidity that the PTAB is now scheduled to finally decide. Cancellation of all, or any one of the ’393 patent claims, would necessarily simplify the pretrial and trial issues in this action. As noted above, Merck has filed IPR requests as to the eight other patents at issue in this action, which all arise from the same patent specification as JHU’s ’393 patent. The PTAB’s decisions as to these additional patents are expected to issue on a rolling basis by October 15, 2024. To the extent that the PTAB shares the same view that any of the additional JHU patents should be cancelled, it would provide further support for staying this action pending the PTAB’s final assessment. This is reinforced by JHU’s admission that its ’393 patent has “similar (if not identical)” validity

⁵ Ex. A-3 at 66 (emphasis added).

⁶ Ex. A-4 at 5 (emphasis added).

issues to each of the other patents at issue in this action.⁷

Courts routinely grant stays when, as here, faced with such factually overlapping patent and non-patent claims.”⁸ Cancellation would also simplify any presentation of evidence and argument as to noninfringement should any of JHU’s patents remain after the PTAB’s final determinations. A stay would also help to avoid decisions in this Court, including a jury verdict, that would be inconsistent with any determination by the PTAB that JHU’s patents are unpatentable.

Finally, a stay would not cause any unfair prejudice to JHU. Defendant JHU did not bring this District Court action, but only counterclaimed for patent infringement, and this case is in its early stages. The claim construction hearing has not yet occurred; the anticipated fact depositions have not been scheduled except for a single deposition of a third-party witness; expert discovery has not begun; and the schedule beyond dispositive motions, including pretrial and trial, has not been set. Also, JHU does not compete with Merck for sales of any drug product, and JHU seeks only monetary damages for alleged patent infringement. In similar situations where the case is in its early stages and/or where only monetary damages are sought, courts routinely grant stay requests in view of parallel PTAB review proceedings.⁹

II. BACKGROUND FACTS

This case arose as an action for breach of contract brought by Merck based on JHU’s refusal to permit Merck to continue its right to use the data and results from the Parties’ joint

⁷ ECF No. 51 at 4.

⁸ *Gratuity Sols., LLC v. Toast, Inc.*, No. 1:22-CV-11539-JEK, 2024 WL 1770816, at *4 (D. Mass. Apr. 24, 2024) (quotation marks omitted).

⁹ *E.g., GCE Gas Control Equip., Inc. v. 3B Med. Mfg., LLC*, No. CV TDC-22-2550, 2024 WL 217752 (D. Md. Jan. 18, 2024).

research clinical study for any legitimate business purpose.¹⁰ Merck's right is set out in the Parties' written contract in Section 9.A.¹¹ That right was called into question by JHU threatening to sue Merck for alleged patent infringement. In addition to its claim for breach of contract, Merck filed this action seeking a judgment declaring that it does not infringe JHU's patents.

On April 21, 2023, JHU brought counterclaims alleging patent infringement. (ECF No. 17.) On May 22, 2023, JHU added claims of infringement as to four additional patents. (ECF No. 40.) Currently, fact discovery is not scheduled to close until August 15, 2024, expert discovery has not begun, a claim construction hearing has not yet occurred, and a trial date is not set. (ECF Nos. 57, 67.)

By statute, Merck could file an IPR against JHU's '393 patent on November 28, 2023,¹² and Merck filed a petition for the PTAB to institute an IPR against that patent two days later on November 30, 2023. Merck then filed IPR petitions against all of the remaining patents that JHU asserted in its counterclaims. An *inter partes* review is a trial proceeding conducted at the United States Patent Office in front of the PTAB to review the patentability of issued patent claims. See Inter Partes Review, USPTO, <https://www.uspto.gov/patents/ptab/trials/inter-partes-review> (last visited June 14, 2024). The PTAB may authorize an IPR only where "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). As noted above, on June 13, 2024, the PTAB instituted an IPR on the '393 patent. Over the next four months, the PTAB will decide the remainder of Merck's IPR petitions for the remaining patents at issue.¹³ 35 U.S.C. § 314(b).

¹⁰ ECF No. 1 at ¶¶ 26, 47-54.

¹¹ ECF No. 1 at ¶¶ 26; ECF No. 1, Ex. C at § 9.A.

¹² See 35 U.S.C. § 311(c).

¹³ The PTAB will render the institution decisions for U.S. Patent Nos. 10,934,356; 11,325,974;

The PTAB will issue final decisions within 12 months of its institution decisions. *Id.* 316(a)(11); *see also* 37 C.F.R. § 42.100.

III. THE PTAB’S INSTITUTION DECISION

The PTAB “institut[ed] trial on all grounds of challenge presented in [Merck’s] Petition.” (Ex. A-1 at 34.) These grounds are invalidity for anticipation and obviousness, which are contentions that Merck has also made in this District Court action responding to the counterclaims. The PTAB declared that “we are persuaded that the merits of [Merck’s] challenges are compelling.” (*Id.* at 33; *see also id.* at 33-34 (“the merits of [Merck’s] challenge (factor 6), tend to indicate we should institute an *inter partes* review.”).) Such “compelling” merits findings are reserved for cases where “the evidence, if unrebutted in trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence.” (*Id.* at 4.) The PTAB further explained that, “the interest of efficiency and integrity in the overall patent system may be served by instituting a trial and allowing the proceeding to continue in the event the parallel proceeding settles or fails to resolve the patentability question presented in this proceeding.” (*Id.* at 33.)

IV. ARGUMENT

A. The Legal Standard for Issuing a Stay

“Courts have inherent power to manage their dockets and stay proceedings including the authority to order a stay pending PTO proceedings” such as “IPR proceedings before the PTAB.” *GCE Gas Control*, 2024 WL 217752, at *2 (citing *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426-27 (Fed. Cir. 1988).)

When considering whether to stay federal court proceedings while PTO proceedings are

11,325,975; and 11,339,219 by the end of September 2024, and for U.S. Patent Nos. 11,649,287; 11,643,462; 11,629,187; and 11,634,491 by the middle of October 2024.

pending, courts weigh three factors: (1) “the stage of the proceedings”; (2) “whether a stay would simplify issues and the trial of the case”; and (3) “whether a stay would unduly prejudice the nonmoving party.” *Id.* (granting a stay pending an IPR concerning the asserted claims); *AbCellera Biologics Inc. v. Berkeley Lights LLC.*, No. 20-CV-08624-LHK, 2021 WL 4499231, at *1-*2 (N.D. Cal. Aug. 26, 2021) (granting a stay upon the filing of IPR petitions directed to only some of the claims at issue); *Lyft, Inc. v. AGIS Software Dev. LLC*, No. 21-CV-04653-BLF, 2022 WL 1592441, at *6 (N.D. Cal. May 19, 2022) (granting a stay where the parties are not competitors and the party alleging infringement had “little urgency” in pursuing its infringement claims); *PopSockets LLC v. Quest USA Corp.*, No. 17CV3653FBCLP, 2018 WL 4660374, at *2 (E.D.N.Y. Sept. 28, 2018) (adopting a recommendation for a stay of the entire case in view of IPR proceedings because “[t]hrough the patent and non-patent claims are legally unrelated, the underlying factual disputes are intertwined.”).

B. Each of the Applicable Factors Weigh in Favor of Staying This Action

(1) The Stage of the Proceedings Weighs in Favor of a Stay

“Among the measures of the stage of the proceedings to be considered are ‘whether discovery is complete and whether a trial date has been set.’” *GCE Gas Control*, 2024 WL 217752, at *2 (quoting *VirtualAgility Inc. v. Salesforce.com. Inc.*, 759 F.3d 1307, 1315 (Fed. Cir. 2014)). Neither of those things has come to pass here, favoring a stay.

This action is at an early stage.¹⁴ The Parties are currently engaged in fact discovery with both Parties still in the process of collecting, producing, and seeking documents from the other side. (Ex. A at 2.) No depositions have been taken. *Id.* Only one out of the many anticipated

¹⁴ “The relevant point in time by which to assess the stage of the proceedings is the time when the motion to stay was filed.” *GCE Gas Control*, 2024 WL 217752, at *3.

fact depositions has been scheduled. *Id.* The claim construction hearing is not scheduled to occur until August 20, 2024 and expert discovery is not scheduled to begin until September 16, 2024. (ECF Nos. 67, 57.) The schedule for pre-trial order, pretrial motions, and trial have not been established. *See GCE Gas Control*, 2024 WL 217752, at *3 (the stage of the proceedings favored a stay where initial claim construction briefs had been submitted and a trial date had not yet been set); *Princeton Digital Image Corp. v. Konami Digital Entm't Inc.*, C.A. No. 12-1461-LPS, 2014 WL 3819458, at *4 (D. Del. Jan. 15, 2014) (granting a stay where the most significant case events—i.e., *Markman* hearing, completion of expert discovery, and filing of case dispositive motions—had not yet occurred); *see also* Ex. A-1 at 32 (“Patent Owner cites to no investment in the district court proceeding by either the parties or the court beyond the usual effort in beginning a litigation. Because the district court case is in its early stages, with no substantive orders specific to the facts or circumstance of the case, we are not persuaded that *Fintiv* factor 3 weighs in favor of denying institution of a trial.”).)

A stay at this time would promote efficiency as it would conserve judicial resources as well as the time and resources of the Parties and all fact witnesses. In addition, having the benefit of the PTAB’s final determination before taking the majority of fact depositions would allow the Parties to streamline their questioning and time with witnesses. Further, a stay has the potential to reduce the number of witnesses for deposition and trial. Thus, this factor heavily weighs in favor of a stay.

(2) A Stay Would Simplify the Issues and the Trial of the Case

The likelihood of issue simplification in this action weighs strongly in favor of granting a stay. As courts have explained, where the PTAB institutes an IPR, “continuing [the] litigation will likely result in the unnecessary expenditure of the parties’ and the court’s time and resources

on claims that may be fundamentally altered by the [PTAB's] determination.” *Paice LLC v. Ford Motor Co.*, No. CV WDQ-14-00492, 2014 WL 12934576, at *5 (D. Md. Nov. 6, 2014) (quoting *Univ. of Virginia Patent Found. v. Hamilton Co.*, No. 3:13-CV-00033, 2014 WL 4792941, at *2 (W.D. Va. Sept. 25, 2014)) (quotation marks omitted).

The PTAB has already instituted an IPR as to all of the asserted claims of the '393 patent. As JHU itself represented in its submissions to the PTAB, “litigating substantially overlapping patent issues in two forums is *inefficient and burdens the Board, the District Court, and the Parties*” (Ex. A-3 at 66 (emphasis added)) and, if the case proceeds in two forums, “the Parties, the District Court and the Board will be addressing the same issues, *duplicating effort and risking inconsistent outcomes for no reason*” (Ex. A-4 at 5 (emphasis added)). Indeed, Congress established the IPR procedure to “limit unnecessary and counterproductive litigation costs.” H.R. Rep. No. 112-98, at 40 (2011). And here, the probability of the PTAB ultimately invalidating at least some, if not all, of JHU's patent claims is especially high given the PTAB's finding that “the merits of [Merck's] challenges are compelling” (Ex. A-1 at 33), a finding reserved for cases where “the evidence, if unrebutted in trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence” (Ex. A-5 at 4). *See also Commscope Techs. LLC v. Dali Wireless, Inc.*, IPR2022-01242, Paper 23 at 3-4 (P.T.A.B. Feb. 27, 2023) (explaining that a compelling merits finding is appropriate where “it is highly likely that the petitioner would prevail with respect to at least one challenged claimed.”) (designated precedential and binding on the PTAB).¹⁵

To be clear, all of the asserted patents share the identical specification and all of the

¹⁵ This decision, marked by the PTAB as precedential, is available at <https://www.uspto.gov/sites/default/files/documents/IPR2022-01242CommScopeTechv.DaliWirelessDecision.pdf> (last visited June 13, 2024).

asserted claims are similar because they all are directed to methods of treating patients having “microsatellite instability-high or DNA mismatch repair deficient” cancer¹⁶ with pembrolizumab. (ECF No. 51 at 4 (JHU represented to the Court that the “patents share a common specification, have the same inventors, and the infringement and validity issues for each patent are similar (if not identical)” and that the claims are similar).) All of those facts increase the likelihood that the PTAB will institute IPRs for the additional patents.

Indeed, the likelihood that the PTAB will institute all of the IPRs is high here because the PTAB already instituted the first IPR, all of JHU’s patents are similar, and all of Merck’s IPR petitions rely on the same primary reference to cancel all of the claims asserted in the District Court action. *See Lyft*, 2022 WL 1592441, at *3 (finding that the simplification factor favored a stay because the pending IPR petitions were “substantively identical” to petitions that resulted in institution); *Lighting Sci. Grp. Corp. v. Shenzhen Jiawei Photovoltaic Lighting Co.*, No. 16-CV-03886-BLF, 2017 WL 2633131, at *3 (N.D. Cal. June 19, 2017) (finding that the simplification factor favored a stay because “it seems highly likely” that “the PTAB will institute IPR” on the pending petitions where the pending petitions and instituted petitions concern patents that “are related” and the petitions “involve similar subject matter, and there is substantial overlap in prior art and arguments”); *Topia Tech., Inc. v. Dropbox Inc.*, No. 23-CV-00062-JSC, 2023 WL 3437823, at *5-6 (N.D. Cal. May 12, 2023) (finding it likely that the PTAB would institute some or all IPR petitions, in part, because the patents share the same specification).

Even if the PTAB does not institute all of the remaining IPR petitions, “numerous courts have found that the simplification factor can weigh in favor of a stay even when IPR was not

¹⁶ Both microsatellite instability-high and DNA mismatch repair deficient refer to a cancer having the same genetic defect.

instituted as to all patents at issue, such that IPR would not resolve all issues in the case.” *GCE Gas Control*, 2024 WL 217752, at *4. For example, in *GCE Gas Control Equipment, Inc.*, two IPRs were filed against two asserted patents. *Id.* Even though only one of the IPRs was instituted, the Court granted a stay. *Id.* The Court explained that even though “it is highly likely that litigation of the present case will continue after the conclusion of the [instituted] IPR Proceeding, whether because that proceeding may not result in the invalidity of all claims on that patent, because PTAB has not yet and may never institute the [other] IPR Proceeding, or both,” a stay was warranted. *Id.* at *4-*5.

Other districts have proceeded in accord. For example, in *AbCellera*, the court granted a stay when IPR petitions directed to only some of the asserted claims in three patents were filed, even though the plaintiff had asserted infringement of many claims from seven patents. 2021 WL 4499231, at *1. In fact, the court maintained that stay even after the PTAB refused to institute IPRs on two of the three petitions. *AbCellera Biologics Inc. v. Berkeley Lights, Inc.*, No. 20-CV-08624-JST, 2022 WL 20016824, at *2 (N.D. Cal. Aug. 22, 2022). In another case, *Centripetal Networks, Inc. v. Palo Alto Networks, Inc.*, the court granted a stay when the PTAB instituted IPRs for only 5 of the 13 patents at issue in the district court. No. 2:21CV137 (RCY), 2022 WL 610176, at *5 (E.D. Va. Mar. 1, 2022).

Here, JHU’s counterclaims assert **144 patent claims**. All of those are subject to IPR review and/or petitions for review, as discussed above. Any reduction in that number based on PTAB review will simplify this action. Even if the PTAB institutes review of additional patents and not others, any PTAB final written decisions will provide insight and guidance to streamline issues before the Court. *GCE Gas Control*, 2024 WL 217752, at *5 (whether some or all of the IPRs are instituted, “if certain claims are canceled or amended to cure invalidity, that result

‘would eliminate the need to try the infringement issue’ relating to such claims” (quoting *Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 721 F.3d 1330, 1340 (Fed. Cir. 2013)); *Finjan, Inc. v. FireEye, Inc.*, No. 13-03133 SBA, 2014 WL 2465267, at *2 (N.D. Cal. June 2, 2014) (finding that “the PTO’s expert opinion will provide guidance for the Court on pertinent issues” and streamline the case). For example, the PTAB’s opinion can assist with claim construction. *Amsted Rail Co., Inc. v. Hum Indus. Tech., Inc.*, No. 4:22-CV-00445-AGF, 2023 WL 2864553, at *4 (E.D. Mo. Apr. 10, 2023) (“the need for claim construction may be avoided entirely (and if already done, will have been a significant waste of resources). But even if all of the patent claims survive, the Court may benefit from the expert opinion of the PTO and clarifying the scope of the claims.”); *see also Baxter Int’l, Inc. v. CareFusion Corp.*, No. 15-CV-09986, 2017 WL 11624669, at *2 (N.D. Ill. May 31, 2017) (“The PTAB’s final written decisions will also provide the Court with guidance on claim construction from a panel of patent experts”) (collecting cases).

Given the ability of PTAB proceedings to simplify the case and trial, courts can issue stays pending IPR proceedings even before the PTAB renders any institution decision. *See, e.g., AbCellera*, 2021 WL 4499231, at *1-*2; *Uniloc 2017 LLC v. Microsoft Corp.*, No. SACV1802053AGJDEX, 2019 WL 6974354, at *1 (C.D. Cal. Aug. 9, 2019); *Core Optical Techs., LLC v. Fujitsu Network Commc'ns, Inc.*, No. SACV1600437AGJPRX, 2016 WL 7507760, at *2 (C.D. Cal. Sept. 12, 2016). Here, however, the Court has the benefit of an institution decision that reflects significant concerns with the grant of JHU’s patent.

As to the breach of contract issue, that is Plaintiff Merck’s claim. Merck is willing to stay those claims pending review of the IPR proceedings. The invalidity issues in the PTAB overlap with and influence Merck’s breach of contract action and noninfringement claims and

JHU's infringement counterclaims. The PTAB's decisions can be dispositive of the noninfringement claims and infringement counterclaims. If there are no valid patent claims, then there can be no infringement. The PTAB cancelling any of the claims would also simplify the action by removing claims that the experts would need to opine on and that the jury would need to consider. Additionally, changing the claims presented to a jury could entirely change any damage calculation that the jury undertakes or whether the jury finds infringement at all.

Further, the complicated factual overlap between the patent and non-patent issues warrant staying the whole case. For example, important facts are relevant to both the contract and non-contract claims, such as the details of the Parties' working together on the joint clinical research study as well as JHU's purported invention story. The patent and non-patent issues also both share important witnesses, such as the named patent inventors. *See Gratuity Sols*, 2024 WL 1770816, at *4; *RealID Spark, LLC v. Microsoft Corp.*, No. 2:22-CV-00942-TL, 2024 WL 343224, at *1 (W.D. Wash. Jan. 30, 2024) (staying the whole case in view of the institution of an IPR, in part because the non-patent claims and patent claims "involve some (though not total) overlap of facts and witnesses . . ."); *Amsted Rail*, 2023 WL 2864553, at *4 (quotation marks omitted) (collecting cases); *see also PopSockets*, 2018 WL 4660374, at *2 (adopting a recommendation for a stay because "[t]hough the patent and non-patent claims are legally unrelated, the underlying factual disputes are intertwined.").

Beyond that, Merck's breach of contract claim that is at the forefront of this action necessarily involves JHU patents. Specifically, Merck's claims arise from JHU improperly using patents that it obtained and demanding money from Merck with allegations of patent infringement, despite the Parties' written contractual provisions forbidding exactly JHU's actions. If JHU has no patents continuing to threaten Merck, in breach of the Parties' contract,

Merck's need for continuing to pursue a breach of contract action may be diminished.

Even if JHU somehow obtained a favorable final decision in the IPR proceedings, this would also narrow the issues because of the potential estoppel effect of such final determination.¹⁷ *See* 35 U.S.C. § 315(e). In contrast, forcing the Parties to litigate issues relating to the patents at issue in parallel with the IPR proceedings will make the action even more complex and could lead to inconsistent findings. This would be contrary to the purpose of IPRs, which were “intended to provide [a] ‘quick and cost effective *alternative*’ to litigation.” *WesternGeco LLC v. ION Geophysical Corp.*, 889 F.3d 1308, 1317 (Fed. Cir. 2018) (quoting H. Rep. No. 112-98, at 48 (2011)) (emphasis added). Accordingly, this factor strongly favors a stay.

(3) A Stay Would Not Unduly Prejudice JHU

“In assessing the undue prejudice factor, courts focus primarily on the level and nature of competition between parties, particularly whether they were direct competitors such that one party may irreparably lose market share to the other while the patent litigation remains unresolved.” *GCE Gas Control*, 2024 WL 217752, at *5. Here, the Parties are not competitors, which weighs in favor of a stay. *See id.* Merck makes and sells Keytruda[®] and JHU does not make any product of its own, but rather uses Keytruda[®] and other drugs for its own benefit to treat cancer patients. In asserting counterclaims alleging patent infringement, JHU is thus equivalent to a non-practicing entity. “The risk of harm is reduced when [a party] is a non-practicing entity.” *Paice*, 2014 WL 12934576, at *4.

Moreover, JHU seeks only monetary damages in this action, and not injunctive relief.

¹⁷ Merck would be estopped in the District Court from raising any invalidity argument that it raised or reasonably could have raised during the IPR after a final determination in the IPR proceedings. *See* 35 U.S.C. § 315(e).

(ECF No. 40 at 5, 59.) “[A] stay will not diminish the monetary damages to which [JHU] will be entitled if it succeeds in its infringement suit—it only delays realization of those damages. . . .” *NSixty, LLC v. A2Z, Inc.*, No. CV MJG-17-1987, 2018 WL 9944991, at *2 (D. Md. Jan. 4, 2018) (citing *VirtualAgility Inc.*, 759 F.3d at 1318). Thus, JHU will face no undue prejudice from a stay.

“Courts also consider whether the moving party unduly delayed in filing the PTO proceedings or the motion to stay based on a ‘dilatory motive’ to gain a tactical advantage.” *GCE Gas Control*, 2024 WL 217752, at *5. Here, Merck did not act with any dilatory motive to gain a tactical advantage. Merck diligently prepared and filed its IPR petitions in a reasonable timeframe, particularly given the large number of patents and patent claims asserted by JHU and JHU’s repeated refusal to narrow the scope of its allegations. Merck filed the ’393 patent IPR petition within two days of the ’393 patent becoming IPR eligible. 35 U.S.C. § 311(c). Merck continued filing IPR petitions against JHU’s many patents, and finished filing in March 2024, which was only one month after the last JHU patent became IPR eligible. 35 U.S.C. § 311(c). Upon Merck’s first IPR being instituted, Merck quickly moved for a stay.

JHU cannot credibly argue that it would be unduly prejudiced by a stay. Its own actions confirm it saw no urgency in asserting its patents against Merck. JHU obtained its first patent in 2021. It was not until Merck filed a complaint against JHU for breach of contract following the issuance of JHU patents and its threats of infringement, that JHU finally filed counterclaims asserting infringement in April 2023. JHU did not seek any urgent relief, such as a preliminary injunction. JHU’s own conduct in asserting its patents shows a lack of urgency, which weighs against a finding of undue prejudice. *See Baxter*, 2017 WL 11624669, at *4 (“Given that Baxter showed no sense of urgency in enforcing its patents, it is difficult to accept Baxter’s arguments

that a relatively short delay is unfairly prejudicial. Second, Baxter did not seek a preliminary injunction. A party opting not to pursue preliminary injunctive relief can weigh against a finding of undue prejudice, though it is not dispositive.”) (citing *VirtualAgility*, 759 F.3d at 1319) (quotation marks omitted); *Lyft*, 2022 WL 1592441, at *6 (finding the facts that “the parties are not competitors” and that the patent owner “has little urgency in pursuing its infringement claims” favor a stay). This factor strongly favors a stay.

V. CONCLUSION

For all of the above reasons, Merck respectfully requests a stay of all Scheduling Order deadlines and proceedings in this action pending final resolution of IPR2024-00240, which was instituted by the PTAB on June 13, 2024.

Date: June 14, 2024

By: /s/

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Certificate of Service

I, the undersigned attorney, hereby certify that I have caused true and correct copies of the above and foregoing to be sent via email to Defendant's counsel of record on this 14th day of June, 2024.

/s/
Chelsea J. Crawford