IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TREACE MEDICAL CONCEPTS, INC., Plaintiff, v. ZIMMER BIOMET HOLDINGS, INC. and PARAGON 28, INC. Defendants.	C.A. No. 25-592-GBW

DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR
MOTION TO STAY

Ali Razai (*pro hac vice*)
Brandon G. Smith (*pro hac vice*)
MORGAN, LEWIS & BOCKIUS LLP
600 Anton Boulevard, Suite 1800
Costa Mesa, CA 92626
Telephone: 714.830.0600
Fax: 714.830.0700
ali.razai@morganlewis.com
brandon.g.smith@morganlewis.com

Krista Vink Venegas (*pro hac vice*)
MORGAN, LEWIS & BOCKIUS LLP
110 N. Wacker Drive, Suite 2800
Chicago, IL 60606
Telephone: 312.324.1000
Fax: 312.324.1001
krista.venegas@morganlewis.com

Jack Hendershott (*pro hac vice*)
MORGAN, LEWIS & BOCKIUS LLP
101 Park Avenue
New York, NY 10178
Telephone: 212.309.6000
Fax: 212.309.6001
jack.hendershott@morganlewis.com

John V. Gorman (DE Bar No. 6599)
Amy M. Dudash (DE Bar No. 5741)
MORGAN, LEWIS & BOCKIUS LLP
1201 N. Market Street, Suite 2201
Wilmington, DE 19801
Telephone: 302.574.3000
Fax: 302.574.3001
john.gorman@morganlewis.com
amy.dudash@morganlewis.com

Attorneys for Defendants Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.

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Defendants Zimmer Biomet Holdings, Inc. and Paragon 28, Inc. (collectively, "Defendants") move to stay the instant action pending final resolution of post grant review ("PGR") proceedings pertaining to U.S. Patent Nos. 12,268,397 (the "'397 patent"); 12,268,428 (the "'428 patent"); 12,274,481 (the "'481 patent"); and 12,349,941 (the "'941 patent") and *inter partes* review ("IPR") proceeding pertaining to U.S. Patent No. 12,102,368 (the "'368 patent") (collectively, the "PTAB Proceedings"). These patents all recently issued and are all subject to review by the Patent and Trial Appeal Board ("PTAB"). Given the early stage of the instant action, the Court should stay this action while the PTAB completes its review of the asserted patents to conserve Court and party resources. Given the PTAB's preference for PGRs and the high likelihood of institution of the PGRs and the IPR on a recently issued patent, the nascent stage of this action, and the efficiencies that a stay would create, the Court should stay this case.

I. NATURE AND STAGE OF THE PROCEEDINGS

The instant action is in its infancy. Plaintiff Treace Medical Concepts, Inc. ("Plaintiff") commenced this action in May 2025, and alleges infringement of five patents (the "Patents-in-Suit"). *See* D.I. 1; D.I. 12. On December 19, 2025, Defendants began filing petitions with the PTAB, challenging the validity of the Patents-In-Suit. Defendants' first PGR challenged the '397 patent on several grounds. Ex. 1. On December 23, 2025, Defendants filed another PGR challenging the '428 patent. Ex. 2. This was followed, on January 5, 2026, by an IPR challenging the '368 patent. Ex. 3. Then Defendants filed PGRs challenging the '481 patent and '941 patent on January 13, 2026 and March 3, 2026, respectively. Exs. 4 & 5.

Meanwhile in this action, Plaintiff systematically sought stays and extensions. After filing its Amended Complaint on August 13, 2025, Plaintiff stipulated to a forty-five-day stay (D.I. 14), an additional thirty-day-stay (*see* October 30, 2025 text order), and a nine-day extension of the stay (D.I. 17). After the case was stayed for nearly three months, Defendants filed a motion to

dismiss (D.I. 22) at the same time as their first PGR (Ex. 1). Rather than immediately responding to the Motion to Dismiss, Plaintiff requested and the parties stipulated to yet another extension, continuing Plaintiff's deadline to respond to the Motion by forty-six days. *See* D.I. 29. Finally, on February 17, 2026, Plaintiff filed its opposition to Defendants' Motion to Dismiss. Defendants filed their reply on February 24, 2026. *See* D.I. 29.

Plaintiff's various stays and extensions have resulted months of delay such that this case is still in its infancy. The pleadings are still open, the parties have not held any meeting of counsel under Federal Rule of Civil Procedure 26(f), discovery is yet to open, and the Court has not set a schedule. Meanwhile, Defendants have diligently prepared and filed four PGRs and an IPR on the Patents-in-Suit. The institution of these PTAB Proceedings is highly probable. Despite the nascent stage of the instant action and its repeated prior stays, Plaintiff would not consent to a stay pending resolution of the PTAB Proceedings.

II. SUMMARY OF THE ARGUMENT

Granting a stay will allow the PTAB process to substantially streamline, if not wholly obviate, this action. Each of the factors that the Court should consider in assessing Defendants' Motion to Stay weighs in favor of granting a stay here:

1. *First*, a stay will simplify issues for trial and will very likely obviate the need for any trial. It is highly probable that the PTAB will institute the pending PTAB Proceedings. Once instituted, the asserted claims of each of the Patents-in-Suit may be cancelled, resulting in a complete resolution of the instant action. Even if one or more claims survive at the PTAB, the PGR and IPR proceedings will still narrow and clarify the issues for trial in this Court by eliminating the other claim(s), providing relevant intrinsic evidence and claim construction, adjudicating certain invalidity arguments, and estopping Plaintiff from making arguments that are contrary to positions it took during the PTAB Proceedings.

2. *Second*, the early stage of the instant action favors a stay. This case is in a very early phase, with no schedule set and no discovery exchanged. Plaintiff has already requested months of stays and extensions, and a stay pending the PTAB Proceedings will serve to avoid needless discovery and conserve the resources of the Court and the parties.

3. *Third*, Plaintiff will not face any undue prejudice from a stay. Plaintiff has been in no rush to litigate this case. Instead of moving its case forward, Plaintiff has sought multiple stays and an extension. Defendants acted diligently, filing their PGR and IPR petitions before any schedule has been set in this action and promptly moving for a stay thereafter. As institution is highly probable, there is no reason to proceed with the instant action while waiting for the institution decisions to issue.

III. BACKGROUND

Defendants have challenged each of the five Patents-in-Suit at the PTAB, filing four PGR petitions and one IPR petition. Even though under the leadership of the new Director of the Patent and Trademark Office ("PTO") institution rates of IPRs have fallen, the institution rate for PGRs remains strong, with 61% of petitions being instituted in the last twelve months. In fact, the PTAB has designated as precedential multiple opinions highlighting its preference for PGR challenges. For example, in *LifeVac*, the PTO held that "petitions for post-grant review ***are favored*** because they must be filed no later than nine months from the grant of the patent (35 U.S.C. § 321(c)), are close in time to examination, and occur before expectations in the patent rights are strongly settled." *Lifevac, LLC v. DCSTAR Inc.*, IPR2025-00454, Paper 11 at 2 (P.T.A.B. July 11, 2025) (precedential) (Ex. 6). Indeed, the PTAB has declined to discretionarily deny a PGR despite pending litigation with a trial date four months prior to the earliest final written decision. *Multi-Color Corp. v. Brook & Whittle Ltd.*, PGR2025-00025, Paper 10 (P.T.A.B. July 16, 2025) (precedential) (Ex. 7) (holding PGRs "are favored").

The merits of Defendants' petitions are very strong. Each of the patents challenged in PGR petitions recite method claims. Although the '368 patent challenged in an IPR recites "system" claims, it is a system largely defined by its functionality rather than its structure. At a high level, Defendants' petitions explain that each of Plaintiff's patents claims nothing more than a known surgical method using known surgical tools. Indeed, four of the petitions present grounds based on a medical school ***textbook*** that explains basic techniques for performing bunion correction procedures.[1] Each petition explains why it would have been obvious to utilize known surgical instrumentation (e.g., clamps, cutting guides) in these known techniques. The petitions therefore present a classic case of obviousness under *KSR*. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("application of a known technique to a piece of prior art ready for improvement" is obvious). It is likely the petitions will result in cancellation of Plaintiff's claims.

This case is just beginning. Neither the Court nor the parties have invested substantial resources into the case. Although Plaintiff filed this action within months of the Patents-in-Suit issuing, it has been in no rush to litigate this case, seeking or agreeing to over four months of stays or extensions. The Court has not set an initial case management conference, entered a schedule, or set a trial date. The parties have not held a Rule 26(f) conference or served initial disclosures, initial infringement contentions, initial invalidity contentions, or any discovery.

In contrast, Defendants promptly sought PTAB review of the Patents-in-Suit, filing its first petition the same day the stay lifted and the remainder shortly thereafter. *See* Exs. 1-5. In the petitions, Defendants seek cancellation of the claims of the Patents-in-Suit on various grounds.

[1] For the fifth petition on the '941 patent Defendants rely on a publication by one of the purported inventors that provides similar disclosure.

The PTAB's decisions regarding whether to institute review are expected by July-August 2026. *See* 35 U.S.C. § 314(b)(1); 35 U.S.C. § 324(c).

IV. ARGUMENT

"A decision to stay litigation lies within the sound discretion of the court and represents an exercise of the court's 'inherent power to conserve judicial resources by controlling its own docket.'" *Neste Oil OYJ v. Dynamic Fuels, LLC*, C.A. No. 12-1744-GMS, 2013 WL 3353984, at *1, *5 (D. Del. July 2, 2013) (citations omitted). Courts in this District have repeatedly recognized the benefits of staying litigation pending resolution of a PTAB proceeding, especially, where (as here) the litigation is in its early stages. *See, e.g.*, *Arch Chems., Inc. v. Sherwin-Williams Co.*, C.A. No. 18-2037-LPS (D. Del. Nov. 5, 2019) (D.I. 48) (Ex. 8); *CG Tech. Dev., LLC v. William Hill U.S. Holdco*, No. 18-cv-533-RGA, 2019 WL 4098002, at *1 (D. Del. Aug. 29, 2019); *Princeton Digital Image Corp. v. Konami Digital Ent. Inc.*, C.A. No. 12-1461-LPS-CJB, 2014 WL 3819458, at *3-4 (D. Del. Jan. 15, 2014) (collecting cases).

The Court considers three factors in assessing whether to grant a stay: "(1) whether a stay will simplify the issues for trial, (2) whether discovery is complete and a trial date has been set, and (3) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party." *Ethicon LLC v. Intuitive Surgical, Inc.*, C.A. No. 17-871-LPS, 2019 WL 1276029, at *1 (D. Del. Mar. 20, 2019); *see RetailMeNot, Inc. v. Honey Sci. LLC*, C.A. No. 18-937-CFC-MPT, 2020 WL 373341, at *3 (D. Del. Jan. 23, 2020) (considering same factors in determining whether to grant stay pending IPR and PGR proceedings). Here, each of these factors weighs strongly in favor of stay.

A. A Stay Will Simplify—If Not Obviate the Need for—Trial.

A stay of the instant action while the PTAB Proceedings are resolved will simplify the issues for trial and may even obviate the need for any trial.

1. The PTAB Proceedings Will Likely Be Instituted.

Institution is highly likely. All but one of the Patents-in-Suit issued within the last nine months. As a result, Defendants filed PGRs rather than IPRs on those patents. *See* Exs. 1-2, 4-5. The PTAB prefers PGR petitions. *See LifeVac*, IPR2025-00454, Paper 11 at 2; *Multi-Color*, PGR2025-00025, Paper 10 at 2 (each noting the favored status of PGRs). The PTAB's preference for PGRs is born out in the institution rates, which are at 61% for PGRs filed in the last twelve months. *See* Declaration of Amy M. Dudash, ¶ 10; Ex. 9 (only nine discretionary denials in the last twelve months). Based on the low number of discretionary denials of PGRs thus far in 2026, the high institution rate for PGR proceedings is poised to continue. *See id*.

The stated basis for many recent discretionary **IPR** denials—settled expectations—is inapplicable to the PGRs, which must be filed within nine months of the patent issuing. *See Emody, Inc. v. LifeNet Health*, IPR2025-00248, Paper 13 (P.T.A.B. June 26, 2025) (Ex. 10) (denying request for discretionary denial noting that "one of the challenged patents has not been in force for a significant period of time (issued in 2022)" such that "Patent Owner has not developed strong settled expectations that favor discretionary denial"). For the IPR petition, the settled expectations doctrine is not applicable because the patent issued less than eighteen months ago. *See id.*

Furthermore, other common bases for discretionary denial are not applicable. For example, it is unlikely that resolution will occur more quickly in the district court or elsewhere given that no schedule or trial date has been set. Under the *Fintiv* factors, this decreases the possibility of discretionary denial. *See Apple Inc. v. Fintiv, Inc.*, IPR2020, Paper 11, at p. 6 (P.T.A.B. Mar. 20,

2020) (Ex. 11) (factor 2: proximity of the court's trial date to the PTAB's projected statutory deadline for a final written decision).

At bottom, the likelihood of institution of the four PGR petitions and related IPR petition and resulting simplification is high here, which weighs in favor of granting a pre-institution stay. *See, e.g.*, *RetailMeNot*, 2020 WL 373341, at *3 (granting pre-institution stay); *Miics & Partners Am. Inc. v. Toshiba Corp.*, Civ. A. No. 14-803-RGA, 2015 WL 9854845, at *1 (D. Del. Aug. 11, 2015) (same); *Message Notification Techs. LLC v. Microsoft Corp.*, Civ. A. 13-881, 2015 WL 13781851, at *1 n.4 (D. Del. Feb. 24, 2015) (same); *Princeton Digital*, 2014 WL 3819458, at *3-4 (same); *Neste Oil*, 2013 WL 3353984, at *1, *5 (same).

2. The PTAB Proceedings Will Simplify Issues Here.

A stay pending institution of the PTAB Proceedings, and post-institution, will simplify the issues before the Court. "[T]he arguments for a stay pending institution . . . have been strengthened by recent changes in the law: namely, institution must be on all or none of the claims on which IPR is sought and claim construction undertaken by the [PTAB] is now conducted according to the same legal standards this Court must apply." *Arch Chems.*, D.I. 48 (Oral Order granting pre-institution stay). The PGRs not only raised art-based invalidity, but some also raised invalidity based on Section 112. Plaintiff will likely respond to those challenges, along with art-based challenges and claim construction issues, even at the pre-institution stage. Plaintiff's pre-institution responses will therefore inform, if not resolve, multiple issues that would otherwise be pending before the Court. In addition, a pre-institution stay will prevent the parties from needlessly utilizing resources over the next several months to develop infringement and invalidity contentions for claims that will never be litigated. A pre-institution stay in this case stands to simplify several issues.

Furthermore, where, as here, all of the Patents-in-Suit and all of the claims of the Patents-in-Suit are challenged in the pending petitions before the PTAB, "the law of probabilities makes it almost certain that the PTAB will grant at least some of the petitions, and that some of the claims will eventually be rejected or modified, and others of them, even if neither rejected nor modified, will garner additional prosecution history that may be relevant to claim construction." *See Miics & Partners*, 2015 WL 9854845, at *1. These statistics support a "fair inference that the issues in this case are apt to be simplified and streamlined to some degree as a result of the [PTAB] proceedings." *Ever Win Int'l Corp. v. Radioshack Corp.*, 902 F. Supp. 2d 503, 506 (D. Del. 2012).

The removal of some or all the claims of the Patent-in-Suit will simplify the issues for discovery and trial in several ways or possibly moot them all. *See Brit. Telecomms. PLC v. IAC/InterActiveCorp.*, Civ. A. No. 18-366-WCB, 2019 WL 4740156, at *8 (D. Del. Sept. 27, 2019) ("[I]f the PTAB invalidates all of the claims before it, the case will unquestionably become simpler."); *SoftView LLC v. Apple Inc.*, No. 12-989-LPS, 2013 WL 4757831, at *1 (D. Del. Sept. 4, 2013) ("Should all of the asserted claims be found invalid, this litigation would be 'simplified' because it would be concluded.").

Further, the PGR and IPR petitions raise various grounds of invalidity for each claim of the Patents-in-Suit, including challenges based on different prior art references. Thus, even if one or more of the claims were to survive PTAB review—which is unlikely—the PTAB Proceedings will still narrow the issues for trial. *See generally Gen. Elec. Co. v. Vibrant Media Inc.*, C.A. No. 1:12-cv-00526-LPS, 2013 WL 6328063, at *1 (D. Del. Dec. 4, 2013) ("Regardless of their outcome, the IPR proceedings will simplify this case, as [defendant] will be estopped from contending that certain prior art invalidates the asserted claims and/or some or all of the asserted

claims will be invalidated."); *RetailMeNot*, 2020 WL 373341, at *5 (discussing fact that estoppel applicable to PGR and IPR proceedings leads to simplification even if challenged claims survive).

The PTAB Proceedings will also illuminate key claim construction disputes. Claim construction has yet to begin in the instant action—Plaintiff has not yet identified which claims it intends to assert, nor have the parties exchanged their lists of the claim terms that they believe need construction, let alone their proposed constructions and supporting intrinsic evidence. As part of the PTAB Proceedings, Plaintiff is likely to make statements relating to its contentions on disputed claim terms, which become part of the intrinsic record. *See 454 Life Scis. Corp. v. Ion Torrent Sys., Inc.*, C.A. No. 15-595-LPS, 2016 WL 6594083, at *3 (D. Del. Nov. 7, 2016) (reasoning that stay may simplify issues for trial through creation of additional prosecution history during PTAB proceedings). Thus, a stay now will enable the Court to have the added benefit of additional intrinsic evidence and the PTAB's view on claim construction. *See Arch Chems.*, C.A. No. 18-2037-LPS, D.I. 48 (PTAB's use of same claim construction standard as this Court have "strengthened" arguments for stay). Even if one or more claims were to survive the PGR or IPR proceedings, the Court's claim construction should be based on the full intrinsic record, including developments in the PTAB Proceedings.

As such, "the only question is not whether the [PTAB] results will simplify the trial, but what the extent of simplification will be." *Huvepharma Eood & Huvepharma, Inc. v. Associated Brit. Foods, PLC*, C.A. No. 18-129-RGA, 2019 WL 3802472, at *1 (D. Del. Aug. 13, 2019). Here, the answer is that the simplification resulting from the PTAB's application of prior art and construction of the claims in the Patents-In-Suit will be significant and may even obviate the need for a trial all together.

B. The Early Stage of the Instant Action Favors a Stay.

"Motions to stay are most often granted when the case is in the early stages of litigation." *Princeton Digital*, 2014 WL 3819458, at *3. "Granting such a stay early in a case can be said to advance judicial efficiency and 'maximize the likelihood that neither the Court nor the parties expend their assets addressing invalid claims.'" *Id.*, at *3. Here, there is no scheduling order and discovery has yet to begin. Thus, the instant action is at the earliest stage.

Accordingly, a stay of the litigation at this juncture would result in significant savings to both the Court and the parties because time and resources have not yet been invested in scheduling, discovery, claim construction, or trial. In sum, "[s]tays are favored when [as here] the 'most burdensome stages of the case—completing discovery, preparing expert reports, filing and responding to pretrial motions, preparing for trial, going through the trial process, and engaging in post-trial motions practice—all lie in the future.'" *Bio-Rad Lab'ys, Inc. v. 10X Genomics, Inc.*, Civ. A. No. 18-1679-RGA, 2020 WL 2849989, at *1 (D. Del. June 2, 2020). Accordingly, this factor weighs strongly in favor of a stay. *See, e.g.*, *Ever Win*, 902 F. Supp. 2d at 507-08 (finding this factor "weighs strongly in favor of a stay" where "[n]o initial disclosures have been exchanged, no Scheduling Order has been entered, no discovery has occurred, claim construction has not been briefed, and neither a *Markman* hearing nor a trial date have been set").

C. A Stay Will Not Unduly Prejudice Plaintiff.

Plaintiff's conduct undercuts any argument that it will be prejudiced, much less unduly prejudiced, by the requested stay. Plaintiff sought consecutive stays of this action, resulting in the case being stayed for nearly eighty days. D.I. 14; 16. Then, after the stay expired, Defendants responded to the complaint by moving to dismiss the operative complaint, and Plaintiff *once again* sought to delay the litigation, seeking a forty-six-day extension of time to respond to Defendants' motion to dismiss. D.I. 29. Plaintiff's own delays in pursuing the instant lawsuit undercut any

assertion that this is a "time [is] of the essence" matter where Plaintiff faces undue prejudice from a stay. *Cf. Celorio v. On Demand Books, LLC*, Civ. A. No. 12-821-GMS, 2013 WL 4506411, at *1 n.1 (D. Del. Aug. 21, 2013). Further, Plaintiff's failure to seek a preliminary injunction or seek to expedite any claim for relief (and instead seeking consecutive stays of the case) demonstrates the lack of prejudice from a stay pending final resolution of the PTAB Proceedings. *See Neste Oil*, 2013 WL 3353984, at *4; *Ever Win*, 902 F. Supp. 2d at 511 ("Plaintiff never sought a preliminary injunction, which suggests that any prejudice to Plaintiff that might result from delaying the ultimate resolution of this dispute is not as severe as it contends.").

Each of the three undue prejudice factors courts consider supports a stay here: (1) the timing of the request for review and the timing of the request for a stay, (2) the status of the review proceeding, and (3) the relationship between the parties. *See 454 Life Scis. Corp.*, 2016 WL 6594083, at *4.

First, the timing of the PTAB Petitions and stay request weighs strongly in favor of a stay. "The more diligent a defendant is in seeking [PTAB] review, the less likely it is that the non-movant will be prejudiced by a stay or that the court will find the defendant's filing of the [PTAB] petition to be a dilatory tactic." *Bonutti Skeletal Innovations, L.L.C. v. Zimmer Holdings, Inc.*, C.A. No. 12-cv-1107 (GMS), 2014 WL 1369721, at *2 (D. Del. Apr. 7, 2014). Here, Defendants promptly sought a stay before the PTAB Proceedings were initiated and before any significant activity occurred in the instant litigation. Thus, this is a not a case where a defendant only filed a PTAB petition after "any negative case event . . . such that the requests could be said to be driven by an inappropriate or bad-faith desire to stall this litigation." *SenoRx, Inc. v. Hologic, Inc.*, Civ. A. No. 12-173-LPS-CJB, 2013 WL 144255, at *7 (D. Del. Jan. 11, 2013). Mere delay in litigation "does not, by itself, establish *undue* prejudice." *Neste Oil*, 2013 WL 424754, at *2.

Second, the stage and duration of the PTAB Proceedings will not unduly prejudice Plaintiff. Due to the statutory six-month institution deadline and one-year final written decision deadline, PTAB proceedings are "a more expeditious process," "which merits weight in this analysis." *See Princeton Digital*, 2014 WL 3819458, at *5. Plaintiff will not be prejudiced by temporarily pausing this action while the PTAB considers the validity of the claims of the Patents-in-Suit because—like the public, this Court and Defendants—Plaintiff will benefit from the timely resolution of important patentability issues. *See IOENGINE, LLC v. PayPal Holdings, Inc.*, Civ. A. No. 18-452-WCB, 2019 WL 3943058, at *6 (D. Del. Aug. 21, 2019) ("The prospect that contemporaneous IPR decisions will have a significant effect on the issues presented in the litigation counsels in favor of a stay."). Further, Plaintiff will be directly involved in the PTAB Proceedings and will be able to litigate its positions before the PTAB.

Third, any purported competitive relationship between parties does not create undue prejudice. Competition between the parties is not dispositive of the question of undue prejudice. *See Ethicon*, 2019 WL 1276029, at *2-3 (granting stay despite fact that parties were competitors in three-player market due to, *inter alia*, lack of evidence that competitor status "was the motivation for [defendant]'s litigation strategy, or that [defendant] could and should have filed its IPR petitions much sooner than it did"); *454 Life Scis. Corp.*, 2016 WL 6594083, at *5 (granting stay finding parties' status as competitors to not be "of overwhelming significance"); *Bio-Rad*, 2020 WL 2849989, at *2 ("The parties are competitors, but I do not think that any resulting prejudice from a stay would be 'undue.'"). Here, Plaintiff waited to file suit until well over a year after the Accused Product launched. *See* D.I. 12, ¶ 60 (alleging product launched in early 2024). Nor did Plaintiff seek primarily injunctive relief. Further, Defendants acted diligently in seeking PTAB review of the Patents-in-Suit, filing their Petitions within months of the commencement of

the lawsuit, and for the PGR Petitions, within less than a year of the patents' issuance. These facts each outweigh any potential competition between the parties. *See, e.g.*, *Ethicon*, 2019 WL 1276029, at *2-3 (analyzing similar factors and granting stay). The parties' status as purported competitors is not a significant factor warranting denial of a stay here.

In contrast, forcing the parties and the Court to address some of the same claim construction and invalidity issues ***in parallel*** with the PTAB Proceedings would be prejudicial to all stakeholders. *See Huvepharma*, 2019 WL 3802472, at *1 ("Plaintiffs contemplate having anticipation and obviousness tried twice, whereas a stay will mean that those issues will only need to be tried once."). Indeed, allowing the PTAB Proceedings and the instant action to proceed in parallel creates a significant risk of inconsistent outcomes, which would only inject confusion into this case.

V. CONCLUSION

For the foregoing reasons, the Court should stay the instant action pending conclusion of the PTAB Proceedings regarding the Patents-in-Suit.

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Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

/s/ Amy M. Dudash

John V. Gorman (DE Bar No. 6599)
Amy M. Dudash (DE Bar No. 5741)
1201 N. Market Street, Suite 2201
Wilmington, DE 19801
Telephone: 302.574.3000
Fax: 302.574.3001
john.gorman@morganlewis.com
amy.dudash@morganlewis.com

Ali Razai (*pro hac vice*)
Brandon G. Smith (*pro hac vice*)
600 Anton Boulevard, Suite 1800
Costa Mesa, CA 92626
Telephone: 714.830.0600
Fax: 714.830.0700
ali.razai@morganlewis.com
brandon.g.smith@morganlewis.com

Krista Vink Venegas (*pro hac vice*)
110 N. Wacker Drive, Suite 2800
Chicago, IL 60606
Telephone: 312.324.1000

Attorneys for Defendants Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.

Fax: 312.324.1001
krista.venegas@morganlewis.com

Jack Hendershott (*pro hac vice*)
101 Park Avenue
New York, NY 10178
Telephone: 212.309.6000
Fax: 212.309.6001
jack.hendershott@morganlewis.com