

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

MODERNATX, INC. and MODERNA US, INC.,

Plaintiffs,

v.

PFIZER INC., BIONTECH SE, BIONTECH
MANUFACTURING GMBH, and BIONTECH US
INC.,

Defendants.

Case No. 1:22-cv-11378-RGS

**DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR
MOTION TO STAY PENDING FINAL DETERMINATION OF INSTITUTED IPRS**

This case should be stayed in light of a material change in the litigation landscape. On March 19, 2024, an arm of the Patent Office—the Patent Trial and Appeal Board (“PTAB”)—publicly docketed its decisions instituting *inter partes* review (“IPR”) of United States Patent Nos. 10,702,600 (“the ’600 patent”) and 10,933,127 (“the ’127 patent”), two of the three patents asserted in this litigation.¹ The PTAB found that there was “compelling” evidence suggesting that the Patent Office “materially erred” in issuing the patents. Ex. 1, *BioNTech SE & Pfizer Inc. v. ModernaTX, Inc.*, IPR2023-01358, Paper 19 at 14-15 (P.T.A.B. Mar. 19, 2024) (“the ’600 patent Institution Decision”); Ex. 2, *BioNTech SE & Pfizer Inc. v. ModernaTX, Inc.*, IPR2023-01359, Paper 20 at 15 (P.T.A.B. Mar. 19, 2024) (“the ’127 patent Institution Decision”). As a result, the PTAB rejected Moderna’s objections and instituted *inter partes* review. In light of

¹ The PTAB’s Institution Decisions are attached as Exhibit 1 and 2 to the Declaration of Gabrielle M. Landes (“Landes Decl.”). Exhibit (“Ex.”) cites herein refer to exhibits in this declaration.

those decisions, Pfizer and BioNTech request that the Court stay this litigation for the reasons set forth below.

Moderna obtained the three patents-in-suit² after Pfizer and BioNTech had designed their COVID-19 vaccine to combat the pandemic, and announced their work on the vaccine to the public. Then, without any prior accusation, Moderna sued Pfizer and BioNTech for patent infringement on August 26, 2022. In response, Pfizer and BioNTech—in addition to challenging the validity of the asserted claims in this Court—exercised their statutory right, under 35 U.S.C. § 311(a), to petition the PTAB to reconsider its grant of two of Moderna’s incredibly broad patents-in-suit.

In exercising its opportunity to be heard before the PTAB as to whether *inter partes* review was warranted, Moderna urged the PTAB to decline to institute *inter partes* review both as a procedural matter under *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (precedential),³ and on the merits of Pfizer and BioNTech’s invalidity challenge. The PTAB considered Moderna’s procedural arguments—including the current case schedule, work completed to date, and the likely trial date—and found that the *Fintiv* factors favored exercising discretion to decline instituting trial. Nevertheless, the PTAB decided to institute review of the ’600 and ’127 patents notwithstanding the litigation before this Court. The PTAB did so expressly because it found the merits of Pfizer and BioNTech’s invalidity challenge to be “compelling,” meaning that “the evidence, if unrebutted in trial, would plainly lead to a conclusion that one or

² U.S. Patent No. 10,898,574 (Moderna claims it relates to a discovery of 1-methylpseudouridine), granted January 26, 2021, and U.S. Patent Nos. 10,702,600 and 10,933,127 (Moderna claims they cover any mRNA encoding any betacoronavirus spike protein or parts thereof), granted July 7, 2020 and March 2, 2021, respectively.

³ *Fintiv* provides a set of factors the PTAB reviews when it considers (in its discretion) whether to deny review because there is a pending parallel litigation relating to the same patent(s).

more claims are unpatentable by a preponderance of the evidence.” Ex. 1 at 14-15, 18 (quoting Ex. 3, Vidal Guidance Memorandum, USPTO (June 21, 2022), https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621.pdf at 4); *see also* Ex. 2 at 15, 18 (similar). The PTAB also concluded that the “[Patent] Office materially erred” in allowing the challenged patents to issue and that review by the PTAB was warranted despite the existence of this parallel litigation:

Turning to the second part of the *Advanced Bionics* framework, based on the present evidentiary record, we determine that the Office materially erred in allowing the challenged claims. Even if the Office was previously presented with Schrum and Geall, there is no indication that the Examiner appreciated the full scope of their disclosures. Further, as explained in Section III, we find that Petitioner has made a compelling merits showing at this stage for at least Ground 2, based on the alleged obviousness of the challenged claims over the combined teachings of Schrum and Geall. The strength of Petitioner’s threshold showing on this ground supports a conclusion that the Office erred in overlooking those references’ material teachings in route to allowing the claims of the ’127 patent without a single prior art rejection being made.

Ex. 2 at 15; *see also* Ex. 1 at 14-15. Given the PTAB’s finding of a compelling merits challenge—and the resulting high likelihood that the PTAB could narrow this case from three patents to one—Pfizer and BioNTech respectfully move to stay this litigation pending the PTAB’s decision.

As prefaced on the parties’ meet-and-confer, Moderna will no doubt argue that the PTAB’s institution decisions or Pfizer and BioNTech’s motion have come too late, or that the invalidity grounds in the two proceedings are separate. Pfizer and BioNTech do not dispute that they did not file a stay motion at the same time they filed their *inter partes* review petitions, before the PTAB made its institution decision. Pfizer and BioNTech also do not dispute that they continued to defend against Moderna’s claims of patent infringement in this litigation as they worked toward preparing to petition the PTAB. But now, having the benefit of the PTAB’s expert

review of the '600 and '127 patents, Pfizer and BioNTech file this motion to (1) alert the Court to this development; (2) explain how it materially implicates what will happen in the pending district court dispute between the parties, and (3) ask the Court to simplify these proceedings by granting a stay.

As further explained below, whether Pfizer and BioNTech ultimately win or lose before the PTAB, the result will unquestionably narrow the scope of the litigation. This Court and the Massachusetts citizens called to serve on the jury should not be required to spend time considering numerous, complex issues regarding the '127 and '600 patents when the PTAB has expressed a likelihood that these patents will not survive its invalidity analysis—and did so with powerful language. In particular, the PTAB preliminarily determined that Pfizer and BioNTech's invalidity case is "compelling" and that the Examiner "materially erred" by allowing these patents to issue. Ex. 1 at 14-15; Ex. 2 at 15. And, as this case boils down to a demand by Moderna for money on recently issued patents, there is no prejudice in a delay of definite length, as the PTAB is required by statute to issue its final decision by March 6, 2025. In weighing Moderna's demand for money now versus the cost to the Court and public if Pfizer and BioNTech prevail before the PTAB (which is now likely according to the PTAB's institution decision), concern for the wasted public resources should prevail.

Put simply, allowing the PTAB to issue its final determination, before continuing this case means that efficiencies go up and the risks of wasting time and effort go down, all at no prejudice to Moderna. Thus, for these reasons and the reasons below, Pfizer and BioNTech respectfully move the Court to stay this case until the PTAB issues its final determination on its *inter partes* reviews of U.S. Patent Nos. 10,702,600 and 10,933,127.

I. BACKGROUND

Plaintiffs ModernaTX, Inc. and Moderna US, Inc. (“Moderna”) sued Defendants BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech US Inc. (collectively, “BioNTech”) and Pfizer Inc. (“Pfizer”) on August 26, 2022. *See generally* D.I. 1, Compl. Moderna has alleged that three of its patents—U.S. Patent Nos. 10,898,574 (“the ’574 patent”), 10,702,600 (“the ’600 patent”), and 10,933,127 (“the ’127 patent”)—cover BioNTech’s and Pfizer’s COVID-19 vaccine, Comirnaty®. *Id.* at ¶¶ 84, 105, 123. The parties have completed fact discovery and are currently exchanging expert reports, with expert discovery closing on June 7, 2024. D.I. 62, Scheduling Order. Opening dispositive-motion briefs are due June 28, 2024. *Id.* The Court has informed the parties that a trial date will be set after resolution of dispositive motions. *See* D.I. 225, Order Den. Moderna’s Mot. to Set a Trial Date.

On August 28, 2023, Pfizer and BioNTech timely petitioned the PTAB to initiate *inter partes* review of the ’600 and ’127 patents in view of specific prior art grounds. As the Court is aware, an *inter partes* review is a trial proceeding conducted at the Patent Office before the PTAB to review the patentability of one or more claims in an issued patent. *See Inter Partes Review*, USPTO, <https://www.uspto.gov/patents/ptab/trials/inter-partes-review> (last visited Mar. 23, 2024). Under 35 U.S.C. § 314(a), the PTAB “may not authorize an *inter partes* review to be instituted” unless the petitioner demonstrates that “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

Moderna filed a fulsome opposition to Pfizer’s and BioNTech’s petitions on December 7th and 8th, arguing that Pfizer and BioNTech had not shown a reasonable likelihood that they would prevail on any of the challenged claims because the cited prior art did not, according to Moderna, render any claim invalid. *BioNTech SE & Pfizer Inc. v. ModernaTX, Inc.*, IPR2023-01358, Paper 8 at 1-3 (P.T.A.B. Dec. 8, 2023); *BioNTech SE & Pfizer Inc. v. ModernaTX, Inc.*,

IPR2023-01359, Paper 9 at 1-3 (P.T.A.B. Dec. 7, 2023). Moderna also raised a procedural challenge, arguing for denial under *Fintiv* in view of the parallel litigation before this Court. *See* Exs. 1 and 2. Thereafter, the PTAB granted the parties additional briefing on (1) discretionary denial under *Fintiv* and (2) statements in Moderna’s opposition submission that Pfizer and BioNTech identified as inconsistent with Moderna’s own previous representations to the Food & Drug Administration (“FDA”), in contravention of governing regulations. *See* 87 Fed. Reg. 45764–67 (July 29, 2022) (dictating that “[f]or instance, in PTAB proceedings, parties should not take a position about the patentability of challenged claims that is inconsistent with positions taken in submissions to other Government agencies regarding the same subject matter”); Ex. 1 at 71 n.31 (discussing regulation and its application here).

On March 6, 2024, the PTAB granted Pfizer’s and BioNTech’s petitions.⁴ Exs. 1 and 2. The PTAB found that most of the *Fintiv* factors counseled in *favor* of exercising its discretion to *deny* the petitions. Ex. 1 at 29; Ex. 2 at 29. The PTAB nevertheless decided to institute trial because Pfizer and BioNTech had “made a compelling merits showing” of unpatentability, and that the Patent Office “materially erred in allowing the challenged claims,” outweighing the discretionary considerations. Ex. 1 at 14-15; Ex. 2 at 15. In doing so, the PTAB also found that Moderna’s previous representations to the FDA contradicted the positions that Moderna took before the PTAB. Ex. 1 at 58, 60. For example, the PTAB noted that “[Moderna]’s arguments regarding skepticism of mRNA vaccines appear to be, on the present record, undermined by the very art [Moderna] cites as well as by its own statements to the FDA.” Ex. 1 at 58. Similarly, the PTAB was persuaded that Moderna’s “own representations, including to the FDA, suggest that prior studies with DNA and saRNA [self-amplifying mRNA] delivery systems are

⁴ These decisions were made public on March 19, 2024.

informative—supporting a ‘proof of concept’ with mRNA vaccines encoding a spike protein,” contrary to what Moderna said in its submission. Ex. 1 at 60; *see also id.* at 71-72 (describing an aspect of Moderna’s argument as “disingenuous” in light of Moderna’s representations to the FDA). Consequently, the PTAB instituted *inter partes* review of all claims of the ’600 and ’127 patents challenged by Pfizer and BioNTech and asserted by Moderna in this litigation. The claims now subject to the PTAB’s review constitute over 75% of the claims at issue before this Court:

Patent No.	Asserted Claims	Instituted Claims
U.S. Patent No. 10,702,600	1, 2, 4–6, 8–12, 16, 17, 20, 21, 26	1, 2, 4–6, 8–12, 16, 17, 20, 21, 26
U.S. Patent No. 10,933,127	1–3, 6–9, 11–13, 17, 18, 20	1–3, 6–9, 11–13, 17, 18, 20
U.S. Patent No. 10,898,574	1-4, 6-10	N/A

Under 35 U.S.C. § 316(a)(11), the PTAB’s final determination is due one year after institution, which means the PTAB’s final determination on the ’600 and ’127 patents is expected by March 6, 2025.

II. LEGAL STANDARD

The Court has broad discretion in controlling its own docket, including the inherent power to stay proceedings. *See Clinton v. Jones*, 520 U.S. 681, 706 (1997); *Murata Mach. USA v. Daifuku Co.*, 830 F.3d 1357, 1362 (Fed. Cir. 2016) (citing *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936)); *ACQIS, LLC v. EMC Corp.*, 109 F. Supp. 3d 352, 355–56 (D. Mass. 2015) (citing *Landis*, 299 U.S. at 254 and *Ethicon Inc. v. Quigg*, 849 F.2d 1422, 1426-27 (Fed. Cir. 1988)). Here, the motion is brought in the face of instituted *inter partes* review proceedings.

The purpose of *inter partes* review is to allow the Patent Office, “an executive agency with specific authority and expertise in patent law” to “reconsider its own decisions,” thereby “establish[ing] a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs.” *MCM Portfolio LLC v. Hewlett-Packard Co.*, 812 F.3d 1284, 1290-91 (Fed. Cir. 2015) (internal quotations omitted). Thus, while

the decision to stay is made on a case-by-case analysis based on the totality of the circumstances, *ACQIS*, 109 F. Supp. 3d at 356, courts generally recognize a “liberal policy” in favor of staying cases pending PTAB review of issued patents, including *inter partes* review. *Downing Wellhead Equip., LLC v. Intelligent Wellhead Sys., Inc.*, No. 1:23-cv-01180, 2024 WL 625372, at *6 (D. Colo. Feb. 14, 2024) (analyzing legislative history).

Courts typically consider three factors in deciding whether to stay a district court proceeding pending an IPR:

- (1) the stage of the litigation, including whether discovery is complete and a trial date has been set;
- (2) whether a stay will simplify the issues in question and the trial of the case; and
- (3) whether a stay will unduly prejudice or present a clear tactical disadvantage to the nonmoving party.

Teva Pharms. Int’l GmbH v. Eli Lilly & Co., No. 18-cv-12029-ADB, 2019 WL 1767394, at *6 (D. Mass. Apr. 22, 2019).

III. ARGUMENT

Each of the above three factors courts consider on motions like this one supports a stay. A stay will save the Court and the parties from having to expend resources on dispositive motions or pretrial work on two patents that are likely invalid. Likewise, should the case get there, a stay will save the jury and the Court from having to consider these patents and the complex issues that they present at trial. Even if, contrary to the PTAB’s initial decision, Moderna is able to overcome the “compelling” merits and one or more claims survive *inter partes* review, the final written decision will nevertheless simplify the issues remaining before this Court. And, because Moderna is seeking money damages only (and not injunctive relief), there is also no prejudice to Moderna due to the requested stay.

A. Factor 1: The PTAB’s strong signal on the merits supports a stay

Even when a case has already proceeded to discovery, courts in this District recognize that there are substantial efficiencies to be gained from a stay pending IPR. *See ACQIS*, 109 F. Supp. 3d at 357. In *ACQIS*, a court in this District granted a stay “[n]otwithstanding the fact that substantial document and written discovery has already occurred, and a claim construction opinion has been issued, [because] a significant amount of work still remains to be done by the parties and this Court. Other courts have stayed cases that were further along than this one pending IPR.” *Id.* (collecting cases). Other courts in this Circuit have found this factor to be neutral at this stage of the litigation. *See SurfCast, Inc. v. Microsoft Corp.*, No. 2:12-CV-333-JDL, 2014 WL 6388489, at *2 (D. Me. Nov. 14, 2014) (finding this factor neutral where, on one “hand, discovery is complete, a *Markman* order has been issued,” but on the other “hand, a trial date has not been set and a large volume of work remains before trial including the resolution of the pending summary judgment, *Daubert*, and other motions, as well as likely motions in limine and other pre-trial proceedings”).

Here, the work that remains for the parties and for the Court—including dispositive motions, *Daubert* motions, pretrial disclosures, and trial—is significant, warranting a stay. *See e.g., Dentsply Sirona, Inc. v. Edge Endo, LLC*, No. 1:17-cv-01041, 2018 WL 4773369, at *2 (D.N.M. Oct. 3, 2018) (“Although progress has been made in this case, the substantial and significant work *remaining* in this case weighs toward granting the stay.”) (emphasis in original). Consequently, given that “a stay could conserve the resources of the parties and the Court,” this factor should weigh in favor of a stay. *See DiversiTech Corp. v. RectorSeal, LLC*, No. CV 20-11896-NMG, 2021 WL 2953324, at *2 (D. Mass. July 14, 2021).

Although the PTAB’s institution decisions are not final, the detailed findings—specifically that material errors were made in granting the patents and the petitions presented compelling merits

challenges—are significant. A stay will therefore conserve resources and avoid wasted time and effort on behalf of the parties and this Court.

B. Factor 2: The case will be simplified after the PTAB issues its final written decisions

The second factor—simplification—also favors a stay. Where the PTAB finds the petitioner has raised a compelling case on the merits, “there is a significant likelihood of simplification, given that the PTAB had found there is not only a reasonable likelihood of unpatentability, but also a compelling unpatentability challenge.” *Speir Techs. Ltd. v. Apple, Inc.*, No. 5:23-cv-00095-EJD, 2023 WL 2714931, at *2 (N.D. Cal. Mar. 30, 2023) (internal quotations omitted). This is particularly so where, like here, the PTAB’s conclusions were also supported by Moderna’s own submissions to the FDA that contradicted arguments made by Moderna to the PTAB. The PTAB, in short, looked at the totality of the evidence before it at the institution stage and found a compelling case that the Patent Office erred in granting the patents.

If the PTAB cancels the challenged claims, two of the three asserted patents and 28 of the 37 asserted claims (75 %) will drop out of this case. This narrowing would greatly simplify the issues before the Court. Courts in this District have granted a stay even where the IPR proceedings “do not involve all asserted patents or claims[.]” *ACQIS*, 109 F. Supp. 3d at 358; *see also Koninklijke Philips N.V. v. Wangs Alliance Corp.*, No. 1:14-cv-12298-DJC, Dkt. 156 (D. Mass. Jan. 19, 2016) (granting stay where IPR was instituted for six of the eight patents-in-suit, concluding that “IPR is likely to narrow this case in some way—saving time and effort in the long-run—and the parties and the Court can then proceed with this narrower scope through the remainder of the litigation”).

By way of a non-exhaustive list of savings, dispositive motions and trial would be streamlined in the likely event that the PTAB invalidates the ’600 and ’127 patents. For example,

the numerous arguments related to the now-construed claim terms “betacoronavirus,” “S Protein,” and “open reading frame” would not need to be presented to the Court or jury. The ’600 and ’127 patents also raise significant issues about the breadth of the claims reciting those terms—as *Markman* showed—with the Examiner having expressly stated he was interpreting the patents in a manner that would exclude the COVID-19 vaccine. *See* D.I. 76, Defs.’ Opening Claim Construction Br., at Exhibit K and Exhibit L. Focusing on only one patent and its disclosures would streamline any dispositive motions and, if necessary, trial. The two named inventors of the ’600 and ’127 patents would no longer be needed at trial, and the disputes over the prior art’s teaching about betacoronavirus vaccines and the scope of the ’600 and ’127 patents would similarly be eliminated.

Even in the unlikely event that the PTAB upholds one or more of the challenged claims, the issues in this case will still be simplified, because the PTAB’s final written decision will trigger estoppel provisions that will limit arguments available to Pfizer and BioNTech to only those which could not have been raised in the IPR. *See* 35 U.S.C. § 315(e)(2). Furthermore, the Court will have the benefit of the PTAB’s decision and analysis. *PersonalWeb Techs., LLC v. Apple, Inc.*, 69 F. Supp. 3d 1022, 1027-28 (N.D. Cal. 2014) (“Either the claims, already found reasonably likely to be invalid, will become moot, or the Court will have the benefit of the PTAB’s findings. Under both outcomes, the issues in question and trial of the case will be simplified.”).

C. Factor 3: Moderna will not be unduly prejudiced or tactically disadvantaged by a stay because it took them years to even obtain their patents and they admittedly seek money damages only

The final factor also favors a stay because Moderna faces no undue prejudice. Moderna is seeking money damages only, not injunctive relief. D.I. 1, Compl. at ¶ 28 (“[T]his lawsuit is narrowly drawn in terms of the relief it seeks. Moderna is not seeking an injunction: it is not

seeking to remove Comirnaty® from the market or to prevent its future sale.”). This undermines any claim Moderna may make of undue prejudice. *ACQIS*, 109 F. Supp. 3d at 358 (“ACQIS did not seek a preliminary injunction in this case, undermining its claim of undue prejudice.”). Even if Moderna ultimately prevails after a stay, the delay will not affect the ultimate judgment it seeks. Moderna’s theory of prejudice articulated during the parties’ meet-and-confer—delay in resolving its claim for infringement—is therefore unavailing.⁵ “In assessing a request for a stay pending IPR, mere delay does not rise to the level of undue prejudice.” *ACQIS*, 109 F. Supp. 3d at 358 (internal quotations omitted).

That the parties are competitors also does not equate to undue prejudice given the absence of any request for injunctive relief. *Teva Pharms. Int’l GmbH*, 2019 WL 1767394, at *8 (“Where relief from the injuries flowing from the alleged infringement will not be impaired by a stay, the undue prejudice factor is not overborne by the fact of the parties’ business relationship alone. . . . Teva has not sought a preliminary injunction. There is no indication that the imposition of a stay at this time will cause Teva to lose any presently available legal remedies, such as money damages.” (internal citations omitted)).

Finally, the parties are well funded. As is well known, the COVID-19 vaccines generated billions of dollars in revenue—for both sides. Moderna has a large cash reserve and billions in projected revenue,⁶ and a stay will not impact Moderna’s ability to recover in the unlikely event it

⁵ Particularly so in view of the PTAB’s statutory deadline to provide a final written decision by March 2025.

⁶ Press Release, Moderna, Moderna Reports Fourth Quarter and Fiscal Year 2023 Financial Results and Provides Business Updates (Feb. 22, 2024), <https://investors.modernatx.com/news/news-details/2024/Moderna-Reports-Fourth-Quarter-and-Fiscal-Year-2023-Financial-Results-and-Provides-Business-Updates/default.aspx>.

obtains a favorable judgment in this case. *See Teva Pharms. Int'l GmbH*, 2019 WL 1767394, at *8 (“Any delay to a party’s recovery of money damages is not meaningful where the prevailing party in patent cases may recover prejudgment interest.”) (cleaned up).

IV. CONCLUSION

Given the significant likelihood of gained efficiencies, simplification of the issues, and conservation of public resources, Pfizer and BioNTech respectfully request the Court stay this case until the PTAB issues its final written decision on its *inter partes* review of U.S. Patent Nos. 10,702,600 and 10,933,127.

Dated: March 27, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Gregory M. Boucher, hereby certify that on March 27, 2024, I caused the foregoing motion to be electronically filed with the Clerk of the Court using the CM/ECF system, which will simultaneously serve notice of such filing to counsel of record to their registered electronic mail addresses.

/s/ Gregory M. Boucher

Gregory M. Boucher (BBO# 665212)