

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ETHICON, INC.,  
Petitioner,

v.

BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM,  
Patent Owner.

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IPR2019-00406  
Patent 6,596,296 B1

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Before SUSAN L. C. MITCHELL, AVELYN M. ROSS,  
KRISTIL R. SAWERT, *Administrative Patent Judges.*

ROSS, *Administrative Patent Judge.*

DECISION  
Denying Institution of *Inter Partes* Review  
35 U.S.C. § 314, 37 C.F.R. § 42.4

## I. INTRODUCTION

Ethicon, Inc. (“Petitioner”) filed a Petition (Paper 2, “Pet.”) requesting *inter partes* review of claims 1, 4, 11, 16, 17, 20, and 26 of U.S. Patent No. 6,596,296 B1 (Ex. 1001, “the ’296 patent”). The Board of Regents, The University of Texas System (“Patent Owner”) filed a Preliminary Response to the Petition (Paper 26, “Prelim. Resp.”).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. § 42.4(a). The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted “unless the Director determines . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition.”

For the reasons set forth below, upon considering the Petition and evidence of record, we determine that it is appropriate to exercise discretion under § 314(a). Accordingly, we deny the Petition, and do not institute an *inter partes* review.

### A. Related Proceedings

Petitioner identifies the pending district court litigation styled *Board of Regents, The University of Texas System et al. v. Ethicon, Inc. et al.*, 1:17-cv-01084 (W.D. Tex.) (“the Western District of Texas litigation” in the “Western District of Texas”). Pet. 2, *see also* Patent Owner’s Mandatory Notices, Paper 7, 1. Petitioner also identifies its co-pending petition, seeking to institute *inter partes* review of U.S. Patent No. 7,033,603 (“the ’603 patent”) as a related proceeding, and states that the ’603 patent is a continuation-in-part of the ’296 patent. Pet. 2–3; IPR2019-00407, Paper 2; *see also* Patent Owner’s Mandatory Notices, Paper 7, 1.

The '296 patent is asserted against other defendants in the following pending litigations:

*Board of Regents, The University of Texas System et al. v. Boston Scientific Corporation*, 1:18-cv-00392 (D. Del.);

*Board of Regents, The University of Texas System et al. v. Medtronic, Inc. et al.*, No. 1:17-cv-00942 (W.D. Tex.) (dismissed without prejudice on July 19, 2018).

Pet. 3–4; *see also* Patent Owner's Mandatory Notices, Paper 7, 1. The '296 patent is also the subject of a separate petition for *inter partes* review styled *Medtronic, Inc. et al. v. Board of Regents, the University of Texas System et al.*, IPR2019-00037, Paper 2 (PTAB Oct. 9, 2018).

#### *B. The '296 Patent*

The '296 patent, titled “Drug Releasing Biodegradable Fiber Implant,” issued on July 22, 2003.<sup>1</sup> Ex. 1001, codes (45), (54). The '296 patent is directed to tissue engineering compositions and, in particular to, “biodegradable polymer fibers capable of the controlled delivery of therapeutic agents.” *Id.* at 2:41–45.

According to the '296 patent, “there are several primary avenues investigators are using to engineer tissues” that include creating a scaffold in the form of a three-dimensional polymer network. *Id.* at 1:20–26. “[T]he scaffold may be biodegradable, meaning that over time it will break down both chemically and mechanically.” *Id.* at 1:49–51. “[A] polymer scaffolding provides not only the mechanical support, but also the three-dimensional shape that is desired for the new tissue.” *Id.* at 2:15–18. The

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<sup>1</sup> The '296 patent claims priority to U.S. provisional application No. 60/147,827, which was filed on August 6, 1999. Ex. 1001, code (60). The specific priority date of the challenged claims currently is not at issue in this proceeding, and we need not make any determination in this regard.

'296 patent purports that “[m]ost current methodologies provide no specific means of actively assisting the incorporation of blood vessels into and throughout the polymer matrix.” *Id.* at 2:21–23. In contrast, “[t]he present invention provides compositions and methods that promote the directed migration of appropriate cell types into the engineered extracellular matrix.” *Id.* at 2:27–30.

The '296 patent describes creating heterogeneous scaffolds by encapsulating therapeutic agents into individual fibers of a three-dimensional fiber matrix. *Id.* at 8:32–35. “The therapeutic agents are released from each individual fiber slowly, and in a controlled manner.” *Id.* at 8:36–37.

The '296 patent describes processes for fabricating polymer fibers containing therapeutic agents. *Id.* at 17:36–19:36 (Example 1). “First, a biodegradable polymer . . . [is] dissolved in some appropriate solvent (A) at concentrations ranging from 5 to 30 wt % . . . In this embodiment, solvent (A) has low miscibility with water, and is very miscible with the coagulation bath solvent (B).” *Id.* at 17:42–50. The biodegradable polymer may include “poly(L-lactic acid) (PLLA), poly(DL-lactic acid), polycaprolactone, poly(glycolic acid), polyanhydride, or copolymers or blends of these or other biodegradable polymers.” *Id.* at 17:43–46. “Once the polymer is dissolved, an aqueous solution containing both the biomolecules(s) of interest and a surfactant, is added to the polymer solution.” *Id.* at 17:52–54. “Using some form of mechanical energy such as sonication, vortexing, or shear forces generated by forcing the liquid through a small orifice, a water-in-oil type emulsion is formed between the aqueous and organic phases.” *Id.* at 18:1–4.

The '296 patent further describes extruding the formed emulsion into a coagulation bath containing solvent (B). *Id.* at 18:12–13. “Solvent (B)

must be highly miscible with solvent (A), and must be a non-solvent for the polymer.” *Id.* at 18:14–16. The ’296 patent explains that:

Because solvent (A) is highly miscible with coagulating bath solvent (B), it freely diffuses from the polymer solution stream, into the coagulating bath. The polymer, however, is not soluble in solvent (B), and therefore begins to precipitate upon itself, forming the outer sheath of a fiber and trapping virtually all of the dispersed aqueous phase of the emulsion within the forming fiber. In this way, the fiber is loaded with the drug or protein of interest.

*Id.* at 18:22–30. “Preferred choices of solvent (A) include chloroform and methylene chloride.” *Id.* at 17:51–52. Examples of solvent (B) include isopropyl alcohol and hexane. *Id.* at 18:15–22.

### C. Illustrative Claims

Petitioner challenges claims 1, 4, 11, 16, 17, 20, and 26 of the ’296 patent. Independent claim 1 is the only independent claim challenged and is reproduced below.

1. A composition comprising at least one biodegradable polymer fiber wherein said fiber is composed of a first phase and a second phase, the first and second phases being immiscible, and wherein the second phase comprises one or more therapeutic agents.

Ex. 1001, 27:54–58.

### D. The Asserted Unpatentability Challenges

Petitioner asserts that claims 1, 4, 11, 16, 17, 20, and 26 would have been unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C.	Reference(s)/Basis
1, 11, 16, 17, 26	§§ 102 and 103	Song <sup>2</sup>
4, 20	§ 103	Song

<sup>2</sup> Song, US 5,364,627, issued November 15, 1994 (Ex. 1005, “Song”).

<b>Claim(s) Challenged</b>	<b>35 U.S.C.</b>	<b>Reference(s)/Basis</b>
4	§ 103	Song, Billmeyer, <sup>3</sup> Curatolo <sup>4</sup>
20	§ 103	Song, Sidman <sup>5</sup>
1, 4, 11, 16, 17, 20, 26	§§ 102 and 103	Choi <sup>6</sup>

Petitioner also relies on declaration testimony of David J. Mooney, Ph.D. (Ex. 1002, “the Mooney Declaration”).

## II. ANALYSIS

### A. Discretion Under 35 U.S.C. § 314(a)

Patent Owner does not address the substance of Petitioner’s challenges. *See generally* Prelim. Resp. Rather, Patent Owner argues the Board should exercise its discretion and deny the Petition under 35 U.S.C. § 314(a). *Id.* at 3. Patent Owner explains that the co-pending district court litigation between Patent Owner and Petitioner “has now progressed significantly and a trial is scheduled to begin in approximately three months, on June 22, 2020.” *Id.* at 4 (citing Ex. 2004, 2); *but see* Ex. 3004 (providing notice to the Board that the trial date has been suspended). Patent Owner contends that “[g]iven the advanced stage of the district court litigation, a trial here will not serve as a ‘timely, cost-effective alternative to litigation’ (77 Fed. Reg. 48,680 (Aug. 14, 2012)), but rather as a duplicative proceeding that unnecessarily taxes the Board’s resources.” *Id.* at 5.

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<sup>3</sup> Fred W. Billmeyer, Jr., *Textbook of Polymer Science* 513–532 (2<sup>nd</sup> ed., John Wiley & Sons, Inc.) (1971) (Ex. 1008, “Billmeyer”).

<sup>4</sup> Curatolo, EP 0253554 A2, published January 20, 1988 (Ex. 1009, “Curatolo”).

<sup>5</sup> Sidman, US 4,351,337, issued September 28, 1982 (Ex. 1006, “Sidman”).

<sup>6</sup> Choi et al., US 4,093,709, issued June 6, 1978 (Ex. 1007, “Choi”).

We have discretion to deny a petition for *inter partes* review under § 314(a). *See* 35 U.S.C. § 314(a) (stating “[t]he Director may not authorize an *inter partes* review to be instituted unless . . . .”); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (“[T]he agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.”); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“First of all, the PTO is permitted, but never compelled, to institute an IPR proceeding.” (citing 35 U.S.C. § 314(a))). “[E]vents in other proceedings related to the same patent, either at the Office, in district courts, or the ITC,” may favor “denying a petition even though some claims meet the threshold standards for institution under 35 U.S.C. §§ 314(a).” Consolidated Trial Practice Guide (“Practice Guide”)<sup>7</sup> at 58 (citing *NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8, 11–21 (PTAB Sept. 12, 2018) (precedential). In weighing whether to exercise discretion we balance, *inter alia*, the following factors:

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision;
3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
6. other circumstances that impact the Board’s exercise of discretion, including the merits.

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<sup>7</sup> Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

*Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, 6 (PTAB Mar. 20, 2020) (precedential). We address the application of the *Fintiv* factors below.

1. *whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted*

The first *Fintiv* factor requires consideration of whether the district court has stayed or will stay the proceeding pending *inter partes* review. “A district court stay of the litigation pending resolution of the PTAB trial allays concerns about inefficiency and duplication efforts.” *See Fintiv*, IPR2020-00019, Paper 11, 6. Where a stay has been entered, we weigh this factor strongly against exercising discretion to deny instituting review. *Id.*

Patent Owner argues that the Western District of Texas temporarily stayed merits discovery but that stay was lifted on February 28, 2019—more than a year ago. Prelim. Resp. 2. Further, Patent Owner asserts that “[a]t no point did Ethicon request a stay of the district court case pending resolution of this IPR proceeding.” *Id.* at 3, 12 (“Ethicon never asked the district court to stay its proceeding.”).

We find that this factor does not weigh for or against discretionary denial in this case. Although the Western District of Texas did institute a stay for a discrete period of time, that stay was lifted more than a year ago and the case was allowed to proceed to near completion.<sup>8</sup> Prelim. Resp. 2. Further, there is no evidence to suggest that the Western District of Texas would entertain granting a stay at this late stage even if *inter partes* review were instituted. And, as Patent Owner notes, Petitioner did not seek a stay

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<sup>8</sup> We understand that trial was previously set to begin on June 22, 2020 and that recently the Western District of Texas indefinitely continued the current trial date because of the current pandemic. Ex. 3004, 2.



from the Western District of Texas pending resolution of this proceeding.  
*Id.* at 3.

2. *proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision*

Under the second *Fintiv* factor, “[i]f the [district] court’s trial date is earlier than the projected statutory deadline, the Board generally has weighed this fact in favor of exercising authority to deny institution.” *See Fintiv*, IPR2020-00019, Paper 11, 9.

Patent Owner contends that because trial before the Western District of Texas is presently set for June 22, 2020, “[i]f the Board elects to institute a trial in this matter, that trial is unlikely to conclude before June 2021—nearly a full year *after* the district court will have resolved the parties’ dispute.” Prelim. Resp. 4–5.

Until recently, trial was set to begin on June 22, 2020. This trial date “has been adjourned [and] [t]he trial date has not yet been reset.” Ex. 3004, 2; *see* Ex. 3005 (continuing the trial date); *see also* Supplemental Order Regarding Court Operations Under the Exigent Circumstances Created by the COVID-19 PANDEMIC, May 8, 2020 (W.D. Tex.) (continuing all trials “scheduled to begin on any date from [May 8, 2020] through June 30, 2020”). Though the Western District of Texas has continued the trial date indefinitely, the Court explained that

[t]his should be the number one case on all of your minds because it has been set for June 22<sup>nd</sup> for a long time. The mere fact that we have this pandemic and we may have to put it off only affects the trial date. It does not affect anything else in this case. . . . I expect you to quit working on anything else you might have and treat this case as if it were going to trial on June 22<sup>nd</sup>, because that’s where it has been set.

Ex. 3005, 9:23–10:6. The Court further explained that should the parties waive a jury demand, a trial “will happen sooner if it is scheduled as a bench trial than it will as a jury trial.” *Id.* at 14:20–24. According to the Court, the parties should expect trial to occur within a year. *See id.* at 17:21–23 (“What I’m telling you is that you will get reached in sooner than a year, in all likelihood.”). Both parties withdrew their request for a jury demand. *See* Ex. 3006. Were we to institute *inter partes* review, a final written decision in this proceeding would issue in June 2021—leaving a year before resolution of this proceeding. Given the Western District of Texas’ emphasis that the parallel litigation should proceed as if still set for June 22, 2020, and its expectation of holding a bench trial within a year, this factor weighs strongly in favor of discretionary denial in this case.

3. *investment in the parallel proceeding by the court and the parties*

The third *Fintiv* factor considers “the amount and type of work already completed in the parallel litigation by the [district] court and the parties at the time of the institution decision. Specifically, if at the time of the institution decision, the district court has issued substantive orders related to the patent at issue in the petition, this fact favors denial.” *See Fintiv*, IPR2020-00019, Paper 11, 9–10. Thus, the more advanced the parallel proceeding, the less likely we are to institute an *inter partes* review. *Id.* at 10.

Patent Owner argues that “[g]iven the advanced stage of the district court litigation, a trial here will not serve as a ‘timely, cost-effective alternative to litigation,’ but rather as a duplicative proceeding that unnecessarily taxes the Board’s resources.” Prelim. Resp. 5; *see also id.* at 2 (“[T]he district [court] case has moved forward significantly.”); 4 (“The litigation has now progressed significantly.”). By way of example, Patent

Owner contends that “the parties ha[ve] already completed claim construction discovery and the district court ha[s] issued its *Markman* order, (*id.* at 2)” and “both fact and expert discovery, and all dispositive motions have been filed (*id.*)” Therefore, Patent Owner reasons that a discretionary denial is appropriate. *Id.* at 5.

Here, the both the Western District of Texas and parties have engaged in considerable effort to advance the stage of the parallel litigation. All fact and expert discovery is complete (Prelim. Resp. 2), the parties fully briefed and the Western District of Texas issued a claim construction order (*id.*; Ex. 1018 (Markman Order), and dispositive motions have been filed (Prelim. Resp. 2; Ex. 2006 (Motion for Summary Judgment of Invalidity). We further observe that both motions to exclude and motions in limine have been fully briefed. *See Board of Regents, The University of Texas System et al. v. Ethicon, Inc. et al.*, 1:17-cv-01084 (LY), (W.D. Tex. May 8, 2020), Dkt. Nos. 119, 120 (motions to exclude), 156, 161 (motions in limine). Also, the parties are to file proposed findings of fact and conclusions of law no later than July 20, 2020. Ex. 3006 (Order Granting Motion to Continue). Therefore, because of the advanced stage of the Western District of Texas litigation—particularly at a time prior to institution of *inter partes* review—this factor weighs heavily in favor of exercising discretion to deny institution under § 314 (a).

4. *overlap between issues raised in the petition and in the parallel proceeding*

The fourth *Fintiv* factor requires consideration of “inefficiency and the possibility of conflicting decisions.” *See Fintiv*, IPR2020-00019, Paper 11, 12. Therefore, “if the petition includes the same or substantially the same claims, grounds, arguments, and evidence, as presented in the parallel

proceeding, this fact has favored denial.” *Id.* The *Fintiv* panel acknowledged that “the degree of overlap is highly fact dependent” and encouraged the parties “to indicate whether all or some of the claims challenged in the petition are also at issue in the district court.” *Id.* at 13.

Patent Owner argues that there is also significant overlap in the issues before the Board and that before the Western District of Texas. Prelim. Resp. 5–9. In particular, asserts “[t]he invalidity issues that the district court will consider and decide **overlap completely** with the invalidity issues that the Board is being asked to consider.” *Id.* at 6. According to Patent Owner, “Ethicon even offers the same expert—Prof. David J. Mooney—to address invalidity in both proceedings.” *Id.* at 8.

We determine that this factor weighs heavily in favor of exercising discretion under § 314(a). The claims challenged here are completely subsumed by those Petitioner seeks to invalidate in the Western District of Texas. *Compare* Pet. 8 (identifying claims 1, 4, 11, 16–17, 20, and 26 as challenged claims) *with* Ex. 2006, 12–28 (requesting summary judgment of invalidity for claims 1, 2, 4, 11, 16–17, 20, and 26). Furthermore, Ethicon relies on the same prior art combinations and the same expert in both its Petition and the parallel district court litigation. *Id.* Though Petitioner in the parallel litigation did not rely on the Curatolo reference (presented as an alternative reference to Billmeyer in the Petition (*see* Pet. 8)) in its summary judgment motion, Petitioner does include Curatolo in the invalidity contentions accompanying its Answer to the Amended Complaint. *See* Ex. 2007, Exhibit A. Accordingly, the posture and scope of the Western District of Texas litigation weighs strongly in favor of exercising discretion to deny institution under § 314(a).

5. *whether the petitioner and the defendant in the parallel proceeding are the same party*

According to the fifth *Fintiv* factor, “[i]f a petitioner is unrelated to a defendant in an earlier [district] court proceeding, the Board has weighed this fact against exercising discretion to deny institution.” *See Fintiv*, IPR2020-00019, Paper 11, 13–14. “Even when a petitioner is unrelated to a defendant, however, if the issues are the same as, or substantially similar to, those already or about to be litigated, or other circumstances weigh against redoing the work of another tribunal, the Board may, nevertheless, exercise the authority to deny institution.” *Id.* at 14.

Patent Owner asserts that both “Ethicon and [The University of Texas] are parties to the underlying district court litigation.” Prelim. Resp. 5. Petitioner and Patent Owner are the defendant and plaintiff, respectively, in the Western District of Texas litigation. *Id.*; *see* Exs. 2001, 2003, 2007. Therefore, we find that this factor weighs in favor of exercising discretion to deny instituting *inter partes* review.

6. *other circumstances that impact the Board’s exercise of discretion, including the merits*

Lastly, “all relevant circumstances,” including the merits, are considered in assessing whether to exercise discretion to deny institution of *inter partes* review. *Fintiv*, IPR2020-00019, Paper 11, 14.

Patent Owner asserts that Ethicon’s “lack of diligence” and “strategic choices” favor denial of *inter partes* review. Prelim. Resp. 11–13. In particular, Patent Owner explains that “Ethicon waited until ***four days before*** the one-year bar in 35 U.S.C. § 315(b) to file its Petition” and that it filed its Petition at a time when it “knew (or should have known) that the Board had suspended IPR proceedings involving State universities pending

resolution of the UMN Appeal.” *Id.* at 11. Patent Owner explains that even if the Board had not stayed this proceeding, “a final written decision in this proceeding would be due (coincidentally) on the same day that the district court trial would commence. Thus, the Board would still be considering the same issues that the district court was actively considering in parallel.” *Id.* at 12.

Without more, we do not view mere delay, until shortly before the statutory deadline to file a petition, as exhibiting lack of diligence or a strategic choice such that denial of *inter partes* review is appropriate. Thus, this factor does not weigh in favor of or against discretionary denial in this case.

#### 7. *summary*

Therefore, after considering all of the evidence and arguments presented, we determine that the factors weigh in favor of exercising discretion to deny institution. In weighing the factors, we determine that the advanced stage of the Western District of Texas litigation and the likelihood the parallel litigation will be concluded prior to any final written decision in this case, the identity of the parties in this and the parallel litigation, the near identity of the unpatentability grounds advanced by Petitioner in both the parallel proceeding and this proceeding, and the significant investment by the Western District of Texas, as well as the parties, in the parallel litigation to be particularly persuasive. Accordingly, we exercise discretion to deny institution of *inter partes* review.

#### B. *Sovereign Immunity*

Patent Owner also argues, that “[The University of Texas] is an arm of the state of Texas, and as such is immune from this administrative adjudicatory proceeding under Supreme Court precedent.” Prelim. Resp. 13.

Patent Owner “acknowledges that the Federal Circuit has ruled that states are not immune from IPR proceedings” and that “the Federal Circuit’s ruling is binding on this Board.” *Id.* (citing *Regents of the Univ. of Minn. v. LSI Corp.*, 926 F.3d 1327 (Fed. Cir. 2019), *cert. denied*, 140 S.Ct. 908 (U.S. Jan. 13, 2020)). Therefore, Patent Owner “will not expand on its sovereign immunity argument further here, but reserves its right to do so on appeal and/or in a cert. petition following any final written decision” and “[b]y defending itself on the merits of this proceeding, UT does not waive its right to be immune from this proceeding and from any decision this Board may render impacting UT’s ‘296 Patent.” *Id.* at 13–14.

Because we exercise discretion to deny institution of *inter partes* review under 35 U.S.C. § 314 (a), we need not reach Patent Owner’s sovereign immunity argument.

### III. CONCLUSION

For the foregoing reasons, we exercise discretion and deny the Petition. Accordingly, we do not institute *inter partes* review of the ’296 patent.

### IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, the Petition (Paper 2) is *denied* as to the challenged claims of the ’296 patent; and

FURTHER ORDERED that no *inter partes* review is instituted.

IPR2019-00406  
Patent 6,596,296 B1

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