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Paper No. 7
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORP. and EDWARDS LIFESCIENCES LLC,
Petitioners,

v.

EVALVE, INC.
Patent Owner.

IPR2019-01546
Patent 7,736,388 B2

Before SHERIDAN K. SNEDDEN, SUSAN L.C. MITCHELL, and DAVID COTTA, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Edwards Lifesciences Corporation and Edwards Lifesciences LLC ("Petitioners" or "Edwards") filed a Petition requesting an *inter partes* review of claims 1, 4, 6, 9–11, 14, 16–17, 20, 22, 25–28, 31, and 33–34 of U.S. Patent No. 7,736,388 B2 (Ex. 1001, "the '388 patent").[1] Paper 1 ("Pet."). Evalve, Inc. ("Patent Owner" or "Evalve") filed a Preliminary Response to the Petition. Paper 6 (Prelim. Resp.).[2]

Institution of *inter partes* review is authorized by statute only when "the information presented in the petition ... demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 35 U.S.C. § 314; *see* 37 C.F.R. § 42.4. For the reasons discussed below, upon consideration of the Petition, the Preliminary Response, and the supporting evidence, we exercise our discretion under 35 U.S.C. § 314(a) and deny institution of *inter partes* review.

A. Related Proceedings

Petitioner and Patent Owner both identify *Abbott Cardiovascular Systems, Inc., v. Edwards Lifesciences Corp.,* 1:19-cv-00149-MN (D. Del.) as relating to the '388 patent. Pet. 1; Paper 3, 2. Both parties also identify two additional patents, U.S. Patent Nos. 7,563,267 and 8,057,493, which are related to the '388 patent, for which Petitioner also requested *inter partes* review. *See* IPR2019-01132; IPR2019-01301. Pet. 1; Paper 3, 2. Both of

[1] Petitioner identifies Edwards Lifesciences Corporation and Edwards Lifesciences LLC as the real parties in interest. Pet. 1.
[2] Patent Owner identifies Evalve, Inc., the assignee of the '388 patent, and Abbott Cardiovascular Systems, Inc., the exclusive licensee of the '388 patent as real parties in interest. Paper 3, 2.

these requests for *inter partes* review were denied on the merits. *See* IPR2019-01132, Paper 15; IPR2019-01301, Paper 15.

In IPR2019-01479, involving the same parties and challenging U.S. Patent No. 7,288,907 B2 (which had also been asserted by Patent Owner in the above-referenced Delaware litigation), we recently denied institution of *inter partes* review under 35 U.S.C. § 314(a). IPR2017-01479, Paper 7. In that denial, we stated:

> In summary, Edwards's Petition includes issues that are substantially the same as issues, arguments, and evidence presented in the district court proceeding. The issues presented in the Petition that differ from what was argued in district court do not appear to meaningfully distinguish the arguments in this proceeding from those in [] the district court. The district court has expended substantial resources to gain familiarity with and resolve issues that are also the most dispositive issues presented in the Petition, and the district court is set to complete trial well before any *inter partes* review could be completed and a final decision from the Board would be issued. In these circumstances, consistent with the Board's precedential decision in *NHK Spring* [*Co., Ltd. v. Intri-Plex Technologies, Inc*., IPR2018-00752, Paper 8, 11–21 (PTAB Sept. 8, 2018) (precedential)], we exercise our discretion to deny institution under § 314(a).

Edwards Lifesciences Corp. v. Evalve, Inc., IPR2019-01479, Paper 7, 12–13 (PTAB Feb. 26, 2020).

B. The '388 Patent (Ex. 1001)

The '388 patent, entitled "Fixation Device and Methods for Engaging Tissue," generally relates to medical devices and methods "adapted for fixation of tissue at a treatment site." Ex. 1001, 3:31–32. More particularly, the '388 patent describes a medical device used to repair "cardiac valves, and particularly the mitral valve, as a therapy for regurgitation. The

invention enables two or more valve leaflets to be coapted using an 'edge-to-edge' or 'bow-tie' technique to reduce regurgitation, yet does not require open surgery through the chest and heart wall as in conventional approaches." *Id.* at 3:38–43. The '388 patent also states that the medical devices "are adapted to be reversible and removable from the patient at any point without interference with or trauma to the internal tissues." *Id*. at 3:27–29.

Figures 10A and 10B of the '388 patent set forth below show fixation device 14 in the closed position. *Id*. at 20:20–21, 28–30.

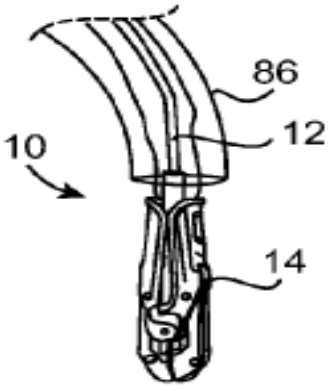

FIG. 10A

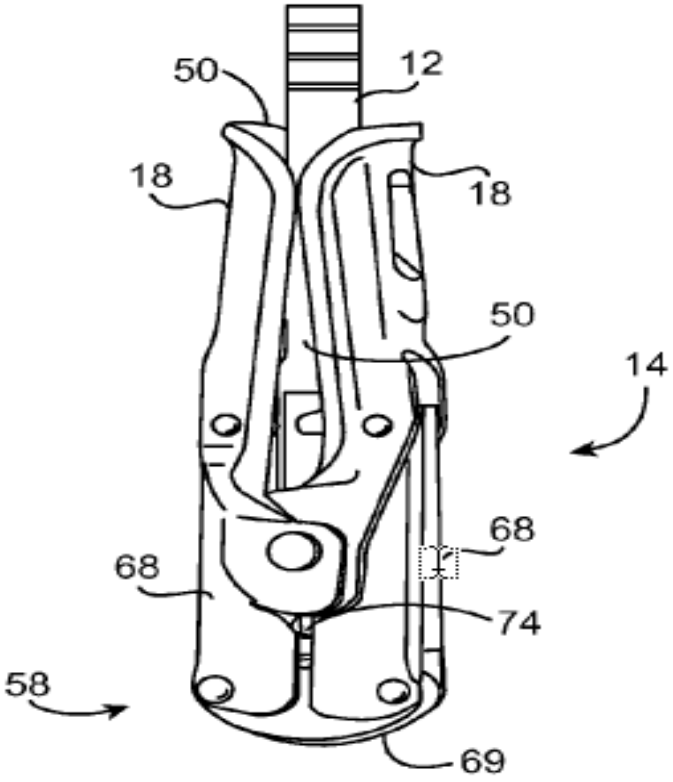

FIG. 10B

Figure 10A, set forth above, shows an embodiment of interventional tool 10 that includes fixation device 14 coupled to shaft 12 that is delivered through catheter 86 in the closed position. *Id*. at 20:20–28. Figure 10B is a larger view of Figure 10A and includes actuation mechanism 58 that moves

the distal elements between the open, closed, and inverted positions. *Id*. at 20:28–30, 38–51. These two figures are further described as follows.

> In the closed position, the opposed pair of distal elements 18 are positioned so that the engagement surfaces 50 face each other. Each distal element 18 comprises an elongate arm 53 having a cupped or concave shape so that together the arms 53 surround the shaft 12 and optionally contact each other on opposite sides of the shaft. This provides a low profile for the fixation device 14 which is readily passable through the catheter 86 and through any anatomical structures, such as the mitral valve. . . . [T]he actuation mechanism 58 comprises two legs 68 which are each movably coupled to a base 69. The base 69 is joined with an actuator rod 64 which extends through the shaft 12 and is used to manipulate the fixation device 14.

Id. at 20:30–43.

Figures 11A and 11B of the ’388 patent, set forth below, show fixation device 14 in the open position.

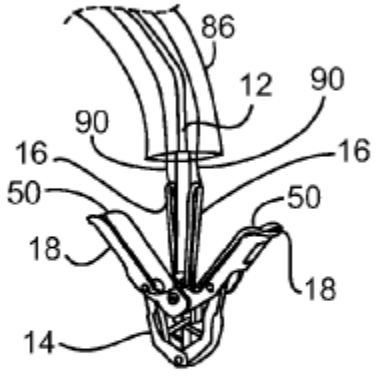

FIG. 11A

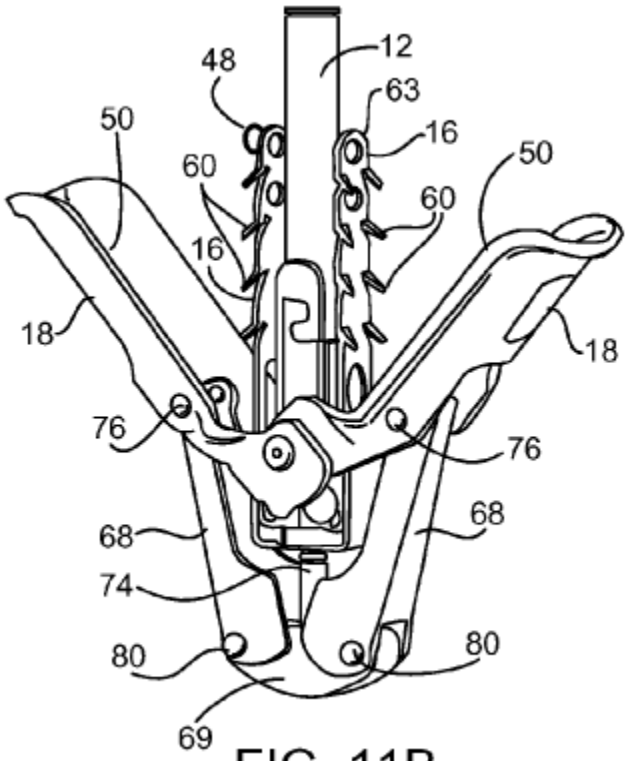

FIG. 11B

In this open position shown in Figures 11A and 11B above, fixation device 14 can engage the leaflets of the mitral valve to repair it. *Id*. at 21:35–50. To repair the mitral valve,

> interventional tool 10 is advanced through the mitral valve from the left atrium to the left ventricle. The distal elements 18 are oriented to be perpendicular to the line of coaptation and then positioned so that the engagement surfaces 50 contact the ventricular surface of the valve leaflets, thereby grasping the leaflets. The proximal elements 16 remain on the atrial side of the valve leaflets so that the leaflets lie between the proximal and distal elements. In this embodiment, the proximal element 16 have frictional accessories, such as barbs 60 which are directed toward the distal elements 18. However, neither the proximal elements 16 nor the barbs 60 contact the leaflets at this time.
>
> The interventional tool 10 may be repeatedly manipulated to reposition the fixation device 14 so that the leaflets are properly contacted or grasped at a desired location. Repositioning is achieved with the fixation device in the open position.

Id. at 21:39–55.

The ’388 patent also describes inverting fixation device 14 to aid in repositioning or removal of the device. *Id*. at 21:60–22:23. Figures 12A and 12B set forth below show fixation device 14 in the inverted position. *Id*. at 21:60–63.

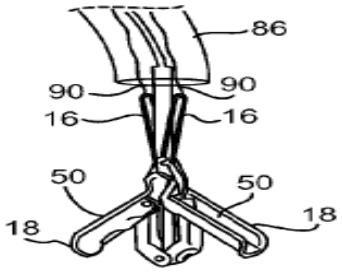

FIG. 12A

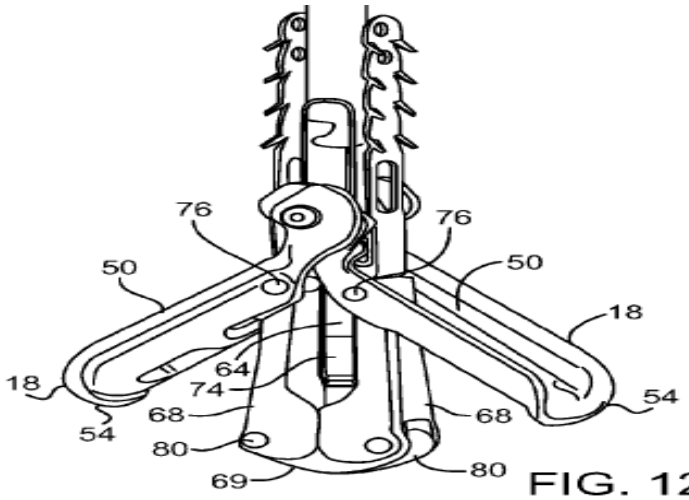

FIG. 12B

Figures 12A and 12B set forth above showing fixation device 14 in the inverted position demonstrate that by further advancing stud 74 relative to coupling member 19, distal elements 18 are further rotated so that the engagement surfaces 50 face outwardly and free ends 54 point distally, with each arm 53 forming an obtuse angle relative to shaft 12. *Id*. at 21:61–67. The '388 patent further states:

> In this illustration, the proximal elements 16 remain positioned against the shaft 12 by exerting tension on the proximal element lines 90. Thus, a relatively large space may be created between the elements 16, 18 for repositioning. In addition, the inverted position allows withdrawal of the fixation device 14 through the valve while minimizing trauma to the leaflets. Engagement surfaces 50 provide an atraumatic surface for deflecting tissue as the fixation device is retracted proximally. It should be further noted that barbs 60 are angled slightly in the distal direction (away from the free ends of the proximal elements 16), reducing the risk that the barbs will catch on or lacerate tissue as the fixation device is withdrawn.

Id. at 22:11–23.

C. Challenged Claims

Petitioner challenges claims 1, 4, 6, 9–11, 14, 16, 17, 20, 22, 25–28, 31, 33, and 34 of the '388 patent. Pet. 28–29. Claims 1 and 17 are

independent, and the remaining claims depend directly or indirectly from these two independent claims. Ex. 1001, 54:40–56:61. Claim 17 is representative and reproduced below.

> 17. A fixation device for engaging a heart valve tissue, said device comprising:
>
> a coupling member;
>
> a pair of fixation elements, each of the pair having a first end, a free end opposite the first end and an engagement surface there between for engaging the heart valve tissue, the first ends being pivotably coupled to the coupling member such that the fixation elements are movable from a closed position wherein the free ends are disposed at a first separation angle to an open position, wherein the free ends are disposed at a second separation angle, and wherein the fixation elements are adapted to atraumatically grasp and release the heart valve tissue, wherein the free ends are adapted to minimize trauma to the tissue, and wherein the engagement surfaces comprise a concave region in which the coupling member at least partially nests when the pair of fixation elements are in the closed position thereby reducing profile of the device; and
>
> a pair of proximal elements each having a first end and a free end opposite the first end, the first ends being coupled to the coupling member such that the free ends of the proximal elements are movable relative to the coupling member, wherein each proximal element is at least partially recessed in the concave region of one of the pair of fixation elements when the heart valve tissue is not disposed there between, and wherein the proximal elements comprise a surface defining a plurality of openings therein.

Id. at 55:48–56:13.

D. The Asserted Ground of Unpatentability

Petitioner challenges the patentability of claims 1, 4, 6, 9–11, 14, 16, 17, 20, 22, 25–28, 31, 33, and 34 of the ’388 patent on the following grounds:

Ground	References	Basis	Claims Challenged
1	Kuehn[3], Tremulis[4], Roth[5], Skelton[6], and the knowledge of a POSITA[7]	§ 103(a)	1, 4, 6, 9–11, 14, 16, 17, 20, 22, 25–28, 31, 33, and 34
2	Kuehn, Tremulis, Roth, Skelton, Goldfard[8], and the knowledge of a POSITA	§ 103(a)	1, 4, 6, 9–11, 14, 16, 17, 20, 22, 25–28, 31, 33, and 34

Petitioner submits the Declaration of Dr. Ivan Vesely (Ex. 1002) in support of institution of *inter partes* review. Patent Owner submits the Declarations of Christopher G. Quinn (Ex. 2001) and Dr. Joshua D. Rovin (Ex. 2003) in support of its Preliminary Response.

II. ANALYSIS

A threshold issue raised by the Preliminary Response is whether we should deny institution under 35 U.S.C. § 314(a) in view of the overlap between the Petition and the district court litigation, and the progress and expected completion date of the district court litigation. Prelim. Resp. 7–12. As we determined in IPR2019-01479, because we determine that the

[3] Kuehn et al., US Patent No. 6,165,183, issued Dec. 26, 2000 (Ex. 1005, "Kuehn").
[4] Tremulis et al., WO 2003/020179 A1, published March 13, 2003 (Ex. 1017, "Tremulis").
[5] Roth, US Patent No. 6,346,074 B1, issued Feb. 12, 2002 (Ex. 1006, "Roth").
[6] Skelton et al., US Patent 4,340,091, issued Jul. 20, 1982 (Ex. 1007, "Skelton").
[7] Person of Ordinary Skill in the Art ("POSITA").
[8] Goldfarb et al., US 2002/013571 A1, published Jan. 31, 2002 (Ex. 1008, "Goldfarb").

specific factual circumstances of this case warrant denial of institution under § 314(a), this threshold issue is dispositive.

In the precedential *NHK Spring* decision, the Board denied institution under 35 U.S.C. §§ 325(d) and 314(a). *NHK Spring Co., Ltd. v. Intri-Plex Technologies, Inc.,* IPR2018-00752, Paper 8, 11–21 (PTAB Sept. 8, 2018) (precedential). In the § 314(a) portion of its analysis, the Board noted that a district court proceeding involving the same patent was scheduled to go to trial before a final decision would have been due in the Board proceeding, and the Board proceeding would involve the same claim construction standard, the same prior art references, and the same arguments as in the district court. *Id.* at 19–21. The Board determined that these circumstances supported denial of the petition under § 314(a), considering the AIA's objective "to provide an effective and efficient alternative to district court litigation." *Id.* at 20.

The facts of the present case, like those in *NHK,* support the conclusion that granting institution would not achieve the AIA's objective of providing "an effective and efficient alternative to district court litigation."

First, trial is set to conclude well before a final decision would be due in this proceeding. Here, the district court has scheduled a five-day jury trial to begin on May 6, 2020. Ex. 3001, November 21, 2019, minute order. The Court's comments in the docket reflect an intent to preserve this trial date. *Id.* at docket entry 333 (considering Patent Owner's motion to amend the complaint to be withdrawn because it would require a substantial of extension of the trial date). Also, it appears from the district court's docket that extensive pre-trial briefing by the parties, including motions to

exclude or strike expert testimony, is well underway. *See* Ex. 3001, docket entries 352–359. The parties are also seeking partial summary judgment on various issues in view of the upcoming trial. *Id*. at docket entries 340–351. Accordingly, we expect that the jury trial in the district court proceeding would conclude more than ***ten months*** before a final decision would be due. *See* Prelim. Resp. 9; 35 U.S.C. § 316(a)(11); 37 C.F.R. § 42.100; *NHK,* IPR2018-00752, Paper 8, 19–20 (exercising discretion to deny institution where trial was set to occur six months before the Board's expected final decision).

Second, there is substantial overlap between the arguments raised in the district court litigation and those raised in the Petition. Petitioner relies predominantly on the same prior art – Kuehn, Tremulis, Roth, and Skelton – in both proceedings to challenge patentability and articulates substantially the same arguments as to why the combination of the teachings of these references renders obvious claims 1, 4, 6, 10, 11, 14, 16, 1720, 22, 33, and 34 of the '388 patent. *Compare* Pet. 30–79 (argument with respect to Grounds 1 and 2), *with* Ex. 2063, 193–238 *and* Ex. 2013 (redline comparison of arguments from the Petition and arguments in the invalidity contentions filed in the district court litigation). In addition, the claim constructions requested in this proceeding overlap with those addressed in the district court proceeding and would be decided under the same claim construction standard.[9] Pet. 22–28; Ex. 2061, 2–3, 11–13; Ex. 2062, 2.

Third, both the parties and the district court have already directed substantial time and energy toward resolving the district court litigation.

[9] The claim construction standard to be employed in an *inter partes* review recently changed from broadest reasonable interpretation to "the same claim construction standard used by Article III federal courts . . . which follow

According to Patent Owner, as of the filing of its Preliminary Response, the parties had "produced over 2 million pages of documents and . . . taken around 50 depositions." Prelim. Resp. 8. Similarly, as already discussed, the district court has been asked to decide a motion of a temporary restraining order (Ex. 3001, docket entry 63), a motion for a preliminary injunction (*id.* at docket entries 164, 165, and 166),[10] and claim construction (*id.* at docket entry 297). The District Court held lengthy hearings regarding the preliminary injunction motion and claim construction that involve many of the issues presented here. *Id.* at docket entry 122 (minute order giving the parties 3 hours each to present arguments regarding the preliminary injunction motion); *id.*at docket entry 219 (minute order allocating 3 hours to be split between the parties for a *Markman* hearing). The district court has also been asked to rule on numerous discovery disputes. *Id.* at docket entries 26, 66, 74, 75, 184, 265, and 305, and at March 22, 2019 minute order.

Given how far advanced the litigation is, the continued indication that trial will proceed as scheduled, and the substantial work involving many of the same issues presented here already accomplished by the district court and the parties, institution of an *inter partes* review here cannot be considered to be an efficient or effective alternative to the litigation.

Petitioner adds Goldfarb in Ground 2 as an additional prior art reference to the Ground 1 combination "[t]o remove any doubt that Kuehn's

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Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc) and its progeny." *See* 37 C.F.R. § 42.100(b)(2019).

[10] The parties' briefing on the motion for a preliminary injunction included "voluminous declarations and more than 450 exhibits." Ex. 3001, docket entry 118 (ordering hyperlinked briefs and declarations to facilitate review).

fixation elements are moveable in both directions between positions . . . and to remove any doubt that the device would have an actuation mechanism capable of orchestrating such movement," because "it would have been obvious to a POSITA to modify Kuehn's device to include distal element tie wires as disclosed in Goldfarb," for the same reasons that a POSITA would have added Roth's tie wires. Pet. 79. The claim charts that Petitioner provided in the district court litigation identifying the bases for its invalidity contentions did not include Goldfarb. *See generally,* Ex. 2063. We find that the addition of Goldfarb, which, Petitioner asserts like Roth teaches the use of tie wires, does not meaningfully differentiate the arguments presented in the Petition from the arguments made in the district court such that we should consider the issue on the merits here. *See* Pet. 78 (citing Ex. 1008 ¶¶ 89, 97). Also, Petitioner listed Goldfarb as potentially invalidating art in the district court litigation, but chose to not avail itself fully of the opportunity to present its arguments regarding the validity of the claims with respect to this prior art. *See id.* at 3, 53–54 (listing Goldfarb in Exhibit A as "invalidating prior art"), 193 (reserving right to rely on references from Exhibit A).

For similar reasons, we do not find that the addition of a challenge to claims 9, 25–28, or 31,[11] which were not challenged in the district court proceeding, meaningfully distinguishes the two proceedings, and Petitioner has not articulated a basis for finding such a distinction. Moreover, Patent

[11] Even though claims 1 and 4 were not asserted or challenged in the district court proceeding, claim 6, which was so asserted and challenged, depends directly on claim 4 and indirectly on claim 1. Ex. 1001, 55, 9–10, 13–14. Therefore, in the district court proceeding, Petitioner does address how the limitations of claims 1 and 4 are met by the prior art. *See* Ex. 2063, 193–216.

Owner has not asserted that Petitioner infringes claims 1, 4, 9, 25–28, or 31, so denying Petitioner the ability to challenge these claims in this proceeding is not unduly prejudicial to Petitioner. Ex. 2063, 1. In this regard, this case is similar to *Next Caller v. TRUSTID*, IPR2019-00961, Paper 10 (PTAB Oct. 16, 2019), where the Board exercised its discretion to deny institution in view of a district court proceeding even though Petition addressed more claims than were asserted in the district court proceeding. *Id.* at 14 (explaining, "Next Caller does not argue that the nonoverlapping claims differ significantly in some way, nor does Next Caller argue whether it would be harmed if we do not institute on the nonoverlapping claims.").

In summary, as we concluded in IPR2019-01479, we determine here that Edwards's Petition includes issues that are substantially the same as issues, arguments, and evidence presented in the district court proceeding. The issues presented in the Petition that differ from what was argued in district court do not appear to meaningfully distinguish the arguments in this proceeding from those in that the district court. The district court has expended substantial resources to gain familiarity with and resolve issues that are also the most dispositive issues presented in the Petition, and the district court is set to complete trial well before any *inter partes* review could be completed and a final decision from the Board would be issued. In these circumstances, consistent with the Board's precedential decision in *NHK Spring*, we exercise our discretion to deny institution under § 314(a).

III. CONCLUSION

For the foregoing reasons, we exercise our discretion under 35 U.S.C. § 314(a) and decline to institute an *inter partes* review of the challenged claims of the ’388 patent.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* as to all challenged claims of the ’388 patent and not trial is instituted.

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