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Paper No. 11
Entered: October 7, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT VASCULAR, INC., ABBOT LABORATORIES, ABBOTT CARDIOVASCULAR SYSTEMS, and ABBOTT VASCULAR SOLUTIONS, INC.,
Petitioner,

v.

FLEXSTENT, LLC,
Patent Owner.

IPR2019-00882
Patent 6,187,035 B1

Before BENJAMIN D. M. WOOD, JACQUELINE T. HARLOW, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Abbott Vascular, Inc., Abbott Laboratories, Abbott Cardiovascular Systems, Inc., and Abbott Vascular Solutions, Inc. (collectively, "Petitioner") filed a Petition requesting *inter partes* review of claims 1–3 of U.S. Patent No. 6,187,035 B1 ("the '035 patent"). Paper 1 ("Pet."). FlexStent, LLC. ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp."). Petitioner submitted an authorized Reply to the Preliminary Response. Paper 9 ("Reply"). Patent Owner submitted an authorized Sur-Reply. Paper 10 ("Sur-Reply").

We have authority to determine whether to institute *inter partes* review under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted unless the information presented in the Petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Having considered the arguments and the evidence presented, for the reasons described below, we determine that Petitioner has demonstrated that there is a reasonable likelihood that it would prevail with respect to at least one of the claims challenged by the Petition. Accordingly, we institute an *inter partes* review of all claims and all grounds asserted in the Petition.

B. Additional Proceedings

Petitioner represents that the '035 patent has been asserted in the following district court case: *FlexStent LLC v Abbott Laboratories et al*., No. 5-18-cv-02479 (C.D. Cal. filed Nov. 26, 2018). Pet. 1.

C. The ’035 Patent (Ex 1001)

The ’035 patent, titled “Vascular Stent,” issued on February 13, 2001, from U.S. Patent Application No. 09/118,133, filed on July 16, 1998. Ex. 1001, codes (54), (45), (21]), (22). The ’035 patent claims priority to Korean Application 97-33064, which was filed on July 16, 1997. *Id.* at code (30). A copy of the priority document and an English translation thereof are of record. Ex. 1005.

The ’035 patent relates to vascular stents. Ex. 1001, Abstr. Vascular stents are used to treat coronary artery obstructive disease caused by atheromatous plaque resulting in decreased blood flow, angina, or even death. *Id.* at col. 1, ll. 10–36. Stents are used to expand the constricted blood vessel to its normal width and restore normal blood flow. *Id.* at col. 1, ll. 27–31.

The ’035 patent teaches a vascular stent comprising wide vertical branches and narrow horizontal branches. Ex. 1001, Abstr. The ’035 patent teaches that the horizontal branches should have wave form projections. *Id.* The resulting stent allows for a thinner profile and maximum flexibility of the stent. *Id.* at col. 1, ll. 50–54.

D. Illustrative Claim

Of the challenged claims, claims 1 is independent. Claims 2 and 3 depend from claim 1. Claim 1 reads as follows:

> 1. A vascular stent which comprises vertical branches whose width and thickness range 0.09 to 0.12 mm and 0.08 to 0.12 mm, respectively, and horizontal branches having wave form projections, whose width and thickness range 0.05 to 0.08 mm and 0.08 to 0.12 mm, respectively.

E. The Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable on the following grounds. Pet. 3.

Reference(s)	Basis	Claims Challenged
Richter-Handbook[1] and Richer '404[2]	§ 103(a)	1–3
Fischell '114[3] and Penn[4]	§ 103(a)	1–3

Petitioner also relies on the Declaration of Kondapavulur T. Venkateswara-Rao. Ex. 1002.

II. ANALYSIS

A. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b).[5] Under this standard, we construe the claim

[1] Richter et al., *NIR Stent, Transforming Geometry*, in HANDBOOK OF CORONARY STENTS 137 (PATRICK W. Serruys. ed. 1997) ("Richter-Handbook") (EX. 1008).
[2] Richter, US 5,807,404, issued Sept. 15, 1998 ("Richter '404") (Ex. 1010).
[3] Fischell et al., EP 699114 A1, published Aug. 30, 1995 ("Fischell '114") (Ex. 1012).
[4] Penn et al., WO 97/32543, published Sept. 12, 1997 ("Penn") (Ex. 1013).
[5] The Office has changed the claim construction standard in AIA proceedings to replace the broadest reasonable interpretation standard with the same claim construction standard used in a civil action under 35 U.S.C. § 282(b) in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018). The change applies to petitions filed on or after November 13, 2018. *Id.* Because the present Petition was filed on March 26, 2019, we construe the claims in accordance with the federal district court standard.

"in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.* Furthermore, at this stage in the proceeding, we need only construe the claims to the extent necessary to determine whether to institute *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy . . . .'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

While Petitioner has proposed construction of various terms including "vertical branches" and "horizontal branches having wave form projections," Pet. 24–28, Patent Owner does not contest these proposed constructions. *See* Prelim. Resp. 1 & n.1. Moreover, as seen from the discussion below, we discern no need to construe any of the terms in the claims to decide whether to institute *inter partes* review. Therefore, we decline to adopt Petitioner's proposed constructions at this time.

B. Level of Ordinary Skill in the Art.

The level of ordinary skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner contends that a person of ordinary skill in the art at the time the '743 patent was filed would have had

> at least a bachelor's degree in mechanical or biomedical engineering or materials science (or equivalent), with at least two years' industry experience, equivalent research, or advanced degrees relating to the design of implantable medical

> devices, or an advanced degree in mechanical or biomedical engineering or materials science, with at least one year of industry experience.

Pet. 28 (citing Ex. 1002 ¶ 34). Petitioner further contends that the person of ordinary skill in the art "may have worked on a team working with or consulting a stent-implanting physician, such as an interventional cardiologist." *Id.* At this stage of the proceeding, and without opposition from Patent Owner at this time, we determine that Petitioner's description of the level of ordinary skill in the art is supported by the current record. *See* Ex. 1002 ¶ 34. For this decision, therefore, we adopt Petitioner's description.

We also note that the applied prior art reflects the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

C. Effective Filing Date

On its face, the '035 patent claims priority to Korean Patent application No. 97-33064, filed July 16, 1997 ("Korean Application"). Ex. 1001, at code 30). Petitioner contends that the '035 patent in not entitled to that date but that the effective filing date is July 16, 1998, the date the U.S. application was filed. Pet. 22. Specifically, Petitioner contends that the claims are not entitled to the filing date of the Korean Application as the Korean Application does not disclose certain dimensional limitations recited in the claims. *Id.* at 23. Petitioner contends that the Korean Application does not disclose the width of either the vertical or horizontal branches. *Id.* Petitioner also contends that the Korean Application does not disclose the full range of thicknesses, widths, and branch lengths recited in the claims. *Id.* at 23–24.

Patent Owner does not address this argument in its Preliminary Response.

For a claim to have the benefit of an earlier-filed application, the earlier application must comply with the written description requirement of 35 U.S.C. § 112. *In re Zeigler*, 992 F.2d 1197, 1200 (Fed. Cir. 1993)

The test is whether the specification "describe[s] an invention understandable to [a] skilled artisan and show[s] that the inventor actually invented the invention claimed." *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013) (quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010)). Pointing to an obvious difference is not enough; the specification must describe "the invention, with all its claimed limitations." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

For claims directed to numerical ranges, the written description must include the claimed ranges or clearly guide the skilled person to them. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326–27 (Fed. Cir. 2000); *Eiselstein v. Frank*, 52 F.3d 1035, 1040 (Fed. Cir. 1995) (a disclosed range of 45–55% did not support the claimed 50–60% range).

We have considered Petitioner's argument as well as the evidence of record. Normally, Patent Owner would have the burden of production during trial on this issue but Patent Owner has not addressed the issue in its Preliminary Response. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1379–81 (Fed. Cir. 2015). Therefore, we conclude that, for purposes of this decision, the present claims are not entitled to the filing date of the Korean Application.

Claim 1 calls for the width of the vertical branches range from 0.09 mm to 0.12 mm and the thickness of the vertical branches range from 0.08 to

0.12 mm. Ex. 1001, col. 4, ll. 7–9. With respect to the horizontal branches, claim 1 calls for a width ranging from 0.05 to 0.08 mm and a thickness ranging from 0.08 to 0.12 mm. *Id.* at col. 4, ll. 11–12. Claim 2 adds the limitation that the lengths of the branches from 1.5 to 4.5 mm for the vertical branches and from 1.0 to 3.0 mm for the horizontal branches. *Id.* at col. 4, ll. 13–15.

A review of the English translation of the Korean Application reveals that the Korean Application does not disclose any of the ranges recited in claims 1 and 2. We find nothing in the Korean Application that discloses the width of either the vertical or the horizontal branches. With respect to the thickness of the branches, the Korean Application discloses a single value of 0.09 mm x 0.08 mm without teaching whether this dimension is for the vertical or horizontal branch. Ex. 1005, 8–9. Disclosure of this single value does not support the range recited in the claim. Similarly, the Korean Application only discloses a single value for the length of the vertical branch (2.0 mm) and a single value for the length of the horizontal branch (2.25mm). Ex. 1005, 12, Fig. 4. Again, this is insufficient to support the ranges recited in claim 2.

D. Obviousness Based on Richter-Handbook Combined with Richter '404

Petitioner asserts that claims 1–3 are unpatentable under 35 U.S.C. § 103(a) as obvious over Richter-Handbook combined with Richter '404. Pet. 30–52.

The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art,

(3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham*, 383 U.S. at 17–18. If the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains, the claim is unpatentable under 35 U.S.C. § 103(a).[6] *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 406 (2007).

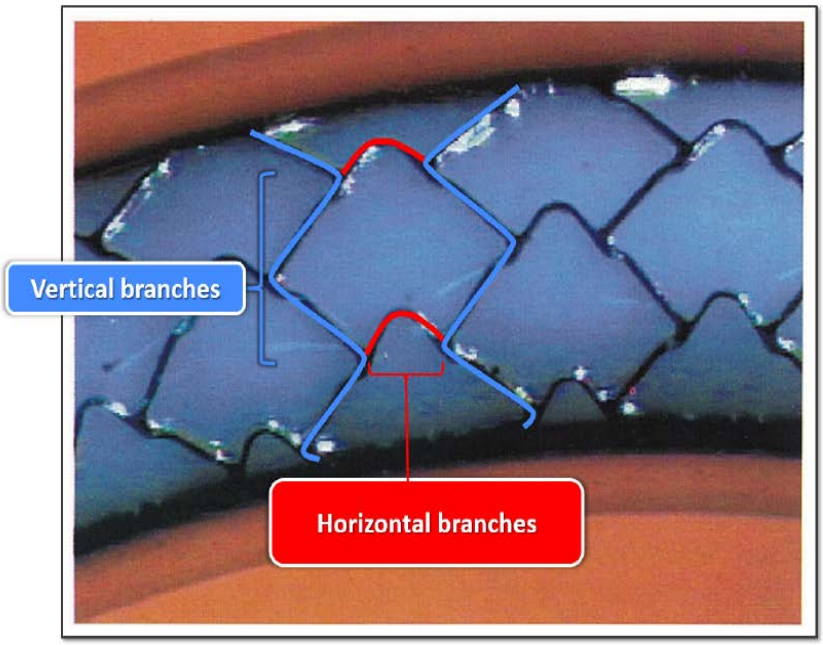
"Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination." *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). "Rather, obviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention." *Id.*

1. Richter-Handbook (Ex. 1008)

As shown in the annotated[7] figure below, Richter-Handbook discloses a stent having vertical and horizontal branches where the horizontal branches have wave form projections. Ex. 1008, 140, Fig. 15.3.

[6] The Leahy-Smith America Invents Act ("AIA") amended 35 U.S.C. § 103. *See* Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011). Because the '035 patent was filed before the effective date of the relevant amendment, the pre-AIA version of § 103 applies.

[7] For purpose of this decision, we adopt the annotation scheme used by Petitioner with red highlighting denoting horizontal branches and blue highlighting denoting vertical branches

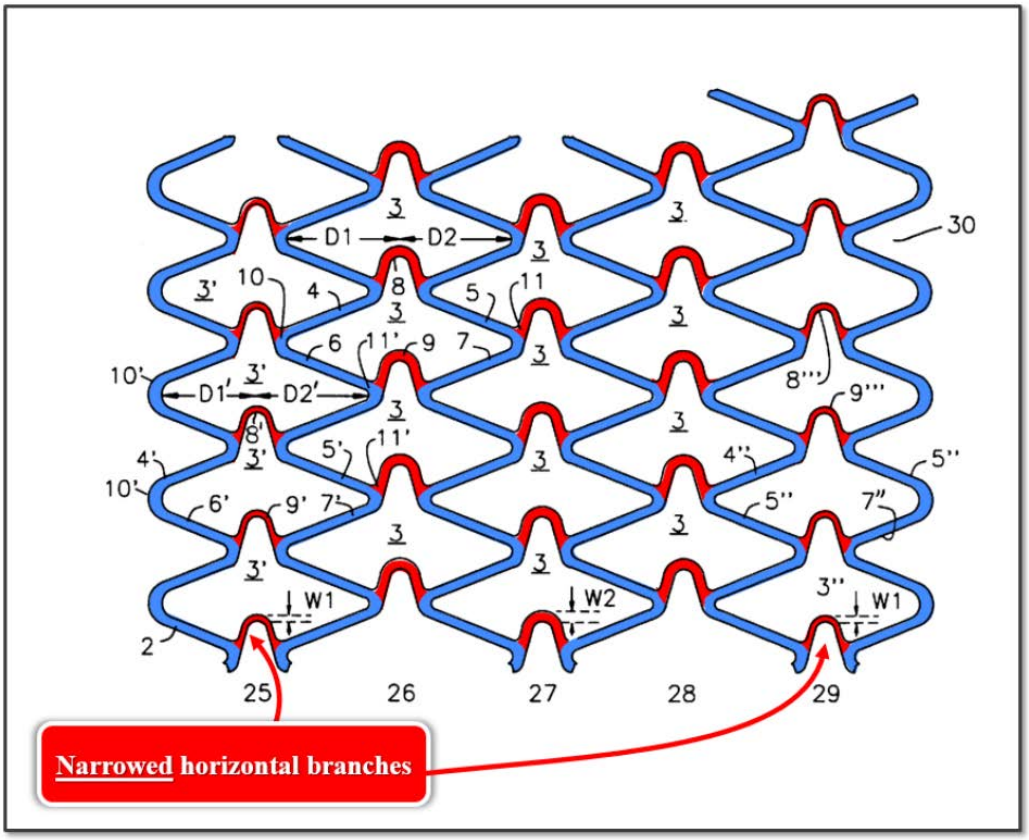


Annotated Figure 15.3 from Richter-Handbook showing a stent with vertical branches in blue and horizontal branches in red. Pet. 12.

Richter-Handbook teaches that the branches (struts) have a thickness of 0.1 mm. *Id.* at 137.

2. Richter ’404 (Ex. 1010)

As shown in the annotated drawing below, Richter ’404 teaches a vascular stent having vertical and horizontal branches with the horizontal branches having wave form projections.



Annotated Figure 10 of Richter '404 showing vertical branches in blue and horizontal branches in red. Pet. 33.

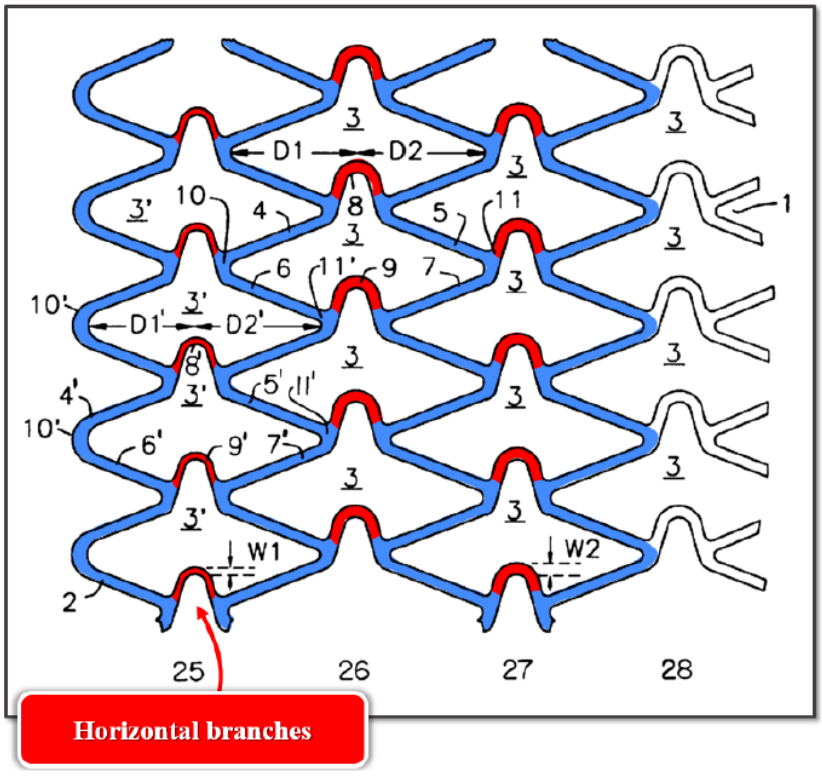
Richter '404 teaches that at least some of the horizontal branches have a width 40 to 50% narrower than the vertical branches resulting in improvement of the stent's lateral flexibility. Ex. 1010, col. 6, l. 67–col. 7, l. 3.

3. Obviousness Analysis

Petitioner contends that Richter-Handbook teaches a vascular stent that has vertical and horizontal branches where the horizontal branches have wave form projections. Pet. 31(citing Ex. 1008, Fig. 15.3 and Ex. 1002 ¶ 108). Petitioner also contends that Richter-Handbook teaches that the vertical branches have a thickness and width of 0.10 mm. *Id.* at 35 (citing

Ex. 1008, 137 and Ex. 1002 ¶¶117–118. Petitioner supports this contention by pointing to the teaching in Richter-Handbook that the branches are square and that the thickness of the branches is 0.10 mm. *Id.*; Ex. 1008, 137. Petitioner contends that one skilled in the art would understand Richter-Handbook as describing a vertical branch that has a thickness and a width of 0.10 mm, which is within the range recited in claim 1 for the vertical branch. Pet. 35–36; Ex. 1002 ¶¶ 117–118.

Petitioner contends that both Richter-Handbook and Richter '404 teach that the horizontal branches have wave form projections. Pet. 37–39. In support of this contention, Petitioner points to Figure 15.3 of Richter-Handbook, shown above, and Figure 2 of Richter '404, shown below.



Annotated Figure 2 of Richter '404 showing horizontal branches. *Id.* at 39.

Petitioner's declarant, Dr. Rao, testifies that these figures show stents where the horizontal branches have wave form projections. Ex. 1002 ¶¶ 120–122.

Petitioner contends that the teachings of Richter-Handbook combined with the teachings of Richter '404 teach the limitations calling for the width of the horizontal branches to range from 0.05 mm to 0.08 mm and the thickness to range from 0.08 to 0.12 mm. Pet. 43–46. In support of this contention, Petitioner points to the teaching of Richter-Handbook that the branches are square and have a thickness of .01 mm. Pet. 43; Ex. 1008, 137; Ex. 1002 ¶¶ 132–133. Petitioner contends that this teaching meets the claim limitation calling for a thickness of between 0.08 and 0.12 mm. Pet. 43.

With respect to the width of the horizontal branches, Petitioner contends that Richter '404 teaches that the width of the horizontal branch can be narrowed by 40 to 50%, resulting in a width of 0.05 to 0.06 mm. Pet. 44–45 (citing Ex. 1010, col. 6, l. 67–col. 7, l. 3; Ex. 1002 ¶ 135). Petitioner also contends that Richter '404 teaches that while the width of the branch is narrowed, the thickness is held constant. Pet. 45 (citing Ex. 1010 col. 6, ll. 60–65). Petitioner contends that when the teachings of both Richter references are combined, the resulting stent has horizontal branches with a thickness of 0.1 mm and a width of from 0.05 to 0.06 mm, falling within the ranges recited in the claims. Pet. 45–46.

Petitioner contends that one skilled in the art would have been motivated to combine the teachings of the references as the principal author of Richter-Handbook and the principal inventor of Richter '404 are the same and both relate to the same type of vascular stent. Pet. 46–47; Ex. 1002 ¶ 140. Petitioner also contends that Richter '404 expressly teaches modifying the stent disclosed in the Richter-Handbook and teaches that such a modification results in greater flexibility, which improves the ability to

traverse curved blood vessels. Pet. 47 (citing Ex. 1010, col. 6, ll. 57–60; Ex. 1008, 138).

Patent Owner has not offered any specific arguments regarding the teachings of Richter-Handbook or Richter '404 other than to contend, in the context of its arguments under 35 U.S.C. § 325(d), that the references are cumulative of the art considered by the Examiner during prosecution and that the arguments presented by Petitioner are substantially the same as the Examiner's reasoning. Prelim Resp. 4–6. Patent Owner also contends that the evidence of unexpected results presented during prosecution, which overcame the Examiner's rejection, is applicable to the arguments presented by Petitioner. Prelim. Reps. 7–11.

As discussed more fully below, we are not persuaded by Patent Owner's argument that the teachings of the Richter references[8] are substantially the same as the art cited by the Examiner nor are the arguments presented by Petitioner substantially the same as the Examiner's reasoning.

As to Patent Owner's contention regarding unexpected results, we have considered this evidence but, as explained in greater detail below, Petitioner presents evidence that calls into question whether the results reported to the Examiner by Dr. Jung during prosecution were in fact unexpected in light of the presently asserted prior art. In addition, Petitioner has not been able to fully respond to that evidence as it applies to the teachings of the asserted references, including deposing the inventor about the statements made in his declaration. Accordingly, we find that Patent

[8] We use the term Richter references to refer collectively to Richter Handbook and Richter '404.

Owner's evidence is better evaluated in the context of a completed trial where the record has been fully developed.

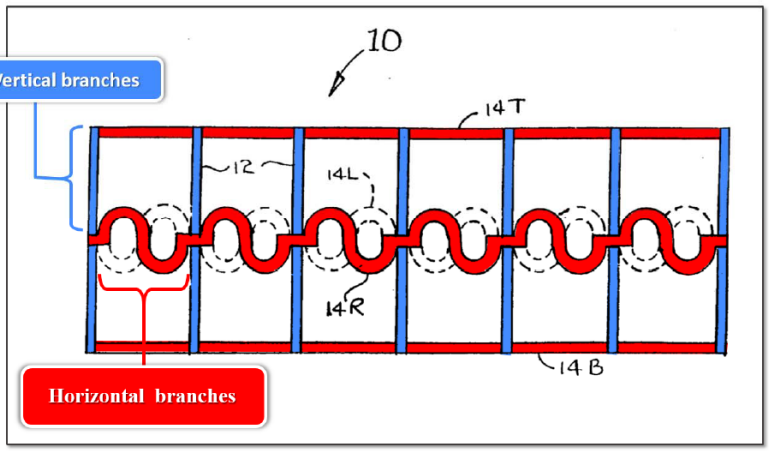
Based upon our review of the current record, we discern no deficiency in Petitioner's characterization of the cited references and the knowledge in the art, or in Petitioner's assertions as to the reasonable inferences an ordinary artisan would make from those references. Thus, based on the information presented at this stage of the proceeding, Petitioner has shown that there is a reasonable likelihood that it would prevail in establishing the unpatentability of independent claim 1 over the combined references. Further, at this stage in the proceeding, for reasons discussed by Petitioner (*see* Pet. 48–53), we are satisfied that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of dependent claims 2 and 3.

E. Obviousness Based on Fischell '114 Combined with Penn

Petitioner contends that claims 1–3 would have been obvious over the teachings of Fischell '114 combined with Penn.

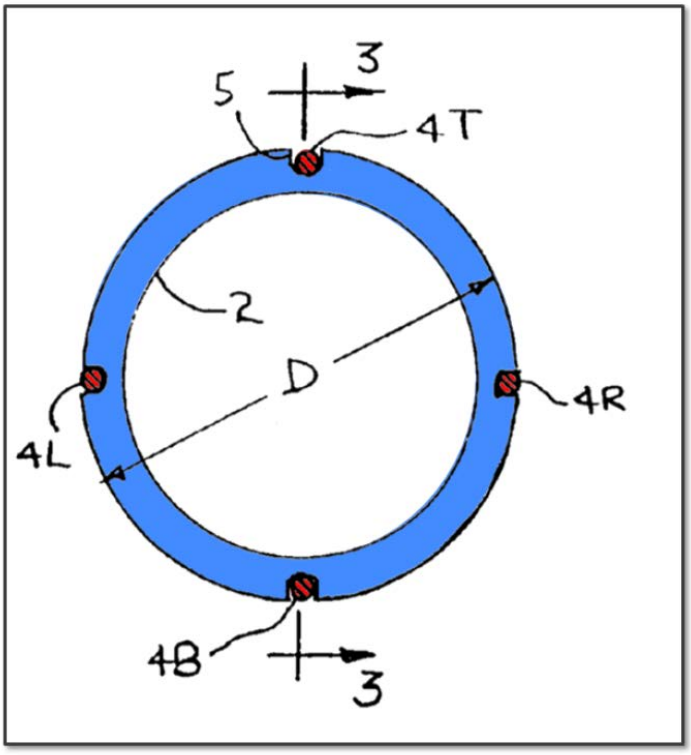
1. Fischell '114

Fischell '114 discloses a vascular stent with vertical and horizontal branches where the horizontal branches have wave form projections. Pet. 55–57; Ex. 1012, Abstract, Figure 8 shown below.



Annotated Figure 8 of Fischell '114 showing the vertical branches in blue and the horizontal branches in red. Pet. 56.

Fischell '114 teaches that the horizontal branches have different dimensions from the vertical branches. Ex. 1012, Fig. 2, shown below.



Annotated Figure 2 of Fischell '114 showing a cross section of the stent with a vertical branch in blue and horizontal branches in red. Pet. 57.

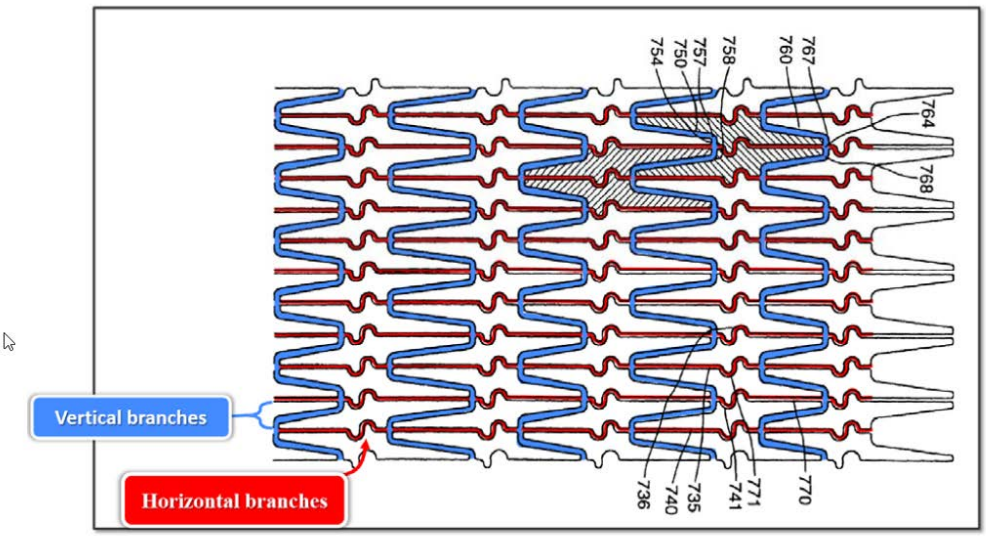
Fischell '114 teaches:

> The dimensions of stent rings [vertical branches] are typically 0.1 to 0.3 mm thick, with a width of 0.1 to 0.5 mm and an outside diameter D between 2.0 and 30.0 mm depending on the luminal diameter of the [ ]vessel into which it is inserted. The length of the stent could be between 1 and 10 cm. The wire diameter for the longitudinals [(vertical branches)] would typically be between 0.05 and 0.5 mm.

Ex. 1012, col. 5, ll. 50–56

2. Penn

As shown below in annotated Figure 8, Penn discloses a vascular stent having vertical and horizontal branches where the horizontal branches include wave form projections. Ex. 1013, Fig. 8, 17, ll. 7–14.



Annotated Figure 8 of Penn showing vertical and horizontal branches. Pet. 59.

Penn teaches that the addition of the S-shaped portions serve "to increase the bending points in the stent allowing the stent to bend while avoiding buckling," thus improving flexibility. Ex. 1013, 17, ll. 10–11.

> Referring to Figure 3, reproduced below, Penn also teaches
>
> strut 270 is thinner in dimension that any of the segments making up concave-shaped wall 250 and convex-shaped wall 260. Thus, strut 270 may be considered as a relatively thin retention wire which reconciles the need for retaining flexibility in the strut with mitigating lifting of rounded shoulders 257,[ ]258 when the stent is delivered to the target body passageway through a relatively tortuous route.

Ex. 1013, 14, ll. 23–28.

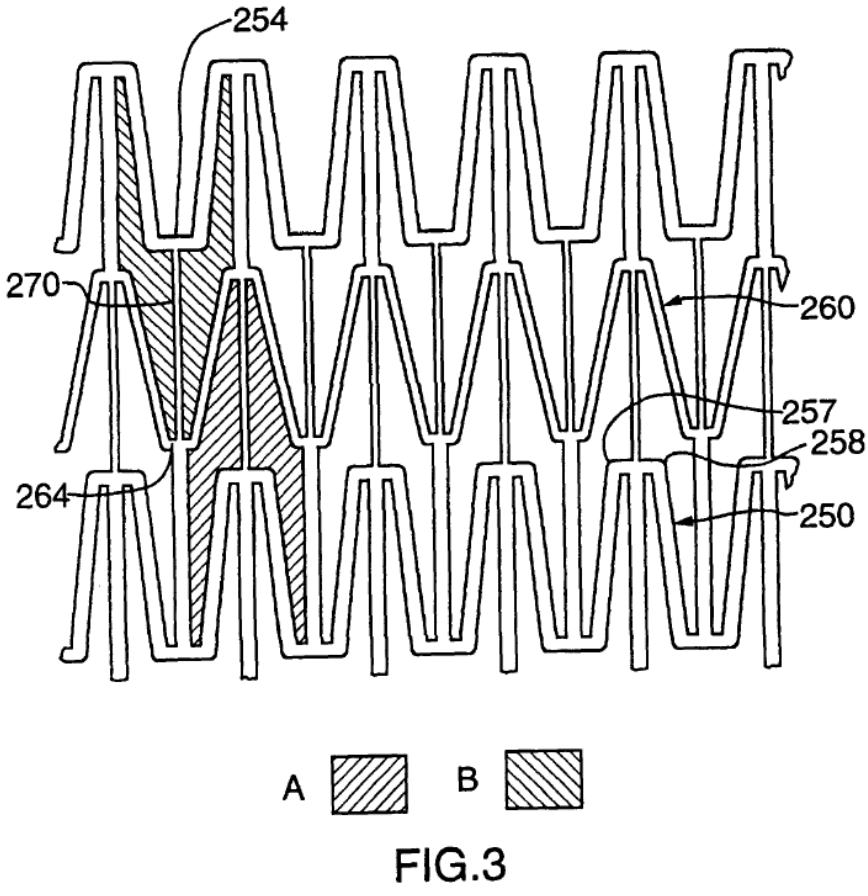


FIG.3

Figure 3 of Penn showing a portion of the stent pattern.

3. Obviousness Analysis

Petitioner contends that the stent rings disclosed in Fischell ’114 correspond to the vertical branches of the instant claims and that Fischell

’114 teaches that the stent rings have a thickness of 0.1 to 0.3 mm and a width of 0.1 to 0.5 mm. Pet. 59–61. Petitioner contends that these ranges overlap with the ranges recited in the claims and render the ranges obvious. *Id.* In support of these contentions, Petitioner relies on Figures 2 and 8 of Fischell ’114 as well as the teachings of the dimensions of the stent rings. Ex. 1012, col. 5, ll. 50–54.

Petitioner contends that one skilled in the art would have been motivated to vary the dimensions of the stent rings as it was known in the art to vary the stent ring sizes to accommodate different blood vessel sizes. Pet. 62–63. In support of this argument, Petitioner relies on the testimony of Dr. Rao that one skilled in the art would routinely vary the ring width and thickness depending on the diameter of the stent to be used. *Id.* at 63 (citing Ex. 1002 ¶¶ 170–171). Dr. Rao also testifies that the diameter of the stent will vary depending on the blood vessel where the stent will be placed. Ex. 1002 ¶¶ 170–171.

Petitioner contends that Fischell ’114 teaches that the vertical branches are linked by “undulating longitudinals,” which are the same as horizontal branches recited in the claims. Pet. 65 (citing Ex.1012, col. 4, l. 57–col. 5, l. 4). Petitioner also contends that Penn teaches the use of wave form projections. Pet. 66–67 (citing Ex. 1013 Fig. 7; Ex. 1002 ¶¶ 178–180).

Petitioner contends that Fischell ’114 teaches that the horizontal branches are formed of wires having a diameter (i.e., both a thickness and width) of from 0.05 to 0.5 mm overlapping with the ranges recited in claim 1 of the’035 patent. Pet. 70 (citing Ex. 1012, col. 5, ll. 55–56; Ex. 1002 ¶ 186).

Petitioner contends that one skilled in the art would have been motivated to combine the teachings of Fischell ’114 and Penn as Penn

teaches that the use of the wave form projections helps increase the flexibility of the stent. Pet. 68–70. Petitioner contends that one skilled in the art would have used the narrower horizontal branches as Fischell '114 teaches that the ideal stent would have the minimum width and thickness to minimize thrombosis at the stent sited while also providing sufficient strength to resist elastic recoil of the artery. *See* Pet. 70–71; Ex. 1002 ¶ 174.

Patent Owner has not offered any specific arguments regarding the teachings of Fischell '114 or Penn other than to contend, in the context of its arguments under 35 U.S.C. § 325(d), that the references are cumulative of the art considered by the Examiner during prosecution and that the arguments presented by Petitioner are substantially the same as the Examiner's reasoning. Prelim Resp. 4–6. Patent Owner also contends that the evidence of unexpected results presented during prosecution, which overcame the Examiner's rejection, is applicable to the arguments presented by Petitioner. Prelim. Resp. 7–11.

As discussed more fully below, we are not persuaded by Patent Owner's arguments that the teachings of the Fischell '114 and Penn are substantially the same as the art cited by the Examiner and that the arguments presented by Petitioner are substantially the same as the Examiner's reasoning.

As to Patent Owner's contention regarding unexpected results, we have considered this evidence but, as explained in greater detail below, Petitioner presents evidence that calls into question whether the results reported to the Examiner by Dr. Jung during prosecution were in fact unexpected in light of the presently asserted prior art. In addition, Petitioner has not been able to fully respond to that evidence as it applies to the asserted references, including deposing the inventor about the statements

made in his declaration. Accordingly, we find that Patent Owner's evidence is better evaluated in the context of a completed trial where the record has been fully developed.

Based upon our review of the current record, we discern no deficiency in Petitioner's characterization of the cited references and the knowledge in the art, or in Petitioner's assertions as to the reasonable inferences an ordinary artisan would make from those references. Thus, based on the information presented at this stage of the proceeding, Petitioner has shown that there is a reasonable likelihood that it would prevail in establishing the unpatentability of independent claim 1 over the combined references. Further, at this stage in the proceeding, for reasons discussed by Petitioner (*see* Pet. 74–80), we are satisfied that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of dependent claims 2 and 3.

F. Discretion to Deny Institution under 35 U.S.C. §§ 325(d) and 314(a)

Patent Owner contends that we should exercise our discretion under either 35 U.S.C. § 314(a) or § 325(d) and deny the Petition. Prelim Resp. 1.

With respect to § 314(a), Patent Owner contends that we should deny the Petition as there is a co-pending district court litigation, which will analyze the same issues and be resolved before any trial on the Petition concludes. *Id.* (citing *NHK Spring Co. v. Intri-plex Techs., Inc.*, IPR2018-00752, Paper 8 at 20 (PTAB Sept. 12, 2018) (precedential)). *Id.*

Patent Owner also argues that we should exercise our discretion under § 325(d) as the art cited in the Petition is cumulative of the art and arguments relied upon by the Examiner during prosecution. Prelim. Resp. 4–6. According to Patent Owner, the factors recited in *Becton, Dickinson &*

Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 at 17 (PTAB Dec. 15, 2017) (precedential) weigh in favor of denying the Petition. *Id.* at 4

We have considered Patent Owner's arguments and, after weighing the factors listed in *Becton* and considering the Board's decision in *NHK*, we decline to exercise our discretion to deny the Petition under either 35 U.S.C. § 314(a) or § 325(d).

1. Discretion under 35 U.S.C. § 325(d)

Institution of *inter partes* review is discretionary. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) ("[T]he PTO is permitted, but never compelled, to institute an IPR proceeding."). Section 325(d) gives us express discretion to deny a petition when "the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. § 325(d). In evaluating whether to exercise our discretion under § 325(d), we weigh the following non-exclusive factors:

> (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art; (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments.

Becton, Paper 8 at 17–18 (precedential).

a. Factors (a) through (d)

Patent Owner contends that all of the art asserted by Petitioner is the same as or substantially similar to the art[9] relied upon by the Examiner and is cumulative. Prelim. Resp. 12–13. Patent Owner contends that both Fischell '442 and the references asserted by the Petitioner disclose stents with vertical and horizontal branches where the horizontal branches have wave form projections. *Id.* at 13. Patent Owner contends that like Fischell '442, the references asserted in this case fail to disclose the precise dimension ranges recited in the claims. *Id.*

Patent Owner contends that the arguments presented by Petitioner are also substantially the same as the Examiner's reasoning. Prelim. Resp. 5–6. Patent Owner contends that both the Examiner and Petitioner proposed modifying the prior art stents in the same manner using the same reasoning. *Id.*

Petitioner responds that none of the cited references were before the Examiner and that the reasoning used by the Examiner is not the same as the arguments Petitioner presents here. Pet. 30–31, 55, 58, 93; Reply 6–8. In particular, Petitioner contends that the asserted references teach dimension ranges that are close to or overlap with the ranges recited in the claims, which was information that was not before the Examiner. Reply. 8–9.

We have considered the arguments presented by the parties as well as the evidence of record and conclude that Petitioner has the better position

[9] During prosecution of the '035 patent, the Examiner rejected the pending claims under 35 U.S.C. § 103(a) as obvious over Fischell et al., US 5,607,442, issued March 4, 1997 ("Fischell '442."). Ex. 1004, 81. Neither Petitioner nor Patent Owner submitted a copy of Fischell '442 with their briefing; therefore, we have added a copy to the record. Ex. 3001.

with respect to *Becton* factors (a)–(d). During prosecution, the Examiner rejected the pending claims as obvious over the teachings of Fischell '442. Ex. 1004, 81. The Examiner found that Fischell '442 taught a stent with vertical and horizontal sides with undulating projections. *Id.* While the Examiner found that Fischell '442 did not teach the specific widths and thicknesses of the claims, the Examiner also found that it would have been an obvious matter of design choice to modify the stents of Fischell '442 to create a stent with the recited dimensions. *Id.* A review of Fischell '442 confirms the Examiner's conclusion that Fischell '442 does not teach the dimensions of the branches. While Fischell '442 discloses a stent with vertical and horizontal branches where the horizontal branches include wave form projections, we discern no teaching in Fischell '442 regarding the dimensions of the branches. Ex. 3001.

In contrast, the Richter-Handbook teaches a stent having dimensions within the recited ranges, with the exception of the width of the horizontal branches, which the Richter-Handbook discloses as having a width just outside the recited range (0.1 mm vs 0.05 to 0.08 mm). Ex. 1008, 137. In addition, Richter '404 teaches modifying the stent such that the width is reduced by 40 to 50% and teaches that by reducing the width, the flexibility of the stent is improved. Ex. 1010, col. 6, l. 67–col. 7, l. 3. Similarly, Fischell '114 teaches a stent where the ranges of dimensions for the vertical and horizontal branches overlap with the ranges recited in the claims. Ex. 1012, col. 5, ll. 50–56. From the foregoing, we find that while the references advanced by Petitioner relate to similar inventions as Fischell '442, the reference the Examiner relied upon in the obviousness rejection, the combination of the Richter references, provides dimensions similar to or overlapping with the dimensions recited in claim 1—teachings

absent from Fischell ’442. The same is true for Fischell ’114. The Richter references and Fischell ’114 describe stents that are closer to the claimed invention than that described in Fischell ’442 and are more relevant than Fischell ’442. Thus, the art advanced by Petitioner contains significant differences from the art relied upon by the Examiner and is not cumulative of the art of record.

We likewise find that there are significant differences between the reasoning presented by the Examiner and the arguments made by Petitioner.

In the rejection, the Examiner found that it would have been a matter of design choice to modify the stents disclosed in Fischell ’442, for which no branch dimensions were specified, to create the claimed stent. Ex. 1004, 81. Petitioner, on the other hand, provides specific arguments based on references that disclose branch dimensions as to why one skilled in the art would have modified the references to produce the claimed invention. For example, Petitioner argues that one skilled in the art would have modified the width of the stent disclosed in Richter-Handbook based on the teachings of Richter ’404 that reducing the width by 40 to 50% improves the flexibility of the stent. Pet. 47; Ex. 1010, col. 6, l. 57–col. 7, l. 3. Petitioner likewise contends that Fischell ’114 teaches overlapping ranges rendering the claimed ranges prima facie obvious.

On balance, we find factors (a) through (d) weigh against denying the Petition. The art relied upon by Petitioner was not before the Examiner and provides significant teachings that were not contained in the reference that the Examiner relied upon in a rejection. In addition, the specific arguments presented by Petitioner are substantively different than reasoning used by the Examiner.

b. Factors (e) and (f)

Patent Owner contends that *Becton* factors (e) and (f) weigh in favor of denying the Petition as Petitioner has failed to show that the Examiner improperly relied on Patent Owner's evidence of unexpected results in allowing the claims. Prelim. Resp. 17–28. Patent Owner contends that Petitioner has not shown that the results reported by Dr. Jang are not commensurate with the scope of the claim. *Id.* at 17–19. Patent Owner contends that Petitioner has not established that the width and thickness of the branches are result-effective variables. *Id.* at 20–24. Patent Owner also contends that Petitioner has not shown that the results reported by Dr. Jang could be found in the art. *Id.* at 26–27.

Petitioner responds that factors (e) and (f) weigh against denying the Petition. Pet. 92–93. Petitioner contends that the Examiner improperly relied on attorney argument that the results presented in the Jang Declaration[10] were unexpected. *Id.* Petitioner contends that the statement that the results reported in the Jang Declaration are unexpected only appears as part of the attorney argument in the response to the rejection and that attorney argument alone is not sufficient to establish that the results are unexpected. Pet. 81 (citing *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997)).

Petitioner also contends that the evidence in the Jang Declaration does not support a finding of unexpected results in that

> (1) the experiments performed were not commensurate with the scope of the claimed invention; (2) the variables tested and claimed were known to be result-effective variables in the prior art that were routinely optimized; and (3) the results reported by

[10] Declaration, filed Mar. 22, 2000. Ex. 1004, 94 ("Jang Declaration").

> the inventor had been found in the prior art and were not unexpected.

Pet. 82.

We have considered the arguments presented by the parties and conclude that factors (e) and (f) do not weigh in favor of denying the Petition. In particular, we observe that the prior art described in the Petition—which was not before the Examiner—calls into question whether Dr. Jang's results were indeed unexpected. *See* Pet. 90–92. For example, in contrast to the prior art considered by the Examiner, the presently asserted references include specific teachings regarding stent branch dimensions and performance. *See id.* Moreover, as Petitioner points out, rather than being unexpected or novel, based on the record before us, Dr. Jang's experimental results are consistent with the characterizations of prior art stents described in the Petition. *See id.* at 90–91. Thus, while the Examiner may have found the evidence of unexpected results to be persuasive in the context of the prior art evaluated during prosecution, in view of the teachings regarding stent dimensions and performance disclosed by the prior art asserted in this proceeding, we agree with Petitioner that the additional facts and evidence presented in the Petition warrant reconsideration of the Examiner's findings regarding unexpected results.

After considering the *Becton* factors we conclude that the facts in the present case do not weigh in favor of exercising our discretion and deny the petition.

2. Discretion Under 35 U.S.C. §314(a)

Patent Owner contends that the existence of a co-pending district court proceeding that will analyze the same issues as the present proceeding and resolve them before any trial on the present Petition supports exercising

our discretion to deny the Petition under 35 U.S.C. § 314(a). Prelim. Resp. 1–4. In support of this contention, Patent Owner cites to *NHK*, where the Board denied a petition where the co-pending district court action was scheduled to go to trial before any trial in the proposed proceeding and would address the same prior art. *Id.*

Petitioner responds that, in this case, the existence of a co-pending district court action does not weigh in favor of denying the Petition. Reply 2–5. Petitioner contends that it was prompt in filing its Petition and that the district court proceeding is in its early stages. *Id.* at 2–3. Petitioner argues the district court proceeding may not necessarily proceed to trial before a final decision issues in this proceeding. *Id.* at 4. Petitioner contends that while its initial motion for a stay pending resolution of this *inter partes* review ("IPR") was denied, the court invited Petitioner to refile its motion should an IPR be instituted. *Id.* Petitioner also notes that Patent Owner did not oppose its initial motion for a stay, and, thus, it will be difficult for Patent Owner to "credibly oppose or even argue that it is prejudiced by a post-institution stay." *Id.*

Petitioner also contends that the Board and the district court will not hear the same validity challenges. *Id.* at 5. Petitioner contends that it will present in district court evidence of prior art products that cannot be presented in an IPR. *Id.* at 5. Petitioner also contends that while there may be some overlap in the prior art, Petitioner has presented a strong case of unpatentability, which weighs against denying the Petition. *Id.* at 6. In support of this contention, Petitioner points to the fact that Patent Owner has not substantively disputed any of Petitioner's arguments on the merits. *Id.*

Patent Owner contends that the lack of delay on the part of Petitioner is irrelevant, as the Board in *NHK* did not rely on the Petitioner's delay in

denying the petition. Sur-Reply 1. Patent Owner also contends that the co-pending district court proceeding is further along than Petitioner suggests and further along than the district court proceeding in *NHK*. Sur-Reply 1–3. In support of this contention, Patent Owner points to the fact that significant fact discovery has already taken place with over 200,000 pages of documents produced and depositions being scheduled. *Id.* at 3. In addition, in *NHK*, trial was scheduled to start seven months after the decision to institute was to issue, whereas in the present case the district court trial will occur within four months of any decision to institute. *Id.* at 1–2.

With respect to the district court granting a stay, Patent Owner contends that this is pure speculation on the part of Petitioner. *Id.* at 3. Patent Owner contends that the possibility of a stay actually weighs in favor of denial in that if a stay is granted, it will significantly delay resolution of the issues concerning the ’035 patent. *Id.* at 3–4. Patent Owner also contends that a stay is unlikely as the district court proceeding will be nearing completion of discovery and trial will be only a few months away. *Id.* at 4.

We have considered the positions of the parties and find that the status of the district court proceeding does not warrant denying the Petition. The decision whether to exercise discretion to deny institution is based on “a balanced assessment of all relevant circumstances in the case, including the merits.” Office Trial Practice Guide, July 2019 Update,[11] 84 Fed. Reg. 33925 (July 16, 2019) (hereinafter “TPGU”) at 25. As to the merits here, as explained above, Petitioner presents compelling—and presently

[11] Available at https://www.uspto.gov/TrialPracticeGuide3.

unrebutted—evidence and arguments concerning the unpatentability of the challenged claims.

In addition, on this record, we also find that considerations of fairness and efficiency weigh in Petitioner's favor. *See General Plastic Industrial Co. v. Canon Kabushiki Kaisha*, Case IPR2016-01357, Paper 19 at 18 (PTAB Sept. 6, 2017) (precedential as to § II.B.4.i) (stating that discretionary denial factors should assess efficiency and fundamental fairness). As to fairness in this case, Petitioner was diligent in filing the present Petition, doing so before it filed an answer in the district court proceeding. Reply 2. Patent Owner acknowledges Petitioner's timeliness, but contends the Board is compelled to deny institution because "*NHK* holds that the Board should exercise its discretion to deny review when review would lead to inefficiencies, even when petitioner files its petition promptly." Sur-reply, 1. We disagree.

Here, the potential inefficiencies are less of a concern than in *NHK*. First, the district court proceeding remains in its early stages. While discovery in the district court proceeding has commenced, fact discovery will not close, and expert discovery will not begin, until after issuance of this decision. Ex. 2004. Likewise, summary judgment briefing and claim construction have not yet taken place. Reply 3; Ex. 2004. Petitioner also contends that the district court proceeding will involve prior art products, which are not asserted in this IPR, potentially enabling the district court to focus its limited trial time on the prior art products, should the need arise to do so. *Id.* at 5; *see* 35 U.S.C. § 311(b). Finally, with respect to the issuance of a stay, the district court's denial considered that the Board had not yet decided whether to institute *inter partes* review. Ex. 2003, 3. The district court went on to state "[i]f the PTAB institutes IPR, the Court can decide

whether a stay is warranted at that time," and denied Petitioner's Motion to Stay without prejudice. *Id*.

Accordingly, in view of the strength of the Petition, Petitioner's diligence in not delaying the filing of its Petition, the early stage of the district court litigation, the fact that Petitioner may rely IPR-ineligible grounds before the district court, and the possibility that the district court proceeding might be stayed pending *inter partes* review, we decline to exercise our discretion to deny the Petition. We do so mindful of the prospect of the district court proceeding to trial within four months of this decision. Treating that factor alone as dispositive, however, as it would be on this record, would be at odds with the Trial Practice Guide's guidance that discretionary denial factors are not dispositive but part of a balanced assessment that includes the merits. TPGU at 25. It would, in effect, create a rule that imminent trial dates will require denial of IPRs in every case. We decline to do adopt such a bright-line rule.

III. CONCLUSION

Petitioner has shown a reasonable likelihood that it would prevail in establishing unpatentability of claims 1–3 as obvious over Richter-Handbook combined with Richter '404.

Petitioner has shown a reasonable likelihood that it would prevail in establishing unpatentability of claims 1–3 as obvious over Fischell '114 combined with Penn.

We also decline to exercise our discretion to deny the Petition under 35 U.S.C. § 314(a) and § 325(d).

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 1–3 of the ’035 patent on the following grounds of unpatentability:

A. Claims 1–3 under 35 U.S.C. § 103(a) as obvious over Richter-Handbook and Richter ’404;

B. Claims 1–3 under 35 U.S.C. § 103(a) as obvious over Fischell ’114 and Penn; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this Decision.

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