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Paper 48
Date: October 2, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

FLEXSTENT,
Patent Owner.

IPR2019-00882
Patent 6,187,035 B1

Before BENJAMIN D. M. WOOD, SUSAN L. C. MITCHELL, and JOHN E. SCHNEIDER, *Administrative Patent Judges.*

SCHNEIDER, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying Patent Owner's Motion to Strike
Granting Petitioner's Motion to Exclude
35 U.S.C. § 318(a)

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–3 of U.S. Patent 6,187,035 B1 ("the '035 patent," Ex. 1001). We have jurisdiction under 35 U.S.C. § 6, and enter this Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, we determine that Abbott Vascular, Inc., Abbott Laboratories, Abbott Cardiovascular Systems, Inc., and Abbott Vascular Solutions, Inc. (collectively, "Petitioner") have shown by a preponderance of the evidence that claims 1–3 are unpatentable.

A. Background

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 2 ("Pet."). Petitioner supported the Petition with the Declaration of Kondapavulur T. Venkateswara-Rao, Ph.D. Ex. 1002. FlexStent, LLC. ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp."). Petitioner submitted an authorized Reply to the Preliminary Response. Paper 9. Patent Owner submitted an authorized Sur-Reply. Paper 10

On October 7, 2019, pursuant to 35 U.S.C. § 314(a), we instituted trial to determine whether any of the challenged claims are unpatentable on the grounds raised in the Petition. Paper 11 ("Inst. Dec."). We also declined to exercise our discretion to deny the Petition under 35 U.S.C. §§ 314(a) or 325(d). Inst. Dec. 21–31.

Patent Owner filed a Patent Owner's Response. Paper 19 ("PO Resp."). Patent Owner supported its response with the Declaration of Dr. Ronald J. Solar. Ex. 2019. Petitioner filed a Reply to the Patent Owner's Response. Paper 23 ("Reply"). Patent Owner filed a Sur-Reply. Paper 33 ("Sur-Reply").

On July 14, 2020, the parties presented arguments at an oral hearing. Paper 40. The hearing transcript has been entered into the record. Paper 47 ("Tr.").

B. Real Parties in Interest

Petitioner identifies the real parties in interest as Abbott Vascular, Inc., Abbott Laboratories, Abbott Cardiovascular Systems, Inc., and Abbott Vascular Solutions, Inc. Pet. 1. Patent Owner identifies the real party in interest as FlexStent, LLC. Paper 4, 1. Patent Owner also states that Pratima Instruments, LLC is the parent of FlexStent, LLC. *Id.*

C. Related Matters

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.

D. The '035 Patent

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), and (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, code (57). 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. *Id.* at code (57). 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.

E. Illustrative Claims

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.

F. Evidence

Petitioner relies of the following references:

Richter et al., *NIR Stent, Transforming Geometry*, in HANDBOOK OF CORONARY STENTS 137 (Patrick W. Serruys, ed. 1997) (“Richter-Handbook”) (Ex. 1008).

Richter, US 5,807,404, issued Sept. 15, 1998 (“Richter ’404”) (Ex. 1010).

Fischell et al., EP 0669114 A1, published Aug. 30, 1995 (“Fischell ’114”) (Ex. 1012).

Penn et al., WO 97/32543, published Sept. 12, 1997 (“Penn”) (Ex. 1013).

G. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–3 would have been unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–3	103(a)	Richter-Handbook, Richter '404
1–3	103(a)	Fischell '114, Penn

II. ANALYSIS

A. Legal Standards

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 v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). 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).[1] *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] 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.

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*, 383 U.S. at 17–18; *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 '035 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.*

Patent Owner has not proposed a different definition of a person of ordinary skill in the art, *see* PO Resp. 1–21, and Patent Owner's Expert, Dr. Solar, applied Petitioner's definition of a person of ordinary skill in the art in his analysis. Ex. 2019, 7–8.

Accordingly, for this Decision, we adopt Petitioner's definition, and also note that the prior art demonstrates the appropriate level of ordinary skill in the art, which is consistent with Petitioner's definition. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art, itself, can reflect appropriate level of ordinary skill in art). Moreover, we have reviewed the credentials of Drs. Rao and Solar and consider each of them to

be qualified to provide their opinion on the level of skill and the knowledge of a person of ordinary skill in the art at the time of the invention.

C. 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). Under this standard, we construe the claim "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, we only need to construe terms that are in controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Petitioner has proposed construction of the term "vertical branches." Pet. 24–28. For purposes of this proceeding, Patent Owner has accepted this definition proposed by Petitioner. PO Resp. 1. Since the term "vertical branches" is not in controversy, we need not construe the term expressly here to resolve the controversy between the parties.

The parties have proposed different constructions for the term "horizontal branches having waveform projections." Pet. 24–28; PO Resp. 1–7. Patent Owner also contends that the claims should be construed to require all horizontal branches in a stent to meet the shape and size limitations recited in the claims for the branches. PO Resp. 7–21. Petitioner does not agree. Reply 2–5. We address each of these issues in turn.

1. Horizontal branches having waveform projections.

Petitioner contends that the claim term horizontal branches refers to the longitudinal portions of the stent which connect or link the vertical or circumferential portions of the stent. Pet. 24–25. Examples of vertical and

horizontal branches are shown in Figure 3 of the '035 patent, as annotated by Petitioner, reproduced below.

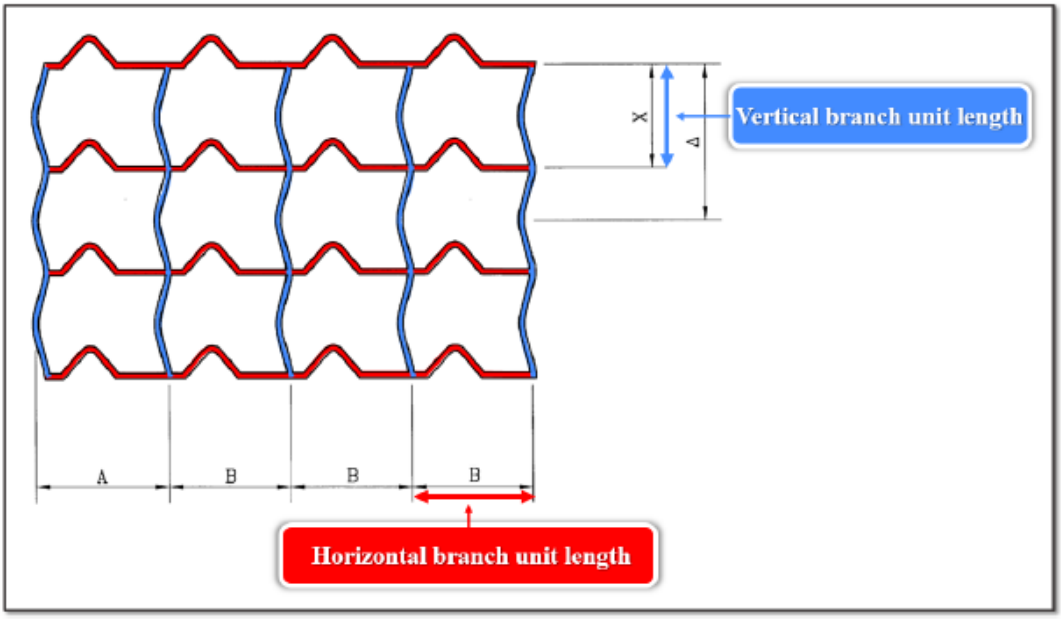


Figure 3 of the '035 patent, as annotated by Petitioner, shows vertical (blue) and horizontal (red) branches of an embodiment of the invention. Pet. 26.

Petitioner contends that the term waveform projection refers to a horizontal branch which is not straight but deviates from an imaginary straight line between two adjacent vertical branches. *Id.* at 26. Petitioner contends that a waveform projection can have a variety of shapes including U-shaped, sinusoidal, triangular, square, or rectangular. *Id.* at 27–28.

Petitioner argues that while the '035 patent shows a preferred embodiment, where the horizontal branch comprises a straight portion in addition to a waveform segment, the claims should not be construed to require a straight portion for the claimed horizontal branches. *Id.* at 27.

Patent Owner contends that the term "horizontal branches having waveform projections" should be construed to mean "links or connectors

that extend generally longitudinally between vertical branch attachments and comprise a portion in the shape of a wave that protrudes or projects from a portion extending in the prevailing longitudinal direction." PO Resp. 1 (emphasis omitted). Patent Owner contends that its proposed construction is correct and gives meaning to the term "projections." *Id*. at 1–2.

Patent Owner contends that its proposed construction is compelled by the ordinary meaning of the term and by the intrinsic evidence. *Id.* at 2–5. For example, Patent Owner contends that the figures of the '035 patent show a projection having a straight portion. *See id.* at 4. Patent Owner contends that Petitioner's proposed construction deviates from the plain meaning of the term and renders the term "projections" superfluous. *Id.* at 5–6.

We considered the arguments presented by the parties and the evidence of record and conclude that Petitioner's proposed construction is proper. The evidence of record shows that the term "projection" refers to something which extends out from something else. Ex. 2014, 1362; *see also* Ex. 2015, 1402; Ex. 2016, 1813–14; Ex. 2013, 1546. The evidence also shows that the term "wave form" modifies the term "projection," requiring the "projection" to have a shape of a wave or a curve. Ex. 2013, 2150; Ex. 2014; 1908.

Using these common definitions, we agree with Petitioner that the term "horizontal branches having waveform projections" refers to horizontal branches which have a waveform shape and project out from the points where the horizontal branches meet the vertical branches. *See* Pet. 26–28.

The intrinsic evidence does not dictate a different result. While we agree with Patent Owner that the figures of the '035 patent show a projection arising from a straight portion of a horizontal branch, we discern nothing in the Specification, nor does Patent Owner point to anything in the

Specification, which limits the invention to the specific embodiment shown in the drawings. *See, e.g.,* Ex. 1001, col. 2, ll. 15–40. "A claim is not limited to inventions looking like those in the drawings." *Skedco, Inc. v. Strategic Operations, Inc.*, 685 F. App'x 956, 960 (Fed. Cir. 2017).

We are not persuaded by Patent Owner's argument that Petitioner's construction renders the term "waveform projection" superfluous. PO Resp. 6–7. We agree with Petitioner that, as used in the challenged claims, the term describes the shape of the projections. Reply 10. Patent Owner's expert, Dr. Solar, acknowledged that the term waveform narrows the term projection. Ex. 1058, 205–206. Thus, the term "waveform" does not render the term "projection" superfluous.

Patent Owner argues that the term must include a straight portion because it allows the stent to be pressed into a thinner profile when crimped. PO Resp. 5 (citing Ex. 1001, col. 1, ll. 41–42). Although this may be true, the claims do not recite a limitation calling for a thinner profile. Moreover, the evidence or record demonstrates that a thinner profile can be achieved without the presence of a straight horizontal portion. *See, e.g.*, Ex. 1008, 139 (NIR stent has a very low profile).

2. Not All Branches must have the Same Dimensions

Patent Owner contends that claim 1 requires that all the branches must meet the shape and size limitation of the claims. PO Resp. 7. Specifically, Patent Owner contends that all horizontal branches, and not just a subset, must have a width and thickness range of 0.05 to 0.08 mm and 0.08 to 0.12 mm, respectively. *Id.* (citing Ex. 2019, 24–25). Similarly, Patent Owner contends that all vertical branches must have a width and a thickness range of 0.09 to 0.12 mm and 0.08 to 0.12 mm, respectively. *Id.*

Patent Owner contends that while the claims use the term "comprising" and that the term "comprising" is generally construed as permitting additional elements, the claims, as worded, limit all branches, both vertical and horizontal, to the shape and dimensions recited in the claims. PO Resp. 7. Patent Owner contends that the term "branches whose width and thickness range" indicates that the term "branches" is closed-ended and requires that all branches meet the width and thickness requirements recited in the claims. *Id.* at 8. Patent Owner contends that Petitioner is improperly trying to make the claims open-ended. *Id*. at 9.

In support of its contention that all of the branches must meet the width and thickness requirements, Patent Owner cites to *Apple Inc. v. Samsung Elecs. Co*., 695 F.3d 1370 (Fed. Cir. 2012) and *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337 (Fed. Cir. 2007). *Id.* at 9–11. Patent Owner contends, like the claims in *Apple* and *Dippin' Dots*, the claims here should be interpreted as excluding branches which do not meet the width and thickness requirements set forth in the claims. *Id.*

Petitioner responds "nothing in the claim forecloses a stent from having additional unrecited branches." Reply 3. Petitioner argues that "[t]he open-ended phrase 'comprises' allows for additional vertical/horizontal branches to be present, as long as at least two of each type satisfy the claimed characteristics." *Id.* at 3–4. Petitioner contends that the Federal Circuit's decisions in *Apple* and *Dippin' Dots* are distinguishable from the facts in the present case. *Id.* at 4–5.

Petitioner contends that the intrinsic record does not support Patent Owner's proposed construction. *Id.* at 5–6. Petitioner also contends that the extrinsic evidence does not support Patent Owner's construction. *Id.* at 6–9.

We have considered the arguments advanced by the parties and the evidence of record and conclude that the claims do not require that all branches must meet the width and thickness requirements of the claims. It is black letter law that the use of the term "comprises" is a term of art used in claim language that means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim. *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997). Thus, the plain language of the claims allows additional elements to be present, including branches that do not possess the recited limitations.

This approach is consistent with that taken by the Federal Circuit in *Therasense, Inc. v. Becton, Dickinson & Co*, 593 F.3d 1325 (Fed. Cir. 2010) and *ResQNet.com, Inc. v. Lansa, Inc*., 346 F.3d 1374, 1382 (Fed. Cir. 2003). In *Therasense*, the Federal Circuit considered whether a claimed electrode strip "comprising . . . a reference or counter electrode . . . spaced downstream of said working electrode in said sample transfer path" was invalid in view of a prior art reference with a counter electrode spaced downstream of only one of several working electrodes. *Therasense*, 593 F.3d at 1329. The court explained "[t]he claims require only that a single counter electrode be spaced downstream of a single working electrode." *Id*. at 1335. "[T]he open-ended transitional phrase 'comprising' allows for additional working electrodes to be present in the claimed invention," and "it is sufficient for purposes of the 'downstream' limitation if the counter electrode is located downstream of only a single, 'said,' working electrode" of the several working electrodes in the device. *Id*.

Likewise, in *ResQNet.com*, the court held a "comprising" claim, reciting "each of a plurality of fields" to require "at least two," but not all, fields, have the recited characteristics. 346 F.3d at 1382.

Patent Owner does not contest the general proposition of patent law that the term "comprises" allows the presence of unrecited elements, but contends that the term "comprises" only allows the presence of elements other than vertical or horizontal branches. PO Resp. 8, Tr. 49–50. Patent Owner argues that allowing the presence of branches that do not meet the requirements of the claims would remove the limitations present in the claims. PO Resp. 8. Patent Owner contends that the use of the term "branches whose width and thickness range" signifies that all branches must have the required width and thickness. *Id.*

We are unpersuaded by this argument. Allowing the presence of some branches that do not meet the dimensional and shape requirements of the claim because of the use of the "comprising" transitional phrase does not read out the express limitations recited in the claims. The claim still requires that at least some of the branches meet the claim requirements. Thus, the limitations have effect and limits the claim.

The cases cited by Patent Owner do not support Patent Owner's proposed claim construction. In *Apple*, the claim term at issue called for "each heuristic module" to possess certain characteristics. 695 F.3d at 1377. The Federal Circuit found that the use of the term "each heuristic module" meant that all the heuristic modules must possess those characteristics. *Id.* at 1378–79. The present claims to not use the language "each" to denote that all the branches must have the recited width and thickness.

With respect to *Dippin' Dots*, we begin by noting that the claim at issue in *Dippin' Dots* was a method claim, and the language "comprising" related to the steps of the method and not the resulting product, which appear in the method claim as "beads" and "said beads." 476 F.3d at 1343. Thus, the language "comprising" would have allowed additional method

steps. *Id.* In contrast, the present claims are directed to a composition of matter (i.e., an apparatus, and more specifically a stent) and the use of the term "comprising" permits additional elements in the stent.

In addition, in *Dippin' Dots*, the specification of the patent at issue specifically described the "beads" produced by the process as having a smooth and spherical appearance. *Id.* Moreover, the patentee in *Dippin' Dots* had argued that the term "bead" should be construed as a small round ball or round drop. *Id.* The Court held that the term "'comprising' does not reach into each of the six steps to render every word and phrase therein open-ended— especially where . . . the patentee has narrowly defined the claim term it now seeks to have broadened." *Id.*

In the present case, the Specification does not contain an explicit and limiting teaching that all branches must meet the recited limitations. In fact, the Specification teaches that the branches can have dimensions outside the claimed ranges. For example, the Specification teaches that the horizontal branches may have a width of up to 0.09 mm. Ex. 1001, code (57), col. 2, ll. 26–27. Construing the claims to permit some branches that do not meet the express claim limitations would not negate or render superfluous the express claim requirement that at least two of the branches meet the recited dimensional and shape requirements of the claims.

Patent Owner contends that the Specification and prosecution history of the '035 patent support its contention that all the branches must meet the requirements recited in the claims. PO Resp. 11–19. Patent Owner contends that the Specification teaches that the stents of the invention provide superior flexibility. Patent Owner contends that one skilled in the art would understand that, to achieve the desired flexibility, all of the branches of the

stent must meet the shape and dimensions expressly recited in the claims. *Id.* at 15 (citing Ex. 2019, 32–36).

Patent Owner also contends that the claimed stent provides improved clinical outcomes resulting from the design of the stent. *Id.* at 16–17. Patent Owner contends that one skilled in the art would understand that, to achieve the desired clinical outcome, all the branches of the stent must have the recited shape and dimensions. *Id.*

We remain unpersuaded by Patent Owner's arguments. Although the Specification refers to improved flexibility, we note that this is a desired objective of the invention and is not a limitation on the claims. Patent Owner's argument would have us read into the claims a requirement for some particular degree of flexibility that is not there.

> While a court may look to the specification and prosecution history to interpret what a patentee meant by a word or phrase in a claim, extraneous limitations cannot be read into the claims from the specification or prosecution history. . . . In other words, a court may not read into a claim a limitation from a preferred embodiment, if that limitation is not present in the claim itself.

Bayer AG v. Biovail Corp., 279 F.3d 1340, 1348 (Fed. Cir. 2002).

Moreover, the evidence of record teaches that flexibility can be achieved in stents which do not have all of the branches falling within the shape and dimensions recited in the claims. For example, Patent Owner's expert testified that a stent with waveform projections on only some of the horizontal branches would still be a very flexible stent. Ex. 1058, 164–166.

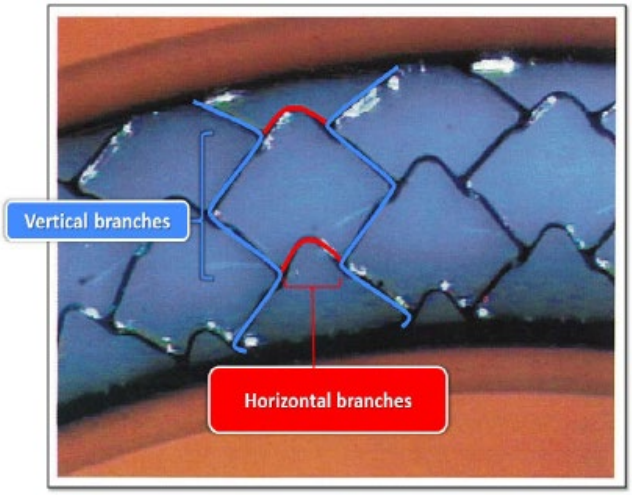
Based on the foregoing, we conclude that the claims do not exclude the presence of some branches that do not meet the shape and dimension requirements recited in the claims.

D. Ground 1 – Obviousness based on Richter-Handbook combined with Richter '404

Petitioner contends that claims 1–3 are unpatentable under 35 U.S.C. § 103(a) as obvious over the Richter-Handbook combined with Richter '404. Pet. 30–52. Patent Owner disagrees. PO Resp. 21–49.

1. Richter-Handbook

As shown in the annotated[2] 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.



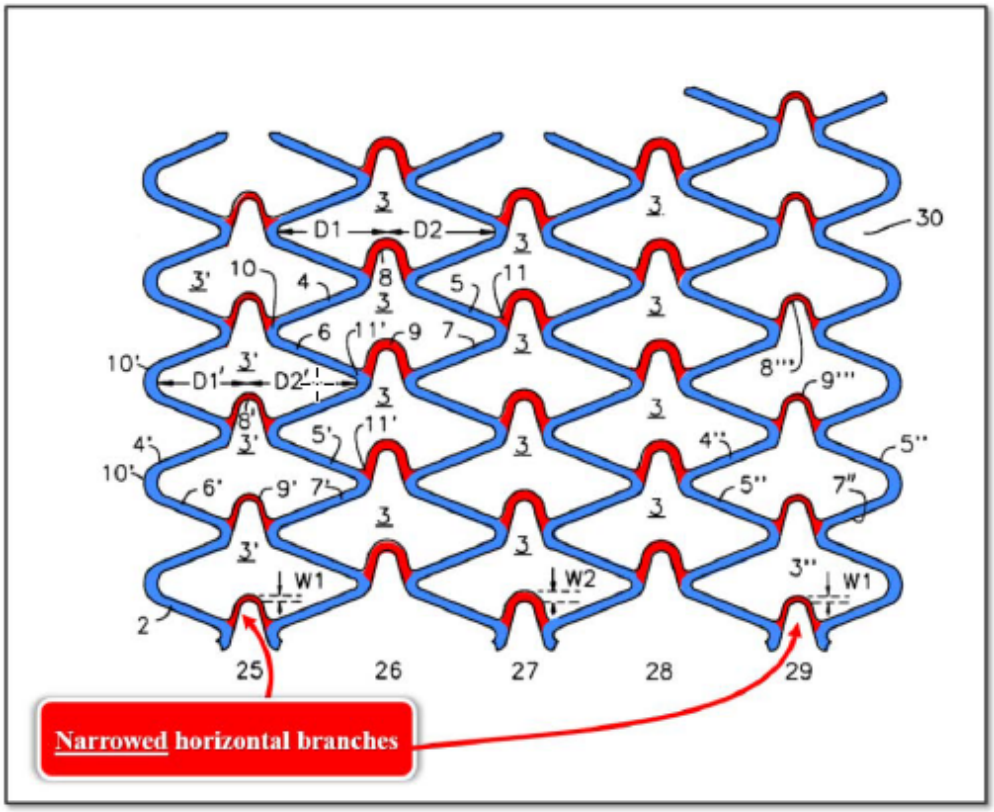
Annotated figure 15.3 from Richter-Handbook showing a stent with vertical branches in blue and horizontal branches in red. Pet. 12.

Richter-Handbook teaches that all the branches (struts) have a thickness of 0.1 mm. Ex. 1008, 137.

[2] 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.

2. Richter '404

As shown in the annotated Figure 10 of Richter '404 below, Richter '404 teaches a vascular stent having vertical and horizontal branches with 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 that the vertical branches, resulting in an improvement in the stent's lateral flexibility. Ex. 1010, col. 6, l. 67 – col. 7, l. 3.

3. Analysis of Claim 1

Claim 1 is the sole independent claim. Petitioner contends that the subject matter of claim 1 would have been obvious to one of ordinary skill in

the art at the time the invention was made over Richter-Handbook combined with Richter '404. Pet. 34–48.

a) A vascular stent which comprises

Petitioner contends that the Richter-Handbook describes a vascular stent. Pet. 34. Patent Owner does not contest this contention. *See* PO Resp. 22–23.

Regardless of whether this preamble language is limiting, we find, based on the uncontested evidence cited by Petition, that it is disclosed in the asserted prior art. Pet. 34;Ex. 1008, 138.

b) Vertical branches whose width and thickness range from 0.09 to 0.12 mm and 0.08 to 0.12 mm, respectively

Petitioner contends that Richter-Handbook teaches this limitation. Petitioner contends that Richter-Handbook teaches that the struts are square in shape and that the struts have a thickness of 0.1 mm. Pet. 34–35 (citing Ex. 1008, 137, Ex. 1002 ¶¶ 117–118). Petitioner contends that the struts of Richter-Handbook are the same as the branches recited in claim 1. *Id.*

Patent Owner contends that Richter-Handbook does not disclose the required dimensions of the vertical branches, specifically, the width of the branches. PO Resp. 22–23, 31–38. Patent Owner contends that the teaching in Richter-Handbook, relating to strut design, is not directed to the cross-section of the strut but, instead, describes the pattern formed by the struts when the stent is expanded. *Id.* at 31–38. Patent Owner contends that this interpretation is supported by the teachings of other chapters of the Richter-Handbook, where the term is used to describe the shape of the cells formed. PO Resp. 32–33. Patent Owner contends that, at best, Richter-Handbook is ambiguous about the width of the strut and, therefore, does not render claim 1 obvious. *Id.* at 38–40.

We have considered the arguments presented by the parties and the evidence of record and conclude that Richter-Handbook teaches stents having vertical branches with a thickness and a width of 0.10 mm. This falls within the ranges recited in claim 1 for thickness and width.

Richter-Handbook teaches that the struts or branches have a thickness of 0.1 mm and that the strut design is square. Ex. 1008, 137. We agree with Dr. Rao that, as used in the chapter of the Richter-Handbook cited by Petitioner, the term "strut design" refers to the shape of the strut itself and not the shape created by the branches when the stent is expanded. Ex. 1038 ¶¶ 48–50. Given that the strut is square shaped, one skilled in the art would understand that the thickness and width of the strut are the same – 0.1 mm. *Id.*

We are not persuaded by Patent Owner's argument that Richter-Handbook's reference to a square shape is to the shape of the cells created by the vertical and horizontal branches when the stent is expanded. PO Resp. 33–34. Richter-Handbook refers to the structure formed by the struts when the stent is expanded as a cell and describes the shape of the cells as "diamond-like." Ex. 1008, 141. Patent Owner's expert agreed that the cells shown in Richter-Handbook are diamond-like. Ex. 1058, 215–219. Given that the cited chapter of Richter-Handbook explicitly uses the term "diamond-like" to describe the cells and the term "square" to describe the struts which form the cells, we agree with Dr. Rao that one skilled in the art would understand that the term "square" refers to the shape of the strut and not the cells that are formed when the stent is expanded. Ex. 1038 ¶¶ 48–50.

c) Horizontal branches having wave form projections

Petitioner contends that this limitation is taught by either Richter-Handbook alone or in combination with Richter '404 and, if needed, Israel.[3] Pet. 37–42. In support of this contention, Petitioner points to Figure 15.3 of the Richter-Handbook (reproduced below) and Figure 2 of Richter '404 (reproduced below), which show horizontal branches that comprise wave form projections that connect the vertical branches. Pet. 37–39.

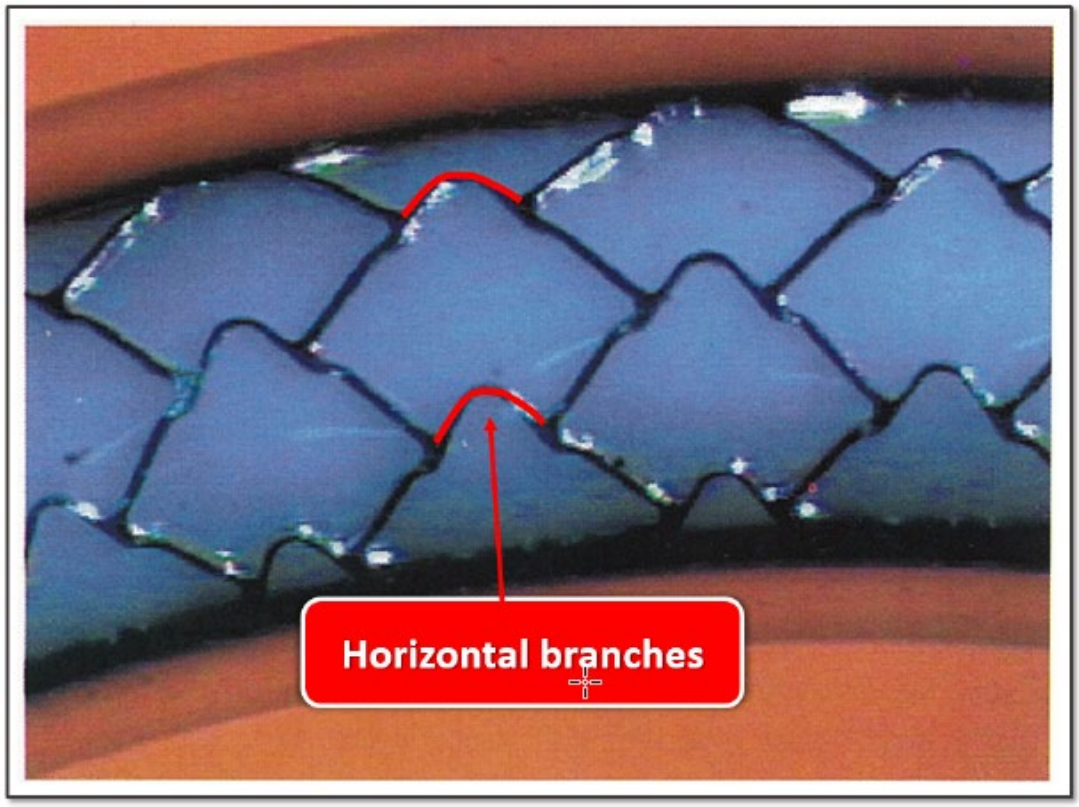


Figure 15.3 of Richter-Handbook annotated by Petitioner to show the horizontal branches in red. Pet. 38.

[3] Israel et al., US 5,733,303, issued March 31, 1998 (Ex. 1011, "Israel").

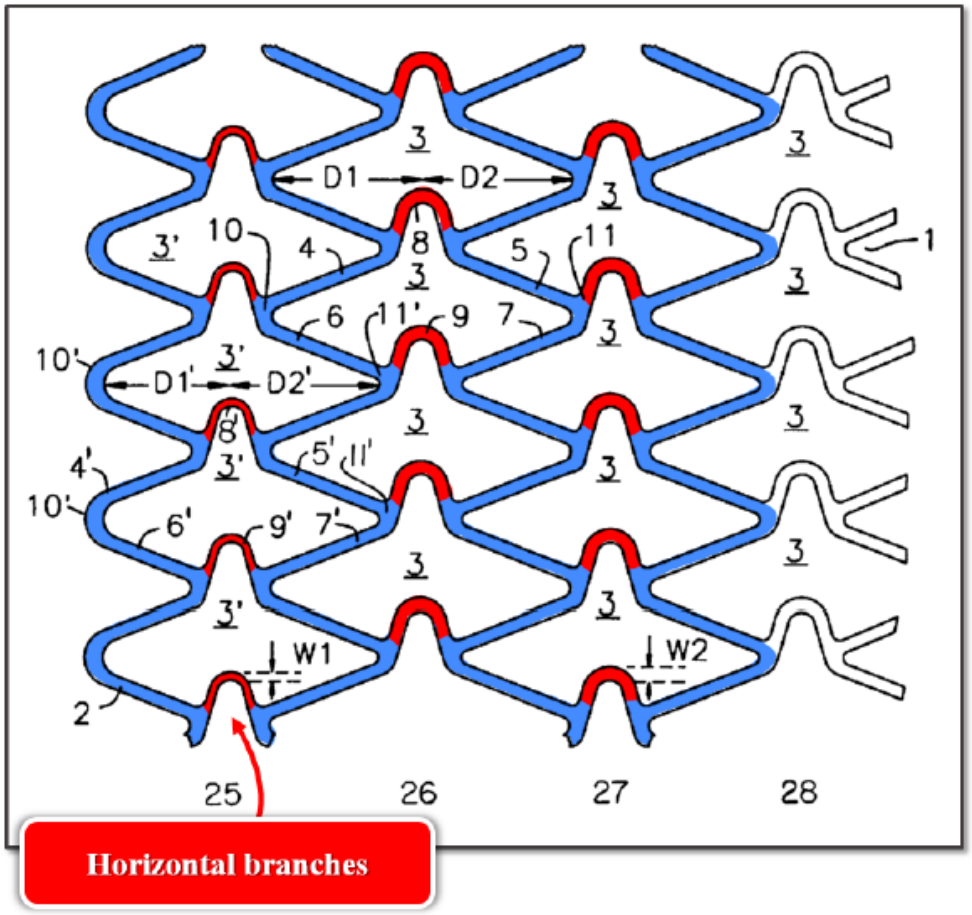


Figure 2 of Richter '404 annotated by Petitioner to show the horizontal branches in red and the vertical branches in blue. Pet. 39.

Petitioner contends that the claims do not require that the horizontal branches include a straight portion (in addition to a wave form portion) but, if the claims were construed to include a straight portion, then that limitation is taught by Israel which is incorporated by reference into Richter '404. Pet. 39–41. In support of this contention, Petitioner points to Figure 2 of Israel (reproduced below), which Petitioner argues shows horizontal branches with straight portions as well as wave form portions. *Id.*

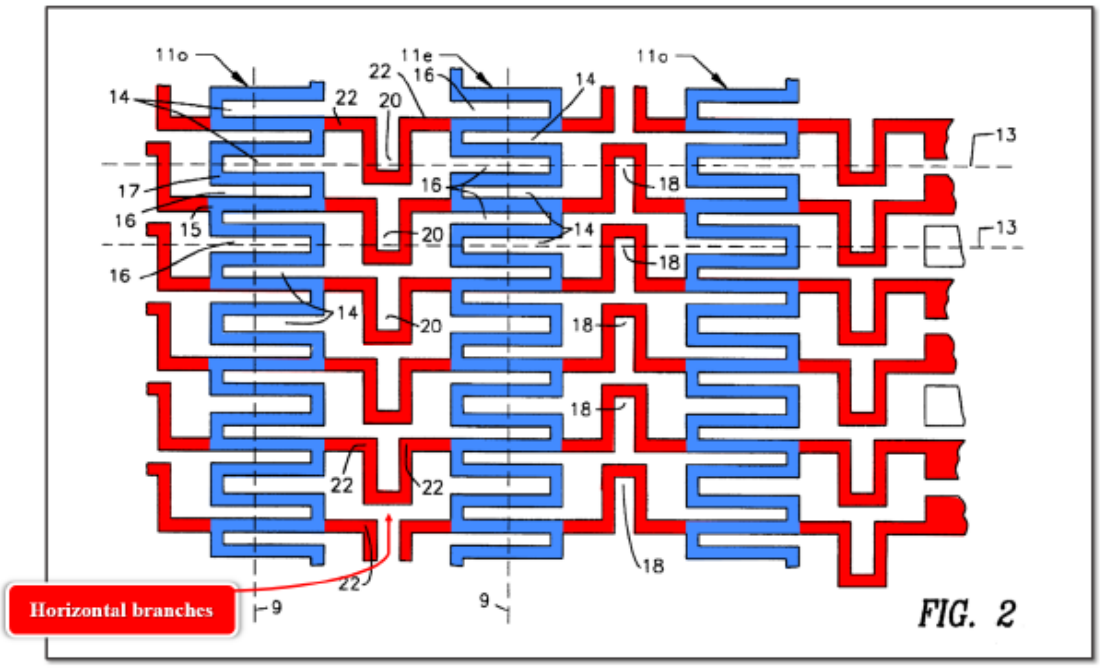


Figure 2 of Israel annotated by Petitioner to show horizontal elements in red and vertical elements in blue. Pet. 41.

Patent Owner contends that neither of the Richter references teaches or suggests horizontal branches having wave form projections. PO Resp. 40–47. Patent Owner contends that the u-shaped branches shown in the Richter references are not wave form projections, as the u-shaped potions do not project from a longitudinal or straight portion of the horizontal branch. *Id.* at 41–42. Patent Owner also argues that one skilled in the art would not have incorporated the teachings of Israel into the teachings of the Richter references as the Richter-Handbook teaches away from such a combination. *Id.* at 44–47.

We have considered the arguments presented by the parties and the evidence of record and find that Richter-Handbook and Richter '404 both teach horizontal branches having wave form projections. As discussed above, we have declined to adopt Patent Owner's construction that the wave

form projection must project out from a linear portion of the horizontal branch or have a particular "wave" shape. As shown above, both Richter-Handbook and Richter '404 teach curved, wave-shaped horizontal branches that project out from between the vertical branches. Richter-Handbook, Fig. 15.3; Richter '404, Fig. 2; Ex. 1002 ¶¶ 120–122. Having found that the Richter references teach this element, we need not consider the parties' arguments regarding Israel.

4. Whose width and thickness range from 0.05 to 0.08 mm and 0.08 to 0.12 mm, respectively

Petitioner contends that Richter-Handbook combined with Richter '404 teaches this limitation. Pet. 42–46. Petitioner contends that Richter-Handbook teaches that the horizontal struts or branches have a thickness and width of 0.10 mm. *Id.* at 43 (citing Ex. 1008, 140; Ex. 1002 ¶ 132). Petitioner contends that Richter '404 teaches narrowing the horizontal branches by 40 to 50% to improve the flexibility of the stent which would reduce the width of the stent to between 0.05 and 0.06 mm. *Id.* at 44–45 (citing Ex. 1010, col. 6, l. 67 – col 7, l. 3; Ex. 1002 ¶ 135). Petitioner contends that Richter '404 teaches that the thickness of the branches remains that same. *Id.* at 45 (citing Ex. 1010, col. 6, ll. 60–65).

Patent Owner contends that while Richter '404 teaches to narrow the width of some of the horizontal branches, Richter '404 does not teach narrowing all of the horizontal branches as required by the claims. PO Resp. 24–25. Patent Owner contends that Richter '404 teaches the use of narrow horizontal branches at the ends of the stents to address problems that occur at the ends of the stent. *Id.* at 26. Patent Owner contends that it would not have been obvious to apply Richter's teaching to narrow the horizontal branches in the middle of the stent to problems which occur at the ends of

the stents. *Id.* at 26–30. Patent Owner also contends that narrowing all of the horizontal branches would obliterate Richter '404's teaching of a stent with variable features. *Id.* at 30–31. Patent Owner also contends that neither Richter reference teaches the width of the horizontal branch. *Id.* at 31–40.

We have considered the arguments presented by the parties and the evidence of record and conclude that the teachings of Richter-Handbook combined with those of Richter '404 teaches the limitation calling for horizontal branches having a width and thickness ranging from 0.05 to 0.08 mm and 0.08 to 0.12 mm, respectively. As discussed above, Richter–Handbook teaches a stent where both the vertical and horizontal branches are square in shape and have a thickness of 0.10 mm. Ex. 1008, 137. This falls within the horizontal thickness range recited in claim 1. Richter '404 teaches:

> In the embodiment shown in FIGS. 1 and 2 [reproduced below], the U-shaped loops 8' and 9' of row 25 are provided with the same thickness of material as the U-shaped loops 8 and 9 of the cells 3 in rows 26, 27, and 28, however, U-shaped loops 8' and 9' are not as wide. As shown in FIGS. 1 and 2, U-shaped loops 8' and 9' have a width W1 that is less than the width W2 of U-shaped loops 8 and 9 in the cells 3 of rows 26, 27, and 28. In a preferred embodiment, W1 is about 50% narrower than W2. In an especially preferred embodiment, W1 is about 40% narrower than W2.

Ex. 1010, col. 6, l. 60 – col. 7, l. 3.

Figures 1 and 2 of Richter '404 are reproduced below.

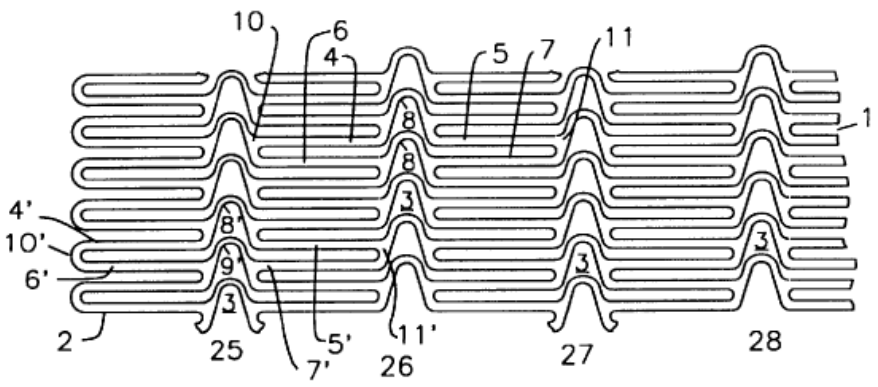


FIG. 1

Figure 1 of Richter ’404 shows a pattern of an embodiment of the stent in an unexpanded state. Ex. 1010, col. 5, ll. 10–11.

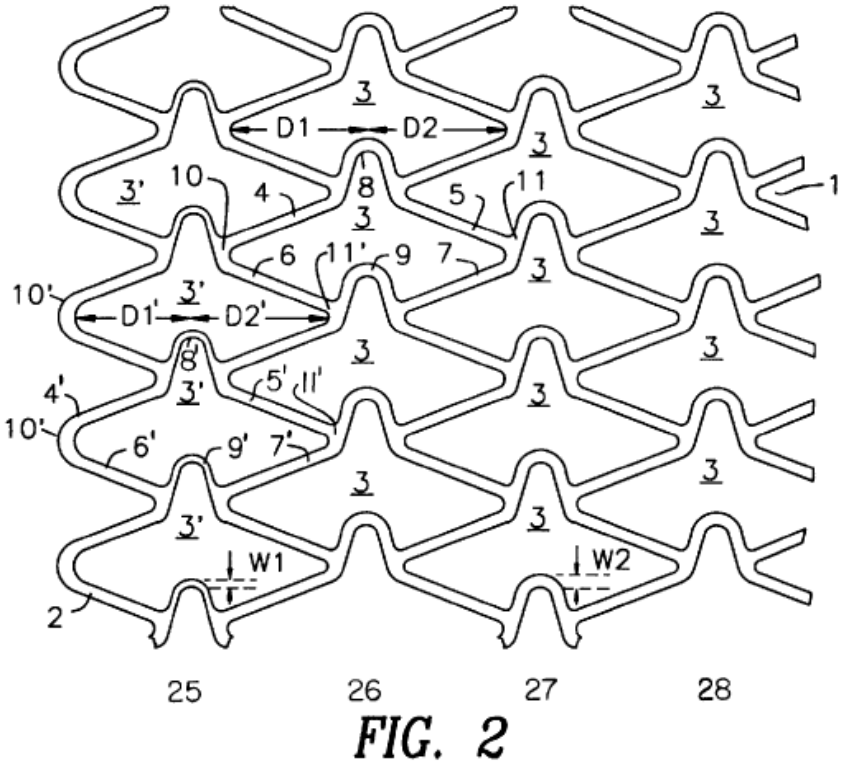


FIG. 2

Figure 2 of Richter ’404 shows a pattern of a stent in the expanded state. Ex. 1010, col. 5, ll. 13–14.

We agree with Dr. Rao that reducing the width of the horizontal branches of Richter-Handbook as taught by Richter '404 would result in horizontal branches having a width of from 0.05 mm to 0.06 mm. Ex. 1002 ¶¶ 134–136. This range overlaps with the horizontal width range recited in claim 1 – 0.05 to 0.08 mm. Ex. 1001, col. 4, ll. 10–11.

We are unpersuaded by Patent Owner's arguments that neither Richter reference teaches that all the horizontal branches must possess the dimensions recited in claim 1. Patent Owner's argument is premised on construing the claims as requiring all horizontal branches of the stent to meet the dimension limitations. As discussed above, we decline to construe the claims in that manner, rather, we construe the claims to require that at least two or more of the horizontal branches meet the dimension requirements of claim 1. *See* Section II.C.2, *supra.* Richter '404 unequivocally teaches that at least some of the horizontal branches meet the dimension limitations of claim 1. Ex. 1010, col. 6, l. 60 – col. 7, l. 3.

With respect to Patent Owner's argument regarding the failure of either of the Richter references to teach the width and thickness of the stents, we note that the argument presented is the same as for the width and thickness of the vertical branches discussed above. *See* PO Resp. 31–40. For the reasons stated above, we find this argument unpersuasive.

5. Analysis of Claim 2

Claim 2 depends from claim 1 and adds the limitation that the lengths of the vertical and horizontal branches range from 1.5 to 4.5 mm and 1.0 to 3.0 mm, respectively. Ex. 1001, col. 4, ll. 12–14.

Petitioner contends that the subject matter of claim 2 is taught by either Richter-Handbook alone or in combination with Richter '404. Pet. 48–52. Petitioner contends that while Richter-Handbook is silent as to the length

of the branches, the length of the branches can be readily calculated from Figure 13.5 of the Richter-Handbook. *Id.* at 48–49. In support of this contention, Petitioner offers the testimony of Dr. Rao, who used the photograph in Figure 13.5, combined with the disclosure in Richter-Handbook regarding the width of the branches, to calculate the length of the branches. *Id.* (citing Ex. 1002 ¶¶ 144–151).

Petitioner also contends that based on the teachings of Richter-Handbook and Richter '404, one skilled in the art would have known that the length of the branches can be varied depending on the desired properties of the stent and thus is a matter of design choice. *Id.* at 50–52.

Patent Owner does not offer a separate argument for claim 2. *See* PO Resp. 21–50.

We find that the subject matter of claim 2 would have been obvious over Richter-Handbook and Richter '404. Richter '404 teaches that the size and shape of the cells of a stent are driven by the application for the stent. Ex. 1010, col. 4, ll. 46–50. Richter '404 also teaches that vertical branch lengths can alter the radial strength of the stent. *Id.* at col. 2, ll. 3–17. Richter '404 teaches that altering the length of the branches can ensure the best fit for the anatomy of the target area. *Id.* at col. 4, ll. 55–64.

We also agree with Petitioner that even if the Richter references are silent as to the specific lengths of the branches of the stents, it would be a matter of design choice. *See Rexnord Indus., LLC v. Kappos*, 705 F.3d 1347, 1356 (Fed. Cir. 2013) (undisclosed 10 mm claimed dimension in a conveyor belt was an obvious "design choice" because it was small enough to avoid catching and pinching fingers).

6. Analysis of Claim 3

Claim 3 depends from claim 1 and adds the limitation that the diameter and length of the stent range from 1.0 to 5.75 mm and 9.0 to 60 mm, respectively. Ex. 1001, col. 4, ll. 15–17.

Petitioner contends that the subject matter of claim 3 is taught by Richter-Handbook. Pet. 53. Petitioner contends that Richter-Handbook teaches that the stents can have an expanded diameter of from 2 to 5 mm and can have a length of 9, 16, and 32 mm. *Id.* (citing Ex. 1008, 137; Ex. 1002 ¶ 155).

Patent Owner does not present a specific argument regarding claim 3. *See* PO Resp. 21–50.

We find that Richter-Handbook teaches the limitations recited in claim 3. Richter-Handbook teaches that the available expanded diameters of the NIR stents range from 2 to 5 mm and the available lengths are 9, 16, and 32 mm. Ex. 1008, 137. These values fall squarely within the ranges recited in claim 3.

7. Motivation to Combine the References

Petitioner contends that one skilled in the art would have been motivated to combine the teachings of Richter-Handbook and Richter ’404 to produce a stent meeting the limitations of claim 1. Pet. 46–48. Petitioner contends that the motivation stems from the fact that the Richter references are by the same author and from the same company. *Id.* at 46–47 (citing Ex. 1002 ¶ 140). Petitioner also contends that one skilled in the art would have been motivated to combine the references, as Richter teaches that narrowing at least some of the horizontal branches improves the flexibility of the stent. *Id.* at 47–48 (citing Ex. 1010, col. 6, ll. 57–60; Ex. 1002 ¶ 140).

Patent Owner does not present a specific argument regarding any lack of motivation to combine the Richter references.[4]

Based on the foregoing, we find that one skilled in the art would have been motivated to combine the teachings of Richter-Handbook and Richter '404 to produce a stent meeting the limitation recited in claim 1. Richter-Handbook and Richter '404 relate to stents made by the same company, Medinol, Ltd. Ex. 1008, 137; Ex. 1010, code (73). Richter '404 teaches that the flexibility of a stent having the same configuration as shown in the Richter-Handbook can be improved by narrowing at least some of the horizontal branches. Ex. 1010, col. 6, l. 60 – col. 7, l. 3. We agree with Dr. Rao that this would have led one skilled in the art to modify the stent taught in the Richter-Handbook as taught by Richter '404 to produce the stent described in claim 1. Ex. 1002 ¶¶ 140–142.

8. Unexpected Results

Before any final obviousness determination, we must consider the evidence of obviousness in light of any objective evidence of nonobviousness presented by Patent Owner. *See Graham*, 383 U.S. at 17–18 ("Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy."); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk*

[4] While Patent Owner's Response includes section titled "Petitioner's purported motivations to combine fail," that portion of the Response relates to a motivation to combine the teachings of Israel with the Richter references. PO Resp. 48–50. Our Decision does not rely on the combination of the Richter references with Israel as discussed above.

Drilling USA, Inc., 699 F.3d 1340, 1349 (Fed. Cir. 2012) ("This objective evidence must be 'considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.'" (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983))).

Objective evidence of nonobviousness is relevant only if there is a nexus between the evidence and the claimed invention. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019). A presumption of nexus applies if the asserted objective evidence "is tied to a specific product and that product 'embodies the claimed features, and is coextensive with them.'" *Id.* (quoting *Polaris Indus., Inc. v. Artic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018)). To the extent that a presumption of nexus does not apply, Patent Owner may still prove nexus "by showing that the evidence of secondary considerations is the 'direct result of the unique characteristics of the claimed invention.'" *Id.* at 1374 (quoting *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996)). The stronger the showing of nexus, the greater the weight accorded to the objective evidence of nonobviousness. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 (Fed. Cir. 1985).

Patent Owner presents arguments and evidence directed to an objective indicia of non-obviousness – unexpected results. PO Resp. 71–76. Patent Owner contends that the data reported by the inventor, Dr. Jang, in his declaration, submitted during prosecution, shows that the stents of the invention "achieve much better results than ones whose horizontal or vertical branches fall outside the claimed ranges. They substantially reduce restenosis, fracturing, recoil, and thrombosis." *Id.* at 72 (citing Ex. 2019 ¶¶ 125–128; Ex. 1004, 94–97). Patent Owner contends that the results achieved were surprising and unexpected. *Id.* at 74.

Petitioner contends that the Jang Declaration, which serves as the basis of Patent Owner's argument and its expert's testimony about unexpected results should be excluded from consideration. Paper 38, 1 ("Pet. Mot. Excl."). Petitioner contends that the Declaration constitutes inadmissible hearsay and Dr. Solar's reliance on the Declaration is improper. *Id.* Petitioner also argues that the Declaration and Dr. Solar's testimony based on the Declaration should be excluded as Patent Owner declined to make Dr. Jang available for deposition, despite Dr. Jang providing assistance to Patent Owner and its expert in this proceeding and in the related district court proceeding. Paper 44, 5 ("Pet. Reply Mot. Excl.").

Petitioner also contends that even if the Board were to consider Dr. Jang's Declaration and Dr. Solar's testimony on unexpected results, the evidence does not support a finding of unexpected results. Reply 27–31. Petitioner contends that the results reported in Dr. Jang's Declaration do not make sense and cannot be properly relied upon. *Id.* at 28–29. Petitioner also contends that Petitioner has not had an opportunity to depose Dr. Jang about the results, despite Dr. Jang having an *ex parte* conversation with Dr. Solar, Patent Owner's expert. *Id.* at 29–30. Finally, Petitioner contends that the art shows that the results achieved by Dr. Jang were not unexpected. *Id.* at 30–31.

a) Petitioner's Motion to Exclude

We begin our analysis by looking at whether we should exclude Dr. Jang's Declaration and Dr. Solar's testimony based on that Declaration.

The Jang Declaration is a Declaration executed by the inventor of the '035 patent, Dr. Jang, during prosecution of the '035 patent. Ex. 1004, 94–98. In the Declaration, Dr. Jang reports the results of a series of experiments performed by him or under his supervision purportedly relating to the stents

claimed in his application. *Id.* at 94. The Declaration was submitted to support an argument made during prosecution that the claimed stents "are optimized to provide unexpectedly high efficiency of stenting." Ex. 1004, 92.

In his Declaration submitted in this proceeding, Patent Owner's expert, Dr. Solar, relied on Dr. Jang's Declaration as the sole support of his conclusion that stents meeting the limitations of the claims exhibited unexpected results. Ex. 2019, 125–135.

As discussed above, Petitioner contends that the Jang Declaration and Dr. Solar's testimony based on the Jang Declaration should be excluded as they are impermissible hearsay and because Petitioner was not afforded an opportunity to depose Dr. Jang about his Declaration and the work he reported in the Declaration. Pet. Mot. Excl. 1–10.

Patent Owner contends that the Jang Declaration is not hearsay with respect to its use in interpreting the claims. Paper 41, 3–6 ("PO Opp. Pet. Mot. Excl.). Patent Owner also contends that even if the Declaration were hearsay, Dr. Solar properly relied on the Declaration in forming his opinions, and it would be proper for the Board to consider the Declaration when reviewing Dr. Solar's testimony. *Id.* at 7–8. Patent Owner contends that Petitioner's arguments concerning the nature of Dr. Jang's Declaration go to the weight that should be afforded evidence, not its admissibility. *Id.* at 10–12.

Patent Owner also argues that 37 C.F.R. § 42.65(b) is inapplicable as Dr. Jang's Declaration is not expert testimony and that Petitioner waived any objection to the Declaration. *Id.* at 13. Patent Owner concludes by arguing that Petitioner's failure to depose Dr. Jang is a result of Petitioner failure to properly seek Dr. Jang's deposition through appropriate channels. *Id.* at 14.

We have considered the arguments presented by the parties as well as the evidence of record and conclude that Dr. Jang's Declaration and Dr. Solar's testimony which relies on Dr. Jang's Declaration should be excluded from consideration. Our decision to exclude Dr. Jang's Declaration and related testimony by Dr. Solar is based on Patent Owner's failure to secure Dr. Jang's attendance at a deposition requested by Petitioner as well as the testimony by Dr. Solar regarding the nature of the evidence discussed in Dr. Jang's Declaration.

While Dr. Jang is not a party to this proceeding, Patent Owner and its expert, Dr. Solar, rely on the substance of that Declaration of Dr. Jang to support Patent Owner's contentions regarding the unexpected results achieved by the claimed stents. *See, e.g.*, PO Resp. 71 (citing Jang Declaration to support the contention that the claimed stents substantially reduced restenosis, fracturing, recoil, and thrombosis); Ex. 1019, 130 (citing to Jang Declaration as showing reduced restenosis). As noted in the Patent Trial and Appeal Board Consolidated Trial Practice Guide dated November 2019 ("Guide"), "a party presenting a witness's testimony by affidavit should arrange to make the witness available for cross-examination. This applies to witnesses employed by a party as well as experts *and non-party witnesses*." Guide, 23 (emphasis added). While the Declaration was not specifically prepared for this proceeding, Patent Owner has relied upon it and made it a key part of its case. *See, e.g.,* PO Resp. 71–76. As we noted in our Decision to Institute, Patent Owner's evidence of unexpected results is better evaluated in the context of a fully developed record including the benefit of cross-examination of Dr. Jang. Inst. Dec. 14–15. Patent Owner's failure to cooperate with Petitioner to facilitate the Deposition of Dr. Jang deprives Petitioner and the Board of a fully developed record.

Patent Owner's contention that Dr. Jang is not a party to this proceeding and resides in Korea, which precludes Patent Owner from making him available, is not persuasive. *See* PO Opp. Pet. Mot. Excl. 14–15. Patent Owner was able to make Dr. Jang available to its expert, Dr. Solar, who discussed Dr. Jang's Declaration with Dr. Jang to confirm his opinions. Ex. 1058, 11–13. In addition, Dr. Jang has been involved in the related district court proceedings. Pet. Reply Mot. Excl. 4–5. It would be manifestly unfair for Patent Owner to affirmatively rely on the Declaration of Dr. Jang and allow its expert, Dr. Solar, to discuss that Declaration with Dr. Jang, while at the same time contending that it has no control over Dr. Jang and refusing to present him for deposition. Ex. 1063 (email detailing Petitioner's attempts to depose Dr. Jang). The unfairness of Patent Owner's position warrants excluding the Jang Declaration and the testimony of Dr. Solar that relies on that Declaration.

We also conclude that Patent Owner, as the party proffering the Jang Declaration to support the alleged unexpected results, had an obligation to secure attendance of the witness at deposition when requested by Petitioner, or risk the Board declining to give weight to those declarations." *L'Oreal USA, Inc. v. Liqwd, Inc.*, PGR2018-00025, Paper 107, 55–60 (PTAB July 30, 2019) (giving little weight to inventor (alleged third-party) declaration submitted during prosecution and related expert testimony on alleged unexpected results because Patent Owner did not make the inventor available for cross examination on the testing reported in the declaration). *HTC Corp. v. NFC Tech., LLC*, IPR2014-01198, Paper 41, 4–5 (PTAB Nov. 6, 2015) (striking declaration of non-party witness who refused to participate in deposition noticed by petitioner).

We are also persuaded to exclude Dr. Jang's Declaration as it lacks adequate details as contemplated by our rules, and is not trustworthy. 37 C.F.R. § 42.65 relates to expert testimony and what is required when a party relies on a technical test and related testing data. Although Patent Owner does not offer Dr. Jang as an "expert," its retained expert Dr. Solar does rely on the substance of Dr. Jang's Declaration and the testing work and data reported in the Declaration to support his opinions. We find that the factors listed in Section 42.65 provide guidance as to the trustworthiness of Dr. Jang's evidence as well as Dr. Solar's testimony based on that evidence.

37 C.F.R. § 42.65(b) provides:

> If a party relies on a technical test or data from such a test, the party must provide an affidavit explaining:
> (1) Why the test or data is being used;
> (2) How the test was performed and the data was generated;
> (3) How the data is used to determine a value;
> (4) How the test is regarded in the relevant art; and
> (5) Any other information necessary for the Board to evaluate the test and data.

As discussed above, Patent Owner, both directly and through its expert, relies on the tests reported by Dr. Jang in his Declaration. PO Resp. 71–76. We agree with Petitioner that Dr. Jang's Declaration fails to meet the requirements of Section 42.65. Pet. Mot. Excl. 6. For example, while Dr. Jang reports data regarding the percentage of recoiling exhibited by certain stents, Dr. Jang does not describe the test used to determine recoiling or whether the test used was one known and accepted in the art. Ex. 1004, 95–96. Dr. Jang also does not explain how the data he collected was used to determine the values reported in his Declaration. *Id.*

The inadequacy of the disclosure in Dr. Jang's Declaration is further illustrated by Dr. Solar's testimony regarding the Declaration. When asked about the portion of Dr. Jang's Declaration relating to fracturing observed in the stents, Dr. Solar testified:

> In reading – in reading his declaration, he just notes that fracturing occurred in those groups and doesn't explain about the percentage.
>
> Clearly, in his experiments there's a lot more information than what's described in this very short declaration. And I do not have that information. So it's difficult for me to answer some of your questions.

Ex. 1058, 74.

Based on the foregoing, we grant Petitioner's motion to exclude Dr. Jang's Declaration and the testimony of Dr. Solar that relies on Dr. Jang's Declaration. We need not address Petitioner's hearsay objections as we grant Petitioner's motion because the information in Dr. Jang's Declaration is inherently inadequate and untrustworthy.

b) Evidence of Unexpected Results is Unpersuasive

We find that even if we were to consider the substance of Patent Owner's evidence of unexpected results, that evidence is not persuasive and does not outweigh the evidence of obviousness on this record.

We begin by noting that Dr. Jang's work was directed to optimizing the parameters of the stents. Ex. 1004, 94. For example, he states "it is clearly determined that the thickness of subject vascular stent (i.e., 0.08 to 0.12mm) is optimized to provide high efficiency of stenting." *Id.* at 95. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456 (CCPA 1955).

We also note that the express affirmative statement in the prosecution history that the results were "unexpected" is not the testimony of Dr. Jang in his Declaration, but is mere attorney argument. *Compare* Ex. 1004, 92, *with* Ex. 1004, 94–97 (Dr. Jang's Declaration (discussing a "clear demonstration" that the widths of the branches in the stents "are optimized to provide high efficiency of stenting")). "Attorneys' argument is no substitute for evidence." *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989).

While Dr. Solar has testified that, in his opinion, the results reported in Dr. Jang's Declaration were unexpected, we would afford that testimony little weight if considered. Ex. 2019, 134. As Dr. Solar testified, the data reported in Dr. Jang's Declaration is incomplete. Ex. 1058, 74. Dr. Solar also testified that he did not know if the data reported by Dr. Jang was statistically significant or which standards Dr. Jang used to determine restenosis. *Id.* at 123.

We also find that the data reported by Dr. Jang does not compare the stents of his invention with the closest prior art. *See* Ex. 1004, 94–99. "To be particularly probative, evidence of unexpected results must establish that there is a difference between the results obtained and those of the closest prior art, and that the difference would not have been expected by one of ordinary skill in the art at the time of the invention." *Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014). Although Dr. Jang compared stents having varying thickness and widths, the stents appear to have all been based on Dr. Jang's design. *See* Ex. 1004, 95–97. Dr. Jang does not report the results for any prior art stents, such as the Richter-Handbook stent that reports a recoil of less than 1%, less than that reported by Dr. Jang. *Compare* Ex. 1004, 94, *with* Ex. 1008, 137.

9. Conclusion

Based on the foregoing, we conclude that the subject matter of challenged claims 1–3 would have been obvious over Richter-Handbook combined with Richter '404. The combined teachings of the Richter references disclose the creation of a stent having dimensions falling within the limitations recited in the claims.

We also conclude, for the reasons discussed above, that one skilled in the art would have been motivated to combine the teachings of the Richter references to produce the claimed stent with a reasonable expectation of success.

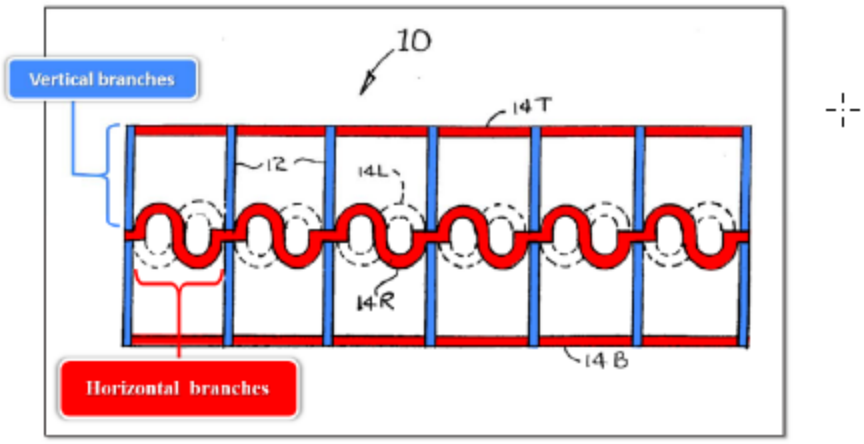
Finally, with respect to the evidence of unexpected results, we grant Petitioner's motion to exclude the Jang Declaration and the testimony of Dr. Solar based on that Declaration. We also conclude that, even if Dr. Jang's Declaration were considered, the evidence of record does not persuasively establish unexpected results to support a conclusion of non-obviousness.

E. Ground 2 – Obviousness Based on Fischell '114 and Penn

Petitioner contends that the subject matter of claims 1–3 would have been obvious to one of ordinary skill in the art at the time the invention was made over Fischell '144 combined with Penn. Pet. 55.

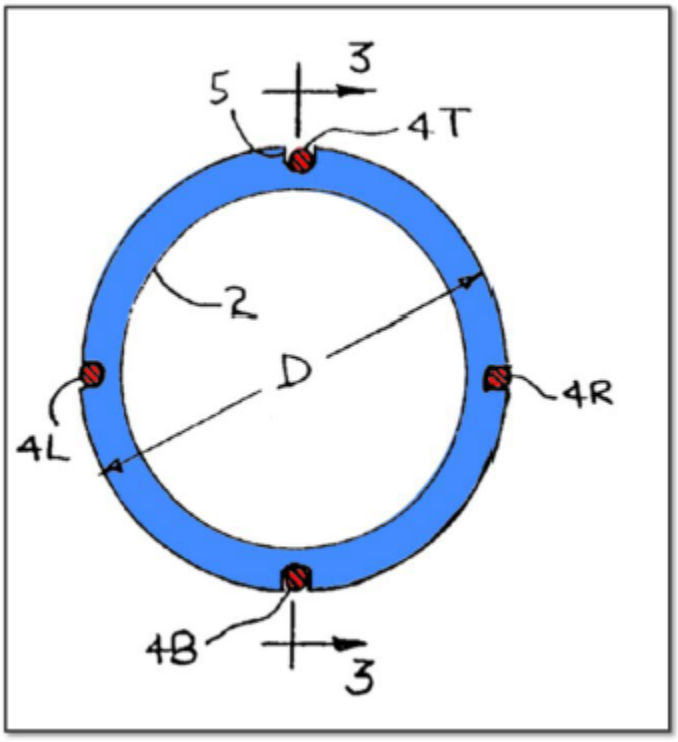
1. Fischell '114

Fischell '114 discloses a vascular stent with vertical and horizontal branches where the horizontal branches have wave form projections. Pet. 55–57; Ex. 1012, code (57), Fischell 14's Figure 8 is shown below.



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

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



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

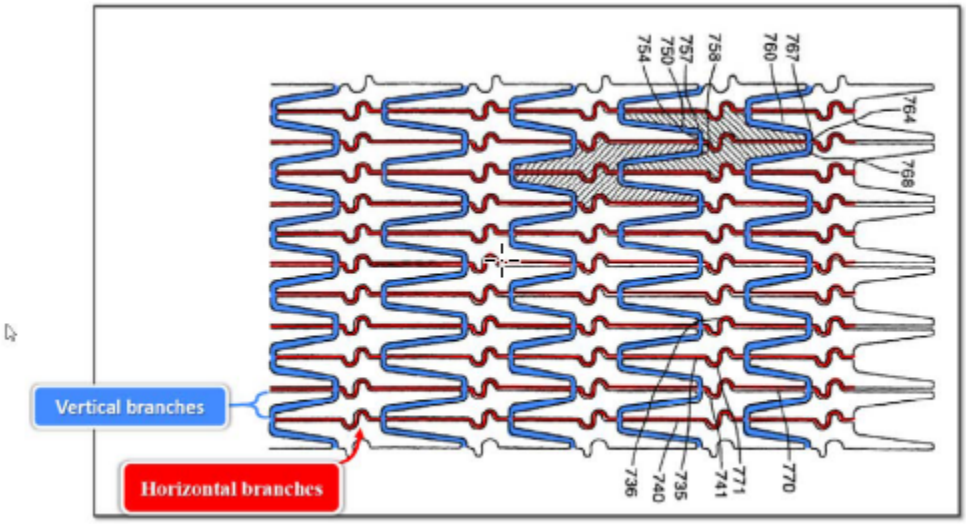
Fischell '114 teaches:

> 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 of Penn, reproduced below, Penn discloses a vascular stent having vertical and horizontal branches where the horizontal branches include wave form projections. Ex. 1013, Fig. 8, p. 17, ll. 7–14.



Annotated Figure 8 of Penn shows vertical branches in blue and horizontal branches in red. 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, p. 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, p. 14, ll. 23–28.

Figure 3 of Penn is reproduced below.

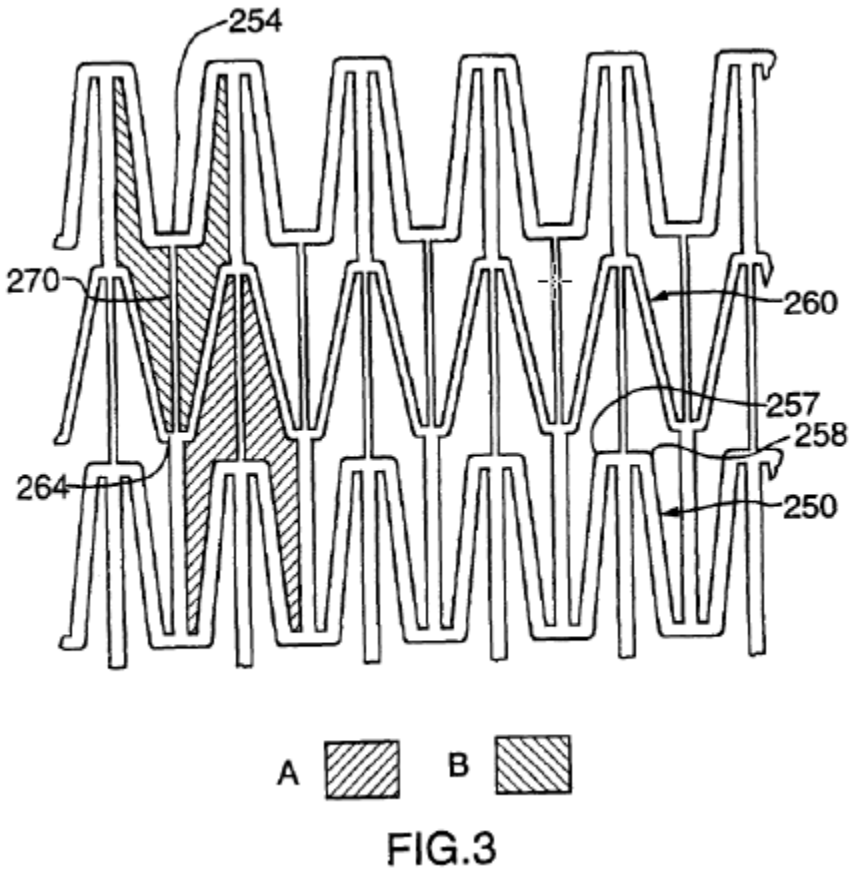


FIG.3

Figure 3 of Penn shows a portion of a stent pattern.

3. Analysis of Claim 1

Claim 1 is the sole independent claim. Ex. 1001, col. 4, ll. 7–11. Petitioner contends that the subject matter of claim 1 would have been obvious to one of ordinary skill in the art at the time the invention was made over Fischell '114 combined with Penn. Pet. 55.

a) A vascular stent which comprises

Petitioner contends that Fischell '114 teaches this limitation. *Id.* Petitioner contends that Fischell '114 teaches a stent that can be used in an artery or any other vessel in the human body. *Id.* at 55–56 (citing Ex. 1012, code (57))).

Patent Owner does not contest this contention. *See* PO Resp. 50–71.

We find that Fischell '114 teaches a vascular stent. Fischell '114 teaches "[a]n expandable stent that can be used in an artery or any other vessel of the human body." Ex. 1012, code (57).

b) Vertical branches whose width and thickness range from 0.09 to .12 mm and 0.08 to 0.12 mm, respectively

Petitioner contends that Fischell '144 teaches this limitation. Pet. 59–65. Petitioner contends that Fischell '114 teaches that the thickness of the vertical branches ranges from 0.1 to 0.3 mm and the width ranges from 0.1 to 0.5 mm, which overlaps with the ranges recited in claim 1. *Id.* at 60. Petitioner contends that one skilled in the art would have selected the specific width and thickness of the branches based on the vessel where the stent was to be placed. *Id.* at 62–64.

Patent Owner contends that while the ranges overlap, the breadth of the ranges recited in Fischell '114, when compared to the narrow range recited in claim 1, precludes a finding of obviousness. PO Resp. 51–53. Patent Owner also contends that it would not have been obvious to select a

thickness and width at the lower end of the range cited in Fischell '114. *Id.* at 53–56. Patent Owner contends that a stent having branches at the lower end of the range cited by Fischell '114 would not be operative, as the stent would have a high degree or recoil and fracturing. *Id.* at 57–59.

We have considered the arguments presented by the parties and the evidence of record and find that Fischell '114 teaches the limitation calling for vertical branches whose width and thickness range from 0.09 to 0.12 mm and 0.08 to 0.12 mm, respectively.

Fischell '114 teaches: "The dimensions of stent rings 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." Ex. 1012, col. 5, ll. 50–54. The rings described in Fischell '114 are the equivalent of the vertical branches recited in claim 1. *See* Ex. 1002 ¶ 158. The thickness and width of the rings recited in Fischell '114 overlap with the ranges recited in claim 1 rendering the limitation obvious. *In re Peterson*, 315 F.3d 1325, 1329–30 (Fed. Cir. 2003).

Fischell '114 also teaches that the dimensions of the stent depend on the luminal diameter of the vessel where the stent is to be placed. Ex. 1012, col. 5, ll. 50–54. Fischell '114 also teaches that one application of stents with highly curved or undulating longitudinals is in coronary arteries. Ex. 1012, code (57), col. 2, ll. 31–44, col. 5, ll. 3–8; Ex. 1002 ¶ 172. The art teaches that coronary arteries are significantly narrower than other arteries and typically have a diameter of 2–5 mm. *See* Ex. 1018, col. 8, ll. 4–13 (discussing typical diameters of various blood vessels); Ex. 1024, 237, Table 2 (diameter measurements of main coronary arteries); Ex. 1002 ¶¶ 170–171. We agree with Dr. Rao that designing a stent for use in a coronary artery would lead one skilled in the art to consider stents having vertical branches

falling within the lower end of the range taught in Fischell '114. Ex. 1002 ¶¶ 173–174.

The case cited by Patent Owner does not dictate a different result. Patent Owner cites to *Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc.*, 655 F.3d 1291 (Fed. Cir. 2011), for the proposition that where a disclosed range embraces a large number of variants, a smaller range falling within the larger range is not rendered obvious. PO Resp. 51–52. Patent Owner's reliance on *Genetics Institute* is misplaced.

Unlike the claims in the '035 patent, the claims at issue in *Genetics Institute* did not address a numeric range but a range of different structures of truncated proteins for human Factor VIII. *Genetics Institute*, 655 F.3d at 1295. The court found that the prior art disclosed about 68,000 truncated variants, making the disclosed range extremely broad. *Id.* at 1306. The court also found that there was no motivation to make the larger truncated proteins covered by the claims at issue as the reference was directed to making smaller truncated proteins. *Id.*

This is in contrast with the present case where the claims are directed to specific sets of values of four different dimensional parameters. *See* Ex. 1001, col. 4, ll. 7–12. Moreover, as discussed above, Fischell '114 teaches adjusting the size of the stent, including branch width and thickness depending on the diameter of the vessel where the stent is being deployed. Ex. 1012, col. 5, ll. 50–54. Fischell '114 also teaches that the stents disclosed therein include stents for coronary arteries. *Id.* at code (57). Thus, unlike the prior art in *Genetics Institute*, Fischell '114 teaches one skilled in the art about the desirability of operating at the lower end of the disclosed range.

We are also unpersuaded by Patent Owner's contention that Fischell '114 is inoperable at the lower values taught. PO Resp. 57–59. Patent Owner contends that Petitioner relies on an embodiment of Fischell '114 that teaches that the horizontal branches lie within cutouts of the vertical branches. *Id.* at 57–58. Patent Owner contends that the cutouts would weaken the rings, reducing the strength of the vertical branches. *Id.* (citing Ex. 2019, 111). Patent Owner contends that the resulting weakness would result in fracturing. *Id* at 59.

We begin by noting that Patent Owner relies on the testimony of Dr. Solar with regard to the deficiencies of the Fischell '114 stent. *Id.* at 58. Dr. Solar, in turn, relies on Dr. Jang's Declaration (discussed above) and the data that shows that for stents of the invention, stents with a thickness below the cited ranges exhibit fracturing. Ex. 2019, 111. Not only have we excluded this testimony as without adequate basis and unreliable, but we find this testimony unpersuasive. As Drs. Rao and Solar have testified, the performance of any given stent is based on a number of factors, including the material used to make the stent, the shape of the cells created when the stent is expanded, and the dimension of the branches. Ex. 1002 ¶ 212 (factors which impact stent performance include stent design, stent material, heat treatment, and the like); Ex. 2020, 63 (to determine where a stent was a good stent, one needs to look at dimensions in the context of the material used). Moreover, neither Dr. Solar nor Dr. Jang actually tested a stent disclosed by Fischell '114, nor do they point to any work by others testing the Fischell '114 stents. *See* Ex. 2019, 111.

Moreover, Fischell '114 teaches that, in addition to the cut out design shown above, the stent can be made from a single piece of metal, which would eliminate the alleged weakness asserted by Dr. Solar. Ex. 1012, col.

6, ll. 1–9; Ex. 1038 ¶ 75. Fischell '114 also teaches that in the embodiment calling for the horizontal branches to be placed into cutout, the horizontal branches can be spot welded. Ex. 1012, col. 4, ll. 1–10. In yet another embodiment, the horizontal branches are placed on the inside perimeter of the vertical branches. *Id.* We are persuaded by Dr. Rao's testimony based on these teachings of Fischell '114 that each of these embodiments would not likely exhibit the weakened structure described by Dr. Solar. Ex. 1038 ¶¶ 75–82.

c) Horizontal branches having wave form projections

Petitioner contends that Fischell '114 alone or in combination with Penn teaches this limitation. Pet. 65–67. Petitioner contends that Fischell '114 teaches that the longitudinals are undulating in shape as shown in Figure 8 below. Pet. 65–66.

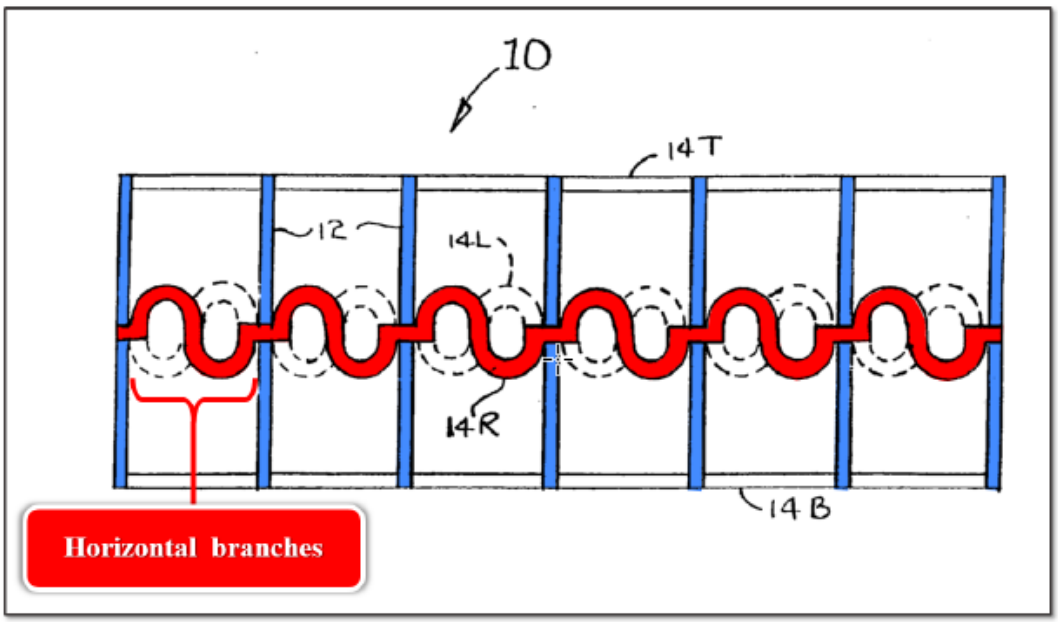


Figure 8 of Fischell '114, annotated to show undulating horizontal branches in red. Pet. 66.

Petitioner contends that if the claims were construed to require the horizontal branches to have a straight portion, then that limitation is taught by Penn. Pet. 66.

Patent Owner contends that Fischell '114 does not teach this limitation, as Fischell '114 does not teach that all the horizontal branches are undulating, and teaches modifying Fischell '114 to have all the horizontal branches to be undulating would render Fischell '114 inoperable. *Id.* at 60–65. Patent Owner also contends that the claims require the horizontal branches to have a straight portion and that Fischell '114 does not teach this. *Id.* at 66–67. Patent Owner contends that it would not have been obvious to use the horizontal branches of Penn in the stents of Fischell '114. *Id.* at 67–71.

We have considered the arguments presented by the parties and evidence of record and conclude that Fischell '114 teaches this limitation. As shown above in Figure 8, Fischell '114 discloses undulating longitudinals. Ex. 1012, code (57). We agree with Dr. Rao that the undulating longitudinals are the same as horizontal branches having wave form projections as the undulating portions have a shape rising and falling in a wave. Ex. 1002 ¶ 175.

We are unpersuaded by Patent Owner's arguments that Fischell '114 does not teach that all the horizontal branches must have wave form projections and that Fischell '114 does not teach horizontal branches having a straight portion in addition to the wave form projection. PO Resp. 60–71. As discussed above, we have declined to construe the claims as calling for **all** the horizontal branches to have wave form projections and have also declined to construe the claims as calling for horizontal branches having a straight portion as well as a wave form projection. *See* Section II.C, *supra.*

d) Whose width and thickness range from 0.05 to 0.08 mm and 0.08 to 0.12 mm, respectively

Petitioner contends that Fischell '114 teaches this limitation. Pet. 70–71. Petitioner contends that Fischell '114 teaches that the horizontal branches are formed as wires which have a diameter from 0.05 to 0.5 mm. *Id.* (citing Ex. 1012, col. 5, ll. 55–56; Ex. 1002 ¶ 186). Petitioner contends that the range recited in Fischell '114 overlaps with the range recited in the claims. *Id.* Petitioner goes on to contend that a person of ordinary skill in the art would have been motivated to look at the lower end of the range recited in Fischell '114 for coronary applications. *Id.*

Patent Owner contends that, like the vertical branches, the range of values recited in Fischell '114 is much broader than the range recited in the claims. PO Resp. 52–53. Patent Owner contends that the breath of the range precludes a finding of obviousness. *Id.* Patent Owner again contends that one skilled in the art would not have been motivated to look to the lower end of the range recited in Fischell '114. *Id.* at 54–60.

We have considered the arguments presented by the parties and the evidence of record and find that Fischell '114 teaches the limitation calling for width and thickness ranges of from 0.05 to 0.08 mm and 0.08 to 0.12 mm, respectively. Fischell '114 teaches: "The wire diameter for the longitudinals would typically be between 0.05 and 0.5 mm." Ex. 1012, col. 5, ll. 55–56. We agree with Dr. Rao that the longitudinals of Fischell '114 correspond to the horizontal branches of the challenged claims. Ex. 1002 ¶¶ 60, 62, 158, 175, 179, and 186.

Patent Owner's arguments regarding the range of values recited in Fischell '114 for the horizontal branches are identical to the arguments discussed above for the vertical branches of Fischell '114. For the reasons

discussed above, we find these arguments unpersuasive. *See* Section II.E.3.b, *supra.*

4. Analysis of Claim 2

Claim 2 depends from claim 1 and adds the limitation that the lengths of the vertical and horizontal branches range from 1.5 to 4.5 mm and 1.0 to 3.0 mm, respectively. Ex. 1001, col. 4, ll. 12–14.

Petitioner contends that the subject matter of claim 2 is taught by Fischell '114. Pet. 71–77. With respect to the vertical branches, Petitioner contends that while Fischell '114 does not specifically state a unit length for the vertical branches, one skilled in the art would understand that the vertical branches of Fischell '114 have a length of from 1.6 mm to 23.6 mm, which overlaps with the range recited in claim 2. *Id.* at 72–73 (citing Ex. 1012, col. 3, ll. 11–13, col. 5, ll. 51–52; Ex. 1002 ¶¶ 190–193).

With respect to the horizontal branches, Petitioner contends that while Fischell '114 does not disclose a specific range for the horizontal branch lengths, one skilled in the art would understand that the horizontal branches have a length of from 1.67 mm to 5 mm. *Id.* at 74–77 (citing Ex. 1012, col. 4, l. 38; col. 5, ll. 54–55; Ex. 1002 ¶¶ 194–196).

Patent Owner has not presented any separate arguments regarding the patentability of claim 2. *See* PO Resp. 50–71.

We find that Fischell '114 teaches the vertical and horizontal branch lengths recited in claim 2.

Fischell '114 teaches that the stents have "a multiplicity of rings . . . which are spaced apart by four wires called longitudinals." Ex. 1012, col. 3, ll. 43–44. As discussed above, the rings of Fischell '114 are the same as vertical branches and the longitudinals are the same as horizontal branches, as those terms are used in the '035 patent. Fischell '114 teaches that the

diameter of the stents can range from 2.0 to 30 mm. Dr. Rao has testified that this equates to a circumference ranging from 6.28 mm to 94.2 mm. Ex. 1002 ¶ 191. Dr. Rao goes on to testify that, using Fischell '114's teaching that there are four longitudinals, this calculates to a vertical branch length of from 1.6 mm to 23.4 mm. *Id.* The values overlap with the range recited in claim 2. *See In re Peterson*, 315 F.3d at 1329–30.

With respect to the horizontal branches, the stents illustrated in Fischell '114 have six longitudinals. *See, e.g.*, Ex. 1012, Figure 8, reproduced below.

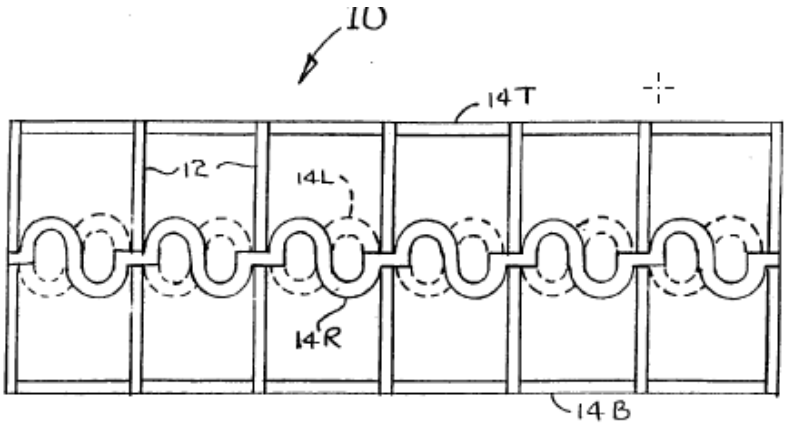


FIG. 8

Figure 8 of Fischell '114 shows an expanded stent.

Fischell '114 teaches that the length of the stent can range from 1 to 10 cm. *Id*. at col. 5, ll. 54–55. Dr. Rao testifies that, given the teaching of Fischell '114, he calculates the length of the horizontal braches to range from 1.67 mm to 16.67 mm, which overlaps with the range recited in claim 2. Ex. 1002 ¶ 195.

5. Analysis of Claim 3

Claim 3 depends from claim 1 and adds the limitation that the diameter and length of the stent range from 1.0 to 5.75 mm and 9.0 to 60 mm, respectively. Ex. 1001, col. 4, ll. 15–17.

Petitioner contends that Fischell '114 teaches this limitation. Pet. 77–78. Petitioner contends that Fischell '114 teaches that the diameter of the stents can range from between 2.0 and 30.0 mm and that the length of the stents can range from between 1 and 10 cm. *Id.* (citing Ex. 1012, col. 5, ll. 50–55). Petitioner contends that these ranges overlap with those recited in claim 3. *Id.*

Patent Owner has not presented any additional arguments regarding the patentability of claim 3 other than those presented for the patentability of claim 1 from which it depends. *See* PO Resp. 50–71.

We find that Fischell '114 teaches the subject matter of claim 3. Fischell '114 teaches:

> The dimensions of stent rings 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.

Ex. 1012, col. 5, ll. 50–55. These values overlap with the ranges recited in claim 3. *See In re Peterson*, 315 F.3d at 1329–30.

6. Motivation to Combine

The parties' arguments concerning whether one skilled in the art would have been motivated to combine the references focus on the motivation to combine Fischell '114 with Penn. Pet. 68–70; *see* PO Resp. 62–71. In reaching our conclusion that the subject matter of the claims would have been obvious, we have not relied on the combination of Fischell

’114 and Penn, but what one of skill in the art would glean from the teachings of Fischell alone. Therefore, we need not address the issues of whether one skilled in the art would have been motivated to combine the references.

7. Unexpected results

As discussed above, Patent Owner contends that there is sufficient evidence of unexpected results to support a conclusion of non-obviousness. Section II.D.8, *supra.* For the reasons discussed above, we find the evidence of unexpected results unreliable, and thus, unpersuasive. *Id.*

8. Conclusion

Based on the foregoing, we conclude that the subject matter of the challenged claims would have been obvious over Fischell ’114. Fischell ’114 teaches each of the limitations in the challenged claims, including ranges of thickness, width and length of both the vertical and horizontal branches, as well as horizontal branches having wave form projections. Fischell ’114 also teaches modifying the dimensions of the branches depending on the size of the vessel where the stent is placed, including use of the stents in coronary arteries. Finally, we are unpersuaded by Patent Owner’s evidence of unexpected results.

F. Patent Owner’s Motion to Strike

Patent Owner has moved to strike certain arguments made by Petitioner in its Reply as presenting new arguments or evidence. Paper 25 (“Mot. Strike”). Specifically, Patent Owner argues that we should strike the following arguments:

> That a width of 0.1 mm for the Richter-Handbook would have been obvious to try;
>
> That the cross-section of the stent in the Richter-Handbook was square;

That all the horizontal branches of Fischell '114 could be undulating;

The cylindrical tube embodiment of Fischell '144; and

Modification of Fischell '114 to increase the gap between the vertical branches.

We address each of these arguments in turn.

1. Obvious to use a thickness of 0.1 mm

Patent Owner contends that Petitioner's Reply improperly raised for the first time an argument that a branch diameter was a readily achievable option, making it obvious to try that diameter for the horizontal branches. Mot. Strike 2.

We deny this portion of the motion as moot. As shown by our analysis, we did not rely on this argument by Petitioner in reaching our conclusion of obviousness based on the Richter references. *See* Section II.D, *supra.*

2. Richter-Handbook's teaching of a square cross-section

Patent Owner contends that Petitioner has improperly relied on new evidence in support of its argument that the cross-section of the stent disclosed in the Richter-Handbook has a square cross-section. Mot. Strike 3–4. Specifically, Patent Owner contends that the Morton-Article[5] and testimony based on that article should be excluded. *Id.*

We deny this portion of the motion as moot. Our conclusion that the challenged claims are unpatentable does not rely on the Morton-Article or any testimony based on that article.

[5] A.C. Morton et al., *Response of very small (2mm) porcine coronary arteries to balloon angioplasty and stent implantation*, 90 HEART 324–27 (2004) (Ex. 1037, "Morton-Article").

3. Undulating Branches of Fischell '114

Patent Owner argues that Petitioner's argument that Fischell '114 teaches that all the longitudinals can be undulating should be stricken as it presents a new argument. Mot. Strike 4–7.

We deny this portion of the motion as moot. Our conclusion that the challenged claims are unpatentable does not rely on Fischell '114 teaching that all the longitudinals can be undulating. *See* Section II.E.3.

4. Fischell '114's thin walled embodiment

Patent Owner argues that we should strike the Petitioner's argument based on the thin walled embodiment disclosed in Fischell '114. Mot. Strike 7–8. Patent Owner contends that it is improper for Petitioner to rely on an embodiment not discussed in its Petition. *Id.*

Petitioner responds that the thin walled embodiment of Fischell '114 was raised to rebut Patent Owner's contention that one skilled in the art would not design Fischell '114's stent with the disclosed dimensions, as using a cutout design would allegedly result in fractures. Paper 27, 5.

We agree with Petitioner and deny this portion of the motion to strike. Petitioner's arguments regarding the alternate embodiments of the Fischell '114 stent were made to address Patent Owner's arguments that the Fischell '114 stent would be inoperable. Reply 21–22; PO Resp. 58–60. Reliance on additional evidence in genuine response to Patent Owner's arguments and evidence is proper. *See Ericsson Inc. v. Intellectual Ventures I LLC*, 901 F.3d 1374, 1381 (Fed. Cir. 2018); *Anacor Pharm., Inc. v. Iancu*, 889 F.3d 1372, 1380–81 (Fed. Cir. 2018) (explaining that in an *inter partes* review introduction of new evidence "is to be expected" after the petition, and it is proper to present such new evidence if, for example, it is "a legitimate reply to evidence introduced by the patent owner").

5. Modification of Fischell '114

Patent Owner argues that we should strike Petitioner's argument that the stent of Fischell '114 could be modified to incorporate Penn's horizontal branches as it presents a new argument. Mot. Strike 8–10.

We deny this portion of the motion to strike as moot. Our conclusion that the challenged claims would have been obvious over Fischell '114 does not rely on incorporating the horizontal branches of Penn into the stent of Fischell '114. *See* Section II.E.3, *supra.*

6. Conclusion

For the reasons stated above, Patent Owner's Motion to Strike is denied.

III. CONCLUSION

We conclude that Petitioner has satisfied its burden of demonstrating by a preponderance of the evidence that claims 1–3 are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–3 of U.S. Patent 6,187,035 B1 have been shown to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude is granted;

FURTHER ORDERED that Patent Owner's Motion to Strike is denied;

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1–3	103(a)	Richter '404, Richter-Handbook	1–3	
1–3	103(a)	Fischell '114, Penn	1–3	
Overall Outcome			1–3	

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