**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | |
|---|---|
| In re *Inter Partes* Review of: | ) |
| U.S. Patent No. 6,187,035 | ) |
| Issued: February 13, 2001 | ) |
| Application No.: 09/118,133 | ) |
| Filing Date: July 16, 1998 | ) |

**For: Vascular Stent**

**FILED VIA E2E**

# PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,187,035

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# I. INTRODUCTION

Petitioner requests *inter partes* review of claims 1-3 of U.S. Patent No. 6,187,035, titled "Vascular Stent" ("'035 patent") (Ex. 1001). According to USPTO records, the '035 patent is assigned to FlexStent LLC.

The '035 patent is directed to a vascular stent with horizontal branches having waveforms and which are thinner than the vertical branches. These common features were taught by prior art references not before the examiner. The claims also recite numerical ranges for the dimensions of the branches and the stent itself. These, too, were taught by the prior art and varied predictably, allowing POSITAs to routinely optimize these parameters.

Accordingly, Petitioner asks the Board to institute review of the '035 patent and find all challenged claims unpatentable.

# II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

## A. Real Parties in Interest (37 C.F.R. § 42.8(b)(1))

The real-parties-in-interest are Abbott Vascular, Inc., Abbott Laboratories, Abbott Cardiovascular Systems, Inc., and Abbott Vascular Solutions, Inc. (collectively, "Petitioner").

## B. Related Matters (37 C.F.R. §42 8(b)(2))

The '035 patent has been asserted in the following district court case pending in the Central District of California: *FlexStent, LLC v. Abbott Laboratories et al.*, CACD-5-18-cv-02479, filed November 26, 2018.

### C. Lead and Backup Counsel and Service Information

Under 37 C.F.R. §§ 42.8(b)(3), 42.8(b)(4), and 42.10(a), Petitioner designates the following lead counsel:

- Michael A. Morin (Reg. No. 40,734), michael.morin@lw.com, Latham & Watkins LLP; 555 Eleventh Street, NW, Suite 1000; Washington, DC 20004-1304; 202.637.2298 (Tel.); 202.637.2201 (Fax)

Petitioner also designates the following backup counsel:

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- S. Giri Pathmanaban (Reg. No. 75,986), giri.pathmanaban@lw.com, Latham & Watkins LLP; 140 Scott Drive, Menlo Park, CA 94025; 650.470.4851 (Tel.); 650.463.2600 (Fax).

Under 37 C.F.R. § 42.10(b), a Power of Attorney from Petitioner is attached. Petitioner consents to electronic service.

### D. Fee for *Inter Partes* Review

The Director may charge the fee specified by 37 C.F.R. § 42.15(a) to Deposit Account No. 506269.

## III. GROUNDS FOR STANDING (37 C.F.R. § 42.104(A))

Petitioner certifies that the '035 patent is available for *inter partes* review and that the Petitioner is not barred or estopped from requesting *inter partes* review of the challenged claims of the '035 patent on the grounds identified herein.

## IV. IDENTIFICATION OF CLAIMS BEING CHALLENGED (37 C.F.R. § 42.104(B))

### A. Statutory Ground for the Challenge

Petitioner requests *inter partes* review of claims 1-3 of the '035 patent on these grounds:

| Ground | Claims | Basis |
|---|---|---|
| 1 | 1-3 | § 103: Richter-Handbook (Ex. 1008) in view of Richter-404 (Ex. 1010) and the knowledge of a POSITA |
| 2 | 1-3 | § 103: Fischell (Ex. 1012) in view of the knowledge of a POSITA, with or without Penn (Ex. 1013) |

## V. OVERVIEW OF THE '035 PATENT

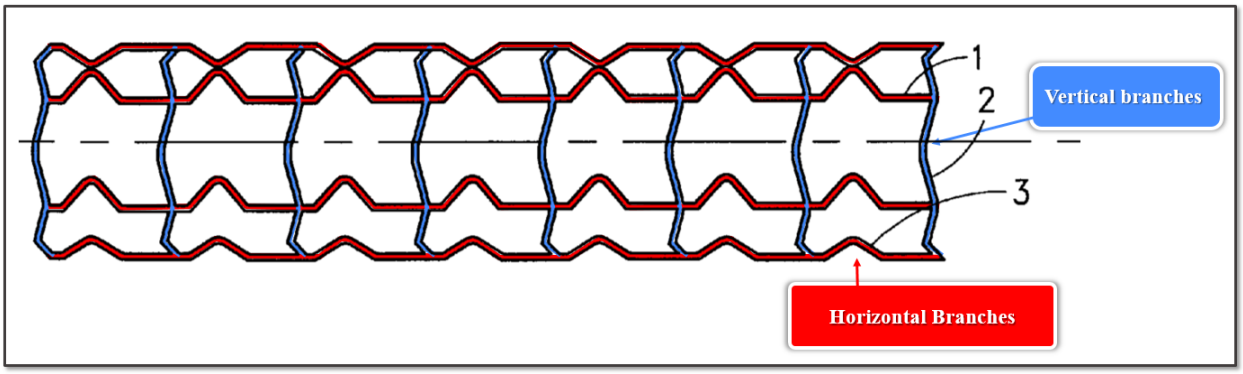
### A. The '035 Patent

The '035 patent relates to "vascular stents," including those used to treat "coronary artery obstructive disease." '035 patent, 1:5-15. Stents were commonly crimped to a small diameter on a balloon, delivered to a narrowing, or stenosis, in a coronary artery in that state, and then expanded against the artery's wall by inflating the balloon. *Id.*, 1:20-24. This plastically deforms the stent's branches so the stent

permanently achieves its desired larger diameter. The balloon is deflated and removed, and the expanded stent remains in place and holds the vessel open to restore normal blood flow. '035 patent, 1:20-31; Rao ¶ 37.

The '035 patent alleges to improve upon existing stents by providing a stent of "superior flexibility." '035 patent, 1:44-46.

The '035 patent's stent has "vertical branches," labeled "2" (and annotated in blue) in Figure 2A below, oriented circumferentially around the cylindrically-shaped stent. *Id.*, 2:22-25. Horizontal branches "1" with waveforms "3" (annotated in red) are linked to vertical branches and oriented longitudinally along the stent. *Id.*, 2:24-25.

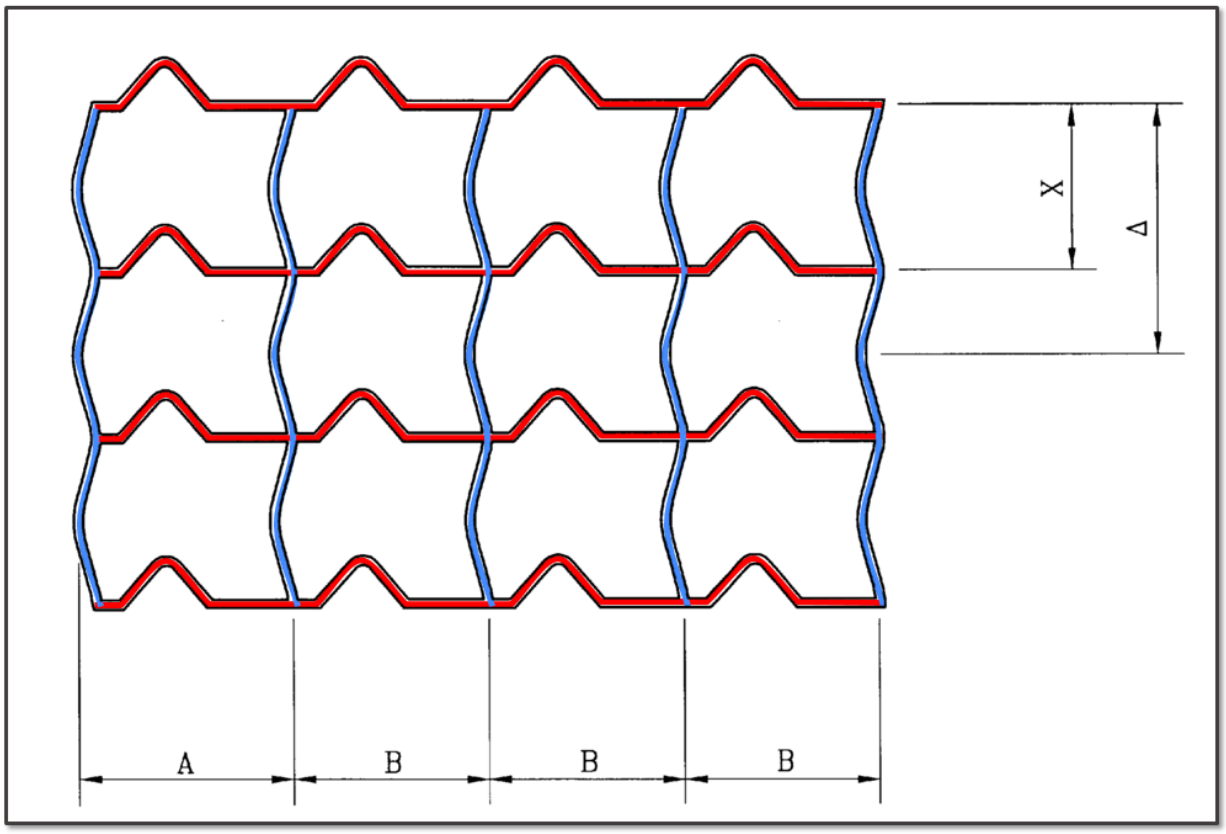



*Id.*, Fig. 2A (annotated); Rao ¶ 38.[1]

[1] Where possible, figures in this Petition have been annotated to show vertical branches in blue and horizontal branches in red.

"Vertical branches" are frequently called "zig-zagging rings" or "cylindrical elements," and "horizontal branches" are often called "links," or "connectors." Rao ¶ 40.

Annotated Figure 3 shows the same stent in two dimensions, as if the stent was unrolled from its tubular shape.

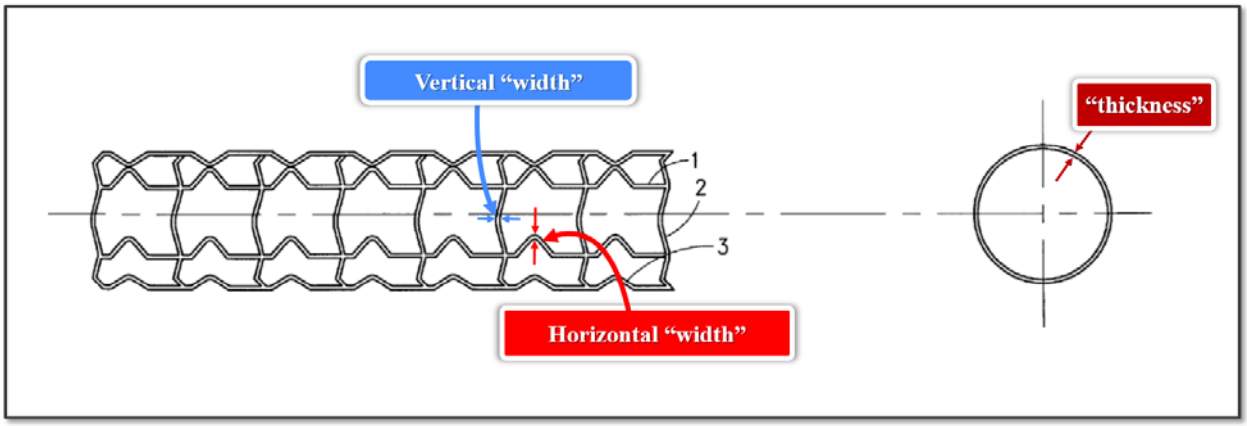



'035 patent, Fig. 3 (annotated); Rao ¶ 39.

As seen in the above figures, the vertical branches have a zig-zag pattern rather than being straight. Rao ¶ 40. This allows the stent to have a small outside diameter when delivered to a narrowed artery, and then expanded to restore the artery to its healthy diameter. '035 patent, 2:55-63.

The horizontal branches are not straight, either. The specification states that their non-linearity adds longitudinal flexibility to the stent, making it easier to deliver through highly curved anatomy. *Id.*, 1:34-36, 2:17-40, 3:2-5.

The '035 patent also describes various dimensions for the claimed stent, including the "width" and "thickness" of the horizontal and vertical branches. In the '035 patent, "thickness" is measured radially from the stent's inner surface to the outer surface, while the "width" is the other cross-sectional dimension. This is shown in annotated Figures 2A and 2B below.




*Id.*, Figs. 2A, 2B (annotated); Rao ¶ 41.

Stents can have either the same or different thicknesses for the vertical and horizontal branches. When a stent is fabricated using the common (and the '035 patent's preferred) technique of laser-cutting the stent pattern from a stainless steel tube with a uniform thickness, all branches would have the same thickness (*i.e.*, the thickness of the tube). '035 patent, 2:41-45; Rao ¶ 42; *see also* '035 FH (Ex. 1004), 95-96 (inventor declaration specifying single thickness for all branches); Ogi (Ex.

1019), 2:32-38, 6:43-46. But a stent can have different thicknesses if the branches are fabricated separately and then welded together to form the stent. Rao ¶ 42; Fischell (Ex. 1012), 4:1-10, 5:50-56. The challenged claims cover both scenarios, when the thicknesses are the same and when they are different.

### B. The Challenged Claims and State of the Art

Claim 1 is an open-ended "comprising" claim that recites a stent with "vertical branches" that are between 0.08-0.12 mm thick and 0.09-0.12 mm wide. The "horizontal branches" have waveform-projections, and are between 0.08-0.12 mm thick and 0.05-0.08 mm wide. Claims 2 and 3 each depend from claim 1. Claim 2 further requires unit lengths of 1.5-4.5 mm for the vertical branch and 1.0-3.0 mm for the horizontal branch. Claim 3 requires the stent to have a diameter of 1.0 to 5.75 mm and to be 9.0-60 mm long.

A vascular stent is crimped to a small diameter when tracked through arteries to reach the target narrowing in a diseased blood vessel and then expanded to restore the blood vessel to its normal, healthy diameter. A stent's dimensions (*e.g.*, diameter and arithmetically-linked vertical branch unit lengths[2]) change depending on the

[2] From simple geometry, the vertical branch unit length equals $(\pi * D)/n$, where D is the stent diameter and n is the number of horizontal branches around the stent's circumference. Rao ¶ 45.

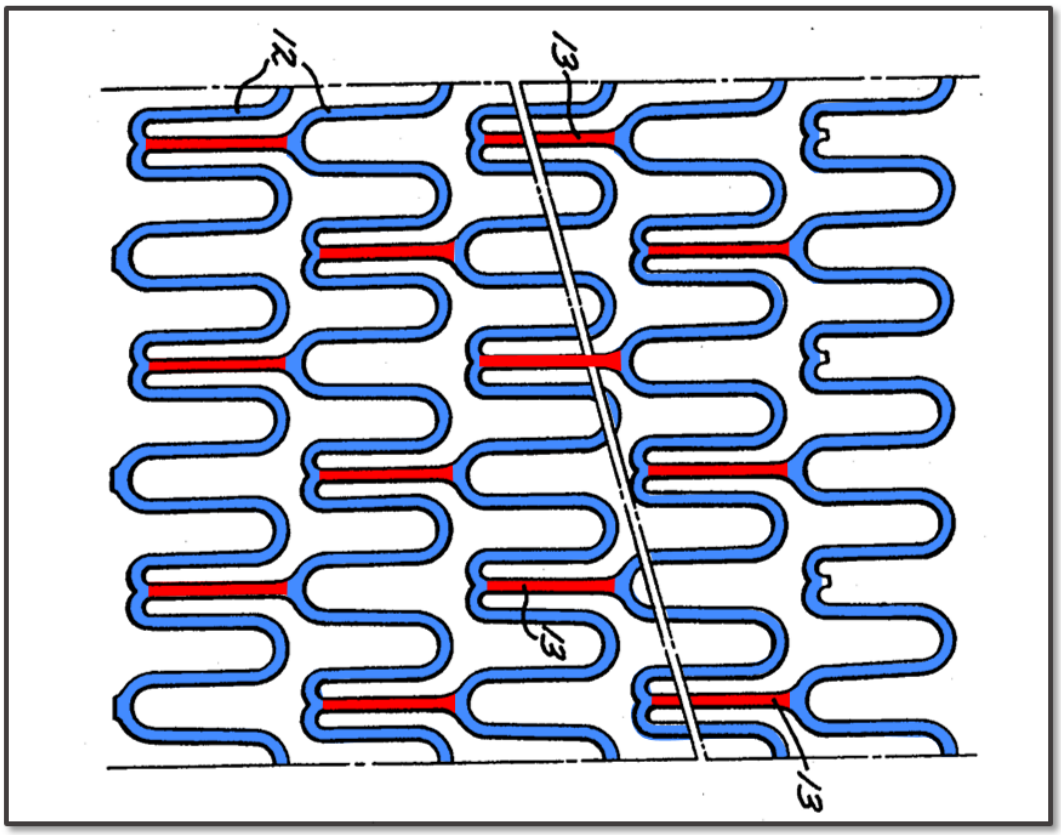
state of the stent, *e.g.*, as-manufactured, fully crimped (unexpanded), partially expanded, or fully expanded. Rao ¶ 45. Claims 2 and 3 recite such dimensions, but do not specify whether the claimed stent must be in any, all, or some combination of the above enumerated states when it possesses the recited dimensions. For the purposes of this proceeding, Petitioner contends that claims 2 and 3 are satisfied so long as the stent has the recited dimensions in any of the above states.

The following paragraphs discuss the claimed features in the context of the known state of the art at the time (circa 1997-1998).

### 1. Vascular Stents with a Ring-and-Link Structure Like the '035 Patent Were Widely Known

"Ring-and-link" stents were used to treat narrowed blood vessels well before the '035 patent was filed in 1998, and were, by that time, already the most popular coronary stent design. Rao ¶ 55.

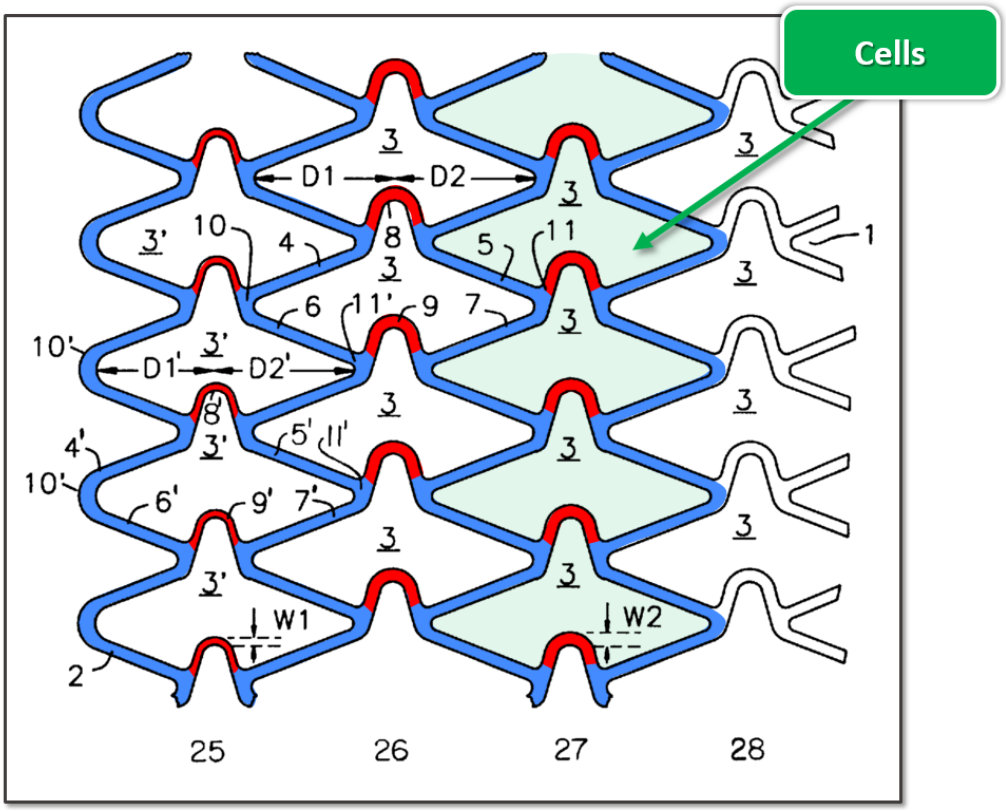
A ring-and-link stent has short, radially expandable cylindrical elements ("rings") connected to one another by generally longitudinally extending elements ("links" or "connectors") as shown in annotated Figure 5 (flattened view) of Lau's unexpanded stent below (rings shown in blue; links/connectors in red).




Lau (Ex. 1014), Fig. 5 (annotated); Rao ¶¶ 52-53.

The rings, when radially compressed on an uninflated balloon have a low profile for insertion and delivery to the target stenosis. When expanded in place by the balloon, the rings exert force radially outward against the narrowed arterial wall to open it and hold it open. The links connect and stabilize the rings while allowing them to move relative to one another. Lau, 4:65-68, 5:7-15; Rao ¶¶ 52. With multiple straight links connecting adjacent cylindrical elements, Lau explains that the stent is "flexible along its length and about its longitudinal axis but which is still very stiff in the radial direction in order to resist collapse." Lau, 2:7-12. Collectively, the rings and links are called "struts" or "branches." Rao ¶ 54;

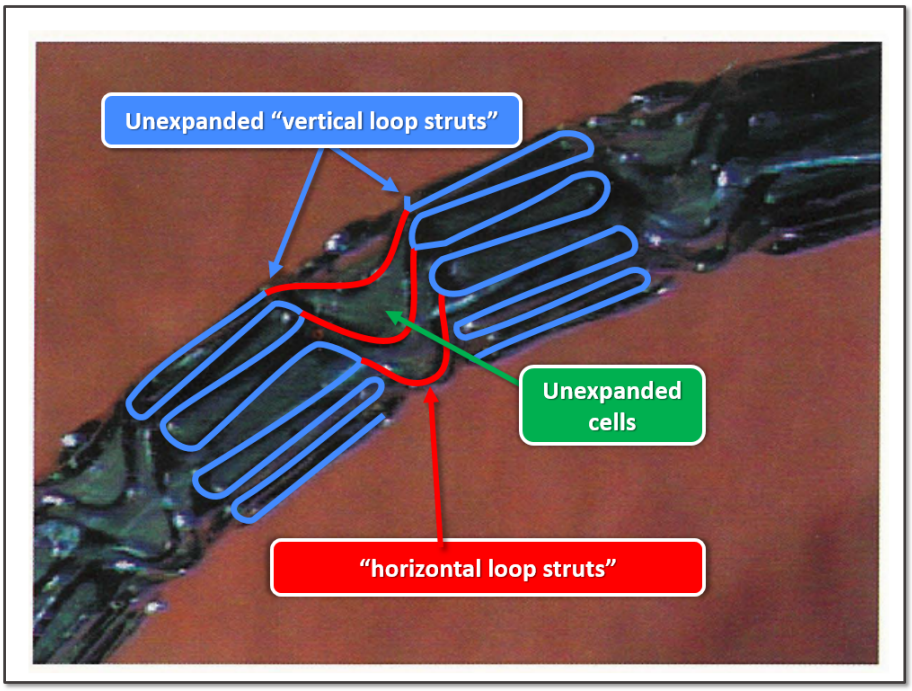
Richter-794 (Ex. 1016), 3:27-31 ("strut" means "any structural member of a stent, such as any radial, longitudinal, or other members made from wire, cut stock or other materials."). And the bounded open spaces created by the intersecting struts/branches are sometimes called "cells." Rao ¶ 54. For example, Richter-404 (Ex. 1010) discloses a ring-and-link stent where the straight links have been replaced by "U"-shaped connectors, for additional flexibility, and the expanded cells are labeled 3 and 3'. Richter-404, 5:57-63.



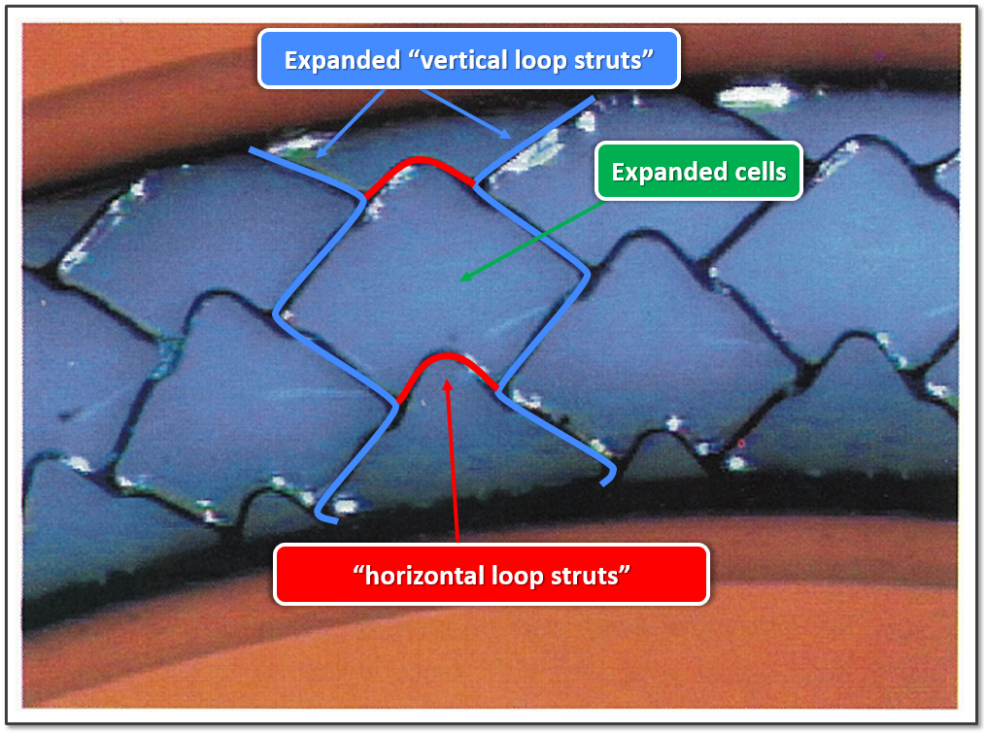

Richter-404, Fig. 2 (annotated); Rao ¶ 54.

Ring-and-link stents were commonplace and played a "key role" in cardiac care by 1997-1998. *See, generally,* Reference Guide (Ex. 1015); Handbook (Ex.

1008); Handbook 2nd (Ex. 1009); Hsieh-Yee Decl. (Ex. 1035) ¶¶ 26-103 (expert librarian declaration establishing authenticity and public availability of Exhibits 1008 and 1009); Rao ¶ 55. An example of a traditional ring-and-link stent is the NIR stent, shown below in its unexpanded and expanded states on a bend. The zig-zagging rings (referred to as "vertical loop struts") allow the stent to be easily crimped down to a narrow diameter on an uninflated balloon (Fig. 15.2), and then expanded (Fig. 15.3), while the links (referred to as "horizontal loop struts") provide flexibility to the stent.

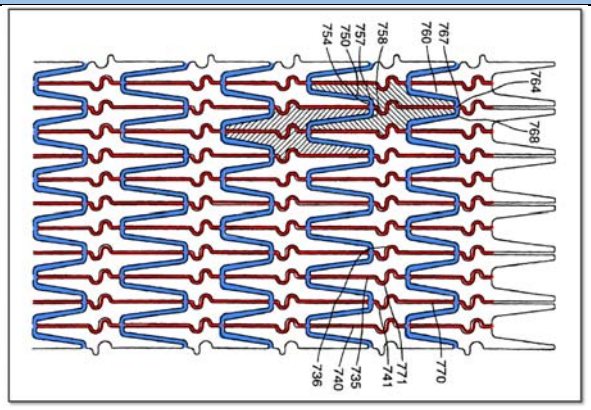
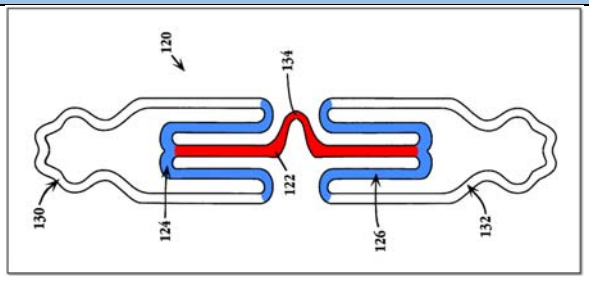
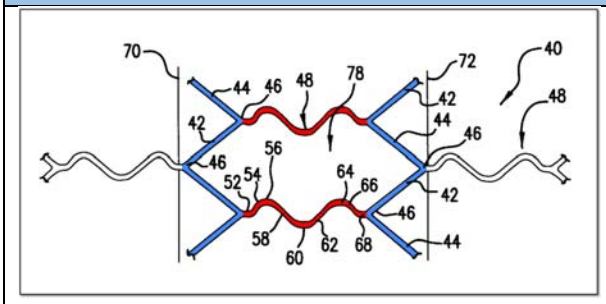
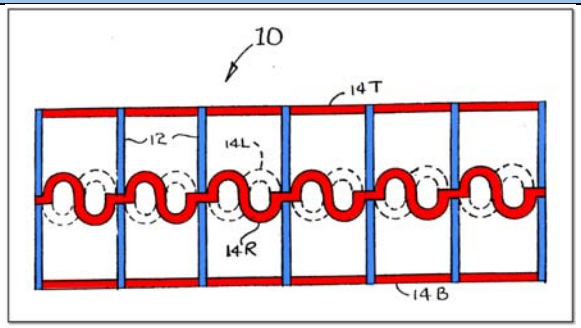
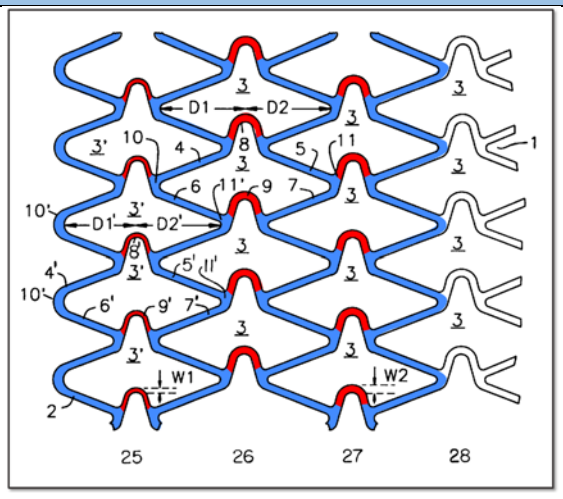
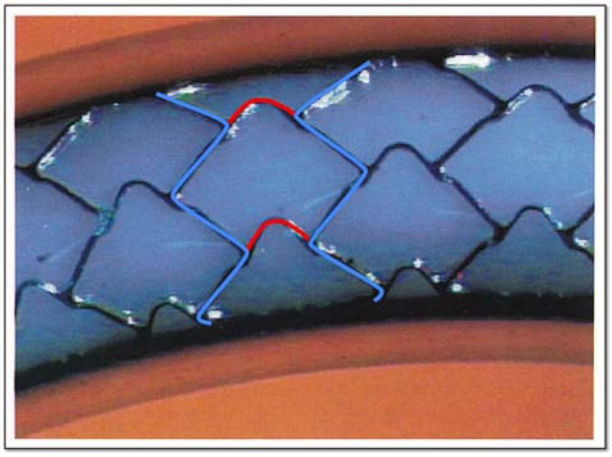


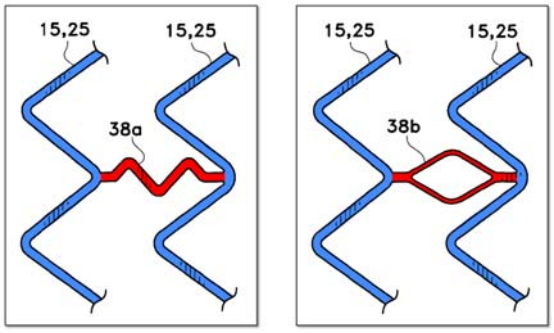
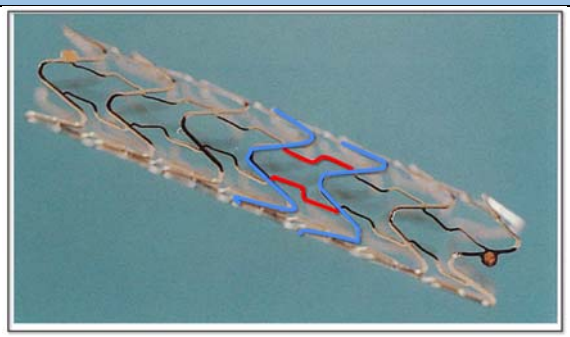
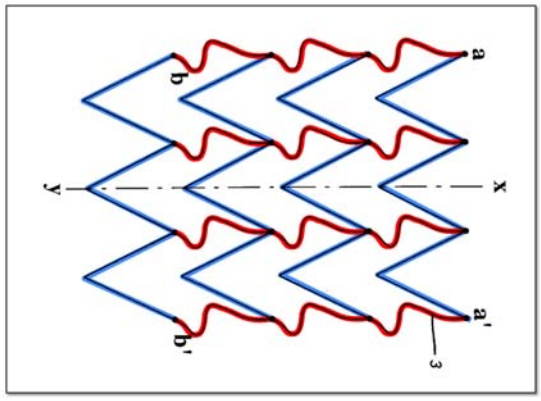
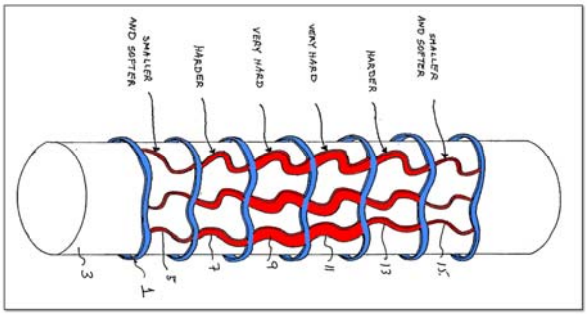

Handbook, Fig. 15.2 (annotated).



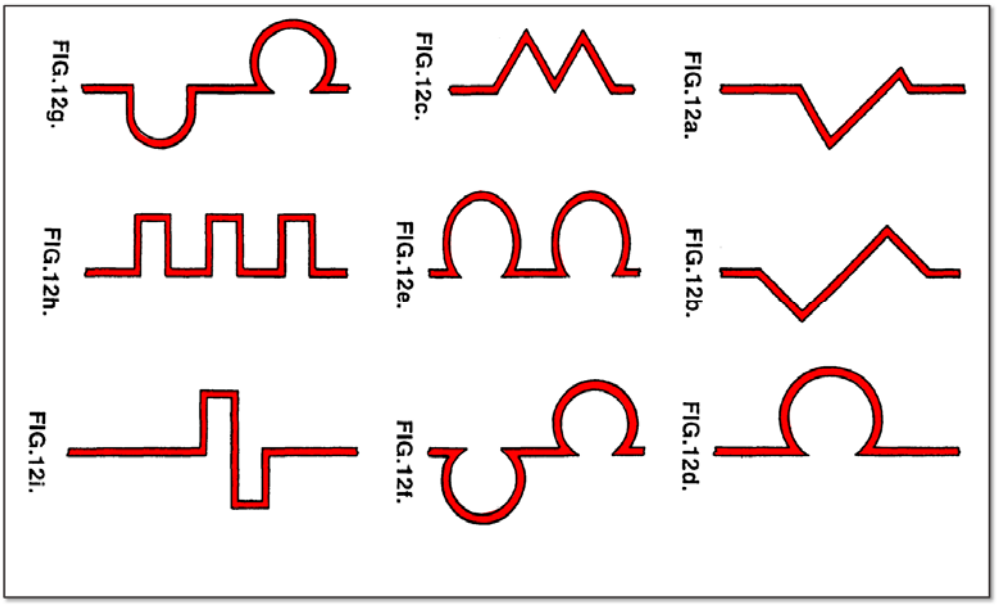

Handbook, Fig. 15.3 (annotated); Rao ¶ 55.

While the '035 patent uses different terminology, calling portions of the rings "vertical branches" and the links "horizontal branches," it is referring to the same structures. Rao ¶ 56. The claims also recite links having waveform-projections. But ring-and-link stents having the claimed waveform-projections were well-known by 1997:

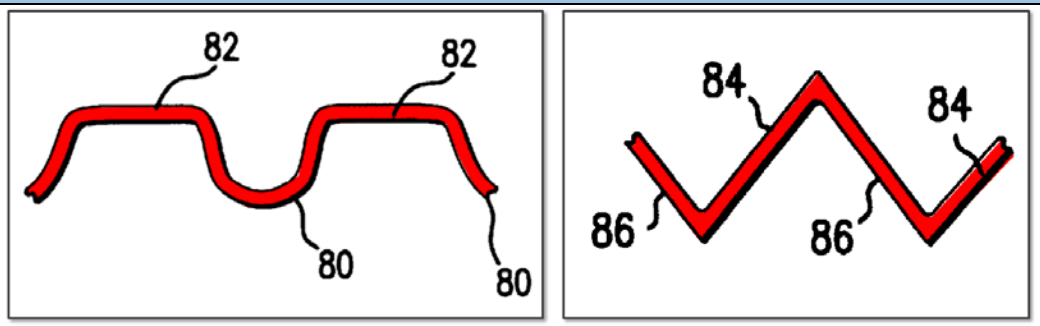
| **Prior-art horizontal branches having waveform-projections (red)** | |
|---|---|
| Penn (Ex. 1013), Fig. 8 | Dinh (Ex. 1018), Fig. 4A |
|  |  |
| Roubin (Ex. 1017), Fig. 4A | Fischell, Fig. 8 |
|  |  |
| Richter-404, Fig. 2 | Handbook, Fig. 15.3 |
|  |  |

| Ogi, Figs. 5A, 5B | Handbook, Fig. 17.2(b) |
|---|---|
|  |  |
| **Wijay (Ex. 1020), Fig. 2** | **Globerman (Ex. 1021), Fig. 2** |
|  |  |

Penn, Figs. 12a-12i




Roubin, Figs. 7-8



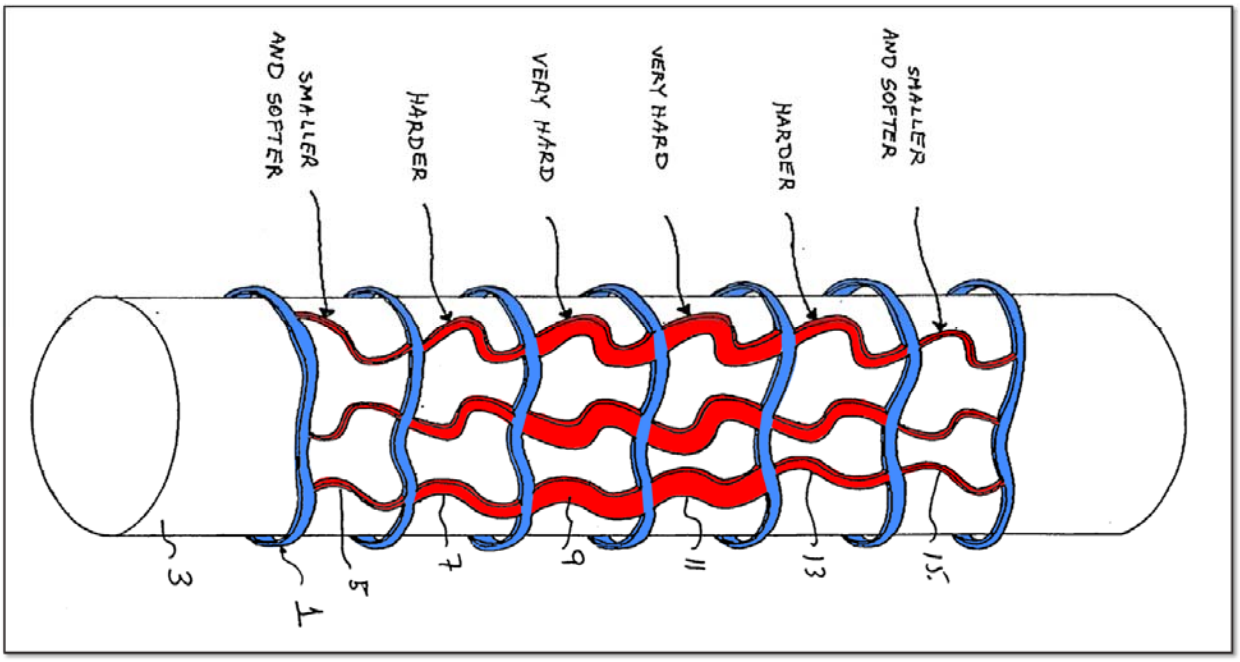

Rao ¶¶ 57-73 (annotating figures); Penn, 17:25-18:11; Roubin, 6:40-50.

The prior art also taught that the shape of the waveform-projections, which were sometimes called "flexure means," "is not particularly restricted provided that it confers lateral flexibility to the unexpanded stent," and thus a design choice among many possibilities. Penn, 5:8-11 (flexibility provided by waveform-projections), 4:22-5:27, 18:15-31, Fig. 11; Handbook, 139, Fig. 15.1 (waveform-projections

provide flexibility); Wijay, 5:45-50. The prior art also taught that these waveform-projections in the horizontal links served the ***exact same purpose*** identified in the '035 patent, *i.e.*, to "provide[] superior flexibility" for tracking the stent through curved arteries on its way to a target narrowing. *Compare* '035 patent, 1:50-54, 2:23-27, 2:35-40, *with, e.g.*, Penn, 10:14-18; Fischell, Abstract, 5:5-8; Richter-404, 1:51-54; Rao ¶¶ 56-75 (discussing those and other prior art stents having horizontal branches with waveform-projections).

Thus, as of the '035 patent's priority date, a POSITA understood that the links in a ring-and-link style stent can take on ***many*** shapes, and that substituting one shape for another is how the designer predictably improved flexibility over the same stent with straight links. Rao ¶¶ 74-75.

The '035 patent claims also recite having narrower horizontal branches than vertical branches. But the prior art taught this feature, and again that it served the ***exact same purpose*** identified in the '035 patent, *i.e.*, "improved flexibility of the vascular stent." '035 patent, 2:35-40; *see* Richter-404, 6:57-7:3 (40-50% narrower); Penn, 14:19-29 (thinner link increases flexibility); Fischell, 5:50-54; Dinh, 6:11-14, 7:25-28; Ogi, 8:1-22, 8:33-35, Fig. 5c; Rao ¶¶ 57, 60-62, 65, 67-69, 70, 72-75 (providing additional description regarding the foregoing). Globerman, for example, labels thinner struts as "smaller and softer" and thicker struts as "harder" and explains that thinner struts ease flexibility:

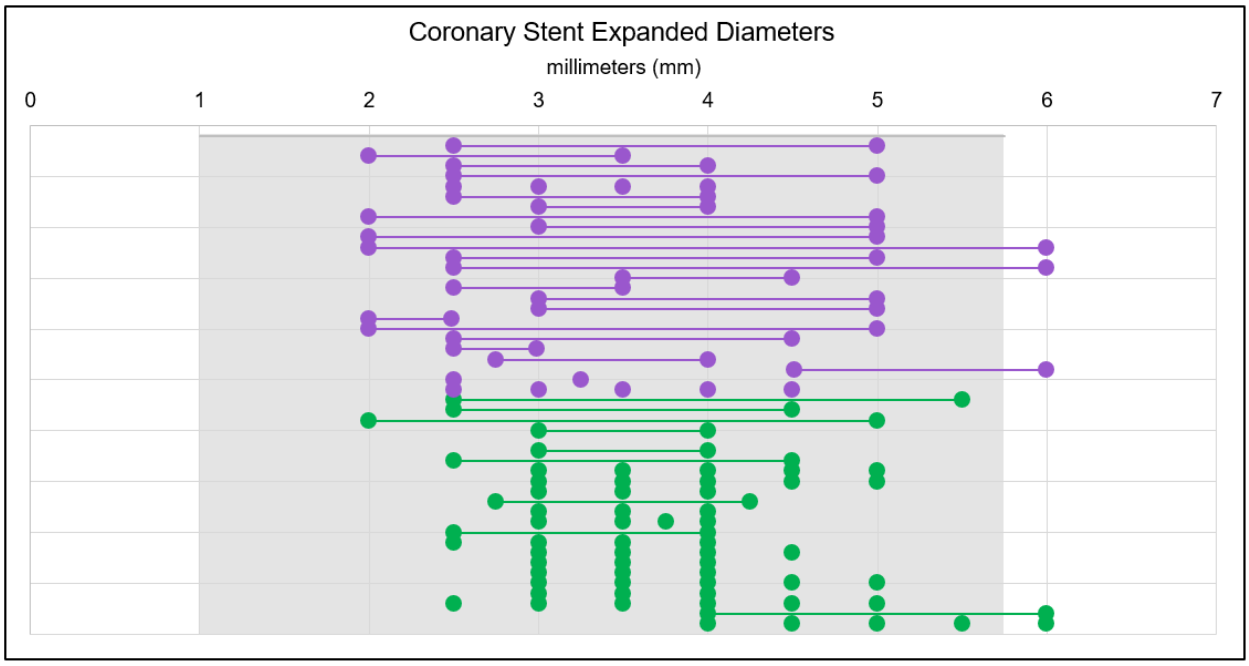


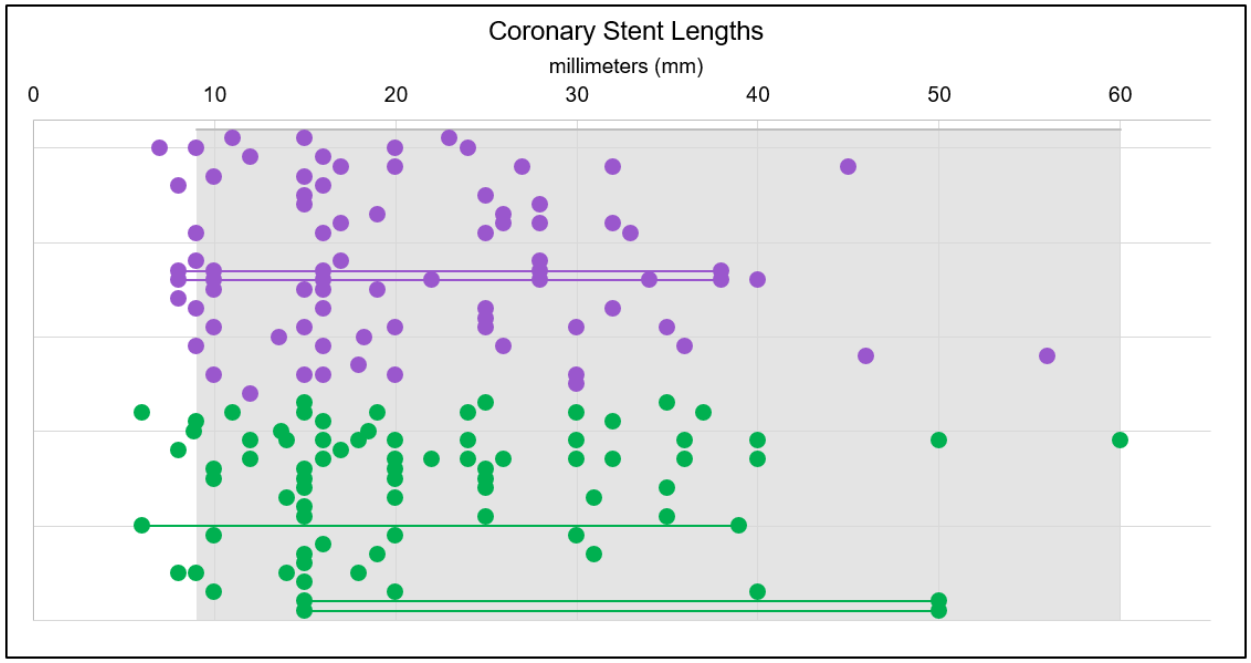

Globerman, Fig. 2 (colors added), 3:7-16; Rao ¶¶ 72-73.

### 2. Optimal Stent Dimensions Vary Depending on the Vessel Being Treated

The size and morphology of the vessel to be treated determines the proper stent length, diameter, and branch thickness, so stent manufacturers commonly provided a range of stent sizes to cover various artery sizes. Reference Guide, 6; '035 patent, 2:48-49. A clinician then selected a properly sized stent based on the patient and her/his target lesion: the stent's expanded diameter should approximately match the treated vessel's healthy diameter, and it should be long enough to cover the diseased area of the artery but short enough to avoid affecting more healthy regions. Reference Guide, 6-7; Roubin, 1:32-44; Fischell, 5:50-54; Myler, 6:10-17 (Ex. 1022); Rao ¶¶ 76-78, 80.

For example, coronary arteries (when healthy) have diameters between 2 mm and 5 mm, and thus so did (and still do) expanded coronary stents. *Id.*; Dinh, 7:67-8:3. Similarly, typical coronary stents are around 10-30 mm long. Myler, 6:32-35. These dimensions for the claimed stent diameters and lengths (claim 3) were reflected in numerous coronary stents available prior to July 1998. Rao ¶¶ 79-80, 82-84. Plotted below are coronary stent expanded diameters and lengths reported in the Handbook 2nd (Ex. 1009, purple) and Handbook (Ex. 1008, green), compared to the ranges claimed by the '035 patent (shaded grey).

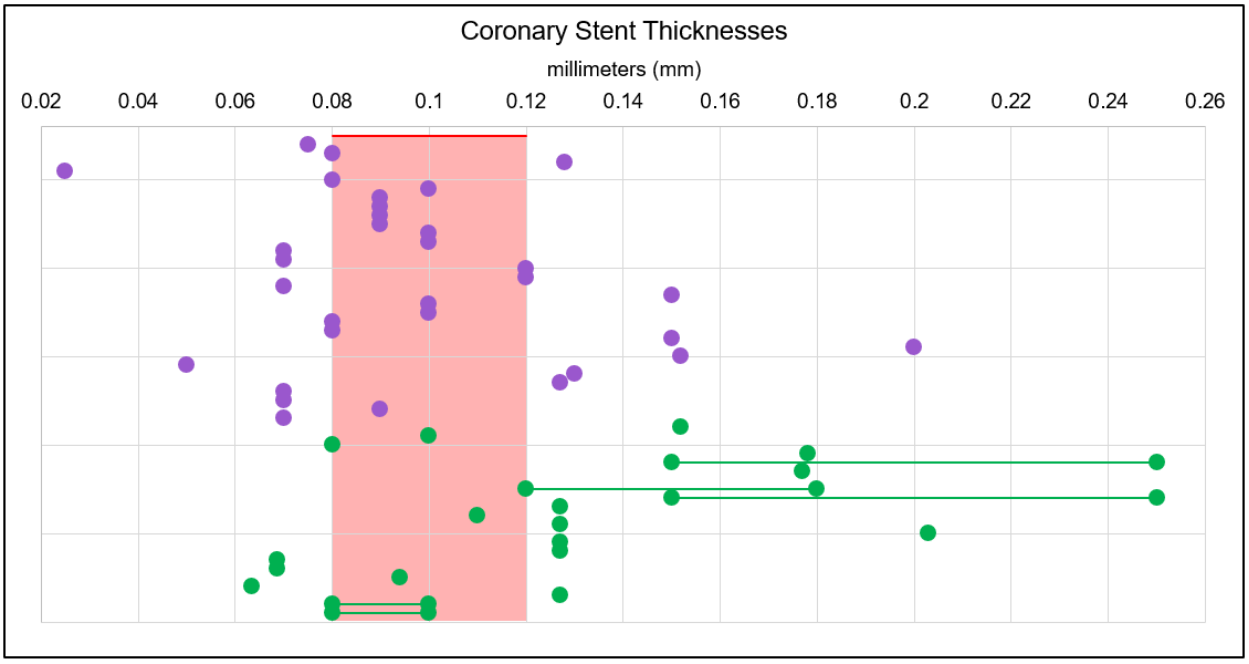





Rao ¶¶ 82-84, Appendix A (providing the plotted numerical values).

Additionally, POSITAs knew to size a stent's struts appropriately for a particular vessel. Overly thick stent struts "effectively create an obstruction to blood flow," provide design limitations that "often result in large gaps" between the struts, and "adversely affect stent flexibility." Richter-794, 2:7-14; Rao ¶¶ 81-85; Ogi, 5:36-44 ("minimiz[ing] the wall thickness and lumenal encroachment of the stent . . . minimizes the risks of blood cell damage and thrombosis associated with disruption of the blood flow profile"). Conversely, struts that are too thin can cause a stent to fracture in response to bending stresses or pressure exerted by the vascular wall, and such stents may not have adequate structural strength. *See, e.g.*, Globerman, 1:23-26. These factors varied predictably depending on the location and diameter of the vessel being treated. Rao ¶ 81. Thus, the thicknesses of stents designed for coronary

applications generally ranged from 0.07 mm to 0.15 mm, as shown in the plot below comparing coronary stent thicknesses in the Handbooks (purple and green) compared to the ranges claimed by the '035 patent (shaded red).




Rao ¶¶ 81-86, Appendix A (providing the plotted numerical values).

POSITAs also "chang[ed] dimension, flexibility, rigidity, size of cells" (the claimed "unit lengths"), "shape of cells, and response to pressure as dictated by specific applications" of a stent to treat "non-uniformity" in a blood vessel. Richter-404, 4:46-50; *see also id.*, 2:3-17 (vary length of branches to alter radial strength), 4:50-55 (shrink cell to reduce likelihood of tissue prolapse through the cell's open space), 4:55-64 (increase size of cells to increase softness at the ends of the stent or allow access to side branch of artery), 6:22-25 (vary number of rows of cells, cells per row, and shape of cell as required for application), 6:57-7:2 (narrow

widths of horizontal branches to improve flexibility); Roubin, 7:49-59 (varying length of branches predictably affects flexibility); Rao ¶¶ 87-88.

So the patient's anatomy significantly dictates stent dimensions. Once a POSITA knew the specific patient characteristics, *e.g.*, diameter and length of the lesion to be treated, whether the stent would need to be delivered through tortuous anatomy (therefore requiring flexibility), and any non-uniformities in the vessel being treated, POSITAs commonly arrived at the desired dimensions by experimenting with stents having varied branch widths, thicknesses, cell shapes, and so forth. Rao ¶ 90. And changing these variables to arrive at the desired properties of a stent was expressly referred to in the prior art as a matter of "routine experimentation." Myler, 5:57-60; *see* Saunders (Ex. 1023), 2:33-38; Fischell, 5:50-55, 1:19-23; Roubin, 7:61-67, 8:37-41; Dinh, 5:62-6:36; Rao ¶ 89. Supplementing that routine experimentation, commonly available computer tools were also utilized by designers to "ensure ideal expansion, structural integrity and long term durability" of a stent with the desired dimensions. *See* Handbook, 53. Thus, the claims are simply directed to the width, thickness, and unit lengths of the branches for a stent of the required stent diameter and length. Rao ¶ 90.

## VI. THE '035 PATENT IS ENTITLED TO A FILING DATE NO EARLIER THAN JULY 16, 1998

The '035 patent is entitled priority only to its actual filing date of July 16, 1998, not to the July 16, 1997 filing date of Korean Patent Application No. 97-33064.

The Petitioner bears the burden of demonstrating unpatentability. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1379 (Fed. Cir. 2015). But when, as here, the examiner did not expressly address the priority issue and the Petitioner provides invalidating art, the burden of production shifts to the patentee. *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305-06 (Fed. Cir. 2008).

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. *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998); 35 U.S.C. § 119(d).

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). 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).

Here, the challenged claims 1-3 of the '035 patent are not entitled to the earlier filing date at least because the Korean Application does not disclose the claimed dimensional limitations.

***First***, the Korean Application lacks any disclosure of a "width" of any branch, much less vertical branches and horizontal branches having ***different*** widths from "0.09 to 0.12 mm" or "0.05 to 0.08 mm," respectively, as claimed in claim 1. This alone defeats any claim to priority. *Lockwood*, 107 F.3d at 1565, 1572; Rao ¶¶ 92-93.

***Second***, the Korean Application lacks sufficient support for the claimed vertical and horizontal branch thicknesses that fall within the range of 0.08 to 0.12 mm. The Korean Application refers to a thickness of "0.090 mm x 0.080 mm or less." Ex 1005, 8-9. This is incomprehensible as a disclosure of a thickness, and is at best ambiguous as to what thickness it refers to (horizontal, vertical, or both). Additionally, the Korean Application fails to disclose the upper end of the claimed range, *i.e.*, 0.10-0.12 mm, foreclosing a finding of sufficient support. *Purdue*

*Pharma*, 230 F.3d at 1326-27 (written description requires "reasonable clarity"); Rao ¶ 93.

The Korean Application also lacks sufficient support for claim 2's recited vertical and horizontal branch unit lengths of 1.5-4.5 mm and 1.0-3.0 mm, respectively. The Korean Application discloses only specific values (2.0 mm vertical branches and horizontal branches of 2.25 mm), which is insufficient support for the claimed ranges. *See* Korean Application, 12; Rao ¶ 94.

## VII. CLAIM CONSTRUCTION

In *inter partes* review, the Board uses the same *Phillips* claim construction standard used by the courts. 37 C.F.R. § 42.100(b).[3]

### A. "vertical branches" and "horizontal branches having wave form projections"

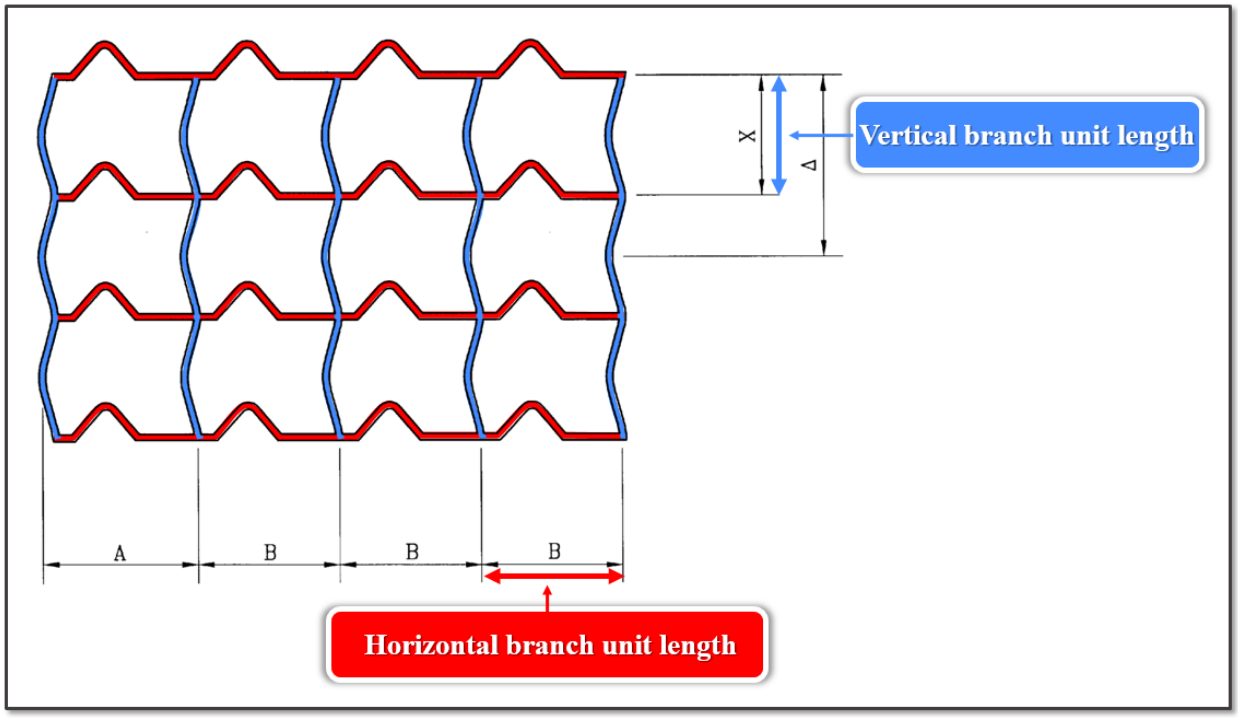
The Board should construe "vertical branches" to mean "portions of the stent that extend generally circumferentially between horizontal branch attachments" and "horizontal branches having wave form projections" as "links or connectors that extend generally longitudinally between vertical branch attachments and comprise a waveform-shape." Rao ¶ 97. This does not restrict the waveform to a particular

[3] Depending on Patent Owner's response, Petitioner reserves the right to make alternative arguments in other venues, including that the claims are indefinite where that defense is available.

shape or require (or rule out) horizontal branches with straight horizontal portions in addition to a waveform-shape.

The "vertical" and "horizontal" terms are straightforward when looking at a flattened two-dimensional diagram of the stent in Figure 1 of the '035 patent, oriented on the page the way it is. But stents are cylindrical, so the "vertical" portion becomes a circumferential portion of the stent (also known as a "ring" or a "cylindrical element" in the art) and the "horizontal" portion becomes a generally longitudinal portion (also known as a "link" or "connector"). Rao ¶¶ 97-98.

Both the "horizontal" and "vertical" branches in the '035 patent refer not to the shape of the branches, but the general overall direction in which they extend between adjacent branches. Specifically, the '035 patent speaks of vertical and horizontal branches regardless of whether they encompass straight or curved portions. First, the depicted "vertical" branches are not straight in a two-dimensional view (or perfectly circular in a three-dimensional cylindrical view)—they are zig-zagged in Figs 2 and 3 of the '035 patent so as to allow the stent to be radially crimped to a small diameter for delivery and then radially expanded to a larger diameter for implantation.




'035 patent, Fig. 3 (annotated), 1:66-2:3, 2:64-67; Rao ¶¶ 99-100.

Second, each horizontal branch has a waveform-projection—which is not straight, *i.e.*, it deviates from the imaginary straight line between the points of attachment to adjacent vertical branches. The "unit length" of the horizontal branch (annotated in Figure 3 above) is the length between two adjacent vertical branch attachments *including* the waveform-projection. The waveform-projection is part of the horizontal branch, and "horizontal" despite deviating from the above referred-to imaginary straight line. Rao ¶ 101.

Thus, having a straight portion is unnecessary for a stent element to be either a "vertical" branch or a "horizontal" branch. Whereas vertical branches extend generally circumferentially between horizontal branches, the horizontal branches are

oriented in the generally longitudinal direction between vertical branch attachments. Rao ¶ 102; Section V.B.1 (State of the Art) above. This is consistent with the ordinary usage of "vertical" and "horizontal" branches or struts in the stent field. Rao ¶¶ 102-103; Israel (Ex. 1011), 3:8-13 (zig-zagging rings are the "vertical meander pattern"), 3:3-7 ("horizontal" meander pattern includes nonlinear loops 18 and 20), Fig. 2 (horizontal pattern including elements 18, 20, 22, vertical elements 11e and 11o); Handbook, 140, Fig. 15.3 ("vertical loop struts" and "horizontal loop struts," both of which are non-linear); Fischell, 2:53-57; Lau, 4:17-20.

Moreover, although the horizontal branches in the preferred embodiment include straight portions, it is improper to import that feature into the claims. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005). The claims ***do not*** require a straight portion in the horizontal branch—they only require that the horizontal branches have "wave form projections." And the key object of the alleged invention *i.e.*, to "endow[] the stent with excellent flexibility," is achieved by the shape and size of the waveform-projection, its deviation from a straight line so as to be able to elongate or shrink, not by the presence or absence of any unclaimed straight portions. Rao ¶ 104; *see* '035 patent, 1:50-54, 2:24-40; Penn, 5:8-11, Fig. 11; Fischell, 5:5-8; Wijay, 5:37-41; Dinh, 2:9-11.

Further, the plain meaning of "wave form projection" includes any shape projecting off an imaginary straight line between the endpoints of the connector:

U-shaped, sinusoidal, triangular, square, rectangular, etc. Roubin, 6:15-50, Figs. 4A, 4B, 7, 8; Penn, 17:25-18:11, Figs. 7-8, 12a-12i; Korean Application, 6-2 ("U-shaped" waveform-projection); Section V.B.1 above (exemplary waveform-shapes in prior art horizontal branches); Rao ¶ 105 (additional examples).

## VIII. PERSON HAVING ORDINARY SKILL IN THE ART

The '035 patent relates to vascular stents suitable for implantation into the human body. A person of ordinary skill in the art in 1997 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. That POSITA may have worked on a team working with or consulting a stent-implanting physician, such as an interventional cardiologist. Rao ¶ 34.

This Petition does not turn on this precise definition, and the claims would be obvious from the perspective of any reasonable POSITA. *Id.* ¶ 35

## IX. OBVIOUSNESS LAW FOR CLAIMED RANGES

A range is disclosed when the range encompasses the prior art's value or range. *King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1277 (Fed. Cir. 2010) ("[W]hen, as by a recitation of ranges or otherwise, a claim covers several

compositions, the claim is 'anticipated' if one of them is in the prior art.") (internal citation omitted).

A claimed range is prima facie obvious if it "overlap[s] or lie[s] inside ranges disclosed by the prior art[.]" *In re Wertheim*, 541 F.2d 257, 267 (C.C.P.A. 1976); *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003) ("[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness."). "Such overlap itself provides sufficient motivation to optimize the ranges." *In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (internal citation omitted).

Once prima facie obviousness is established, the burden shifts to the patentee to rebut the presumption by showing that (1) the claimed range "produce[s] a new and unexpected result which is different in kind and not merely in degree from the results of the prior art[,]" *i.e.*, it is directed to a "critical" range, (2) "that the prior art taught away from the claimed range[,]" (3) the change is to a parameter not recognized as "result effective," or (4) the prior art range is so broad that it does not invite routine optimization. *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006 (Fed. Cir. 2018) (internal citations and quotations omitted).

Unexpected results do not, however, include results that merely "differ by percentages[.]" *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 739 (Fed. Cir. 2013), *citing, e.g., In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005). Those results

are "differences in degree rather than kind" that would be "within the capabilities of one skilled in the art at the time." *Galderma*, 737 F.3d at 739. And a reference only teaches away if a POSITA would be "discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *Id.*, 738. "A reference does not teach away, however, if it merely expresses a general preference for an alternative invention but does not criticize, discredit, or otherwise discourage investigation into the invention claimed." *Id.*

## X. PRECISE REASONS FOR THE RELIEF REQUESTED

### A. Ground 1: Claims 1-3 Are Unpatentable Over Richter-Handbook (Ex. 1008) and Richter-404 (Ex. 1010) in View of the Knowledge of a POSITA

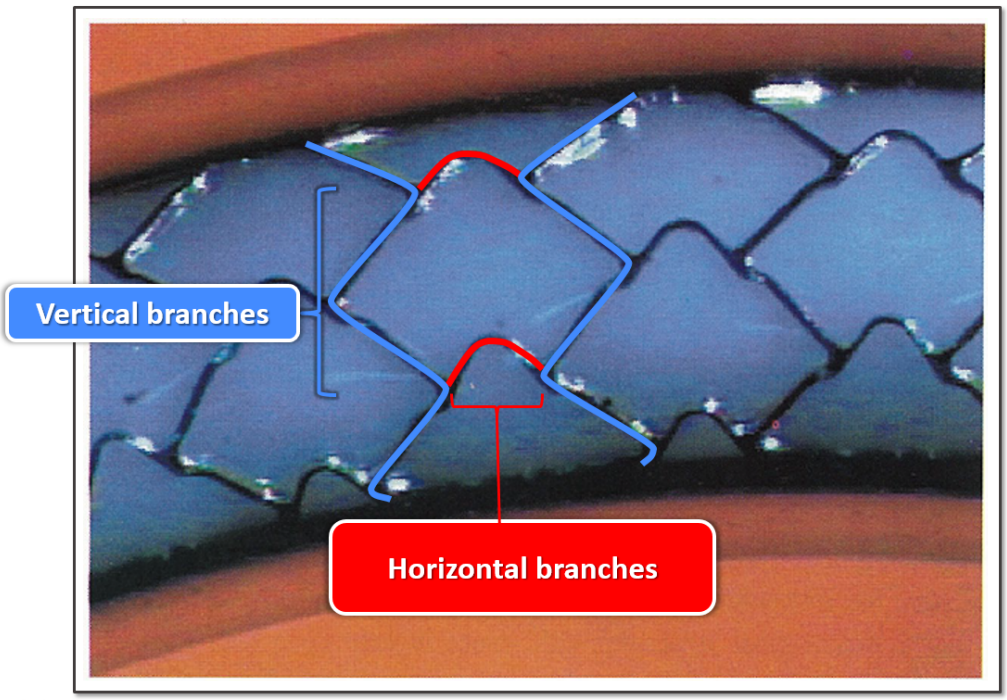
#### 1. Overview—Richter-Handbook and Richter-404 Disclose All the Claim Elements

The Handbook (specifically Chapter 15 by Richter, or "Richter-Handbook") is § 102(b) prior art: it was published and publicly available by June 27, 1997, more than one year before the '035 patent's filing date. *See* Section VI above (the '035 patent is entitled only to its actual filing date); Hsieh-Yee Decl. (Ex. 1035) ¶¶ 26-65 (expert librarian declaration establishing authenticity and public availability). It is also prior art under § 102(a): it was publicly available before the '035 patent's earliest claimed effective filing date. *Id.*

Richter-404 is § 102(e) prior art because it is a U.S. patent filed before the '035 patent's actual and earliest-claimed filing dates. The examiner did not consider

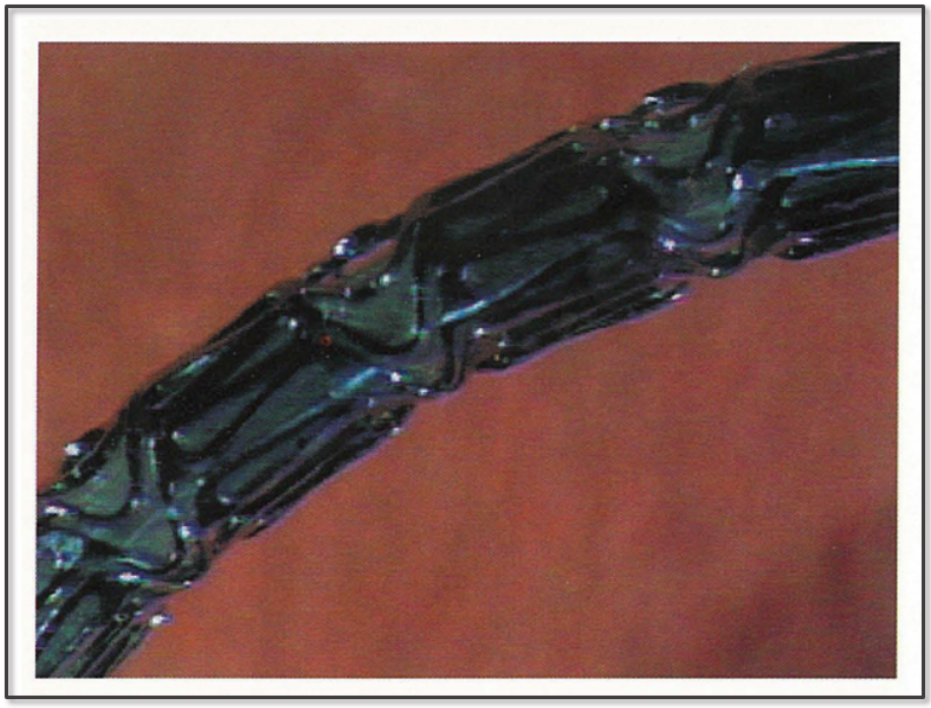
these references during prosecution.

These references disclose the "NIR" stent (or some close design), which was developed and commercialized by the lead author/inventor's (Dr. Jacob (Kobi) Richter's) company, Medinol Ltd., before the date of the alleged invention. Rao ¶ 106. The NIR stent has vertical and horizontal branches (rings and links), and the horizontal branches have waveform-projections, as annotated in Figure 15.3 of the Handbook below:




Handbook, Fig. 15.3 (annotated); Rao ¶ 108.

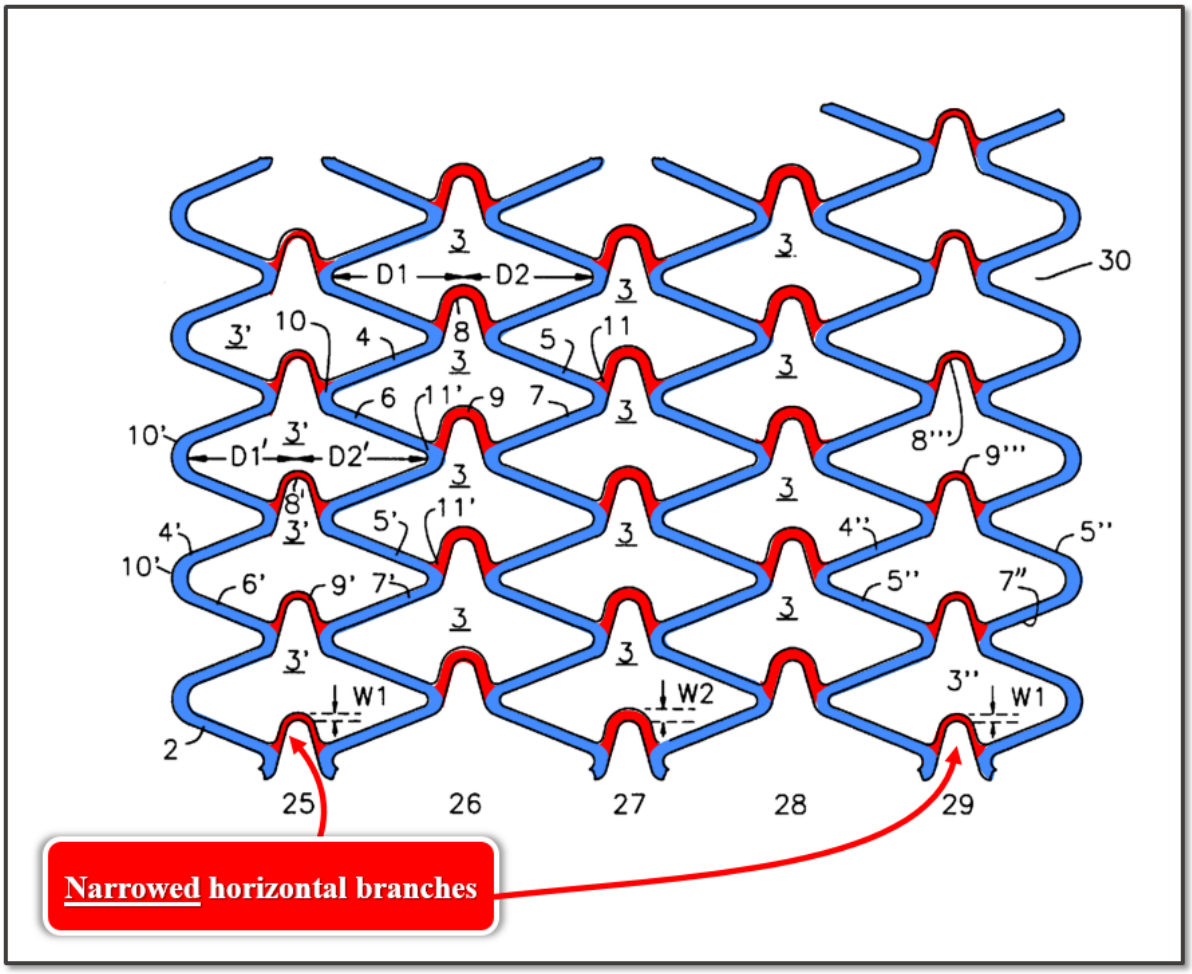
The unexpanded stent is shown in Figure 15.2 below.



Handbook, Fig. 15.2.

As discussed below, the Richter-Handbook discloses or establish prima facie obviousness of the branch and stent dimensions in claims 1-3, except that its horizontal branches are 0.10 mm wide rather than 0.05-0.08 mm as required by claim 1. Rao ¶¶ 110-112.

Richter-404 is by the *same lead author* and further teaches narrowing the horizontal branches of this *same* NIR stent by 40-50% (*i.e.*, reducing the width from 0.10 mm to 0.05-0.06 mm) to improve the stent's lateral flexibility:




Richter-404, Fig. 10 (annotated), 6:67-7:3; Rao ¶ 112.

Additionally, the claims do not require the horizontal branches to have straight horizontally-directed portions in addition to the waveform-projection. *See* Section VII (Claim Construction) above. Nevertheless, Richter-404 teaches an alternative design in which the horizontal branches have both waveform-projections and straight horizontally-directed portions. Specifically, Richter-404 states that the NIR stent may be "constructed in a manner in accordance with the stent described in U.S. patent application Ser. No. 08/457,354," which issued as U.S. Patent No. 5,733,303

to Israel (Ex. 1011).[4] Richter-404, 5:49-51; Rao ¶¶ 113-14. As discussed below with respect to limitation [1b], Israel teaches that the horizontal branches of the NIR stent can include straight portions and waveform-projections.

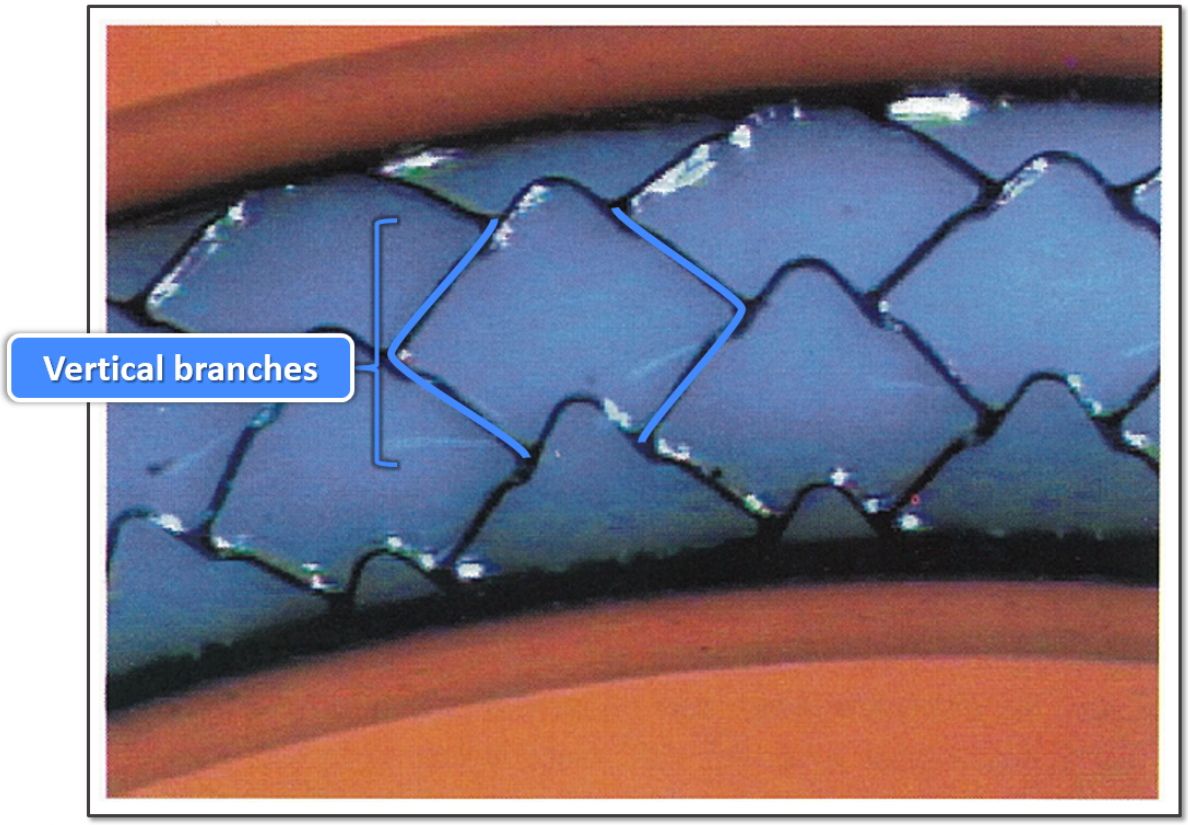
Thus, the Richter-Handbook and Richter-404 together render obvious claims 1-3, and a POSITA would have been motivated to combine them as discussed in Section X.A.2.c below.

**2. Claim 1**

**a. [1a]—"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."**

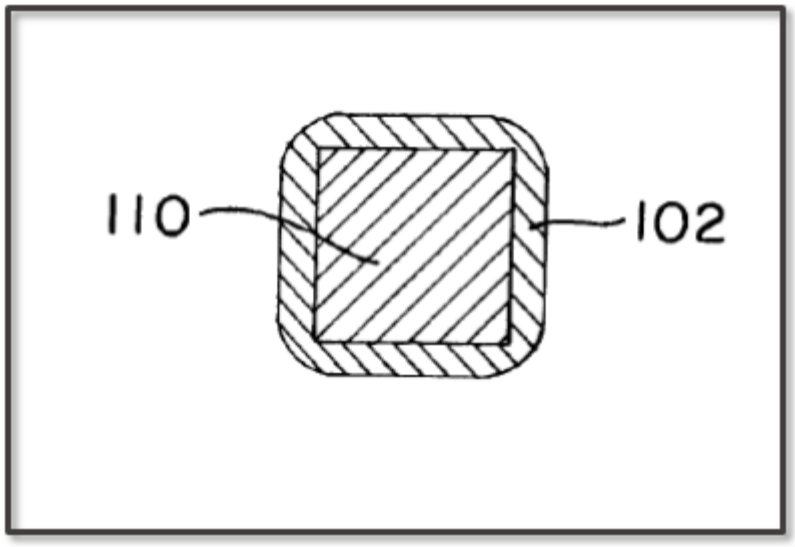
The Richter-Handbook describes a vascular stent with "vertical loop struts" that extend circumferentially and correspond to the claimed "vertical branches" as annotated in Figure 15.3 below.

[4] Israel is incorporated by reference into Richter-404 (Richter-404, 5:50-54) and is itself § 102(e) art based on its May 31, 1995 filing date. Because it is expressly incorporated into Richter-404, it is not a separate reference per se. If the Board requires listing it as a separate reference, this Ground is further in view of Israel, and the motivations to combine remain the same.



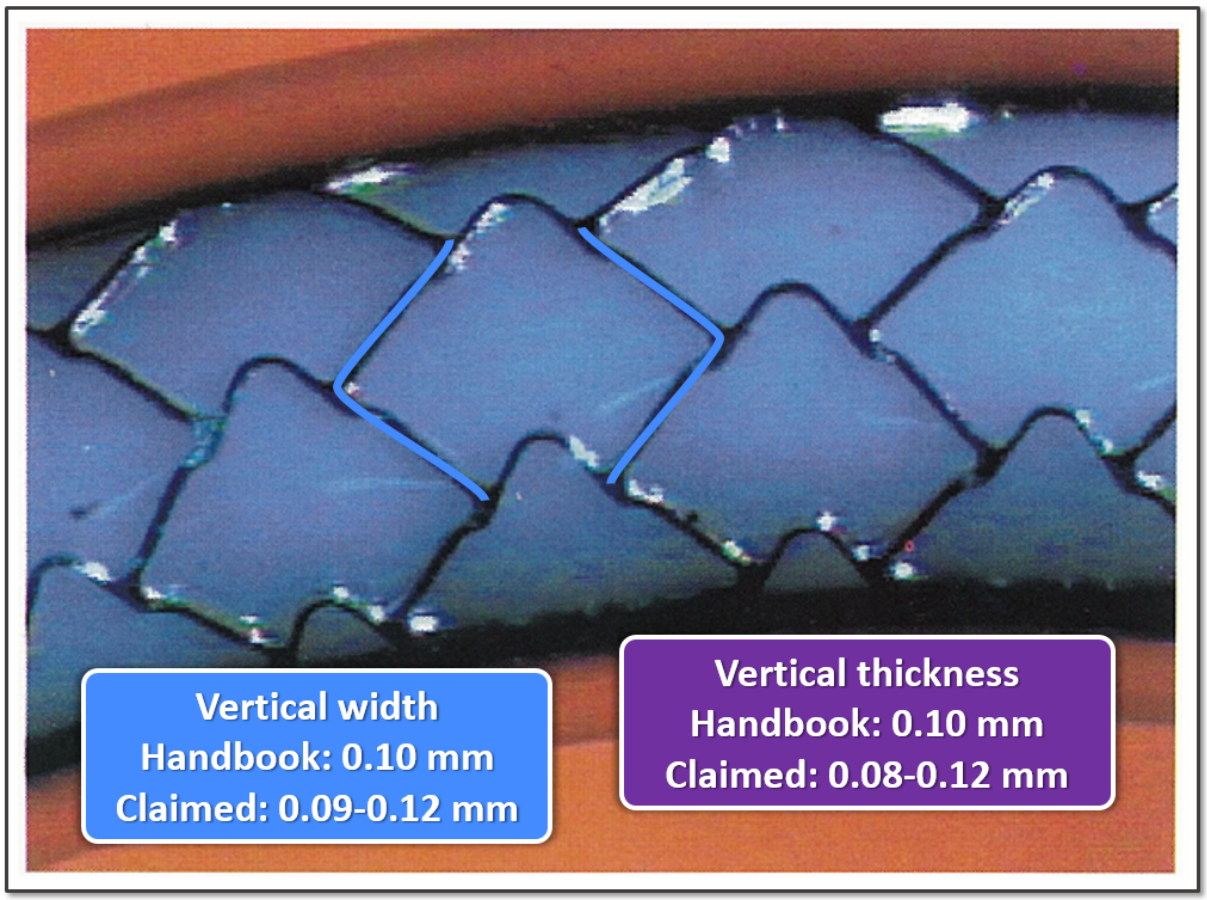

Handbook, Fig. 15.3 (annotated); *see also id.*, 140; Rao ¶ 116.

The Richter-Handbook teaches that the NIR stent has a "Strut Design" of "Square" and a "strut thickness" of "0.1 mm." Handbook, 137. A POSITA understood that "Strut design" and "Strut thickness" refer to the square cross-sectional shape of the struts, including both the vertical branches and the horizontal branches, which the Richter-Handbook calls "vertical loop struts" and "horizontal loop struts," respectively, with a width and thickness of 0.10 mm. Rao ¶¶ 117-118. That the width and thickness of a square strut are the same is confirmed in Richter-794, another patent to Dr. Richter, which depicts the same stent as Richter-404 and a strut with a square cross-section:




Richter-794, Fig. 1B, 3:47-52; Rao ¶ 118.

Vertical loop branches with a width and thickness of 0.10 mm fall within and so disclose the claimed dimensions for the vertical branches as annotated on Figure 15.3 below. *King Pharms.*, 612 F.3d at 1277.



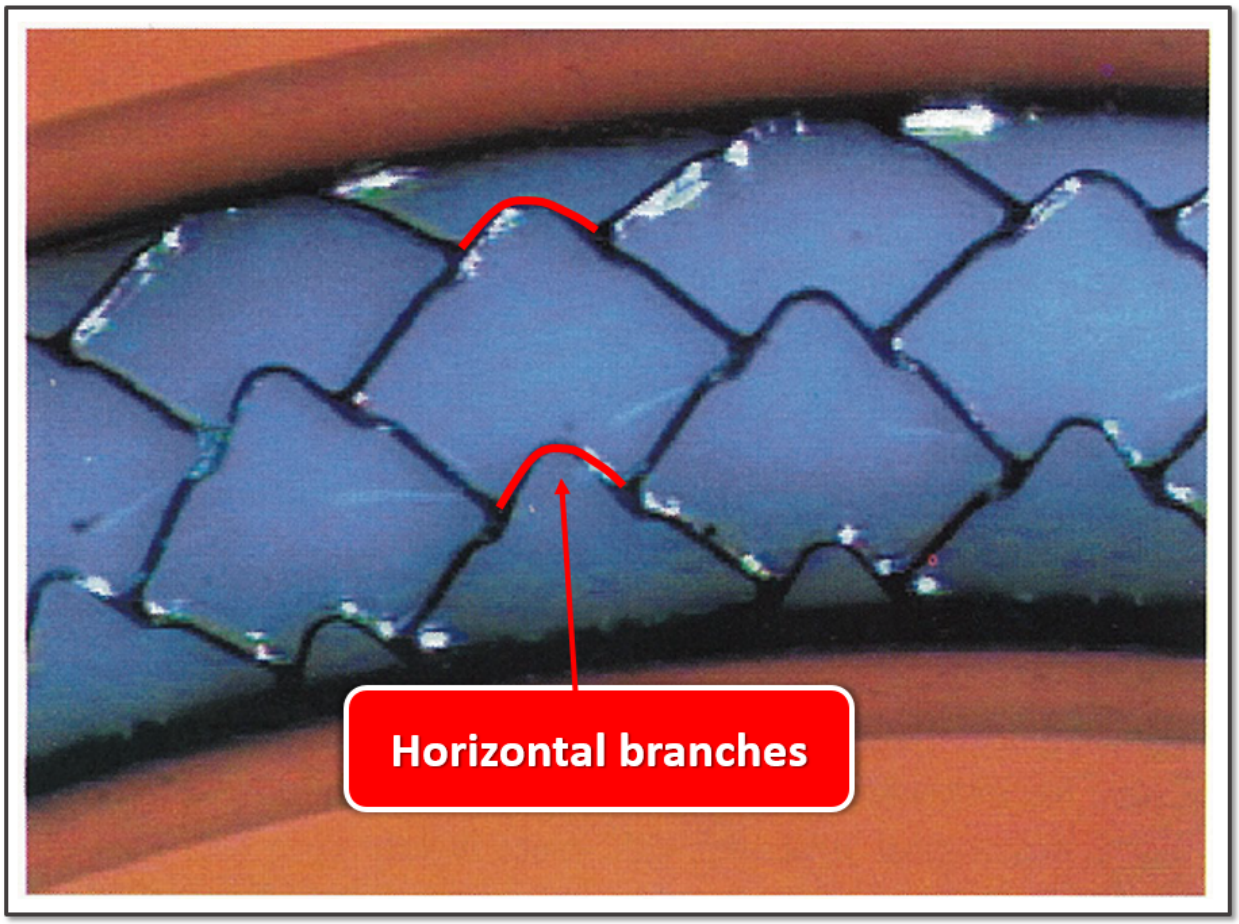

Handbook, Fig. 15.3 (annotated); Rao ¶ 119.

**b. [1b]—"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."**

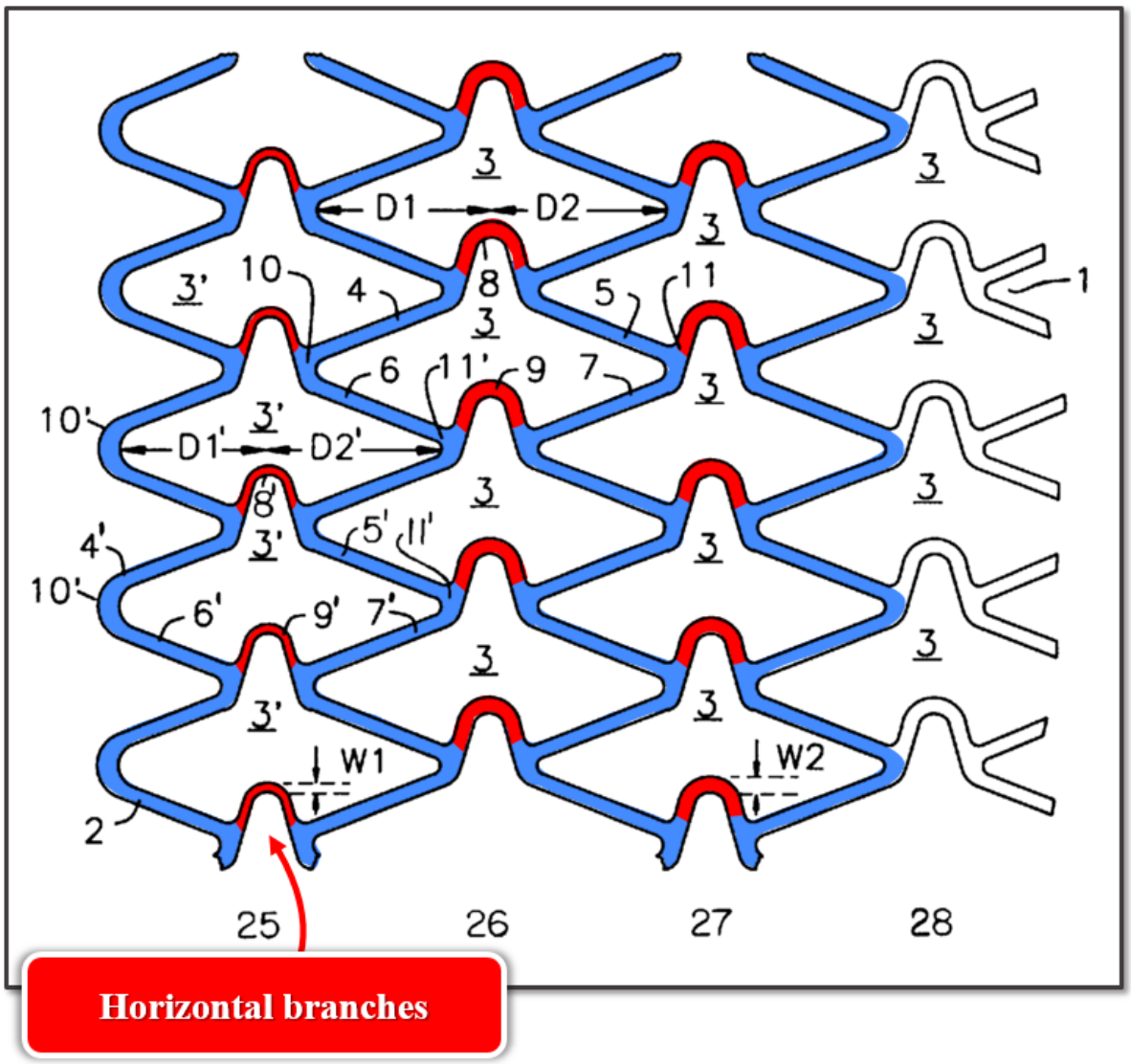
**Horizontal Branches Having Waveform-Projections**

The Richter-Handbook explains that the NIR stent has "horizontal loop struts" that extend generally longitudinally along the length of the stent. As annotated in

Figure 15.3, they comprise a waveform-projection and correspond to the claimed horizontal branches having waveform-projections.




Handbook, Fig. 15.3; *see also id.*, 140; Rao ¶ 120. They are also disclosed by Richter-404 as annotated in Figure 2 below.

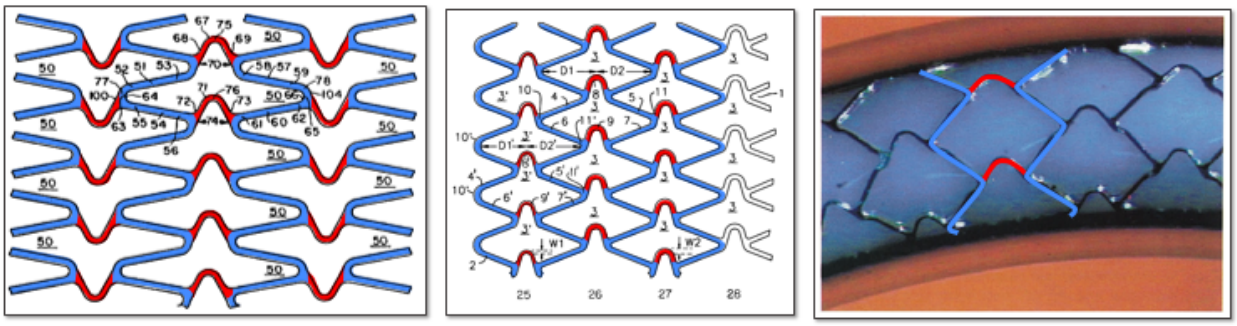



Richter-404, Fig. 2 (annotated); Rao ¶¶ 121-122. Thus, the Richter references each teach "horizontal branches having wave form projections."

As discussed above, the claims do not require the horizontal branches to have straight horizontal portions. If they did, Richter-404 discloses that design by its express incorporation of Israel.

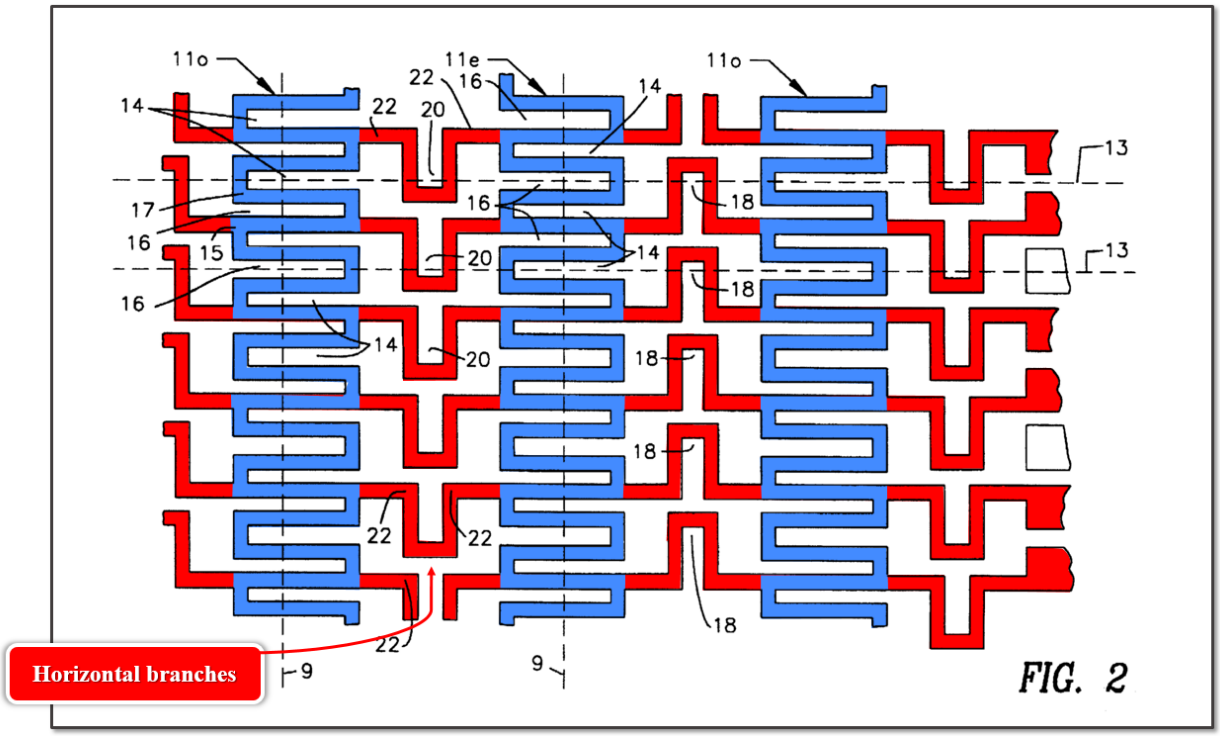
As background, Israel is from the same company as Richter-404 and the Richter-Handbook, Medinol Ltd., and discloses an earlier iteration of the same

general NIR stent design. This is shown in a comparison of annotated Figure 8 of Israel with Figure 2 of Richter-404 and Figure 15.3 of the Richter-Handbook.



Israel, Fig. 8 (annotated); Richter-404, Fig. 2 (annotated); Handbook, Fig. 15.3 (annotated); Rao ¶¶ 123-125.

Israel also discloses an alternative embodiment wherein the horizontal branches (portions of what are referred to as "horizontal meander patterns" of the stent) can be formed as having "loops, labeled 18 and 20" (waveform-projections) ***and*** "extended straight section[s] labeled 22" as shown in annotated Figure 2 of Israel below.




Israel, Fig. 2 (annotated), 3:3-24 (referring to "vertical" patterns 11o and 11e, and "horizontal" patterns comprising elements 18, 20, and 22); Rao ¶ 126.

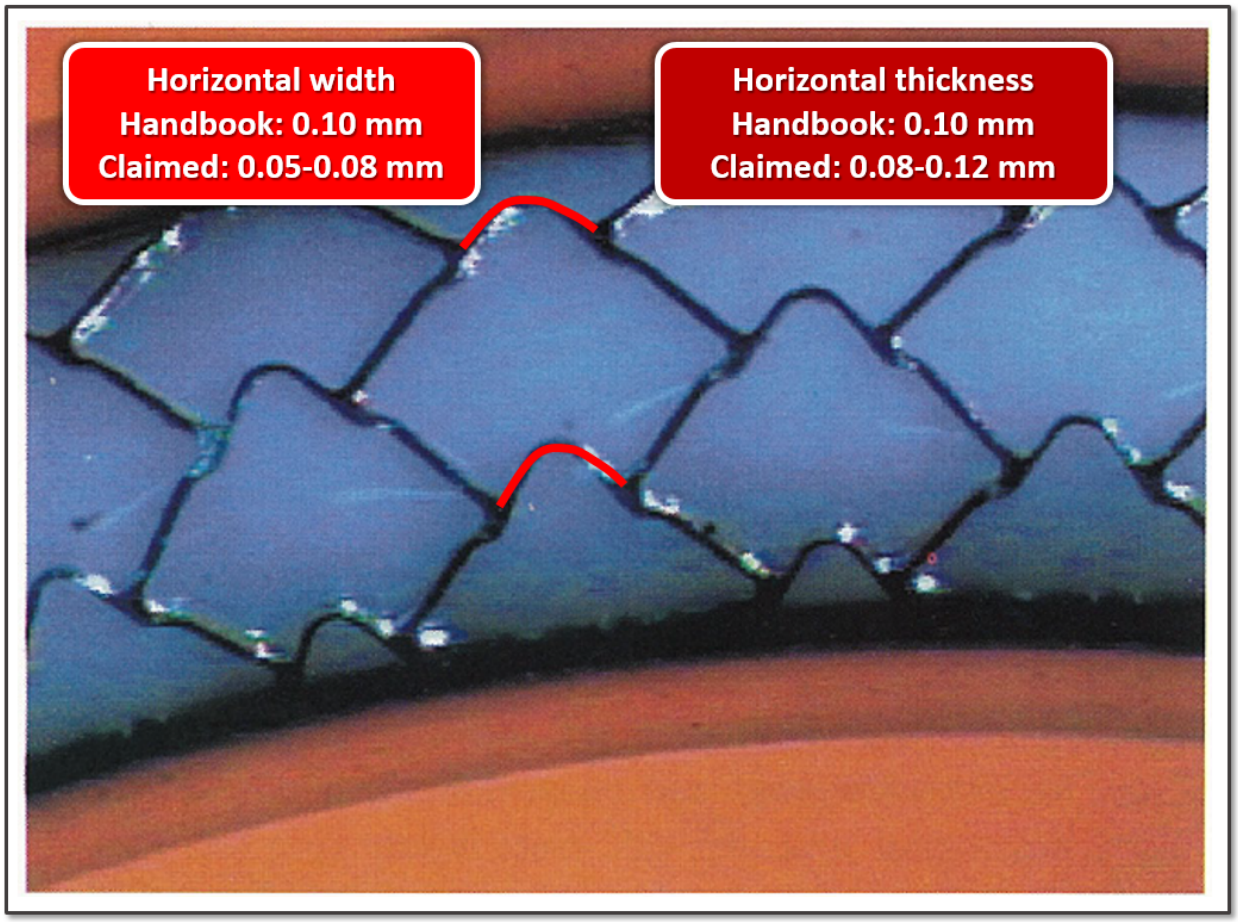
Israel teaches that the horizontal branch design of Figures 2 and 8 (with or without straight portions) provide the same benefits of improved flexibility to the stent. Israel, 4:5-25, 4:36-56, Figs. 7-8.

Thus, a POSITA would have combined the NIR stent's horizontal branches with Israel's alternative horizontal branch, which comprises horizontal portions on either side of the wave-form projections: (1) there were two obvious design choices for the shape of the horizontal branches (Richter-Handbook and Richter-404/Israel), which address the same objective (adding flexibility) in the same way (by including a waveform-projection in the horizontal branches) but with or without straight

portions; (2) the two references show the demand for designs that address the known desire to improve flexibility; (3) Israel's horizontal branches were a common and known design that could be used in the NIR stent disclosed in Richter-404 and the Richter-Handbook; and (4) the Richter-Handbook stent would have had a reasonable chance of success if modified to use such a design as evidenced by numerous other prior art stents disclosing the use of horizontal branches having alternating straight segments and waveform-projections. Rao ¶¶ 127-131, 104; Israel, 4:5-25, 5:58-65; Richter-404, 5:50-53; Richter-Handbook, 138-139, 141; Section V.B above (State of the Art); *see Philips Lighting N. Am. Corp. v. Wangs All. Corp*., 727 F. App'x 676, 680–82 (Fed. Cir. 2018), *citing KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 416 (2007). A POSITA also would have tried the alternative design in Israel because Richter-404 expressly states that different-shaped horizontal branches could be used with the NIR stent and that the NIR stent may be made "in a manner in accordance with" Israel's stent. Richter-404, 7:55-60, 5:51-54; *Asyst Techs., Inc. v. Emtrak, Inc*., 544 F.3d 1310, 1315 (Fed. Cir. 2008) (replacing a bus connector with a multiplexer connector was "little more than 'the simple substitution of one known element for another, and thus the use of a multiplexer instead of a bus does not render the invention of the '421 patent nonobvious.") (internal citation omitted).

**Horizontal Branch Width and Thickness**

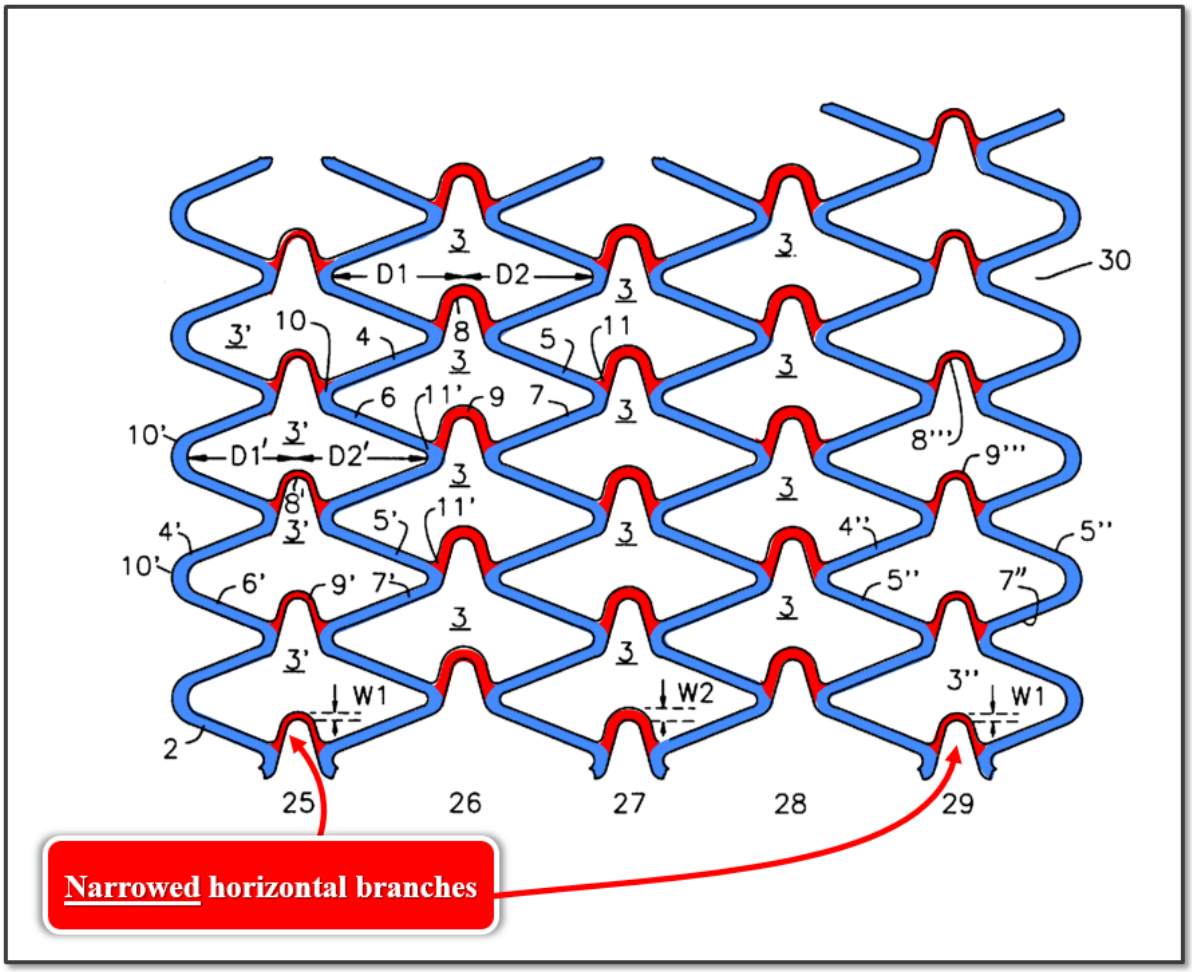
As discussed regarding limitation [1a], the Richter-Handbook discloses "horizontal loop struts" (horizontal branches having waveform-projections) with a width and thickness of 0.10 mm. *See* Section X.A.2.a above; Richter-Handbook, 140; Rao ¶ 132; Richter-794, 3:47-52, Fig. 1B. The Richter-Handbook thus discloses the claimed thickness of the horizontal branches as annotated in Figure 15.3 below. *See King Pharms.*, 612 F.3d at 1277.




Handbook, Fig. 15.3 (annotated); Rao ¶¶ 132-133.

As annotated, the Richter-Handbook teaches horizontal branches that are

0.10 mm wide, which are slightly larger than the claimed 0.05-0.08 mm range. Richter-404, however, teaches narrowing horizontal branches of the NIR stent to provide even "[g]reater flexibility" to the stent. Richter-404, 6:57-60. Specifically, Richter shows narrowed horizontal branches (8' and 9') in the rows labeled "25" and "29."

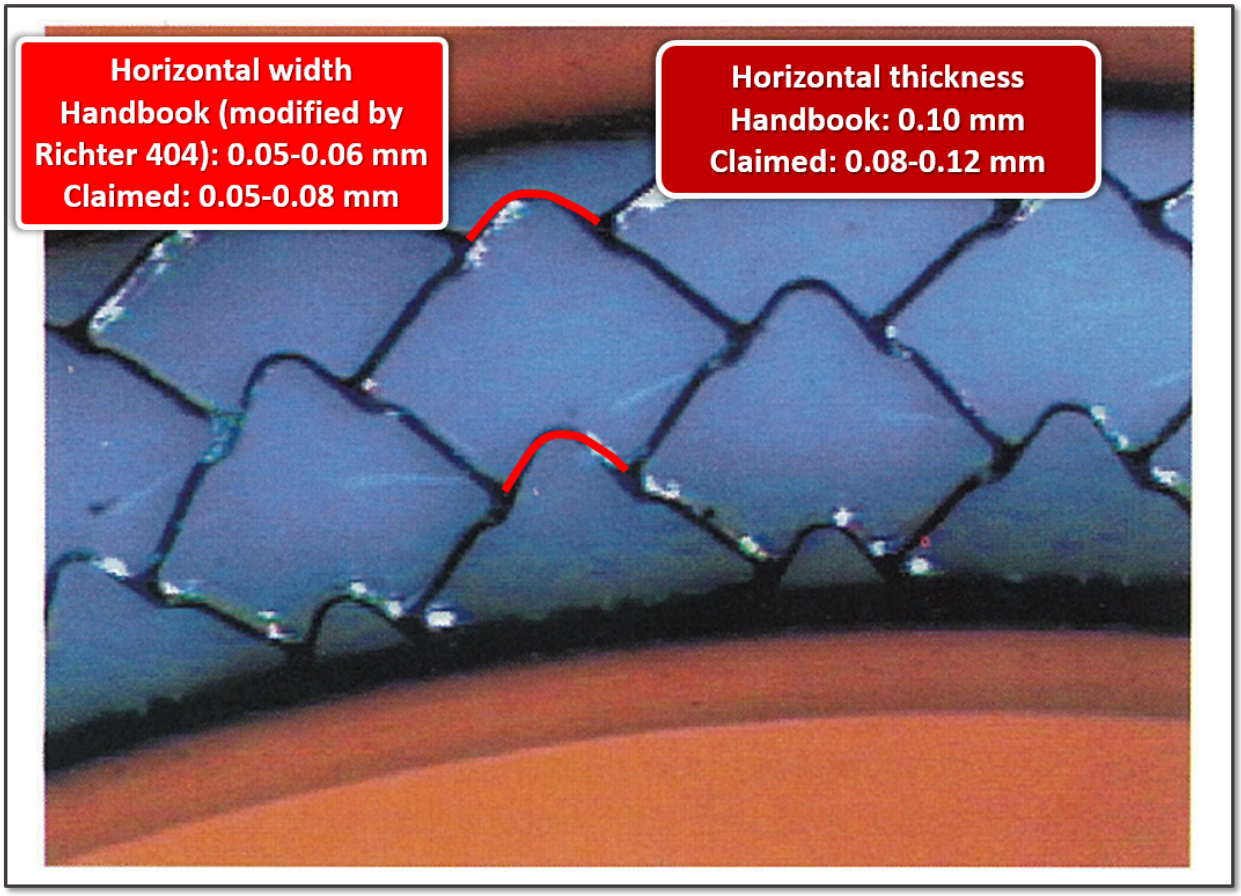



Richter-404, Fig. 10 (annotated); Rao ¶ 134. Richter-404 explains that loop W1 "is about 50% narrower" (and "in an especially preferred embodiment . . . about 40% narrower") "than W2," and is therefore 0.05 or more preferably about 0.06 mm.

Richter-404, 6:67-7:3; Rao ¶ 135. Richter-404 also expressly states that the "thickness of material" is unchanged in the narrowed branches. Richter-404, 6:60-65 (narrowed "U-shaped loops 8' and 9' of row 25 are provided with the ***same thickness of material*** as the U-shaped loops of the cells 3 in rows 26, 27 and 28.").

The narrowing of two rows of horizontal branches in the Richter-Handbook, as taught by Richter-404 satisfies claim 1. Because claim 1 is an open-ended "comprising" claim, it does not require every horizontal branch to be within the claimed range.

Implementing Richter-404's straightforward modification to the NIR stent described in the Richter-Handbook results in horizontal branches of width 0.05-0.06 mm (*i.e.*, 40% to 50% less than 0.1 mm) and thickness 0.1 mm (*i.e.*, "the same thickness" as the other struts), as indicated in annotated Figure 15.3 of the Richter-Handbook below.




Handbook, Fig. 15.3 (annotated); Rao ¶¶ 136-139.

Because these dimensions are within the claimed ranges, the Richter-Handbook in view of Richter-404 discloses "horizontal branches having wave form projections" having the claimed dimensions. *King Pharms.*, 612 F.3d at 1277.

**c. Motivation to Combine Richter-Handbook with Richter-404**

A POSITA would have been motivated to combine Richter-404 and the Richter-Handbook, and implement Richter-404's straightforward modification to the NIR stent in the Richter-Handbook. ***First***, they both were lead authored by the

same inventor, Dr. Jacob (Kobi) Richter, and described the same stent from the same company. *Ex Parte Mettke, No*. 2008-0610, 2008 WL 4448201, at *17 (B.P.A.I. Sept. 30, 2008), *aff'd*, 570 F.3d 1356 (Fed. Cir. 2009) (finding motivation to combine four prior art references to invalidate the claim because they are "***from the same corporation***, [], and expressly teach modifications, variations, and improvements to a pay-for-use public communications terminal."); Rao ¶ 140.

***Second***, Richter-404 expressly teaches a modification and provides a motivation to combine: it discloses the same stent as the Richter-Handbook, and teaches narrowing one or more horizontal branches of the NIR stent by 50%, or more preferably by 40%, compared to other horizontal branches. Richter-404, 6:57-7:3. Such narrowing provides "[g]reater flexibility" to the stent, which a POSITA would have wanted to improve trackability in traversing curved blood vessels. Richter-404, 6:57-60; Handbook, 138 ("The flexibility of a stent, a long stent especially, is a major parameter in determining its trackability into the naturally curved and tortuous anatomy of diseased coronary arteries."); Rao ¶ 141; Section V.B (State of the Art above).

***Third***, Richter-404 solves the same problem that the '035 patent allegedly solved. Increased flexibility is the same solution to the same problem of having a flexible stent for adapting a stent to the anatomy of the vessel during delivery that the inventor of the '035 patent supposedly sought by claiming horizontal branches

with widths narrower than vertical branches. *See* '035 patent, 1:50-54. A POSITA would have looked to modify the NIR stent disclosed in the Richter-Handbook to further increase flexibility, and Richter-404 describes such a modification, so a POSITA would have reasonably expected that the modification would succeed. Rao ¶¶ 140-142; *see ABT Sys., LLC v. Emerson Elec. Co.*, 797 F.3d 1350, 1360 (Fed. Cir. 2015) ("a court . . . may find a motivation to combine prior art references in the nature of the problem to be solved.") (citations omitted).

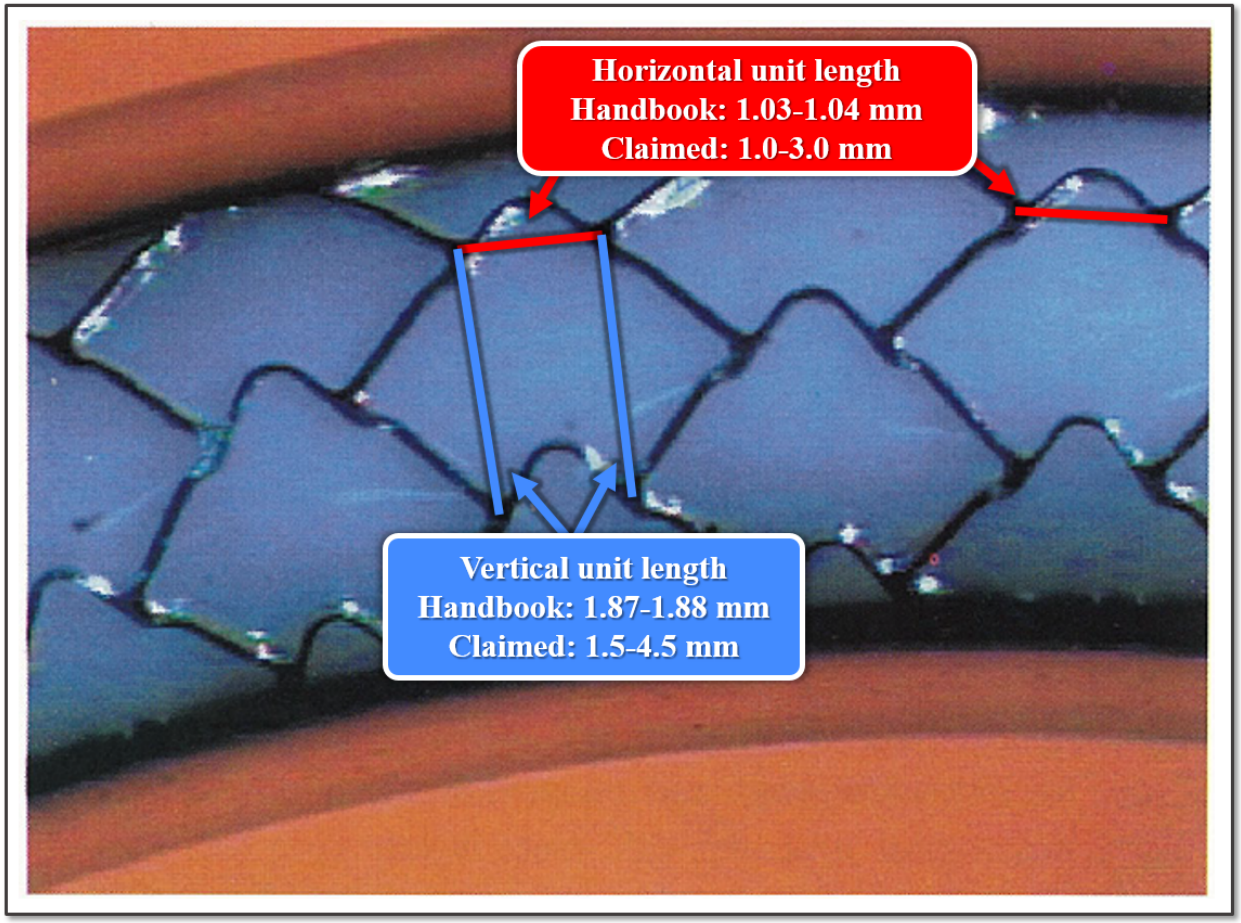
**3. Claim 2**

**a. "The vascular stent of claim 1, wherein unit lengths of the vertical branch and the horizontal branch range 1.5 to 4.5 mm and 1.0 to 3.0 mm, respectively."**

The Richter-Handbook discloses and/or renders obvious the claimed ranges. As used by the '035 patent, the vertical branch unit length is equal to the center-to-center distance between adjacent horizontal branch attachments, and the horizontal branch unit length is equal to the center-to-center distance between adjacent vertical branch attachments. *See* '035 patent, 2:64-67, Fig. 3; Rao ¶ 143. Although the Richter-Handbook does not expressly list these dimensions for the NIR stent, it provides a photograph of an "expanded NIR stent" in Figure 15.3 and the vertical branch width of 0.1 mm (*see* discussion and citations regarding limitation [1a] above) from which the horizontal and vertical branch unit lengths can be determined.

*See REG Synthetic Fuels, LLC v. Neste Oil Oyj*, 841 F.3d 954, 958-61 (Fed. Cir. 2016) (finding disclosure in prior art reference despite need to derive values).

Using the width of the vertical branch for scale, Dr. Rao calculated the horizontal and vertical branch unit lengths of the expanded NIR stent shown in Fig. 15.3, and they fall within the claimed ranges as annotated below.



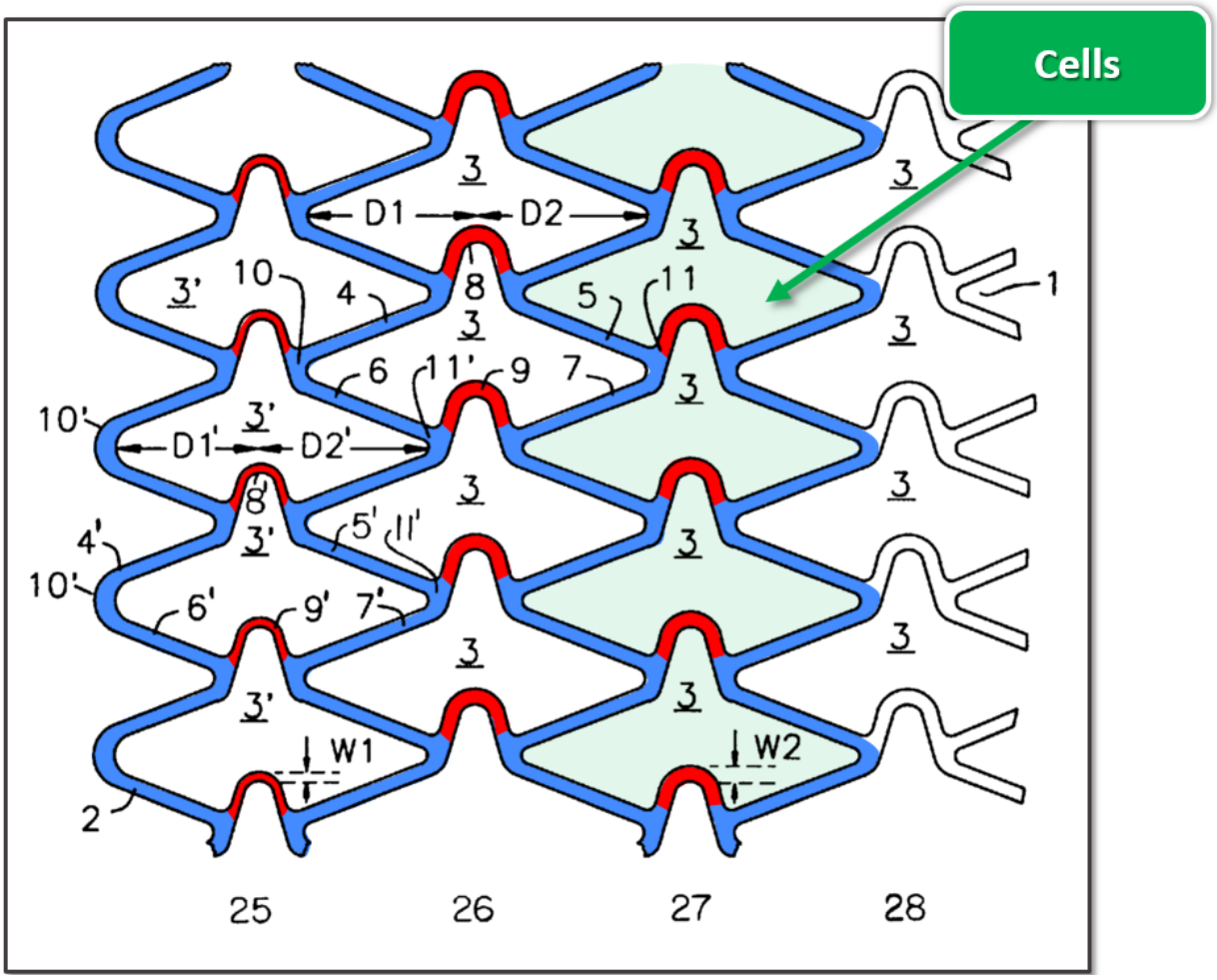

Handbook, Figure 15.3 (annotated), 140; Rao ¶¶ 144-151 (measuring pixels to calculate proportions).

Accordingly, the Richter-Handbook expressly discloses the claimed ranges. Moreover, even if there were slight deviations in the above measurements, a

POSITA would have found the differences to be minor and would not have expected the NIR stent to have different properties than the claimed invention. Rao ¶¶ 151-152. Thus the claimed ranges are also prima facie obvious. *See Haynes Int'l, Inc. v. Jessop Steel Co.*, 8 F.3d 1573, 1577 n.3 (Fed. Cir. 1993), clarified on reh'g, 15 F.3d 1076 (Fed. Cir. 1994) ("a prima facie rejection is properly established when the difference in range or value is minor.") (citations omitted).

And nothing suggests that claim 2's ranges are critical, deliver unexpected results, or represent any particular advance in the art to overcome the prima facie obviousness case established by the disclosed values. To the contrary, a POSITA would have understood that varying the height and width of the cells (the vertical and horizontal branch unit lengths, respectively) of the NIR stent was within the knowledge of a POSITA and had predictable outcomes in view of Richter-404. Rao ¶¶ 152-153.

As discussed in Section V.B (State of the Art), Richter-404 teaches that the horizontal and vertical branches of the NIR stent form "cells," one row of which are annotated green in Figure 2 of Richter-404 below.




Richter-404, Fig. 2 (annotated); Rao ¶ 153.

Richter-404 teaches that a stent can be modified by changing the "size of cells" or "shape of cells" in different portions of the stent as "dictated by specific applications." Richter-404, 4:46-50; *see also id.*, 2:3-17 ("reducing the length of some sections," *e.g.*, vertical unit lengths, of the stent can alter the "radial strength of a stent," which can be beneficial in circumstances, such as for "stents supporting ostia"), 4:55-64 (expanding the cell by increasing vertical and/or horizontal branch lengths could allow access to a side branch of the artery and imparts a "desired

degree of softness" to "best fit with the anatomy of the target area"), 1:36-50 (flexibility and radial support can be varied by "changing the cell shape and size"); Rao ¶ 154. Other prior art references provide similar motivations to vary horizontal and vertical branch widths for particular applications. *Id.*; *see, e.g.*, Roubin, 7:49-59, 8:3-6.

The Richter-Handbook's NIR stent, as modified by Richter-404, discloses the alleged inventive aspects of the '035 patent: a stent with narrower horizontal branches than vertical branches, and with horizontal branch waveform-projections, which achieves the same objective (greater flexibility). Thus, even if claim 2's dimensions are not expressly disclosed (they are), arriving at the claimed dimensional ranges would have been obvious in view of the Richter-Handbook and Richter-404. *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); *In re Applied Materials*, 692 F.3d at 1295-98 (it would have been obvious to double the prior art's disclosed dimensions and arrive at the claimed size because "it is not inventive to discover the optimum or workable ranges by routine experimentation.") (internal citation omitted).

**4. Claim 3**

**a. "The vascular stent of claim 1, wherein diameter and length of the stent range 1.0 to 5.75 mm and 9.0 to 60 mm, respectively."**

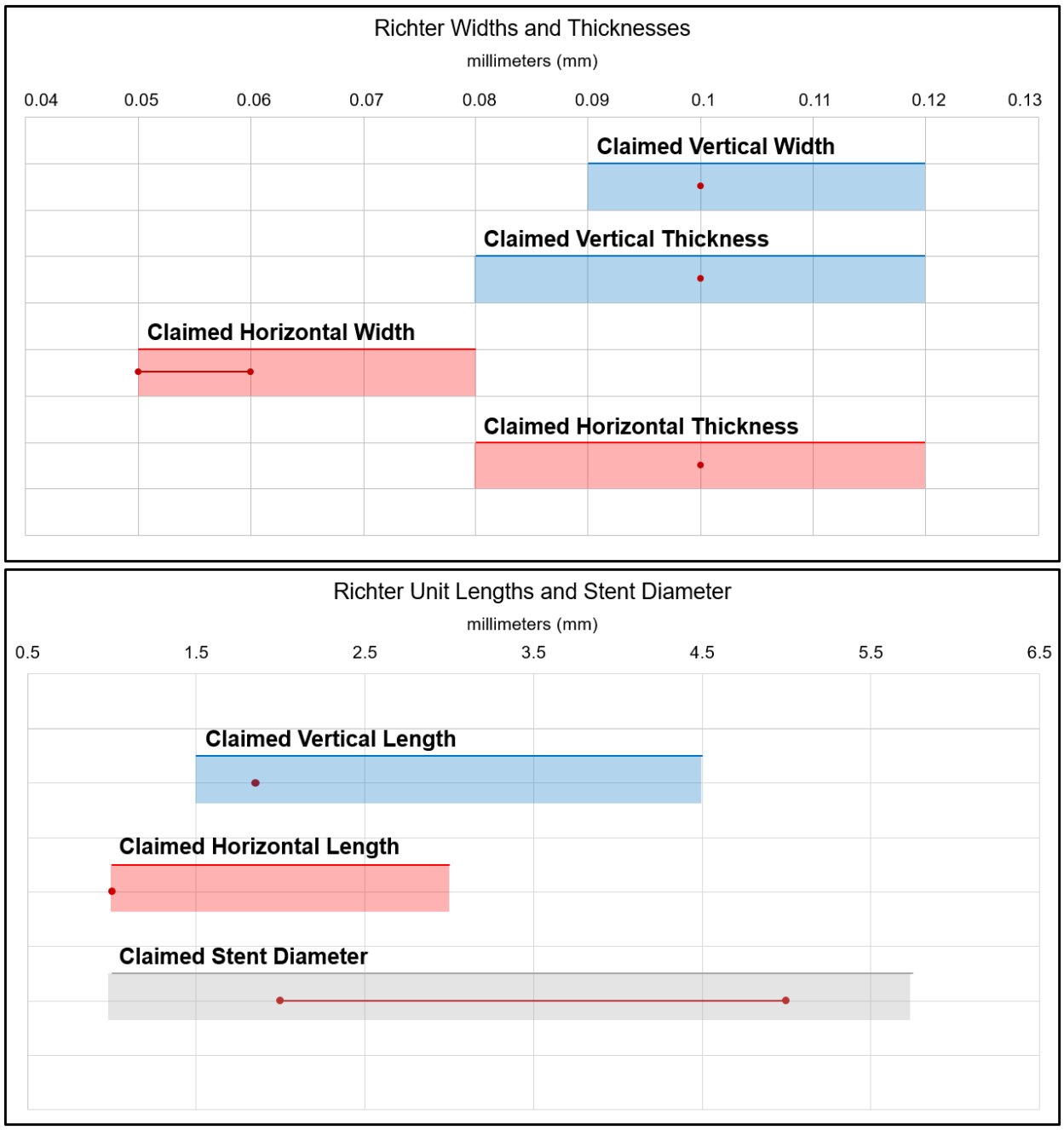
The Richter-Handbook discloses these ranges: its NIR stent had "available expanded diameters: 2-5 mm" and "lengths: 9, 16, and 32 mm." Handbook, 137; Rao ¶ 155; *see King Pharms.*, 612 F.3d at 1277.

**5. Summary of Disclosed Dimensions**

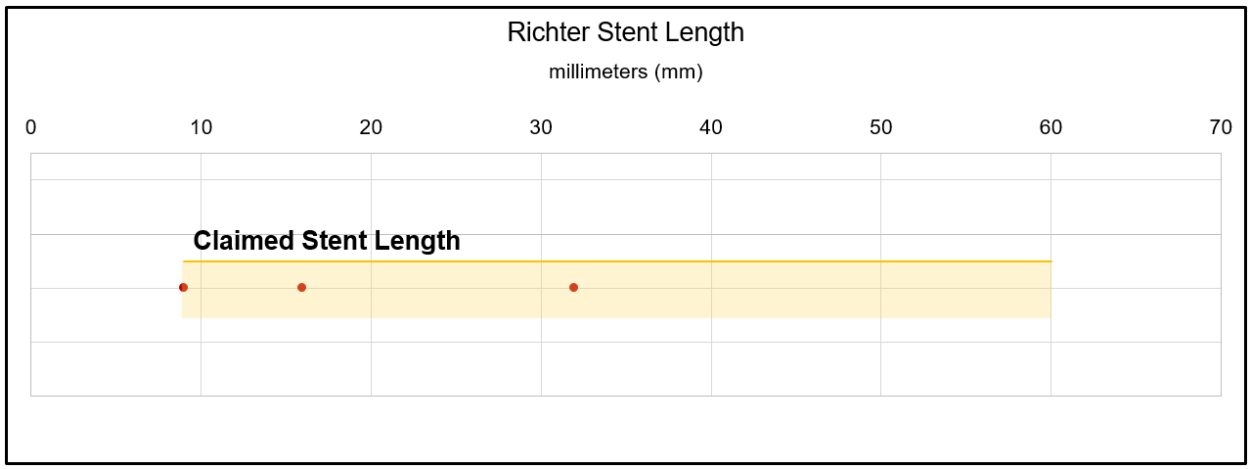
Below is a summary table of the claimed dimensional ranges compared with the corresponding dimensions disclosed by the Richter-Handbook in view of Richter-404, as identified above, followed by a graphical representation with the claimed dimensions shown in shaded boxes and the prior art dimensions disclosed by Richter-Handbook in view of Richter-404 as red dots.

| Claim | Dimension | | '035 patent (mm) | Richter-Handbook (mm) |
|---|---|---|---|---|
| 1 | vertical branch | width | 0.09-0.12 | 0.10 |
| | | thickness | 0.08-0.12 | 0.10 |
| | horizontal branch | width | 0.05-0.08 | 0.05-0.06* |
| | | thickness | 0.08-0.12 | 0.10 |
| 2 | branch unit length | vertical | 1.5-4.5 | 1.87-1.88 |
| | | horizontal | 1.0-3.0 | 1.03-1.04 |
| 3 | stent | diameter | 1.0-5.75 | 2.0-5.0 |
| | | length | 9.0-60 | 9, 16, and 32 |

* As modified by Richter-404.
Rao ¶ 156.


Richter Widths and Thicknesses
millimeters (mm)
0.04
0.05
0.06
0.07
0.08
0.09
0.1
0.11
0.12
0.13
Claimed Vertical Width
Claimed Vertical Thickness
Claimed Horizontal Width
Claimed Horizontal Thickness


Richter Unit Lengths and Stent Diameter
millimeters (mm)
0.5
1.5
2.5
3.5
4.5
5.5
6.5
Claimed Vertical Length
Claimed Horizontal Length
Claimed Stent Diameter




*Id*.

### B. Ground 2: Claims 1-3 Are Unpatentable over Fischell (Ex. 1012) in View of the Knowledge of a POSITA, Alone or in View of Penn (Ex. 1013)

#### 1. Overview

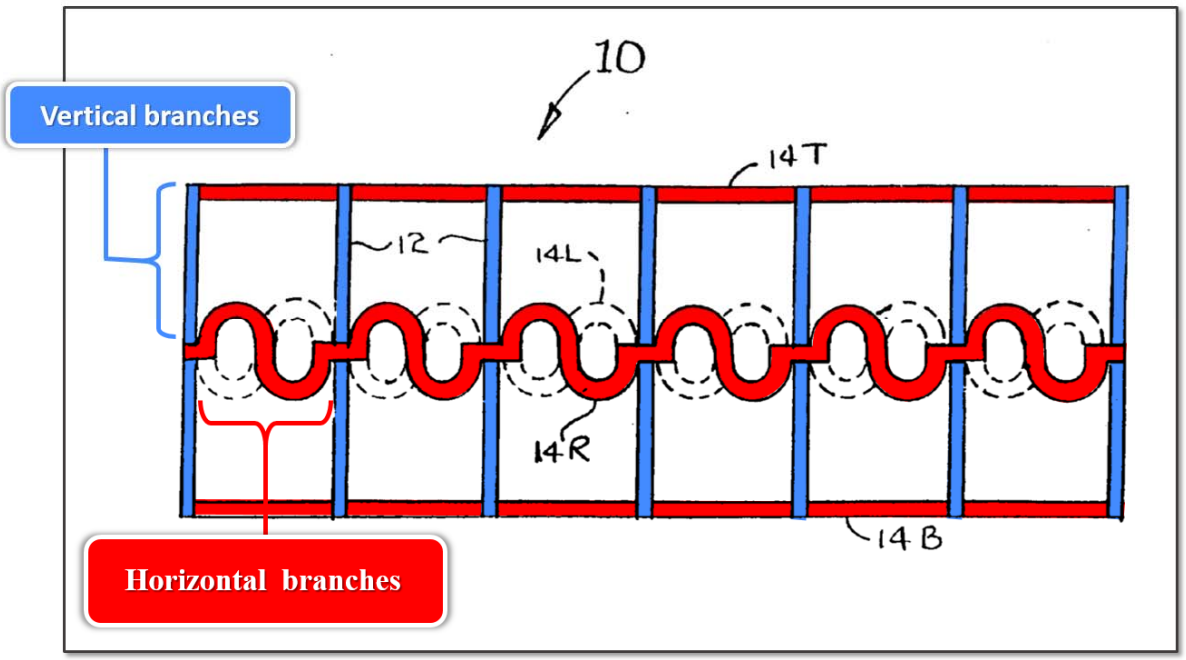
##### a. Fischell Discloses All the Claim Elements

Fischell is prior art under at least 35 U.S.C. § 102(b) because it was published on August 30, 1995, more than one year before the '035 patent's earliest claimed priority date and its actual filing date. The examiner did not consider Fischell (Ex. 1012) during prosecution of the '035 patent.[5]

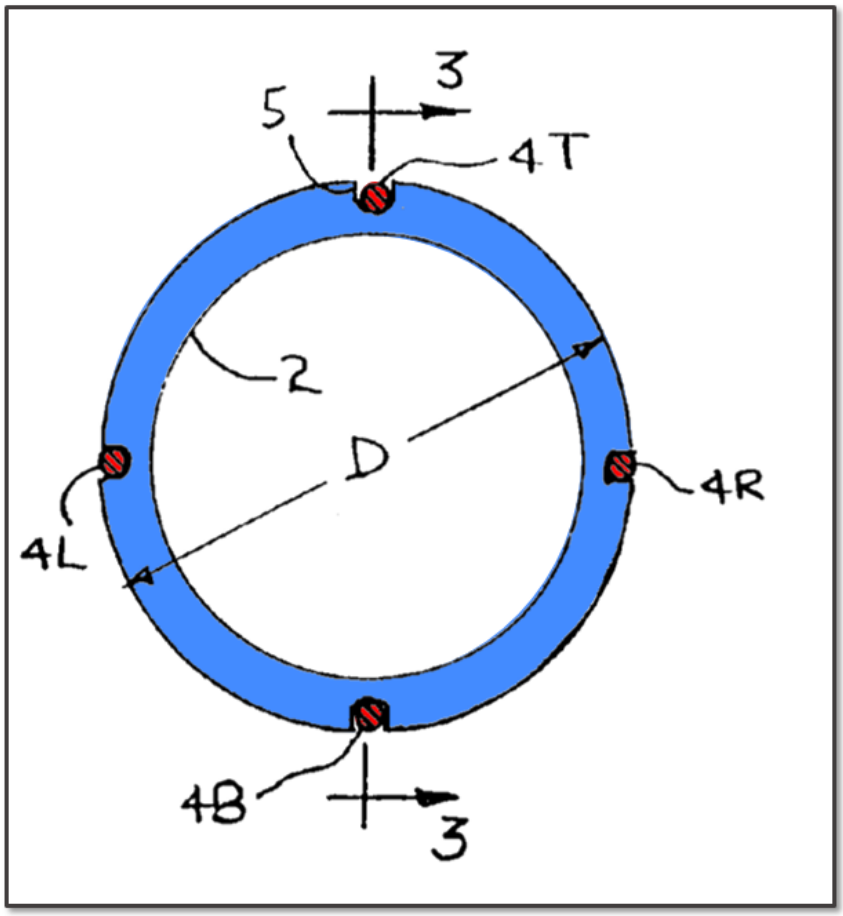
Fischell, like the '035 patent, is directed to a design for a ring-and-link

[5] As discussed in Section XI.A below, the examiner considered a different Fischell reference, the Fischell '442 patent, that did *not* disclose the claimed dimensional requirements.

"expandable stent that can be used in an artery" and specifically explains how the use of a waveform-projection allows the stent to be particularly useful in curved coronary arteries. Fischell, Abstract, 5:3-8. The stent structure when expanded includes a "multiplicity of closed, generally circular rings" (vertical branches) and a multiplicity of "undulating longitudinals," portions of which connect the rings longitudinally. *See id.*, Abstract, 1:34-43. These undulating longitudinals thus have "horizontal branches" having waveform-projections between the circular rings, as annotated in Figures 8 and 2 below, which show the expanded stent.




Fischell, Fig. 8 (annotated); Rao ¶ 158.




Fischell, Fig. 2 (annotated); Rao ¶ 158 (also explaining that the above figure is representative of a transverse cross section of Figure 8 at one of the rings).

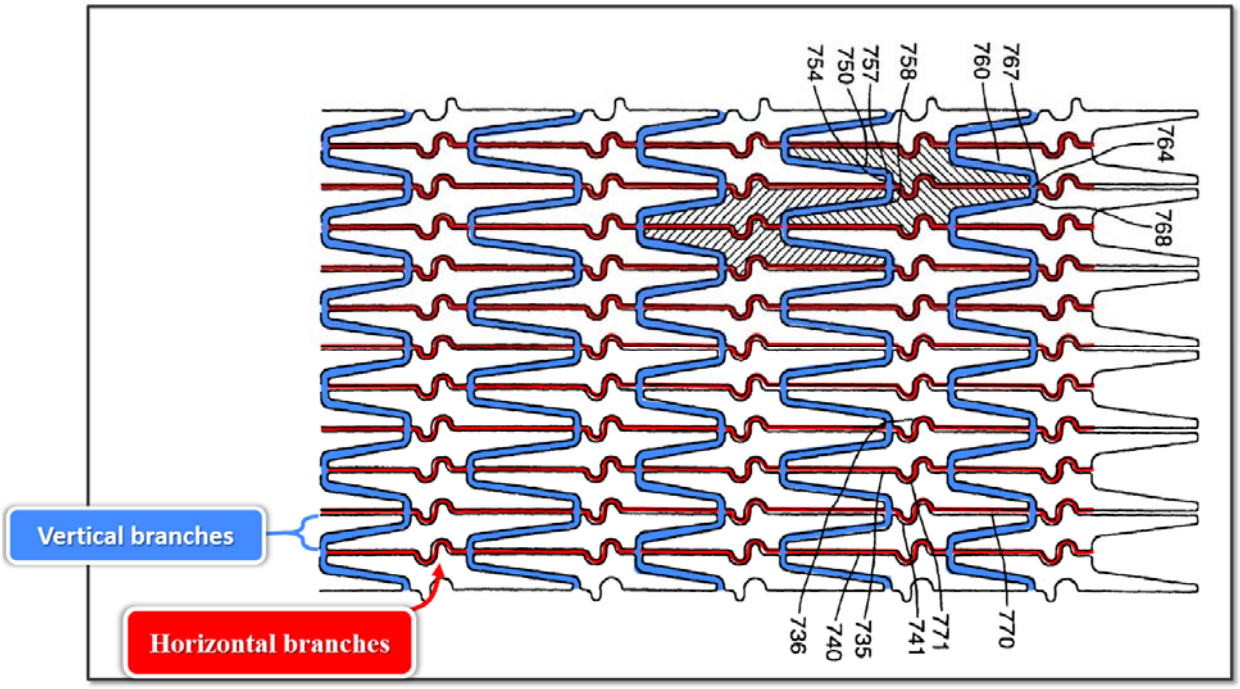
Fischell states that its stent having these undulating horizontal branches can be employed in "highly curved vessels such as some coronary arteries." Fischell, 2:41-44. Fischell also discloses dimensional ranges that overlap with the ranges claimed by the '035 patent, rendering claims 1-3 of the '035 patent prima facie obvious as discussed below. Rao ¶¶ 159-60. As with Ground 1, a table and graphical summary of the disclosed dimensions in Fischell compared with the claimed ranges are provided at the end of this ground.

**b. Penn (Ex. 1013)**

Penn is prior art under at least 35 U.S.C. § 102(a) because it was published in English on September 12, 1997, which is before the actual filing date of the '035 patent. Further, it is evidence of a POSITA's general knowledge around the time of the purported invention. Penn was not cited or considered during prosecution of the '035 patent.

As discussed with respect to limitation [1b] in Ground 1, there is no claim requirement that the horizontal branches comprise horizontal straight portions in addition to the waveform-projection, and it would be improper to read such a requirement into the claims from the preferred embodiments. Even if that were required, it would have been obvious in view of Penn.

Penn discloses the same concept of the '035 patent and Fischell: a ring-and-link stent with horizontal branches having waveform-projections (*e.g.*, Penn refers to horizontal branches having wave-form projections as "flexure means" and gives a rotated "S"-shape as one of many examples), and where the horizontal branches are narrower than the vertical branches. As shown in annotated Figure 8 below, Penn also discloses that the horizontal branches (red) can include straight portions as well.



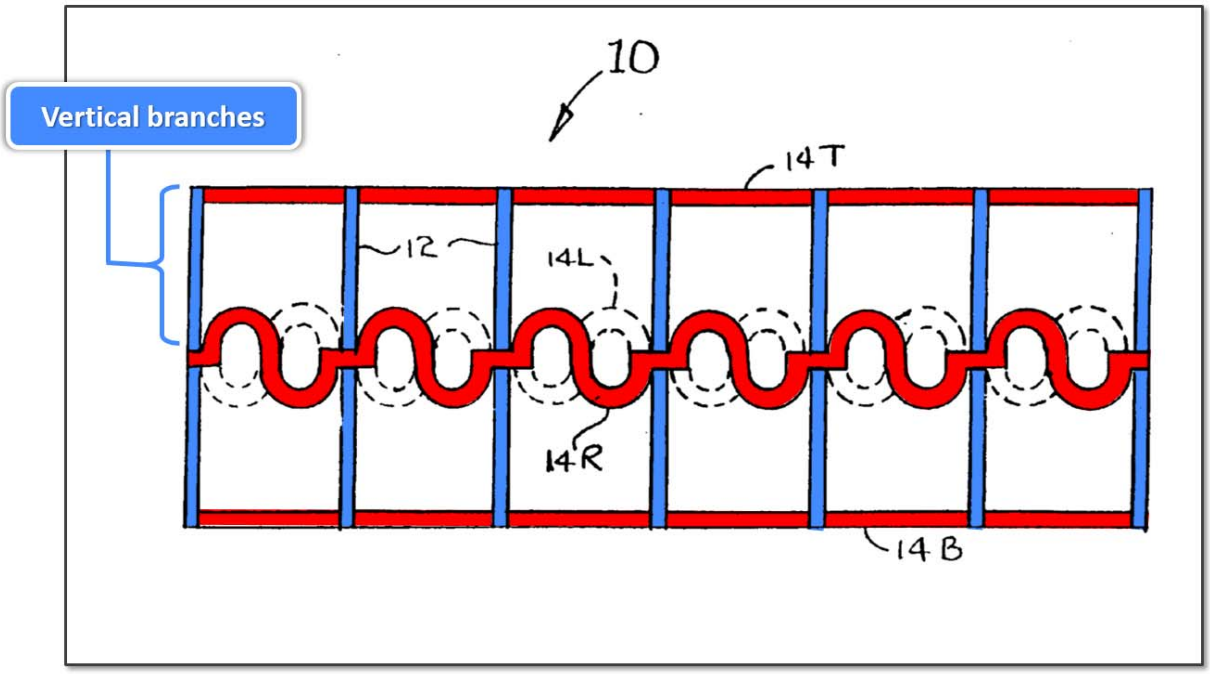

Penn, Fig. 8 (rotated and annotated), 17:7-14; *see also id.*, 14:19-28 (horizontal struts can be made narrower than vertical struts to improve flexibility), Figs. 3, 6, 7, 9; Rao ¶¶ 163-165.

Motivations to combine Fischell with Penn are provided below in connection with limitation [1b].

**2. Claim 1**

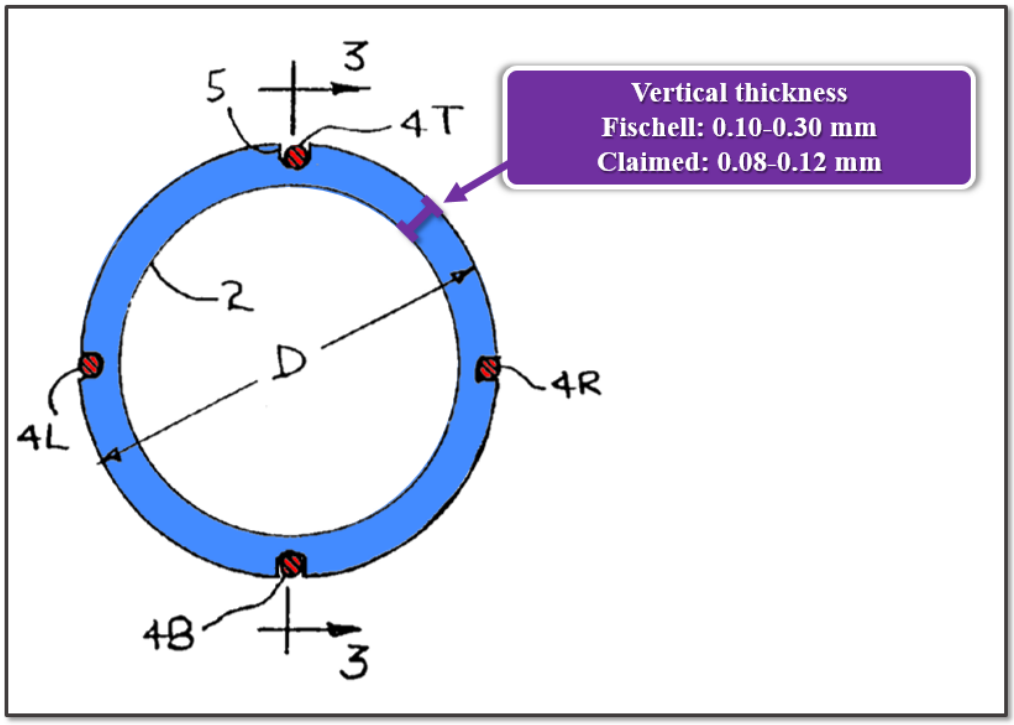
**a. [1a]—"A vascular stent which comprises vertical branches whose width and thickness range 0.09 to 0.12 mm and 0.08 to 0.12 mm, respectively."**

Fischell teaches "an expandable stent . . . used in an artery or any other vessel of the human body." Fischell, Abstract. The stent has circular "stent rings" that extend circumferentially around the stent and correspond to the claimed "vertical branches" as annotated in Figure 8 (showing the expanded stent) below.

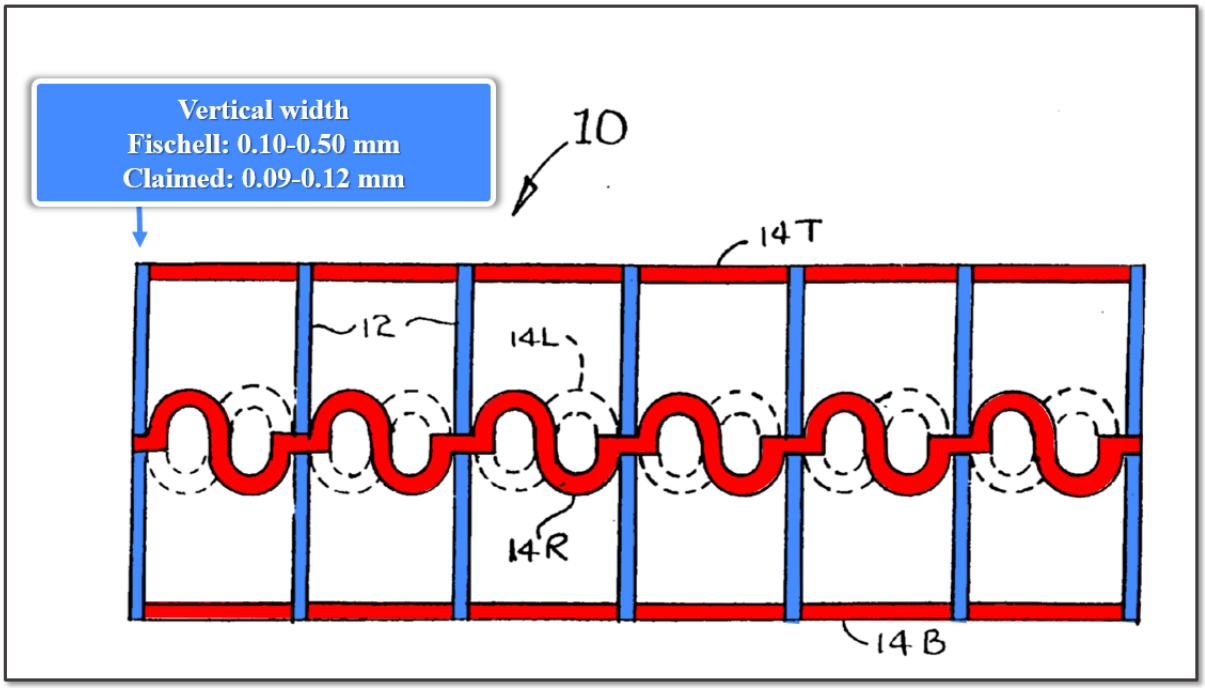



Fischell, Figure 8 (annotated), 3:40-44; Rao ¶ 166.

Fischell teaches that the "dimensions of stent rings are typically 0.1 to 0.3 mm thick, with a width of 0.1 to 0.5 mm." Fischell, 5:50-54. These dimensions overlap with the claimed dimensions as shown in annotated Figs. 2 and 8 below.

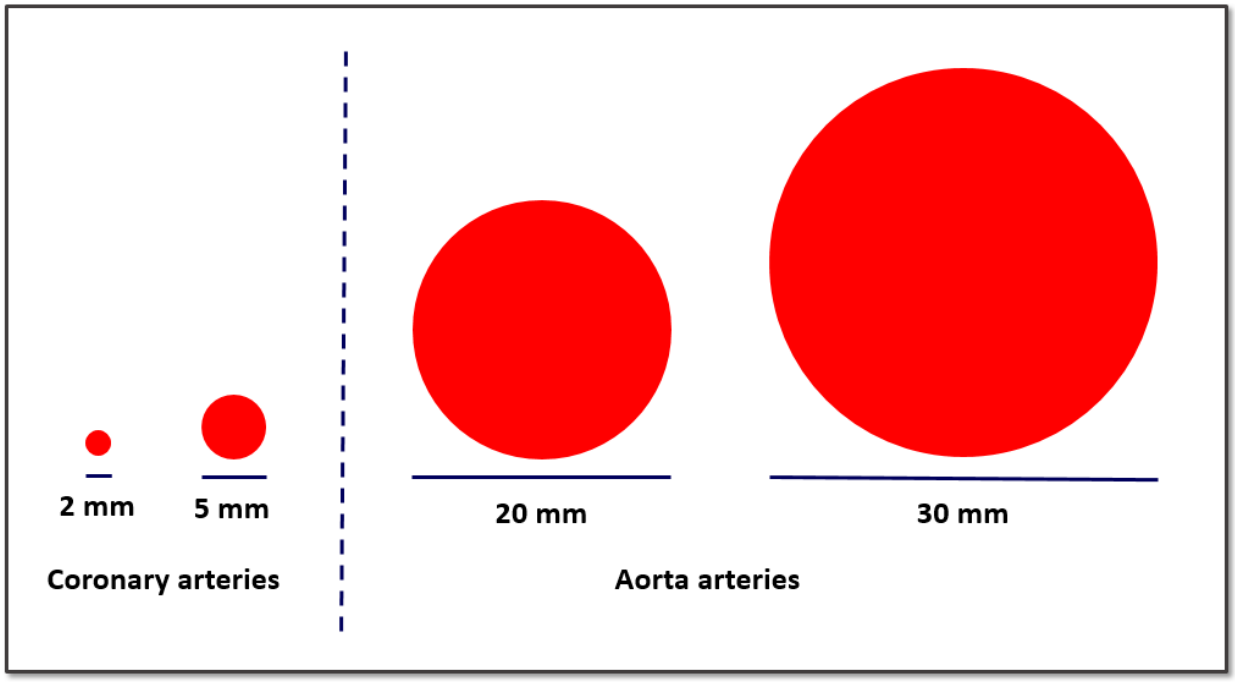



Fischell, Fig. 2 (annotated); Rao ¶ 167.




Fischell, Fig. 8 (annotated); Rao ¶¶ 168-169. This establishes prima facie obviousness. *In re Peterson*, 315 F.3d 1325, 1330.

Moreover, while Fischell's dimensions are broader than the claimed ranges, going from the disclosed ranges to the claimed ranges required nothing more than routine optimization. A POSITA would have understood that Fischell's dimensions (including branch widths and thicknesses) apply to a wide range of vessel sizes, based on the disclosed stent diameter range from 2 to 30 mm. Rao ¶¶ 170. For example, stent diameters at the low end of this range correspond to stents used in the coronary system (typically ranging from about 2-5 mm in diameter), whereas stent diameters at the high end would correspond to larger arteries like the aorta (20-30 mm or more in diameter); *see*, *e.g.*, Dinh, 8:4-13 (describing average vessel diameters); Dodge Paper (Ex. 1024), 237; Rao ¶¶ 170-171. A visual depiction of these different vessel diameters to scale with one another are shown below.



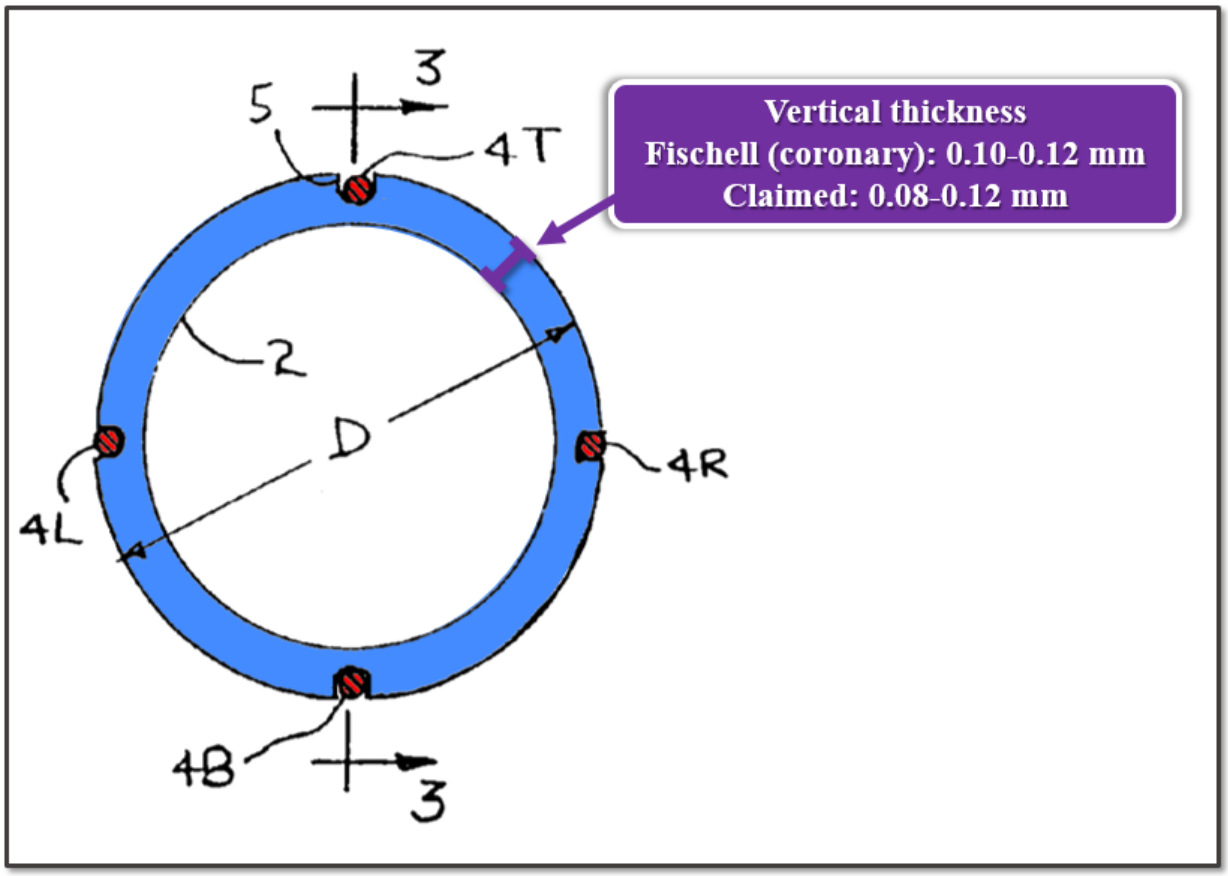
Rao ¶ 170.

A POSITA would have understood that the branch widths and thicknesses of a stent, used to open and hold open an artery like scaffolding, would be smaller for coronary arteries and larger for aorta arteries. *Id.* ¶ 171; *see also* Section V.B above (State of the Art).

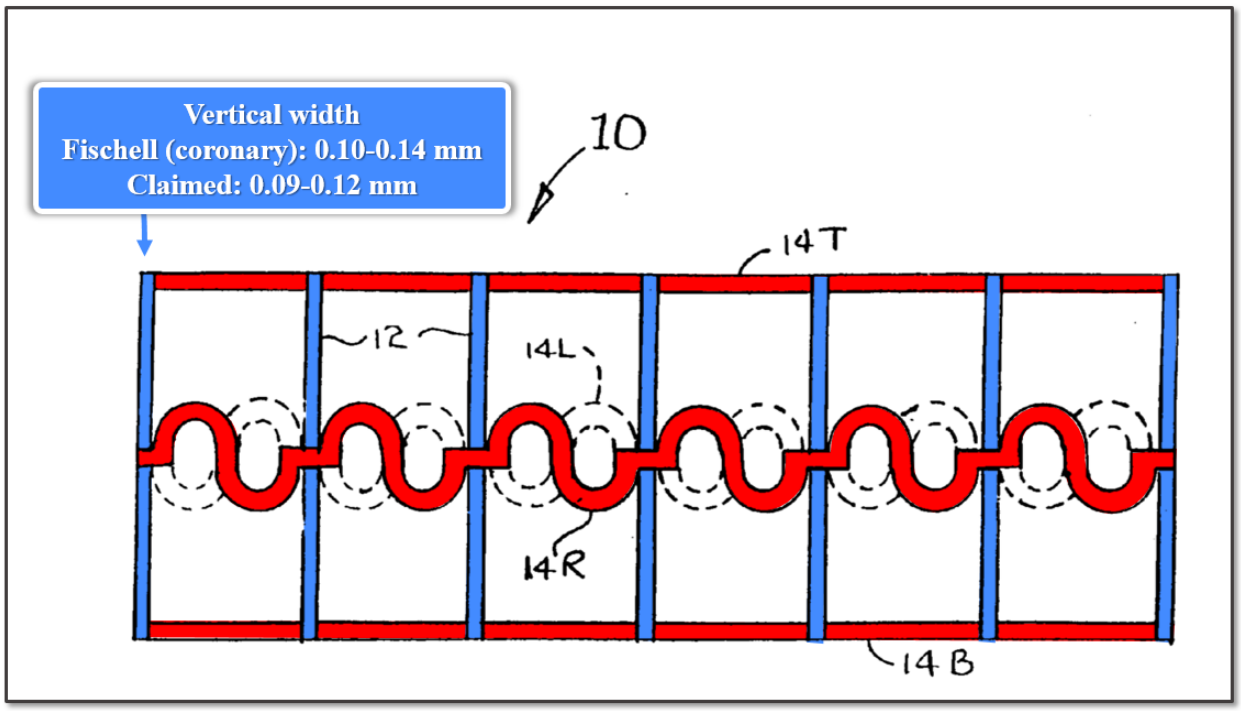
Further, Fischell expressly discloses that its stent design shown in Figure 8 above, with horizontal branches having waveform-projections ("undulating longitudinals"), was for coronary applications. Fischell, Abstract, 2:41-44, 5:3-8; Rao ¶ 172. A typical coronary stent diameter of 2-5 mm corresponds to approximately the lower 10.7% of the 2-30 mm range disclosed in Fischell for its stents. *Id.*

As a result, as of the '035 patent's priority date, a POSITA implementing a 2-5 mm stent for "highly curved vessels such as some coronary arteries" (Fischell, Abstract) would have started by looking to the bottom 10.7% of Fischell's ranges for widths and thicknesses with the understanding that they would correspond to those smaller diameter stent sizes. Rao ¶ 173. This is especially so here, where a POSITA would have first tried values at or close to the bottom end of those disclosed in Fischell, which correspond to the claimed ranges, to avoid adverse effects while still having sufficient strength and to avoid overly occluding the artery with the stent. Fischell, 1:19-23 (teaching that a POSITA would seek to minimize a stent's branch

size to minimize thrombosis, while also seeking sufficient hoop strength to resist elastic recoil); Rao ¶¶ 173-174. This corresponds to vertical branch thicknesses of approximately 0.10 to 0.12 mm (bottom 10.7% of 0.1-0.3 mm) and vertical branch widths of approximately 0.10 to 0.14 mm (bottom 10.7% of 0.1-0.5 mm), which almost entirely overlap with the claimed ranges as annotated in Figures 2 and 8 below.




Fischell, Fig. 2 (annotated); Rao ¶ 173.



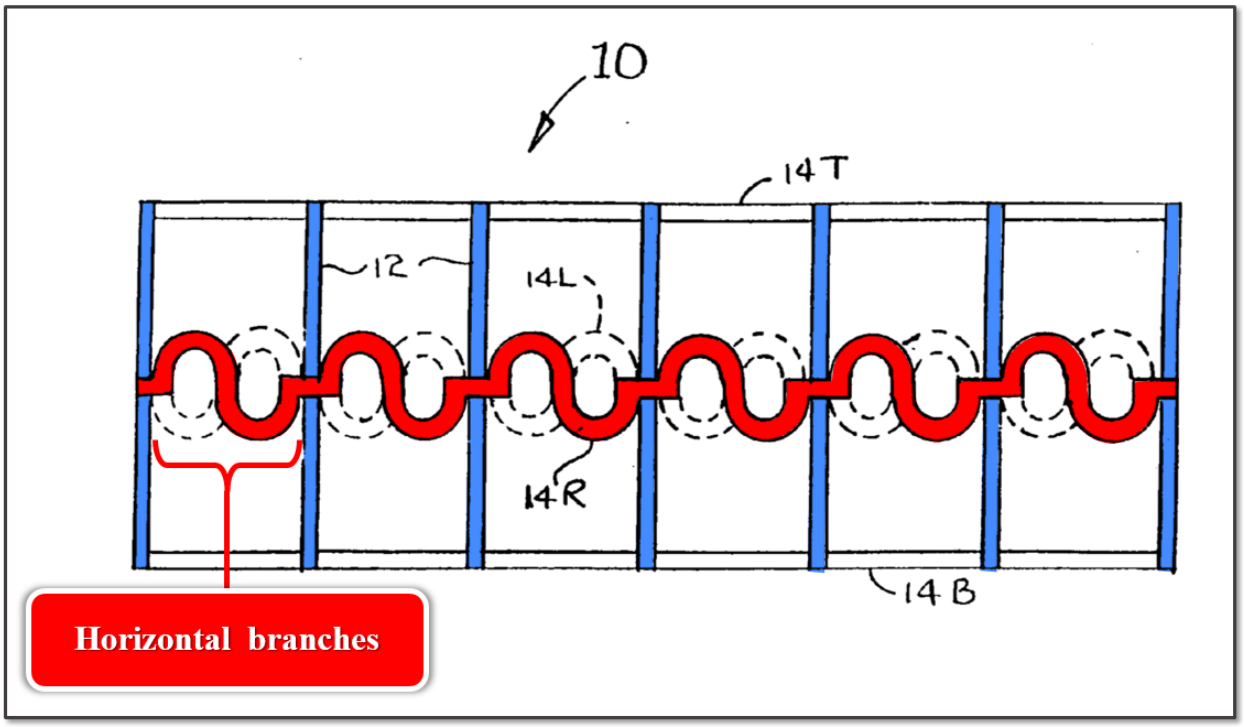

Fischell, Fig. 8 (annotated); Rao ¶ 173.

This nearly perfect overlap with the prior art presents a strong prima facie obviousness case. *E.I. DuPont*, 904 F.3d at 1006

**b. [1b]—"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."**

**Horizontal Branches Having Waveform-Projections:**

Fischell discloses that the stent rings (vertical branches) are linked by two or more "undulating longitudinals." Fischell, 4:57-5:4. Two of these longitudinals, one annotated red in Figure 8 below, comprise undulating portions (with a shape rising and falling in a wave, having a crest and a trough) and therefore disclose the claimed "horizontal branches having wave form projections."



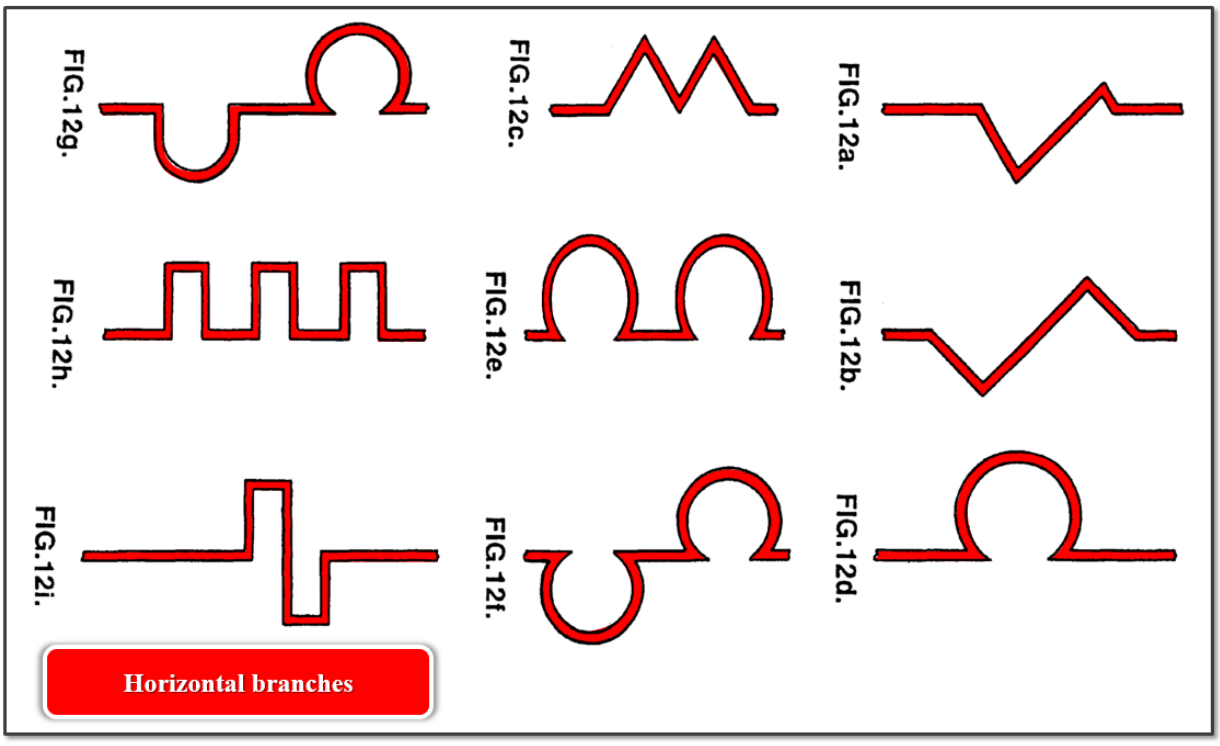

Fischell, Fig. 8 (annotated), 3:42-44, 4:57-5:4; Rao ¶ 175.

The two depicted undulating longitudinals, 14L and 14R, are more than enough to satisfy claim 1, which is an open-ended "comprising" claim. *See* Fischell, 5:3-4; Rao ¶ 176. Notably, Fischell's undulating structures have the same purpose as the waveforms in the '035 patent—*i.e.*, they help the stent "bend more easily during insertion into a vessel" so that it is "more readily adaptable for placement in curved vessels such as some coronary arteries." Fischell, 5:5-8; *see also* '035 patent, 2:24-27; Rao ¶ 177.

Furthermore, even if horizontal branches with both waveform-projections along with straight horizontal portions were required by the claims (they are not), that would have been obvious in view of Penn.

Penn discloses that for a ring-and-link stent, "[t]he specific shape of the

flexure means"—the '035 patent's waveform-projection—"is not particularly restricted provided that it confers lateral flexibility to the unexpanded stent," and that the flexibility/rigidity of the stent could be controlled by using waveforms of different shapes and/or sizes. Penn, 5:8-11, 18:12-19:9. For example, the horizontal branch can be comprised entirely of a waveform (*see id.*, Fig. 7), have alternating straight portions and waveform portions (*see id.*, Fig. 8 (annotated in the Penn Overview section above and incorporated here)), or could be substituted with any one or more of the alternative horizontal branches having waveform-projections in Penn's Figs. 12a-12i, annotated below.




Penn, Figs. 12a-12i (annotated), 17:25-18:11; Rao ¶¶ 178-180.

**c. Motivations to Combine Fischell and Penn**

As of the '035 patent priority date, a POSITA reading Fischell would have been motivated to combine its horizontal branches with Penn's horizontal branches (Penn, Figs. 8, 12a-12i). Penn explicitly provides such motivation—it teaches that horizontal branches having shapes rising and falling in waves (as in Fischell) are preferably combined with straight portions, and that such a modification improves the lateral flexibility of the stent and reduces foreshortening. Penn, 5:30-6:2 ("the sinusoidal or S-shaped section is adjacent the second apex of the polygon and the remaining portion of the strut is substantially straight. This feature improves the lateral flexibility of the stent thereby facilitating implantation thereof and may further mitigate longitudinal shortening of the stent upon expansion."), 15:29-16:7, Fig. 8. Penn also teaches that, like Fischell, its stent designs would be desirable for implantation in coronary arteries. *Id.*, 19:13-22. A POSITA would also have been motivated to utilize Penn's horizontal branches because the shape of the longitudinal can affect crimping onto a balloon, and Penn's designs would better "facilitat[e] implantation" of the stent in its crimped/unexpanded state. Penn, 5:32-6:2, Fig. 8; Rao ¶¶ 181-182.

Moreover, a POSITA would have read Penn with the benefit of knowing that (and how) Penn was actually implemented. Rao ¶¶ 183-184. Specifically, a POSITA would have also been aware that one embodiment of Penn's stent was

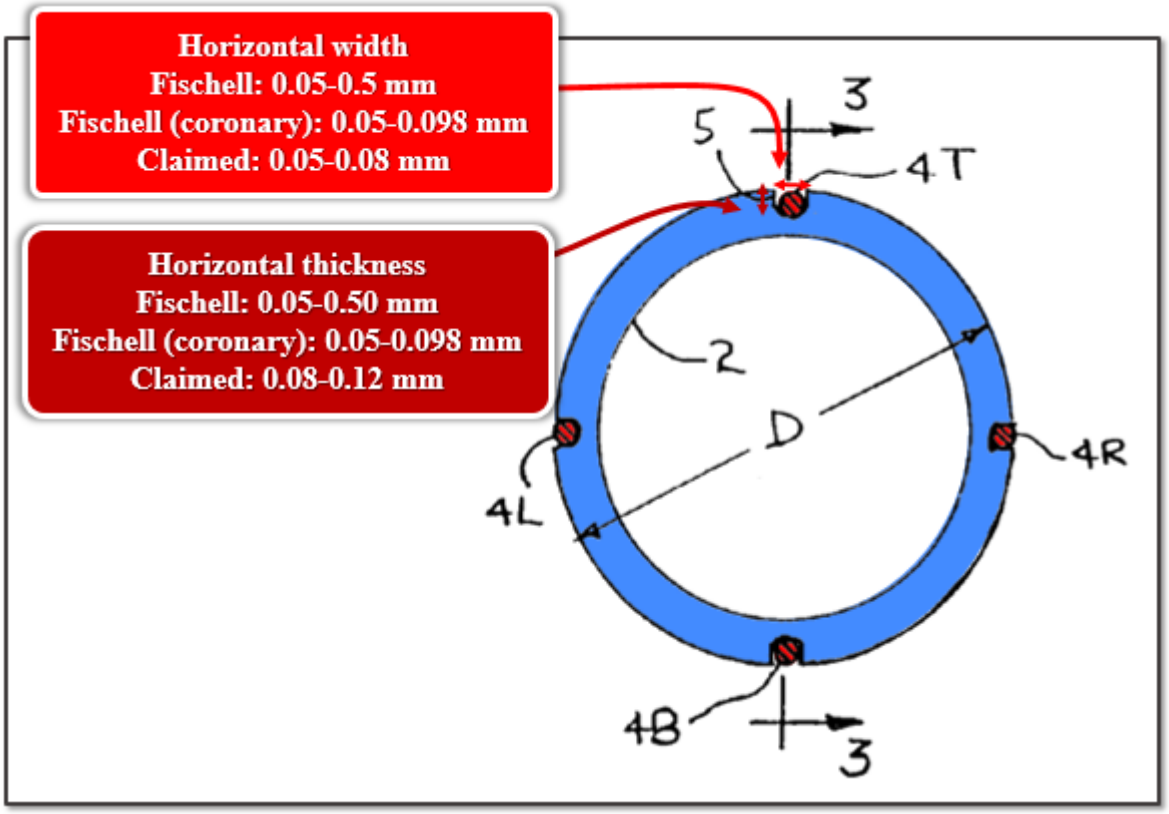
developed by the lead author/inventor's (Dr. Penn's) company, DivYsio Solutions Ltd., before the date of the alleged invention. *See* Handbook 2nd, 203-212; Hsieh-Yee Decl. (Ex. 1035) ¶¶ 66-103 (expert librarian declaration establishing authenticity and public availability of the Handbook 2nd). That coronary stent was designed with strut widths between 0.05 and 0.083 mm, strut thicknesses of 0.101 mm, expanded diameters of 3.0 to 4.0 mm, lengths of 15 and 28 mm, and either 6 or 12 circumferential cells. *Id.*, 204, Figs. 20.3(a)-(d); Rao ¶ 184. These dimensions fall within the ranges disclosed by Fischell, indicating that Penn's horizontal branches could have been used in Fischell's stent and with Fischell's disclosed dimensions with a reasonable expectation of success and without malfunctioning. Rao ¶ 185; Fischell, 5:50-54; Handbook 2nd, 204, Figs. 20.3(a)-(d).

In sum, a POSITA would have combined Fischell's undulating horizontal branches with Penn's horizontal branches having alternating sinusoidal waveform and straight portions, because (1) there were two obvious design choices for the shape of the horizontal branches (Fischell and Penn), which address the same problem (adding flexibility) in the same way (by adding a waveform-projection to the horizontal branches) but with or without straight horizontal portions as well; (2) the two references show the demand for designs that address the known desire to improve flexibility of a stent used for coronary applications; (3) Penn's horizontal

branches were a common and known design that could be used in Fischell's stent; and (4) the Fischell stent would have a reasonable expectation of success and would not malfunction if modified to use such a design. Rao ¶¶ 181-185, 104; Section V.B (State of the Art) above; *see Philips Lighting*, 727 F. App'x at 680-82, *citing* KSR, 550 U.S. at 416.

**Horizontal Branch Width and Thickness**

Fischell discloses horizontal branches that are narrower than the vertical branches. Specifically, the horizontal branches are formed as wires having a "diameter" (*i.e.*, both the thickness and width) that would "typically be between 0.05 and 0.5 mm." Fischell, 5:55-56; *Cf. id.*, 5:51-52 (vertical branches are at least 0.10 mm wide); Rao ¶ 186. Fischell's longitudinals with 0.08 mm diameter (*i.e.*, a thickness of 0.08 mm and a width of 0.08 mm) overlaps with the claimed ranges and establishes prima facie obviousness. *See In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997). That case is strengthened here, where a POSITA would have been motivated to look to the lower 10.7% of Fischell's wire diameters for coronary applications, 0.05-0.098 mm, and the overlap falls near the midpoint of that narrower range. Rao ¶¶ 187, 170-173; *see* limitation [1a] above (Fischell's horizontal branches having undulations (here, waveform-projections) were for coronary stents, with dimensions corresponding to the bottom 10.7% of Fischell's disclosed ranges).




Fischell, Fig. 2 (annotated); Rao ¶ 188.

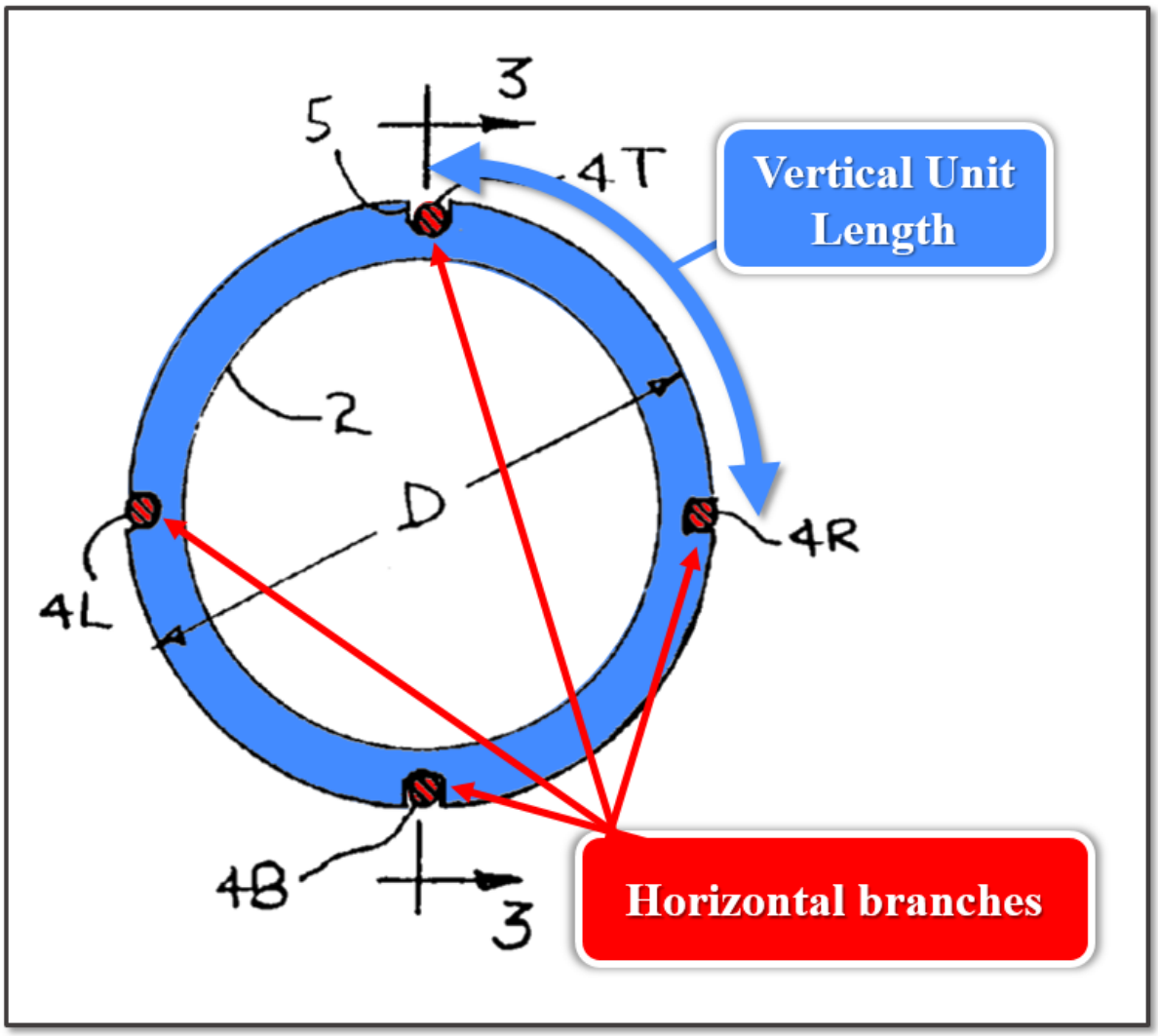
**3. Claim 2**

**a. "The vascular stent of claim 1, wherein unit lengths of the vertical branch and the horizontal branch range 1.5 to 4.5 mm and 1.0 to 3.0 mm, respectively."**

Fischell discloses examples of stents within the claimed ranges, but the unit lengths must be converted, or calculated, from the disclosed stent diameters, stent lengths, and number of rings and longitudinals. Rao ¶ 189; *REG Synthetic Fuels*, 841 F.3d at 958-61 (express disclosure despite need to convert values).

**Vertical Branch Unit Length**

Fischell discloses "a multiplicity of rings 2 which are spaced apart by four wires called longitudinals." Fischell, 3:42-44. This forms four "vertical branches," and four corresponding "vertical branch unit lengths," along the circumference of the stent as annotated in Figure 2 of Fischell below.

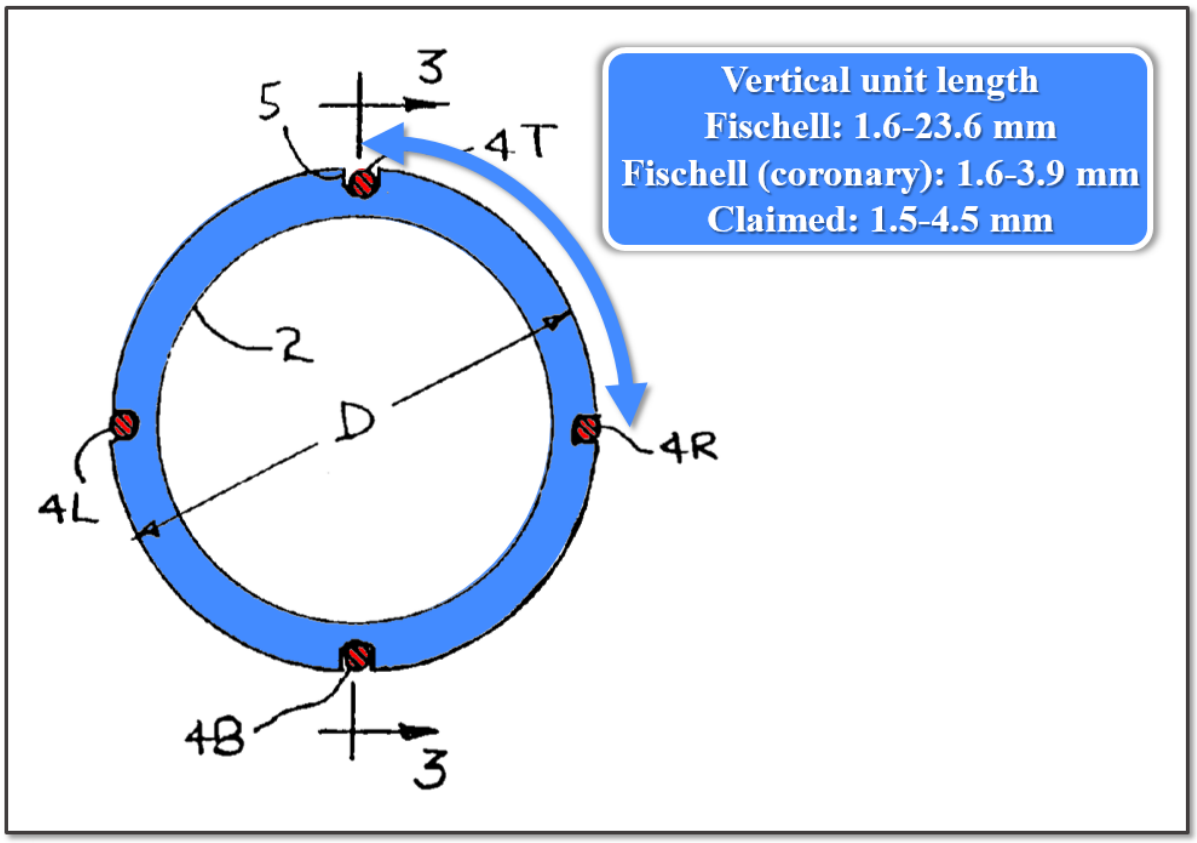



Fischell, Fig. 2 (annotated); *see also id.*, 3:11-3 ("Fig. 2 is a transverse cross section at section 2-2 of Fig. 1 illustrating how the longitudinals are joined to the rings."); Rao ¶ 190.

The "unit length" of each vertical branch—the center-to-center distance between two adjacent horizontal branches—is therefore equal to the circumference of the stent divided by four, the number of longitudinals (or in this case, horizontal branches). *Id.* ¶ 191. Fischell teaches the diameter is "between 2.0 and 30.0 mm," which corresponds to circumferences between 6.28 mm (2.0 mm * π) and 94.2 mm (30.0 mm * π). Fischell, 5:51-52; Rao ¶ 191. With four vertical branches, as disclosed by Fischell, the vertical branch unit lengths range from 1.6 mm (6.28 mm ÷ 4 longitudinals) and 23.6 mm (94.2 mm ÷ 4 longitudinals). *Id.*

Additionally, and for the same reasons explained with respect to Ground 1, a POSITA would have been motivated to select diameters from 2 to 5 mm in Fischell when designing a coronary stent because those diameters correspond to the typical healthy sizes of coronary arteries. *See* Section V.B.2 (State of the Art); Rao ¶ 192. Stents with diameters of 2 to 5 mm and four longitudinals would have vertical branch unit lengths between 1.6 and 3.9 mm. *Id.*

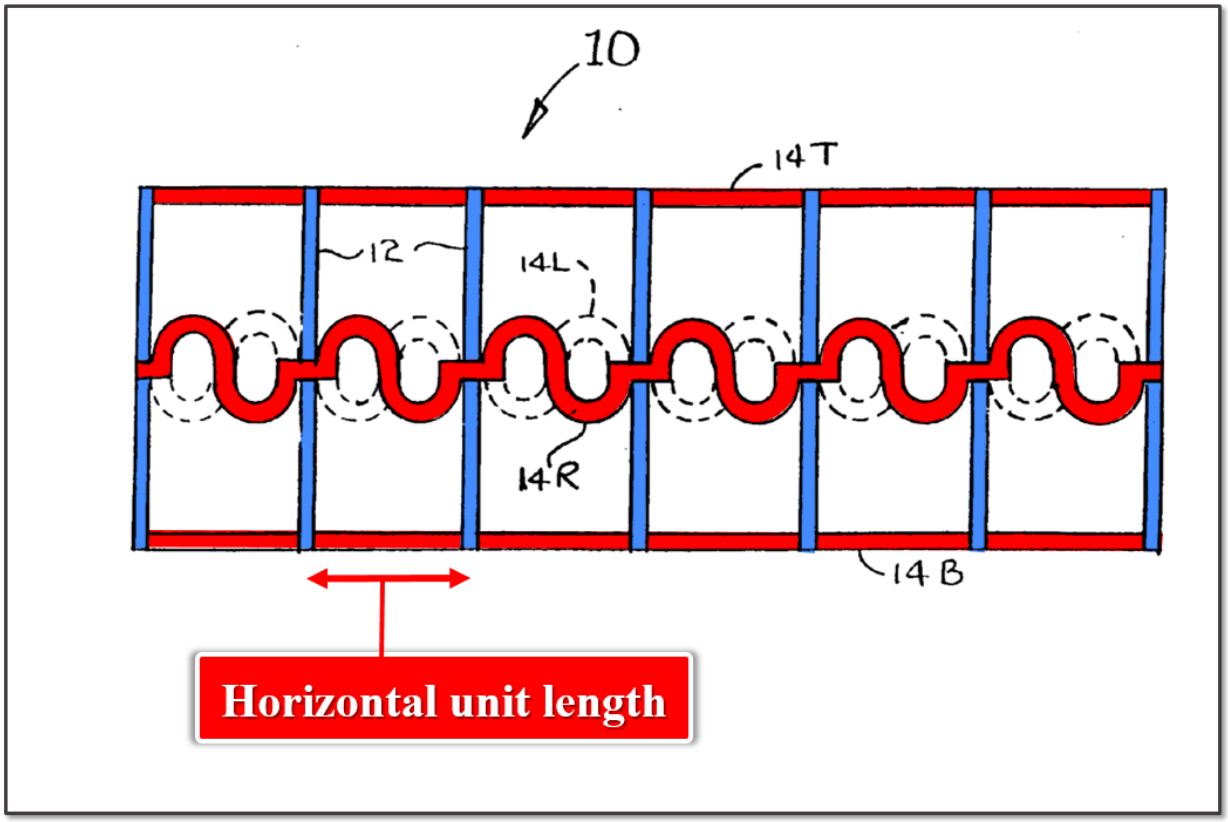
Thus as annotated in Figure 8 below, Fischell's vertical branch unit lengths determined from the disclosed diameter ranges overlap with and establish prima facie obviousness of the claimed ranges, and for a coronary stent would fall entirely within the claimed range in view of a POSITA's knowledge of known coronary artery diameters.




Fischell, Fig. 2 (annotated); Rao ¶ 193.

**Horizontal Branch Unit Length**

Fischell illustrates a stent having seven rings, corresponding to six horizontal branches, along the length of the stent as annotated in Fig. 8 below.



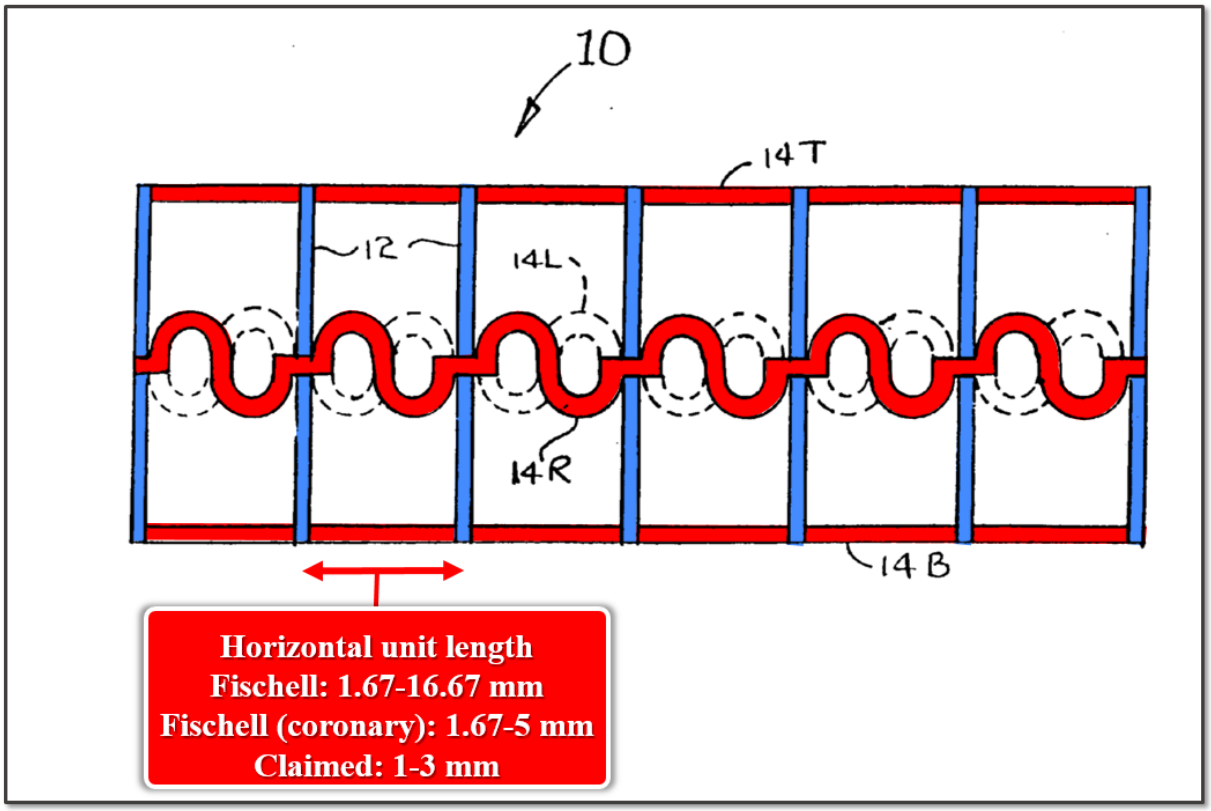

Fischell, Fig. 8 (annotated); *see id.*, 4:38; Rao ¶ 194. Thus, the horizontal branch unit length of Fischell's disclosed stent embodiment can be determined by dividing the stent length by six (the number of horizontal branches). *Id.*

Fischell teaches stent lengths between 1 cm and 10 cm. Fischell, 5:54-55. Therefore, the disclosed stent has a horizontal unit length ranging from 1.67 mm

(1 cm ÷ 6 branches) to 16.67 mm (10 cm ÷ 6 branches), which overlaps with and establishes prima facie obviousness of the claimed ranges.[6] Rao ¶ 195.

Furthermore, a POSITA designing Fischell's coronary stent would have looked to stent lengths ranging from 10 mm to 30 mm, as was also known to be typical for coronary applications. Myler, 6:10-17; Section V.B.2 above (State of the Art); Rao ¶ 196. As annotated in Figure 8 below, a coronary stent in Fischell with lengths 10 mm to 30 mm corresponds to horizontal unit lengths of 1.67 mm to 5 mm, which substantially overlaps with the claimed ranges.

[6] Fischell also discloses that the "stent can be made longer by adding rings or increasing the separation between rings." Fischell, 3:47-50. Likewise, the stent can be made shorter by reducing the number of rings or decreasing the spacing between rings. *Id.*, 3:50-52. Thus, Fischell teaches that horizontal branch unit lengths were known result-effective variables that could be routinely optimized to arrive at the claimed range. *See In re Applied Materials*, 692 F.3d at 1295; Rao ¶ 198.




Fischell, Fig. 8 (annotated); Rao ¶ 197.

**4. Claim 3**

**a. "The vascular stent of claim 1, wherein diameter and length of the stent range 1.0 to 5.75 mm and 9.0 to 60 mm, respectively."**

Fischell teaches the stent having a diameter "between 2.0 and 30.0 mm" and length "between 1 and 10 cm" (10-100 mm). Fischell, 5:50-55. These ranges overlap with the claimed ranges and establish prima facie obviousness of claim 3. The '035 patent admits there is no criticality of these ranges for diameter and length, which simply depend on "those of [sic] blood vessel in which the stent is inserted," which here were the well-known sizes for coronary stents. '035 patent, 2:45-49;

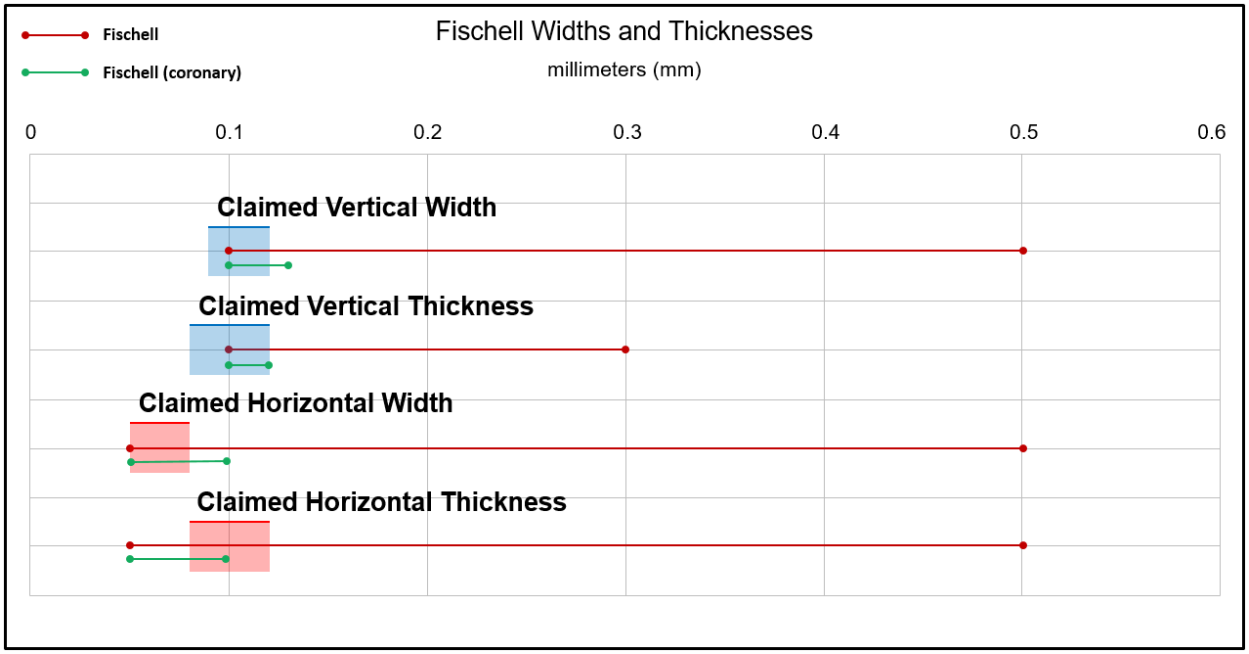
Section V.B.2 (State of the Art). Moreover, Fischell discloses that its stent having undulating longitudinals (horizontal branches having wave form projections) was designed for coronary applications. This would have motivated a POSITA to select diameters between 2-5 mm and lengths of 10-30 mm from Fischell's disclosed dimensions in view of the known anatomy of coronary arteries. *See* Rao ¶ 201; Fischell, Abstract, 2:41-44, 5:3-8; Section V.B.2 above (State of the Art).

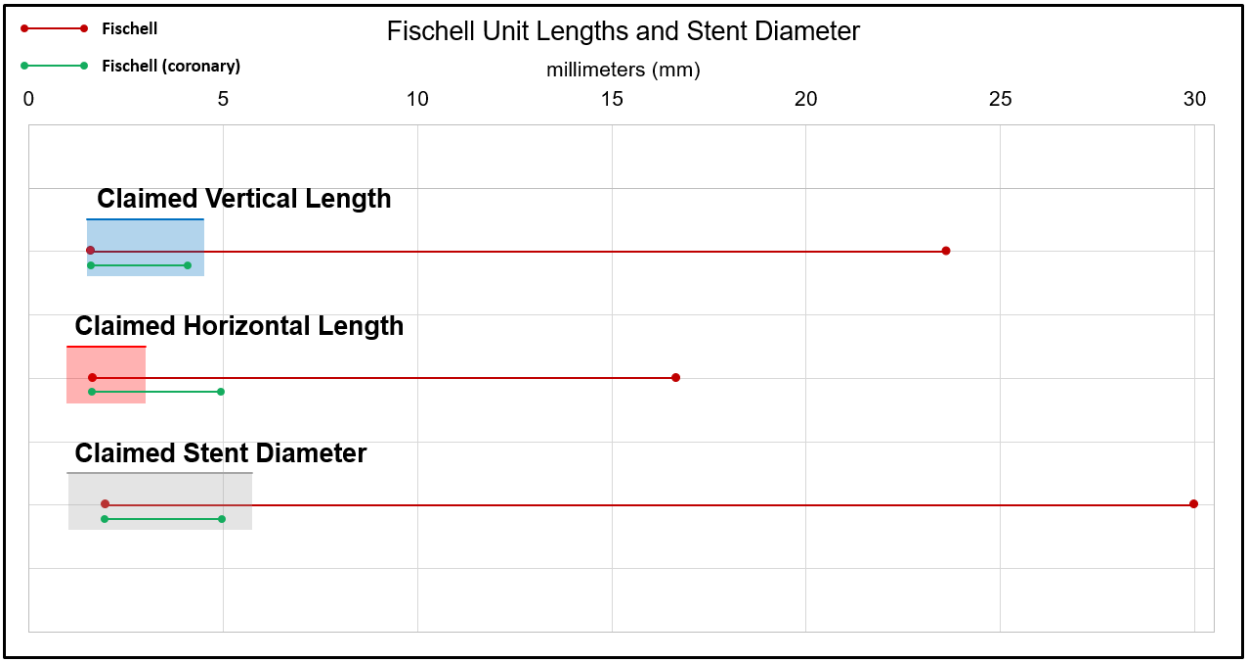
**5. Summary of Disclosed Dimensions**

Provided below is a table and graphs comparing Fischell's disclosed dimensions with the claimed ranges, as well as the dimensions a POSITA would have been motivated to try when designing a coronary stent in view of Fischell and the knowledge of common coronary stent dimensions (*e.g.*, diameter and length).

| **Claim** | **Dimension** | | **'035 patent (mm)** | **Fischell (mm)** | **Fischell (coronary) (mm)** |
|---|---|---|---|---|---|
| 1 | vertical branch | width | 0.09-0.12 | 0.1-0.5 | 0.1-0.14 |
| | | thickness | 0.08-0.12 | 0.1-0.3 | 0.1-0.12 |
| | horizontal branch | width | 0.05-0.08 | 0.05-0.5 | 0.05-0.098 |
| | | thickness | 0.08-0.12 | 0.05-0.5 | 0.05-0.098 |
| 2 | branch unit length | vertical | 1.5-4.5 | 1.6-23.6 | 1.6-3.954 |
| | | horizontal | 1.0-3.0 | 1.67-16.67 | 1.67-5 |
| 3 | stent | diameter | 1.0-5.75 | 2-30 | 2-5 |
| | | length | 9.0-60 | 10-100 | 10-30 |

Rao ¶ 202.


Fischell
Fischell (coronary)
Fischell Widths and Thicknesses
millimeters (mm)
0
0.1
0.2
0.3
0.4
0.5
0.6
Claimed Vertical Width
Claimed Vertical Thickness
Claimed Horizontal Width
Claimed Horizontal Thickness


Fischell
Fischell (coronary)
Fischell Unit Lengths and Stent Diameter
millimeters (mm)
0
5
10
15
20
25
30
Claimed Vertical Length
Claimed Horizontal Length
Claimed Stent Diameter


Rao ¶ 202.

## XI. THE EXAMINER ERRED IN GRANTING THE '035 PATENT BASED ON ALLEGEDLY UNEXPECTED RESULTS

During prosecution, the examiner rejected all claims as obvious over U.S. Patent No. 5,607,442 to Fischell ("'442 patent," which is not Ex. 1012, also by Fischell). '035 FH (Ex. 1004), 81. The examiner explained that the '442 patent taught vertical branches and horizontal branches having waveforms, but did not "specify widths and thickness of 0.09 to 0.12 mm and 0.08 to 0.12 mm . . . etc." *Id.* The examiner stated that those dimensions would be an "obvious matter of design choice" that involved "a mere change in the size of components" and properly rejected the claims. *Id.*

Instead of amending its claims, the applicant submitted a declaration from Dr. Jang (the inventor), discussed in the following section below, who declared that he performed experiments *in response to* the office action allegedly showing that the dimensional ranges in claim 1 had been "optimized." '035 FH, 88-89 (applicant's

remarks), 94-98 (inventor declaration). Notably, Dr. Jang did not describe the "optimized" results as "unexpected," and, as explained below, they were not. *See id.*, 94-98.

Relying solely on Dr. Jang's declaration, the prosecuting attorney nevertheless argued to the examiner that "the thickness and width of branches of the claimed vascular stent are optimized to provide ***unexpectedly*** high efficiency of stenting," and the claims were "patentable over the art of record in that the cited references do not teach the width and thickness ranges for the vertical and horizontal branches which are recited in the present claims." *Id.*, 89.

That the patent prosecutor declared that results were "unexpected" should have been unimportant to the examiner, as it is merely attorney/patent agent argument with no appropriate and supporting evidence such as a well-reasoned and credible POSITA declaration with supporting evidence from a respected source. *See In re Geisler*, 116 F.3d at 1470. The examiner erred in allowing the claims. The examiner stated that "[applicant's] response and attached declaration (dated 3/27/00) have been carefully reviewed by the examiner," without explanation. '035 FH, 100. Had the examiner actually carefully reviewed the proffered declaration and applied the correct law, the examiner would have found that the declarant described, at best, routine optimization and that the attorney's characterization of the declaration was unsupported—the declarant never claimed the results were unexpected. Further, the

purported experiments were not commensurate with the scope of the claims and the results obtained were not unexpected, but already known in the art. Rao ¶¶ 205-208.

As a result, the examiner arrived at his erroneous fact-finding without any reasoned basis, and without the benefit of the new art, argument, documentary evidence, and expert testimony presented herein.[7] Accordingly, the Board should reach the merits of this Petition.

### A. The Examiner Erred in Allowing the '035 Patent Based on Unexpected Results

The inventor's declaration submitted during prosecution does not establish unexpected results and cannot rebut the obviousness case presented by this Petition: (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 the inventor had been found in the prior art and were not unexpected.

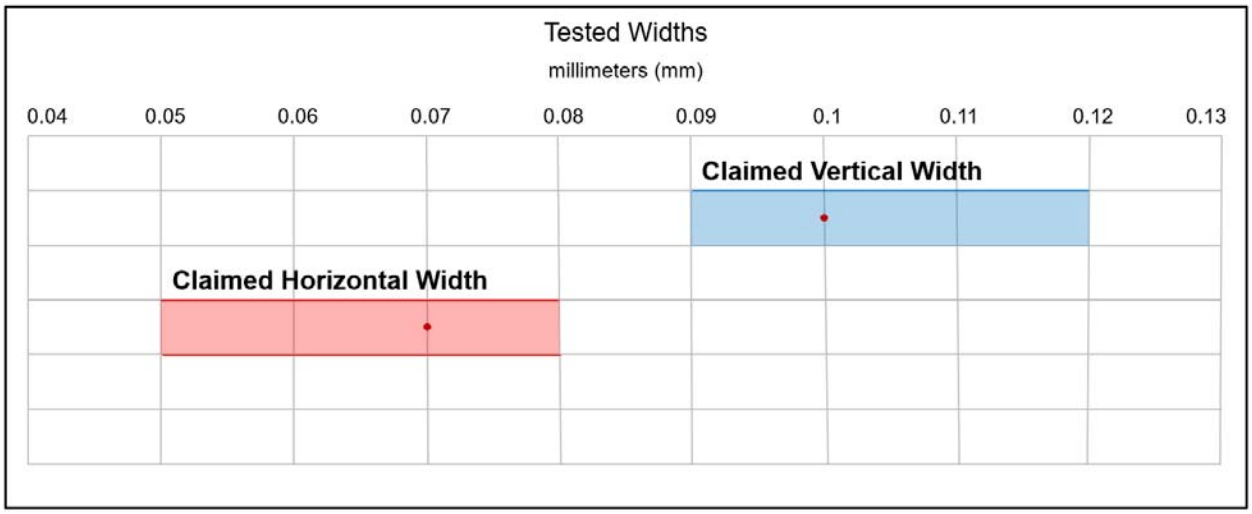
[7] The examiner appears to have performed only a single search for prior art, using the search string "stent same horizontal same vertical," which resulted in 16 hits. '035 FH, 7.

### 1. Dr. Jang's Experiments Were Not Commensurate with the Scope of the Claims

To show unexpected results for a claimed range, the objective evidence provided must be "commensurate in scope with the degree of protection sought by the claimed subject matter[.]" *In re Harris*, 409 F.3d at 1344; *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983) (internal citations omitted). In *In re Harris*, the applicant sought to overcome an obviousness rejection of claims to a nickel-based super-alloy that included twelve elements defined by a range of weight percentages. 409 F.3d at 1340. The applicant submitted experimental evidence comparing "an alloy centrally located within claim 1's range, to four commercial alloys" that were each prior art. *Id.* at 1343. When compared to the prior art alloys, the claimed alloy showed "32% to 43% improvement in stress rupture life[,]" which Harris claimed showed unexpected results. *Id.* at 1344. But because the experiments were directed to an elemental composition that was "at or near the midpoint of the claimed range," the record did not show that any "improved performance would result if the weight-percentages were varied within the claimed ranges." *Id.* So, even if "the results were unexpected" the evidence could not rebut prima facie obviousness because it did not "cover[] the scope of the claimed range." *Id.* Here, the same scope problem infects the purported evidence in Dr. Jang's declaration. *See* Rao ¶¶ 228-240.

For example, in experiment 1 ("Thickness of branches of stent"), Dr. Jang purports to have investigated the effect of thickness on stent efficiency only for stents

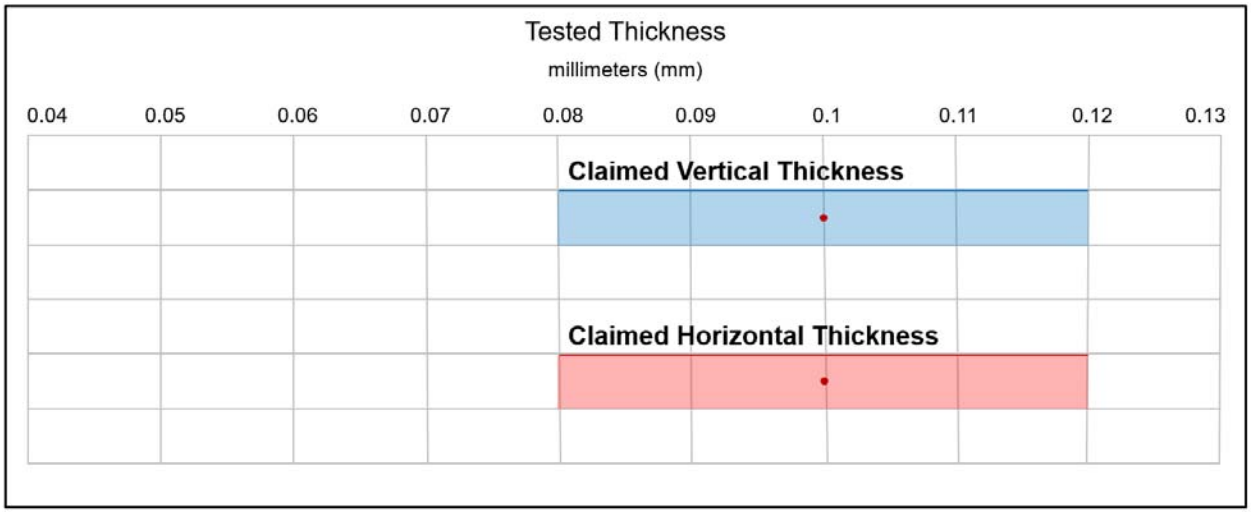
having 0.10 mm-wide vertical branches and 0.07 mm-wide horizontal branches. '035 FH, 94-95. The claims of the '035 patent, however, are broader than these specific widths as shown in the plot below, with the tested widths shown as red dots and the claimed ranges as shaded regions:




Rao ¶ 229. Testing only a portion of a claimed range—let alone a ***single*** value—cannot establish unexpected results for the entire range. *See In re Peterson*, 315 F.3d at 1331 (finding data at 0% to 2% rhenium insufficient to show unexpected results for claimed range of 1% to 3% rhenium).

Dr. Jang's experiment 2 ("Widths of branches of stent") is also insufficient. *First*, Dr. Jang identifies an alleged clinical trial comparing two stents, "a stent whose thickness of branches are 0.1 mm and widths of horizontal and vertical branches are 0.1 mm, respectively; and, a stent whose thickness of branches are 0.1 mm and widths of horizontal and vertical branches are 0.07 mm and 0.1 mm,

respectively." '035 FH, 95-96. Fixing the thickness of the branches at 0.1 mm, is not commensurate with the claimed 0.08-0.12 mm thickness ranges for each of the horizontal and vertical branches as shown in the plot below.




*Compare id. with* '035 patent, claim 1; Rao ¶ 230. Likewise, widths of 0.07 mm and 0.1 mm for the horizontal and vertical branches are not commensurate in scope with the claimed ranges of 0.05 to 0.08 mm and 0.09 to 0.12 mm respectively. *Compare* '035 FH, 96, *with* '035 patent, claim 1.

*Second*, Dr. Jang asserts that in experiment 2 he tested different widths of the branches (holding the thicknesses at a constant 0.1 mm), and the results allegedly showed a lower percentage of "recoiling" within the claimed ranges. *Id*. But he ***admits*** that the better recoiling results were not for the entire claimed range. Instead, the recoiling was lower "***provided that***"—only if—"the widths of horizontal and vertical branches ***are 0.07 mm and 0.10 mm***, respectively." *Id*. Put simply, Dr. Jang's experiment 2 showed lower recoiling percentages ***only*** for (1) a single point

of the claimed horizontal branch width range, and (2) a single point of the claimed vertical branch width range. *See id.*; Rao ¶¶ 230-231.

Consequently, Dr. Jang's experiments cannot establish unexpected results commensurate with the scope of the claims. Simply showing there may have been an improvement for a stent that falls near the midpoint of the claimed ranges "does not show that the improved performance would result if the [stent dimensions] were varied within the claimed ranges." *In re Harris*, 409 F.3d at 1344.

Besides failure to establish unexpected results across the claimed ranges, Dr. Jang's declaration is lacking in several other ways. *First*, the claims require "horizontal branches having wave form projections." '035 patent, claim 1. Dr. Jang's declaration does not disclose the shape or size of the stents he purportedly tested in ***any*** of his experiments or if they had waveforms. A POSITA understood that stent geometry and stent diameter had a significant impact on the stent's mechanical properties. Rao ¶ 233.

*Second*, Dr. Jang did not disclose the material of the stents he tested, nor did he disclose how that material was processed, *e.g.*, its heat treatment. And a POSITA would have understood that the choice of material and its heat treatment dramatically affects the stent's mechanical properties, including recoil. Rao ¶ 234. One can only assume from Dr. Jang's declaration that he tested a single material and heat treatment, neither of which are disclosed. *Id.* But the claims are not so limited, and

could cover stents made from a variety of common stent materials, such as steel, Nitinol, or Cobalt Chromium. *See* '035 patent, claim 1. For this reason as well, the testing is "not commensurate in scope" with the claims and cannot rebut a prima facie obviousness case. Nor does Dr. Jang's declaration provide the "fundamental requirement" that the unexpected results have a "nexus between the evidence and the merits of the *claimed invention*." *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (internal citation and quotation omitted).

Finally, any unexpected results must be supported by factual, not speculative, evidence. *See In re Geisler*, 116 F.3d at 1470. Dr. Jang not only failed to describe sufficiently the stent(s) he actually used, he also did not disclose with sufficient specificity what tests he actually performed or the results of those tests. Rao ¶¶ 236-237. Dr. Jang simply provided summary tables that purportedly supported the benefits of the claimed ranges, without providing comprehensive results that could be used to test the veracity of his claimed optimizations. *See* '035 FH, 2, 3 (Table 1 and 2 from inventor declaration). This conclusory evidence cannot demonstrate unexpected results. *In re Inland Steel Co.*, 265 F.3d 1354, 1365-66 (Fed. Cir. 2001) (affirming Board's determination of no unexpected results, where the patentee "offered only a few data points from one experiment" and "did not offer comprehensive test results"); Rao ¶¶ 238-240.

### 2. The Width and Thickness of Horizontal and Vertical Branches Were Known Result-Effective Variables

Dr. Jang's declaration also cannot establish unexpected results because the dimensional variables he tested, the width and thickness of vascular stent components, were already known to be result-effective variables. *In re Applied Materials*, 692 F.3d at 1295 (When dimensional variables are known in the art to be "result-effective," then the mere optimization of those variables will be "within the grasp of one of ordinary skill in the art" and do not show unexpected results); Rao ¶¶76-77, 81, 87-88, 210-212. Variables are "result-effective" if there is any "recognition in the prior art that a property is affected by the variable[]" *See E.I. DuPont*, 904 F.3d at 1006 (quotations omitted). If it is known that a dimensional variable is result-effective, "it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Geisler*, 116 F.3d at 1470 (citations omitted). For example, in *In re Harris*, the patentee submitted evidence that an alloy falling within its claimed ranges showed a "32 to 43% improvement in stress rupture life" when compared with commercial prior art alloys. 409 F.3d at 1343-44. This improvement did "not represent a 'difference in kind' that is required to show unexpected results" because the prior art taught that limiting the claimed percentages would improve factors relating to the stress-rupture life. *See id.* at 1344; *see also Galderma*, 737 F.3d at 739.

Here, Dr. Jang's experiments identify purported results of routine changes of the thickness and width of the horizontal and vertical branches to determine sizes that improved efficiency, as determined as a percentage of recoiling. '035 FH, 95-97; Rao ¶¶ 210-227 (also explaining importance of recoil). But the prior art was replete with disclosures that the recoil percentage, risk of thrombosis, and flexibility of a stent were directly affected by the width and thicknesses of the stent components. *See*, *e.g.*, Richter-794 (Ex. 1016), 2:7-14; Ogi (Ex. 1019), 5:36-44; Fischell (Ex. 1012), 1:19-23, 5:50-54; Section V.B above (State of the Art); Rao ¶¶ 81, 88, 174, 218-220.

And Dr. Jang discusses an alleged "clinical trial" that compared two stents with different dimensions, finding that a stent falling near the midpoint of the claimed ranges had a slightly lower percentage of restenosis compared with another stent with a horizontal branch width outside of the claimed dimensions. '035 FH, 96. However, it was already known that the ability to prevent restenosis was directly affected by the "radial strength of the stent," which is "in part a of [sic] function of the material from which it is formed and the design and configuration of the stent." Dinh, 8:40-45. Richter-404 disclosed that modifying the widths of a stent's horizontal branches can help reduce "flare outs" at the ends of the stent, where flare outs can cause injury to the vessel. Richter-404 (Ex. 1010), 2:3-42, 6:65-7:19 (disclosing that a stent with narrower horizontal branches at its ends makes the ends

softer and reduces trauma to the vessel when compared with conventional stents). Similarly, Ogi disclosed that a stent with more flexibility "results in better hemodynamics through the stent when implanted, thereby reducing the risk of thrombosis." Ogi, 7:3-14. Thus, because the prior art already recognized the effects of the width and thicknesses of the branches of a stent on recoil and restenosis, any alleged improvements found by Dr. Jang did "not represent a 'difference in kind' that is required to show unexpected results." *In re Harris*, 409 F.3d at 1343-44 (internal citation omitted).

Finally, while Dr. Jang independently tested each variable claimed (width and thickness of the vertical and horizontal branches respectively), he never tested or produced results for the interaction between those combined sets of variables. Across his experiments, Dr. Jang simply varied one variable while holding the others constant and reported the results. *See* '035 FH, 95-96; Rao ¶ 232. That is not enough to show that the interaction of the variables was unexpected. *In re Applied Materials*, 692 F.3d at 1298 (to show unexpected results of multiple result-effective variables, a patentee needs to show something "unpredictable or unexpected ***in the interaction of the variables***[]" as claimed).

### 3. The Predictable Results Reported by Dr. Jang Had Already Been Found in the Prior Art

The results reported by Dr. Jang were already found in the prior art. As shown in the Richter-Handbook, the "NIR Stent"—the subject of Ground 1 in this

Petition—showed a recoil of <1%, which is ***better than*** what the applicant relied on for the allegedly "optimized" stent in the three experiments. *C.f.* Richter-Handbook (Ex. 1008), 137; '035 FH, 89, 95-97. Likewise, Dinh describes ***the same experiments*** (testing elastic recoil of stents falling within the claimed dimensional ranges) and achieving ***the same results*** (less than 2 percent elastic recoil) as reported by Dr. Jang. Rao ¶¶ 223-225; *see* Dinh, 8:13-27 (elastic recoil testing), 6:25-28 (dimensions), Fig. 5A (exemplary unit cell with dimensions). And the Handbook reports several other stents with wall thicknesses and widths that fell within the claimed ranges, and had minimal recoiling. Rao ¶¶ 226. In other words, Dr. Jang's tests were merely ***consistent with*** what was known in the prior art, not unexpected or novel.

Thus, the examiner erred in granting the '035 patent based on unexpected results, and no showing of unexpected results can overcome the obviousness of the claims. Other than the alleged unexpected results addressed above, there are no other secondary considerations known to Petitioner or alleged by Patent Owner. Should Patent Owner proffer any other evidence of secondary considerations in its Preliminary Response, that evidence should not be considered for institution purposes, or Petitioner should be given leave to file a reply with rebuttal evidence. *See Garmin International, Inc. v. Wisconsin Archery Products, LLC*, IPR2018-01137 (Paper 11) at 29. If Patent Owner cites the commercial success of Petitioner's

products accused of infringement, Petitioner disputes that (1) its products practice the claims of the '035 patent and (2) any nexus exists between the commercial success of Petitioner's products and the claimed inventions of the '035 patent, and should be permitted a reply to rebut such allegations.

### B. The Office Should Exercise Its Discretion Under 35 U.S.C. § 325(d) to Institute the Grounds in This Petition

The Board enunciated six non-exclusive factors to consider when deciding whether to exercise discretion under 35 U.S.C. § 325(d) based on arguments presented during prosecution:

> (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 the prior art or arguments.

*Becton, Dickinson & Co. v. B. Braun Melsungen AG*, No. IPR2017-01586, Paper 8 at 17-18 (Dec. 15, 2017), designated Informative on March 21, 2018. All these factors heavily favor Petitioner.

Factors (a), (b), and (c) relate to evaluating prior art and favor Petitioner. During prosecution the examiner was not provided with and identified no prior art references that disclosed the claimed dimensional ranges. In contrast, the newly presented art, evidence, and arguments in both grounds above specifically disclose, or substantially overlap with, the claimed dimensions and establish a compelling obviousness case.

Factors (d) and (f) also favor Petitioner. The prior art herein was not before the examiner. Unlike the art before the examiner, this new art (and supporting evidence) shows that the claimed ranges were known, and that the results of the inventor's experiments were not unexpected. There is *zero* overlap between the new evidence and arguments in this Petition and the arguments made during examination.

Factor (e) favors Petitioner because, as explained in the preceding section, the examiner erred by relying on attorney argument and a defective inventor declaration that did not squarely address unexpected results.

## XII. CONCLUSION

For the above reasons, the Board should institute *inter partes* review of claims 1-3 of the '035 patent.

Respectfully submitted,

Dated: March 26, 2019

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**CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24**

I hereby certify that this Petition complies with the word count limitation of 37 C.F.R. § 42.24(a)(1)(i) because the Petition contains a total of 13,992 words, which is the sum of 13,618 words calculated by Microsoft Word's word-count feature and 374 words hand-counted in the annotated figures. This total excludes the cover page, signature block, and the parts of the Petition exempted by 37 C.F.R. § 42.24(a)(1).

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## CERTIFICATE OF SERVICE

The undersigned certifies that a complete copy of this Petition for *Inter Partes* Review of U.S. Patent No. 6,187,035 and all Exhibits and other documents filed together with this Petition were served on the official correspondence address for the patent shown in PAIR and a courtesy copy to FlexStent, LLC's current litigation counsel:

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