UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ABBOTT LABORATORIES and ABBOTT CARDIOVASCULAR SYSTEMS INC.,

Petitioners,

v.

CARDINAL HEALTH SWITZERLAND 515 GMBH,

Patent Owner

_____

Case IPR: IPR2019-00098

U.S. Patent No. 6,699,278
(Claims 2-5)

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PETITION FOR *INTER PARTES* REVIEW

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TABLE OF EXHIBITS

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1002	Declaration of Brian J. Brown with *curriculum vitae* ("Brown Decl.")
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1004	U.S. Patent No. 6,312,459
1005	U.S. Patent No. 6,540,774 ("Cox")
1006	U.S. Patent No. 6,190,406 ("Duerig-Burpee")
1007	U.S. Patent No. 6,309,414 ("Rolando")
1008	U.S. Patent No. 5,913,895
1009	M.J.B. Kutryk and P.W. Serruys, "2. Stents Currently Available," *Coronary Stenting: Current Perspectives, a Companion to the Handbook of Coronary Stents*, February 1999, p. 46
1010	T. Royer, "22. The Seaquence™ Stent," *Handbook of Coronary Stents, 3rd Edition* (Edited by P. W. Serruys and M. J. Kutryk), March 2000, pp. 171-176
1011	D.F. Fischell et al., "21. The Balloon Expandable (BX™) Stent," *Handbook of Coronary Stents, 2nd Edition* (Edited by P. W. Serruys and M. J. Kutryk), 1998, pp. 213-219
1012	U.S. Patent No. 6,042,606
1013	U.S. Patent No. 5,697,971

Exhibit	Description
1014	Excerpts from the prosecution history of the 278 patent
1015	Information Disclosure Statements from the 278 patent prosecution history
1016	Plaintiffs' First Supplemental Response To Interrogatory No. 1 Of Abbott's Updated First Set Of Interrogatories in *Tim A. Fischell et al. v. Cordis Corp.*, Case No. 16-928 (PGS) (LHG) (served on August 11, 2017)
1017	District Court of New Jersey, Local Patent Rule §3.4A
1018	*The American Heritage Dictionary of the English Language, Third Edition*, 1992, p. 1835
1019	*Webster's Third New International Dictionary of the English Language Unabridged*, 1993, p. 2339
1020	R.E. Putnam, *Builder's Comprehensive Dictionary*, 1984, p. 436
1021	W.F. Chen, *Handbook of Structural Engineering*, 1997, pp. 17-15 to 17-17
1022	K.F. Faherty & T.G. Williamson, *Wood Engineering and Construction Handbook, Third Edition*, 1997, pp. 4.40, 4.41, and 4.45
1023	C.H. Jensen & R.D. Hines, *Interpreting Engineering Drawings, Fifth Edition*, 1994, pp. 70-71
1024	J.G. Anderson, *Technical Shop Mathematics, Second Edition*, 1983, pp. 178-83

Exhibit	Description
1025	Excerpts from the prosecution history of Application No. 09/899,147
1026	Excerpts from the prosecution history of Application No. 09/718,558 (issued as U.S. Patent No. 6,706,061)
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1031	U.S. Patent No. 5,935,108
1032	U.S. Patent No. 5,409,454
1033	U.S. Patent No. 5,984,973
1034	E.J. Hearn, *Mechanics of Materials 2, Third Edition*, 1997, pp. 427, 434-35
1035	J.E. Pope, *Rules of Thumb for Mechanical Engineers*, 1997, pp. 299-300, 307
1036	Y.C. Pao & M. Foltz, *Engineering Drafting and Solid Modeling with SILVERSCREEN*, 1993, p. 61

Inter partes review ("IPR") is respectfully requested for claims 2-5 of U.S. Patent No. 6,699,278 ("the 278 patent" or "278") (Ex. 1001). The 278 patent issued with claims 1-3 on March 2, 2004. A Certificate of Correction issued on October 27, 2015, adding claims 4-5. The 278 patent is purportedly assigned to Cardinal Health Switzerland 515 GMBH ("Cardinal" or "Owner").

I. MANDATORY NOTICES UNDER 37 C.F.R. §42.8

A. Real Party-In-Interest Under 37 C.F.R. §42.8(b)(1)

Abbott Laboratories and Abbott Cardiovascular Systems Inc. (collectively "Petitioner") are the real parties-in-interest.

B. Related Matters Under 37 C.F.R. §42.8(b)(2)

The 278 patent is at issue in the following contract-related litigation pending in the District of New Jersey: *Tim A. Fischell et al. v. Cordis Corp.,* Case No. 16-928 (PGS) (LHG) ("the litigation"). Petitioner is an intervenor in the litigation. Plaintiffs in the litigation are not the current owners of the 278 patent, but were involved in founding a company that previously owned (at least in part) the application that ultimately issued as the 278 patent. Also, two of the Plaintiffs in the litigation (Robert Fischell and David Fischell) are named inventors on the 278 patent. The other named inventor on the 278 patent – Janet Burpee – is not a Plaintiff in the litigation. In the litigation, Plaintiffs have asserted contract-based claims for royalties. Plaintiffs have not asserted any claims for patent infringement.

C. Lead And Back-Up Counsel Under 37 C.F.R. §42.8(b)(3)

Petitioner provides the following designation of counsel. Pursuant to 37 C.F.R. §42.10(b), a Power of Attorney accompanies this Petition.

LEAD COUNSEL	BACK-UP COUNSEL
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D. Service Information Under 37 C.F.R. §42.8(b)(4)

Please address all correspondence to the lead counsel at the address provided in Section I.C of this Petition. Petitioner also consents to electronic service by email at: Abbott278IPR@mcandrews-ip.com.

II. PAYMENT OF FEES UNDER 37 C.F.R. §42.103

Petitioner authorizes the PTO to charge Account No. 13-0017 for the fees set forth in 37 C.F.R. §42.15(a) for this Petition and for any additional fees associated with this IPR.

III. IPR REQUIREMENTS UNDER 37 C.F.R. §42.104

A. Grounds For Standing Under 37 C.F.R. §42.104(a)

Petitioner certifies that the 278 patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR.

B. Identification Of Challenge Under 37 C.F.R. §42.104(b) And Relief Requested

Petitioner requests *inter partes* review of claims 2-5 of the 278 patent based on 35 U.S.C. §102 (anticipation) and §103 (obviousness) as summarized in the table below, and as further explained herein, and requests that each claim be found unpatentable.[1] A detailed explanation of how claims 2-5 are unpatentable is provided in Section VII below, including an identification of where each claim element is found in the prior art. Additional explanation and support is provided in the Declaration of Brian Brown at Exhibit 1002 (hereinafter "Brown declaration" or "Brown Decl."), as cited herein.

Review of claims 2-5 is requested in view of the knowledge of a person of ordinary skill in the art ("POSA") and the prior art references in the table below. Additional sample references cited herein – and in the Brown declaration – demonstrate the POSA's knowledge at the time of the alleged inventions.

[1] Because claims 2-5 have effective filing dates before March 16, 2013, Petitioner cites pre-AIA §§102 and 103 herein.

GROUND	PROPOSED GROUNDS FOR THE 278 PATENT
1	Claims 2, 4, and 5 are anticipated by WO 98/58600 ("Hilaire")
2	Claims 2, 4, and 5 are obvious over Hilaire in view of a POSA's knowledge or USPN 6,309,414 ("Rolando")
3	Claims 2-5 are anticipated by USPN 6,540,774 ("Cox")
4	Claims 2, 4, and 5 are obvious over Cox in view of a POSA's knowledge or Rolando
5	Claim 3 is obvious over Cox in view of a POSA's knowledge or USPN 6,190,406 (Duerig-Burpee)
6	Claims 2-3 are anticipated by Duerig-Burpee
7	Claims 4-5 are obvious over Duerig-Burpee in view of a POSA's knowledge or Cox

IV. BACKGROUND OF THE 278 PATENT

A. Technology At Issue, Terminology Used In The 278 Patent, And Prior Art Admissions In the 278 Patent

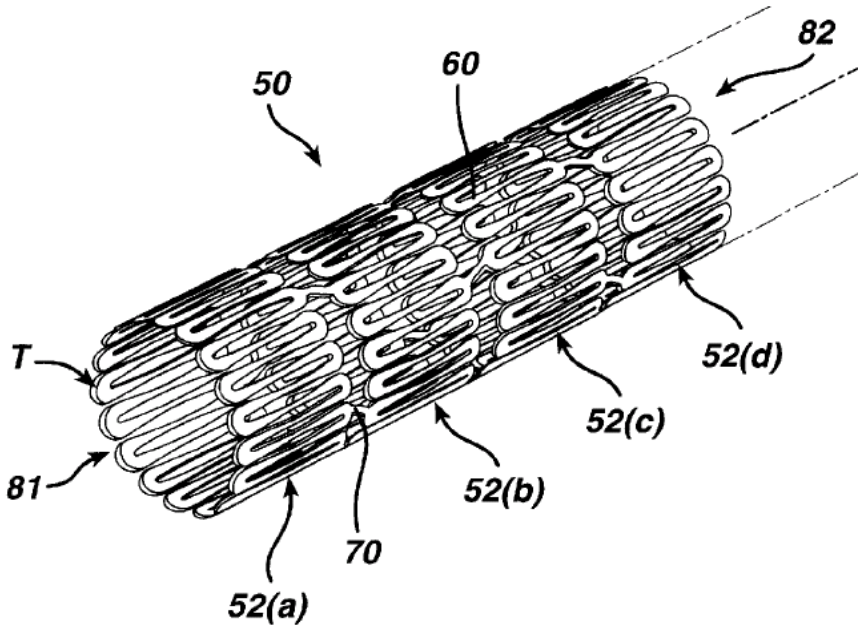
The 278 patent relates to stents. Generally speaking, stents are expandable tubular devices used to treat diseased vessels. (Brown Decl. (Ex. 1002) ¶18.) Typically, unexpanded stents are delivered to a treatment site, where they are expanded against a vessel wall to hold the vessel open. (*Id.*) As the 278 specification admits, stents were "well known" by the 278 provisional application filing date of September 22, 2000 (hereinafter the alleged invention date of the 278 patent):

> Stents are well known medical devices that are used for maintaining the patency of a large variety of vessels of the human body. A more

> frequent use is for implantation into the coronary vasculature [where] stents have been used for this purpose for more than ten years ....

(Ex. 1001 at cover page, 1:11-15.) By that time, the stent art was crowded. (Brown Decl. ¶19.)

The stents of the 278 claims are in the form of thin-walled tubular structures having a uniform thickness, as was typical of stents at that time. Indeed, the 278 specification acknowledges that, "[i]n current stent designs such as the BX Velocity® stent, [the stent components] are formed from a single piece of metal having a uniform wall thickness ...." (Ex. 1001 at 1:30-34.) At the time of the alleged 278 inventions, stents were commonly made by laser cutting a metal tube having uniform thickness. (*Id.* at 7:65-67 (prior art stents are "typically fabricated" by laser cutting a metal tube); Brown Decl. ¶23.) To help understand the structure of the disclosed stents, the figures of the 278 patent depict cylindrical stents as if they were in the form of flat sheets (as often is done in stent-related patents). (Ex. 1001 at Figs. 1-2, 5, 8, & 10; Brown Decl. ¶20.) But a stent is actually tubular, as shown in this example from the prior art:



(Ex. 1006 (Duerig-Burpee) at Fig. 3; Brown Decl. ¶20.)

A stent of the 278 patent comprises a multiplicity of circumferential segments which the 278 patent calls "circumferential sets of strut members." (Ex. 1001 at 1:20-28, 8:58-63, claim 2.) The stent has "end sets" of strut members located at each end of the stent, such as those highlighted in green in Figure 5 below (one of which is labeled 22). (*See also id.* at 8:46-63.) The stent also has "central sets" of strut members positioned between the end sets of strut members, such as those highlighted in yellow in Figure 5 below (one of which is labeled 26). (*Id.*) Each circumferential set of strut members forms a closed cylindrical portion of the stent, as reflected, for example, in Figure 5:

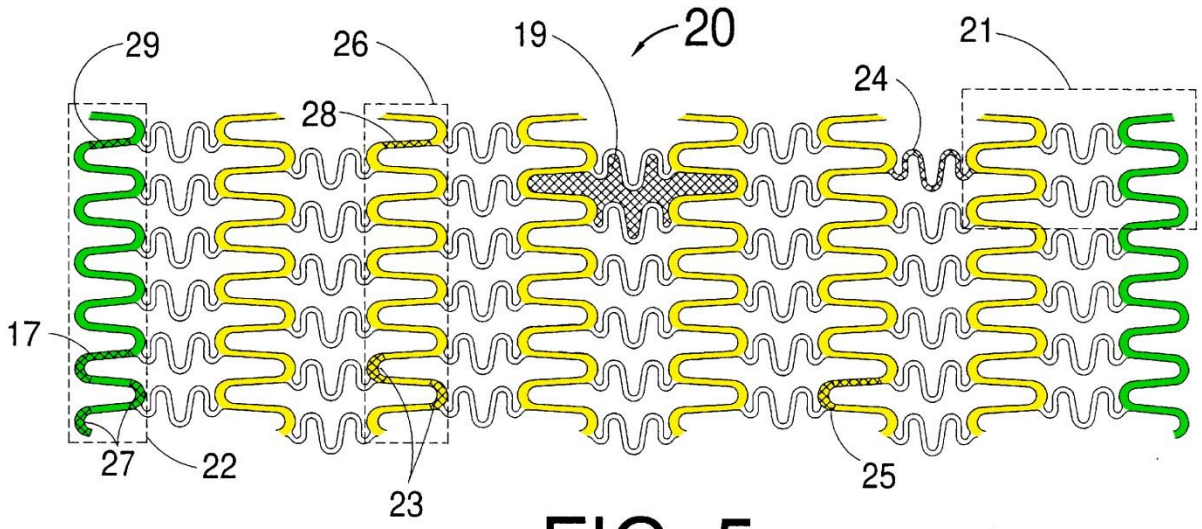


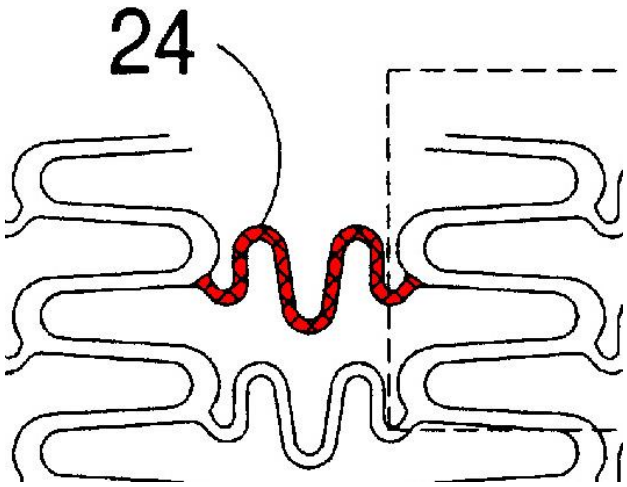
FIG. 5

(*Id.* at Fig. 5; *see also id.* at 1:23-26, 8:58-63.)[2]

The "circumferential sets of strut members" are longitudinally separated from each other and are connected by one or more "longitudinally extending links." (*See, e.g., id.* at 3:48-51 ("The stents described herein [typically have] a curved section of a central set of strut members connected to an adjacent set of strut members by a longitudinally extending link."), 7:3-7.) These "longitudinally extending links" that space apart adjacent sets of strut members can be a variety of shapes (e.g., straight or undulating). (*Id.* at 1:20-23, 10:48-51 ("[T]he present invention strut designs will function with any link shape …."); Brown Decl. ¶25.)

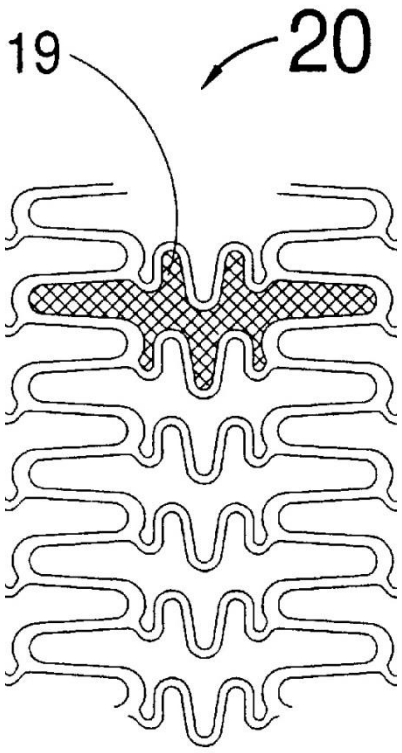
[2] All emphasis herein is added (including any coloring and cross-hatching) unless otherwise indicated. All cross-hatching in the 278 figures is original.

One example of a longitudinally extending link is item 24 in Figure 5 (highlighted in red):



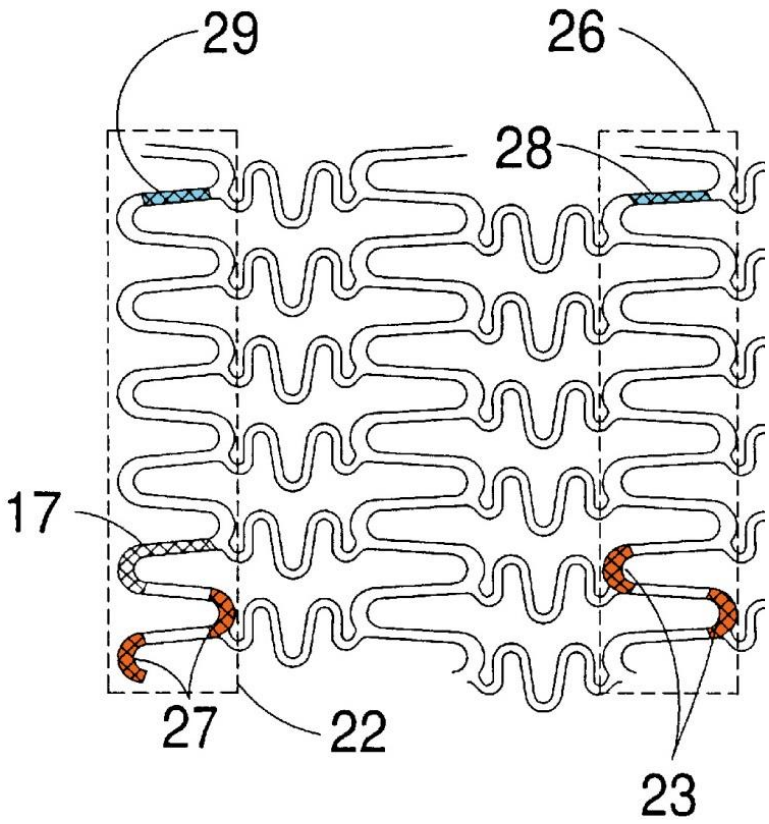
(Ex. 1001 at Fig. 5 (excerpt); *see also id.* at Fig. 1 (item 4), 7:3-7.)

The combination of "circumferential sets of strut members" separated by "longitudinally extending links" results in a stent having multiple bounded spaces, or "cells," an example of which is labeled 19 and cross-hatched in Figure 5:



(*Id.* at Fig. 5 (excerpt); *see also id.* at 8:64-66.)

According to the 278 patent, the "circumferential sets of strut members" are formed from certain sub-parts. Specifically, using Figure 5 as an example, the "circumferential sets of strut members" are formed from a multiplicity of connected "curved sections" (examples labeled 27 and 23 and highlighted in orange below) and "diagonal sections" (examples labeled 29 and 28 and highlighted in blue below):



(*Id.* at Fig. 5 (excerpt); *see also id.* at 1:28-30, 8:50-55, claim 2.) In this sample figure, the "diagonal sections" generally correspond to the straight portions connecting two curved sections. (Brown Decl. ¶27.)

Importantly, as of the earliest possible priority date in 2000, none of the above-described stent features (e.g., "curved sections," "diagonal sections," "circumferential sets of strut members," or "longitudinally extending links") were new. Quite the opposite, they were long known in the art. (*See, e.g.*, Brown Decl. ¶¶23-32.) Indeed, the 278 specification repeatedly admits this fact when describing and depicting the prior art in (a) the "Background Of The Invention" section (Ex. 1001 at 1:9-34) and (b) the "PRIOR ART" Figures 1 and 2. (*See also*

id. at 7:1-25 (describing Fig. 1), 7:57-8:17 (describing Fig. 2); Brown Decl. ¶¶23-32.) Using the admitted "PRIOR ART" Figure 1 and the same color scheme as above, the image below shows end sets (green and labeled 2) and central sets (yellow and labeled 6) of strut members in the prior art:

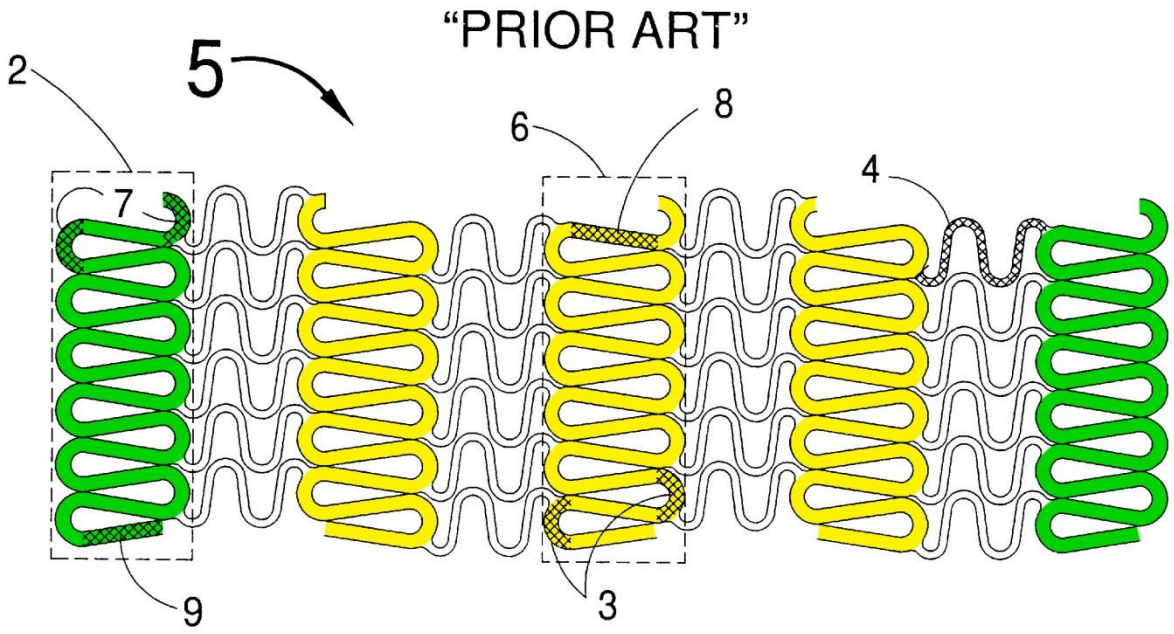


FIG. 1

(Ex. 1001 at Fig. 1.) That same "PRIOR ART" figure depicts curved sections (orange and labeled 7 and 3), diagonal sections (blue and labeled 9 and 8), and longitudinally extending links (red and labeled 4):

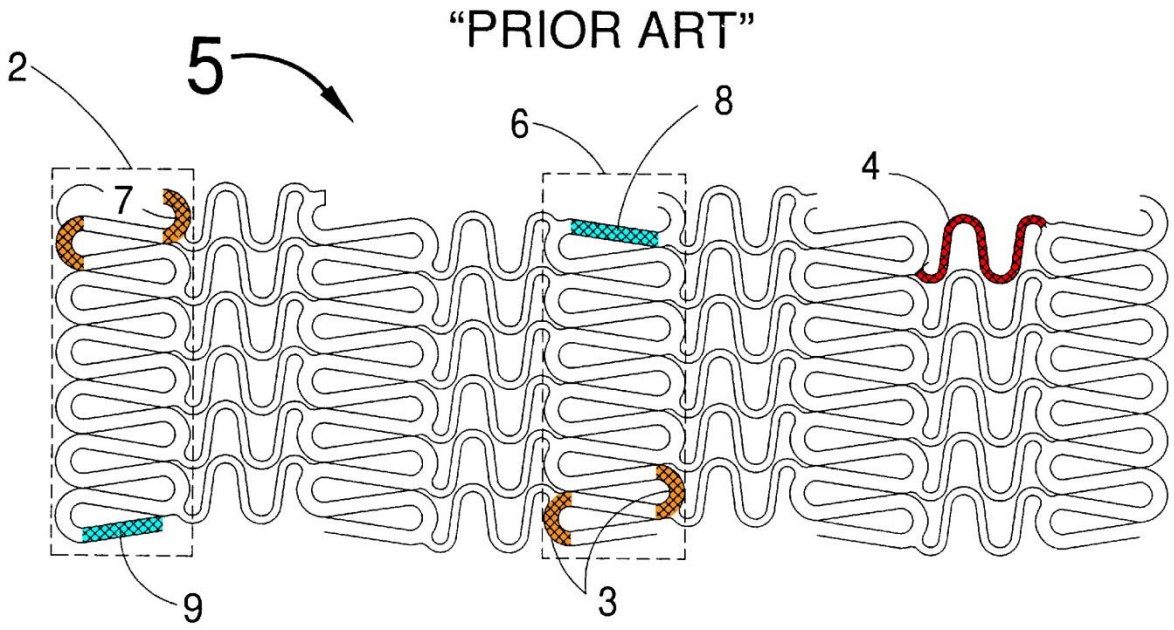


FIG. 1

(*Id.*)

B. The Alleged Invention Of Challenged Claims 2-5

The 278 specification purports to disclose several "novel design elements." (*Id.* at 2:21-5:26.) Claims 2-5 are directed to one of those allegedly novel ideas, i.e., a stent having certain diagonal sections with a tapered shape wherein the width at the center of the diagonal section is ***different*** than the width at either end of the diagonal section. (*Id.* at independent claim 2.) The width at the center of the diagonal section can be ***greater*** than the width at either end. (*Id.* at dependent claims 4-5.) Alternatively, the width at the center can be ***less*** than the width at either end. (*Id.* at dependent claim 3.) An example of a wider-at-the-center

diagonal section is shown in Figure 8 of the 278 patent (*see, e.g.*, items 39 and 38 highlighted in blue):

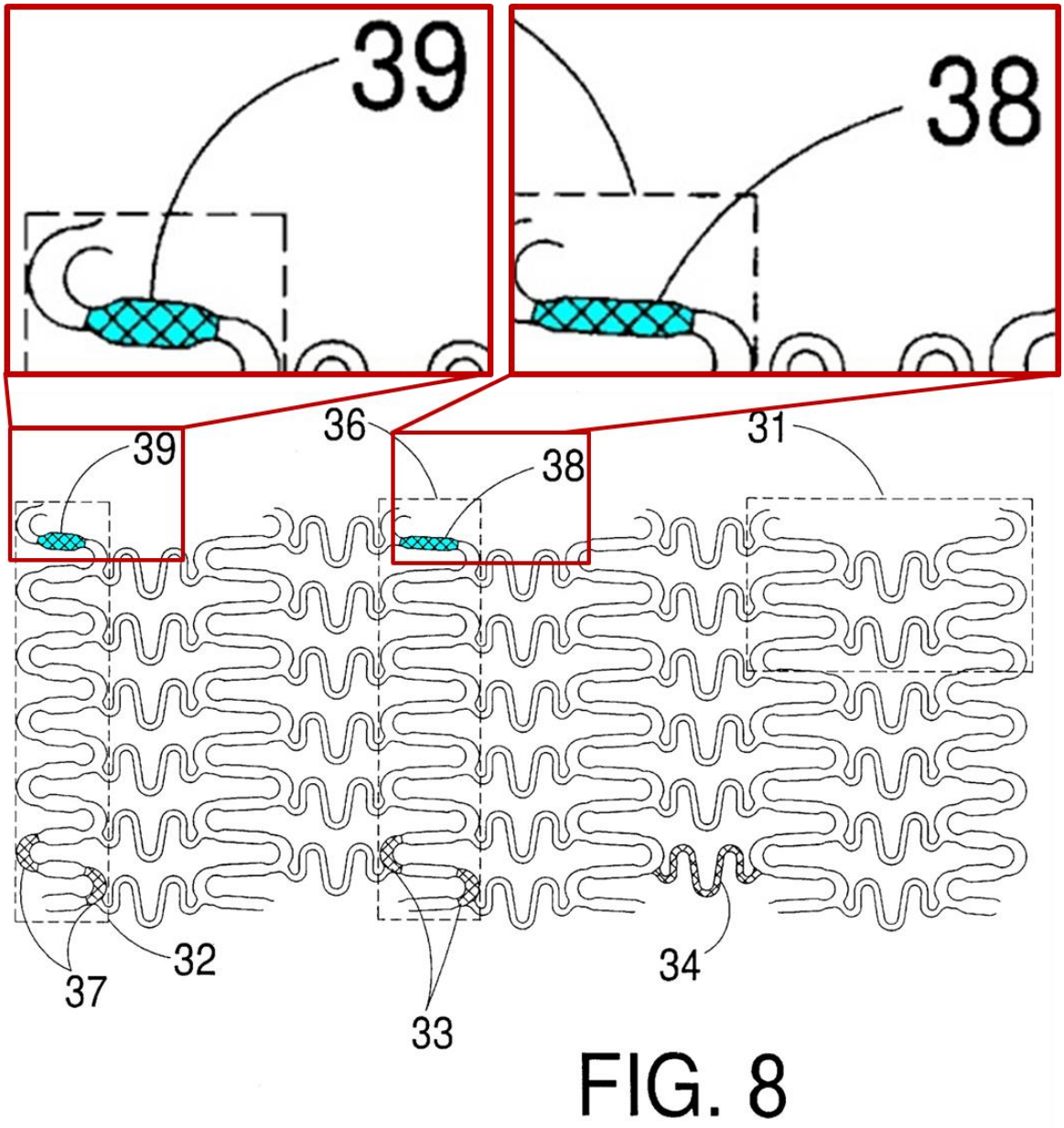


FIG. 8

(*Id.* at Fig. 8 (blow outs added).) An example of the alternative narrower-at-the-center diagonal section is shown in Figure 10 (*see, e.g.*, item 48 highlighted in blue):

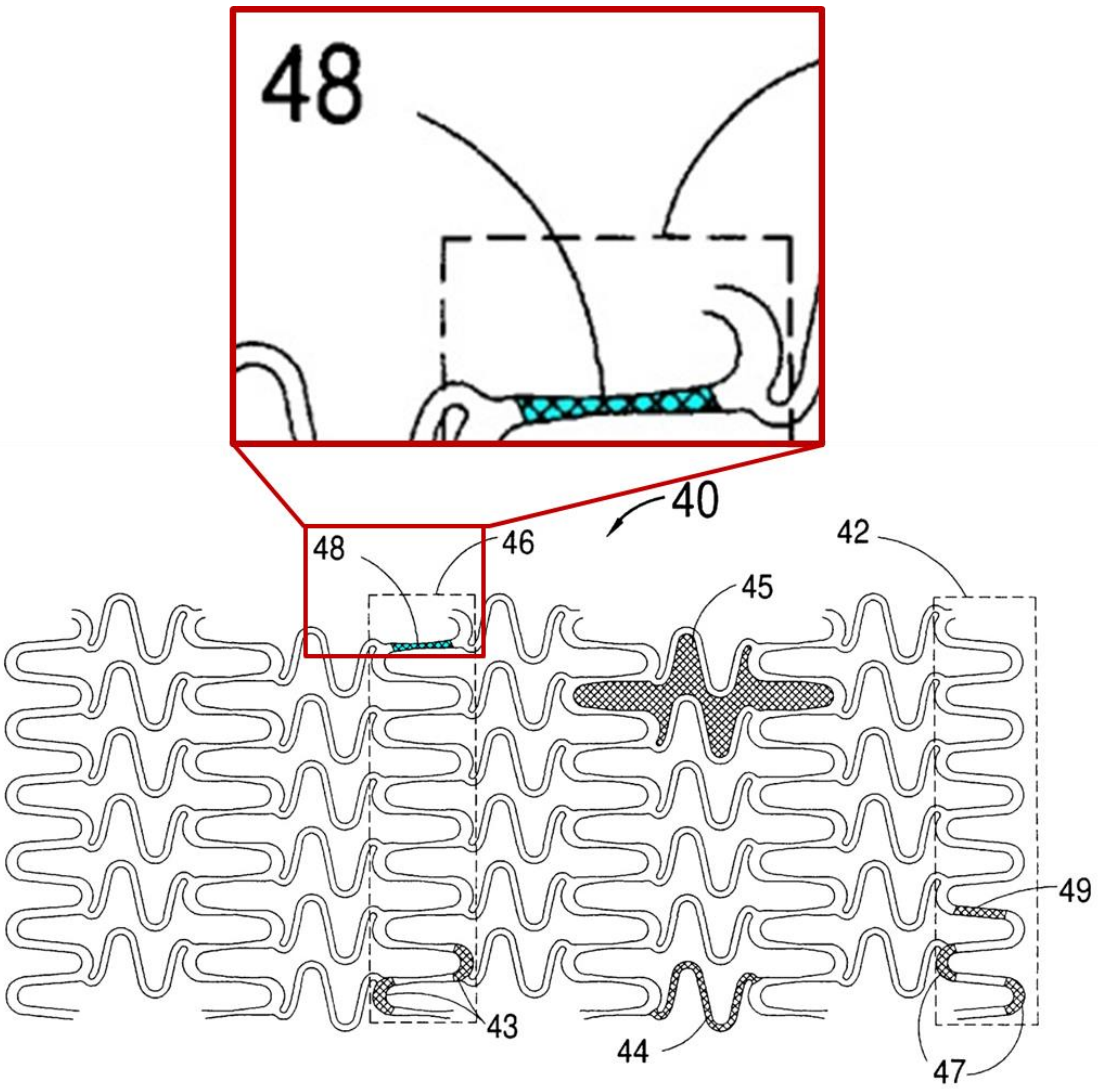


FIG. 10

(*Id.* at Fig. 10 (blow out added).)

Claims 2-5 are listed fully below (with the purportedly novel feature emphasized):

> 2. A stent in the form of a thin-walled, multi-cellular, tubular structure having substantially uniform thickness throughout the length of the tubular structure, a [sic] the stent comprising a multiplicity of circumferential sets of strut members, each of the strut members being

substantially the same thickness, each set of strut members being longitudinally separated each from the other and connected each to the other by one or more longitudinally extending links, each set of strut members forming a closed, cylindrical portion of the stent, each set of strut members comprising a multiplicity of connected curved sections and diagonal sections, the sets of strut members including end sets of strut members located at each end of the stent and central sets of strut members positioned between the end sets of strut members, the diagonal sections of the central sets of strut members have a center and two ends, ***at least one of the diagonal sections of the central sets of strut members having a tapered shape wherein the width of the at least one diagonal section is different at the center of the diagonal section as compared to the width at either end of that diagonal section.***

3. The stent of claim 2 wherein the width of the at least one diagonal section is ***less*** at the center of that diagonal section compared to the width at either end of that diagonal section.

4. The stent of claim 2 wherein the width of the at least one diagonal section is ***greater*** at the center of that diagonal section as compared to the width at either end of that diagonal section.

5. [T]he stent of claim 2 wherein the diagonal sections of the end sets of strut members have a center and two ends, ***at least one of the diagonal sections of the end sets of strut members has a tapered shape wherein the width of the at least one diagonal section is greater at the center of the diagonal section as compared to the width at either end of that diagonal section.***

In short, claims 2-4 require at least one diagonal section of the central sets of strut members to have a tapered shape wherein the width at the center is either different (claim 2), less (claim 3), or greater (claim 4) than the width at either end. Claim 5, in turn, requires (1) at least one diagonal section of the central sets of strut members to have a tapered shape wherein the width at the center is different than the width at either end and (2) at least one diagonal section of the end sets of strut members to have a tapered shape wherein the width at the center is greater than the width at either end.

As shown, claims 2-5 do not recite any purpose in connection with the claimed physical characteristics of the diagonal sections. The 278 specification, however, provides some reasons. The width of the tapered diagonal section can be ***greater*** at the center than the width at either end to increase stent radiopacity (e.g., for viewing the stent under x-ray fluoroscopy during the implantation procedure). (*Id.* at 5:42-47, 11:62-12:36 ("A wider piece of metal will be more radiopaque."), 1:35-36, Title.) Alternatively, the width of the tapered diagonal section can be ***less*** at the center than the width at either end to decrease stent radiopacity and/or "reduce the metal strain as the stent is expanded." (*Id.* at 10:55-11:1, 2:63-65, 5:32-37.)

As for the shape of the diagonal section, the 278 patent broadly and generically references a "tapered" shape without qualification. (*See, e.g.*, *id.* at

2:56-60, 3:19-20, 5:32-37, 5:42-47, claims 2 & 5; Brown Decl. ¶¶35, 66.) At the time of the alleged 278 inventions, there were many commonly known tapered shapes (e.g., symmetrical two-sided tapers, non-symmetrical one-sided tapers, full-length tapers, partial-length tapers, conical tapers, etc.). (Brown Decl. ¶¶35, 63, 65; §VI *infra*.) The 278 patent does not restrict in any way the shapes that the taper must have, nor does the specification say anything about the advantages of one tapered shape over another. The 278 patent likewise does not indicate that the alleged inventions apply only to certain tapered shapes and not others. The unrestricted breadth of "tapered shape" is further reflected by the different examples of "tapered" diagonal sections in the 278 patent figures (of the few examples depicted). For instance, Figure 7 shows a change in width ***over the full length*** of diagonal section 28':

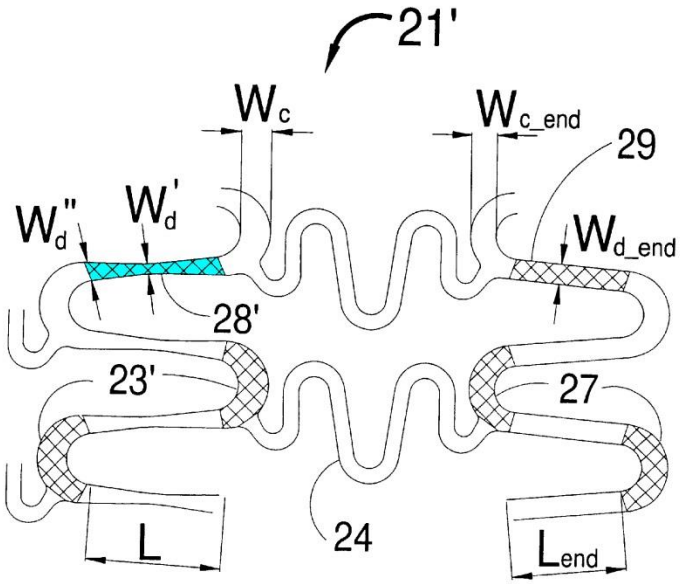


FIG. 7

In contrast, tapered diagonal sections 38 and 39 in Figure 9 have a change in width ***over a short distance at the ends*** of the diagonal sections:

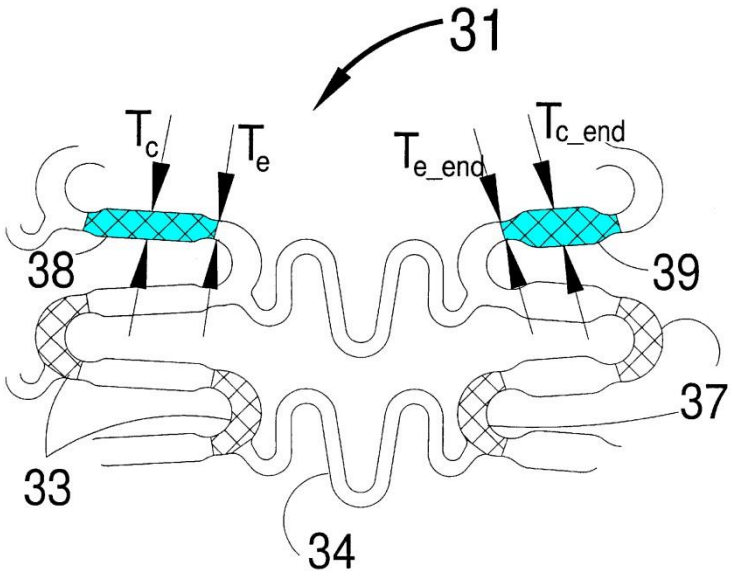


FIG. 9

C. 278 Prosecution History

The 278 prosecution history is short, with only two office actions and minimal substance. The original application had 19 claims. (Ex. 1014 at ABTF000005864-68.) Original claims 6 and 15-18 correspond to issued claims 1-5, respectively. (*Id.*)

The first office action was a restriction requirement. (Ex. 1014 at ABTF000007158-62.) In response, the applicants selected one species. (*Id.* at ABTF000007319-20.)

In the second office action, the examiner narrowed the claims at issue to pending claims 6, 15, and 16. (*Id.* at ABTF000007321-26.) The examiner then rejected those claims based on only two references. (*Id.*) Those two references disclosed stent diagonal sections with varying ***thickness***, not ***width*** as claimed.[3] In a subsequent interview and response, the applicants highlighted the examiner's error and amended the claims to make clear that the claimed stents had uniform thickness, not width. (*Id.* at ABTF000007441-57.) The examiner then allowed the pending claims (and the claims depending therefrom) without ever citing any reference from the large body of prior art disclosing stent diagonal sections with varying ***width*** (as Petitioner does herein). (*Id.* at ABTF000007458-68.)

During prosecution, the applicants submitted over 115 references. (Ex. 1015.) Despite the large quantity, the applicants never highlighted any of the 115+ references nor indicated that any one reference was more pertinent than any other. In any event, none of the references cited in the grounds of this Petition was ever raised by the PTO (indeed, most of them were never disclosed to the PTO).

[3] As reflected in the 278 patent discussion above, "thickness" as used in the 278 patent refers to the stent wall thickness, i.e., the thickness of the stent in the radial direction. "Width," on the other hand, refers to the distance across a component of the stent. (Brown Decl. ¶22.)

D. 278 Priority

The 278 application was filed on July 6, 2001. It purports to claim priority to a provisional application filed on September 22, 2000. Thus, the earliest possible filing priority date is September 22, 2000.

In the pending litigation referenced in Section I.B, to the extent Plaintiffs (including named 278 inventors) allege a 278 invention date earlier than the filing dates, they were required to ***definitively*** identify the earliest alleged invention date ***and*** identify all evidence establishing that alleged invention date (e.g., conception, diligence, etc.). Plaintiffs have alleged a conception date of September 1999, and in support, cite 20 pages (currently designated confidential by Plaintiffs). (*See*, *e.g.*, Ex. 1016 (Plaintiff Interrog. Resp.) at 3.) That cited "support" does not remotely show the necessary conception or diligence to establish a September 1999 priority date. That said, each of the references that form the grounds herein has an effective priority date before September 1999.

E. Level Of Skill In The Art

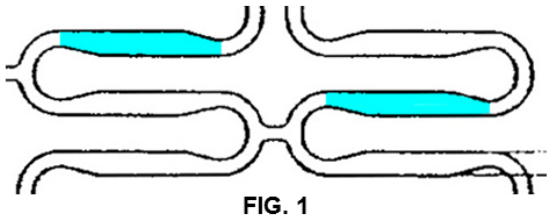
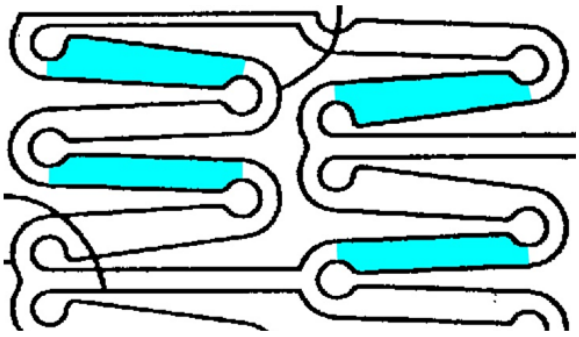
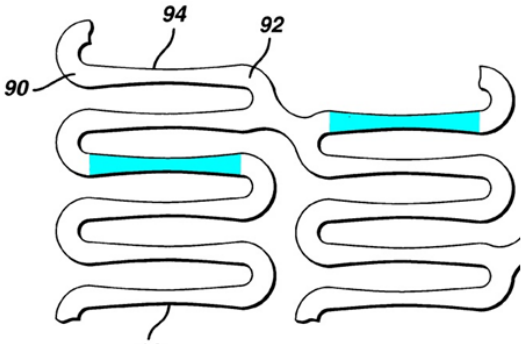
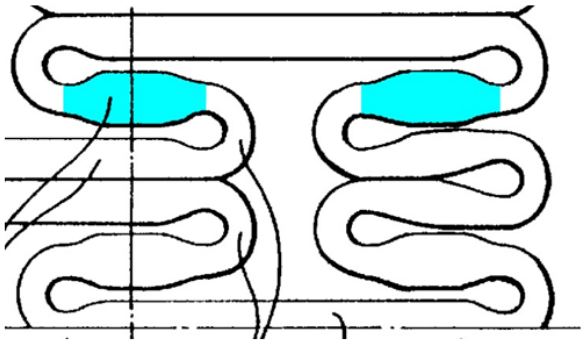
A POSA at the time of the alleged 278 inventions was an engineer with (a) a degree in mechanical or biomedical engineering and (b) at least several years of stent experience. The POSA would have worked on a design team that may have included a stent-implanting physician, such as an interventional cardiologist. (Brown Decl. ¶40.)

V. OVERVIEW OF THE STATE OF THE ART

As the 278 specification admits, stents in the form of thin-walled, multi-cellular tubular structures having a uniform wall thickness were well-known and standard as of the alleged 278 invention date. (Ex. 1001 at 1:9-34, 7:24-26, Figs. 1-2.) The 278 specification likewise admits – both in its figures and text – that stents having the other claimed stent components were already known in the art, including stents comprising (a) circumferential sets of strut members formed from connected curved sections and diagonal sections; (b) end sets and central sets of such strut members; (c) the sets of strut members forming closed cylindrical portions of the stents; and (d) one or more longitudinally extending links connecting the sets of strut members. (*Id.* at 1:9-34, Figs. 1-2, 7:1-25 (describing Fig. 1), 7:57-8:17 (describing Fig. 2).) Beyond the 278 specification admissions, Petitioner's prior art cited herein confirms that this basic stent structure was well known. It was also common knowledge to a POSA. (Brown Decl. ¶¶28, 43-44.)

The only purportedly "new" feature in claims 2-5 is the claimed stent diagonal sections having a tapered shape wherein the width at the center of the diagonal section is different (greater or less) than the width at either end. (Brown Decl. ¶33.) ***But this concept was not remotely new at the time of the alleged invention date for the 278 patent.*** (*See, e.g., id.* ¶¶45-54.) To the contrary, it likewise was well known for many years prior to the 278 application. Indeed,

below is a mosaic of sample excerpts from the prior art that form the grounds in this Petition showing numerous examples of tapered stent diagonal sections (highlighted in blue) wherein the width at the center is different (greater or less) than the width at either end:[4]

<table>
<tr><th colspan="2">SAMPLE TAPERED DIAGONAL SECTIONS FROM PRIOR ART</th></tr>
<tr><th>HILAIRE (Ex. 1003)</th><th>COX (Ex. 1005)</th></tr>
<tr><td> 
FIG. 1
 
FIG. 2</td><td> 
FIG. 5</td></tr>
<tr><th>DUERIG-BURPEE (Ex. 1006)</th><th>ROLANDO (Ex. 1007)</th></tr>
<tr><td> 
FIG. 4A</td><td> 
FIG. 4</td></tr>
</table>

There are many additional prior art examples, including:

[4] Petitioner addresses each reference in detail in §VII.

SAMPLE TAPERED DIAGONAL SECTIONS FROM OTHER PRIOR ART

SEAQUENCE (Ex. 1009)

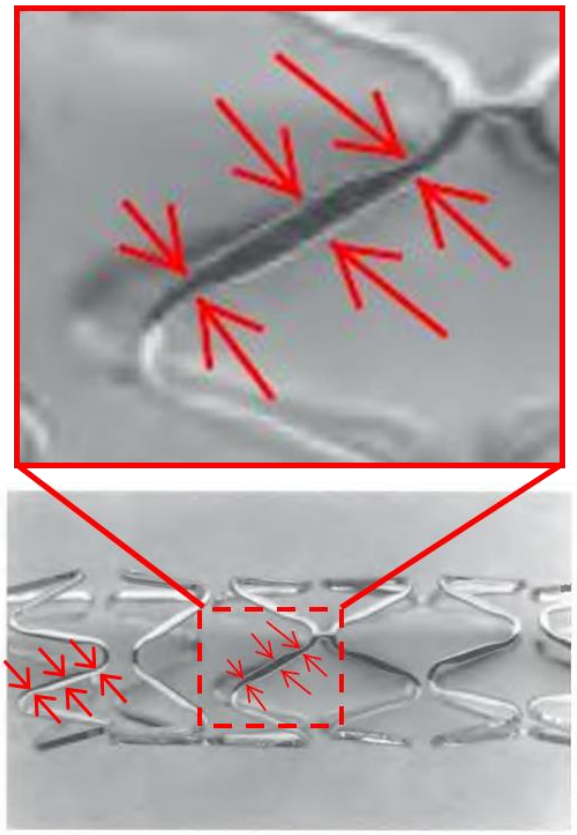


Figure 2.18: An expanded Seaquence stent showing variable width of the stent struts.

(p. 46)

BX STENT (Ex. 1011)

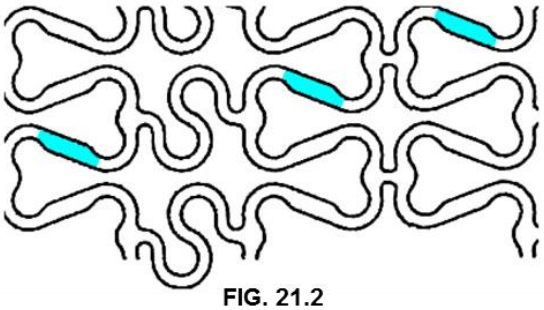


FIG. 21.2

USPN 5,913,895 (Ex. 1008)

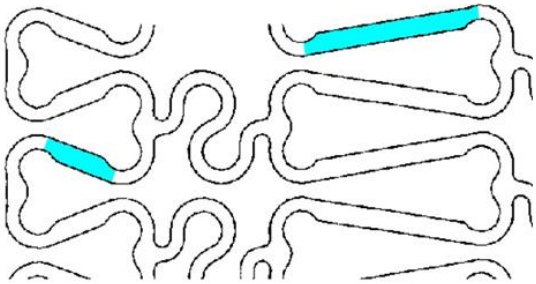


FIG. 1

USPN 6,312,459 (Ex. 1004)

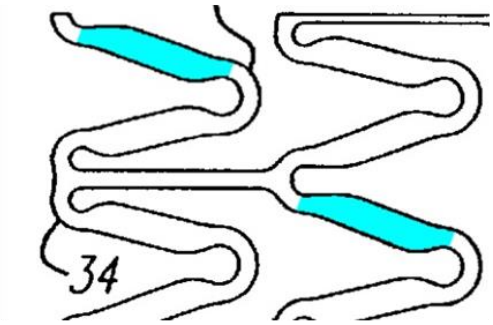


FIG. 7

USPN 6,042,606 (Ex. 1012)

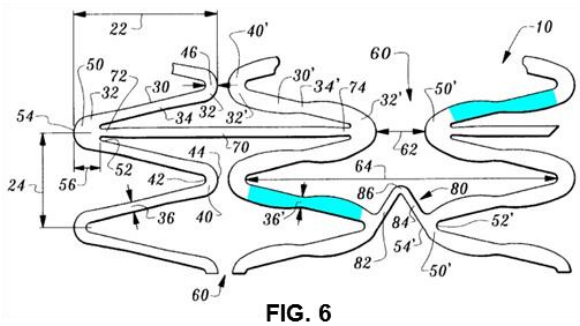


FIG. 6

(Ex. 1004 at Fig. 7 (excerpt); Ex. 1008 at Fig. 1 (excerpt); Ex. 1009 at 46 (red arrows and blow out added); Ex. 1011 at Fig. 21.2 (excerpt); Ex. 1012 at Fig. 6; *see also* Ex. 1010 at 171-74.)

The prior art not only depicts and describes the claimed tapered diagonal sections, but it also teaches multiple reasons for that design, ***including the same reasons identified in the 278 patent***. For instance:

- to achieve desired radiopacity (*see, e.g.*, Ex. 1005 (Cox) at 4:52-59 ("[T]he width of the stent in [the diagonal sections can] be varied in order to increase or decrease the radiopacity of the stent ...."); Ex. 1004 at Abstract, 3:42-48, 8:28-36; *compare* Ex. 1001 (278 patent) at 2:63-65, 5:32-37, 5:42-47);
- to achieve uniform stent expansion and a favorable distribution of radial forces on the stent and vessel wall after stent expansion (*see, e.g.*, Ex. 1003 (Hilaire) at 1:34-2:24; Ex. 1007 (Rolando) at 9:65-10:2; Ex. 1009 at 46; Ex. 1010 at 171, 174); and
- to resist stent deformation, more uniformly distribute strain, minimize fatigue risks, and avoid stent fracturing (*see, e.g.*, Ex. 1006 (Duerig-Burpee) at 6:8-39, 6:61-7:6, 4:23-29, 3:65-4:9; Ex. 1003 (Hilaire) at 4:34-5:2; Ex. 1012 at 3:16-29, 7:19-37,

> 6:28-39, claims 1 & 10 (using the term "thickness" to mean the same as "width" in the 278 patent); *compare* Ex. 1001 (278 patent) at 10:67-11:1).

These reasons were not only disclosed in the prior art, but they were also well known to POSAs. (Brown Decl. ¶54.)

Finally, consistent with the POSA's common knowledge, the prior art confirms that it was well known that the curved sections of circumferential sets of strut members experienced higher stresses during stent expansion than the diagonal sections. (*See, e.g., id.*; Ex. 1005 (Cox) at 4:42-47; Ex. 1004 at 6:62-64, 7:66-8:34; Ex. 1006 (Duerig-Burpee) at 3:65-4:9.) Thus, as of the alleged 278 invention date, it was not inventive to vary the width of the lower-stress diagonal sections (e.g., wider at the center). (*See, e.g.*, Brown Decl. ¶¶54, 122, 149; Ex. 1005 (Cox) at 4:42-65 ("An increase or decrease of the width of the strut in these low stress regions of the cylindrical element generally will not alter the overall mechanical properties of the stent."); Ex. 1004 at 7:66-8:36, 3:42-48, 7:16-26.)

In short, claims 2-5 are not inventive. Indeed, not only were the alleged inventions in those claims well known before the alleged 278 invention date, but numerous references anticipate the claims.

VI. CLAIM CONSTRUCTION UNDER 37 C.F.R. §42.104(B)(3)

Claims subject to IPR shall receive the "broadest reasonable construction in light of the specification of the patent in which" they appear. 37 C.F.R. §42.100(b). Accordingly, all claim terms have been accorded their broadest reasonable interpretation in light of the 278 specification, including their plain and ordinary meaning to a POSA.[5] Petitioner addresses one claim term in further detail below.

Specifically, each of the challenged claims recites diagonal sections having a "***tapered shape***." "Tapered" is a common, everyday word. It is not unique to stents or scientific fields generally. A "tapered shape" means "a shape that transitions in width over a length," consistent with dictionaries, engineering textbooks, PTO findings, and everyday usage, including the use of "tapered" by others in the intravascular device field (as shown below). (Brown Decl. ¶¶62-73.) In other words, as widely known (and confirmed by those same sources), "tapered shape" encompasses a large variety of shapes (*id.* ¶¶62-65**)**, but excludes abrupt "step" changes in width at a single point (*id.* ¶62). For these reasons, Petitioner does not believe it needs a detailed claim construction analysis. That said, for the

[5] Because litigation has a different claim construction standard, Petitioner reserves all of its rights with regard to constructions in the pending litigation.

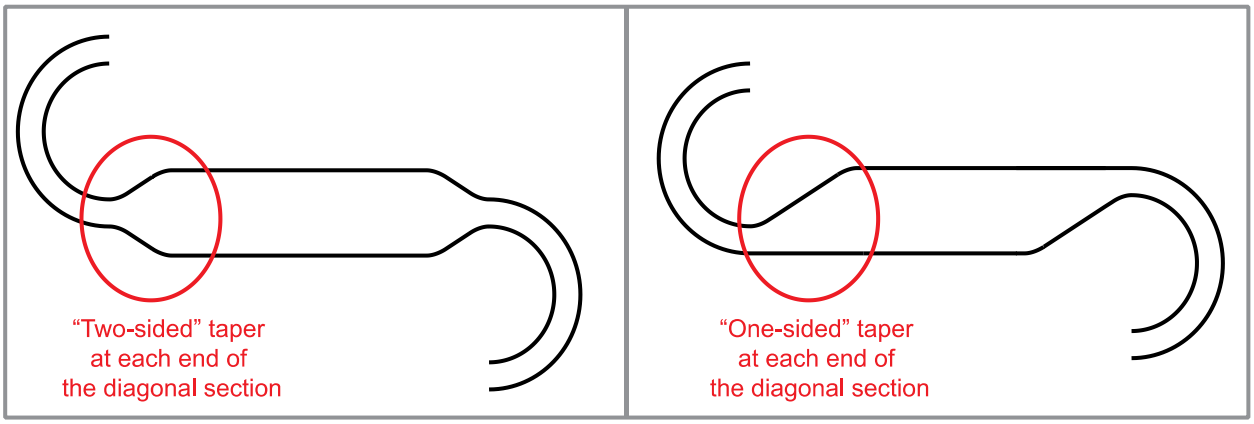
reasons stated below, Petitioner will address "tapered shape" out of an abundance of caution.

In the litigation, claims 2, 4, and 5 of the 278 patent are at issue. Petitioner served initial invalidity contentions for those claims under the local patent rules. In their responses, Plaintiffs (including named 278 inventors) were required to identify any 278 claim elements allegedly missing from the cited prior art. (Ex. 1017 at §3.4A(a).) Notably, for Petitioner's primary prior art cited herein, Plaintiffs did not specifically contest any claim element except "the diagonal sections ... having a tapered shape" wherein the width at the center is different or greater than the width at either end.[6] And the only way Plaintiffs could contest that element (and avoid admitted anticipation) was by advancing an extremely narrow and unsupported construction of "tapered shape" contrary to its ordinary meaning.[7] Specifically, in the litigation, Plaintiffs have asserted that "tapered shape" means "a shape with a generally uniform and gradual decrease or increase in width ***about a centerline***." In other words, Plaintiffs allege that "tapered shape" should be limited to an arbitrary, narrow subset of tapered shapes that are symmetrical "two-

[6] Duerig-Burpee was not part of Petitioner's initial invalidity contentions, which were served early in discovery.

[7] As shown herein, even under Plaintiffs' erroneous "tapered shape" construction, the challenged claims are unpatentable.

sided" tapers and excludes any other tapers (e.g., non-symmetrical "one-sided" tapers), examples of which are shown below:

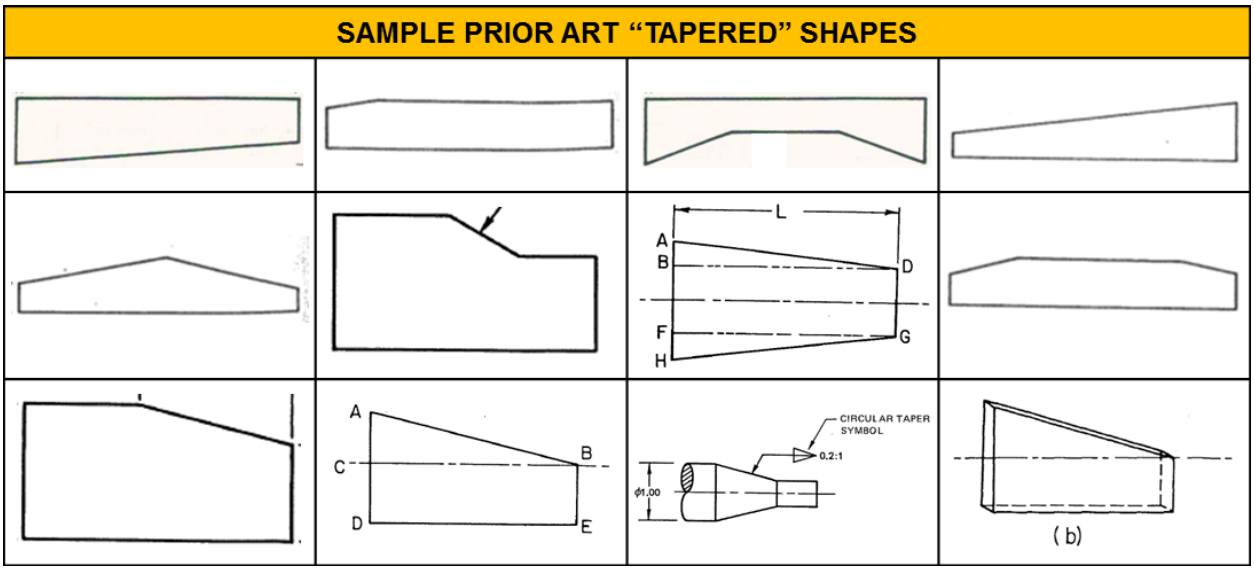


(Brown Decl. ¶56.) Plaintiffs' assertion is wrong. Petitioner does not know whether Owner (Cardinal) will advance the same erroneous "tapered shape" construction as Plaintiffs in the litigation. If so, it is erroneous for at least the following reasons.

First, dictionaries broadly define "taper" or "tapered" to mean "[s]omething that narrows down along a length," "a gradual decrease in thickness or width of an elongated object," or "to make thinner or narrower at one end" (or the like). (Ex. 1020 at ABTF000196464; Ex. 1018 at ABTF000196840 (noun definition no. 4.a and transitive verb definition no. 1); *see also* Ex. 1019 (noun definition 2b); Brown Decl. ¶64.) Dictionaries do not limit "tapered" to just one subset of tapered shapes, nor do they require a generally uniform increase or decrease "about a centerline."

Second, consistent with the dictionary definitions, the ordinary meaning of "tapered shape" encompasses a wide variety of tapered shapes, including

symmetrical two-sided tapers, non-symmetrical one-sided tapers, full-length tapers, partial-length tapers, and conical tapers as well as tapers at one end, both ends, and/or in the middle portion of a shape. (Brown Decl. ¶¶35, 63.) This is confirmed, for example, by numerous prior art engineering textbooks which describe each of the following exemplary shapes as "tapered":



(*Id.* ¶65; Exs. 1021-24.)

Third, the 278 patent broadly and generically references a "tapered" shape without qualification. (*See, e.g.*, Ex. 1001 at 2:56-60, 3:19-20, 5:32-37, 5:42-47, claims 2 & 5; Brown Decl. ¶¶35, 66.) As noted above, the 278 patent does not restrict the shape of the taper in any way, nor does the specification say that one taper shape has any advantage over another (e.g., there is no assertion of any advantage in having generally uniform changes in width "about a centerline"). In fact, the 278 specification never mentions "about a centerline" or symmetry at all.

The 278 specification likewise does not indicate that the alleged inventions apply only to certain tapered shapes and not others. The unrestricted breadth of "tapered shape" is further reflected by the different examples of "tapered" diagonal sections in the 278 figures. (Brown Decl. ¶¶36, 67.) For instance, tapered diagonal section 28' in Figure 7 has a change in width ***over the full length*** of the diagonal section while tapered diagonal sections 38 and 39 in Figure 9 have a change in width ***over a short distance at the ends*** of the diagonal sections:

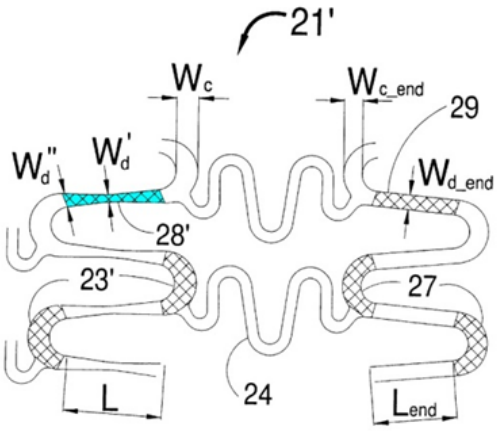


FIG. 7

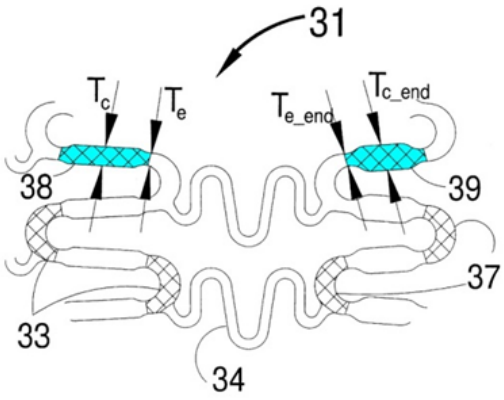


FIG. 9

Other portions of the specification likewise suggest a broad understanding of "tapered shape" consistent with its ordinary meaning. (*See, e.g.*, Ex. 1001 at 2:60-63 ("The curved sections should be tapered (wider at the center compared to the ends) ...."); *see generally* Brown Decl. ¶¶66-69.)

Fourth, consistent with the ordinary meaning of "tapered," the PTO has repeatedly found – in applications involving named inventors from the 278 patent – that "tapered shape" encompasses shapes that do ***not*** have generally uniform

changes in width "about a centerline," including non-symmetrical one-sided tapers. (Brown Decl. ¶¶70-71.) For example, Application No. 09/899,147 was filed on the same day as the 278 application and claims priority to the same provisional application underlying the 278 patent. (Ex. 1025 at ABTF000196869.) Dependent claims 10-14 of that application recited the same "tapered shape" diagonal section language as claims 2-5 of the 278 patent. (*Id.* at ABTF000196901; Brown Decl. ¶70.) The PTO concluded that the diagonal section in the following prior art stent – having non-symmetrical one-sided tapers – met the "tapered shape" claim language (including wider at the center than at either end):

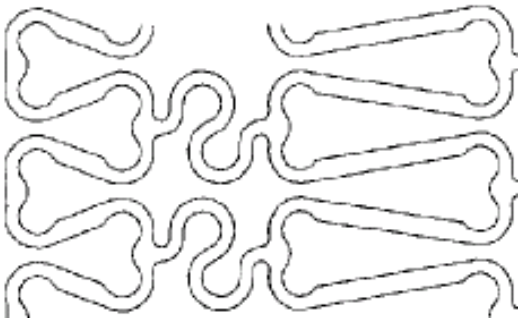
(Ex. 1013 (USPN 5,697,971) at Fig. 7 (excerpt); Ex. 1025 at ABTF000197172-73, ABTF000197175-77 (citing Fig. 7 of USPN 5,697,971).) In the words of the PTO:

> Regarding [pending] claim 10, [USPN 5,697,971] discloses that ***the diagonal sections of the central sets of strut members has a tapered shape*** wherein the width of the at least one diagonal section is ***different*** at the center of the diagonal section as compared to the width at either end of that diagonal section (***see FIG. 7 diagonal sections*** of the U members). ... Regarding [pending] claim 12, [USPN 5,697,971] discloses that the width of the diagonal section is ***greater*** at the center of that diagonal section as compared to the width at

> either end of that section (***see FIG. 7 diagonal sections*** of the U-shaped members).

(Ex. 1025 at ABTF000197176.) These specific PTO "diagonal section" findings were never contested and the application was ultimately abandoned. (*See generally* Brown Decl. ¶70.)

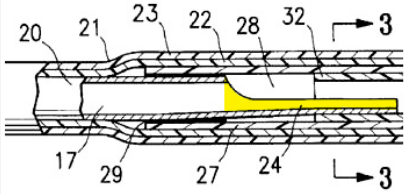
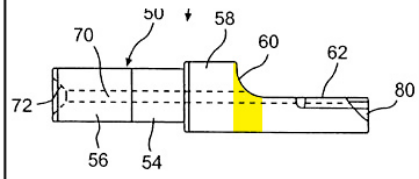
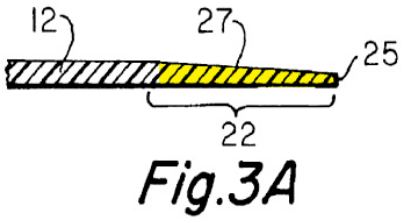
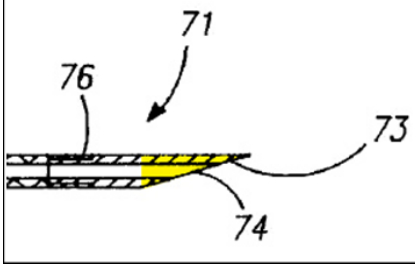
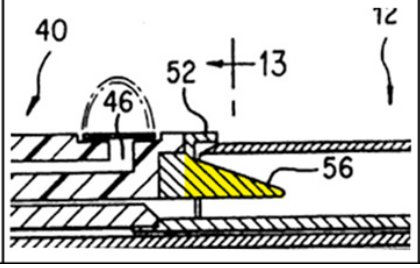
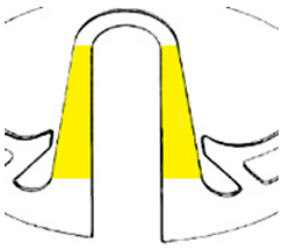
The PTO reached the identical conclusion in the prosecution of another co-pending application involving some of the named 278 inventors. Specifically, dependent claims 22-27 of Application No. 09/718,558 recited the same "tapered shape" diagonal section language as claims 2-5 of the 278 patent. (Ex. 1026 at ABTF000196367-68; Brown Decl. ¶71.) The PTO cited Figure 1 from USPN 5,913,895 (Ex. 1008) against those claims, an excerpt of which is provided below:



(Ex. 1026 at ABTF000196400-01; Ex. 1008 at Fig. 1 (excerpt).) The PTO found that the non-symmetrical one-sided tapers in the above diagonal sections met the "tapered shape" claim language (including wider at the center than at either end).

(Ex. 1026 at ABTF000196401.) Again, the applicants never contested these specific PTO findings.[8] (*See generally* Brown Decl. ¶71.)

Fifth, consistent with Petitioner's proposed construction of "tapered shape," companies in the intravascular device field routinely use "tapered" (or the like) to describe a wide variety of tapered shapes, including non-symmetrical one-sided tapers. Here are a few prior art examples – highlighted in yellow – from patents owned by major industry participants such as Advanced Cardiovascular Systems, SciMed Life Systems, Medtronic AVE, St. Jude Medical, and others:

USPN 6,193,686 (Ex. 1028) at Fig. 1	USPN 6,511,470 (Ex. 1029) at Fig. 8	USPN 5,984,963 (Ex. 1030) at Fig. 3A
		
USPN 5,935,108 (Ex. 1031) at Fig. 2	**USPN 5,409,454 (Ex. 1032) at Fig. 12**	**USPN 5,984,973 (Ex. 1033) at Fig. 3**
		

(Brown Decl. ¶72.)

[8] The applicants ultimately overcame the examiner's rejections by making unrelated amendments to the independent claim.

Finally, Plaintiffs' narrow construction of "tapered shape" is contrary to black letter law. Specifically, in the litigation, Plaintiffs essentially assert that "tapered shape" should be limited to generally uniform changes in width "about a centerline" because the two "tapered" ***examples*** in the 278 figures allegedly fit their self-serving construction. That position is fundamentally flawed. *See, e.g.*, *Bomtech Elecs., Co. v. Medium-Tech Medizingerate Gmbh*, 2014 WL 1651259, at *9 (PTAB 2014) ("It is axiomatic that claims typically are not limited to the disclosed embodiments."); *Advanced Cardiovascular Sys. v. Scimed Life Sys., Inc.*, 261 F.3d 1329, 1339 (Fed. Cir. 2001) ("Since nothing in the specification assigns significance to the fact that the drawings align the connecting elements parallel both to each other and to the stent's longitudinal axis, we will not allow this aspect of the drawings to be imported into the claims as a limitation."). For instance, if a specification generically references a "table," that term would not be narrowly limited to "round tables" simply because the sample table depicted in the specification figure was round. *See, e.g., Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1306-07 (Fed. Cir. 2003) ("[T]he mere fact that the patent drawings depict a particular embodiment of the patent does not operate to limit the claims to that specific configuration."). In any event, as noted above, if anything, the two ***examples*** depicted in the 278 figures suggest that "tapered shape" encompasses a variety of tapered shapes since the two examples

are different (e.g., the example in Figures 7 and 10 shows a change in width ***over the full length*** of the diagonal sections while the example in Figures 8 and 9 shows a change in width of ***over a short portion at the ends***).

In sum, "tapered shape" means "a shape that transitions in width over a length." (*See generally* Brown Decl. ¶¶55-73.)

VII. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE 278 PATENT IS UNPATENTABLE

Petitioner seeks review of claims 2-5 of the 278 patent. Claim 2 is an independent claim. Claims 3-5 depend from claim 2.

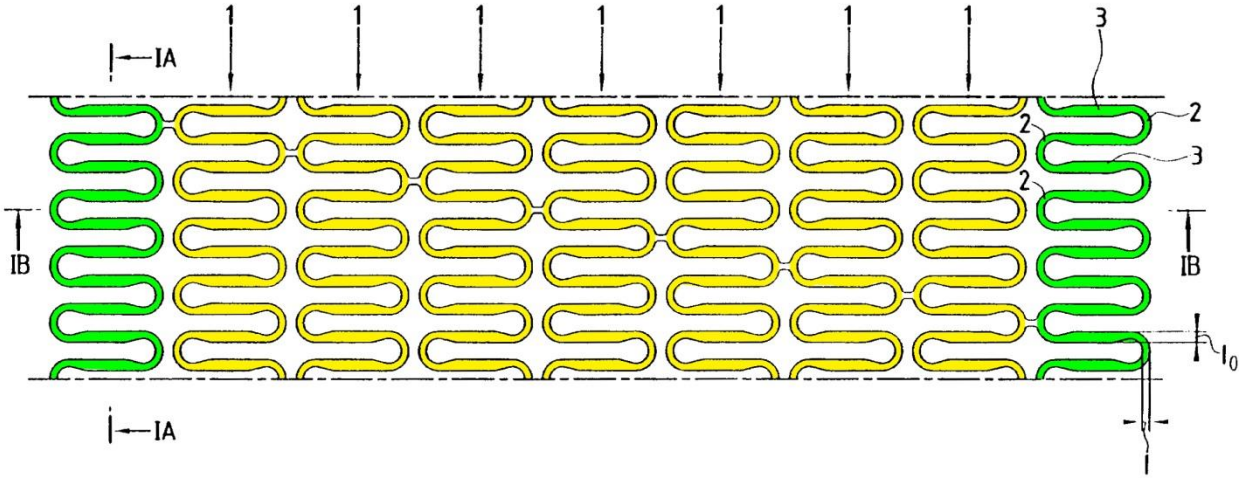
A. Ground 1: Hilaire Anticipates Claims 2, 4, And 5

Hilaire (Ex. 1003) is a PCT application that published on December 30, 1998. It therefore constitutes prior art under 35 U.S.C. §102(b). Hilaire was not disclosed or cited during the 278 prosecution.

Like the 278 patent, Hilaire is directed to thin-walled "expandable tubular" stents for use in body passages such as blood vessels. (*Id.* at Abstract, 1:1-15, 2:14-24, 4:20-23, claim 1.) Hilaire's stents can have uniform thickness (*id.* at 6:10-15, Fig. 1A, 3:15-16, 4:15-23) or varied thickness (*id.* at 6:16-19, Fig. 2A).

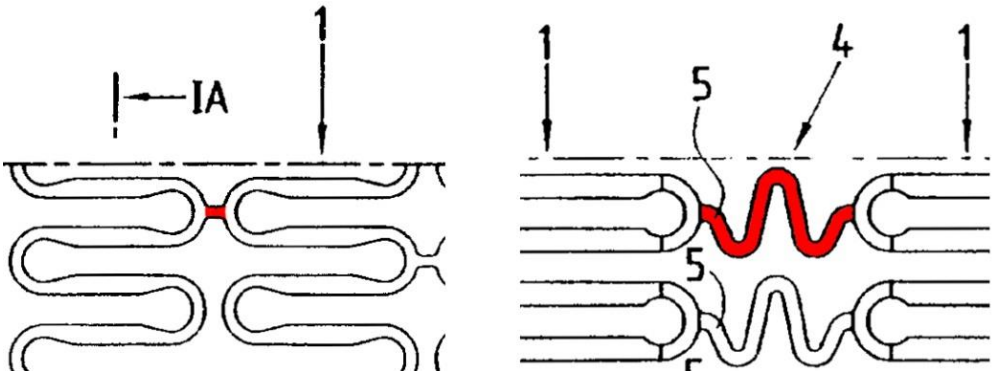
Hilaire's stents have a multiplicity of "zigzag" circumferential sets of strut members which Hilaire calls "tubular elements." (*Id.* at 3:28-35, Figs. 1-2 (item 1), Abstract, 2:14-24.) Each "tubular element" forms a closed cylindrical portion of the stent. (*Id.*) Using Figure 1 as an example, Hilaire's stents have end sets of

strut members (highlighted in green) and central sets positioned between the end sets (highlighted in yellow):

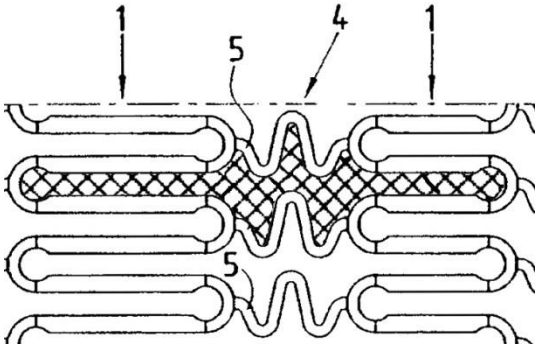


(*Id.* at Fig. 1.)

As shown in Figures 1 and 2, Hilaire's sets of strut members or "tubular elements" are longitudinally separated from each other. (*See also id.* at 3:28-32 ("a plurality of tubular elements ... aligned along a common longitudinal axis ..."), Abstract (same).) Each pair of adjacent tubular elements is spaced apart by a "plurality" of longitudinally extending links which Hilaire calls "linking members." (*Id.* at 3:28-32, Abstract, 2:14-24.) Hilaire discloses that the linking members "can have a very wide variety of configurations." (*Id.* at 5:3-4.) For instance, they can be straight (e.g., Fig. 1), or more preferably, bent with a "zigzag" shape (e.g., item 4 in Fig. 2). (*Id.* at 5:7-16.) Sample longitudinally extending "linking members" from Figures 1 and 2 are highlighted in red below:



(*Id.* at Figs. 1 & 2 (excerpts).) Hilaire's combination of "tubular elements" spaced apart by "linking members" results in a stent having multiple cells, an example of which is cross-hatched below using Figure 2 of Hilaire as an example:

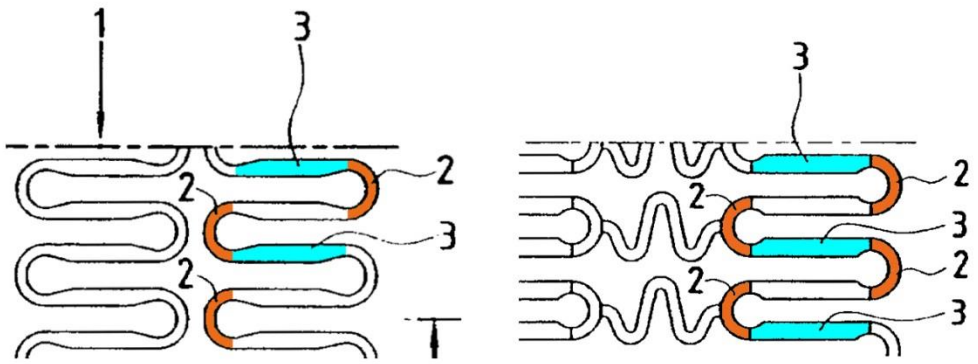


(*Id.* at Fig. 2 (excerpt).)

As shown in Figures 1 and 2, and described in the specification, Hilaire's circumferential sets of strut members (or "tubular elements") comprise a multiplicity of connected curved sections (which Hilaire calls "bent portions" or "bent extreme portions") and diagonal sections (which Hilaire calls "rectilinear portions" or "rectilinear intermediate portions"). (*Id.* at 3:33-35, 1:20-23, 2:14-24, Abstract; Brown Decl. ¶87.) For example, Hilaire states:

> Each tubular element 1 consists of a strip forming a zigzag corrugation defining ***bent extreme portions 2*** which are successively connected together in pairs in opposite directions by ***rectilinear intermediate portions 3***.

(Ex. 1003 at 3:33-35.) Sample curved sections (labeled 2 and highlighted in orange) and diagonal sections (labeled 3 and highlighted in blue) are shown in excerpts from Figures 1 and 2 of Hilaire below:



Like the diagonal sections in the 278 patent, Hilaire's "rectilinear portions" always spread out at an angle to the stent's longitudinal axis when the stent expands. (*See, e.g.*, Brown Decl. ¶87.)[9]

[9] Like the 278 specification, Hilaire teaches that the above-described basic stent structure was already known in the art, including (a) longitudinally separated end sets and central sets of circumferential strut members ("tubular elements"); (b) curved sections ("bent portions"); (c) diagonal sections ("rectilinear portions"); and

Lastly, in both the end sets and central sets of strut members, Hilaire's diagonal sections have a tapered shape wherein the width at the center is different than the width at either end (i.e., 278 claim 2). Specifically, the width at the center is greater (i.e., 278 claims 4 and 5). For instance, Hilaire describes one example wherein the diagonal sections ("rectilinear portions") have the same thickness but greater width than the curved sections ("bent portions"). (Ex. 1003 at 4:20-23 (thickness of rectilinear and bent portions is 0.15 mm, while width of rectilinear and bent portions is 0.15 mm and 0.10 mm, respectively).) Consistent with elementary design principles and a POSA's common sense, Hilaire then broadly teaches that, in all embodiments (uniform and non-uniform thickness), the diagonal sections should be tapered – ***without restriction as to the shape of the taper, e.g., one-sided or two-sided*** – to avoid stent fractures:

> According to one particular characteristic common to both embodiments of the invention, ***the ... width transitions between the rectilinear portions 3 and bent portions 2 will be gradual*** in order to avoid the formation of an incipient fracture.

(*Id.* at 4:34-5:2; *see also id.* at claim 5; Brown Decl. ¶¶54 (fourth bullet), 89; Exs. 1034-36.) Beyond the text, Hilaire depicts two ***sample*** stents having tapered

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(d) a plurality of longitudinally extending links ("linking members"). (Ex. 1003 at 1:10-33; Brown Decl. ¶88.)

diagonal sections (highlighted in blue) wherein the width at the center is greater than the width at either end:

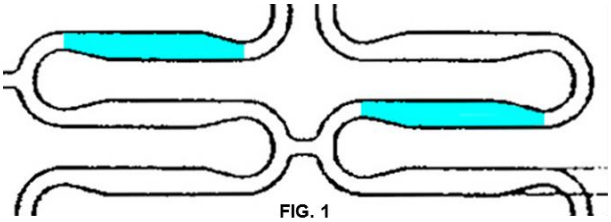


FIG. 1

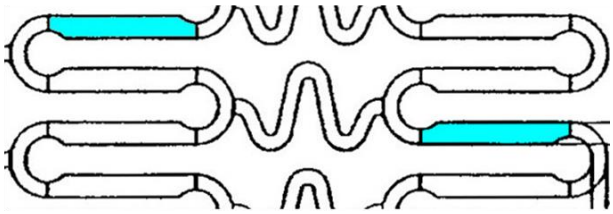
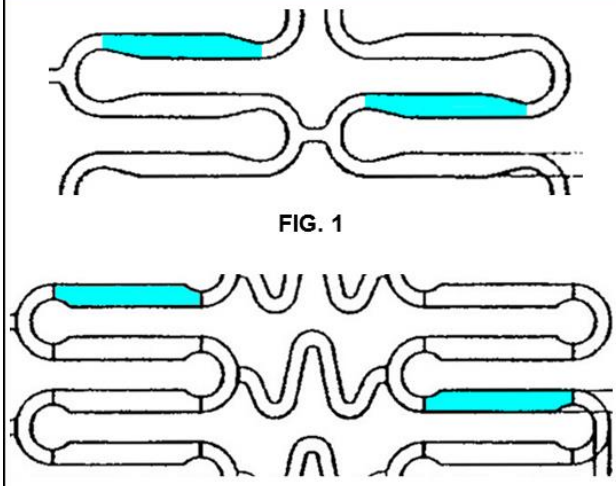
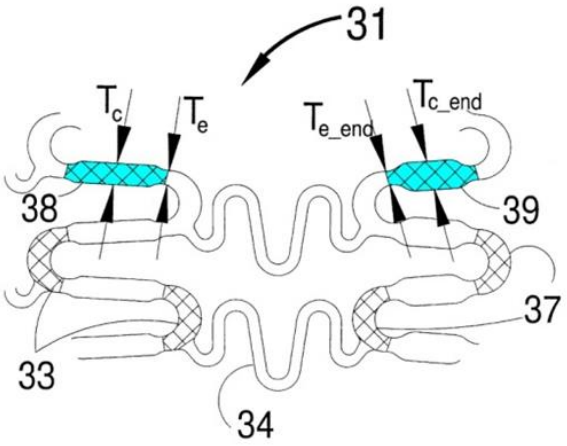


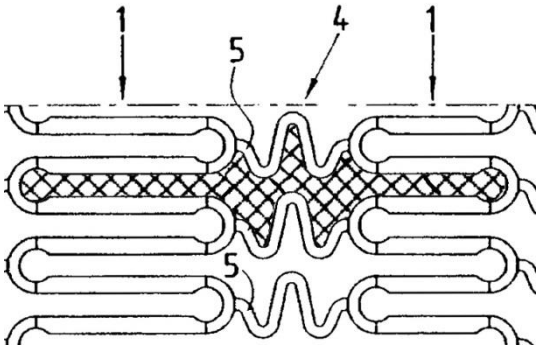
FIG. 2

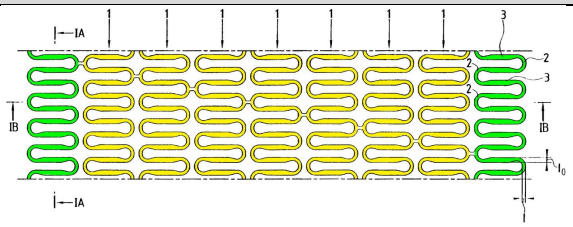
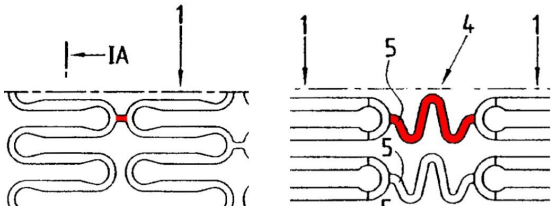
(Ex. 1003 at Figs. 1 & 2 (excerpts).) A side-by-side comparison of these sample prior art tapered diagonal sections with sample diagonal sections from the 278 patent that are described as "tapered" highlights their similarity and lack of any relevant difference:

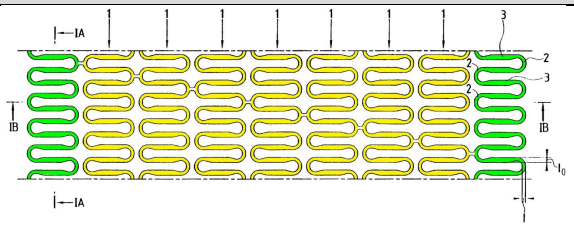
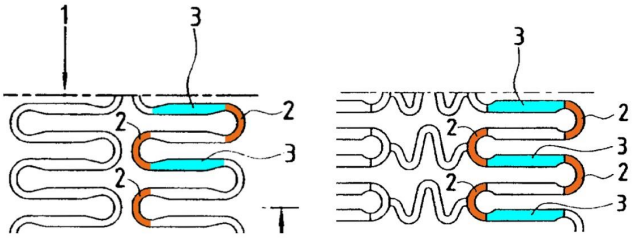
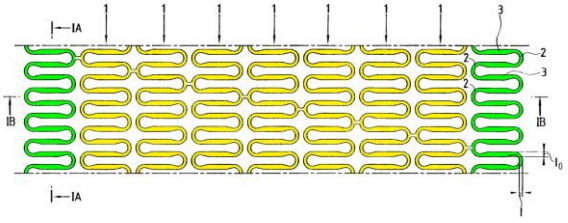
HILAIRE	278 PATENT
 FIG. 1 FIG. 2	 FIG. 9

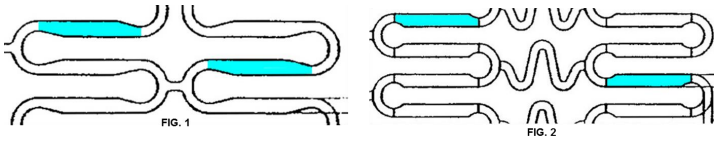
According to Hilaire, its stent design addresses a known problem in the art, i.e., non-uniform stent expansion and poor distribution of radial forces on the stent after expansion. (*Id.* at 1:34-2:24.)

In short, as shown above, and as further shown and summarized by exemplary cites in the claim chart below (as well as in the Brown declaration at ¶¶80-92), Hilaire anticipates claims 2, 4, and 5 of the 278 patent.

278 Patent	Hilaire (Ex. 1003)
2[a]. A stent in the form of a thin-walled, multi-cellular, tubular structure	Abstract ("expandable tubular device"); 3:28-32 ("tubular body" defined by a plurality of tubular elements connected by a plurality of linking members that form multiple cells); 2:14-24 (same); 4:20-23 (thin-walled); 6:10-15; 1:1-23 (known in prior art); Claim 1; Figs. 1-2 (*see* sample cross-hatched cell from Fig. 2 excerpt below);  *See also* Brown Decl. ¶¶81, 86, 92
[2b] having substantially uniform thickness throughout the length of the tubular structure,	Figs. 1-1B (showing uniform thickness); 3:7-18 (figure description); 6:10-15 (making stent from tube with "constant thickness"); 4:15-23 (uniform thickness example); 6:23-24 (making stent from sheet "of approximately constant thickness"); 1:16-23 (known in prior art); *see also* Brown Decl. ¶¶81, 92
[2c] a [sic] the stent comprising a multiplicity of circumferential sets of strut members,	Abstract ("assembly of ***tubular elements*** aligned along a common longitudinal axis"); 3:28-32 (same); 2:14-24 (same); Claim 1; 1:16-23 (known in prior art); Figs 1-2 (item 1, *see* green and yellow highlighting below):

278 Patent	Hilaire (Ex. 1003)
	 *See also* Brown Decl. ¶¶82, 84, 88, 92
[2d] each of the strut members being substantially the same thickness,	*See* citations in this chart for element [2b]
[2e] each set of strut members being longitudinally separated each from the other and	*See* citations in this chart for element [2c]
[2f] connected each to the other by one or more longitudinally extending links,	Abstract (adjacent tubular members joined by a "plurality of ***linking members***"); 3:28-32 (same); 2:14-24 (same); 5:3-16 (linking members "can have a very wide variety of configurations"); Claims 1 & 7-8; 1:16-23 (known in prior art); Figs 1-2 excerpts (*see* red highlighting below):  *See also* Brown Decl. ¶¶85, 92
[2g] each set of strut members forming a closed, cylindrical portion of the stent,	Abstract ("***tubular elements***"); 3:28-32 (same); 2:14-24 (same); Claim 1; 1:16-23 (known in prior art); Figs 1-2 (item 1, *see* green and yellow highlighting below):

278 Patent	Hilaire (Ex. 1003)
	 *See also* Brown Decl. ¶¶82, 92
[2h] each set of strut members comprising a multiplicity of connected curved sections and diagonal sections,	3:33-35 ("Each tubular element 1 consists of a strip forming a zigzag corrugation defining ***bent extreme portions 2*** which are successively connected together in pairs in opposite directions by ***rectilinear intermediate portions 3***."); Abstract (same); 2:14-24 (same); Claim 1 (same); Figs. 1-2 excerpts (sample curved sections labeled 2 and highlighted orange; sample diagonal sections labeled 3 and highlighted blue):  *See also* Brown Decl. ¶¶87-88, 92
[2i] the sets of strut members including end sets of strut members located at each end of the stent and central sets of strut members positioned between the end sets of strut members,	3:28-32; Claim 1; Figs. 1-2 (*see, e.g.*, end sets highlighted green and central sets highlighted yellow below):  *See also* Brown Decl. ¶¶83, 92
[2j] the diagonal sections of the central	4:34-5:2 ("***[T]he ... width transitions between the rectilinear portions 3 and the bent portions 2 will be***

278 Patent	Hilaire (Ex. 1003)
sets of strut members have a center and two ends, at least one of the diagonal sections of the central sets of strut members having a tapered shape wherein the width of the at least one diagonal section is different at the center of the diagonal section as compared to the width at either end of that diagonal section.	***gradual*** in order to avoid the formation of an incipient fracture."); 4:20-23 (width of rectilinear portion is greater than bent portion); Claims 1, 2 (width of rectilinear portion is greater than bent portion), & 5 (change in width is gradual); Figs. 1-2 excerpts (*see* blue highlighting):  FIG. 1 FIG. 2 *See also* Brown Decl. ¶¶89-92
4. The stent of claim 2 wherein the width of the at least one diagonal section is greater at the center of that diagonal section as compared to the width at either end of that diagonal section.	*See* citations in this chart for element [2j]
5. [T]he stent of claim 2 wherein the diagonal sections of the end sets of strut members have a center and two ends, at least one of the diagonal sections of the end sets of strut members has a tapered shape wherein the width of the at least one diagonal section is greater at the center of the diagonal section as compared to the width at	*See* citations in this chart for element [2j]

278 Patent	Hilaire (Ex. 1003)
either end of that diagonal section.	

B. Ground 2: Hilaire In View Of A POSA's Knowledge Or Rolando Renders Obvious Claims 2, 4, And 5

As shown above, Hilaire plainly anticipates claims 2, 4, and 5 of the 278 patent. To the extent any limitation of claims 2, 4, and 5 is not disclosed in Hilaire, those claims would have been obvious at the time of the alleged inventions at least in view of a POSA's knowledge or Rolando. (Brown Decl. ¶¶93-105.) In particular, in the pending litigation, the only limitation alleged by Plaintiffs to be missing from Hilaire is the claimed diagonal section(s) having a "tapered shape" that is wider at the center than at either end. (Ex. 1027 (Plaintiffs' Invalidity Contention Responses) at 1467, 1477, 1487, 1499-500 (characterizing the Hilaire "600" publication); Brown Decl. ¶94.) Plaintiffs' assertion appears to be based on Plaintiffs' erroneous proposed construction of "tapered shape" (which would arbitrarily limit that term to a narrow subset of tapered shapes having a generally uniform change in width "about a centerline"). Although Plaintiffs' assertion is wrong (as previously shown in §VI), Petitioner addresses it in these obviousness combinations out of an abundance of caution.

In *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), the Supreme Court mandated an "expansive and flexible" obviousness approach. *Id.* at 1739. The

Court was particularly concerned with patents that merely combined prior art elements with no unexpected results. *Id.* Under the Supreme Court's expansive and flexible approach, the reason(s) to combine references can come from a variety of sources, including the specific prior art references, the prior art collectively, known needs or problems in field, a POSA's knowledge and common sense, substituting one known element for another to achieve predictable results, etc. *See, e.g.*, *id.* at 1742-43.

Here, claims 2, 4, and 5 would have been obvious in view of Hilaire in combination with a POSA's knowledge. As explained in Section V, *supra*, tapered stent diagonal sections – wherein the width at the center is different (greater or less) than either end – were well known in the art as reflected by the prior art mosaics repeated below:

SAMPLE TAPERED DIAGONAL SECTIONS FROM PRIOR ART

HILAIRE (Ex. 1003)

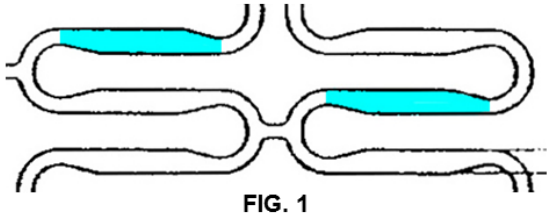


FIG. 1

FIG. 2

COX (Ex. 1005)

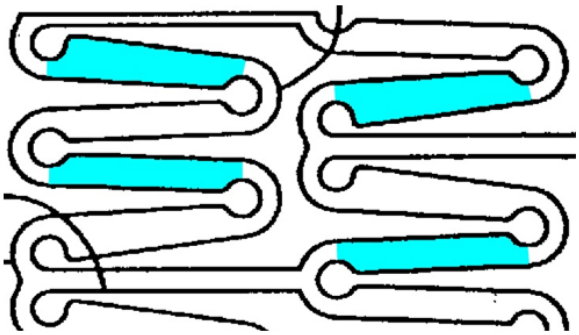


FIG. 5

DUERIG-BURPEE (Ex. 1006)

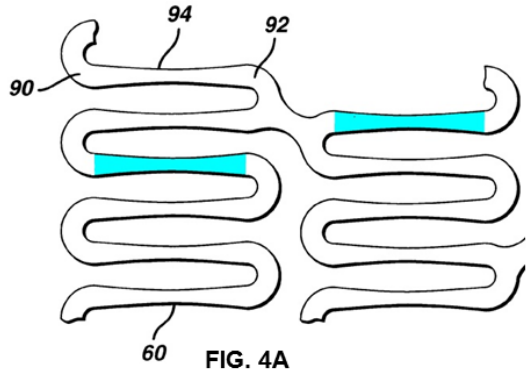


FIG. 4A

ROLANDO (Ex. 1007)

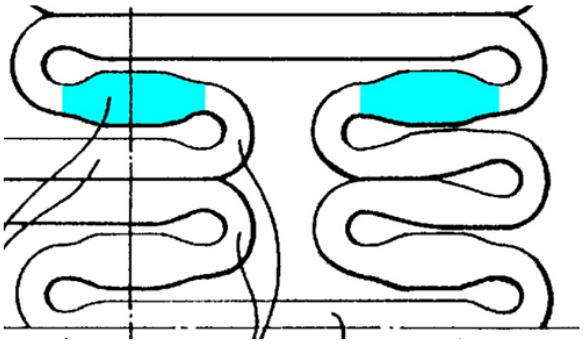


FIG. 4

SAMPLE TAPERED DIAGONAL SECTIONS FROM OTHER PRIOR ART

SEAQUENCE (Ex. 1009)

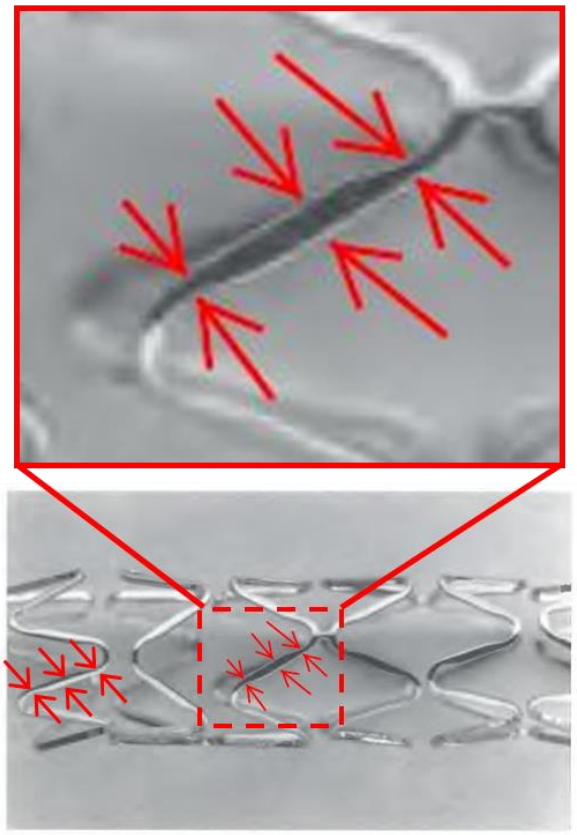


Figure 2.18: An expanded Seaquence stent showing variable width of the stent struts.

(p. 46)

BX STENT (Ex. 1011)

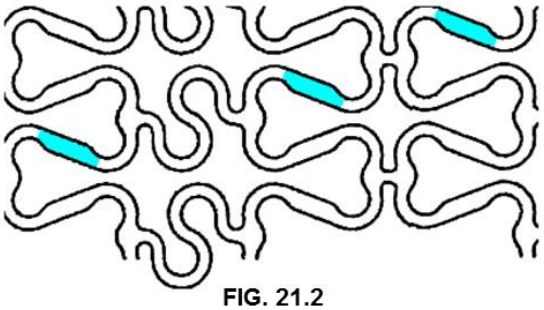


FIG. 21.2

USPN 5,913,895 (Ex. 1008)

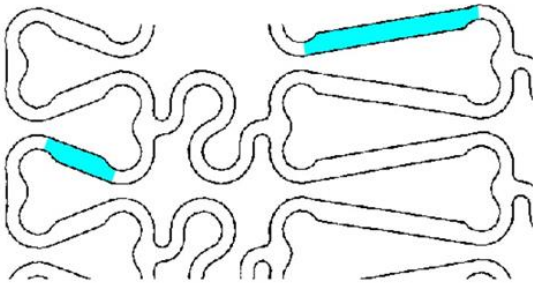


FIG. 1

USPN 6,312,459 (Ex. 1004)

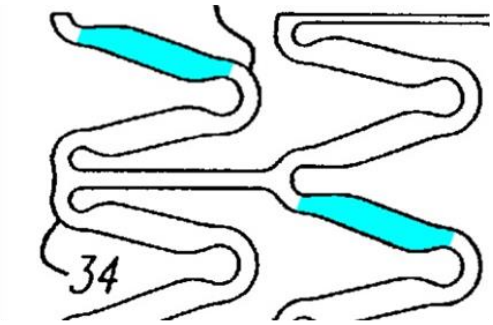


FIG. 7

USPN 6,042,606 (Ex. 1012)

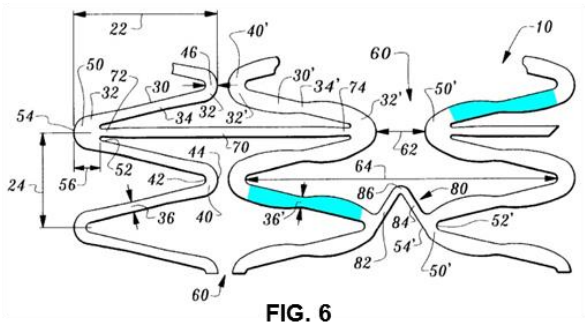


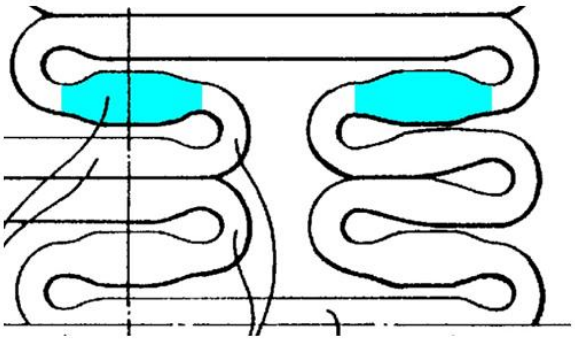
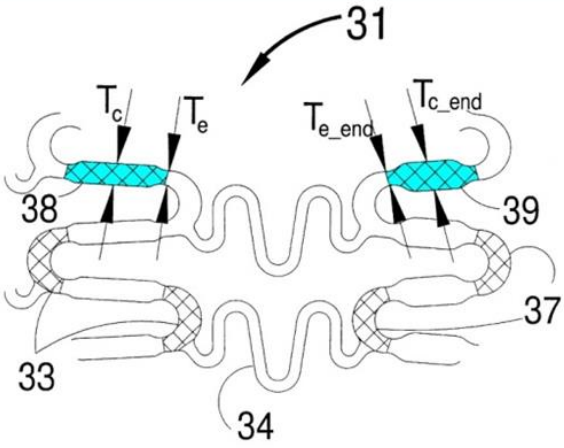
FIG. 6

As shown, known examples included tapered diagonal sections ***with generally uniform changes in width "about a centerline"*** (e.g., Rolando, Duerig-Burpee, etc.). POSAs also knew many reasons ***why*** it would have been desirable to incorporate such tapered designs into Hilaire (e.g., desired stent radiopacity, uniform stent expansion, favorable distribution of radial forces, etc.). (Brown Decl. ¶¶54, 96; §V, *supra*.) Indeed, Hilaire itself identifies the known problem of stent fracturing that can be avoided by tapering the diagonal section width (without restriction as to the shape of the taper). (Ex. 1003 at 4:34-5:2.) By teaching the use of tapered diagonal sections generally, Hilaire alone provides motivation to incorporate into Hilaire specific tapered diagonal sections known to POSAs as those too would reasonably be expected to achieve the advantage taught by Hilaire. (Brown Decl. ¶¶96-97.) Moreover, at most, the combination of Hilaire with a POSA's knowledge involves the simple substitution of one known exemplary diagonal section shape for another to obtain predictable results. (*Id.* ¶97.) Claims 2, 4, and 5 especially cannot be considered inventive over this combination given that the 278 patent ***says nothing*** about the alleged significance of one tapered shape (e.g., two-sided taper with generally uniform changes in width "about a centerline") versus another (e.g., one-sided taper). (*Id.* ¶¶35, 98.)

Claims 2, 4, and 5 likewise would have been obvious in view of Hilaire in combination with Rolando (Ex. 1007). (Brown Decl. ¶¶99-105.) Rolando is

entitled "Angioplasty Stents," i.e., the same field as Hilaire. Rolando issued on October 30, 2001, with a filing priority of November 4, 1997. It therefore is prior art under 35 U.S.C. 102(e). Rolando was not disclosed or cited during the 278 prosecution.

Rolando specifically teaches tapered diagonal sections – which Rolando calls "arms" or "arm sections" – wherein the width is greater at the center as compared to either end. (*See, e.g.*, Ex. 1007 at Fig. 4.) Further, Rolando's diagonal sections have generally uniform changes in width about a centerline. (*Id.*) Rolando teaches using such tapered diagonal sections in both the end sets and central sets of strut members. (*Id.*) Here is a side-by-side comparison of Rolando's tapered diagonal sections in an excerpt from Figure 4 with sample diagonal sections from the 278 patent that are described as "tapered" (i.e., they are essentially identical):

ROLANDO	278 PATENT
 FIG. 4	 FIG. 9

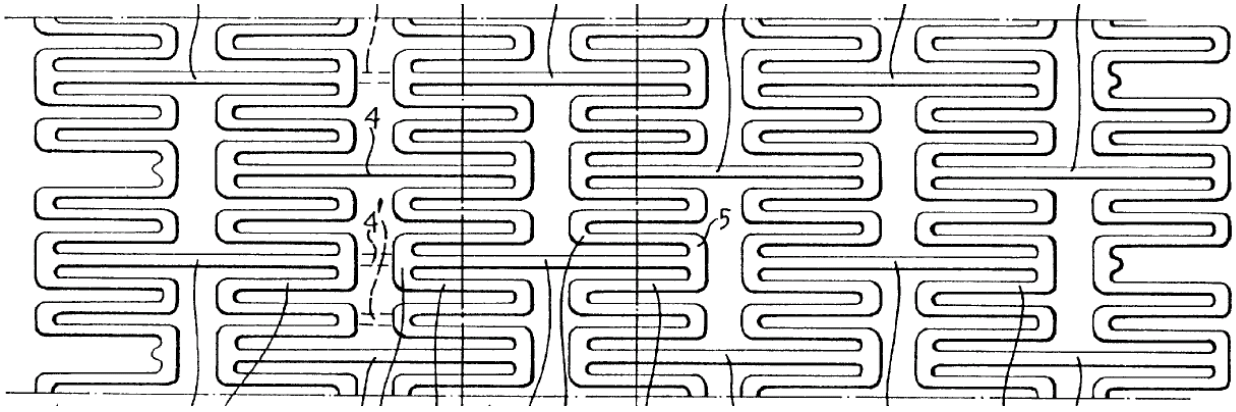
Notably, Rolando teaches that the wider tapered diagonal section shape provides for a more uniform load distribution – similar to one of the goals highlighted in Hilaire (thus supporting their combination):

> By virtue of their flattened shape the arms 6 expose a wider surface to the wall of the lumen supported by the stent in its radially expanded condition. The wall of the lumen is therefore subjected to a distributed load preventing the formation of concentrated stress regions.

(*Id.* at 9:65-10:2; Ex. 1003 (Hilaire) at 2:8-13 (invention seeks to provide, *inter alia*, "a good distribution of the radial forces" after stent expansion).) Rolando further teaches that its tapered diagonal sections (or "arm sections") can be used in stents with varied thickness (as in Figure 4) or with stents having uniform wall thickness that are laser cut from a tube, e.g., as shown in Figures 1-3. (Ex. 1007 at

9:65-10:15, Figs. 1-3, 4:13-21 (laser cutting), claim 2 (same); Brown Decl. ¶102.)

Figure 3 of Rolando depicts a well-known, basic stent design:



(Ex. 1007 at Fig. 3; Brown Decl. ¶102.) Claim 9 of Rolando – which depends from claim 1 – captures the above concept for stents having uniform wall thickness. (Ex. 1007 at claims 1 & 9; Brown Decl. ¶¶103-04; *see also* Ex. 1007 at claim 2 (stent of claim 1 can be laser cut from a tube).)

Given that (1) Hilaire teaches using tapered diagonal sections generally that are wider at the center as compared to either end, (2) Rolando teaches a specific example of such a tapered diagonal section that has a generally uniform change in width about a centerline, and (3) Hilaire and Rolando teach analogous reasons for using such tapered diagonal sections, it would have been obvious to a POSA to combine Hilaire with Rolando in the manner recited in claims 2, 4, and 5 of the 278 patent with a reasonable expectation of success. (Brown Decl. ¶105.) Moreover, at most, the combination of Hilaire and Rolando involves the simple

substitution of one known exemplary diagonal section shape (e.g., Figure 1 of Hilaire) for another (e.g., Figure 4 of Rolando) to obtain predictable results. (*Id.*)

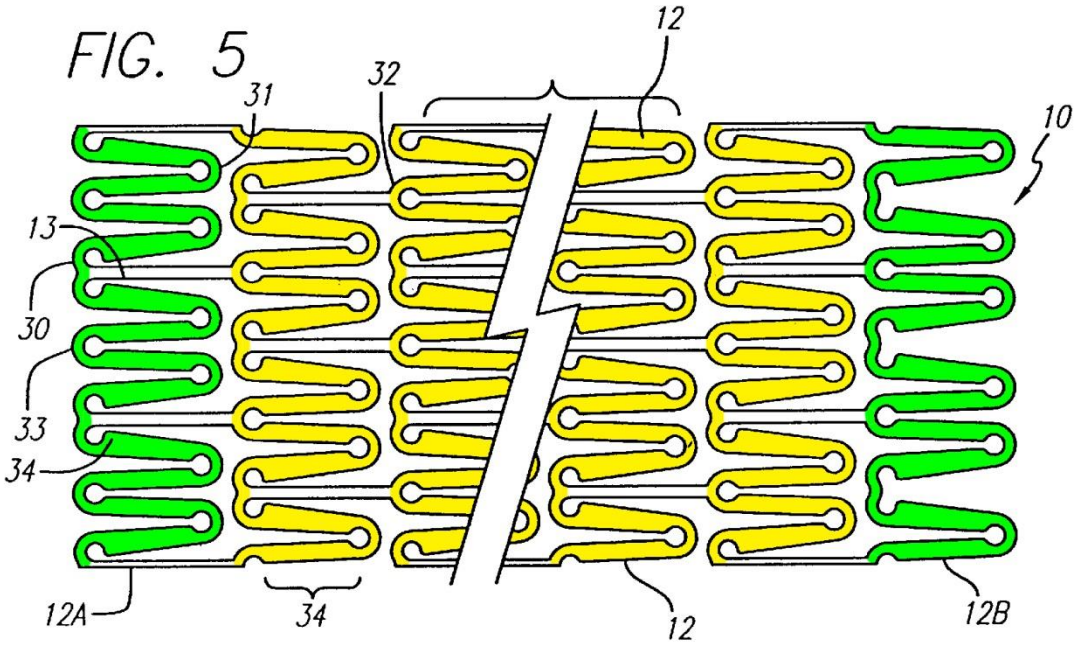
C. Ground 3: Cox Anticipates Claims 2-5

Cox (Ex. 1005) is a U.S. patent entitled "Stent Design With End Rings Having Enhanced Strength And Radiopacity." It issued on April 1, 2003, with a filing priority of August 31, 1999. Cox therefore constitutes prior art under 35 U.S.C. §102(e). Cox was not disclosed or cited during the 278 prosecution, but a related WO publication (WO 01/15632) was one of the 115+ references submitted via IDSs. That related publication was never discussed by the examiner nor applied in any rejections during the 278 prosecution.

Like the 278 patent, Cox "relates to expandable endoprosthesis devices, generally called stents ...." (*Id.* at 1:7-10.) Such stents "are generally cylindrically shaped devices ...." (*Id.* at 1:17-20, Abstract.) Cox's stents preferably are made by laser cutting a "thin-walled tubular member" having a uniform thickness. (*Id.* at 13:5-39, 9:52-56 ("Given a stent having a constant thickness ...."), 12:50-54.)

Cox's stents have a multiplicity of "serpentine" circumferential sets of strut members which Cox calls "cylindrical elements." (*See, e.g., id.* at 4:25-32 ("[The] stents of the present invention include a plurality of adjacent cylindrical elements (also known as or referred to as 'rings') ...."), Abstract, 7:45-49, Fig. 4 (item 22), Fig. 5 (items 12, 12A, and 12B), claims 1-16.) Each "cylindrical element" forms a

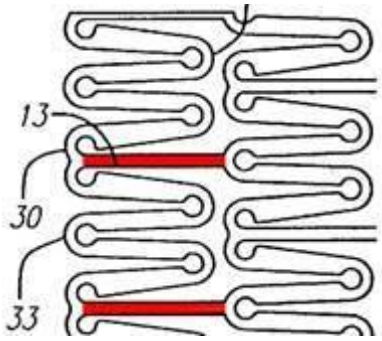
closed cylindrical portion of the stent. (*Id.*) Using Figure 5 as an example, Cox's stents have end sets of strut members (labeled 12A and 12B and highlighted in green) and central sets positioned between the end sets (labeled 12 and highlighted in yellow):



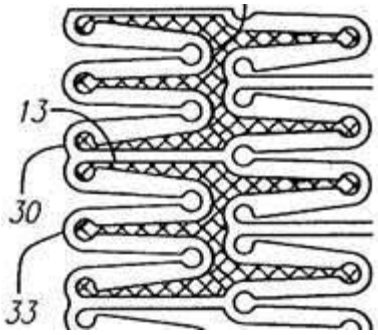
(*Id.* at Fig. 5.)

As shown in the figures, Cox's sets of strut members or "cylindrical elements" are longitudinally separated from each other. (*See also id.* at 4:25-29 (cylindrical elements are "arranged in alignment along a longitudinal stent axis"), Abstract, 5:28-35, claim 8.) Each pair of adjacent cylindrical elements is spaced apart by one or more longitudinally extending links which Cox calls "interconnecting members." (*Id.* at Abstract, 4:32-34, 5:6-8 (number and location of interconnecting members can be varied as desired), Figs. 1-3 & 5-6 (item 13),

Fig. 4 (item 23), claims 1-16 ("plurality of interconnecting members").) Examples of "interconnecting members" are highlighted in red below (labeled 13 in Figure 5):



(*Id.* at Fig. 5 (excerpt).) Cox's combination of "cylindrical elements" spaced apart by "interconnecting members" results in a stent having multiple cells, examples of which are cross-hatched in the following excerpt from Figure 5:



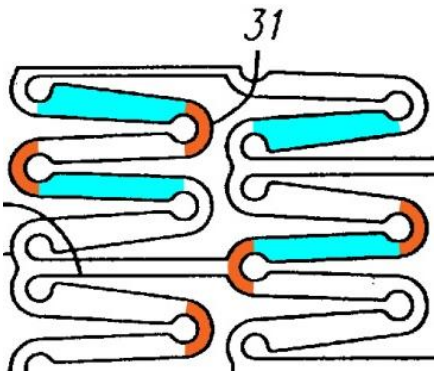
(*Id.* (excerpt).)

As shown for example in Figure 5, and described in the specification, Cox's circumferential sets of strut members (or "cylindrical elements") comprise a multiplicity of connected curved sections (which Cox calls, e.g., "peaks and

valleys" or "peak portions and valley portions") and diagonal sections (which Cox generally calls "linking portions"). For example, claim 8 of Cox states:

> [T]he plurality of adjacent cylindrical elements [contain] alternating ***valley portions and peak portions*** with ***linking portions*** interconnecting said valley portions and peak portions ....

(*Id.* at claim 8; *see also id.* at 9:27-30 (prior art stent in Figure 4 has "linking portions 28 which extend between and connect the peak portions and valley portions on the cylindrical element 22."), 10:10-13 (similar description of Figs. 5-6), 12:21-24.) Sample curved sections (highlighted in orange) and diagonal sections (highlighted in blue) are shown in the Figure 5 excerpt below:



(*Id.* at Fig. 5 (excerpt).)[10]

[10] Like the 278 specification and Hilaire, Cox teaches that the above-described basic stent structure was already well known in the art (indeed, Cox depicts a "typical" prior art stent in Figure 4 and incorporates many prior art stent patents by

Lastly, in both the end sets and central sets of strut members in preferred embodiments, Cox's diagonal sections have a tapered shape wherein the width at the center is different than the width at either end (i.e., 278 claim 2). Specifically, the width at the center can be wider (i.e., 278 claims 4 & 5) or narrower (i.e., 278 claim 3).

A wider-at-the-center embodiment is depicted in Figures 5-6 and described in Cox's Abstract, specification, and claims. (Ex. 1005 at Figs. 5-6, 4:14-17, 10:23-26, 11:10-14, 11:60-64, Abstract, claims 1-2 & 8-9; Brown Decl. ¶¶116-17.) For example, dependent claim 9 requires:

> The stent of claim 8, wherein each of said cylindrical elements has linking portions [i.e., diagonal sections] having strut widths which are ***wider*** than the strut widths of the valley portions and peak portion[s] [i.e., curved sections] of said cylindrical element[s].

(Ex. 1005 at claim 9.) Consistent with elementary design principles and a POSA's common sense, POSAs reading Cox would understand that the wider "linking portion" diagonal sections smoothly transition to the narrower width of the

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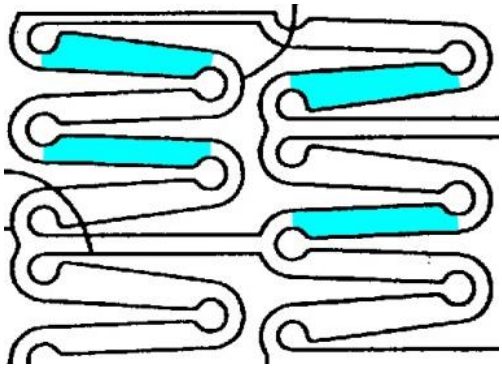
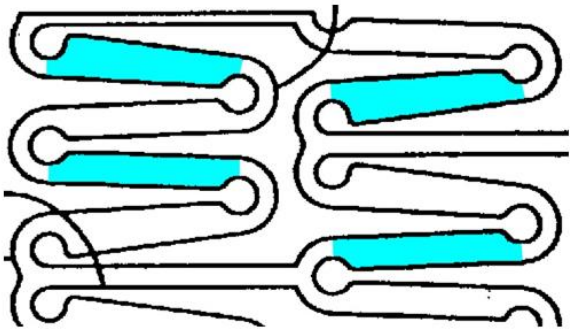
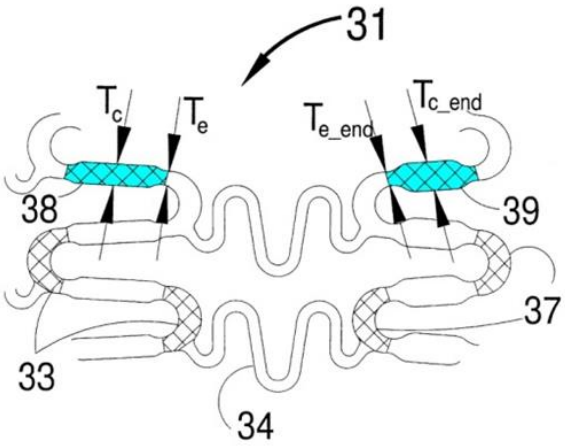
reference). (*Id.* at Fig. 4, 9:6-41 (describing the "typical" prior art stent in Figure 4), 1:54-67; Brown Decl. ¶114.)

"peak/valley" curved sections.[11] (Brown Decl. ¶¶116, 54 (fourth bullet).) This is confirmed, for instance, by the following ***examples*** of Cox's tapered diagonal sections depicted in Figure 5 (highlighted in blue):



(Ex. 1005 at Fig. 5 (excerpt).) The above diagonal sections have two different shapes – one with a one-sided taper at each end of the diagonal section (lower two examples in blue) and one that additionally generally tapers along the full length of the diagonal section (upper two examples in blue). A side-by-side comparison of these examples from Cox with sample diagonal sections from the 278 patent that are described as "tapered" highlights their similarity and lack of any relevant difference:

[11] And like Hilaire, Cox nowhere restricts the shape of the width transition (e.g., symmetrical two-sided vs. non-symmetrical one-sided).

COX	278 PATENT
 FIG. 5	 FIG. 9

Cox also describes a narrower-at-the-center embodiment. (*Id.* at Abstract, 11:57-12:4, 4:17-21, 5:40-44, 6:31-35; *see also id.* at Figs. 10-11, 7:14-18, 12:5-37.) For example, the Abstract states:

> If a high radiopaque material is utilized and reduced radiopacity is desired, the width of the strut in the low stress region of the stent [i.e., "linking portion" diagonal section] can be designed to be ***narrower*** than the strut width in the high stress regions [i.e., "peak/valley" curved sections].

(*Id.* at Abstract.) Again, POSAs would understand that the narrower "linking portion" diagonal sections smoothly transition to the wider "peak/valley" curved sections. (Brown Decl. ¶118; *see also, e.g.*, Ex. 1005 at Figs. 10-11.)

Beyond describing and depicting the anticipating designs, Cox discloses multiple reasons for the designs (***including the same reasons disclosed in the 278 patent***). For instance, consistent with a POSA's common knowledge, Cox

explains that a stent should have an appropriate amount of radiopacity (e.g., so the stent can be adequately seen under fluoroscopy). (Ex. 1005 at 3:40-44; Brown Decl. ¶54.) Cox also explains that, "[g]enerally, stents having wider struts are more radiopaque than stents with narrower struts." (Ex. 1005 at 2:50-52.) Then, like the 278 patent, Cox teaches ***widening or narrowing*** the diagonal sections (i.e., the low stress regions of the cylindrical elements) to achieve the desired radiopacity:

> The present invention also relates to the control of the radiopacity of a stent by varying the strut geometry along the stent. By making the width of the strut either ***wider or narrower*** in different regions of the stent, the properties of the stent can be customized for a particular application ***in order to achieve the desired amount of strength and radiopacity for the stent***. ... The regions of the cylindrical element between the peaks and valleys generally form the low stress regions of the stent which do not experience high stresses and strains during radial expansion, thus allowing ***the width of the stent in these regions to be varied in order to increase or decrease the radiopacity of the stent***, as needed ....

(*Id.* at 3:64-4:3, 4:52-58; *see also id.* at 4:12-15 (same), 6:32-35 (same), 5:40-44 (same), 11:57-60 (same), Abstract (same).) Thus, for example, if increased radiopacity is desired, the diagonal sections can be widened. (*Id.* at 4:14-17, 10:23-26, 11:10-14, 11:60-64, Abstract, claims 1-2.) Alternatively, if reduced

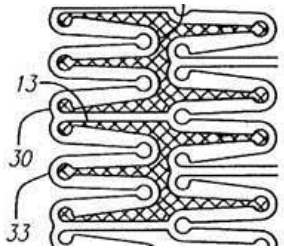
radiopacity is desired, the diagonal sections can be narrowed. (*Id.* at 4:17-21, 11:64-12:4, Abstract; *see also generally* Brown Decl. ¶¶119-21.)

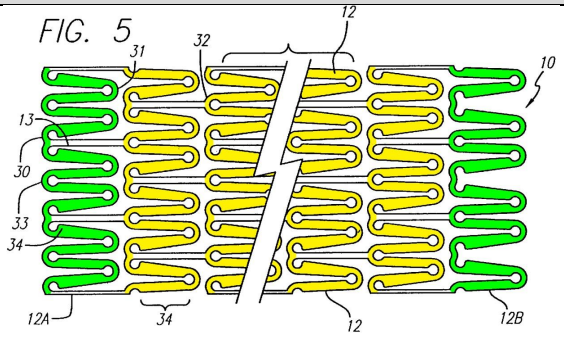
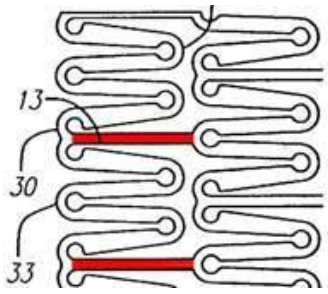
Consistent with a POSA's common knowledge at the time of the alleged 278 inventions, and as indicated in some of the Cox quotes above, Cox further teaches that the changes in width generally should be made in the diagonal sections – as opposed to the curved sections – because the diagonal sections are lower stress regions that are less susceptible to cracking during stent expansion:

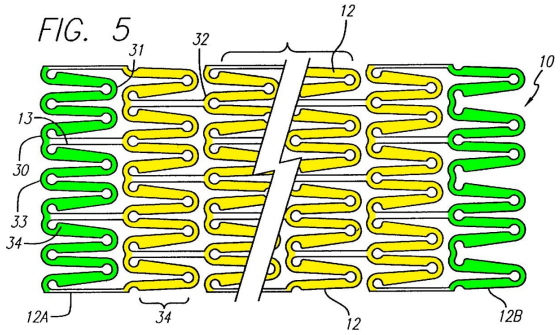
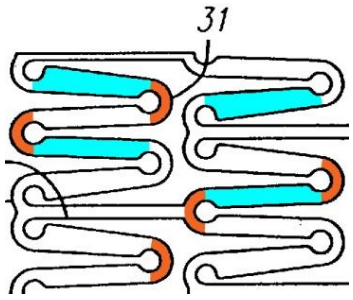
> [The] valleys and peaks constitute the aptly-named high stress regions of the stent which are susceptible to stress fractures during expansion. For this reason, the width of the strut in the peak and valley portions of the cylindrical element should remain relatively fixed and uniform so that high stresses will not be concentrated in any one particular region of the pattern, but will be more evenly distributed along the peaks and valleys, allowing them to expand uniformly. The regions of the cylindrical element between the peaks and valleys generally form the low stress regions of the stent which do not experience high stresses and strains during radial expansion …. An increase or decrease of the width of the strut in these low stress regions of the cylindrical element generally will not alter the overall mechanical properties of the stent.

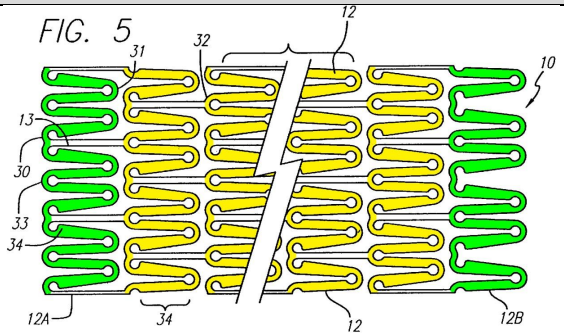
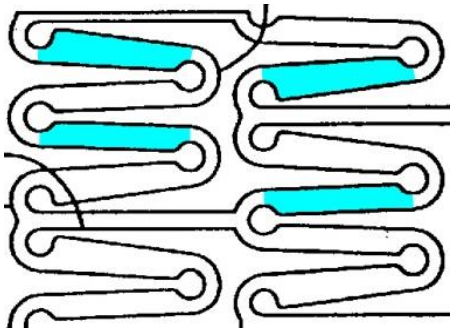
(Ex. 1005 at 4:44-65; *see also id.* at 9:56-10:28, 9:19-30, 2:50-56, 8:57-59, 4:4-24, claims 1-3; Brown Decl. ¶¶54, 122.)

In short, as shown above, and as further shown and summarized by exemplary cites in the claim chart below (as well as in the Brown declaration at ¶¶106-23), Cox anticipates claims 2-5 of the 278 patent.

278 Patent	Cox (Ex. 1005)
2[a]. A stent in the form of a thin-walled, multi-cellular, tubular structure	13:5-39 (stent made from "thin-walled tubular member"); Abstract (stent consists of a plurality of "cylindrical elements"); 1:17-20 (stents are "generally cylindrically shaped devices"); Figs. 1-3; Claims 1-16; Fig. 5 excerpt (*see* below – multiple cells);  *See also* Brown Decl. ¶¶107, 112, 123
[2b] having substantially uniform thickness throughout the length of the tubular structure,	13:5-39 (stent made from laser cutting a tube having a single thickness); 9:52-56 ("Given a stent having a constant thickness ...."); 12:50-54; *see also* Brown Decl. ¶¶107, 123
[2c] a [sic] the stent comprising a multiplicity of circumferential sets of strut members,	4:25-29 ("[The] stents of the present invention include a plurality of adjacent ***cylindrical elements*** (also known as or referred to as 'rings') ... arranged in alignment along a longitudinal stent axis."); Abstract; 7:45-49; 5:28-35; Claims 1-16; Fig. 4 (item 22); Fig. 5 (items 12, 12A, and 12B, *see* green and yellow highlighting below):

278 Patent	Cox (Ex. 1005)
	 *See also* Brown Decl. ¶¶108, 110, 123
[2d] each of the strut members being substantially the same thickness,	*See* citations in this chart for element [2b]
[2e] each set of strut members being longitudinally separated each from the other and	*See* citations in this chart for element [2c]
[2f] connected each to the other by one or more longitudinally extending links,	Abstract (cylindrical elements are "interconnected by one or more ***interconnecting members***"); 4:32-34; 5:6-8 (number and location of interconnecting members can be varied); Claims 1-16 ("plurality of interconnecting members"); Figs. 1-3 & 5-6 (item 13); Fig. 4 (item 23); Fig. 5 excerpt (*see* red highlighting below):  *See also* Brown Decl. ¶¶111, 123
[2g] each set of strut members forming a	Abstract ("cylindrical elements"); 4:25-29 ("[The] stents of the present invention include a plurality of

278 Patent	Cox (Ex. 1005)
closed, cylindrical portion of the stent,	adjacent ***cylindrical elements*** (also known as or referred to as 'rings') ...."); 7:45-49; Claims 1-16; Figs. 1-3; Fig. 4 (item 22); Fig. 5 (items 12, 12A, and 12B, *see* green and yellow highlighting below):  *See also* Brown Decl. ¶¶108, 123
[2h] each set of strut members comprising a multiplicity of connected curved sections and diagonal sections,	Claim 8 ("[T]he plurality of adjacent cylindrical elements ... containing alternating ***valley portions and peak portions*** [i.e., curved sections] with ***linking portions*** [i.e., diagonal sections] interconnecting said valley portions and peak portions ...."); 9:27-30 (prior art stent in Figure 4 has "linking portions 28 which extend between and connect the peak portions and valley portions of the cylindrical element 22."); 10:10-13 (similar description of Figs. 5-6); 12:21-24; Fig. 5 excerpt (*see* sample curved sections and diagonal sections highlighted orange and blue, respectively, below):  *See also* Brown Decl. ¶¶113, 123
[2i] the sets of strut members including end	Fig. 5 (end sets highlighted green and central sets highlighted yellow below):

278 Patent	Cox (Ex. 1005)
sets of strut members located at each end of the stent and central sets of strut members positioned between the end sets of strut members,	 *See also* Brown Decl. ¶¶109, 123
[2j] the diagonal sections of the central sets of strut members have a center and two ends, at least one of the diagonal sections of the central sets of strut members having a tapered shape wherein the width of the at least one diagonal section is different at the center of the diagonal section as compared to the width at either end of that diagonal section.	1. ***Width at center of tapered diagonal section (i.e., low stress region of the cylindrical element) can be greater or less than the width at either end:*** 3:64-4:3 & 4:52-59 ("[T]he width of the stent in these [low stress] regions [can] be varied in order to increase or decrease the radiopacity of the stent"); 4:12-15 (same); 6:31-35 (same); 5:40-44 (same); 11:57-60 (same); Abstract (same) 2. ***Width at center of tapered diagonal section is greater than the width at either end:*** Claim 9 ("The stent of claim 8, wherein each of said cylindrical elements has linking portions [i.e., diagonal sections] having strut widths which are ***wider*** than the strut widths of the valley portions and peak portions [i.e., curved sections] of said cylindrical element[s]."); 4:14-17; 10:23-26; 11:10-14; 11:60-64; Abstract; Claims 1-2 & 8-9; Figs. 5-6 (*see* blue highlighting below in excerpt from Fig. 5):  3. ***Width at center of tapered diagonal section is less***

278 Patent	Cox (Ex. 1005)
	than the width at either end: Abstract ("[T]he width of the strut in the low stress region of the stent [i.e., "linking portion" diagonal section] can be designed to be ***narrower*** than the strut width in the high stress regions [i.e., "peak/valley" curved sections]."); 11:57-12:4 (same); 4:17-21; *see also id.* at Figs. 10-11; 7:14-18; 12:21-24; Brown Decl. ¶¶115-23
3. The stent of claim 2 wherein the width of the at least one diagonal section is less at the center of that diagonal section compared to the width at either end of that diagonal section.	*See* citations in items 1 and 3 for element [2j] in this chart
4. The stent of claim 2 wherein the width of the at least one diagonal section is greater at the center of that diagonal section as compared to the width at either end of that diagonal section.	*See* citations in items 1 and 2 for element [2j] in this chart
5. [T]he stent of claim 2 wherein the diagonal sections of the end sets of strut members have a center and two ends, at least one of the diagonal sections of the end sets of strut members has a tapered shape wherein the width of the at least one diagonal section is greater at the center of the diagonal section as	*See* citations in items 1 and 2 for element [2j] in this chart

278 Patent	Cox (Ex. 1005)
compared to the width at either end of that diagonal section.	

D. Ground 4: Cox In View Of A POSA's Knowledge Or Rolando Renders Obvious Claims 2, 4, and 5

As shown above, Cox plainly anticipates claims 2-5 of the 278 patent. To the extent any limitation of claims 2, 4, and 5 is not disclosed in Cox, those claims would have been obvious at least in view of a POSA's knowledge or Rolando. (Brown Decl. ¶¶124-28.) As with Hilaire, in the pending litigation, the only limitation specifically alleged by Plaintiffs to be missing from Cox is the claimed diagonal section(s) having a "tapered shape" wherein the width of the diagonal section at the center is different (greater or less) than the width at either end. (*See, e.g.*, Ex. 1027 at 1465-66, 1474 (characterizing the Cox "774" patent); Brown Decl. ¶125.) Again, Plaintiffs' assertion appears to be based on Plaintiffs' erroneous proposed construction of "tapered shape." Although Plaintiffs' assertion is wrong (as previously shown in §VI), Petitioner addresses it in these obviousness combinations out of an abundance of caution.

Specifically, claims 2, 4, and 5 would have been obvious at the time of the alleged inventions in view of Cox in combination with a POSA's knowledge. (Brown Decl. ¶¶126-27.) As explained in Sections V and VII.B, *supra*, tapered stent diagonal sections – wherein the width at the center is different (greater or

less) than the width at either end – were well known in the art. Known examples included tapered diagonal sections with generally uniform changes in width "about a centerline." (*See supra* §§V & VII.B.) As also explained previously, POSAs knew many reasons ***why*** it would have been desirable to incorporate into Cox such tapered designs that were wider at the center as compared to either end. (*Id.*; Brown Decl. ¶54.) Indeed, like the 278 patent, Cox itself specifically teaches widening the diagonal sections to increase stent radiopacity. (*See, e.g.*, Ex. 1005 at 4:14-17, 10:23-26; Brown Decl. ¶¶119-20, 122.) By teaching the use of widened tapered diagonal sections generally, Cox alone provides motivation to incorporate into Cox specific tapered diagonal sections known to POSAs. (Brown Decl. ¶126.) Moreover, at most, the combination of Cox with a POSA's knowledge involves the simple substitution of one known exemplary diagonal section shape for another to obtain predictable results. (*Id.*)

Claims 2, 4, and 5 likewise would have been obvious in view of Cox in combination with Rolando. (*Id.* ¶128.) As shown above, Cox teaches using widened diagonal sections and the need to avoid concentrated stress and strain regions (*see, e.g.*, Ex. 1005 at 9:19-27). As explained in Section VII.B, *supra*, Rolando teaches a specific example of such a diagonal section, i.e., a two-sided tapered diagonal section having generally uniform changes in width about a centerline. (§VII.B.) Rolando also teaches benefits associated with this design

similar to Cox, such as better load distribution that prevents "the formation of concentrated stress regions." (*Id.*; Ex. 1007 at 9:65-10:2.) Given that (1) Cox teaches using tapered diagonal sections generally that are wider at the center as compared to either end, (2) Rolando teaches a specific example of such a tapered diagonal section, and (3) Cox and Rolando teach analogous reasons for using such tapered diagonal sections, a POSA had ample reasons to combine those references in the manner recited in claims 2, 4, and 5 of the 278 patent with a reasonable expectation of success. (Brown Decl. ¶128.) Moreover, at most, the combination of Cox and Rolando involves the simple substitution of one known exemplary diagonal section shape (e.g., Figure 5 of Cox) for another (e.g., Figure 4 of Rolando) to obtain predictable results. (*Id.*)

E. Ground 5: Cox In View Of A POSA's Knowledge Or Duerig-Burpee Renders Obvious Claim 3

In contrast to dependent claims 4 and 5 of the 278 patent, dependent claim 3 states that the width of the tapered diagonal section is ***less*** (instead of greater) at the center as compared to either end. As shown in Section VII.C, Cox anticipates claim 3. To the extent any limitation of claim 3 is not disclosed in Cox, that claim would have been obvious at the time of the alleged invention at least in view of a POSA's knowledge or Duerig-Burpee. (Brown Decl. ¶¶129-37.)

Claim 3 depends from claim 2. As noted above (§VII.D), the only claim 2 limitation specifically alleged by Plaintiffs to be missing from Cox is the claimed

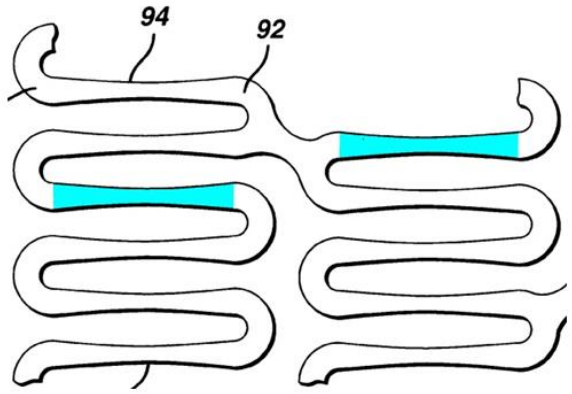
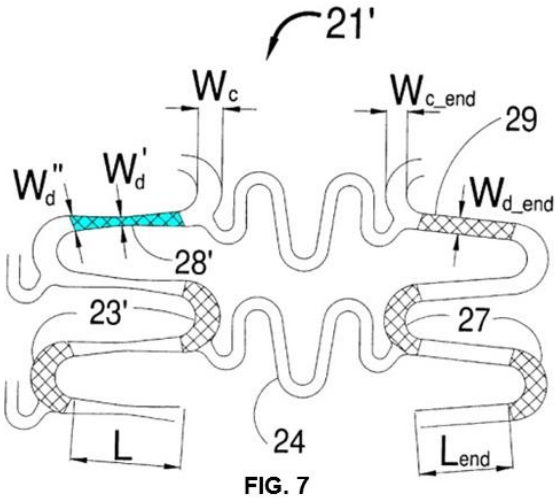
diagonal section(s) having a "tapered shape" wherein the width of the diagonal section at the center is different than the width at either end. (*See, e.g.*, Ex. 1027 at 1465-66, 1474 (characterizing the Cox "774" patent); Brown Decl. ¶130.) As noted earlier, Plaintiffs' assertion appears to be based on Plaintiffs' erroneous proposed construction of "tapered shape." Again, although Plaintiffs' assertion is wrong (as previously shown in §VI), Petitioner addresses it in these obviousness combinations out of an abundance of caution.

Specifically, claim 3 would have been obvious in view of Cox in combination with a POSA's knowledge. (Brown Decl. ¶131.) As explained in Sections V and VII.B, *supra*, tapered stent diagonal sections – wherein the width at the center is different (greater or less) than the width at either end – were well known in the art. As also explained earlier, known examples included tapered diagonal sections with generally uniform changes in width "about a centerline." (*See supra* §§V & VII.B.) As likewise explained previously, POSAs knew many reasons ***why*** it would have been desirable to incorporate into Cox such tapered designs that were narrower at the center as compared to either end. (*Id.*; Brown Decl. ¶54.) Indeed, like the 278 patent, Cox itself specifically teaches narrowing the diagonal sections to decrease stent radiopacity. (*See, e.g.*, Ex. 1005 at 4:17-21, 11:64-12:4; Brown Decl. ¶¶119, 121-22.) By teaching the use of narrowed tapered diagonal sections generally, Cox alone provides motivation to incorporate into Cox

specific examples of such tapered diagonal sections known to POSAs. Moreover, at most, the combination of Cox with a POSA's knowledge involves the simple substitution of one known exemplary diagonal section shape for another to obtain predictable results. (*See generally* Brown Decl. ¶131.)

Claim 3 of the 278 patent is equally obvious in view of Cox in combination with Duerig-Burpee (Ex. 1006). (Brown Decl. ¶¶132-37.) Duerig-Burpee, like Cox, relates to stents. It is entitled "Intravascular Stent Having ***Tapered*** Struts." (Ex. 1006 at cover page.) Janet Burpee – a named inventor on the 278 patent – also is a named inventor on the Duerig-Burpee patent. Duerig-Burpee issued on February 20, 2001, with a filing priority at least as early as February 2, 1999. Duerig-Burpee therefore is prior art under 35 U.S.C. 102(e). Duerig-Burpee was not disclosed or cited during the 278 prosecution.

Like other prior art, Duerig-Burpee confirms that tapered diagonal sections were well known in the art, including ones with uniform changes in width "about a centerline." Indeed, from the following side-by-side comparison, Duerig-Burpee's tapered diagonal sections appear to be the same as those in Figure 7 of the 278 patent:

DUERIG-BURPEE	278 PATENT
 FIG. 4A	 FIG. 7

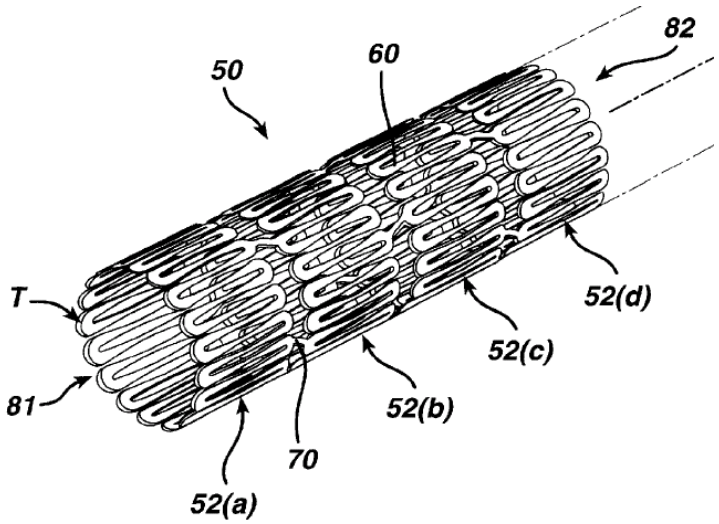
(*Id.* at. Fig. 4A (excerpt).) Duerig-Burpee teaches that its tapered diagonal sections – which Duerig-Burpee calls "longitudinal struts" – can be used to affect strain distribution and minimize stress concentrations. (*See, e.g., id.* at 6:61-7:6, 6:14-17.) Confirming that there are many "tapered" shapes, Duerig-Burpee stresses that ***any taper*** can be used. (*Id.* at 6:32-33 ("[A]ny taper, even a simple linear tapered reduction in width would still represent a significant improvement over a constant width strut.").) That said, Duerig-Burpee teaches that a continuous taper (as shown in its figures) is preferred. (*Id.* at Abstract ("Each of the struts has a width which is greater at its ends than at its center. Preferably, the width continuously tapers from a greater width at the ends to a smaller width at the centers."), 4:49-52 (same), 6:8-14 (same).)

As shown in the next section (§VII.F) (wherein Duerig-Burpee is discussed in more detail), Duerig-Burpee anticipates claims 2-3. But if starting with Cox, and incorrectly assuming Cox does not anticipate claim 3, Cox in combination with Duerig-Burpee renders that claim obvious. For instance, Cox generally teaches using diagonal sections that are narrower at the center as compared to either end. (*See, e.g.*, Ex. 1005 at 4:17-21, 11:64-12:4.) Cox also teaches avoiding concentrated stress and strain regions. (*See, e.g.*, *id.* at 9:19-27.) Similar to Cox, Duerig-Burpee teaches using diagonal sections that are narrower at the center, e.g., to minimize strain concentrations. (*See, e.g.*, Ex. 1006 at 6:61-7:6.) The preferred shape of Duerig-Burpee's two-sided tapered diagonal sections has a generally uniform change in width about a centerline (as depicted in Duerig-Burpee's figures). (*Id.* at Figs. 3-5, 4:49-52, 6:8-14, Abstract.) Given the common teachings of Cox and Duerig-Burpee, a POSA had ample reasons to incorporate Duerig-Burpee's preferred tapered diagonal section into Cox with a reasonable expectation of success. (Brown Decl. ¶137.) Moreover, at most, the combination of Cox and Duerig-Burpee involves the simple substitution of one known exemplary diagonal section shape (e.g., as described in Cox at 11:57-12:4) for another (e.g., Figure 4A of Duerig-Burpee) to obtain predictable results. (Brown Decl. ¶137.)

F. Ground 6: Duerig-Burpee Anticipates Claims 2-3

As noted in the preceding section, Duerig-Burpee (Ex. 1006) is §102(e) prior art, involves a common inventor with the 278 patent (Janet Burpee), and was never disclosed or cited during the 278 prosecution.

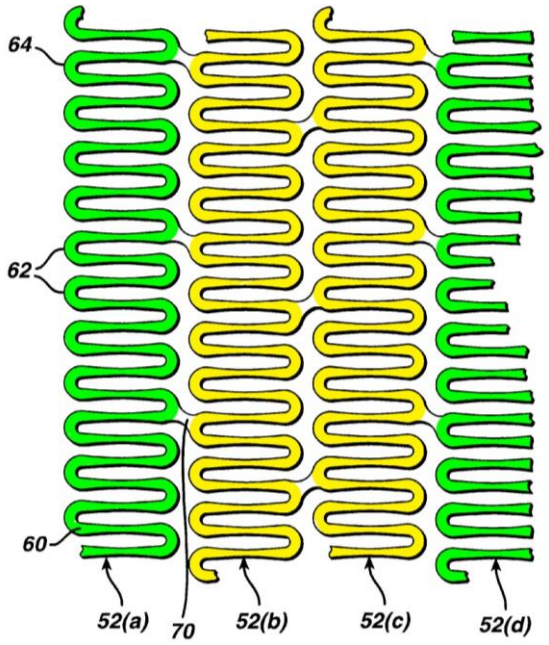
Like the 278 patent, Duerig-Burpee "relates to expandable intraluminal grafts ('stents') …." (*Id.* at 1:10-13.) Such stents have a tubular structure as shown in Figure 3:



(*Id.* at Fig. 3; *see also id.* at 5:27-29 ("Stent 50 is a tubular member ...."), claims 1, 8, & 13.) Duerig-Burpee's stents have a uniform thickness (e.g., labeled "T" in Figure 3) typically resulting from laser cutting a thin-walled tube. (*Id.* at Fig. 3, Abstract (stent has "a thickness"), claims 1-16 (same), 4:37-39 (same), 8:6-10 (stent made from tube with uniform thickness).)

Similar to the other prior art, Duerig-Burpee's stents have a multiplicity of circumferential sets of strut members – which Duerig-Burpee calls "hoops" – that

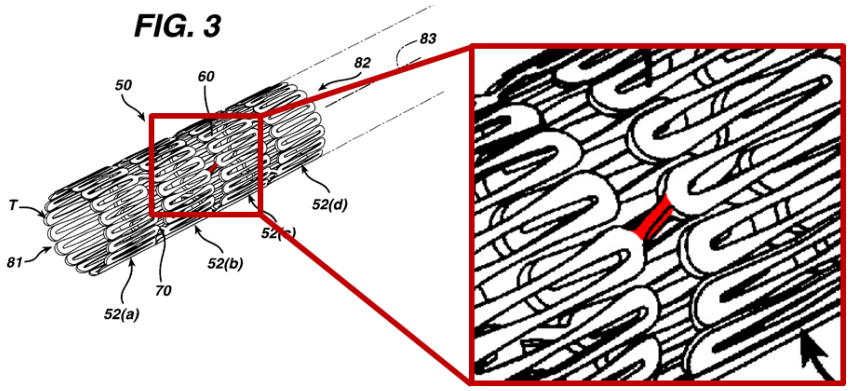
are formed in "an S or Z shape pattern" (e.g., serpentine). (*Id.* at 4:42-43 ("The tubular member has a plurality of adjacent hoops extending between its front and back ends."), Abstract (same), 5:32-41 ("S or Z shape pattern"), Figs. 3-5 (e.g., items 52(a)-(d) in Figs. 3 & 4), claims 1, 8, & 13.) Each "hoop" forms a closed cylindrical portion of the stent. (*Id.*) Using Figure 4 as an example, Duerig-Burpee's stents have end sets of strut members (labeled 52(a) and 52(d) and highlighted in green) and central sets positioned between the end sets (labeled 52(b) and 52(c) and highlighted in yellow):



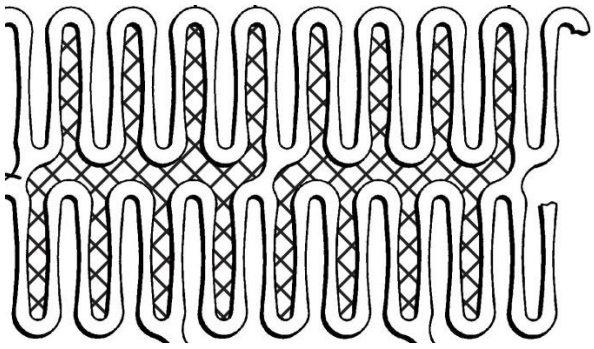
(*Id.* at Fig. 4; *see also id.* at Fig. 3.)

As shown in the figures, Duerig-Burpee's sets of strut members or "hoops" are longitudinally separated from each other. (*See also id.* at claim 1.) Duerig-Burpee teaches that the hoops are spaced apart by a plurality of longitudinally

extending links which Duerig-Burpee calls "bridges." (*Id.* at Abstract ("plurality of bridges connecting adjacent hoops"), 4:47-49, 5:44-48, claims 1, 8, & 13.) Below is an example of a "bridge" from Figure 3 (highlighted in red) that connects two longitudinally separated hoops:



(*Id.* at Fig. 3 (blow out added).) Duerig-Burpee's combination of "hoops" spaced apart by "bridges" results in a stent having multiple cells, examples of which are cross-hatched in the following excerpt from Figure 4:



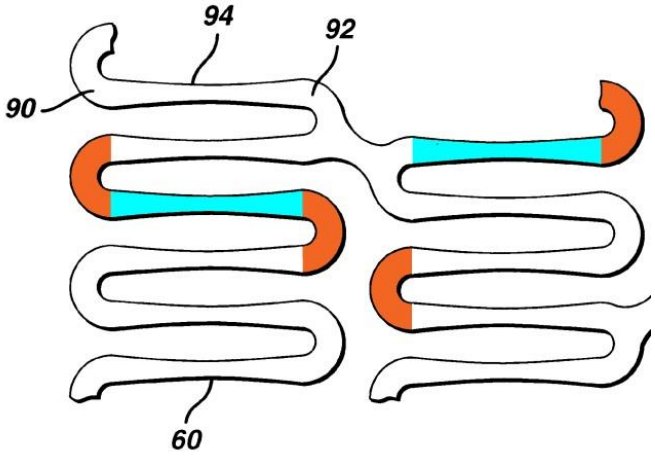
(*Id.* at Fig. 4 (rotated excerpt).)

As shown in Figures 3-5, and described in the specification, Duerig-Burpee's circumferential sets of strut members (or "hoops") comprise a multiplicity of connected curved sections (which Duerig-Burpee calls "loops") and

diagonal sections (which Duerig-Burpee calls "longitudinal struts"). For example, Duerig-Burpee states:

> The [stent] has a plurality of adjacent hoops [that] are formed from a plurality of ***longitudinal struts***, each having opposing ends and a center therebetween. The ends of the struts are shaped to form a plurality of ***loops*** which connect adjacent [longitudinal] struts at the ends of the struts.

(*Id.* at 4:43-47; *see also id.* at 5:32-43, Abstract, claims 1, 8, & 13, Figs. 3-5 (e.g., items 62 in Fig. 4 and item 60 in Fig. 4A).) Consistent with basic stent design at the time of the alleged 278 inventions, Duerig-Burpee further notes that the angle of the diagonal sections ("longitudinal struts") changes upon stent expansion, as reflected in Figure 5. (*Id.* at 6:40-44, 7:17-18, Fig. 5; Brown Decl. ¶145.) Sample curved sections (highlighted in orange) and diagonal sections (highlighted in blue) are shown in Figure 4A below:



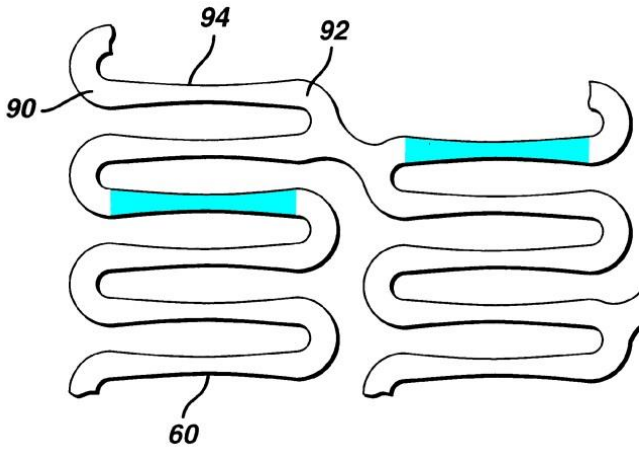
(Ex. 1006 at Fig. 4A (excerpt).)[12]

Lastly, in both the end sets and central sets of strut members, Duerig-Burpee's diagonal sections have a tapered shape wherein the width at the center is different than the width at either end (i.e., 278 claim 2). Specifically, the width at the center is narrower (i.e., 278 claim 3). Such stents are depicted in Figures 3-5 and described in Duerig-Burpee's Abstract, specification, and claims. (*See, e.g.*, Ex. 1006 at Figs. 3-5, Abstract, 4:49-52, 6:9-14, 6:31-33, claims 1-2, 8, & 13.) For example, the "Summary Of The Invention" states:

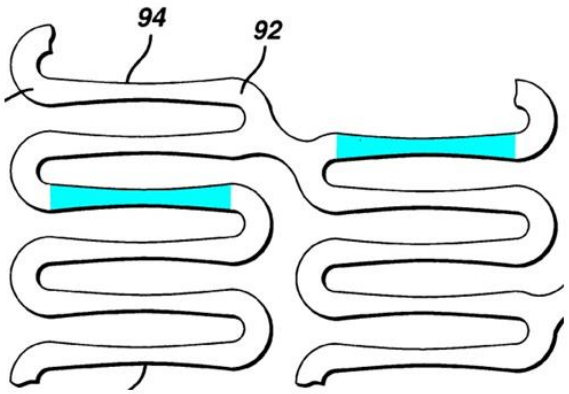
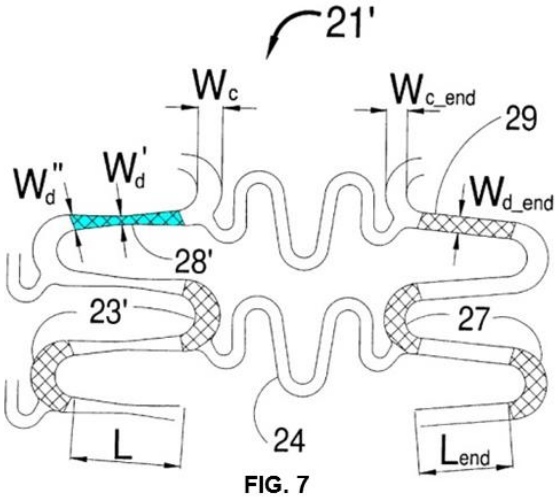
> Each of the [longitudinal] struts [i.e., diagonal sections] has a width which is greater at its ends than at its center. Preferably, ***the width continuously tapers from a greater width at the ends to a smaller width at the center.***

(*Id.* at 4:49-52.) The Duerig-Burpee claims recite the same language. (*Id.* at claims 2, 8, & 13.) Even Duerig-Burpee's title emphasizes the tapered shape, i.e., "Intravascular Stent Having ***Tapered*** Struts." Examples of Duerig-Burpee's tapered diagonal sections from Figure 4A are highlighted in blue below:

[12] Like the 278 specification and the other prior art, Duerig-Burpee teaches that the above-described basic stent structure was already well known in the art. (*Id.* at 8:6-10, 1:43-59, 2:23-26; Brown Decl. ¶146.)



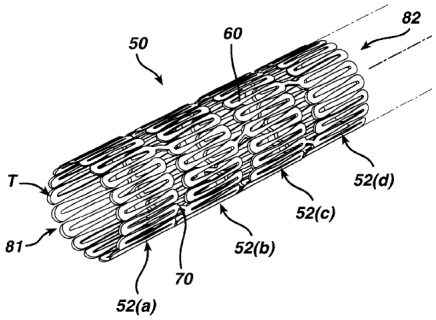
(*Id.* at Fig. 4A (excerpt); *see also id.* at Figs. 4 & 5.) As shown previously, a side-by-side comparison of these examples with sample diagonal sections from the 278 patent that are described as "tapered" shows they are ***essentially identical*** and lack any relevant difference:

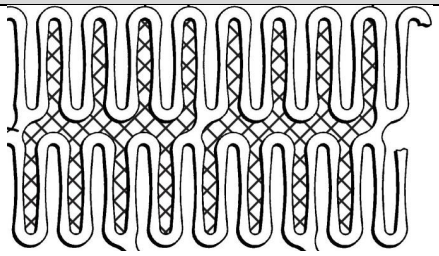
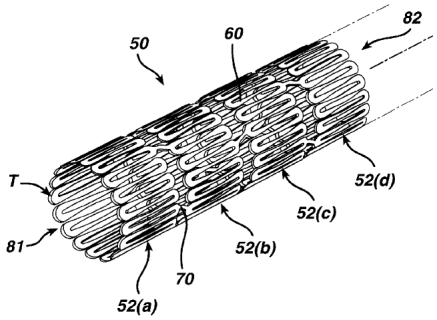
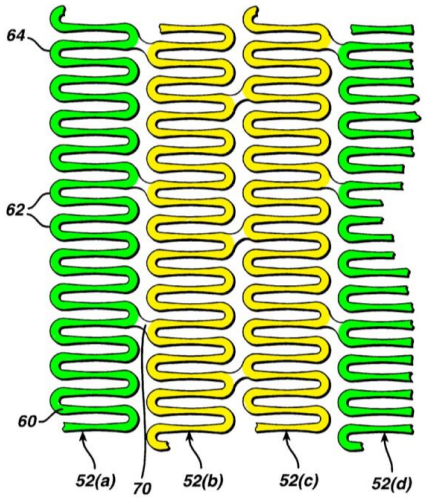
DUERIG-BURPEE	278 PATENT
 FIG. 4A	 FIG. 7

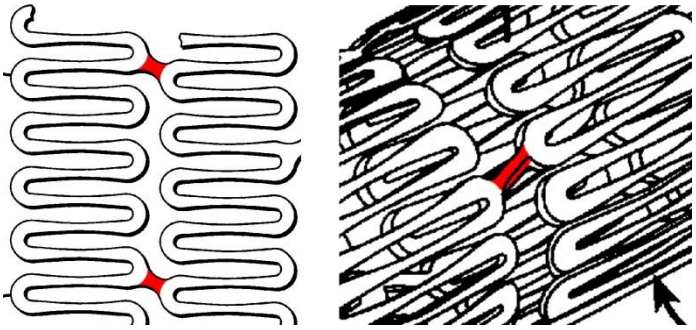
While teaching this preferred tapered shape, Duerig-Burpee emphasizes that "any taper, even a simple linear tapered reduction in width would still represent a significant improvement over a constant width strut." (*Id.* at 6:31-33.)

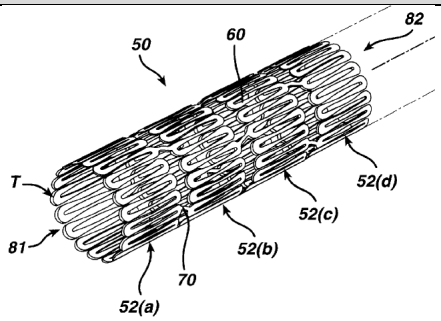
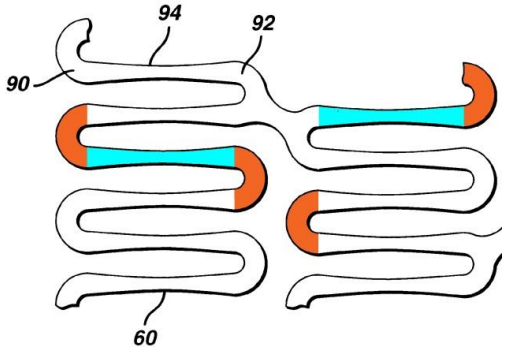
As noted earlier, beyond describing and depicting the anticipating design, Duerig-Burpee discloses multiple reasons for the design. For instance, similar to the 278 patent, Duerig-Burpee teaches that the effect of this tapering will be to "make the overall strain deformation more uniform." (*Id.* at 6:14-17; *see also id.* at 3:65-4:9.) Duerig-Burpee's design also allows the stent to "handle greater fatigue stresses, which could result in a longer lasting and stronger stent." (*Id.* at 6:34-39; *see also id.* at 6:61-7:6, 4:23-29; Brown Decl. ¶149.)

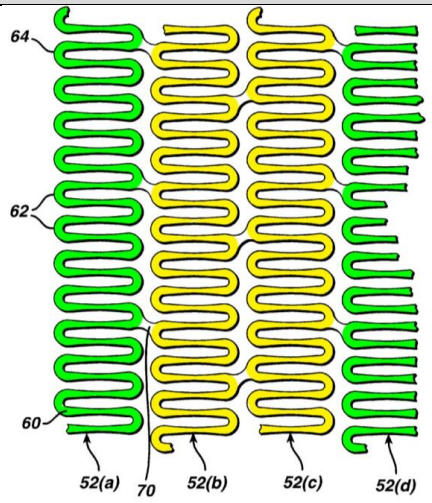
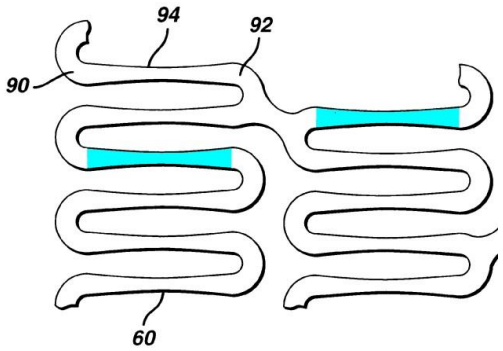
In short, as shown above, and as further shown and summarized by exemplary cites in the claim chart below (as well as in the Brown declaration at ¶¶138-50), Duerig-Burpee anticipates claims 2-3 of the 278 patent.

278 Patent	Duerig-Burpee (Ex. 1006)
2[a]. A stent in the form of a thin-walled, multi-cellular, tubular structure	5:27-29 ("Stent 50 is a tubular member ...."); Claims 1, 8, & 13; 8:6-10; Fig. 3 (thin-walled tubular structure – *see* below):  Fig. 4 rotated excerpt (multiple cells – *see* cross-hatching below):

278 Patent	Duerig-Burpee (Ex. 1006)
	 *See also* Brown Decl. ¶¶139, 144, 150
[2b] having substantially uniform thickness throughout the length of the tubular structure,	Fig. 3 (labeled "T"); Abstract (stent has "a thickness"); Claims 1-16 (same); 4:37-39 (same); 8:6-10 (stent made from tube with uniform thickness); *see also* Brown Decl. ¶¶139, 150
[2c] a [sic] the stent comprising a multiplicity of circumferential sets of strut members,	4:42-43 ("The tubular member has a plurality of adjacent ***hoops*** extending between its front and back ends."); Abstract (same); 5:32-41; Claims 1, 8, & 13; Figs. 3-5 (e.g., items 52(a)-(d) in Figs. 3 & 4, *see* images and green and yellow highlighting below):  

278 Patent	Duerig-Burpee (Ex. 1006)
	See also Brown Decl. ¶¶140, 142, 150
[2d] each of the strut members being substantially the same thickness,	*See* citations in this chart for element [2b]
[2e] each set of strut members being longitudinally separated each from the other and	*See* citations in this chart for element [2c]
[2f] connected each to the other by one or more longitudinally extending links,	Abstract ("plurality of ***bridges*** connecting adjacent hoops"); 4:47-49 (same); 5:44-48 (same); Claims 1, 8, & 13 (same); Figs. 3-5 (e.g., item 70 in Figs. 3-4A and examples highlighted red in excerpts from Figs. 3-4 below):  *See also* Brown Decl. ¶¶143, 150
[2g] each set of strut members forming a closed, cylindrical portion of the stent,	4:42-43 ("The tubular member has a plurality of adjacent ***hoops*** …."); Abstract (same); 5:32-41; Claims 1, 8, & 13; Figs. 3-5 (e.g., items 52(a)-(d) in Fig. 3 below):

278 Patent	Duerig-Burpee (Ex. 1006)
	 *See also* Brown Decl. ¶¶140, 150
[2h] each set of strut members comprising a multiplicity of connected curved sections and diagonal sections,	4:43-47 ("The hoops are formed from a plurality of ***longitudinal struts***, each having opposing ends and a center therebetween. The ends of the struts are shaped to form a plurality of ***loops*** which connect adjacent [longitudinal] struts at the ends of the struts."); 5:32-43 (same); Abstract (same); Claims 1, 8, & 13 (same); 6:40-44; 7:17-18; Figures 3-5 (e.g., items 62 in Fig. 4 and item 60 in Fig. 4A; *see* sample curved sections and diagonal sections highlighted orange and blue, respectively, in excerpt from Fig. 4A below):  *See also* Brown Decl. ¶¶145, 150
[2i] the sets of strut members including end sets of strut members located at each end of the stent and central sets of strut members positioned between the	Fig. 4 (end sets labeled 52(a) and 52(d) and highlighted green and central sets labeled 52(b) and 52(c) and highlighted yellow below):

278 Patent	Duerig-Burpee (Ex. 1006)
end sets of strut members,	 *See* same labels in Fig. 3; *see also* Brown Decl. ¶¶141, 150
[2j] the diagonal sections of the central sets of strut members have a center and two ends, at least one of the diagonal sections of the central sets of strut members having a tapered shape wherein the width of the at least one diagonal section is different at the center of the diagonal section as compared to the width at either end of that diagonal section.	4:49-52 ("Each of the [longitudinal] struts [i.e., diagonal sections] has a width which is greater at its ends than at its center. Preferably, ***the width continuously tapers from a greater width at the ends to a smaller width at the centers."***); Claims 1-2, 8, & 13 (same); Title ("Intravascular Stent Having ***Tapered*** Struts"); Abstract; 6:9-14 & 6:31-33; Fig. 3-5 (*see* blue highlighting in excerpt from Fig. 4A below):  *See also* Brown Decl. ¶¶147-50
3. The stent of claim 2 wherein the width of the at least one diagonal section is less at the	*See* citations in this chart for element [2j]

278 Patent	Duerig-Burpee (Ex. 1006)
center of that diagonal section compared to the width at either end of that diagonal section.	

G. Ground 7: Duerig-Burpee In View Of A POSA's Knowledge Or Cox Renders Obvious Claims 4-5

Claims 4 and 5 of the 278 patent would have been obvious at the time of the alleged inventions at least in view of Duerig-Burpee in combination with a POSA's knowledge or Cox. (Brown Decl. ¶151.) The only difference between Duerig-Burpee and claims 4 and 5 is that claims 4 and 5 require the width at the center of the tapered diagonal section to be ***greater*** (instead of less) than the width at either end. But as explained in Section V, depending on the specific circumstances and/or desired effect, there were numerous known reasons why POSAs would have been motivated to modify Duerig-Burpee's diagonal sections such that that they were ***wider*** at the center as compared to either end. (*See* §V; *see also* Brown Decl. ¶54.) This is confirmed, for example, by Cox, which teaches using diagonal sections wherein the width at the center is greater than the width at either end if increased radiopacity is desired. (*See, e.g.*, Ex. 1005 at 4:14-17.) It is likewise confirmed by many other prior art references cited herein. (*See supra* §§V, VII.A, VII.B; Brown Decl. ¶¶47, 51, 54, 89-91, 100-01.) As such, in those instances where a wider diagonal section was desired (e.g., as known to POSAs or

taught by Cox), it would have been obvious for a POSA to modify Duerig-Burpee's symmetrical, two-sided tapered diagonal sections such that the center was wider – instead of narrower – than either end in the manner recited in claims 4 and 5 of the 278 patent with a reasonable expectation of success. (Brown Decl. ¶151.)

VIII. SECONDARY CONSIDERATIONS

Petitioner believes that claims 2-5 are anticipated on multiple grounds and thus obviousness should not be an issue. That said, Petitioner is not aware of any secondary considerations that would tend to show non-obviousness that have a provable nexus with claims 2-5. (Brown Decl. ¶152.) Indeed, there is nothing in those claims that is not already taught in the prior art. (*Id.*)

IX. CONCLUSION

For the above reasons, Petitioner respectfully requests institution of *inter partes* review of claims 2-5 of the 278 patent.

Respectfully submitted,

Dated: October 19, 2018

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CERTIFICATION OF WORD COUNT UNDER 37 C.F.R §42.24(d)

The undersigned certifies that this Petition for *Inter Partes* Review complies with the requirements of 37 C.F.R. §42.24(a)(1)(i) because the Petition does not exceed 14,000 words in length. Using the "Word Count" tool in Microsoft Word, the number of words in this Petition following the Table of Contents and Table of Exhibits and through the Conclusion section is 13,969 (exclusive of the mandatory notices under 37 C.F.R. §42.8).

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CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 6,699,278 and Exhibits 1001-1036 were served on October 19, 2018, via pre-paid, overnight Federal Express on the patent owner at the correspondence address for the subject patent pursuant to 37 C.F.R. § 42.105 as specified in (a) the Assignments tab on PAIR (identifying the current owner of U.S. Patent No. 6,699,278 and its "Correspondent" address) and (b) the "Correspondence Data" section of the actual assignment document for U.S. Patent No. 6,699,278 obtained from the PTO website:

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1500 Waukegan Rd.
Attn: Kim Luna
Waukegan, IL 60085

Additional copies were served via email on the same date to the listed email address for the subject patent, i.e., patent@cardinalhealth.com.

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