UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION,

Petitioners,

v.

BOSTON SCIENTIFIC SCIMED, INC.,

Patent Owner.

Case IPR2017-01295
Patent 8,709,062 B2

Before the Honorable JAMES A. TARTAL, ROBERT L. KINDER, and AMANDA F. WIEKER, *Administrative Patent Judges.*

DECLARATION OF RONALD J. SOLAR, Ph.D.

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P.O. Box 1450
Alexandria, VA 22313-1450

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I, Ronald J. Solar, state and declare as follows:

I. INTRODUCTION

1. I am currently the President of Renaissance Biomedical, Inc., which performs research and consultation in technical, marketing, commercialization, patent, clinical, and regulatory issues related to the medical device industry. I am also currently the President and CEO of ThermopeutiX, Inc., a company which designs, develops, manufactures, and sells vascular catheter technology and devices, including coronary, peripheral and neuro-vascular catheters and related medical devices.

2. I obtained a Bachelor of Science degree in Metallurgy and Materials Science from the Pennsylvania State University in 1972. My undergraduate thesis was entitled "Failure Analysis of Orthopaedic Implants." I also received a Ph.D. in Materials Science and Biomaterials from the University of Pennsylvania in 1977. My doctoral dissertation was entitled "Corrosion Behavior of Surgical Implant Alloys."

3. I first began working in the balloon catheter field in 1980 when the field was in its infancy and with relatively few procedures using balloon catheters being performed worldwide. Over the next 30 plus years, I worked extensively in researching and developing coronary and peripheral vascular medical devices including balloon catheters and stents.

4. I subscribe to a number of medical journals and medical device industry journals. I attend medical conferences, courses, symposia and workshops, as well as trade shows sponsored for the medical device industry. I attend roughly eight to twelve of such events per year to continue and maintain my expertise and education in the medical device industry, including Transcatheter Cardiovascular Therapeutics (TCT), Leipzig Interventional Course (LINC), EuroPCR, New Cardiovascular Horizons (NCVH), Cardiovascular Revascularization Therapies (CRT), International Conference for Innovations in Cardiovascular Systems (ICI), and courses and annual meetings of the American College of Cardiology (ACC), the European Society of Cardiology (ESC) and the American Heart Association (AHA). I am currently a professional member of the Horizons International Peripheral Group (HIPG), the ESC, and the AHA.

5. To date, I have obtained, as inventor or co-inventor, 58 United States patents and numerous foreign patents, all in the medical device area. Many of these patents relate to stents or stent applications:

- U.S. Patent No. 5,403,341 filed in 1994 and entitled "Parallel Flow Endovascular Stent and Deployment Apparatus Therefore"
- U.S. Patent No. 5,407,432 filed in 1992 and entitled "Method of Positioning a Stent"
- U.S. Patent No. 5,549,635 filed in 1994 and entitled "Non-Deformable Self-Expanding Parallel Flow Endovascular Stent and Deployment Apparatus Therefore"

- U.S. Patent No. 5,669,880 filed in 1993 and entitled "Stent Delivery System"
- U.S. Patent No. 5,810,838 filed in 1997 and entitled "Hydraulic method and apparatus for uniform radial compression and catheter mounting of radially expandable intraluminal stents and stented grafts"
- U.S. Patent No. 6,004,328 filed in 1997 and entitled "Radially Expandable Intraluminal Stent and Delivery Catheter Therefore and Method of Using the Same"
- U.S. Patent No. 6,254,608 filed in 1997 and entitled "Sheathless Delivery Catheter for Radially Expandable Intraluminal Stents and Stented Grafts"
- U.S. Patent No. 6,447,501 filed in 1998 and entitled "Enhanced Stent Delivery System"
- U.S. Patent No. 9,254,208 filed in 2013 and entitled "Oblique Stent"

Specifically, two of the U.S. patents I hold (Nos. 5,810,838 and 5,971,992) relate to methods and apparatuses for crimping a stent. Several other U.S. patents (such as No. 5,403,341) relate to stent securement issues.

6. I am also the author or co-author of about 30 peer-reviewed articles in medical or scientific journals, 7 book chapters, and 54 presentations at scientific sessions of major medical meetings. Many of my articles and presentations relate to stents or stent applications:

- T. Ischinger and R. Solar, "Optimal Stent Expansion by Predilatation with a New Focused Force Balloon Device", CARDIOVASCULAR RADIATION MEDICINE, 4 (Abst.), 2003.

- T. Ischinger, R. Solar and E. Hitzke, "Improved Outcome with Novel Device for Low-Pressure PTCA in De Novo and In-Stent Lesions", CARDIOVASCULAR RADIATION MEDICINE, 4 (1):2-7, 2003.

- T. Ischinger, R. Solar and E. Hitzke, "The FX miniRAIL — Long-Term Reduction in Target Lesion Revascularization of De Novo and In-Stent Lesions", in FRONTIERS IN CARDIOLOGY, 5TH INTERNATIONAL CONGRESS ON CORONARY ARTERY DISEASE, FLORENCE, ITALY, OCT., 2003.

- R. Solar, "sidekick: A New Concept & Device for Bifurcation Stenting", 6TH INTERNATIONAL MEETING ON INTERVENTIONAL CARDIOLOGY, TEL AVIV, ISRAEL, DEC., 2004.

- R. Solar, "The Y Med sideKicK™ Stent Delivery System for the Treatment of Coronary Bifurcation and Ostial Lesions", CARDIOVASCULAR REVASCULARIZATION THERAPIES 2007, Washington, DC, March, 2007.

- R. Solar, "Sidekick Stent System for the Treatment of Coronary Bifurcation and Ostial Lesions," MEETING OF THE EUROPEAN BIFURCATION CLUB, Valencia, Spain, Sept., 2007.

- R. Solar, "The Y-Med SideKicK Stent," CARDIOVASCULAR REVASCULARIZATION THERAPIES 2008, Washington, DC, March, 2008.

- R. Solar, "Targeted Drug Delivery: Beyond Stents and Balloons,"3rd NCVH Latin America, Cartegena, Colombia, March 2014.

I was a co-founder of five successful medical device companies, namely (1) Versaflex Delivery Systems, Inc., (2) ThermopeutiX, Inc., (3) Y Med, Inc., (4) MEDgination, Inc., and (5) Occam International, BV.

7. In 1989, I was recognized by President George Bush as one of the Ten Outstanding Young Americans (TOYA), and Junior Chamber International

selected me as one of the Ten Outstanding Young People of the World for my contributions in medical innovation.

8. For my time, I am being compensated at $550 per hour, my standard rate for this type of consulting activity. My compensation is in no way contingent on the result of this proceeding.

9. A copy of my full curriculum vitae is attached to this Declaration as Appendix A. A list of all intellectual property cases in which I have testified as an expert, either in deposition or trial, is attached as Appendix B.

II. INFORMATION REVIEWED OR CONSIDERED

10. I have reviewed U.S. Patent No. 8,709,062 (the "'062 patent"), the Petition in this proceeding (including the relevant materials it cites), the Board's Institution Decision, the Patent Owner's Preliminary Response, and the prior art references at issue (*i.e.*, U.S. Patent Nos. 5,653,691 (Rupp) and 5,836,965 (Jendersee), and 4,994,032 (Sugiyama)). I provide the following opinions regarding these materials.

III. LEGAL STANDARDS

11. I am not a patent attorney, and I have been instructed on certain aspects of the laws of obviousness to provide context for my opinions.

12. I understand that claims 1-7, 9-15, 17-21, and 23-26 of the '062 patent are at issue in this *Inter Partes* Review proceeding. I further understand that the

Boards instituted one ground of challenge: obviousness of claims at issue in view of Rupp, Jendersee, Sugiyama, and the knowledge of a person of ordinary skill in the art. Institution Decision at 33-34.

13. I understand that a patent is invalid under 35 U.S.C. § 103 only if "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains."

14. I understand that obviousness is ultimately a legal question determined by the Board, but that this legal question is premised on underlying factual issues, including:

a. the scope and content of the prior art;

b. the level of ordinary skill in the art;

c. the differences between the claimed invention and the prior art; and

d. secondary considerations of non-obviousness.

15. I understand that the scope and content of the prior art must be viewed through the perspective of a person of ordinary skill in the art at the time of the invention.

16. I understand that the relevant time of the obviousness inquiry in this case is August 23, 1996, the earliest filing date of the '062 patent.

17. I understand that a patent is not obvious merely by demonstrating that each of its elements was, independently, known in the prior art. I understand that it is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to modify or combine the elements in the way the claimed new invention does. I understand that this rationale must be more than mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. I understand that such a rationale must include a reason that would have prompted a person of ordinary skill in the relevant field to modify or combine the elements in the way the claimed new invention does. I also understand that merely asserting that prior art references are analogous art to each other is not a sufficient articulated reason with a rational underpinning to combine their respective teachings.

18. I understand that the obviousness inquiry takes place at the time of the invention. Therefore, care must be used to avoid the impermissible use of hindsight in an obviousness analysis. I understand that it is improper to use the invention as a plan or template for hindsight reconstruction of bits and pieces of the prior art to form the invention.

19. I understand that an invention may be found obvious if it would have been obvious to a person having ordinary skill in the art to try a course of conduct

constituting or resulting in the invention. When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. However, I understand that evidence of obviousness, especially when that evidence is proffered in support of an "obvious-to-try" theory, is insufficient unless it indicates that the possible options skilled artisans would have encountered were "finite," small," or "easily traversed," and that skilled artisans would have had a reason to select the route that produced the claimed invention.

20. I further understand that an invention is not obvious to try where vague prior art does not guide an inventor toward a particular solution. For example, where there are numerous possible solutions and the prior art gives no indication of which is likely to be successful, "obvious to try" does not prove obviousness. Similarly, if what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, but the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it, then a finding of obviousness is not warranted.

21. I also understand that when the prior art "teaches away" from combining prior art references or certain known elements, discovery of a

successful means of combining them is more likely to be non-obvious. I further understand that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the invention, or would be led in a direction divergent from the path that was taken by the applicant. I also understand that a reference may teach away from a use when that use would render the result inoperable.

22. I understand that there is no suggestion or motivation to make a modification to a prior art reference if the proposed modification would render the prior art invention unsatisfactory for its intended purpose. I also understand that an obviousness allegation cannot be supported by a combination of references that would require a substantial reconstruction and redesign of the elements shown in the primary reference as well as a change in the basic principle under which the primary reference was designed to operate.

IV. THE LEVEL OF ORDINARY SKILL IN THE ART

23. In Mr. Trotta's declaration, he opines that a person of ordinary skill in the art at the time of the claimed invention of the '062 patent "would have had an undergraduate degree in mechanical or manufacturing or material science engineering, as well as at least five years of experience in the industry in designing minimally invasive catheter-based interventions." Ex. 1003 at ¶ 80. Mr. Trotta also states that "[w]ith an undergraduate degree in a different subject matter, one of

ordinary skill in the art would have had five to ten years of experience in the industry in designing minimally invasive catheter-based interventions." *Id*. I generally agree with these definitions and I was a person of ordinary skill in the art under this definition in August 1996.[1]

V. The '062 Patent

24. A stent is a tubular mesh-like implant (most commonly made of metal or alloy) that is placed in a body lumen to keep the lumen open. There are two general stent types: a self-expanding stent and a balloon expandable stent. Ex. 1001 at 1:45-54. In a balloon expandable stent, the stent is mounted on the distal end of a balloon catheter, which traverses the patient's body to the treatment site. Once reaching the treatment site, the balloon is expanded, which leads to the expansion of the stent. The balloon is then deflated to a small profile and withdrawn from the lumen, thus leaving the stent as an implant in the body lumen.

25. In advancing the balloon expandable stent inside the body to the treatment site, the stent must be safely secured on the delivery balloon catheter. *Id*. at 2:15-18. There were two general stent securement methods. One employs "restraining means [such as a sheath] that overlay the stent." *Id*. at 2:21-54. The

[1] I understand that the claimed invention in the '062 patent was conceived prior to August 23, 1996. However, for purposes of this declaration, I use August 23, 1996 as the invention date of the '062 patent.

other involves crimping the stent (*i.e.*, reducing the diameter of the stent) to tightly fit the stent over the balloon catheter. *Id*. at 2:56-59.

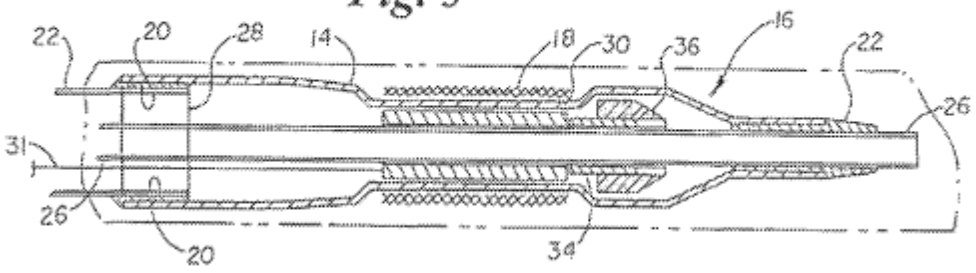
26. The '062 patent relates to the latter method. Specifically, it is directed to stent securement structures for a crimped stent. However, as discussed in the Background of the Invention section of the '062 patent, when a stent is simply crimped on a balloon catheter, the stent still "tends to evidence a certain amount of looseness from its desired close adherence to the overall profile of the underlying catheter and balloon." *Id*. at 3:5-8. In other words, "the stent tends to have a perceptible relatively slack fit in its mounted and crimped position." *Id*. at 3:8-9. As a result, "[d]uring delivery, the stent can [] tend to slip and dislocate from its desired position on the catheter or even separate from the catheter, requiring further intervention by the physician." *Id*. at 9-12.

27. The invention of the '062 patent is directed to a stent securement structure (a "second member" or "proximal member"), which is an enlarged body within the balloon carried by the catheter shaft. *Id*. at 25:40. This structure "secure[s] the stent during tracking and delivery" and "provide[s] a good friction fit to the stent and insure good contact between the stent and underlying balloon and catheter, instead of merely crimping the stent onto the balloon and catheter and the underlying catheter and relying on the bulk of the flaccid balloon to hold the stent on." *Id*. at 3:20-25.

28. The invention of the '062 patent further includes a "first member" and/or a "distal stop" that is also carried by the catheter shaft within the balloon. *Id*. at 9:41, 25:34-36. The distal stop "provide[s] additional resistance to stent movement during delivery and to protect the leading edge of the stent during delivery." *Id*. at 9:43-45.

29. One of the innovative designs of the '062 patent is shown in Figure 3 (reproduced below). Figure 3 shows a "mounting body 30," which is an embodiment of the "second member" or "proximal member" in the claims of the '062 patent. *Id*. at 9:28-34. The mounting body "provides a cushion to support and/or substrate of enlarged diameter relative to the stent to support and hold the stent ["18"] and secure it during crimping and the delivery procedure." *Id*. at 9:29-32. Figure 3 also shows an embodiment of the "first member" or the "distal stop" ("36"), which is tapered at the distal portion. *Id*. at 9:41. As discussed above, the distal stop provides resistance to stent movement and protect stent's leading edge during delivery. *Id*. at 9:43-44.

Fig. 3



30. Among the claims at issue, claims 1, 13, 21, and 26 are independent claims. Claim 1, shown below, is representative of the four independent claims:

> 1. 1. A medical device, comprising:
> an elongate shaft including a first tubular member and a second tubular member;
> a balloon coupled to the shaft;
> a first member coupled to the first tubular member and positioned within the balloon, the first member including a distal stop with a tapered distal portion;
> wherein the distal stop includes a proximal end face extending substantially perpendicular to a longitudinal axis of the elongate shaft;
> a second member coupled to the first tubular member and positioned within the balloon, the second member having a distal end disposed proximal of the distal stop; and
> a medical implant coupled to the shaft and positioned adjacent to the balloon.

31. Among the dependent claims at issue, claim 7 is particularly relevant for purposes of my declaration, which reads as follows:

> 7. The medical device of claim 1, wherein the second member is a support member configured to support the medical implant.

VI. THE SCOPE AND CONTENT OF THE PRIOR ART AND THE DIFFERENCES BETWEEN THE CLAIMED INVENTION AND THE PRIOR ART

A. Rupp

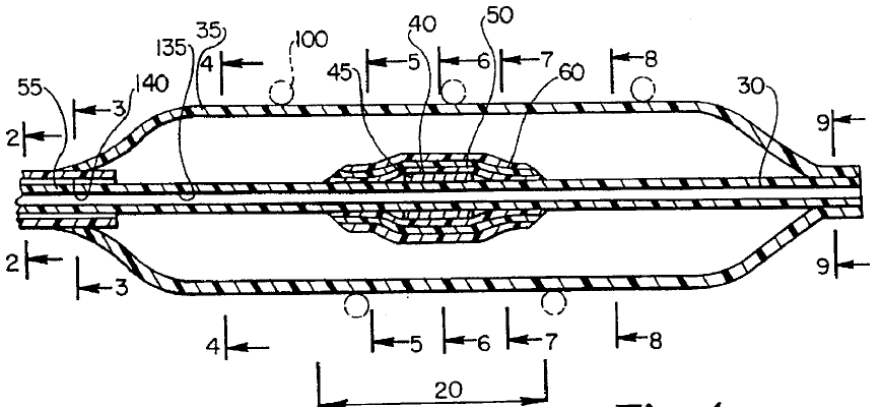
32. Rupp, entitled "Thickened Inner Lumen For Uniform Stent Expansion And Making," is directed to affixing a built-up layer to the outer diameter of an inner lumen of a balloon expandable stent delivery system to "cause the balloon to expand evenly and the stent to deploy uniformly." Ex. 1023 at Abstract. The

specific problem addressed by Rupp is the so-called "dog boning" deformation of the balloon during the expansion process for a certain type of stent. *Id*. at 2:18-37. When the balloon is inflated and such stent begins to inflate, there is a tendency "towards longitudinal compression at the center of the stent." *Id*. at 2:20-21. This increases the metal mass at the center of the stent and in turn increases the "radial hoop strength" at the center (which means that it takes more force to expand the center of the stent). *Id*. at 2:22-26. Consequently, the balloon expands first at the two ends "before expanding at the center," thus creating a dumbbell shaped balloon (*i.e*., the dog boning deformation of the balloon). *Id*. at 2:26-28. While the dumbbell shaped the balloon is formed, the stent "slides down the expanded balloon ends toward the center of the balloon which is as yet unexpanded because of the stent's greater radical hoop strength." *Id*. at 2:29-31. "Because the stent is compressed toward the center of the balloon, complete balloon expansion may not be possible." *Id*. at 2:34-36.

33. In a prior art method to limit the dog boning deformation of the balloon, elastic restraining bands were employed to exert a force at the balloon's ends for countering the balloon deformation force. *Id*. at 2:8-16. Adopting a different approach to address the same problem, Rupp employs a built-up layer on the catheter shaft within the balloon and in the center of the stent. An example of

the built-up layers is shown as "40," "50, and "60" in Fig. 1 of Rupp, reproduced below.

Fig. 1



The cross-sections of the built-up layers ("40," "50, "60") are shown in Figs. 5-7 of Rupp, reproduced below.

Fig. 5

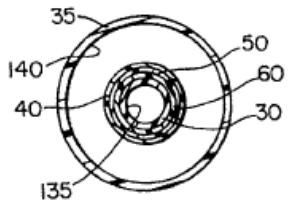


Fig. 6

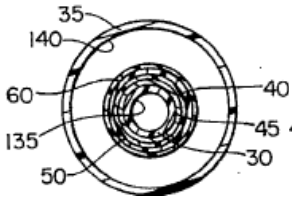
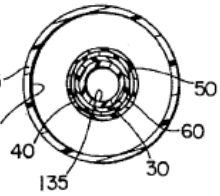


Fig. 7



34. The built-up layer "reduces longitudinal stent slippage during stent expansion and permits uniform radial stent expansion." *Id*. at 2:40-43. Specifically, the built-up layer causes the middle of the stent to be slightly expanded, thus reducing the radial hoop strength and reducing the amount of the force required to expand the middle of the stent. *Id*. at 7:11-14; *see also id*. at 4:58-62 ("Since the portion of the stent 100 situated over the built up section 20 is

already partially expanded, the center of the stent 100 will begin to expand to its full diameter at the same time as the balloon ends begin to expand."); 4:62-67 (The built up layer in the central portion of the stent "improves stent expansion by reducing radial hoop strength at the center of the stent 100 and also giving this area of the stent [] a head start on expansion so as to have the effect of pre-dilating the central portion of the stent.").

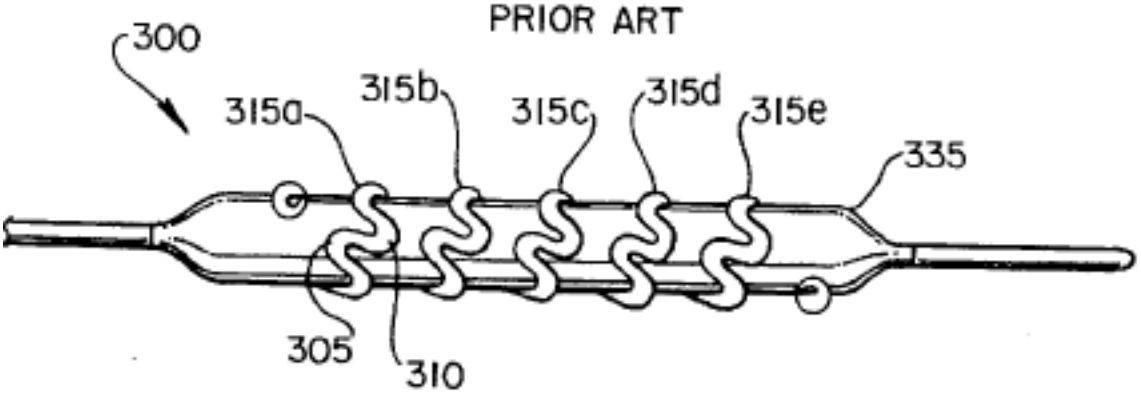
35. In order to expand the middle of the stent, the built up layer "has a tapering profile at either end to direct the stent elements slightly away from the center of the stent as the stent starts to expand." *Id*. at 5:7-9. In particular, "the taper would cause the zig-zag to be canted slightly toward the ends to give them that initial direction as the stent begins to expand." *Id*. at 5:9-12; *see also* Figure 1 ("40," "50, "60"); Figures 5-7 ("40," "50, "60"); 5:50-51 ("The built-up section 20, 120, 220 proximal and distal ends taper down.").

36. The specific type of the stent prone to dog boning deformation of the balloon has a zig-zag form, "such as a sinusoidal wave," as the helical pattern across the length of the stent. One example of such zig-zag stent is the Wiktor stent, shown in Figure 18 of Rupp (reproduced below). *Id*. at Fig. 18; Fig. 1 ("100"). Unlike stents adopting a cylindrical form, there are less metal materials in zig-zag stents, which leads to longitudinal movement of the metal during stent expansion and presents the problem of dog done deformation of the balloon. *Id*. at

4:32-35 ("Stents such as that shown in FIG. 18 having elements 315a-e can expand independently in the longitudinal direction and can present special problems not presented by stents formed of a solid cylinder.").

Fig. 18

PRIOR ART



37. Rupp further teaches that the stent thickness is about one to 15 thousandths of an inch. *Id*. at 3:56-57 ("The stent wire can have a diameter of about 0.001 inches to about 0.015 inches."). The total thickness of all built-up layers can be up to 60 thousandths of an inch at its thickest point (*i.e.*, the center). *Id*. at 5:46-49 ("The total increase in thickness of all the built-up layers …can range from about 0.0001 inches to about 0.060 inches at its thickest point."). The thickness of an individual built-up layer is preferably at least two thousandths of an inch (at its thickest point) and can be up to eight thousandths of an inch (at its thickest point). *Id*. at 51-55 (The thickness of each individual built-up layer ranges between approximately 0.001 inches and 0.010 inches and should more preferably

should range from about 0.002 inches to about 0.008 inches in thickness, but not less than about 0.002 inches in thickness."). The most preferable thickness of a single built-up layer is about three thousandths of an inch (at its thickest point). *Id*. at 5:61-62. "If a built-up layer is too thin it may puncture when crimped between the stent and marker band in addition to insufficiently building up the section to uniformly deploy the stent. If the built up section 20 becomes too thick, the distal end of the catheter will become too stiff and will fail to track properly within tortuous vessels." *Id*. at 5:55-62; *see also* 5:41-44 ("To avoid such leaks and provide a built up section 20 of sufficient thickness to avoid the dumbbell effect, one or more free standing built-up layers can be affixed to the inner lumen tubing 30, 130, 230."). The preferable number of built-up layers is no more than three. *Id*. at 5:45 ("FIGS. 1-9 show 3 such built-up layers, 40, 50 and 60"); 6:14-16 ("The preferred number of built-up layers is not more than 3 because of the amount of time each layer adds to manufacturing….").

38. I understand that Mr. Trotta views the built-up layer of Rupp as the "second member" (or "proximal member") in each claim of the '062 patent at issue. I also understand that Mr. Trotta does not contend that Rupp discloses the distal stop required in the claims of the '062 patent.

1. Rupp Does Not Disclose The Requirement In Claim 7

39. As discussed above, one of the claims of the '062 patent at issue is claim 7, which is directed to "the second member is a support member configured to support the medical implant." Mr. Trotta opines that the built-up layer in Rupp is a support member configured to support the stent, thus meeting the requirement of claim 7. Ex. 1003 at 134 [claim chart]. I disagree.

40. Mr. Trotta states that "Rupp's built up section 20 is a support member designed to support the stent" and cites passages of Rupp at "4:62-5:12, 5:38-45, 6:1-3." *Id*. These passages of Rupp are shown below:

begin to expand. The built up section **20** in the central portion of the stent **100** improves stent expansion by reducing radial hoop strength at the center of the stent **100** and also by giving this area of the stem **100** a head start on expansion so as to have the effect of pre-dilating the central portion of the stent.

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The length of the built up section **20** varies with the length of the stent **100** being deployed. Stents can range from 0.197 inches (5 mm) to 1.97 inches (50 mm) in length. The preferred length of the built up section **20** is equal to one-third of the length of the stent **100**. The built up section **20** should be centered between the proximal and distal ends of stent **100**. The built up section **20** has a tapering profile at either end to direct the stent elements slightly away from the center of the stent as the stent starts to expand. In particular, the taper would cause the zig-zags to be canted slightly toward the ends to give them that initial direction as the stent begins to expand.

…

When a stent **100** is crimped upon a balloon **35**, the plastic balloon is compressed between two pieces of metal, the marker band **45** and the stent **100**. This could cause pin hole leaks if not properly crimped. To avoid such leaks and provide a built up section **20** of sufficient thickness to avoid the dumbbell effect, one or more free standing built-up layers can be affixed to the inner lumen tubing **30**, **130**, **230**. FIGS. **1–9** show 3 such built-up layers, **40**, **50** and **60**.

…

6

The inner lumen tubing **30** can be built up by adding built-up layers **40**, **50**, **60** of a polymer material or by molding. To build up the inner lumen tubing **30** by adding

41. Mr. Trotta does not point to any specific disclosure in the above cited passages that supports his opinion. *See* Ex. 1003 at ¶¶ 142, 143. Nor does he explain how he formed his opinion based on the above passages. *Id*.

42. In my opinion, the built-up layer of Rupp does not meet the requirement of claim 7 of the '062 patent. Specifically, the built-up layer in Rupp is not a support member configured to support the stent. Rather, as shown in the above passages and elsewhere in Rupp discussed above, the built-up layer helps expand the stent, to provide uniform expansion, not support the stent to secure the stent during tracking and delivery. *See, e.g.*, Ex. 1023 at Title ("Thickened Inner Lumen For Uniform **Stent Expansion**…"); Abstract (The built-up layer "causes … **the stent to deploy** uniformly."); 2:40-43 (The built-up layer "reduces longitudinal stent slippage **during stent expansion** …."); 4:58-62 (The built-up layer allows the center of the stent to be "**partially expanded**."); 4:62-67 (The

built up layer in the central portion of the stent "improves **stent expansion** by reducing radial hoop strength at the center of the stent [] and also giving this area of the stent [] a head start on expansion so as to have the effect of pre-dilating the central portion of the stent."); 5:7-12 (The built up layer "has a tapering profile at either end to direct the stent elements slightly away from the center of the stent **as the stent starts to expand**."); 5:9-12 (The taper of the built-up layer would cause the zig-zag to be canted slightly toward the ends to give them that initial direction **as the stent begins to expand**."); 7:11-14 (The built-up layer "causes the middle of the stent []to be slightly expanded, thus reducing the radial hoop strength and reducing the amount of the force required to expand the middle of the stent []."") (emphases added).

43. Rupp's disclosure on stent expansion is contrasted with the '062 patent's disclosure on stent securement. *See, e.g.,* Ex. 1001 at Title ("Stent Delivery System Having **Stent Securement Apparatus**"); 3:13-25 the "**securement device is secured** over the inner catheter beneath the balloon to compensate for the undesired looseness or slack that due to recoil crimping and to aid in **securing the stent to the balloon**," to "**secure[s] the stent during tracking and delivery**" and "provide[s] a good friction fit to the stent and insure good contact between the stent and underlying balloon and catheter, instead of merely

crimping the stent onto the balloon and catheter and the underlying catheter and relying on the bulk of the flaccid balloon to hold the stent on.") (emphases added).

44. Nowhere in Rupp does it indicate that the built-up layer serves the function of supporting a stent. Indeed, in paragraph 42, I quoted every instance in Rupp where the function of the built-up layer is discussed. In each instance, it relates to stent expansion, not stent support required in claim 7 of the '062 patent. If anything, the built-up layer in Rupp is designed to prevent tight crimping of the center of the stent, allowing it to expand first, which is the opposite of supporting a stent required in claim 7 of the '062 patent. *See e.g.,* Ex. 1001 at 2:56-59 ("the stent must be smoothly and **evenly crimped** to closely conform to the overall profile of the catheter and unexpanded balloon") (emphasis added).

B. Jendersee

45. Jendersee relates to an encapsulated balloon expandable stent device to provide stent security during the stent's journey to the target site. Ex. 1016 at Abstract and 1:9-12. As discussed above and in the '062 patent, encapsulation is a stent securement method distinct from crimping used in the '062 patent. Ex. 1001 at 2:21-59. Jendersee itself distinguishes the stent encapsulation method over the stent crimping method. Ex. 1016 at 2:49-3:4. Specifically, Jendersee criticizes the stent crimping method as (1) inadequate because of the limited amount of

securement between the crimped stent and the balloon and (2) unsafe because of the uneven surface of the crimped stent:

> Significant difficulties have been encountered with deployment of known prior art stents, including difficulty in maintaining the stent on the balloon and in achieving symmetrical expansion of the stent when deployed. **Currently, some stent delivery systems retain the stent on the delivery catheter by means of either (a) plastically deforming the stent so that it is crimped onto the balloon**…. **The disadvantage** with these methods **is that the limited amount of securement between the stent and the balloon is not always adequate to insure that the stent will properly stay in place while advancing the stent to and through the target lesion. Additionally, the outer surface of the delivery device is uneven because the stent generally extends outwardly beyond the balloon and may contact a narrowed vessel wall and be displaced while the catheter negotiates a narrowed vessel**.

Id. at 2:49-66 (emphases added). In contrast to stent crimping, Jendersee explains that stent encapsulation "protects the stent and provides a smooth surface for easier passage through vessels." *Id*. at 3:2-4.

46. While citing the benefits of an encapsulated stent, Jendersee aims to improve upon the known expandable stent delivery systems that utilize a removable sheath system on the outside of the stent. In particular, Jendersee explains that the external sheath employed in this known method "increases the crossing profile of the delivery device thereby decreasing the device's ability to track through narrowed and tortuous vasculature." *Id*. at 3:4-7. "This and other complications have resulted in low level of acceptance for such stents." *Id*. at 3:7-8. Jendersee improves upon this known method by eliminating the external sheath:

> A long felt need exists for a delivery and deployment method for stents which ensures positional stability of the stent during delivery **without the need for an external sheath**, **thereby substantially decreasing the cross sectional profile of the balloon delivery device**, and ensures symmetrical expansion of the stent at deployment.

Id. at 3:11-16 (emphasis added).

47. Specifically, Jendersee discloses a stent delivery and deployment method that involves forming the balloon, thus creating "intimate contact" between the balloon and the stent to "assure stent attachment to the balloon, i.e., excapsulation [sic: encapsulation]." *Id*. at 3:20-23. Jendersee's stent encapsulation method includes:

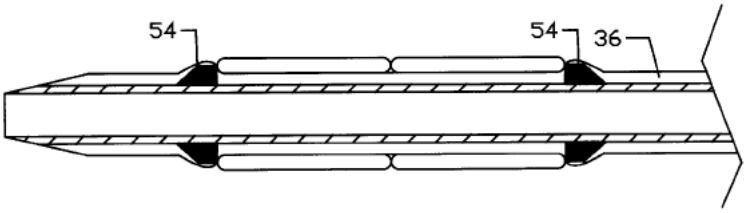
> …the steps of compressing the stent on the outside of the balloon, placing a sheath [which would be later removed once encapsulation is accomplished] over the compressed stent to prevent expansion, and exposing the sheathed stent and balloon to an elevated temperature while pressurizing the balloon. The elevated temperature and pressurization causes the balloon to expand from below the stent to fill at least some of the spaces between the stent and the sheath. Following expansion and exposure to an elevated temperature, the balloon and stent are cooled while maintaining pressure in the balloon, so that the balloon profile will be "frozen around" (formed and somewhat adhered to) the stent.

Id. at 3:33-44. Thus, during the encapsulation process of Jendersee, the balloon "expand[s] part way around the stent and adhere thereto." *Id*.; *see also id*. at Abstract (The balloon is heated and pressurized to expand it "around the stent within the sheath" and then cooled "to cause the balloon to adhere to the stent and to set the shape of the expanded balloon."). Jendersee's method is "especially valuable at the proximal and distal ends of the stent for delivery purposes because

a smoother transition occurs between the distal and proximal surfaces of the balloon catheter and the distal and proximal ends of the stent…." *Id.* at 3:24-29; *see also id*. at 4:23-28 (A specific object of the present invention is to "eliminate[] the need for a deployment sheath and result[s] in a low profile device with a more regular outer surface that may be delivered through tortuous, narrowed vessel.")

48. Mr. Trotta relies on the so-called retainer feature of Jendersee as a "first member" and a "distal stop" required in the claims of the '062 patent. An example of a retainer in Jendersee is shown as "54" in Figure 8 of Jendersee.

FIGURE 8



While the above example shows two retainers within the balloon and at both ends of the stent, Jendersee discloses that retainers may be located on top of the balloon or at either end of the stent. *Id*. at 3:49-52. Further, "the balloon itself may be used to form one or more stent retainers during the encapsulation process." *Id*. at 3:52-54. Jendersee teaches that "[r]etainers assist in delivery by providing a smooth transition between the encapsulated stent and the catheter surface." *Id*. 3:58-60; *see also id*. at 4:40-43 (retainers for "maintaining the stent on the balloon and for forming a smooth outer surface on the encapsulated stent device.").

49. Jendersee does not disclose a second member or a primary member required in each claim of the '062 patent at issue. Nor does Mr. Trotta contend such.

C. Sugiyama

50. Mr. Trotta relies on Sugiyama for the sole purpose of establishing the adhesive bonding requirement in claims 5-6 of the '062 patent. Ex. 1003 at ¶ 144. He does not rely on Sugiyama to establish any other requirement of the claims of the '062 patent.

VII. ONE OF ORDINARY SKILL IN THE ART WOULD NOT HAVE COMBINED RUPP WITH JENDERSEE TO DERIVE THE CLAIMS OF THE '062 PATENT

51. Mr. Trotta opines that "[a] POSITA would have been motivated to add one or both conical retainers taught by Jendersee as a useful adjunct to built-up layer of Rupp to further enhance the securement of the stent, which would yield the same benefits of enhanced the securement and trackability discussed above[.]" Ex. 1003 at ¶ 146. Mr. Trotta further opines that "[a]dding stops at the ends of Rupp's stent would not affect operation of the balloon or reinforcement 9, and would provide a tapered profile under the cone regions of the balloon to help further secure the stent." *Id*. I disagree.

52. As an initial matter, I note that Mr. Trotta does not explain how he derived his opinions.[2] As will be discussed below, in my opinion, a person of ordinary skill in the art would not have combined Rupp with Jendersee to derive the claims of the '062 patent in the relevant time frame.

A. One Of Ordinary Skill In The Art Would Not Have Selected Rupp For Modification To Solve The Problems Encountered By The Inventors Of The '062 Patent

53. First, as discussed above, the problem encountered by the inventors of the '062 patent relates to a stent securement issue. As also discussed above, Rupp addresses the problem of uniform stent expansion. *See, e.g.*, Ex. 1023 at Title ("Thickened Inner Lumen **For Uniform Stent Expansion**…"); Abstract ("The built-up layer is sufficiently thick to **cause …the stent to deploy uniformly**."); 1:6-11 ("**The present invention relates to** an intravascular stent deployment system … with the catheter inner lumen tube having a greater outer diameter for a central portion of the area covered by the stent thereby **permitting more uniform expansion of the stent**."); 2:40-43 ("It is an object of the invention to provide a means for stent deployment which reduces longitudinal stent slippage **during stent expansion**.); 2:55-57 (The built-up layer is sufficiently thick as to **cause … the stent to deploy uniformly**.) (emphases added). Rupp does not at all relate to stent

[2] I also do not know what he means by "reinforcement 9," which is likely a typographical error.

securement issues. I searched Rupp and could not even find the words "securement", "retention", "dislodgement" and derivatives of these terms.

54. Further, the stent securement issue addressed by the '062 patent relates to stent's travel to the treatment **before it is expanded**. The stent expansion problem addressed by Rupp relates to stent expansion—after the stent has already safely traveled to the treatment site. Thus, while the '062 patent and Rupp both relate to stents with a structure within the balloon, they address totally different sets of problems, from both substantive and temporal perspectives. Consequently, to begin solving the stent securement issue, a person skilled in the art would not have consulted with disclosures relating to uniform stent expansion in Rupp for potential solutions for secure stent delivery.

55. Second, in Rupp, the mechanism of action of the built-up layer is to reduce the radial hoop strength of the center of the stent and allow the center of the stent to partially expand first. *Id*. at 4:59-62 ("Since the portion of the stent 100 situated over the built up section 20 is **already partially expanded**…."); at 4:62-67 ("The built-up section 20 in the central portion of the stent 100 improves stent expansion by **reducing radial hoop strength** at the center of the stent 100 and also by giving this area of stem [sic: stent] 100 a head start on expansion so as to have the effect of **pre-dilating the central portion of the stent**.) (emphases added). Specially, the built-up layer is tapered "at either end to direct the stent

elements slightly away from the center of the stent…." *Id*. at 5:7-8. Thus, Rupp's tapered built-up layer is designed to minimize crimping the center of the stent, nearly the opposite of what the inventors of the '062 patent intended to accomplish, which is to maximize stent crimping.

56. Finally, adding the built-up layer of Rupp would add profile (*i.e*., thickness) to a delivery system. During the 1996 timeframe, stent and stent delivery system companies (such as Advanced Cardiovascular Systems, Cordis Corporation, Cook, SciMed Life Systems (Patent Owner's predecessor)) were engaged in profile wars where they competed with each other to develop and market stents or stent delivery systems with the lowest profiles. Even one thousandth of an inch would have mattered at that time. As discussed above, the center of Rupp's built-up layers could add up to 60 thousandths of an inch to the profile of a delivery system (Ex. 1023 at 5:46-51), which would have discouraged a person skilled in the art to employ Rupp's design as a potential solution for a stent security issue for a crimped stent.

B. One Of Ordinary Skill In The Art Would Not Have Combined Rupp With Jendersee To Derive The Claimed Invention Of The '062 Patent

57. A person of ordinary skill in the art also would not have combined Rupp with Jendersee to derive the claimed invention of the '062 patent. First, Jendersee addresses a problem that is totally different than that in Rupp and in the

‘062 patent. As discussed above, Jendersee relates to stent encapsulation, which involves a unique method of stent retention vastly different from stent retention using crimping method as in Rupp and the ‘062 patent. For example, unlike the crimped stent in Rupp and the ‘062 patent, the stent is not crimped in the stent encapsulation method taught in Jendersee.

58. Second, Jendersee teaches away from Rupp and from the solutions of the ‘062 patent. Specifically, Jenderesee criticizes the stent crimping method used in Rupp and the ‘062 patent as inadequate. Ex. 1016 at 2:58-62 (“The disadvantage with these methods [including the stent crimping method] is that the limited amount of securement between the stent and the balloon is not always adequate to insure that the stent will properly stay in place while advancing the stent to and through the target lesion.”); Ex. 1023 at 5:38 (“When a stent 100 is crimped upon a balloon”); 5:41 (“This could cause pin hole leaks if not properly crimped”): 5:56 (“when crimped”); 7:8 (“crimped down”). Thus, Jendersee itself teaches against the combination with Rupp, which employs a stent crimping method, and against the claimed invention of the ‘062 patent, which also employs a crimped stent. Further, Jendersee criticizes an “uneven” outer surface of a delivery device would be unsafe and aims to provide a “smooth surface for easier passage through vessels.” Ex. 1016 at 2:62-66; 3:3-7. In a proposed combination between Rupp and Jendersee, the outer surface of the delivery device would be uneven and

would not be smooth because of the presence of the built-up layer. In particular, as shown in Figure 1 of Rupp (reproduced above), the built-up layer is functionally designed to be tapered and uneven, which would be yet another reason discouraging the combination of Rupp and Jendersee.

59. Finally, Rupp's built-up layer is located at the center of the stent and is tapered with the thickest point in the center. As such, the ends of the stent are more tightly crimped to the catheter than the enlarged center section. In such a configuration, the enlarged center section of the built-up layer would provide resistance to longitudinal compression of the stent (*i.e.*, movement of the ends of the stent) during positioning of the stent as well. Since the center of the stent in Rupp is less tightly crimped, it would be this area, not the ends of the stent, that would be subject to movement during positioning of the stent. The retainers taught in Jendersee would not be useful to protect this section.

60. For all of the reasons above, while I understand that one of ordinary skill in the art is presumed to be aware of Rupp and Jendersee, upon reading them, one would not have any reason to select and modify Rupp or combine it with Jendersee to solve a stent securement problem for a crimped stent dealt with in the '062 patent. In fact, as discussed above, there are important reasons that would have informed a person skilled in the art against choosing the built-up layer in

Rupp for modification, and against the combination of Rupp and Jendersee to address the stent crimping and securement issues encountered in the ‘062 patent.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my personal knowledge.

Executed this 25th day of January, 2018 at San Diego, CA

Ronald J. Solar

Appendix A: CURRICULUM VITAE

Ronald Jay Solar, Ph.D.

12495 Figtree St.
San Diego, CA 92131

Tel.: (858) 864-2922
ronsolar1@aol.com

Education:

1972-1976 **UNIVERSITY OF PENNSYLVANIA** Philadelphia, PA
Ph.D. Metallurgy, Materials Science & Biomaterials
Dissertation: *"Corrosion Behavior of Surgical Implant Alloys"*

1968-1972 **PENNSYLVANIA STATE UNIVERSITY** University Park, PA
B.S. Metallurgy & Materials Science
Thesis: *"Failure Analysis of Orthopedic Implants"*

1964-1968 **NORTHEAST HIGH SCHOOL** Philadelphia, PA

Experience:

1989-Present **RENAISSANCE BIOMEDICAL, INC.** San Diego, CA
President
- Founder
- Research and consultation in design, technical, marketing, patent, clinical and regulatory issues related to the Medical Device Industry

2004-Present **THERMOPEUTIX, INC.** San Diego, CA
President and CEO
- Co-Founder
- Design and development of new medical devices

2004-Present **MINNESOTA MEDTECH, INC.** Rodgers, MN
Director
- Contract manufacturer and supplier to medical device companies

2004-Present **PHARMACO-KINESIS, INC.** Los Angeles, CA
Director
- Design and development of new medical devices and biosensors

2004-2009 **Y MED, INC.** San Diego, CA
Chief Technology Officer
- Co-Founder
- Design and development of new cardiovascular medical devices

- Acquired by CR Bard in 2009

2001-2003 **X TECHNOLOGIES, INC.** Tustin, CA
Chief Technology Officer
- Merger with MEDgination, Inc.
- Acquired by Guidant Corp. in 2003

1998-2001 **MEDgination, INC.** San Diego, CA
President and CEO
- Founder
- Design and development of new medical devices
- Merged with X Technologies in 2001

1992-1995 **OCCAM INTERNATIONAL, BV** Eindhoven, The Netherlands
Supervisory Director
- Co-Founder
- Responsible for all aspects of the Company's business (developer and manufacturer of unique PTCA catheters and other interventional devices)
- Designer of Company's products
- Intellectual property acquired by Cordis in 1995

1988-1989 **MEDTRONIC/VERSAFLEX, INC.** San Diego, CA
Vice President, Research and Development
- Responsible for Company's research and product development efforts in the peripheral and coronary vascular marketplace. Product lines included balloon angioplasty catheters (PTA &PTCA), guidewires and ancillary equipment, stents, atherectomy catheters, laser catheters, angioscopy catheters and custom devices
- Responsible for FDA interface and regulatory matters
- Responsible for clinical studies
- Responsible for patent disclosures and review of applications
- Sales and Marketing support including customer interface
- Member of General Manager's Executive Staff
- Member of parent corporation's (Medtronic) "Science & Technology Committee"
- Member of parent corporation's (Medtronic) Patent Panel

1985-1988 **VERSAFLEX, INC.** San Diego, CA
Vice President and Technical Director
- Co-founder
- Responsible for all technical aspects of the Company, including R&D, product design and development, FDA interface and regulatory matters, clinical studies, patents, production, QC & QA, facilities, etc.
- Sales and Marketing support including customer interface, advertising, trade show exhibit design, international physician workshop, sales training, and customer service
- Corporate officer
- Business plan development
- Acquired by Medtronic in 1988

1983-1985 **SCIMED LIFE SYSTEMS, INC.** Minneapolis, MN

Director, Advanced Product Development

- Set up entire therapeutic catheter business center. Responsible for planning, budget, staffing, R&D, product design and development, clinical studies, pilot production, market research, training, etc.
- Product lines included 2 intraoperative angioplasty catheters, a balloon inflation device, a PTA catheter, guidewires, and a family of PTCA catheters
- Acquired by Boston Scientific

1982-1983 **ADVANCED CARDIOVASCULAR SYSTEMS** Mountain View, CA

Senior Project Engineer

- First senior engineer of Company
- Successfully designed, developed and released to market 5 new PTCA products, and initiated design and development of 4 others
- Responsibilities also included physician interface, R&D staffing, Marketing support, and Manufacturing and QA support
- Acquired by Eli Lilly, and spun off to Guidant

1978-1982 **AMERICAN HOSPITAL SUPPLY CORP.** Irvine, CA

Senior R&D Engineer, American Edwards Laboratories Div.

- Designed and developed 5 new products and established 2 new product lines (Infusion Catheters and Angioplasty Catheters)
- Responsibilities also included physician interface, Manufacturing support, and numerous Marketing efforts, such as, production of in-service films and design of technical and commercial exhibits

Supervisor, R&D Lab/Materials and Process Engineer, Edwards Pacemaker Div.

- Set up R&D laboratory
- Designed test programs to determine pacemaker components efficacy and reliability
- Responsibilities also included QA and Manufacturing support, as well as participation in the design and development of new pacemakers and related products

1977-1978 **ARCO MEDICAL PRODUCTS CO.** Leechburg, PA

Materials Engineer

- Responsibilities included: pacemaker, heart lead and component failure analysis; pacemaker battery testing and development; Marketing, R&D, QA and Manufacturing support

HONORS, AWARDS, PATENTS, ETC.:

- Fifty-eight (58) U.S. Patents (interventional diagnostic and therapeutic catheters, guidewires, vascular stents, stent delivery systems)
- Foreign patents for above
- United States Junior Chamber of Commerce TEN OUTSTANDING YOUNG AMERICANS, 1989
- Junior Chamber International TEN OUTSTANDING YOUNG PEOPLE OF THE WORLD, 1989
- Tau Beta Pi Engineering Honor Society
- Sigma Tau Engineering Honor Society
- Northeast High School (Philadelphia) Alumnus of the Year, 1992
- Leon J. Obermayer Memorial Award Nominee, 1993
- University of Pennsylvania Teaching Fellowship
- National Institute of Dental Research Fellowship
- Cooperative Program in Metallurgy Scholarship
- Pennsylvania State Senatorial Scholarship
- Dean's List
- Board of Directors, member of Executive Committee, Project Concern International
- Cubmaster
- Assistant soccer coach — AYSO

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R. Solar, “Selective Brain Cooling for Neuroprotection,” 15TH INTERNATIONAL MEETING ON INTERVENTIONAL CARDIOLOGY, Tel Aviv, Israel, Dec. 2016

R. Solar. “Selective Endovascular Brain Cooling,” Leipzig Interventional Course (LINC), Leipzig, Germany, January 2017

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THERAPIES, Washington, DC, February 2017

R. Solar, “Nest Generation DCB,” CARDIOVASCULAR REVASCULARIZATION THERAPIES, Washington, DC, February 2017

R. Solar, “Endovascular Selective Cerebral Hypothermia,” CARDIOVASCULAR REVASCULARIZATION THERAPIES, Washington, DC, February 2017

R. Solar, “Neuroprotection by Selective Cerebral Hypothermia,” 32nd Annual Snowmass Symposium, Snowmass, CO, March 2017

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R. Solar, “Mechanism of Balloon angioplasty — The Forgotten Art,” 18th Annual NEW CARDIOVASCULAR HORIZONS, New Orleans, LA, May 2017

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Appendix B: IP Cases Supported by Ronald Jay Solar, Ph.D.

Dates	**Case**	**Matter**	**Represented**	**Testimony***
2014	Vascular Solutions v BSC	Guiding Catheter	Defendant	R
2008-2009	SciCoTec v BSC Civil Action No. 9:07-CV-76	RX catheter	Plaintiff	R, D, A
2008	Spectranetics Corporation v. Medtronic, Inc., et at. Civil Action No. A:07-CA-548 SS	Aspiration catheter	Plaintiff	---
2007	Alt v BSC Case 11 133 Y 02035 06	Stent	Plaintiff	R, D?
2007	Medtronic v. Kyphon Civil Action No. C06-02559 SI	Orthopedic device	Plaintiff	---
2006-2007	BSC v Conor MedSystems Civil Action No. 05-768-SLR	Stent	Defendant	R, D
2006-2007	Schneider (Europe) GmbH v. Conor Medsystems Ireland Ltd., High Court Record No. 2006/1930P	Stent	Defendant	R
2004-2005	Liebel-Flarsheim Co. v. Medrad, Inc. Civil Action No. C-1-98-858	Angiographic injector	Defendant	R
2004	Cordis v Medtronic	Stent	Defendant	---
2002	Cook Inc. v C.R. Bard Civil Action No. IP 00-1791 C•B/S	Stent	Plaintiff	R, D

* R= Report; D= Deposition; A= Arbitration Hearing; T= Trial

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Dates	**Case**	**Matter**	**Represented**	**Testimony***
2001-2002	BSC v Medtronic	RX catheter	Defendant	R, D
1999-2000	J & J v Medtronic	Stent	Defendant	R, D, T
Pre-2000	Cook v J. Wilson	Catheter technology	Plaintiff	R, D, T
	Schneider v SciMed	RX catheter	Plaintiff	R, D, T
	Cordis v SciMed	RX catheter	Plaintiff	---
	Angiomedics v USCI	Guiding catheter	Plaintiff	R, D, T
	USCI v ACS	Guidewire	Defendant	R?, D

* R= Report; D= Deposition; A= Arbitration Hearing; T= Trial