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28**NOT FOR CITATION**

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

MEDTRONIC, INC., ET AL,

Plaintiff,

No. 06-04455 JSW

v.

W.L. GORE & ASSOCIATES, INC.,

Defendants.

**ORDER DENYING W.L. GORE
AND ASSOCIATES, INC.'S
MOTION FOR SUMMARY
JUDGMENT****INTRODUCTION**

Now before the Court for consideration is the Motion for Summary Judgment of Patent Invalidity filed by Defendant W.L. Gore & Associates, Inc (“Gore”). Having considered the parties’ papers, relevant legal authority, the record in this case, and having had the benefit of oral argument, the Court HEREBY DENIES the motion for summary judgment.¹

BACKGROUND

Plaintiffs, Medtronic, Inc., Medtronic USA, Inc., and Medtronic Vascular, Inc. (collectively “Medtronic”), allege that Gore infringes Medtronic’s U.S. Patent Nos. 5,067,957 (“the ‘957 Patent”), 5,190,546 (“the ‘546 Patent”), and 6,306,141 (“the ‘141 Patent”) (collectively, “the Jervis Patents”).² Medtronic also alleges that Gore infringes Medtronic’s

¹ The Court notes that the parties each have violated Northern District Civil Local Rule 3-4(c)(2), which requires footnotes to be in 12 point font. The parties are HEREBY ADVISED that failure to comply with this rule in the future shall result in the Court striking papers from the record.

² Medtronic asserts that Gore infringes claims 1-3, 5-7, 9-16, 18, 22, 24, 37 and 40 of the ‘957 Patent, claim 27 of the ‘546 Patent, and claims 1-7, 9, 18-19, and 22 of the ‘141 Patent. (Declaration of Ellen J. Wang (“Wang Decl.”), Ex. B at 8:7-8, 13:4-5, 17:22-23.)

1 U.S. Patent Nos. 4,886,062 (“the ‘062 Patent”), 6,656,219 (“the ‘219 Patent”), and 6,923,828
2 (“the ‘828 Patent”) (collectively, “the Wiktor Patents”).³ The Jervis and Wiktor Patents each
3 are directed, in general, to medical devices or methods for implanting such medical devices into
4 a human body.

5 Gore moves for summary judgment on the basis that: (1) all asserted claims of the
6 Wiktor Patents are invalid for lack of enablement; (2) all asserted claims of the Jervis Patents
7 are invalid, because the claims are obvious in view of the prior art; and (3) all asserted claims of
8 the Jervis Patents are invalid, because the claims are indefinite.

9 **A. The Wiktor Patents.**

10 The Wiktor Patents are directed to intravascular stents. In the specification, Wiktor
11 describes his invention, generally, as comprising “an open-ended wire formed device of
12 basically cylindrical shape and made of a softer-then [*sic*] spring type metal and fitted over an
13 inflatable element of a typical balloon type catheter. ... The wire formed device is intended to
14 act as a permanent prosthesis stent and is implanted transluminarely.” (*See, e.g.*, Declaration of
15 Jennifer BianRosa (“BianRosa Decl.”), Ex. A (‘062 Patent at 1:14-22).)⁴ The ‘062 Patent was
16 filed on October 19, 1987, and the ‘219 and ‘828 Patents each were filed on November 22,
17 2000. (Bianrosa Decl., Exs. A-C.)⁵ It is undisputed that, at the time the ‘062 Patent was filed, a
18 person of ordinary skill in the art would have a degree in engineering or biomedical engineering
19 and familiarity with implantable medical devices.

20 Claim 5 of the ‘062 Patent, which is representative of the asserted claims of that patent,
21 provides:

22
23

³ Medtronic asserts that Gore infringes claims 5-7, 9-10, and 12-13 of the ‘062
24 Patent, claims 1, 3-4, 6-7 and 9 of the ‘219 Patent, and claims 1, 3-14, and 18-21 of the ‘828
25 Patent. (*See Wang Decl.*, Ex. B at 1:16-17, 3:15-16, 5:15-16.)

26
⁴ The Court cites to references within the patents-in-suit in the following
format: “column:line” or “column:line-column:line.”

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⁵ The ‘219 and ‘828 Patents are continuations-in-part of the ‘062 Patent. Thus,
although the specifications of each of the patents are largely similar, the specifications of the
‘219 and ‘828 Patents contain new matter. When the Court cites portions of the specification
that are common to all three patents, it shall cite only to the ‘062 Patent.

1 A radially-expandable stent for implantation within a body vessel
2 comprising:
3 a stent body having a wall of generally cylindrical shape formed of a
4 helical coil made of a wire, the body having a longitudinal axis and a first
5 diameter;
6 zig-zag means in the wire for allowing radial expansion of the cylindrical
7 stent body from the first diameter to a second larger diameter without
8 significantly altering the body length along the longitudinal axis.

9 ('062 Patent at 5:42-6:7.)

10 Claim 1 of the '219 Patent, which is representative of the asserted claims of that patent,
11 provides:

12 An intravascular stent, comprising:
13 a continuous sinusoidal shaped wire, wherein said wire is coiled to form a
14 helical-shaped stent body, wherein said stent is expandable from a first
15 delivery diameter to a second implanted diameter.

16 (BianRosa Decl., Ex. B ('219 Patent at 8:2-7).)

17 Claim 1 of the '828 Patent, which is representative of the asserted claims of that patent,
18 provides:

19 An intravascular stent, comprising:
20 a generally cylindrical body including a helically coiled wire, wherein said
21 helically coiled wire has generally sinusoidally-shaped waves;
22 wherein said generally cylindrical body is capable of radially expanding.

23 (*Id.*, Ex. C ('828 Patent at 7:47-53.)

24 On August 14, 2007, the Court issued an Order construing the term "stent," as used in
25 the Wiktor Patents, to mean "a supporting device." (Docket No. 91 (Claim Construction Order
26 at 16:21-22); Docket No. 116 (Order Granting Plaintiffs' Motion for Reconsideration at 2:13-
27 25).) In so doing, the Court rejected Gore's proposed construction that the term "stent" should
28 include a "low memory metal" limitation. (Claim Construction Order at 14:15-16:10).⁶ The

⁶ In its Claim Construction Order, the Court stated that a "low memory metal" limitation was the only meaningful difference between independent Claim 14 and dependent Claim 17 of the '062 Patent. (Claim Construction Order at 14:20-21.) The reference to the '062 Patent was a typographical error, and the Court intended to refer to Claims 14 and 17 of

1 Court also concluded that Wiktor “did not disavow clearly the use of self-expanding or resilient
2 stents,” based in part on its conclusion that “Wiktor does not say resilient metal is unsuitable to
3 achieve the object of his invention, namely a stent that expands radially.” (*Id.* at 15:15-17.)

4 **B. The Jervis Patents.**

5 The Jervis Patents are directed to medical devices, or methods for implanting such
6 devices, that utilize shape memory alloys (“SMAs”) and improvements thereon. (*See, e.g.,*
7 BianRosa Decl., Ex. D (‘957 Patent at 1:19-20).) The ‘957 Patent was filed on September 27,
8 1988. The ‘546 Patent was filed on April 9, 1991, and the ‘141 Patent was filed on June 7,
9 1995. It is undisputed that, at the time the first Jervis Patent was filed, a person or ordinary skill
10 in the art would possess a degree in materials sciences or related engineering degree and have
11 some familiarity with implantable medical devices.

12 As Jervis acknowledges in his patents, “[m]aterials, both organic and metallic, capable
13 of possessing shape memory are well known.” (‘957 Patent at 1:23-24.) Jervis also explains
14 that:

15 [a]n article made of [a material capable of possessing shape memory] can be
16 deformed from an original, heat-stable configuration to a second, heat-
17 unstable configuration. The article is said to have shape memory for the
18 reason that, upon the application of heat alone, it can be caused to revert, or
19 to attempt to revert, from its heat-unstable configuration to its original, heat-
20 stable configuration, *i.e.* it “remembers” its original shape.

21 Among metallic alloys, the ability to possess shape memory is a result of the
22 fact that the alloy undergoes a reversible transformation from an austenitic
23 state to a martensitic state with a change in temperature. This transformation
24 is sometimes referred to as a thermoelastic martensitic transformation. An
25 article made from such an alloy ... is easily deformed from its original
26 configuration to a new configuration when cooled below the temperature at
27 which the alloy is transformed from the austenitic state to the martensitic
28 state. The temperature at which this transformation begins is usually referred
to as M_s and the temperature at which it finishes M_f . When an article thus
deformed is warmed to the temperature at which the alloy starts to revert
back to austenite, referred to as A_s (A_f being the temperature at which the
reversion is complete) the deformed object will begin to return to its original
configuration.

26 (‘957 Patent at 1:23-49.)

28 _____
the ‘828 Patent.

1 Jervis describes the disadvantages associated with using SMA devices for medical
2 purposes, including the fact that “it is difficult to control the transformation temperatures of
3 shape memory alloys with accuracy, as they are usually composition-sensitive[.]” (*Id.* at 2:32-
4 35.)

5 The combination of these factors with the limitation that (a) it is inconvenient
6 to have to engage in any temperature manipulation, and (b) human tissue
7 cannot be heated or cooled beyond certain relatively narrow limits ... without
8 suffering temporary or permanent damage is expected to limit the use of SMA
9 medical devices. It would thus be desirable to develop a way in which the
10 advantageous properties of shape memory alloys, i.e. their ability to return to
11 an original shape after relatively substantial deformation, could be used in
12 medical devices without requiring the delicacy of alloying control and/or the
13 temperature control of placement or removal needed by present shape memory
14 alloy devices.

15 ...

16 I have discovered that if, in a medical device containing a shape memory
17 alloy element which uses the shape memory property of that alloy, an
18 element which shows the property of stress-induced martensite is used
19 instead, an improved device results.

20 Accordingly, this invention provides a medical device intended for use
21 within a mammalian body, or in such proximity to a mammalian body that
22 the device is substantially at body temperature, which device comprises a
23 shape memory alloy element, the improvement in which comprises the
24 substitution of an alloy element which displays stress-induced martensite at
25 said body temperature for the shape memory alloy element.

26 (*Id.* at 2:43-66; *see also id.* at 3:1-6.)

27 ANALYSIS

28 A. Legal Standards Applicable to Motions for Summary Judgment.

Summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. *Union States Gypsum Co. v. Nat'l Gypsum Co.*, 74 F.3d 1209, 1212 (Fed. Cir. 1996). The burden of demonstrating the absence of any genuine issue of material fact rests with the moving party. *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1116 (Fed. Cir. 1985). Where, as here, the moving party will bear the burden of proof at trial, that party must come forth with “evidence which would entitle it to a directed verdict if the evidence went uncontradicted at trial.” *Houghton v. South*, 965 F.2d 1532, 1536 (9th Cir. 1992); *cf. Eli Lilly & Co. v. Barr Labs, Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001). In order to defeat summary judgment, the non-moving party must do

1 “more than simply show that there is some metaphysical doubt as to the material facts.”
2 *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Rather, the non-
3 moving party must set forth “specific facts showing that there is a genuine issue for trial.” Fed.
4 R. Civ. P. 56(c); *Matsushita Elec.*, 475 U.S. at 587.

5 “Because a patent is presumed to be valid,” Gore’s “evidentiary burden to show facts
6 supporting a conclusion of invalidity is one of clear and convincing evidence.” *Automotive*
7 *Tech. Int’l Inc. v. BMW of North Am., Inc.*, 501 F.3d 1274, 1281 (Fed. Cir. 2007) (citing *AK*
8 *Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1238-39 (Fed. Cir. 2003)). Gore also must
9 overcome “deference to the [United States Patent and Trademark Office’s (“PTO”)] findings
10 and decisions in prosecuting the patent application. Deference to the PTO is due “[w]hen no
11 prior art other than that which was considered by the PTO examiner is relied on” by the party
12 attacking the patent’s validity. *Boston Scientific Corp. v. Johnson & Johnson*, 534 F. Supp. 2d
13 1062, 1068 (N.D. Cal. 2007) (quoting *American Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d
14 1350, 1359 (Fed. Cir.), *cert denied*, 469 U.S. 821 (1984)).

15 **B. Evidentiary Objections.**

16 Medtronic objects to Exhibits G-H to the BianRosa Declaration, on the ground that the
17 documents contain inadmissible hearsay.⁷ Gore argues that the documents are admissible under
18 Federal Rule of Evidence 801(d)(2)(D), which provides that a statement is not hearsay if “the
19 statement is offered against a party and is ... a statement by the party’s agent or servant
20 concerning a matter within the scope of the agency or employment, made during the existence
21 of the relationship.” Medtronic responds that at the time Wiktor made the statements reflected
22 in these exhibits, he was an independent contractor and not Medtronic’s agent. *See Merrick v.*
23 *Farmers Ins. Group*, 892 F.2d 1434, 1440 (9th Cir. 1990) (finding that district court properly
24 excluded statements where plaintiff had not established statements were made by agents as
25 opposed to independent contractors).

26
27
28 ⁷ The Court has not relied on Exhibit G to the BianRosa Declaration. Therefore, it shall not address the admissibility of the exhibit at this time.

1 The consulting agreement between Wiktor and Medtronic is governed by Minnesota
2 law. (Reply Declaration of Jennifer BianRosa (“BianRosa Reply Decl.”), Ex. W at 7.) Under
3 Minnesota law, the factors to be applied to distinguish between an independent contractor and
4 agency relationship are “(1) [t]he right to control the means and manner of performance; (2) the
5 mode of payment; (3) the furnishing of material or tools; (4) the control of the premises where
6 the work is done; and (5) the right of the employer to discharge. ... In determining whether the
7 status is one of employee or independent contractor, the most important factor considered in
8 light of the nature of the work involved is the right of the employer to control the means and
9 manner of performance.” *Guhlke v. Roberts Truck Lines*, 268 Minn. 141, 143 (1964).

10 The consulting agreement does not state that Wiktor is an independent contractor.
11 Moreover, it provides that Wiktor agrees to consult with Medtronic “and perform development
12 work for Medtronic in the area of vascular stents, *as directed* by Medtronic.” (Bian Rosa Reply
13 Decl., Ex. W at 2-3 (emphasis added).) Medtronic paid Wiktor for his services and at least
14 some of the documents Gore submits suggest that Medtronic furnished Wiktor with materials
15 during the course of their agreement. The Court concludes that Gore has presented sufficient
16 evidence to establish that Wiktor acted as Medtronic’s agent at the time the statements were
17 made. (*See* Docket No. 285, Gore’s Motion for Leave to File Post Summary Judgment Hearing
18 Submission, Exs. A, B.) Further, the statements were made within the scope of Wiktor’s
19 consulting agreement.

20 Therefore, the Court concludes that the statements are non-hearsay and OVERRULES
21 the objections to BianRosa Declaration Exhibits H and I. *See Metro Goldwyn Meyers Studio v.*
22 *Grokster, Ltd.*, 454 F. Supp. 2d 966, 973-74 (C.D. Cal. 2006) (noting that “statement is
23 admissible under Rule 801(d)(2)(D) so long as it is made by an agent within the scope of
24 agency, regardless of the precise contractual relationship between the agent and the party
25 against whom the evidence is offered”); *cf. Beck v. Haik*, 377 F.3d 624, 639-40 & n. 4 (6th Cir.
26 2004) (citing, *inter alia*, *United States ex rel Remtech, Inc. v. National Union Fire Ins. Co.*,
27 2000 WL 1171139 at *3 n.4 (9th Cir. Aug. 17, 2000)) (concluding that statement by a
28 “consultant” qualified as non-hearsay pursuant to Rule 801(d)(2)(D)).

1 **C. Gore Has Not Met Its Burden to Show That the Claims of the Wiktor Patents Are**
2 **Invalid.**

3 **1. Legal Standards Applicable to Enablement.**

4 The specification [of a patent] shall contain a written description of the
5 invention, and of the manner and process of making and using it, in such full,
6 clear, concise, and exact terms as to enable any person skilled in the art to
7 which it pertains, or with which it is most nearly connected, to make and use
8 the same, and shall set forth the best mode contemplated by the inventor of
9 carrying out his invention.

10 35 U.S.C. § 112, ¶ 1 (hereinafter “Section 112, paragraph 1”).

11 “Whether the subject matter of a patent claim satisfies the enablement requirement
12 under [Section 112, paragraph 1] is a question of law ... based on underlying facts.” *Automotive*
13 *Tech. Int’l*, 501 F.3d at 1281. The “enablement requirement is satisfied when one skilled in the
14 art, after reading the specification, could practice the claimed invention without undue
15 experimentation.” *A.K. Steel*, 344 F.3d at 1244. “The full scope of the claimed invention must
16 be enabled.” *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008). Thus, if a
17 patentee “chooses broad claim language,” he or she “must make sure the broad claims are fully
18 enabled.” *Id.*

19 The Federal Circuit has identified several factors to consider “in determining whether a
20 disclosure would require undue experimentation.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir.
21 1988). Those factors include: “(1) the quantity of experimentation necessary, (2) the amount of
22 direction or guidance presented, (3) the presence or absence of working examples, (4) the nature
23 of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the
24 predictability or unpredictability of the art, and (8) the breadth of the claims.” *Id.* These factors
25 are “illustrative, not mandatory. What is relevant depends on the facts[.]” *Amgen, Inc. v. Chugai*
26 *Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 2000).

27 **2. Analysis.**

28 Gore argues that the Wiktor Patents do not enable a “self-expanding zig-zag” stent. To
29 support its position, Gore relies on the specifications of the Wiktor Patents and on Wiktor’s
30 statements that he tried to make a self-expanding “Wiktor stent” but failed. Medtronic counters

1 that Gore focuses on unrecited claim elements and that Gore has not pointed to particular claim
2 language that is not enabled. The Court does not find Medtronic’s argument persuasive.

3 Gore’s enablement argument is premised the Court’s construction of the term stent,
4 which is broad enough to cover a self-expanding or a stent that is expanded by external means.
5 (*See* Claim Construction Order at 14:10-16:21.) Gore correctly argues that, in light of this
6 broad construction, the Wiktor Patents must enable the full scope of embodiments that would
7 fall within the claims. *See, e.g., Sitrick*, 516 F.3d at 999-1000 (noting that plaintiff had argued
8 for a claim construction that would encompass both movies and video games and concluding
9 that patent must enable both embodiments of the invention); *Automotive Tech. Int’l*, 501 F.3d at
10 1282 (concluding that where district court construed claim term to include both mechanical and
11 electronic sensors, “that full scope must be enabled”); *Leibel-Flarsheim Co. v. Medrad, Inc.*,
12 481 F.3d 1371, 1379 (Fed. Cir. 2007).

13 “An enablement analysis begins with the disclosure in the specification.” *Sitrick*, 516
14 F.3d at 1000. Gore argues that the Wiktor Patents “teach against” self-expanding stents and
15 cites to Wiktor’s reference to his U.S. Patent No. 4,649,922, which Medtronic does not dispute
16 is a self-expanding stent. The Federal Circuit has concluded that where a specification teaches
17 against a particular embodiment, that fact can provide evidence that undue experimentation
18 would be necessary. *See, e.g., Liebel-Flarsheim*, 481 F.3d at 1379; *A.K. Steel*, 344 F.3d at
19 1244. Wiktor acknowledges that the stent of the ‘922 Patent has “some drawbacks,” including
20 the fact that “the spring has a fixed diameter and as such is unable to fully conform to the inside
21 wall of the vessel...” (*See* ‘062 Patent at 1:28-42.) Wiktor then notes that two prior art devices,
22 U.S. Patent No. 4,553,545 (the “‘545 Patent”) and U.S. Patent No. 3,868,956 (the “‘956
23 Patent”), teach a method of expanding the diameter of a stent. (*Id.* at 1:45-53.) He criticizes
24 those devices because of the complexity of the methods used and because of the possibility of
25 “blood coagulation and possible thrombosis.” Wiktor’s criticism of the prior art devices does
26 not expressly relate to or encompass the materials from which those devices were made. (*Id.* at
27 1:54-56.)
28

1 In addition to the '545 Patent and the '956 Patent, Wiktor references several other prior
2 art devices, which, like the '545 Patent and the '956 Patent, encompass self-expanding stents as
3 well as stents that are expanded by external means. Wiktor notes that those “references
4 describe and teach various methods of providing or otherwise offering and introducing stents of
5 different types and designs for applications similar to the one described herein in this
6 invention.” (*Id.* at 2:10-31.) Wiktor then describes the benefits of his improved invention,
7 which include: requiring only a “single procedure;” allowing for and “maintain[ing] a very low
8 profile and a small frontal area, so very important for purposes of percutaneous insertion;” and
9 having an “inherent post-expansion radial rigidity and linear flexibility.” (*Id.* at 2:4-9, 2:38-41,
10 3:25-29.) Wiktor states that the invention is “characterized” by a “low memory metal,” which
11 assures that “the radially expanded stent stays expanded thus fulfilling its primary intent and
12 function.” (*Id.* at 3:21-24.) Wiktor also states that the use of a “flexible wire ... allows easy
13 radial expansion and subsequent retention of the radially expanded shape well anchored within
14 a vessel.” (*Id.* at 3:35-37.)

15 In *Liebel-Flarsheim*, the inventors argued for and obtained a claim construction that
16 included an injector with and without a pressure jacket. However, in the specification, they
17 stated that “[w]ithout a pressure jacket, syringes that are able to withstand ... high pressures are
18 expensive and therefore impractical where the syringes are to be disposed.” 481 F.3d at 1379.
19 The Federal Circuit found that critique of the prior art, in combination with the fact that the
20 specification provided “no guidance or suggestion of how to make or use a disposable syringe
21 for high pressure use without a pressure jacket,” supported a conclusion that the claims were
22 invalid for lack of enablement. *Id.* at 1379-80.

23 Similarly, in *A.K. Steel*, the inventors argued for an obtained a claim construction that
24 encompassed two types of aluminum coating, Type 1 and Type 2. The court also noted that the
25 claims required that the “coating wet well.” 344 F.3d at 1244. The court concluded, however,
26 that the disclosure did not enable an embodiment that used Type 1 coating, because “the
27 specification clearly and strongly warns that such an embodiment would not wet well. In
28 particular, the specification warns that silicon content above 0.5% in the aluminum coating

1 causes coating problems.” *Id.* The court found that such language “discourages
2 experimentation with coatings having more than 0.5% silicon, undue or otherwise.” *Id.* In
3 contrast, and as the Court previously noted, Wiktor does not state that the use of resilient metal
4 would be either unsuitable or impractical to achieve the object of the invention. (*See Claim*
5 *Construction Order at 15:16-17.*) Moreover, it is undisputed that self-expanding stents were
6 known in the prior art. Thus, this is not a situation where the specification disclosed a new field
7 of art. *See, e.g., Automotive Techs.*, 501 F.3d at 1284 (concluding that defendant met its burden
8 to show disclosure did not enable a particular embodiment of the invention based, in part, on the
9 fact that the particular embodiment was a new field and no prior art devices existed).

10 Gore also relies on Wiktor’s statements that suggest he tried to create a stent that was
11 “self-expanding” but did not succeed. Specifically, Gore submits a memorandum dated March
12 31, 1990, in which Wiktor states that “I have done some preliminary design and model work on
13 the proposed self-expanding stent, initial work indicates it will be quite difficult, but I shall not
14 give up and will continue to pursue it.” Gore also submits a letter dated May 30, 1995, in which
15 Wiktor states that “[a]fter several discussions with you on this subject, I find myself spending
16 more time dreaming and fantasizing about a self-expanding stent; hopefully those mental
17 calisthenics will develop into something tangible.” (BianRosa Decl., Exs. H-I.)

18 There is no evidence in the record that Wiktor had a degree in engineering or biomedical
19 engineering, as well as a familiarity with implantable medical devices. Assuming that Wiktor
20 was a person of ordinary skill in the art, the fact that Wiktor had “difficulty” in creating a self-
21 expanding stent provides some evidence that further experimentation might be necessary. *See*
22 *Liebel-Flarsheim*, 481 F.3d at 1371 (finding lack of enablement based, in part, on inventors’
23 admission that they tried, but failed, to produce a pressure-jacketless system and decided not to
24 pursue it because it was “to risky”); *A.K. Steel*, 344 F.3d at 1244 (finding lack of enablement
25 based, in part, on failure to utilize Type 1 aluminum coating at the time of filing). However, the
26 applicable standard is whether “undue experimentation” would be required. Gore’s evidence
27 neither suggests why Wiktor had difficulty creating a self-expanding stent of the type claimed
28

1 in the Wiktor Patents nor suggests whether he could build such a stent but could not achieve
2 other aspects of the invention.

3 The Court concludes that the Wiktor Patents must enable a “self-expanding” stent to
4 satisfy the requirements of Section 112, paragraph 1. However, on this record Gore has not met
5 its burden to establish a prima facie case of invalidity for lack of enablement. Accordingly,
6 Gore’s motion is denied on this basis. This ruling is not intended to preclude Gore from
7 presenting additional evidence on the issue at trial.

8 **D. Gore Has Not Met Its Burden to Show That the Claims of the Jervis Patents Are
9 Invalid for Obviousness.**

10 Gore argues that the asserted claims of the Jervis Patents are obvious, because Jervis
11 merely substituted an SMA displaying stress-induced martensite for an SMA displaying
12 temperature-induced martensite in existing medical devices and achieved a predictable result.

13 **1. Legal Standards Applicable to a Determination of Obviousness.**

14 “Section 103 forbids issuance of a patent when ‘the differences between the subject
15 matter sought to be patented and the prior art are such that the subject matter as a whole would
16 have been obvious at the time the invention was made to a person having ordinary skill in the
17 art to which said subject matter pertains.’” *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 127
18 S.Ct. 1727, 1743 (2008) (quoting 35 U.S.C. § 103(a)). “[T]he ultimate conclusion of
19 obviousness is for the court to decide as a matter of law, [however] several factual inquiries
20 underlie this determination.” *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349,
21 1355 (Fed. Cir. 2000). As set forth in the *KSR* case, those factual considerations, which should
22 be judged objectively, are:

23 the scope and content of the prior art ...; differences between the prior art and
24 the claims at issue ... ; and the level of ordinary skill in the pertinent art
25 Against this background the obviousness or nonobviousness of the subject
26 matter is determined. Such secondary considerations as commercial success,
long felt but unresolved needs, failure of others, etc. might be utilized to give
light to the circumstances surrounding the origin of the subject matter sought
to be patented.

27 *KSR*, 127 S.Ct. at 1734 (quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18
28 (1966)); see also *SIBIA*, 225 F.3d at 1355. “The combination of familiar elements according to

1 known methods is likely to be obvious when it does no more than yield predictable results.”

2 *KSR*, 127 S. Ct. at 1739.

3 **2. Analysis.**

4 In support of its argument that the claims of the Jervis Patent are invalid for
5 obviousness, Gore relies on three prior art references: (1) L. Delaey, *et al.*, “Thermoelasticity,
6 Pseudoelasticity and the Memory Effects Associated with Martensitic Transformations,” 9 J.
7 Materials Science 1521-1555 (1974) (“*Delaey*”); (2) L. McDonald Schetky, “Shape-Memory
8 Alloys,” 241 *Scientific American* 5, 74-82 (Nov. 1979) (“*Schetky*”); and (3) Dr. Andrew Cragg,
9 *et al.*, “Nonsurgical Placement of Arterial Endoprostheses: A New Technique Using Nitinol
10 Wire,” 147 *Radiology* 1, 261-63 (April 1983) (“Cragg Stent”).

11 It is undisputed that shape memory alloys were known to display stress-induced
12 martensite at the time Jervis filed the ‘957 Patent. (*See, e.g.*, ‘957 Patent at 1:50-51.) Although
13 the Jervis Patents discuss known prior art medical devices, Jervis states that certain of these
14 prior art medical devices had not been commercialized. (*See, e.g., id.* at 5:1-2, 5:65-66.) Jervis
15 also explained that “the use of the shape memory effect in medical applications is attended with
16 two principal disadvantages.” (*Id.* at 2:30-32.) The first disadvantage is that it is difficult to
17 control the transformation of SMAs displaying temperature-induced martensite with accuracy,
18 “because they are usually extremely composition sensitive.” (*Id.* at 2:33-36.) The second
19 disadvantage is that in many SMAs displaying temperature-induced martensite, there is a large
20 temperature differential (hysteresis) “as the alloy is transformed between the austenitic and
21 martensitic states, so that reversing the state of an SMA element may require a temperature
22 excursion of several tens of degrees Celsius.” (*Id.* at 39-44.)

23 The Cragg Stent article states that the wire Dr. Cragg used “transformed over a broad
24 temperature range..., which required flushing the introducing catheter with cold saline to
25 minimize the transformation of the wire in the catheter.” (BianRosa Decl., Ex. P at 262.)
26 Cragg’s proffered solution to overcome this difficulty was “the development of a wire with a
27 more precise transition testimony.” (*Id.*) Cragg focused on temperature to solve problems with
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1 the art and, thus, taught away from solving this problem using an SMA displaying stress-
2 induced martensite.

3 The Court also has reviewed *Schetky* and *Delaey*. Those articles demonstrate that the
4 properties of shape memory alloys, including the interplay between temperature and stress in
5 the formation of martensite, is highly technical. Further, that interplay is reflected in certain
6 claims of the '957 Patent. (*See, e.g.*, '957 Patent at 11:17-25.) However, Gore's comparison of
7 the asserted claims to these prior art references is supported only by attorney argument. There
8 is insufficient evidence in the record for the Court to ascertain the differences between, for
9 example, subsection (b) of Claim 5 of the '957 Patent and the cited portions of the prior art
10 references. "Unsubstantiated attorney argument regarding the meaning of technical evidence is
11 no substitute for competent, substantiated expert testimony." *Invitrogen Corp. v. Clontech*
12 *Labs.*, 429 F.3d 1052, 1068 (Fed. Cir. 2005). Moreover, Jervis disclosed the Cragg Stent and
13 *Schetky* references during the prosecution of the '957 Patent.⁸ (*See* '957 Patent at p.2.)
14 "[D]eference is therefore due to the PTO's decision to award the patents." *Boston Scientific*
15 *Corp.*, 534 F. Supp. 2d at 1072 (N.D. Cal. 2007); *see also id.* at 1068.

16 Gore also argues that the claims of the Jervis Patents are invalid because when one
17 combines the teachings of the Cragg Stent article and either *Schetky* or *Delaey*, it would have
18 been obvious to substitute a shape memory alloy displaying stress-induced martensite for a
19 shape memory alloy displaying temperature-induced martensite. Medtronic argues that the
20 Court should not consider this theory, because it was not disclosed in Gore's Final Invalidity
21 Contentions. The Court agrees. Gore cites all three references in its Final Invalidity
22 Contentions. (*See, e.g.*, Wang Decl., Ex. B at 8:25-27, 9:11-13, 11:7-9.) However, in Gore's
23 chart identifying those elements of the Cragg Stent article that are present in the claims of the
24 Jervis Patents, Gore does not combine the Cragg Stent article with either *Schetky* or *Delaey*.

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27 ⁸ Medtronic submits evidence that, during the prosecution of the '957 Patent's
28 parent application, the Examiner rejected claims as obvious in light of *Schetky*. (Wang
Decl., Ex. K.) That application, however, was abandoned and, as noted above, the Examiner
allowed the claims of the '957 Patent to issue even in light of *Schetky*.

1 Gore did, however, combine the Cragg Stent article with other prior art references. (*See, e.g.*,
2 Ex. D at 385-389.)

3 Gore argues that the substitution theory is a “species of obviousness,” and that it
4 disclosed “ad naseum” the prior art on which it relied. (*See* Transcript of Hearing (“Tr.”) at
5 69:6-13.) However, Gore candidly admitted at the hearing that this particular theory developed
6 “[a]s we were working on the motion.” (*Id.* at 73:10.) Accordingly, the Court has not
7 considered this theory. *See generally* *O2 Micro Int’l Ltd. v. Monolithic Power Systems, Inc.*,
8 467 F.3d 1355 (Fed. Cir. 2006). For the foregoing reasons, the Court concludes that Gore has
9 not met its burden to establish a prima facie case of invalidity for obviousness. Accordingly,
10 Gore’s motion is denied on this basis.⁹ Again, this ruling is based upon the record currently
11 before the Court and is not intended to preclude Gore from presenting additional evidence on
12 the issue at trial.

13 **E. Gore Has Not Met Its Burden to Show That The Claims Of The Jervis Patents Are**
14 **Invalid for Indefiniteness.**

15 Gore also argues that the asserted claims of the Jervis Patent are invalid for
16 indefiniteness. Gore’s argument focuses on the claim term “stress-induced martensite,” which
17 the Court has construed to mean “martensite that forms from austenite due to stress.” (Claim
18 Construction Order at 7:8-9:4.)¹⁰ Gore does not argue that the term “stress induced martensite”
19 is, itself, ambiguous. (*See* Tr. at 78:3-79:23.) Gore argues, however, that the Court’s
20 construction does not sufficiently delineate the metes and bounds of the claims, because one of
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23 ⁹ Gore’s argument that Claim 27 of the ‘546 Patent is obvious in light of prior
24 art is based primarily on the Cragg Filter article. (*See, e.g.*, Mot. at 23:16-24:4; Appendix
25 1B.) However, for purposes of this motion, Gore withdrew its reliance on that reference.
For this additional reason, the Court concludes that Gore has not met its burden to
demonstrate that Claim 27 of the ‘546 Patent is invalid for obviousness.

26 ¹⁰ Medtronic argues that Gore’s indefiniteness argument must fail because the
27 Court was able to construe the term stress-induced martensite. That fact, however, is not
28 dispositive. “[I]f reasonable efforts at claim construction result in a definition that does not
provide sufficient particularity and clarity to inform skilled artisans of the bounds of the
claim, the claim is insolubly ambiguous and invalid for indefiniteness.” *Star Scientific, Inc.*
v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1371 (Fed. Cir. 2008) (citing *Halliburton*
Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1249-51 (Fed. Cir. 2008)).

1 ordinary skill in the art would not know how much stress-induced martensite must be present to
2 fall within the claims or how to test for stress-induced martensite.

3 **1. Legal Standards Applicable to a Determination of Obviousness.**

4 Section 112, paragraph 2 provides in relevant part: “[t]he specification shall conclude
5 with one or more claims particularly pointing out and distinctly claiming the subject matter
6 which the applicant regards as his invention.” 35 U.S.C. § 112, ¶ 2. “Because claims delineate
7 the patentee’s right to exclude,” Section 112, paragraph 2 “requires that the scope of the claims
8 be sufficiently definite to inform the public of the bounds of the protected invention, *i.e.*, what
9 subject matter is covered by the exclusive rights of the patent.” *Halliburton Energy Servs.*, 514
10 F.3d at 1249; *see also Allen Eng. Corp. v. Bartell Indus. Inc.*, 299 F.3d 1336, 1348 (Fed. Cir.
11 2002) (Section 112, paragraph 2 contains two requirements: (1) the claim must set forth what
12 the patentee regards as his invention; and (2) it must do so with sufficient particularity and
13 distinctness).

14 “In determining whether the claim is sufficiently definite, we must analyze whether ‘one
15 skilled in the art would understand the bounds of the claim when read in light of the
16 specification.’” *Allen*, 299 F.3d at 1348 (quoting *Personalized Media Communications, LLC v.*
17 *Int’l Trade Comm’n*, 191 F.3d 696, 705 (Fed. Cir. 1998)). This latter inquiry can be achieved
18 by a “simple comparison” of the claims with the specification. *Id.* The Federal Circuit has
19 stated that claims that are “‘not amenable to construction or [are] insolubly ambiguous are
20 indefinite.’” *Star Scientific, Inc.*, 537 F.3d at 1371 (quoting *Datamize, LLC v. Plumtree*
21 *Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005)).

22 **2. Analysis.**

23 Gore relies heavily on *Halliburton, supra*, in support of its argument that the claims are
24 indefinite.¹¹ In that case, the patent at issue, which related to oil field drilling fluids, contained

26 ¹¹ Gore also relies on Jervis’s deposition testimony. However, at this stage of
27 the proceedings, “[a] more limited range of evidence should be considered in evaluating
28 validity as opposed to patentability under either portion of section 112, paragraph 2, because
the language of issued claims is generally fixed ..., the claims are no longer construed as
broadly as is reasonably possible, and what the patentee subjectively intended his claims to
mean is largely irrelevant to the claim’s objective meaning and scope.” *Solomon v.*

1 claims that were limited to “fragile gel” drilling fluids. *Halliburton*, 514 F.3d at 1246. The
2 specification included a definition of the term “fragile gel,” and on appeal the plaintiff proffered
3 a three part definition based upon the specification. *See id.* at 1246-47, 1249. The Federal
4 Circuit, however, upheld the district court’s conclusion that the term was indefinite.

5 The court stated that “[e]ven if a claim term’s definition can be reduced to words, the
6 claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into
7 meaningfully precise claim scope.” *Id.* at 1251. The court’s reasoning was based in part on the
8 fact that the plaintiff had failed “to identify the degree of the fragility of its invention.” *Id.* at
9 1253. For example, although the plaintiff stated that the “gel easily transitions to a liquid state
10 upon the introduction of force, ... and returns to a gel when the force is removed,” the plaintiff
11 did not identify “how quickly” these events had to occur to fall within the scope of the claims.
12 *Id.* at 1254. The court, therefore, concluded that because the term “is ambiguous as to the
13 requisite degree of the fragileness of the gel,” the strength of the gel, “and/or some combination
14 of the two,” the defendant met its burden to provide clear and convincing evidence that the term
15 was indefinite. *Id.* at 1256.

16 In contrast to the claim term in dispute in the *Halliburton*, the Court does not find that
17 term stress-induced martensite is a term of “degree.” *See, e.g., Star Scientific*, 537 F.3d at 1372
18 (“We have stated that when a word of degree is used ... the patent’s specification must provide
19 some standard for measuring that degree’ to be definite.”) (internal quotations omitted) Jervis
20 explains that shape memory alloys possess the shape memory quality because “the alloy
21 undergoes a reversible transformation from an austenitic state to a martensitic state with a
22 change in temperature ... sometimes referred to as thermoelastic martensitic transformation.”
23 (*Id.* at 1:22-23, 33-35.) Jervis then notes that “[m]any shape memory alloys ... are known to
24 display stress-induced martensite.” (*Id.* at 1:50-51.) Jervis thus distinguishes between two
25 *forms* of martensite, martensite that is stress-induced or martensite that is temperature-induced.

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27 *Kimberly-Cleark Corp.*, 216 F.3d 1372, 1379 (Fed. Cir. 2000). The Court concludes that
28 Jervis’ deposition testimony does not assist Gore in establishing a prima facie case that the
claims are indefinite.

1 This conclusion is supported by the claims, which do not require the presence of a particular
2 amount or range of martensite. In addition, Jervis distinguished his invention over prior art
3 inventions that utilized shape memory alloys displaying temperature-induced martensite. For
4 these reasons, the Court concludes that the claims of the Jervis Patents “clearly distinguish what
5 is claimed from what went before in the art.” *United Carbon Co. v. Binney & Smith Co.*, 317
6 U.S. 228, 236 (1942).

7 Gore also asserts that the asserted claims are invalid because they do not identify a
8 method by which to test for the presence and amount of stress-induced martensite. Gore relies
9 on *Honeywell Int’l Inc. v. Int’l Trade Comm’n*, 341 F.3d 1332 (Fed. Cir. 2003), in support of
10 this argument. In that case, the patent at issue related to polyethylene terephthalate (“PET”)
11 yarn, with a melting point elevation (“MPE”) that occurred within a particular temperature
12 range. *Id.* at 1334-35. The court noted that the method by which a sample of PET yarn is
13 prepared could affect the value of the MPE. “[B]ecause the sample preparation method is
14 critical to discerning whether a PET yarn has been produced by the claimed process, knowing
15 the proper sample method is necessary to practice the invention.” *Id.* at 1340. However,
16 neither the specification nor the claims disclosed which method of sample preparation should be
17 used to produce an MPE within the acceptable ranges. Accordingly, the court concluded that
18 the term MPE, and all claims including that term, were indefinite and, therefore, invalid. *Id.* at
19 1339-41.

20 Again, the claims of the Jervis Patents do not require a particular amount of stress-
21 induced martensite, and the Court does not find the *Honeywell* case to be on point. Rather, the
22 asserted claims provide further guidance as to the metes and bounds of the claims by stating that
23 the SMA display stress-induced martensite at or near body temperature. (*See, e.g.*, ‘957 Patent
24 at 10:46-48, 11:66-67.) The specification explains that the temperature range for a typical
25 mammalian body is 35°-40° Celsius. (*Id.* at 4:18.) Thus, the claims of the Jervis Patents also
26 “clearly circumscribe what is foreclosed from future enterprise.” *United Carbon Co.*, 317 U.S.
27 at 236.

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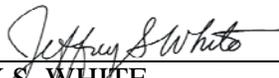
For the foregoing reasons, the Court concludes that Gore has not shown by clear and convincing evidence that the asserted claims of the Jervis Patents are invalid for indefiniteness. The Court's ruling is premised solely on the current record and, therefore, is not intended to preclude Gore from presenting additional evidence on this issue at trial. If, however, Gore has no further evidence in support of its invalidity defense based on the indefiniteness of the claims, this ruling shall be considered final.

CONCLUSION

For the foregoing reasons, Gore's motion for summary judgment is DENIED. In light of this ruling, the Court shall reopen discovery in order for Gore to depose James Peterson. That deposition shall be completed by no later than January 31, 2009, unless the parties show good cause for a brief extension. It is FURTHER ORDERED that the parties shall appear for a status conference on **Friday, March 13, 2009 at 1:30 p.m. for purposes of setting dates for a pretrial conference and trial.**

IT IS SO ORDERED.

Dated: December 9, 2008



JEFFREY S. WHITE
UNITED STATES DISTRICT JUDGE