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United States District Court,
N.D. California.
MEDTRONIC, INC., et al., Plaintiffs,
v.
AGA MEDICAL CORPORATION, Defendant.

No. C-07-0567 MMC.
April 28, 2009.

James J. Elacqua, Andrew Neil Thomases, Ellen J. Wang, Hieu H. Phan, Joshua C. Walsh-Benson, Michelle Wai Yang, Noemi C. Espinosa, Dechert LLP, Mountain View, CA, Karen D. McDaniel, Merchant & Gould, Minneapolis, MN, for Plaintiffs.

Brian Francis McMahon, Steven Daniel Hemminger, Lance A. Lawson, Marissa R. Ducca, Michael S. Connor, Alston & Bird LLP, Charlotte, NC, for Defendant.

**ORDER DENYING DEFENDANT'S MOTION
FOR SUMMARY JUDGMENT OF INVALIDITY;
DENYING PLAINTIFFS' MOTION FOR
SUMMARY JUDGMENT RE: PRIOR ART AND
ANTICIPATION**

MAXINE M. CHESNEY, District Judge.

*1 Before the Court are defendant AGA Medical Corporation's ("AGA") "Motion (# 2) for Summary Judgment of Invalidity under 35 U.S.C. §§ 101 ('Double Patenting'), 102(a) ('Prior Use') and 103 ('Obviousness')," filed February 28, 2009, and plaintiffs Medtronic, Inc., Medtronic USA, Inc., and Medtronic Vascular, Inc.'s (collectively, "Medtronic") "Motion that the Cragg Filter Experiments Are Not Prior Art under 35 U.S.C. § 102 or § 103 and that the Cragg II Paper Is Not Anticipating under § 102," filed

February 27, 2009. With respect to each motion, an opposition and a reply have been filed. Having read and considered the papers filed in support of and in opposition to the motions, the Court rules as follows.

A. Anticipation

Under 35 U.S.C. § 102(a), a person shall be entitled to a patent unless "the invention was known or used by others in this country ... before the invention thereof by the applicant for patent." See 35 U.S.C. § 102(a). "Anticipation requires that each element of the claim at issue is found, either expressly described or under the principles of inherency, in a single prior art reference or that the claimed invention was previously known or embodied in a single prior art device or practice." See *In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1377 (Fed.Cir.2007).

1. AGA's Motion

In its motion, AGA argues that all of the asserted independent claims of the three patents-in-suit, United States Patents Numbers 5,067,967 ("957 patent"), 5,190,546 ("546 patent"), and 6,306,141 ("141 patent"), are invalid, on the ground that such claims were practiced by Dr. Andrew Cragg ("Cragg") and Dr. Kurt Amplatz ("Amplatz") prior to the filing, on October 14, 1983, of the application that ultimately resulted in the issuance of the patents-in-suit. In particular, AGA asserts that Cragg and Amplatz practiced the asserted claims during experiments undertaken in 1982 and 1983 ("Cragg/Amplatz experiments"), which experiments were "memorialized" (see Mot. at 2:16) in an article published in September 1983, specifically, Andrew Cragg et al., *A New Percutaneous Vena Cava Filter*, 141 Am. J. Roentgenology 601 (Sept.1983) ("Cragg II"). (See Decl. Steven D. Hemminger ("Hemminger Decl.") Ex. 24.) As set forth below, the Court finds AGA has failed to show it is entitled to summary judgment of invalidity on the ground of anticipation on the basis of the

Medtronic Exhibit 2004
Edwards v. Medtronic
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Cragg/Amplatz experiments.

To prevail on its motion, AGA must show the Cragg/Amplatz experiments, as memorialized in the Cragg II article, employed a shape memory alloy that “displays” stress-induced martensite. The “display” of stress-induced martensite is a limitation of each of the asserted claims of the patents-in-suit. (See Order Construing Claims, filed Feb. 6, 2008, at 2:3-10.) In support of its argument that Cragg II describes such an alloy, AGA points to the following statement therein: “If the position of the filter was not optimal, it could be withdrawn into the catheter and positioned again.” (See Cragg II at 602.) Thomas W. Duerig (“Duerig”), AGA’s expert, opines that because such withdrawal occurred at a temperature above the temperature at which the filter’s transformation from its martensitic to its austenitic state was complete, if martensite was displayed during such withdrawal, it had to have been induced by stress rather than by a change in temperature. (See Decl. Dr. Thomas W. Duerig in Supp. AGA’s Opp’n (“Duerig Opp’n Decl.”) ¶ 6.) Additionally, Kaushik Bhattacharya, another of AGA’s experts, “rules out ordinary elasticity” as a “deformation mechanism,” for the reason that, in Bhattacharya’s opinion, the filter used by Cragg and Amplatz suffered strains in the range of 2.3% to 4.4%, as compared with the ordinary elasticity of austenite generally, which “can accommodate strains of at most 0.5% to about 1%.” (See Duerig Opp’n Decl. Ex. B (“Expert Report of Prof. Kaushik Bhattacharya”) ¶¶ 26-27, 30-31.)

*2 As Medtronic’s expert, Robert Sinclair (“Sinclair”), notes, however, Cragg II does not disclose the chemical composition of the alloy used by Cragg and Amplatz, or whether the filters at issue “fully deployed” or “achieved body temperature” before being retracted. (See Decl. Dr. Robert Sinclair, PhD (“Sinclair Decl.”) ¶¶ 161.) According to Sinclair “there is insufficient evidence to determine,” under such circumstances, whether the filters changed shape due to the presence of stress-induced martensite or were merely “plastically or elastically deformed.” (See *id.* ¶

166.) ^{FN1} Further, as Medtronic points out, Cragg II never uses the term “stress-induced martensite” and, instead, is focused exclusively on the use of an alloy with a “heat-sensitive memory.” (See Cragg II at 601.)

FN1. Although AGA has challenged, under *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), certain of Sinclair’s opinions, that challenge is not made with respect to the opinions referenced above.

A review of the Cragg II reference reveals that the display of stress-induced martensite is not expressly disclosed therein. AGA, although arguing to the contrary, also asserts, in essence, that stress-induced martensite was “necessarily present, or inherent,” in the alloy used in the experiments. See *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed.Cir.2003) (holding “a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference”) (internal citation omitted). The above-discussed evidence submitted by Medtronic is sufficient, however, to raise a triable issue with respect to the inherency of stress-induced martensite in the alloy used by Cragg and Amplatz. ^{FN2}

FN2. In light of such finding, the Court does not reach Medtronic’s argument that a triable issue exists as to whether the Cragg/Amplatz experiments were publicly accessible. See *Minn. Min. & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1306 (Fed.Cir.2002) (“For purposes of anticipation, a use must be accessible to the public”).

Accordingly, to the extent AGA seeks summary judgment of invalidity on the ground of anticipation, AGA’s motion will be denied.

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2. Medtronic's Motion

In its motion, Medtronic argues that the Cragg/Amplatz experiments do not constitute either prior art or an invalidating prior use and that the Cragg II article does not anticipate any of the asserted claims of the patents-in-suit. As set forth below, the Court finds Medtronic is not entitled to summary judgment with respect to either the Cragg/Amplatz experiments or the Cragg II article.

Medtronic first argues that, even assuming the filters at issue exhibited stress-induced martensite, the Cragg/Amplatz experiments cannot constitute prior art or an invalidating prior use because Cragg did not appreciate what he assertedly had discovered. The Court disagrees. In particular, in the context of prior use under § 102(a), “it is irrelevant that those using the invention may not have appreciated the results.” See *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548 (Fed.Cir.1983). As AGA points out, the cases cited by Medtronic in support of its argument to the contrary are distinguishable. Most of those cases deal either with prior invention under § 102(g) or an earlier statute,^{FN3} see *Coffin v. Ogden*, 18 Wall. 120, 85 U.S. 120, 124-25, 21 L.Ed. 821 (1873); *Invitrogen Corp. v. Clontech Labs.*, 429 F.3d 1052, 1063 (Fed.Cir.2005); *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1331 (Fed.Cir.2001); *Int'l Glass Co. v. United States*, 187 Ct.Cl. 376, 408 F.2d 395, 402 (Ct.Cl.1969), or with prior knowledge, see *In re Borst*, 52 C.C.P.A. 1398, 345 F.2d 851, 853 (C.C.P.A.1965); *In re Schlitter*, 43 C.C.P.A. 986, 234 F.2d 882, 884 (C.C.P.A.1956), rather than prior use. Although one case, *Eibel Process Co. v. Minn. & Ontario Paper Co.*, 261 U.S. 45, 66, 43 S.Ct. 322, 67 L.Ed. 523 (1923), discusses what the Federal Circuit has called “ ‘accidental, unwitting, and unappreciated’ anticipation,” see *Schering Corp.*, 339 F.3d at 1378, even *Eibel*, according to the Federal Circuit, “do[es] not show that inherency requires recognition,” see *id.*^{FN4}

FN3. AGA “is not asserting an invalidity

defense based on prior invention by Dr. Cragg and others.” (See Def.'s Opp'n at 8:13-15.)

FN4. Medtronic also relies on *Medtronic, Inc. v. Daig Corp.*, 611 F.Supp. 1498 (D.Minn.1985), in which the court stated: “When a party asserts that a prior use anticipates a patent claim under § 102(a) or (b), that party must also establish that such a use was of a complete invention, i.e., conceived and reduced to practice, and public,” see *id.* at 1508. In support of this statement, however, the district court relied on *Coffin* and *Int'l Glass Co.*, both of which, as noted, deal with prior invention rather than prior use.

*3 Medtronic next argues that AGA has no evidence Cragg II “enable[s]” any asserted claim of the patents-in-suit. “In order to be anticipating, a prior art reference must be enabling so that the claimed subject matter may be made or used by one skilled in the art.” See *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1381 (Fed.Cir.2006). “In order to enable, the prior art reference must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation.” See *Minn. Min. & Mfg. Co.*, 303 F.3d at 1306.

Here, AGA has presented evidence that Cragg II discloses “the size of nitinol wire used, the annealing time, temperature and method, the size of the catheter used, the A_f temperature, and experimental results” and that, consequently, the article “includes all the information that is required to enable one of ordinary skill in the art to duplicate what Dr. Cragg and his team did ... without undue experimentation.” (See Duerig Opp'n Decl. ¶ 7.) Medtronic has failed to show anything more is required in order to raise a triable issue as to enablement. Cf. *Amgen, Inc. v. Hoescht Marion Roussel, Inc.*, 314 F.3d 1313, 1355 & n. 22 (Fed.Cir.2003) (holding “an accused infringer should be ... entitled to have the district court presume the

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enablement of unclaimed (and claimed) material in a prior art patent defendant asserts against a plaintiff”; noting “by logical extension, our reasoning here might also apply to prior art printed publications as well”).

Medtronic next argues that the Cragg/Amplatz experiments did not employ a shape memory alloy that displays stress-induced martensite and that the Cragg II article does not disclose such an alloy. As discussed above, however, a triable issue exists as to whether the experiments, as described in the article, employed an alloy that necessarily displayed stress-induced martensite.

Accordingly, to the extent Medtronic seeks summary judgment on AGA's defense of invalidity on the basis of anticipation, Medtronic's motion will be denied.

B. Obviousness

Under 35 U.S.C. § 103, a patent is invalid “when the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S.Ct. 1727, 1734, 167 L.Ed.2d 705 (2007) (internal quotation and citation omitted); see also 35 U.S.C. § 103.

1. AGA's Motion

AGA argues that all of the asserted claims of the patents-in-suit that are not anticipated by the Cragg/Amplatz experiments or the Cragg II article are obvious variants of asserted claims that are anticipated by such experiments or such article. As discussed above, however, the Court has found a triable issue exists as to whether any of the asserted independent claims is anticipated, and, consequently, AGA's argument necessarily fails.

*4 AGA next argues that the asserted claims are rendered obvious by a combination of three prior art references, specifically, (1) Andrew Cragg, et al., *Nonsurgical Placement of Arterial Endoprostheses: A New Technique Using Nitinol Wire*, 147 Radiology 261 (Apr.1983) (“Cragg I”), (2) Japanese Patent Application No. S56-144326 (Sept. 12, 1981) (“Miyachi”), and (3) [United States Patent Number 4,490,112](#) (Sept. 2, 1982) (“Tanaka”). (See Hemminger Decl. Exs. 10, 16, 24.) Although a party seeking to demonstrate obviousness on the basis of a combination of prior art references need not show that “some motivation or suggestion to combine the prior art teachings can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art,” see *KSR*, 127 S.Ct. at 1734 (internal quotation and citation omitted), such party nevertheless must show there was “an apparent reason to combine the known elements in the fashion claimed by the patent at issue,” see *id.* at 1740-41.

Here, AGA argues that “one of ordinary skill in the art would have been motivated to combine these references to address the problem stated in the application [for the patents-in-suit], i.e., avoiding the need for controlling the temperature of [a shape memory alloy] medical device when implanting it in a body.” (See Def.'s Mot. at 12:25-27); see also *KSR*, 127 S.Ct. at 1742 (“[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining elements in the manner claimed.”). As Medtronic points out, however, AGA has failed to present any evidence in support of this assertion, nor has AGA presented any evidence suggesting the above-referenced “problem” was “known” in the field at the time of the application for the patents-in-suit. Consequently, AGA has failed to demonstrate a reason to combine the references at issue existed.^{FN5}

FN5. In light of such finding, the Court does not reach Medtronic's argument (a) that there is a triable issue as to the ordinary level of

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skill in the art in 1983, (b) that there is a triable issue as to whether the combination of the three references discloses every limitation of any asserted claim of the patents-in-suit, and (c) that objective indicia of nonobviousness preclude summary judgment in favor of AGA.

Accordingly, to the extent AGA seeks summary judgment of invalidity on the basis of obviousness, AGA's motion will be denied.

2. Medtronic's Motion

Medtronic argues that the Cragg/Amplatz experiments cannot render the asserted claims of the patents-in-suit obvious, on the ground that the experiments do not qualify as prior art under § 102. As discussed above, however, the Court has found a triable issue exists as to whether the experiments constitute prior art, and, consequently, Medtronic's argument necessarily fails.

Accordingly, to the extent Medtronic seeks summary judgment on AGA's defense of invalidity on the basis of obviousness, Medtronic's motion will be denied.

C. Obviousness Type Double Patenting

Obviousness type double patenting (“OTDP”) is “a judicially created doctrine grounded in public policy,” the purpose of which “is to prevent the extension of the term of a patent, even where an express statutory basis for [] rejection is missing, by prohibiting the issuance of the claims in a second patent not patentably distinct from the claims of the first patent.” See *In re Longi*, 759 F.2d 887, 892 (Fed.Cir.1985).^{FN6} The doctrine “preclude[s] a second patent on an invention which would have been obvious from the subject matter of the claims in the first patent, in light of the prior art.” See *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 940 (Fed.Cir.1992) (internal quotation and citation omitted).

FN6. Although, as Medtronic points out, AGA's obviousness type double patenting defense was not pled at the time AGA filed its motion for summary judgment of invalidity, the Court, on April 21, 2009, afforded AGA leave to amend its Answer and Counterclaims to assert such defense.

*5 The “common-place situation” where a “broader claim ‘embraces’ or ‘encompasses’ the subject matter defined by [a] narrower claim,” however, “is not, per se, double patenting.” See *In re Kaplan*, 789 F.2d 1574, 1577-78 (Fed.Cir.1986). Instead, to establish an OTDP defense, “there must be some clear evidence to establish why the variation [between the two claims] would have been obvious which can properly qualify as ‘prior art.’” See *id.* at 1580.

Here, AGA argues that the asserted claims of the '141 patent are invalid on the basis of OTDP in light of [United States Patent Number 5,597,378](#) (“’378 patent”).^{FN7} In particular, AGA argues that any differences between the asserted claims of the '141 patent and certain claims of the '378 patent are “not [] patentable difference[s].” (See, e.g., Def.'s Mot. at 18:1.) As to some of these differences, AGA has presented evidence of prior art that, AGA asserts, renders the difference not patentable. For example, although claim 11 of the '141 patent uses the term “stent,” whereas claim 9 of the '378 patent uses the term “memory allow element” (see '141 patent col. 11, l. 66; '378 patent col. 11, l. 14), AGA has pointed to prior art that discloses the use a “stent” made from an alloy with “shape-memory properties” (see Hemminger Decl. Ex. 24 (Charles T. Dotter, et al., *Transluminal Expandable Nitinol Coil Stent Grafting: Preliminary Report*, 147 *Radiology* 259 (Apr.1983) (“Dotter”))). Similarly, although claim 1 of the '141 patent requires a “guide wire,” whereas claim 34 of the '378 patent does not (see '141 patent col. 11, l. 5; '378 patent col. 14, ll. 39-69), AGA has pointed to prior art that discloses the use of a “guiding wire” to place an

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