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United States District Court,
N.D. California.
MEDTRONIC, INC., et al, Plaintiff,
v.
W.L. GORE & ASSOCIATES, INC., Defendants.

No. 06-04455 JSW.
Dec. 9, 2008.

West KeySummary**Patents 291** 99

291 Patents
291IV Applications and Proceedings Thereon
291k99 k. Description of Invention in Specification. Most Cited Cases

An alleged infringer of patents directed to methods for implanting intravascular stents into a human body failed to establish a prima facie case of invalidity for lack of enablement that patentee was unable to create a self-expanding stent as claimed. A court concluded the patents must enable a "self-expanding" stent to satisfy the enablement requirement of federal patent law. The alleged infringer's evidence neither suggested why a patentee had difficulty creating a self-expanding stent of the type claimed in the patents nor suggested whether he could build such a stent but could not achieve other aspects of the invention. This did not preclude the alleged infringer from presenting additional evidence on the issue at trial. 35 U.S.C.A. § 112.

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Gerard Haddad, Christopher K. Hu, Jennifer Bianrosa, John T. Gallagher, Dickstein Shapiro LLP, William S. Feiler, David H. Pfeffer, Morgan & Finnegan, LLP, New York, NY, Hillary Noll Kalay, Mark Jay Linderman, Sonnenschein Nath & Rosenthal LLP, San Francisco, CA, William J. Maledon, Osborn Maledon, PA, Osborn Maledon, Phoenix, AZ, for Defendant.

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

JEFFREY S. WHITE, District Judge.

INTRODUCTION

***1** 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.[FN1]

FN1. 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.

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"). [FN2] Medtronic also alleges that Gore infringes Medtronic's U.S. Patent Nos. 4,886,062 ("the '062 Patent"), 6,656,219 ("the '219 Patent"), and 6,923,828 ("the '828 Patent") (collectively, "the Wiktor Patents"). [FN3] The Jervis and Wiktor Patents each are directed, in general, to medical devices or methods for implanting such medical devices into a human body.

FN2. 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.)

FN3. Medtronic asserts that Gore infringes claims 5-7, 9-10, and 12-13 of the '062 Patent, claims 1,3-4, 6-7 and 9 of the '219 Patent, and claims 1, 3-14, and 18-21 of the '828 Patent. (*See* Wang Decl., Ex. B at 1:16-17, 3:15-16, 5:15-16.)

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

A. The Wiktor Patents.

The Wiktor Patents are directed to intravascular stents. In the specification, Wiktor describes his invention, generally, as comprising "an open-ended wire formed device of basically cylindrical shape and made of a softer-then [*sic*] spring type metal and fitted over an inflatable element of a typical balloon type catheter .... The wire formed device is intended to act as a permanent prosthesis stent and is implanted transluminarely." (*See, e.g.,* Declaration of Jennifer BianRosa ("BianRosa Decl."), Ex. A ('062 Patent at 1:14-22).) [FN4] The '062 Patent was filed on October 19, 1987, and the '219 and '828 Patents each were filed on November 22, 2000. (Bianrosa Decl., Exs. A-C.) [FN5] It is undisputed that, at the time the ' 062 Patent was filed, a person of ordinary skill in the art would have a degree in engineering or biomedical engineering and familiarity with implantable medical devices.

FN4. The Court cites to references within the patents-in-suit in the following format: "column:line" or "column:line-column:line."

FN5. 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.

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

> A radially-expandable stent for implantation within a body vessel comprising:
>
> a stent body having a wall of generally cylindrical shape formed of a helical coil made of a wire, the body having a longitudinal axis and a first diameter;
>
> zig-zag means in the wire for allowing radial expansion of the cylindrical stent body from the first diameter to a second larger diameter without significantly altering the body length along the longitudinal axis.
>
> ('062 Patent at 5:42-6:7.)

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

***2** An intravascular stent, comprising:

a continuous sinusoidal shaped wire, wherein said wire is coiled to form a helical-shaped stent body, wherein said stent is expandable from a first delivery diameter to a second implanted diameter.

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

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

An intravascular stent, comprising:

a generally cylindrical body including a helically coiled wire, wherein said helically coiled wire has generally sinusoidally-shaped waves;

wherein said generally cylindrical body is capable of radially expanding.

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

On August 14, 2007, the Court issued an Order construing the term "stent," as used in the Wiktor Patents, to mean "a supporting device." (Docket No. 91 (Claim Construction Order at 16:21-22); Docket No. 116 (Order Granting Plaintiffs' Motion for Reconsideration at 2:13-25).) In so doing, the Court rejected Gore's proposed construction that the term "stent" should include a "low memory metal" limitation. (Claim Construction Order at 14:15-16:10). [FN6] The Court also concluded that Wiktor "did not disavow clearly the use of self-expanding or resilient stents," based in part on its conclusion that "Wiktor does not say resilient metal is unsuitable to achieve the object of his invention, namely a stent that expands radially." (*Id.* at 15:15-17.)

FN6. 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 the '828 Patent.

B. The Jervis Patents.

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

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

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

Among metallic alloys, the ability to possess shape memory is a result of the fact that the alloy undergoes a reversible transformation from an austenitic state to a martensitic state with a change in temper-

> ature. This transformation is sometimes referred to as a thermoelastic martensitic transformation. An article made from such an alloy ... is easily deformed from its original configuration to a new configuration when cooled below the temperature at which the alloy is transformed from the austenitic state to the martensitic 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.

***3** ('957 Patent at 1:23-49).)

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

> The combination of these factors with the limitation that (a) it is inconvenient to have to engage in any temperature manipulation, and (b) human tissue cannot be heated or cooled beyond certain relatively narrow limits ... without suffering temporary or permanent damage is expected to limit the use of SMA medical devices. It would thus be desirable to develop a way in which the advantageous properties of shape memory alloys, i.e. their ability to return to an original shape after relatively substantial deformation, could be used in medical devices without requiring the delicacy of alloying control and/or the temperature control of placement or removal needed by present shape memory alloy devices.
>
> ...
>
> I have discovered that if, in a medical device containing a shape memory alloy element which uses the shape memory property of that alloy, an element which shows the property of stress-induced martensite is used instead, an improved device results.
>
> Accordingly, this invention provides a medical device intended for use within a mammalian body, or in such proximity to a mammalian body that the device is substantially at body temperature, which device comprises a shape memory alloy element, the improvement in which comprises the substitution of an alloy element which displays stress-induced martensite at said body temperature for the shape memory alloy element.

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

ANALYSIS

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 "more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). Rather, the non-moving party must set forth "specific facts showing that there is a genuine issue for trial."

Fed.R.Civ.P. 56(c); *Matsushita Elec.,* 475 U.S. at 587.

***4** "Because a patent is presumed to be valid," Gore's "evidentiary burden to show facts supporting a conclusion of invalidity is one of clear and convincing evidence." *Automotive Tech. Int'l Inc. v. BMW of North Am., Inc.,* 501 F.3d 1274, 1281 (Fed.Cir.2007) (citing *AK Steel Corp. v. Sollac & Ugine,* 344 F.3d 1234, 1238-39 (Fed.Cir.2003)). Gore also must overcome "deference to the [United States Patent and Trademark Office's ("PTO")] findings and decisions in prosecuting the patent application. Deference to the PTO is due '[w]hen no prior art other than that which was considered by the PTO examiner is relied on' " by the party attacking the patent's validity. *Boston Scientific Corp. v. Johnson & Johnson,* 534 F.Supp.2d 1062, 1068 (N.D.Cal.2007) (quoting *American Hoist & Derrick Co. v. Sowa & Sons,* 725 F.2d 1350, 1359 (Fed.Cir.), *cert denied,* 469 U.S. 821, 105 S.Ct. 95, 83 L.Ed.2d 41 (1984)).

B. Evidentiary Objections.

Medtronic objects to Exhibits G-H to the BianRosa Declaration, on the ground that the documents contain inadmissible hearsay.[FN7] Gore argues that the documents are admissible under Federal Rule of Evidence 801(d)(2)(D), which provides that a statement is not hearsay if "the statement is offered against a party and is ... a statement by the party's agent or servant concerning a matter within the scope of the agency or employment, made during the existence of the relationship." Medtronic responds that at the time Wiktor made the statements reflected in these exhibits, he was an independent contractor and not Medtronic's agent. *See Merrick v. Farmers Ins. Group,* 892 F.2d 1434, 1440 (9th Cir.1990) (finding that district court properly excluded statements where plaintiff had not established statements were made by agents as opposed to independent contractors).

FN7. 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.

The consulting agreement between Wiktor and Medtronic is governed by Minnesota law. (Reply Declaration of Jennifer BianRosa ("BianRosa Reply Decl."), Ex. W at 7.) Under Minnesota law, the factors to be applied to distinguish between an independent contractor and agency relationship are "(1) [t]he right to control the means and manner of performance; (2) the mode of payment; (3) the furnishing of material or tools; (4) the control of the premises where the work is done; and (5) the right of the employer to discharge.... In determining whether the status is one of employee or independent contractor, the most important factor considered in light of the nature of the work involved is the right of the employer to control the means and manner of performance." *Guhlke v. Roberts Truck Lines,* 268 Minn. 141, 143, 128 N.W.2d 324 (1964).

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

***5** Therefore, the Court concludes that the statements are non-hearsay and OVERRULES the objections to BianRosa Declaration Exhibits H and I. *See Metro Goldwyn Meyers Studio v. Grokster, Ltd .,* 454 F.Supp.2d 966, 973-74 (C.D.Cal.2006) (noting that "statement is admissible under Rule 801(d)(2)(D)

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