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Paper 69
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ST. JUDE MEDICAL, CARDIOLOGY DIVISION, INC.,
Petitioner,

v.

THE BOARD OF REGENTS OF THE UNIVERSITY OF MICHIGAN,
Patent Owner.

Case IPR2013-00041
Patent No. 5,746,775

Before MICHAEL J. FITZPATRICK, RAMA G. ELLURU, and CHRISTOPHER L. CRUMBLEY, *Administrative Patent Judges.*

CRUMBLEY, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318 and 37 C.F.R. §42.73

I. BACKGROUND

Petitioner, St. Jude Medical, Cardiology Division Inc. ("St. Jude"), filed a petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 23 and 25-29 of U.S. Patent No. 5,746,775 ("the '775 patent"). Patent Owner, The Board of Regents of the University of Michigan ("Michigan"), did not file a preliminary response. In a May 2, 2013, Decision to Institute (Paper 12, "Dec."), we granted the petition and instituted trial on the following grounds:

1) Claims 23 and 25-29 as having been obvious over the combined teachings of Levy[1], Kaplan[2], and Holman[3]; and

2) Claims 23, 25, 26, 28, and 29 as having been obvious over the combined teachings of Carpentier[4], Kaplan, and Gong[5].

Dec. 15.

Following institution, Michigan filed a response to the petition (Paper 22, "PO Resp."), and St. Jude filed a reply (Paper 29, "Pet. Reply"). Both St. Jude (Paper 42, "Pet. Mot.") and Michigan (Paper 40, "PO Mot.") filed motions to exclude evidence. We held an oral hearing on January 27, 2014, and a transcript of the oral hearing is included in the record. Paper 68, "Tr."

Both parties presented witness testimony via declaration. With its petition, St. Jude provided a declaration from Svetlana Kaplan, Ph.D. (Ex. 1010), one of the authors of the Kaplan reference, as well as a declaration from Paul W. Bohn, Ph.D. (Ex. 1012). With its response, Michigan presented a declaration from Frederick J.

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[1] U.S. Patent No. 5,094,661, issued March 10, 1992 (Ex. 1002).
[2] Kaplan et al., *Glutaraldehyde Preparation of Coronary Artery Bypass Bioprostheseses,* 38 J. OF SURGICAL RESEARCH 45-54 (1985) (Ex. 1009).
[3] U.S. Patent No. 4,456,589, issued June 26, 1984 (Ex. 1011).
[4] U.S. Patent No. 5,002,566, issued Mar. 26, 1991 (Ex. 1004).
[5] G. Gong et al., *Aldehyde Tanning: The Villain in Bioprosthetic Calcification,* 5 EURO. J. CARDIOTHORACIC SURG. 288-93 (1991) (Ex. 1015).

Schoen, M.D., Ph.D. (Ex. 2000). Finally, along with its reply, St. Jude provided declarations from three additional witnesses: Jonathan T. Butcher (Ex. 1016); Scott Lien (Ex. 1041); and Bruce Lytle, M.D. (Ex. 1065).

We have jurisdiction under 35 U.S.C. § 6(c). This final written Decision, issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73, addresses issues and arguments raised during trial. For the reasons discussed below, we determine that St. Jude has met its burden to prove by a preponderance of the evidence that claims 23 and 25-29 of the '775 patent are unpatentable.

A. The '775 Patent

The '775 patent relates to methods of exposing collagenous biomaterial[6] to an alcohol, in order to inhibit in vivo calcification. Ex. 1001, Abstract, 1:23-27. Prior to implantation in a living being, biomaterials typically are "fixed" or "tanned" using glutaraldehyde ("GA"), to stabilize the tissue against degradation. Pet. 4 (citing Ex. 1001, 2:8-30). Tanning, however, is known to make tissue susceptible to calcification, which is accumulation of calcium salts in the tissue. PO Resp. 3 (citing Ex. 2000 ¶ 11-17). "For implanted biomaterials such as a bioprosthetic heart valve, calcification can be a significant problem, sometimes requiring surgical replacement." *Id.*

The '775 patent is directed to the use of alcohol to mitigate or prevent calcification in GA-pretreated tissue. Ex. 1001, 1:23-27. According to the '775 patent, "*[t]he use of alcohols in biomaterial treatment protocols is well-known*, but is typically limited to its use as a solvent and/or sterilizing agent." *Id.* at 2:59-61 (emphasis added). It further states, "there has never been any teaching or suggestion that ethanol has any effect on prevention of pathologic calcification"

[6] "Biomaterial" refers to collagenous material that may be derived from different animals, typically a mammalian species. Ex. 1001, 3:33-47.

and that "[i]t would be advantageous to use this well-known compound in existing protocols for rendering bioprosthetic tissue calcification resistant." *Id*. at 2:62-67.

The patent states that the alcohol treatment solution is preferably "an aqueous solution of greater than about 50% alcohol, and preferably between 60% to 80% alcohol by volume." *Id* at 4:31-35. The biomaterial is contacted with the alcohol for a period of time sufficient to render the bioprosthetic tissue resistant to in vivo pathologic calcification, "illustratively, from about 20 minutes . . . to in excess of 96 hours." *Id*. at 4:4-9. In preferred embodiments, the biomaterial that has been treated with alcohol should be rinsed prior to implantation or storage to remove excess alcohol and other deleterious components. *Id*. at 5:5-11. In a further embodiment, the alcohol treatment solution contains one or more additional anticalcification agents, including, but not limited to, a soluble salt of a metallic cation, such as Al^{+3} or Fe^{+3}. *Id*. at 5:59-63.

B. Illustrative Claim

Claim 23, the sole independent claim at issue in this trial, is illustrative of the claimed subject matter and reads as follows:

> 23. A method of making calcification-resistant biomaterial for use in the interior of a human or animal, the method comprising the steps of:
>
> a) subjecting glutaraldehyde pre-treated bioprosthetic tissue, wherein the bioprosthetic tissue is a collagenous material derived from a mammalian species selected from the group consisting of bovine pericardium, porcine aortic heart valves, saphenous bypass grafts, aortic homografts, and dura mater, to an aqueous, treatment solution of at least about 50% by volume of a water-soluble C1-C3 aliphatic alcohol for a period of time between about 20 minutes and 96 hours; and
>
> b) rinsing the bioprosthetic tissue.

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, "[a] claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). Under this standard, we construe claim terms using "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997). We presume that claim terms have their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("The ordinary and customary meaning is the meaning that the term would have to a person of ordinary skill in the art in question.") (internal quotation marks omitted). However, a patentee may rebut this presumption by acting as his own lexicographer, providing a definition of the term in the specification with "reasonable clarity, deliberateness, and precision." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

For purposes of our Decision to Institute, we gave each claim term its broadest reasonable interpretation, as understood by one of ordinary skill in the art and consistent with the specification of the '775 patent. We expressly construed the claim term *C1-C3 aliphatic alcohol* as covering trihydric alcohols such as glycerol. Dec. 5-6. Neither party contested this construction during trial, and we discern no reason to modify it. *See* PO Resp. 11 (adopting the Board's construction). Nor did either party raise any additional claim construction issues in their briefs following institution of trial.

At oral hearing, in response to questioning by the panel, the parties raised two additional claim construction issues not set forth in prior briefing, which we address below.

1. *calcification-resistant biomaterial*

First, Michigan contends that the phrase *calcification-resistant biomaterial* in the preamble of claim 23 should be interpreted to be a limitation on the claim and given patentable weight. Tr. 58. We disagree. We will construe a claim term that appears in the preamble of a claim only if it is necessary to "give life, meaning, and vitality" to the claim. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) (citing *Kropa v. Robie*, 187 F.2d 150, 152 (CCPA 1951)). As the Federal Circuit has noted:

> If [] the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation.

Pitney Bowes, 182 F.3d at 1305. Upon review of the claim language, we determine that the inclusion of *calcification-resistant biomaterial* in the preamble of claim 23 does nothing more than state a property that necessarily results from performing the claimed method, which is set forth fully in the body of the claim. *See In re Tomlinson*, 363 F.2d 928, 934 (CCPA 1966) (finding preamble that only stated result of claimed process could not distinguish over prior art). We, therefore, do not interpret the preamble as limiting.

2. *a water-soluble C1-C3 aliphatic alcohol*

Second, the parties disagree whether the claim limitation *at least about 50% by volume of a water-soluble C1-C3 aliphatic alcohol* requires that a single alcohol make up at least about 50% by volume of the solution. Michigan argues that the word "a" should be construed as "one":

> MR. WEINER: I think the claim requires 50 percent of C1-C3 alcohol.
> JUDGE CRUMBLEY: So, you think "a" should be construed to mean "one"?
> MR. WEINER: That's right. Now it's a comprising claim which means you can include other materials in the solution, but to satisfy the claim, you have to have at least 50 percent C1-C3 alcohol.

Tr. 30. In other words, in Michigan's view, one type of C1-C3 aliphatic alcohol must make up at least 50% by volume of the solution, even if other C1-C3 aliphatic alcohols are also present. This would exclude solutions comprising, for example, one-third glycerol and one-third ethanol as disclosed in Carpentier. Ex. 1004, 6:38-46.

St. Jude contends that, because claim 23 uses the transitional phrase "comprising," the word "a" should be construed to mean "one or more." Tr. 11 ("because it is a comprising claim and is open . . . a combination could be contemplated as well").

The Federal Circuit "has repeatedly emphasized that an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.'" *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000). This preference to construe "a" as meaning "one or more" is best described as a rule having extremely limited exceptions. *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008). Only when a patentee evinces a clear intent to limit the meaning of "a"

to "one" is a narrower construction warranted. *Id.*; *cf. Harari v. Lee*, 656 F.3d 1331, 1341 (Fed. Cir. 2011) (finding no "hard and fast rule that 'a' always means one or more than one. Instead, we read the limitation in light of the claim and specification to discern its meaning.").

Upon review of the claims and specification of the '775 patent, we discern no intent by the patentee to limit the meaning of "a" to "one." Nor has Michigan presented any evidence of such an intent. The specification does not prohibit the use of more than one alcohol, or imply that the anticalcification effect is achieved only if a single alcohol is used. Rather, the patent discloses that "a mixture of two or more organic solvents may be used in the practice of the invention, provided that the combined volume of the organic solvents is . . . preferably greater than about 50%." Ex. 1001, 4:37-40. The broadest reasonable interpretation of the claim is that *at least about 50% by volume of a water-soluble C1-C3 aliphatic alcohol* means "at least about 50% by volume of one or more water-soluble C1-C3 aliphatic alcohols."

B. Prior Art References

Neither party disputes that the following five references at issue in the instituted trial are prior art to the '775 patent.[7]

1. Levy

Levy describes methods for treating GA-pretreated bioprosthetic materials, including the claimed bovine pericardium, porcine aortic valve leaflets, and aortic

[7] In our Decision to Institute, we determined that the '775 patent is not entitled to an effective filing date earlier than its actual filing date of October 21, 1993, thereby making Levy (issue date March 10, 1993) prior art under 35 U.S.C. § 102(b) (pre-AIA). Dec. 7-9. Michigan expressly stated that it does not contest this determination. PO Resp. 11.

homografts, in a trivalent aluminum cation (e.g., $AlCl_3$) aqueous solution to prevent calcification after implantation. Ex. 1002, Abstract, 2:50-52, 4:5-11, 4:25-27; *see* Pet. 20-2. Levy states that organic solvents may be used in its invention and exemplifies the use of isopropanol, a C3 aliphatic alcohol. Ex. 1002, 4:15-21. Levy further teaches incubating the bioprosthetic tissue in the treatment solution for a period of time, "illustratively 24 hours." *Id*. at 4:5-7. In addition, Levy describes washing the bioprosthetic tissue with sterile, deionized water after incubating. *Id*. at 4:11-14. Levy does not specify that the isopropanol solution is "an aqueous solution" of "at least about 50% by volume" of the alcohol, as required by claim 23 of the '775 patent.

2. Kaplan

Kaplan discloses storing GA-fixated canine carotid arteries in "50% ethyl alcohol," a C2 aliphatic alcohol. Ex. 1009, p. 48. Moreover, we credit the testimony of Dr. Kaplan, St. Jude's declarant and the first named author of the Kaplan article, that a person of ordinary skill in the art would interpret Kaplan's disclosure of "50% ethyl alcohol" to be a 50% solution of ethyl alcohol in water, i.e., an "aqueous solution." Ex. 1010 ¶¶ 9, 14.[8] Kaplan also discloses that prior to implantation, the treated arteries were rinsed using saline. Ex. 1009, p. 49.

3. Holman

Holman, which is directed to treating animal tissue to make it suitable for implantation in human recipients without rejection or reabsorption, teaches

[8] Michigan disputes whether Dr. Kaplan is a person of ordinary skill in the art of anticalcification. *See infra* note 9. Her qualifications in the field of anticalcification aside, we find that Dr. Kaplan is sufficiently qualified to testify to the fact that "50% ethyl alcohol" would be understood as 50% solution of ethyl alcohol in water. In any event, Michigan has not challenged this assertion by Dr. Kaplan.

subjecting biomaterial to an even greater concentration of alcohol than taught by Kaplan. Specifically, Holman teaches storing bovine pericardial sac tissue in a sterilant comprising one part by volume of propylene oxide and 99 parts by volume of 70% ethanol before implantation. Ex. 1011, Abstract, 2:45-49, 2:51-57.

4. Carpentier

Carpentier describes methods for making calcification-resistant bioprosthetic implants from tanned biological materials, wherein tanning includes GA treatment. Ex. 1004, Abstract, 2:54-56, 2:64-3:3. The treated biological materials include the claimed porcine heart valves, bovine pericardium, human dura matter and the like. *Id*. at 2:59-63. Carpentier further teaches immersing the biological materials in an aqueous solution that includes ferric ions. *Id*. at 4:67-5:5. The aqueous solution may include ethanol, glycerol, or mixtures thereof. *Id*. at 5:12-15. In addition, Carpentier describes a specific example wherein porcine aortic heart valve leaflets are immersed in a commercial grade glycerol solution consisting of 1/3 ethanol (90%), 1/3 aqueous formaldehyde (prepared by mixing 4 parts 37% formaldehyde and 6 parts water), and 1/3 pure glycerol. *Id*. at 6:38-46. Carpentier also provides a preferred embodiment wherein the biological material is immersed in the treatment solution for a period of time ranging from about 24 hours to about 200 hours. *Id*. at 4:67-5:2. Carpentier does not teach "rinsing the bioprosthetic tissue," as required in the final step of claim 23.

5. Gong

Gong attempts to test the hypothesis that aldehydes such as GA cause calcification of tissue, especially when compared to tissue that is treated with only glycerol. Ex. 1015, p. 288. Table 1 of Gong discloses several experimental groups, of which Group A was treated with 99.5% glycerol, whereas Groups B-D

were treated with 99.5% glycerol and then GA or formaldehyde, and Group E was treated with GA and formaldehyde but not glycerol. *Id.* at 289. Figure 2 of Gong compares calcification of samples in Groups A, D, and E, and states that "[v]alves treated with glycerol had a lower incidence of calcification than those treated with glutaraldehyde." *Id*. at 290.

C. Combination of Levy, Kaplan, and Holman

There does not appear to be any significant dispute between the parties that all elements of claims 23 and 25-29 are taught by one or more of Levy, Kaplan, and Holman. With respect to claim 23, for example, our Decision to Institute found that Levy teaches methods for treating GA-pretreated bioprosthetic materials, including the claimed bovine pericardium, porcine aortic valve leaflets, and aortic homografts. Ex. 1002, Abstract, 2:50-52, 4:5-11, 4:25-27. Levy treats the tissue for a period of time, for example 24 hours, in a solution of isopropanol, which is a C3 aliphatic alcohol. *Id*. at 4:5-7, 4:15-21. Kaplan teaches that GA-pretreated tissue may be treated in 50% ethanol, which is at least about 50% by volume of a water-soluble C1-C3 aliphatic alcohol. Ex. 1009, p. 48. Levy teaches rinsing the bioprosthetic tissue after treatment. Ex. 1002, 4:11-14.

Michigan does not challenge any of the foregoing findings from our Decision to Institute, or argue separately any of the limitations of the dependent claims. Rather, Michigan makes several arguments regarding the teachings of the references individually, none of which is persuasive. *See In re Keller*, 642 F.2d 413, 426 (CCPA 1981) (attacking references individually not persuasive where unpatentability based on combination of references). For example, Michigan argues that Levy does not disclose a step of subjecting a GA-pretreated bioprosthetic tissue to a treatment solution of at least 50% of a C1-C3 alcohol, as recited in claim 23. PO Resp. 23. This is immaterial, however, because the

ground of unpatentability does not rely on Levy alone as teaching this limitation. Rather, Levy is relied upon for its teaching of, *inter alia*, a treatment solution comprising isopropanol, a C1-C3 alcohol, whereas Kaplan is relied upon for teaching a greater than 50% solution of ethanol.

Similarly, Michigan contends that Holman does not describe methods of making tissues resistant to calcification, or a step of subjecting a GA-pretreated bioprosthetic tissue to a treatment solution of at least 50% of a C1-C3 alcohol. Again, the ground of unpatentability does not rely on Holman for either of these disclosures, but instead for Holman's teaching that GA-pretreated tissue may be treated with a 70% solution of ethanol. Ex. 1011, Abstract, 2:45-49, 2:51-57.

The real dispute between the parties, therefore, is not over what each reference teaches, but rather whether a person of ordinary skill in the art would have had reason to combine the references, and would have had a reasonable expectation of success in doing so. We address these issues below.

1. Reason to Combine

Michigan argues that St. Jude has not established that a person of ordinary skill would have had reason to combine Levy, Kaplan, and Holman to arrive at the claimed treatment methods. PO Resp. 44. According to Michigan, Levy is directed to methods of using aluminum ions to make tissue calcification-resistant, Holman addresses the use of ethanol as a sterilant, and Kaplan "mentions calcification in the context of GA storage, but does not provide any meaningful information or reliable data concerning anticalcification treatment of tissues." PO Resp. 43. Given these different purposes, Michigan concludes that a person of ordinary skill in the art would have had no motivation to modify the ion-treatment process of Levy with Kaplan or Holman, to result in a different treatment process that uses alcohol for anticalcification. *Id.*

We disagree that the record does not establish a reason to combine. First, despite Michigan's criticism of the Kaplan reference, we conclude that it would have suggested to a person of ordinary skill in the art that ethanol had anticalcification effects. Second, other reasons to combine are found in the prior art.

Kaplan Article

As noted above, Levy discloses a method of treating GA-pretreated tissue in a solution that may include isopropanol, but does not give any guidance as to the amount of isopropanol to be used. St. Jude contends that Kaplan, in teaching treatment in an aqueous solution of 50% ethanol, would have suggested to a person of ordinary skill that the isopropanol of Levy could be replaced with the 50% ethanol solution of Kaplan, thus arriving at the method of claim 23. Pet. 34.

A significant portion of Michigan's response is devoted to criticism of the Kaplan article. PO Resp. 25-31. First, Michigan notes that Kaplan compared GA-stored tissue with GA-treated and ethanol-stored tissue, which could lead to the conclusion that GA causes calcification instead of ethanol preventing it. *Id*. at 27. Second, Michigan contends that the dog model used by Kaplan is unsuitable for calcification studies, and that the protocol only implanted tissue for three weeks, too short a period to observe calcification. *Id*. at 27-29. Finally, Kaplan is said to be lacking necessary information about the test protocol and any quantitative data about its results. *Id*. at 29-31. In support of these arguments, Michigan cites the testimony of Dr. Schoen, who states that he considers Kaplan's observation that tissue stored in 50% ethanol exhibits no calcification to be "vague, lack[ing] necessary detail that should be included in a scientific publication, and leaves open many questions." Ex. 2000 ¶¶ 40-41. Michigan concludes that, because of these deficiencies, "Kaplan provides *no meaningful information* to a person skilled in the

art concerning whether ethanol or any other alcohol would be effective as an anticalcification agent." PO Response 31 (emphasis added).[9]

St. Jude opposes Michigan's arguments on several grounds, including a defense of the dog model and testing period used by Kaplan. Pet. Reply 4-10. According to St. Jude, Kaplan is a peer-reviewed article authored by a research group at the well-known Hope Heart Institute. *Id*. at 4. St. Jude proffers the testimony of Dr. Butcher to support its arguments. Ex. 1016. Dr. Butcher states that the level of information provided in Kaplan is appropriate to both the time and its purpose. *Id*. at 5. Dr. Butcher also notes that a person of ordinary skill in the art would not have concluded that storage in GA increases calcification, because the tissues of Kaplan were saturated fully with GA during pretreatment and could not have absorbed more GA during storage. *Id*.

Michigan's criticisms of the Kaplan article are not wholly without merit. Whatever the faults of the Kaplan experiment, however, we do not find that they rise to such a level that a person of ordinary skill would have disregarded completely the teachings of Kaplan. Kaplan's disclosure that calcification was not seen in vessels stored in 50% ethyl alcohol would have, at minimum, given the person of ordinary skill in the art a reason to investigate further the potential

[9] Michigan also contends that Dr. Kaplan is not a person of ordinary skill in the art, because she admitted under cross-examination that she was unfamiliar with many aspects of calcification, including methods of quantitatively measuring calcification and performing a histological evaluation of tissue. PO Resp. 33. During cross-examination, Dr. Kaplan appears to have been unable to describe what is meant by calcification of tissue. *Id*. (citing Ex. 2013, 21:13-32:12). Dr. Kaplan's level of skill, however, is irrelevant to what the hypothetical person of ordinary skill would have understood the teachings of the Kaplan article to be. Furthermore, this final written Decision does not rely on the testimony of Dr. Kaplan for what one of ordinary skill in anticalcification would have understood regarding the Kaplan article.

anticalcification effects of ethanol, and substitute the 50% ethanol into the method of Levy.

Other Reasons to Combine

We also find that other reasons to combine Levy, Kaplan, and Holman existed at the time of the invention. All three references teach subjecting GA-treated bioprosthetic tissue to treatment with a C1-C3 aliphatic alcohol. Ex. 1002, 4:6-21; Ex. 1009, p. 28; Ex. 1011, 2:46-49. The close structural and functional similarity of the isopropanol of Levy (C_3H_7OH) to the ethanol of Kaplan and Holman (C_2H_5OH) suggests, at minimum, that the two alcohols could be used interchangeably. *See In re Payne*, 606 F.2d 303, 313 (CCPA 1979) ("expectation that compounds similar in structure will have similar properties" supports obviousness). Michigan's argument that a person of ordinary skill would have considered high concentrations of ethanol to be toxic is contradicted by Kaplan and Holman, which use 50% and 70% ethanol without noting any toxic effects. Ex. 1009, p. 48; Ex. 1011, 2:46-49.

Michigan's argument that recognition of the anticalcification effects of ethanol is necessary for a finding of a reason to combine is not persuasive. "In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007). As noted above, we do not interpret the objective reach of the claim, construed under the broadest reasonable interpretation standard, to be limited to the anticalcification effects of ethanol; therefore, it is not dispositive that Levy and Holman use C1-C3 aliphatic alcohol as a solvent or sterilant. Rather, we find that a person of ordinary skill in the art would have had reason to use the 50% ethanol of Kaplan as a storage medium, or the 70% ethanol of Holman as a

sterilant, in place of the isopropanol of Levy, which also acts as a storage medium or sterilant. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 550 U.S. at 416. This modification would have resulted in the claimed invention.

2. Expectation of Success

Michigan argues that there would have been no reasonable expectation of success in combining Levy, Kaplan, and Holman, "because . . . none of the references teach[es] to one skilled in the art the use of ethanol or any alcohol *for anticalcification purposes*." PO Resp. 44 (emphasis added). We do not consider this argument persuasive, as calcification resistance is not an element of the claims. *See KSR*, 550 U.S. at 419 (in an obviousness analysis, "neither the particular motivation nor the avowed purpose of the patentee controls"). Michigan does not argue that a person of ordinary skill in the art would have been unable to incorporate the ethanol of Kaplan or Holman in Levy, nor is there any evidence that the artisan would have expected such an incorporation to be unsuccessful. "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 421.

3. Teaching Away

Finally, Michigan argues that "one skilled in the art would be discouraged from making the asserted combination, as Carpentier and Gong both teach away from using a C1-C3 aliphatic alcohol for anticalcification treatment of a GA-pretreated bioprosthetic tissue." PO Resp. 44. "[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR*, 550 U.S. at 416 (citing *United States v. Adams*, 383 U.S. 39, 51-52 (1966)). A reference teaches away

from a combination when, for example, a person of ordinary skill in the art would be discouraged from following the path set out in the reference, or would be led in a direction divergent from that chosen by the inventor. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). "In general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *Id*.

We address the two references raised by Michigan below.

Carpentier

Michigan contends that Carpentier teaches away from the combination because it discloses that stannic and ferric ions, not the glycerol/ethanol solution in which the ions were dissolved, were responsible for the anticalcification effect observed in Carpentier. *Id*. at 19-21 (citing Ex. 1004, 5:62-6:12). Specifically, Michigan focuses on Carpentier's Example 3, which compares the anticalcification effect of "aged glycerol," which contained ions, to "commercial glycerol," which did not. Ex. 1004, 6:2-12, 6:39-46, 8:1-20. Michigan notes that Carpentier found that commercial glycerol did not have the same anticalcification effect as aged glycerol, but rather "teaches the direct opposite, that uncontaminated glycerol 'does not provide the calcification mitigation' that results when using glycerol that had been contaminated with ferric or stannic ions." PO Resp. 21 (quoting Ex. 1004, 8:3-5).

St. Jude argues that Carpentier's disclosure that the metal ions of an aged glycerol provide the observed anticalcification effect is not a teaching away, as the challenged claims do not exclude metal ions from their scope. Pet. Reply 10.

We do not find that Carpentier teaches away from the invention, for several reasons. First, Michigan narrowly focuses its argument on the anticalcification effects observed by Carpentier; however, as noted above, the reason to combine

Levy, Kaplan, and Holman is broader than calcification resistance. If a person of ordinary skill in the art would have combined the references for a reason other than anticalcification, whether Carpentier teaches away from using alcohol for anticalcification is irrelevant.

Second, we do not consider Carpentier to teach that alcohol *cannot* provide anticalcification effects, but merely that the anticalcification effect of an alcohol containing stannic and ferric ions provides a *greater* anticalcification effect than the alcohol alone. Indeed, Example 3 shows that 4 samples treated with "commercial glycerol" showed no observable calcification. Ex. 1004, 8:12. We understand Carpentier's statement that "commercial glycerol [] does not provide the calcification mitigation as does [aged glycerol]" (*id*. at 8:3-5) to mean that commercial glycerol does not provide *as much* calcification mitigation as aged glycerol, not that commercial glycerol provides *no* calcification mitigation. This falls short of the type of disclosure necessary for a teaching away. *See In re Gurley,* 27 F.3d at 554 ("[a] known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use").

Finally, we note that Michigan's reliance on Example 3 as a teaching away is misplaced, as the Example compares two methods, neither of which is within the scope of the claims. Treatment 1 of Example 3 is "aaa_B/Glut Mg," which we understand to denote treatment with aged glycerol (aaa_B) followed by tanning with glutaraldehyde. Treatment 2 is, similarly, "aaa_C/Glut Mg," denoting treatment with commercial glycerol (aaa_C) followed by tanning with glutaraldehyde. Michigan agreed with this interpretation of Example 3. Tr. 27 ("That's true, for most examples, Carpentier teaches glycerol first and then GA second.").

By contrast, the claims of the present invention—and the methods of Levy, Kaplan, and Holman—each teach fixing tissues with GA first, and then treatment or storage in alcohol. Therefore, even if we were to accept Michigan's characterization of the disclosure of Carpentier and conclude that the reference discourages treatment of tissue with commercial glycerol followed by GA, it does not follow that the reference also discourages treatment of tissue with GA followed by commercial glycerol. For all the foregoing reasons, we do not conclude that Carpentier teaches away from the claimed invention.

Gong

Michigan makes many of the same teaching away arguments with respect to Gong. Table 1 of Gong discloses several experimental groups, of which Group A was treated with only glycerol, whereas Groups B-D were treated with glycerol and then GA or formaldehyde, and Group E was treated with GA and formaldehyde but not glycerol. Ex. 1015, p. 289. Michigan directs our attention to Figure 2 of Gong, which compares calcification of samples in Groups A, D, and E, and states that "[v]alves treated with glycerol had a lower incidence of calcification than those treated with glutaraldehyde." *Id*. at 290. In Michigan's view, the two largest bars of Figure 2 provide a teaching away, because they show that samples treated with glycerol and then GA show increased calcification over samples treated with GA and formaldehyde, but not glycerol. PO Resp. 23; Tr. 31-32 ("Gong teaches the glycerol actually makes calcification worse when used in combination of a GA.").

We find the evidence of a teaching away in Gong lacking for many of the same reasons set forth above with respect to Carpentier. Most significantly, we question the applicability of the examples cited by Michigan to the claims at issue in this trial, as they do not disclose methods within the scope of the claims, or even

similar to the claimed methods. As Michigan acknowledged at oral hearing, the protocol for Group B was to treat with glycerol first, then treat with GA, which is the reverse of that required by the challenged claims. Tr. 32. Even if Figure 2 of Gong teaches that treatment with glycerol then GA is inferior to treating with GA and formaldehyde, it does not follow that the claimed treatment with GA then glycerol is similarly inferior. The evidence does not rise to that required for a teaching away.

Furthermore, we disagree with Michigan's summarization of Gong as teaching that "glycerol actually makes calcification worse." It is impossible to tell from Figure 2, or the other data provided in Gong, whether the difference in calcification between groups D and E exists because glycerol increases calcification, or because formaldehyde decreases it. Gong certainly does not conclude that glycerol makes calcification worse, but rather concludes that glycerol treatment—albeit, in the absence of GA—leads to less calcification than GA treatment. Ex. 1015, p. 291.

D. Combination of Carpentier, Kaplan, and Gong

Again, we do not discern any significant dispute between the parties that all elements of claims 23, 25, 26, 28, and 29 are taught by one or more of Carpentier, Kaplan, and Gong. In our Decision to Institute, we found that Carpentier teaches methods for treating GA-pretreated bioprosthetic materials, including the claimed porcine heart valves, bovine pericardium, human dura matter and the like. Ex. 1004, Abstract, 2:54-56, 2:64-3:3, 2:59-63. Carpentier treats the tissue for a period of time ranging from 24 hours to 200 hours in an aqueous solution comprising ferric ions, 1/3 glycerol, and 1/3 ethanol. *Id*. at 4:67-5:5, 6:38-46. Kaplan teaches rinsing the bioprosthetic tissue prior to implantation. Ex. 1009, pp. 48-49.

Michigan does not challenge any of the foregoing findings from our Decision to Institute, or argue separately any of the limitations present in the dependent claims. In view of our construction of *at least about 50% by volume of a water-soluble C1-C3 aliphatic alcohol* above, however, we revisit our prior determination that an additional element of dependent claim 25 is taught by Carpentier.

Claims 23, 26, 28, and 29 each require at least about 50% by volume of a water-soluble C1-C3 aliphatic alcohol, which we determined above could be met by a combination of alcohols. Carpentier teaches a solution containing 1/3 glycerol and 1/3 ethanol—or 67% alcohol—thereby meeting the 50% requirement of the claims. In our Decision to Institute, we relied on Carpentier as teaching or suggesting all elements of claims 23, 26, 28, and 29, save the rinsing step, which was taught by Kaplan. Dec. 13. We reaffirm that finding today.

Claim 25, however, states that "the alcohol is ethanol." By specifying a single alcohol, claim 25 requires that 50% by volume of the solution is that alcohol, namely ethanol. Carpentier's disclosure of 33% ethanol and 33% glycerol does not meet the additional limitation of claim 25. Instead, we rely on the teaching in Kaplan of treatment with a 50% ethanol solution as meeting this limitation. Ex. 1009, p. 52.

Again, the primary dispute between the parties on this ground of unpatentability is whether a person of ordinary skill in the art would have had reason to combine the references, and would have had a reasonable expectation of success in doing so. We address these issues below.

1. Reason to Combine

Michigan argues that St. Jude has failed to establish that a person skilled in the art would have had reason to combine Carpentier, Kaplan, and Gong.

According to Michigan, Carpentier is directed to methods of using ferric or stannic ions to make tissue calcification-resistant, Gong is concerned with evaluating the effect of aldehydes such as GA on tissue calcification, and Kaplan "mentions calcification in the context of GA storage, but does not provide any meaningful information or reliable data concerning anticalcification treatment of tissues." PO Resp. 46. Given these different purposes, Michigan concludes that a person of ordinary skill in the art would have had no motivation to modify the ion-treatment process of Carpentier with Kaplan or Gong, to result in a different treatment process that uses alcohol for anticalcification. *Id.*

This argument suffers from many of the same faults discussed above in the prior ground of unpatentability. First, we find that Kaplan, at the very least, provides a sufficient suggestion that ethanol has anticalcification properties such that a person of ordinary skill in the art would have reason to investigate using ethanol in the treatment method of Carpentier.

Second, Michigan's argument, to the extent it focuses on the motivation to modify the treatment process of Carpentier that includes ferric and stannic ions, is beside the point. The claims of the '775 patent do not exclude ions; in fact, claim 26 expressly requires the presence of a multivalent metallic cation. There is no reason to modify Carpentier to remove the ion treatment in order to arrive at the claims; the only modification that is required is the inclusion of the rinsing step of Kaplan. Whether there was any recognition of the anticalcification properties of ethanol is not relevant to the question of whether a person of ordinary skill would have added a rinsing step to the method of Carpentier, especially when there is unchallenged testimony in the record that such a step was conventional. Ex. 1010 ¶ 19.

We conclude that St. Jude has established that a person of ordinary skill in the art would have had reason to combine Carpentier, Kaplan, and Gong in the manner set forth above.

2. Expectation of Success

With respect to the combination of Carpentier, Kaplan, and Gong, Michigan again focuses too narrowly on the expectation of success, arguing that "[t]here would [] be no reasonable expectation of success in combining these references, because, . . . none of the references teach[es] the use of ethanol or any alcohol *for anticalcification purposes*." PO Resp. 46 (emphasis added). This argument conflates the reason for the current invention with the expectation a person of ordinary skill would have in successfully making the combination of the teachings of the references. As we stated above, neither the patentee's particular motivation nor its avowed purpose controls the obviousness inquiry. *KSR*, 550 U.S. at 419. We are not persuaded that, even if the prior art lacked recognition of ethanol's anticalcification effects, a person of ordinary skill in the art would have not expected success in combining the treatment process of Carpentier with the rinsing step of Kaplan.

3. Teaching Away

For the same reasons discussed above, we are not persuaded that Carpentier or Gong teaches away from the combination of Carpentier, Kaplan, and Gong.

E. Objective Indicia of Nonobviousness

Michigan contends that objective indicia demonstrate nonobviousness of the challenged claims. PO Resp. 44-45, 47. In particular, Michigan presents evidence of the commercial success of St. Jude's products that are manufactured allegedly

using the patented process, and long-felt need for effective anticalcification treatments. *Id*. at 35-42.

Objective indicia, also called secondary considerations, may provide independent evidence of nonobviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966) ("Such secondary considerations as commercial success, long felt but unsolved 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. As indicia of obviousness or nonobviousness, these inquiries may have relevancy."). Consideration of objective indicia, if presented by a patent owner, is part of the obviousness analysis, not "just an afterthought." *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1357 (Fed. Cir. 2013).

1. Commercial Success

To demonstrate nonobviousness based on commercial success, a patent owner must provide evidence of commercial success, as well as evidence that there is a nexus between that success and the merits of the claimed invention. *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1324 (Fed.Cir.2004). Evidence of nexus requires "proof that the sales were a direct result of the unique characteristics of the claimed invention—as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter." *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996).

Michigan argues that St. Jude's products, specifically the Epic and Trifecta treated valves, have enjoyed commercial success that is due to the use of the invention of the '755 patent. PO Resp. 35-36. Both products use "LinxAC Technology," identified as an anticalcification process developed and patented by Robert Levy, the inventor of the '775 patent. *Id.* at 36 (citing Ex. 2014). Sales of the Epic and Trifecta products have been in excess of $300 million. *Id*. at 39

(citing Ex. 2017). Michigan contends that a nexus exists between these sales and the '775 patent, demonstrated by St. Jude's marketing of the Epic and Trifecta valves, which emphasizes their anticalcification properties. *Id*. Michigan also asserts that during cross-examination, Scott Lien testified that sales of Biocor (an untreated valve) "have been trending down each year since Epic was introduced in 2008, and that sales of Epic have exceeded sales of Biocor in 2009, 2010, 2011, 2012, and the first half of 2013." Paper 66, Redacted Observations on Cross-Examination of Scott R. Lien, 5 (citing Ex. 2033, 71:3-74:24).

St. Jude counters by arguing that Michigan's evidence of sales is insufficient to show commercial success, as the sales are presented in terms of absolute dollar values instead of market share. Pet. Reply 11-12. St. Jude also contends that Michigan has failed to prove a nexus between the sales and the invention of the '775 patent. According to St. Jude, the Epic and Trifecta products are "medical device[s] filled with important technology and features all unrelated to the claimed process." *Id*. at 12 (citing Ex. 1041 ¶¶ 11-15, 18, 19). St. Jude cites the declaration of Dr. Bruce Lytle, who testifies that surgeons purchase heart valves for features other than anticalcification treatments. *Id*. at 13 (citing Ex. 1065 ¶ 22). In addition, St. Jude notes Scott Lien's testimony that his marketing efforts have focused recently on Trifecta valves, which St. Jude argues shows that any downtrend in sales of Biocor is due to factors other than the Linx AC treatment. Paper 50, Response to Observations on Cross-Examination of Scott R. Lien, 5-6.

Upon our review of the record, we are not persuaded that Michigan has established sufficiently that the St. Jude products enjoyed commercial success, or a nexus between any success and the invention claimed in the '755 patent. With respect to commercial success, we note that Michigan's reliance on the total sales figures of the Epic and Trifecta products (PO Resp. 39) are not meaningful in the

absence of comparative data, such as market share information. *See Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed. Cir. 1984); *see also In re Huang*, 100 F.3d at 140 ("[E]vidence related solely to the number of units sold provides a very weak showing of commercial success."). At oral hearing, Michigan conceded that the sales numbers in a vacuum do not tell the Board anything regarding commercial success. Tr. 40-41 ("You're right, dollar figures in a vacuum don't tell it.").

The only comparative data cited by Michigan compares the pricing and sales of St. Jude's Epic (treated) product to the pricing and sales of St. Jude's Biocor (untreated) product. Tr. 43. Comparative product sales within a company, however, cannot provide the evidence of commercial success that could be obtained by comparing competing products marketed by different companies. The relative pricing and sales of St. Jude's Epic and Biocor products may be due to marketing choices by St. Jude, as opposed to any commercial success of the products themselves. Thus, we cannot conclude on this record that the St. Jude products have enjoyed commercial success.

Nor has Michigan presented persuasive evidence of a nexus between any commercial success and the invention claimed in the '775 patent. While we may infer a nexus when "the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent," that is not the case here. *See Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed.Cir.1988). The invention disclosed in the '775 patent is a method, which is used during the manufacture of St. Jude's Epic and Trifecta valves[10] to impart a

[10] A determination that the Epic product is manufactured using the claimed process is outside our purview, and is the subject of an ongoing litigation between the parties. For the purposes of this Decision, we will assume—without deciding—

certain property: calcification resistance. The commercially successful "thing," which Michigan asserts is the Epic and Trifecta, is *not* the invention claimed in the patent. In such a situation:

> When the thing that is commercially successful is not coextensive with the patented invention—for example, if the patented invention is only a component of a commercially successful machine or process—the patentee must show prima facie a legally sufficient relationship between that which is patented and that which is sold.

Id.

Michigan relies heavily on St. Jude's marketing materials to establish a nexus. PO Resp. 39-40. Specifically, Michigan notes that St. Jude markets the Epic valve as identical to the Biocor valve, but incorporating "patented anticalcification technology." *Id*. (citing Ex. 2018). While we recognize that prominence of the patented technology in St. Jude's advertising may create an inference of a nexus (*see Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579 (Fed. Cir. 1997)), the totality of the record before us does not establish such a nexus. Any inference of a link between sales of the Epic and Trifecta valves and the '775 patent's anticalcification treatment must be weighed against the testimony of St. Jude's witnesses. According to Scott Lien, St. Jude's witness, several features such as durability, hemodynamics, and mechanical improvements are incorporated into the Epic and Trifecta valves. Ex. 1041 ¶¶ 11-15, 18, 19. In addition, Dr. Bruce Lytle, another St. Jude witness, testified that these features factor into doctors' purchasing decisions more heavily than the particular anticalcification treatment used on the valves. Ex. 1065 ¶ 22 ("the available

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that the Epic valve is made using the claimed process. At oral argument, St. Jude agreed to such an assumption for the purposes of this proceeding. Tr. 80.

human data do not support selecting any particular [valve] based upon the specific type of antimineralization treatment").

Based on the foregoing, we are unpersuaded that the record establishes a "legally sufficient relationship" between the patented method and the products which are sold. Michigan, therefore, has failed to present evidence sufficient to establish that St. Jude's products enjoy commercial success, or that any nexus exists between such success and the '775 patent.

2. Long-Felt Need

Nor do we find persuasive Michigan's contention that the '775 patent addressed a long-felt, but unsolved, need. To establish such a need, a patent owner must show that there was a persistent problem that was recognized by those of ordinary skill in the art. *See In re Gershon*, 372 F.2d 535, 539 (CCPA 1967). The problem must not have been solved previously by another, and the claimed invention must, in fact, satisfy the long-felt need. *See Newell Companies v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988); *In re Cavanagh*, 436 F.2d 491, 496 (CCPA 1971).

Michigan contends that "[s]ince at least 1980, there has been a recognized need in the art for an effective anticalcification method to address the problem of calcification of GA pre-treated bioprosthetic devices." PO Resp. 41 (citing Ex. 2000 ¶ 17). Even if such a need existed at one time, however, the record clearly shows that it was solved prior to the '775 patent. Both Levy and Carpentier disclose effective anticalcification methods for GA pre-treated bioprosthetic devices, which use metal ions. At oral argument, Michigan conceded as much:

> JUDGE FITZPATRICK: . . . before the invention, were there methods of making tissue calcification resistant?

> MR. WEINER: There were some methods. Some of them, for example, the Levy '661 patent cites a different method for making tissue calcification resistant. There were other methods in the art.
> JUDGE FITZPATRICK: Thank you.
> MR. WEINER: *It would not be correct to say that the '775 patent was the first patent to provide a method for preventing calcification of GA pretreated implanted tissue*.

Tr. 39 (emphasis added).

To distinguish the '775 patent from these prior solutions, Michigan redefines the long-felt need as "render[ing] the tissue resistant to calcification, while eliminating the need for use of potentially harmful metal ions." PO Resp. 42. According to Dr. Frederick Schoen, Michigan's witness, metal ions "can potentially cause problems such as stiffening of the heart valve matrix and metal accumulation-related toxicity problems." Ex. 2000 ¶ 17. There is no evidence in the record, however, that treating GA-pretreated tissue with an alcohol, as required by the challenged claims, solved these problems of stiffening and toxicity.[11] The specification of the '775 patent is silent as to the alleged problems posed by metal ions; indeed, the claimed invention encompasses the use of such ions. Ex. 1001, 5:59-6:10.

Nor do we find it determinative that witnesses such as Dr. Schoen and Dr. Butcher, or references such as Gong, expressed a need in October 1993 for improved anticalcification treatments. Ex. 2000 ¶ 17; Ex. 2031, 32:7-10; Ex. 1015, p. 290. The mere fact that existing products could be improved is not proof of a long-felt, but unmet, need. To the contrary, Michigan conceded that even in the

[11] At oral hearing, Michigan contended that Dr. Schoen offered an opinion that toxicity is not an issue with ethanol treatment. Tr. 38. We are unable to discern any statement by Dr. Schoen in his testimony to that effect.

current state of the art, there potentially could be anticalcification treatments developed that improve beyond the '775 patent. Tr. 38-39.

For these reasons, we find that Michigan has failed to provide sufficient evidence of long-felt, but unmet, need.

F. Conclusion of Obviousness

We have considered the scope and content of the prior art; the differences between the prior art and the challenged claims; the level of ordinary skill in the art; and the objective indicia of nonobviousness. *See Graham*, 383 U.S. at 18-19. Based on our review of the record and the preponderance of the evidence, we conclude that claims 23 and 25-29 would have been obvious over the combined teachings of Levy, Kaplan, and Holman, and that claims 23, 25, 26, 28, and 29 would have been obvious over the combined teachings of Carpentier, Kaplan, and Gong.

G. Motions to Exclude

A motion to exclude is required to preserve an objection to the admissibility of evidence. 37 C.F.R. § 42.64(c). A motion to exclude must identify the objections in the record in order, and must explain why the objected-to evidence is not admissible. *Id*. A motion to exclude, however, may not be used to challenge the sufficiency of the evidence to prove a particular fact. Office Patent Trial Practice Guide, 77 Fed. Reg. 48,765, 48,767 (Aug. 14, 2012). Both parties timely filed motions to exclude in this proceeding; we discuss them, in turn, below.

1. Petitioner's Motion to Exclude

St. Jude seeks to exclude the following evidence: 1) Exhibits 2026-2030, offered during the deposition of Scott Lien, and testimony of Mr. Lien directed to these exhibits; 2) Mr. Lien's cross-examination testimony as to the relative pricing

of Biocor and Epic valves; 3) Mr. Lien's cross-examination testimony as to market share; 4) portions of Dr. Bruce Lytle's cross-examination testimony; and 5) portions of Dr. Jonathan Butcher's cross examination testimony. Pet. Mot. 5-14. The primary basis for each of these objections is that Michigan's cross-examination of the witnesses went beyond the scope of their direct testimony, in violation of 37 C.F.R. § 42.53(d)(5)(ii). Pet. Mot. 5. Additionally, St. Jude objects to Exhibits 2027-2030 for lack of foundation, lack of authentication, and hearsay. *Id.* at 7.

Resolution of St. Jude's motion is unnecessary, as this final written Decision does not rely on Exhibits 2026-2030, or any of the portions of the cross-examination testimony to which St. Jude objected, let alone in a manner adverse to St. Jude. Accordingly, we *dismiss* St. Jude's motion to exclude as moot.

2. Patent Owner's Motion to Exclude

Michigan seeks to exclude Exhibit 1016, the declaration of Dr. Jonathan Butcher, and Exhibits 1017, 1019-1021, and 1023-1040, which were offered in support of Dr. Butcher's testimony. PO Mot. 1. All of the evidence to which Michigan objects was submitted in support of St. Jude's Reply. According to Michigan, the declaration and supporting exhibits were untimely, as they were served in violation of 37 C.F.R. § 42.23(b) ("[a] reply may only respond to arguments raised in the corresponding opposition or patent owner response"); *see also* Office Patent Trial Practice Guide; 74 Fed. Reg. at 48,767 ("a reply that raises a new issue or belatedly presents evidence will not be considered"). Michigan contends that Dr. Butcher's declaration is "new evidence that could have been presented with St. Jude's petition," proffered to cure various alleged deficiencies in the testimony of Dr. Kaplan. PO Mot. 9. Permitting St. Jude to offer Dr. Butcher's declaration and supporting exhibits in reply would, according to

Michigan, "allow[] substitution of a new witness for one that has been discredited." *Id*. at 10.

St. Jude maintains that Dr. Butcher's testimony is proper reply evidence, presented to respond to arguments made in Michigan's patent owner response. Paper 53, Petitioner's Opposition to PO Mot., 2. Specifically, St. Jude points out that Dr. Butcher's testimony responds to Michigan's arguments that a person of ordinary skill would not have found the Kaplan article to be credible. *Id*. at 4. St. Jude also argues that Michigan's objections were not preserved for the motion to exclude, as the objections, as served, failed to identify the grounds for objection with sufficient particularity, as required by 37 C.F.R. § 42.64(b)(1).

At the outset, we disagree that Michigan's objections were not preserved properly. Within five days of service of the Butcher declaration and supporting exhibits, Michigan served objections, objecting to the admissibility of Exhibits 1016-1069 as "untimely." Ex. 2034 (citing 37 CFR 42.23(b); Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,767 (Section II(I)). While the objections served by Michigan were not overly explanatory, our rules only require objections to identify their grounds "with sufficient particularity to allow correction in the form of supplemental evidence." 37 C.F.R. § 42.64(b)(1). The basis of Michigan's objections was that the evidence was untimely, a fault that cannot be corrected through the service of supplemental evidence. For this reason, St. Jude suffered no prejudice from the alleged lack of sufficient particularity in Michigan's objections. Michigan's motion to exclude is procedurally proper.

Nevertheless, we deny Michigan's motion to exclude. To the extent Dr. Butcher's testimony and supporting exhibits address the alleged deficiencies in the experimental protocol of the Kaplan article, these are issues that were raised for the first time by Michigan in its patent owner response. A petitioner is not expected to

anticipate, in its petition, every counterargument a patent owner might make in response. We find Michigan's arguments that St. Jude submitted the testimony of Dr. Kaplan with its petition because it anticipated the deficiencies in the Kaplan article's dog model to be without merit.

To the extent that Dr. Butcher's testimony can be construed as an attempt to "substitute" his testimony as a person of ordinary skill in the art for Dr. Kaplan's testimony, we consider this issue to be moot. Our decision does not rely on Dr. Butcher to establish the level of ordinary skill or inform how a person of ordinary skill would understand the prior art references.

For the foregoing reasons, Michigan's motion to exclude is *denied.*

III. CONCLUSION

We conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 23 and 25-29 are unpatentable under 35 U.S.C. § 103 as having been obvious over the combined teachings of Levy, Kaplan, and Holman, and that claims 23, 25, 26, 28, and 29 are unpatentable under 35 U.S.C. § 103 as having been obvious over the combined teachings of Carpentier, Kaplan, and Gong. St. Jude's motion to exclude is dismissed; Michigan's motion to exclude is denied.

IV. ORDER

In consideration of the foregoing, it is

ORDERED that claims 23 and 25-29 of U.S. Patent No. 5,746,775 are *unpatentable*;

FURTHER ORDERED that Petitioner's motion to exclude is *dismissed*;

FURTHER ORDERED that Patent Owner's motion to exclude is *denied*; and

FURTHER ORDERED that, because this is a final decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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