

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HEART FAILURE TECHNOLOGIES, LLC
Petitioner

v.

CARDIOKINETIX, INC.
Patent Owner

Case IPR2013-00183
Patent 7,582,051

Before THOMAS L. GIANNETTI, MICHAEL J. FITZPATRICK, and
SCOTT E. KAMHOLZ, *Administrative Patent Judges*.

KAMHOLZ, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Heart Failure Technologies, LLC (“Petitioner”) filed a petition to institute an *inter partes* review of claims 1 and 10 of U.S. Patent 7,582,051 (the “’051 patent”). Paper 4 (“Pet.”). Patent Owner CardioKinetix, Inc. timely filed a preliminary response. Paper 10 (“Prelim. Resp.”). The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides as follows:

THRESHOLD.—The Director may not authorize an *inter partes* review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Petitioner presents the following grounds of unpatentability (Pet. 3):

References	Basis	Claims challenged
Murphy (Ex. 1002), ¹ Khairkhahan (Ex. 1004), ² and Lane (Ex. 1006) ³	§ 103	1, 10
Murphy, Khairkhahan, and Salahieh (Ex. 1007) ⁴	§ 103	1, 10
Lesh (Ex. 1003), ⁵ Khairkhahan, Nikolic (Ex. 1005), ⁶ and Lane	§ 103	1, 10
Lesh, Khairkhahan, Nikolic, and Salahieh	§ 103	1, 10

¹ U.S. Patent 7,485,088 B2.

² U.S. Pre-Grant Publication US 2002/0111647 A1.

³ U.S. Patent 7,717,955 B2.

⁴ U.S. Pre-Grant Publication US 2005/0137688 A1.

⁵ U.S. Patent 6,152,144.

⁶ U.S. Pre-Grant Publication US 2003/0050685 A1.

unfurled, the membrane presents a pressure receiving surface 17 (the undersurface, not indicated in Fig. 1). *Id.* at ll. 53-55. The membrane has a peripheral edge 18 (also not indicated in Fig. 1) that may have serrations. *Id.* at ll. 57-58. A continuous expansive strand 19 extends around the periphery of the membrane on the undersurface. *Id.* at 59-60. The strand applies pressure to the membrane to seal the periphery to the wall of the ventricular chamber. *Id.* at 60-63. The strand is biased outwardly and ensures that folds or wrinkles are not formed when the device is expanded for deployment. Col. 3, l. 66 to col. 4, l. 2.

Claim 1 illustrates the claimed subject matter and is reproduced below:

1. A device for treating a patient by partitioning a chamber of the patient's heart into a primary productive portion and a secondary non-productive portion, the device comprising:

an expandable frame formed of a plurality of ribs having distal ends secured to a central hub and free, outwardly flared, proximal ends,

a pressure receiving membrane formed at least in part of flexible material, the membrane forming a recess in an expanded, deployed configuration, wherein the membrane comprises a loose and flexible peripheral region configured to seal to a ventricular wall surface to partition the ventricle and create the secondary non-productive portion, wherein the flexible peripheral region of the membrane comprises notched serrations; and

an outwardly biased member which is secured to the membrane at a position that is radially inward from the loose peripheral region of the membrane, wherein the outwardly biased member is configured to stiffen at least a portion of the membrane so as to reduce wrinkling of the membrane so that the peripheral region of the

membrane may seal against a ventricular wall surface defining in part the heart chamber.

C. Claim Construction

Consistent with the statute and the legislative history of the AIA, the Board will interpret claims of an unexpired patent using the broadest reasonable construction in light of the specification of the patent. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48766 (Aug. 14, 2012); 37 CFR § 42.100(b). Petitioner does not propose any constructions deviating from this standard. Pet. 5. Patent Owner directs no comments to claim construction in the Preliminary Response.

II. ANALYSIS

A. Overview

Petitioner contends that claims 1 and 10 are (1) obvious over Murphy and Khairkhahan in combination with either Lane or Salahieh, and (2) obvious over Lesh, Khairkhahan, and Nikolic, also in combination with either Lane or Salahieh. Pet. 3; *see* chart *supra*.

B. Obviousness of claims 1 and 10 over Murphy, Khairkhahan, and Lane

Petitioner's presentation of this challenge appears at pages 5-17 of the petition.

Murphy describes a device and method for reshaping a ventricle that has non-viable tissue in its wall. Col. 6, l. 65–col. 7, l. 7. The ventricle is reshaped by “imbricating” it, meaning that edges of the ventricle wall having non-viable tissue between them are brought together so that the non-viable tissue is excluded. *Id.*

Figure 2b of Murphy is reproduced below:

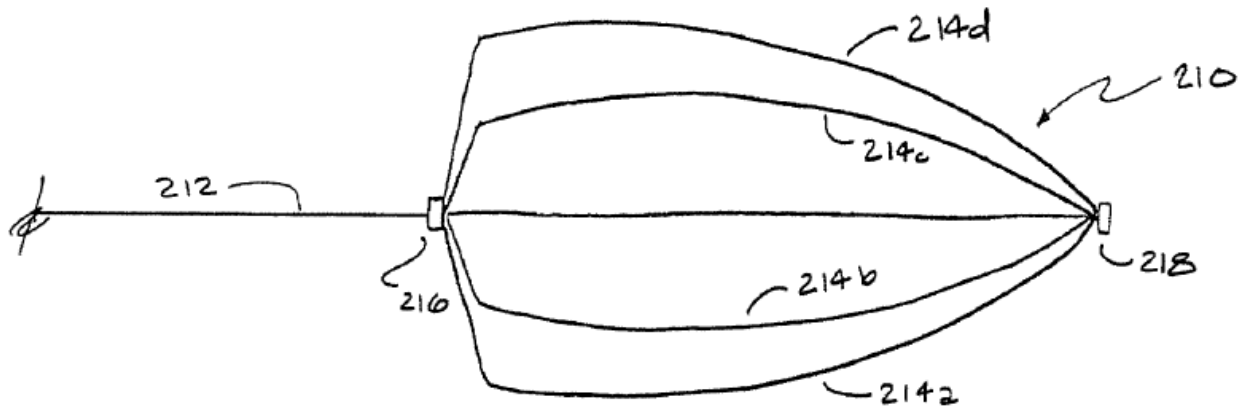


Fig. 2b

Figure 2b shows a shaping device 210, which has a main wire 212 running through its center and a series of back ribs 214a-d coupled to the main wire at collar 216. Col. 4, ll. 45-50. A patch (not shown) may be coupled to the shaping device. Col. 6, ll. 31-33. The patch is sized to cover the non-viable tissue that is to be excluded, col. 8, ll. 6-11, and is positioned to align with that tissue. Col. 10, ll. 44-47. The ventricle wall is reshaped by pressing it against the shaping device using a molding instrument. Col. 7, ll. 8-13. A clasp instrument implements (such as sutures, staples, or clips) to the ventricle wall along the edges of the portion to be excluded. *Id.* at ll. 13-21. When the implements are closed, the ventricle wall will have been pulled over the shaping device and will maintain its shape. *Id.* at ll. 25-28.

Khairkhahan describes devices and methods for occluding the left atrial appendage, a portion of the heart in which blood may clot when it stagnates there during atrial fibrillation. Khairkhahan ¶ [0003].

Figures 3 and 4 of Khairkhahan are reproduced below:

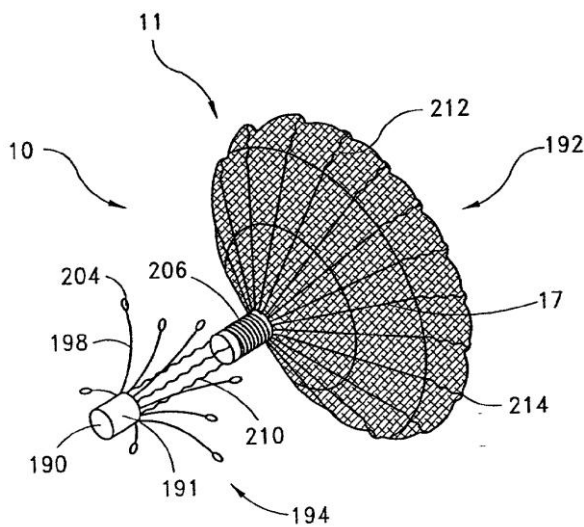


FIG. 3

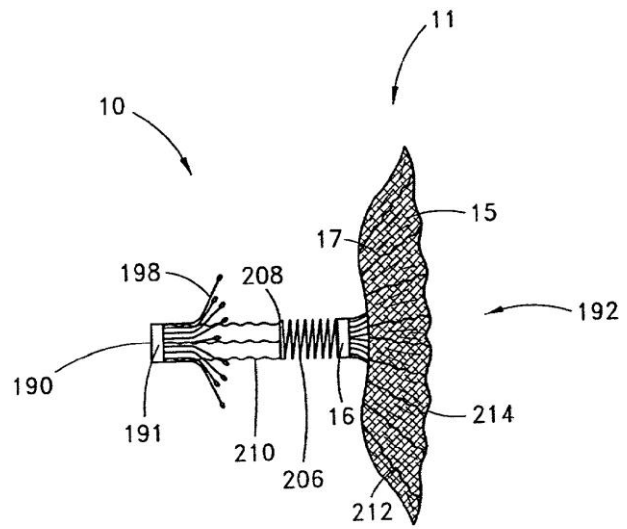
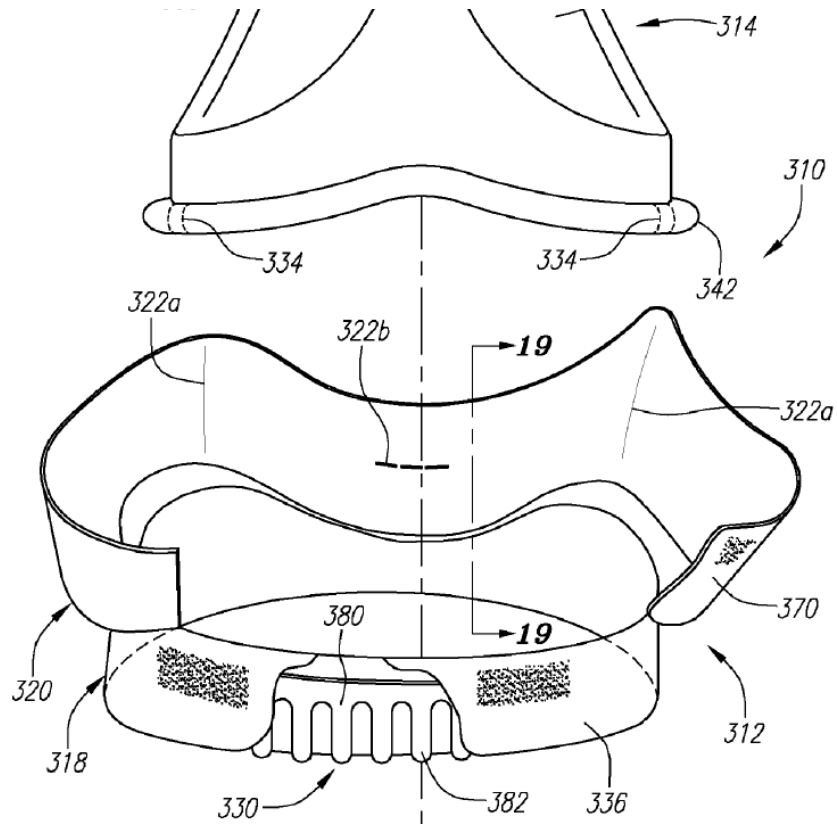


FIG. 4

Figures 3 and 4 show an occluding device 10, which has an occlusion member 11 and stabilizing member 194. *Id.* at ¶ [0062]. The occlusion member includes a mesh-like barrier 15 secured to a frame that is formed by an array of radially outwardly-extending spokes 17. *Id.* at ¶¶ [0044], [0047], [0048]. The spokes extend from hub 16. *Id.* at ¶ [0046]. Each spoke has a proximal zone 212 with an “enhanced degree of flexibility” to assist engagement of the occlusion member with the wall of the left atrial appendage. *Id.* at ¶ [0064]. Each spoke terminates with a proximal point 214, which may be either embedded in the barrier or extend beyond it to assist further with engagement. *Id.* at ¶ [0065].

Lane describes replacement heart valve assemblies. *Abstr.* The assembly includes a prosthesis, which serves as an interface between the surrounding tissue and the replacement valve. Col. 1, ll. 60-67. The prosthesis includes an annular ring that is implantable in the surrounding tissue and a sewing cuff to which the replacement valve is stitched. *Id.*

Detail from Figure 17A is reproduced below:



The detail from Figure 17A shows a heart valve assembly, which includes a prosthesis (gasket member 312) and a valve (crown 314). Col. 24, ll. 19-21. The gasket member includes annular ring 318, flexible baleen element 330, sewing cuff 320, and covering fabric 336. *Id.* at ll. 22-26. The baleen element has a base 380 from which fingers 382 extend. Col. 25, ll. 57-59. The fingers may be biased to extend outwardly. *Id.* at 65-66. When they do so, they press the fabric covering against the surrounding tissue to enhance the seal formed by the gasket member. Col. 27, l. 64 to col. 28, l. 2. The fingers may have uniform or varying lengths, may define undulations or lobes, or may vary in thickness. Col. 26, ll. 4-15; Figs. 20A-D.

Petitioner argues that Murphy and Khairkahan disclose all limitations of each of claims 1 and 10 except the requirement that the peripheral region of the membrane have “notched serrations.” Pet. 6-7. In particular, Petitioner contends

that Khairkhahan discloses the claimed outwardly biased member. Pet. 9, 13. Petitioner argues that Lane discloses the notched serrations. *Id.* at 7-8. Petitioner asserts that a person having ordinary skill in the art would have had reason to combine the relevant teachings of Murphy, Khairkhahan, and Lane to reach the claimed subject matter because these references “are related to the repair of a human heart.” Pet. 5; *see also* Pet. 9.

Patent Owner argues, among other things, that the petition fails to explain how Khairkhahan discloses the outwardly biased member. Prelim. Resp. 10, 37-39. Patent Owner also argues that Petitioner has made no more than a bare assertion of obviousness, without any explanation of how the teachings of the references would be arranged or combined or why a person of ordinary skill would have made the combination. Prelim. Resp. 8, 39-41.

We agree with Patent Owner on both points. The fact that Murphy, Khairkhahan, and Lane all concern human heart repair is not in itself sufficient rationale for making the combination. Many heart repair devices exist. That fact alone would not make it obvious to combine their features. Petitioner must show some *reason* why a person of ordinary skill in the art would have thought to combine *particular* available elements of knowledge, as evidenced by the prior art, to reach the claimed invention. *See KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007). This, the Petitioner has not done. That the references relied upon all relate to human heart repair does not amount to “some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *See id.* (internal quotations omitted).

Moreover, we agree further with Patent Owner that Petitioner has not explained satisfactorily how the references, when combined, meet the “outwardly biased member” limitation. Petitioner relies on Khairkhahan alone for disclosure

of this limitation, but simply reproduces Khairkhahan's Figure 3 and paraphrases two paragraphs of Khairkhahan's specification. *See, e.g.,* Pet. 13. Petitioner does not identify what structure shown or described in these excerpts meets the limitation. No structure shown in the Khairkhahan excerpts Petitioner relies on is plainly an "outwardly biased member" as recited in claims 1 and 10. The petition thus does not make clear the relevance of the cited disclosure to the claim limitation at issue. It was Petitioner's burden to demonstrate how the prior art would have made obvious the claimed subject matter as a whole, and Petitioner has not done this. Petitioner's presentation is incomplete in this respect and, therefore, insufficient to demonstrate a reasonable likelihood of prevailing on this obviousness challenge.

For these reasons, we determine that Petitioner has not demonstrated a reasonable likelihood that claims 1 and 10 are unpatentable over Murphy, Khairkhahan, and Lane.

C. Obviousness of claims 1 and 10 over Murphy, Khairkhahan, and Salahieh

Petitioner's presentation of this challenge appears at pages 17-28 of the petition. This challenge, however, suffers from the same deficiencies discussed above. Petitioner offers the same inadequate rationale for combining the respective references: that they all relate to repair of the human heart. *See* Pet. 18. As discussed, this assertion is insufficient to support an obviousness challenge. *See supra.* Moreover, this challenge also relies on Khairkhahan for disclosing the "outwardly biased member" limitation, but Petitioner does not explain how the cited passages of Khairkhahan meet that limitation. *See, e.g.,* Pet. 25.

For these reasons, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that claims 1 and 10 are unpatentable over Murphy, Khairkhahan, and Salahieh.

D. Obviousness of claims 1 and 10 over Lesh, Khairkhahan, Nikolic, and Lane

Petitioner's presentation of this challenge appears at pages 28-45 of the petition.

Lesh, like Khairkhahan, describes devices and methods for occluding the left atrial appendage. Abstr. Figure 1 is reproduced below:

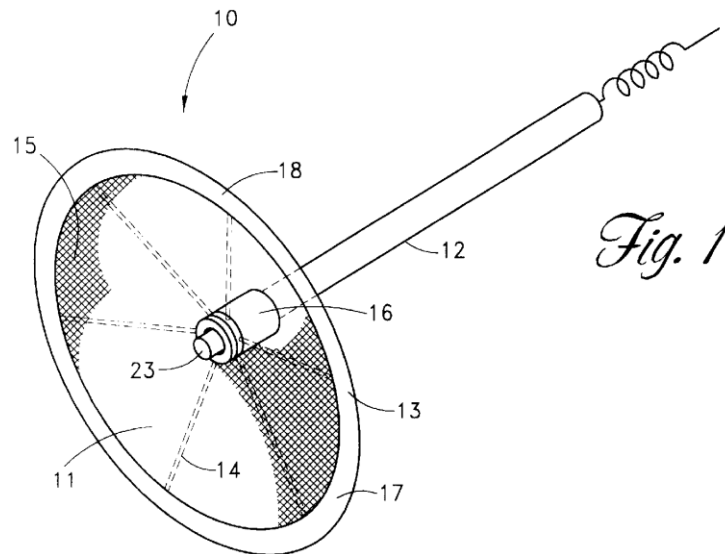


Figure 1 of Lesh shows an occluding device 10 having occluding member 11 and retention member 12. Col. 7, ll. 31-33. The occluding member is disc-shaped and is formed from a frame structure 14 of arms extending from hub 16 to outer rim 13. *Id.* at ll. 35-41. The outer rim may contain a radial hoop 21 that maintains the ring shape of the outer rim and facilitates its radial expansion. *Id.* at ll. 64-67. The outer rim seals against the surface of the left atrial appendage. Col. 8, ll. 60-62.

This challenge suffers from the same deficiencies as the challenges discussed above. Petitioner offers the same inadequate rationale for combining the respective references: that they all relate to repair of the human heart. *See* Pet. 29. As discussed, this assertion is insufficient to support an obviousness challenge. *See supra*.

Petitioner also does not persuade us that the cited references disclose the “outwardly biased member” limitation. Petitioner cites Khairkhahan and Lesh as each disclosing this limitation. *See, e.g.*, Pet. 38-39. Petitioner excerpts from Khairkhahan the same portions as in the challenges discussed *supra*, and similarly gives no explanation as to how the cited passages meet the claim limitation. Petitioner also cites Figures 1-3 of Lesh and portions of the specification that describe the outer rim and the radial hoop. *Id.* Petitioner, however, does not explain how either of these structures satisfies the requirement that the outwardly biased member be “at a position that is radially inward” from the peripheral region of the membrane. As can be seen in Lesh’s Figure 1, and as can be inferred from its name, the outer rim is at the *outermost* edge of the occluding device. Petitioner has not explained how Lesh’s radially outermost position meets the claimed “position that is radially inward.”

Thus, Petitioner has neither provided an adequate rationale for the combination of the cited references, nor shown that the references, when combined, disclose the claimed subject matter or otherwise would have made it obvious. For these reasons, we determine that Petitioner has not demonstrated a reasonable likelihood that claims 1 and 10 are unpatentable over Lesh, Khairkhahan, Nikolic, and Lane.

E. Obviousness of claims 1 and 10 over Lesh, Khairkhahan, Nikolic, and Salahieh

Petitioner's presentation of this challenge appears at pages 45-59 of the petition. This challenge suffers from the same deficiencies discussed in section II.D, *supra*, for the challenge based on Lesh, Khairkhahan, Nikolic, and Lane. Petitioner offers the same inadequate rationale for combining the respective references as for the other challenges: that they all relate to repair of the human heart. *See* Pet. 45. This assertion is insufficient to support an obviousness challenge. Moreover, this challenge relies on Khairkhahan or Lesh for disclosing the "outwardly biased member" limitation, but Petitioner does not explain how the cited passages of Khairkhahan or Lesh meet that limitation. *See, e.g.*, Pet. 54-55.

For these reasons, we determine that Petitioner has not demonstrated a reasonable likelihood that claims 1 and 10 are unpatentable over Lesh, Khairkhahan, Nikolic, and Salahieh.

III. SUMMARY

Petitioner has not shown that there is a reasonable likelihood that it would prevail with respect to at least one of the claims challenged in the petition. The petition is therefore denied.

IV. ORDER

For the reasons given, it is

ORDERED that the petition challenging the patentability of claims 1 and 10 of Patent 7,582,051 is *denied*.

Case IPR2013-00183
Patent 7,582,051

For PETITIONER:

Sanford E. Warren, Jr.
R. Scott Rhodes
AKIN GUMP STRAUSS HAUER & FELD LLP
swarren@akingump.com
srhoades@akingump.com

For PATENT OWNER:

Richard Shoop
James Shay
SHAY GLENN LLP
rick@shayglenn.com
jim@shayglenn.com