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Paper 8
Date: March 26, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND
EDWARDS LIFESCIENCES LLC,
Petitioner,

v.

COLIBRI HEARTVALVE LLC,
Patent Owner.

IPR2020-01649
Patent 9,125,739 B2

Before ERICA A. FRANKLIN, JAMES A. TARTAL, and
ERIC C. JESCHKE, *Administrative Patent Judges.*

TARTAL, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Edwards Lifesciences Corporation and Edwards Lifesciences LLC ("Petitioner") filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claims 1–5 ("the Challenged Claims") of U.S. Patent No. 9,125,739 B2 (Ex. 1001, "the '739 patent"). Paper 2 ("Pet."). Colibri Heart Valve LLC ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b) (2018); 37 C.F.R. § 42.4(a) (2019). An *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . 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." 35 U.S.C. § 314(a). Upon consideration of the Petition, the Preliminary Response, and the evidence of record, we conclude that the information presented shows a reasonable likelihood that Petitioner would prevail in showing the unpatentability of at least one of the Challenged Claims. Accordingly, we authorize an *inter partes* review to be instituted as to the Challenged Claims of the '739 patent on the grounds raised in the Petition. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far (prior to Patent Owner's Response). This is not a final decision as to patentability of claims for which *inter partes* review is instituted. Any final decision will be based on the record, as fully developed during trial.

II. BACKGROUND

A. The '739 Patent

The '739 patent, titled "Percutaneous Replacement Heart Valve and a Delivery and Implantation System," issued September 8, 2015, from

Application No. 14/253,650 ("the '650 Application"), filed April 15, 2014. Ex. 1001, codes (21), (22), (45), (54). The '739 patent states that the '650 Application is a continuation of Application No. 13/675,665 (filed on November 13, 2012), which is a continuation of Application No. 10/887,688 (filed on July 10, 2004, and issued as U.S. Patent No. 8,308,797), which is a continuation-in-part of Application No. 10/037,266 (filed on January 4, 2002) ("the '266 Application").[1] *Id.* at code (63). The replacement heart valve device described by the '739 patent "comprises a stent made of stainless steel or self-expanding nitinol and a completely newly designed artificial biological tissue valve disposed within the inner space of the stent." *Id.* at 4:64–5:1.

Figure 5 of the '739 patent is reproduced below.

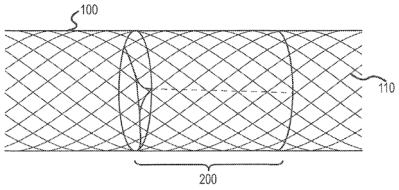

FIG.5

Figure 5 illustrates a side view of a replacement heart valve device mounted within a self-expanding stent in the expanded position. *Id.* at 6:31–34. "The replacement heart valve device comprises a stent member 100 and a flexible valve means 200." *Id.* at 6:55–57. "The stent member 100 includes a length of wire 110 formed in a closed zigzag configuration." *Id.* at 7:32–33. The stent member may be a meshwork of nitinol wire formed into a tubular structure that "flares markedly at both ends in a trumpet-like configuration."

[1] Application No. 10/887,688 was published on May 26, 2005, as US2005/0113910 A1, and is the reference Petitioner identifies as "Paniagua" (Ex. 1015).

Id. at 7:55–63. The "trumpet-like configuration" is not illustrated in Figure 5, or in any other figure of the '739 patent.

The valve means comprises "a generally tubular portion" and, "preferably, a peripheral upstanding cusp or leaflet portion." *Id.* at 6:61–64. The valve means is "flexible, compressible, host-compatible, and non-thrombogenic." *Id.* at 8:27–28. It may be made from various materials, preferably mammal pericardium tissue. *Id.* at 8:28–35. The cusp or leaflet portion of the valve means is generally tubular in shape and comprises two to four leaflets. *Id.* at 7:5–8. The cusp or leaflet portion of the valve means is "formed by folding the pericardium material used to create the valve." *Id.* at 8:44–46. "The starting material is preferably a flat dry sheet, which can be rectangular or other shaped." *Id.* at 8:47–49. The cusps/leaflets "open in response to blood flow in one direction and close in response to blood flow in the opposite direction." *Id.* at 8:49–51.

Figure 8 of the '739 patent is reproduced below.

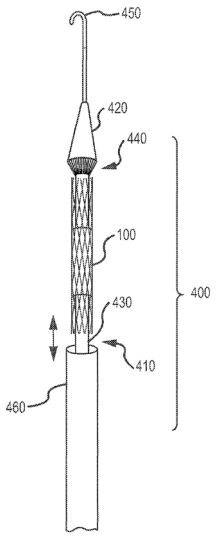

FIG.8

Figure 8 illustrates the "delivery and implantation system of the replacement artificial heart valve," including "flexible catheter 400 which may be

inserted into a vessel of the patient and moved within that vessel." *Id.* at 11:40–44. The '739 patent further explains as follows:

> The distal end 410 of the catheter 400, which is hollow and carries the replacement heart valve device of the present invention in its collapsed configuration, is guided to a site where it is desired to implant the replacement heart valve. The catheter has a pusher member 420 disposed within the catheter lumen 430 and extending from the proximal end 440 of the catheter to the hollow section at the distal end 410 of the catheter. Once the distal end 410 of the catheter is positioned as desired, the pusher mechanism 420 is activated and the distal portion of the replacement heart valve device is pushed out of the catheter and the stent member 100 partially expands. In this position the stent member 100 is restrained so that it doesn't pop out and is held for controlled release, with the potential that the replacement heart valve device can be recovered if there is a problem with the positioning. The catheter 400 is then retracted slightly and the replacement heart valve device is completely pushed out of the catheter 400 and released from the catheter to allow the stent member 100 to fully expand.

Id. at 11:44–62.

B. Illustrative Claim

Petitioner challenges claims 1–5 of the '739 patent. Pet. 1. Claim 1 is independent and claims 2–5 depend from claim 1. Ex. 1001, 14:2–38. Claim 1 is illustrative of the claimed subject matter and is reproduced below.

> 1. An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:
>
> a prosthetic heart valve including:
>
> a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery, wherein the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration; and
>
> a valve means including two to four individual leaflets made of fixed pericardial tissue, wherein the valve means resides

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