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Paper 17
Date: August 13, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND
EDWARDS LIFESCIENCES LLC,
Petitioner,

v.

COLIBRI HEART VALVE LLC,
Patent Owner.

IPR2021-00775
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
Granting Motion for Joinder
35 U.S.C. § 315(c); 37 C.F.R. § 42.122

I. INTRODUCTION

On April 6, 2021, Edwards Lifesciences Corporation and Edwards Lifesciences LLC ("Petitioner" or "Edwards") 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."). Concurrently, Petitioner filed a Motion for Joinder seeking to join *Medtronic CoreValve LLC v. Colibri Heart Valve LLC*, IPR2020-01454 (the "Medtronic IPR"). Paper 3 (the "Motion" or "Mot."). *Inter partes* review was instituted in the Medtronic IPR on March 10, 2021. Medtronic IPR, Paper 11 (PTAB March 10, 2021) (the "Medtronic IPR Institution Decision"). The Petition is substantively identical to the petition on which *inter partes* review was instituted in the Medtronic IPR. *See* Ex. 1025 (comparison of the Petition to the petition in the Medtronic IPR). Colibri Heart Valve LLC ("Patent Owner") did not file a preliminary response to the Petition or an opposition to the Motion.

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) (2020). 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 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. 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. We also grant the unopposed Motion and join Petitioner to the Medtronic IPR (IPR2020-01454).

II. BACKGROUND

A. The '739 Patent

The '739 patent, titled "Percutaneous Replacement Heart Valve and a Deliver 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 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.

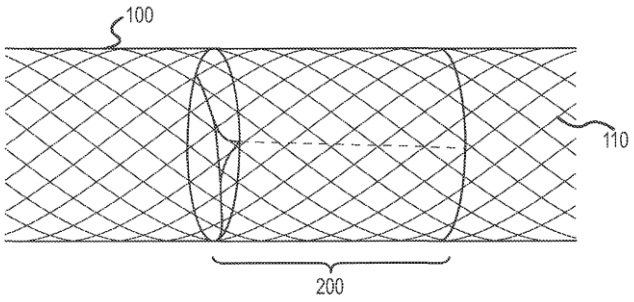

FIG.5

Figure 5 illustrates a side view of a replacement heart valve device mounted within a self-expanding stent in the expanded position. Ex. 1001, 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." *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 of 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.

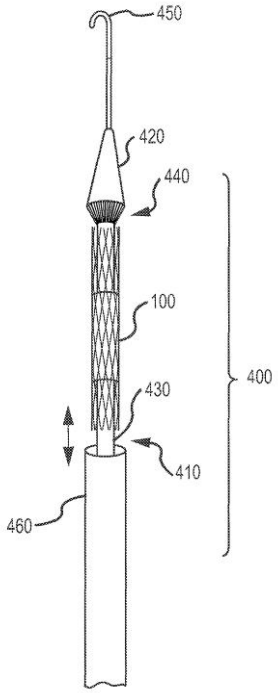

FIG.8

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

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