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Paper 27
Entered: March 24, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC COREVALVE LLC,
EDWARDS LIFESCIENCES CORPORATION, AND
EDWARDS LIFESCIENCES LLC,
Petitioner,

v.

COLIBRI HEART VALVE LLC,
Patent Owner.

IPR2020-01454[1]
Patent 9,125,739 B2

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

TARTAL, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

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[1] Edwards Lifesciences Corporation and Edwards Lifesciences LLC filed a petition in IPR2021-00775 and are joined as petitioner in this proceeding.

We have jurisdiction to conduct this *inter partes* review under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) (2018) and 37 C.F.R. § 42.73 (2020). For the reasons discussed below, we determine Medtronic CoreValve LLC, Edwards Lifesciences Corporation, and Edwards Lifesciences LLC ("Petitioner")[2] has shown by a preponderance of the evidence that claims 1–5 ("the Challenged Claims") of U.S. Patent No. 9,125,739 B2 (Ex. 1001, "the '739 patent") are unpatentable.

I. INTRODUCTION

A. Summary of Procedural History

Medtronic CoreValve LLC filed a Petition on September 2, 2020, pursuant to 35 U.S.C. §§ 311–319, requesting an *inter partes* review of the Challenged Claims. Paper 2 ("Pet."). On March 10, 2021, we instituted an *inter partes* review of the Challenged Claims on all grounds of unpatentability asserted in the Petition. Paper 11. Within one month of institution of review, on April 6, 2021, Edwards Lifesciences Corporation and Edwards Lifesciences LLC filed a petition in IPR2021-00775 substantively identical to the Petition in this proceeding, along with a motion for joinder to this proceeding. IPR2021-00775, Papers 2 and 3. We instituted trial in IPR2021-00775 and granted the motion joining Edwards Lifesciences Corporation and Edwards Lifesciences LLC as petitioner to this proceeding. Paper 17.

[2] Medtronic CoreValve LLC identifies Medtronic Inc. as an additional real party in interest. Pet. 7. Edwards Lifesciences Corporation and Edwards Lifesciences LLC identify no additional real parties in interest. IPR2021-00775, Paper 2, 7.

Colibri Heart Valve LLC ("Patent Owner")[3] filed a Patent Owner Response. Paper 14 ("Resp."). Petitioner filed a Reply to the Patent Owner Response. Paper 18 ("Reply"). Patent Owner filed a Sur-reply in support of the Patent Owner Response. Paper 19 ("Sur-reply").

Following oral argument, we entered a transcript of the hearing in the record. Paper 25 ("Tr."). Petitioner bears the burden of proving unpatentability of each claim it has challenged by a preponderance of the evidence, and the burden of persuasion never shifts to Patent Owner. *See* 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d); *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

B. Related Matters

The '739 patent is also challenged in *Edwards Lifesciences Corp. and Edwards Lifesciences LLC v. Colibri Heart Valve LLC*, IPR2020-01649 (filed September 18, 2020), in which a final written decision is issued contemporaneous with this Decision. The parties identify the '739 patent as a subject of *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No 8:20-cv-847 (C.D. Cal., filed May 4, 2020) (the "CDCA Case"). Pet. 7; Paper 4, 1. In addition to the '739 patent, U.S. Patent No. 8,900,294 ("the '294 patent") is also a subject of the CDCA Case. The '739 patent and the '294 patent each issued from applications that are continuations of U.S. Application No. 13/675,665, and have substantially the same specification. The '294 patent was challenged in a petition for *inter partes* review that was denied. *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, IPR2020-001453, Paper 11 (PTAB Mar. 5, 2021).

[3] Patent Owner identifies no additional real parties in interest. Paper 4, 1.

C. 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, filed April 15, 2014, which claims priority back to Application No. 10/037,266, filed on January 4, 2002. Ex. 1001, codes (21), (22), (45), (54), (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.

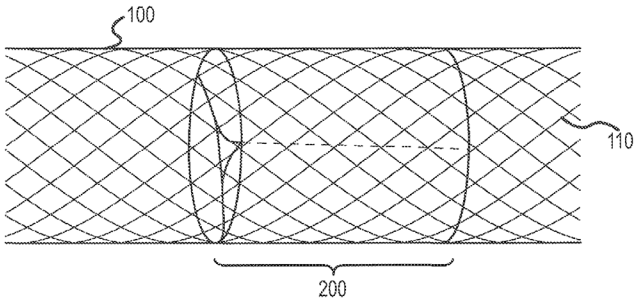

FIG.5

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." *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.

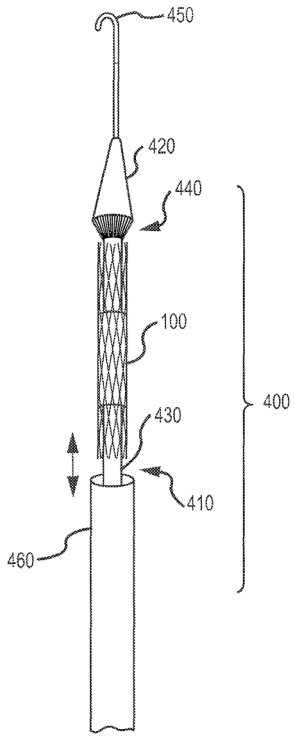

FIG.8

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