United States Court of Appeals for the Federal Circuit

MEDTRONIC, INC., MEDTRONIC VASCULAR, INC.,
Appellants

v.

TELEFLEX INNOVATIONS S.A.R.L.,
Appellee

2021-2359, 2021-2362, 2021-2366

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2020-00129, IPR2020-00134, IPR2020-00138.

Decided: June 5, 2023

JENNIFER L. GRABER, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, DC, argued for appellants. Also represented by BRITTANY BLUEITT AMADI; TASHA JOY BAHAL, MARK CHRISTOPHER FLEMING, HANNAH ELISE GELBORT, MADELEINE C. LAUPHEIMER, Boston, MA.

JOSEPH W. WINKELS, Carlson, Caspers, Vandenburgh & Lindquist PA, Minneapolis, MN, argued for appellee. Also represented by PETER M. KOHLHEPP, TARA CATHERINE NORGARD, J. DEREK VANDENBURGH.

Before MOORE, *Chief Judge*, LOURIE and DYK, *Circuit Judges*.

MOORE, *Chief Judge*.

Medtronic, Inc. and Medtronic Vascular, Inc. (collectively, Medtronic) appeal *inter partes* review decisions of the Patent Trial and Appeal Board holding Medtronic failed to establish the unpatentability of various claims of U.S. Patent Nos. RE45,380; RE45,760; and RE47,379 (the patents-in-suit). Medtronic also appeals the Board's decisions granting Teleflex Innovation S.à.r.l's (Teleflex) motion to amend certain claims of the '379 patent. For the following reasons, we affirm.

BACKGROUND

Coronary artery disease, in which plaque buildup narrows the lumen (i.e., the tubular cavity) of a patient's artery and obstructs blood flow, affects millions of Americans. Cardiologists refer to this narrowing of a patient's artery as stenosis. *See* '380 patent at 1:48–49.[1] For decades, cardiologists have used devices known as guide catheters to deliver interventional cardiology devices (e.g., guidewires, stents, balloon catheters) designed to alleviate stenoses. *Id.* at 1:39–52. Treatment typically involves inserting the guide catheter into the patient's femoral or radial artery and guiding the catheter to the patient's aorta until the distal tip of the catheter reaches the ostium (i.e., opening) of the coronary artery. *Id.* at 1:53–59. Interventional devices can then be inserted into the proximal opening of the catheter, advanced through the lumen of the catheter using a

[1] The patents-in-suit share a common specification. For simplicity, all citations to the written description will refer to the '380 patent.

guidewire, and delivered past the stenosis.[2] *Id.*

These procedures involved certain challenges and risks. For example, "[c]rossing tough lesions can create enough backward force to dislodge the guide catheter from the ostium of the artery being treated," disrupting the procedure and potentially harming the patient. *Id.* at 1:59–63, 4:56–62. This problem drove practitioners to seek new catheter designs and methods with increased "back-up support" that would prevent backward dislodgment of the catheter. *Id.* at 1:59–67. For example, one method disclosed in a prior art journal article (Takahashi) involves a "mother-and-child" technique in which a standard 5 French guide catheter is inserted into a 6 French guide catheter and advanced until its distal tip is deep within the patient's ostium, a technique known as deep seating.[3] *Id.* at 2:40–51; *see* J.A. 2276–80 (Takahashi). However, deep seating using standard guide catheters in the mother-and-child technique also involved risks, including that the stiff distal end of the inner catheter could damage the coronary artery when deeply embedded. '380 patent at 2:51–56.

The patents-in-suit, owned by Teleflex, sought to address these problems by using a coaxial extension catheter insertable into standard guide catheters that offered increased back-up support and the ability to deep seat without the attendant drawbacks of traditional mother-and-child systems. *See id.* at 2:9–27, 4:56–5:27. In a preferred embodiment, the disclosed extension catheter includes three parts: (1) a proximal substantially rigid portion 20 (yellow); (2) a reinforced portion 18 (blue); and (3) a distal

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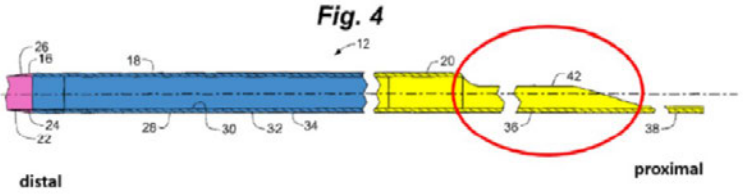
[2] The proximal and distal ends of a catheter respectively refer to the ends nearest to and farthest from the treating physician.

[3] One French is the standard unit of measurement for catheter diameters. One French equals one third of a millimeter. *See* J.A. 1952 ¶ 50.

flexible tip 16 (pink). *See id.* at 6:31–7:15; *see also id.* at Fig. 4 (reproduced below as annotated by Medtronic's expert). The proximal end of the guide extension catheter includes a "side opening," i.e., a partially cylindrical region (red circle), which permits the extension catheter to receive and deliver interventional cardiological devices while it is within the guide catheter. *Id.* at 10:1–20. As depicted in Figure 4, the side opening may include multiple inclined regions separated by a non-inclined region, a structure referred to herein as a double-inclined side opening. The patents-in-suit also disclose and claim embodiments in which the diameter of the extension catheter is no more than one French smaller than the diameter of the guide catheter, thereby preserving maximal volume within the coaxial lumen for receiving interventional devices. *See id.* at 3:28–49.



PROCEDURAL HISTORY

In November of 2019, Medtronic petitioned for *inter partes* review of the patents-in-suit, alleging the challenged claims would have been obvious over U.S. Patent No. 7,604,612 (Ressemann), which discloses an evacuation sheath assembly with a distal side opening used to aspirate embolic material while occluding blood flow using sealing balloons, in view of various combinations of secondary references. The secondary references included: (1) U.S. Patent No. 5,439,445 (Kontos), which discloses a support catheter for delivering angioplasty balloons; (2) U.S. Patent Application Publication No. 2005/0015073 (Kataishi),

disclosing a suction catheter designed to remove thrombi in blood vessels; and (3) Takahashi.

The Board instituted each petition and issued final written decisions holding some claims unpatentable and others not. *Medtronic, Inc. v. Teleflex Innovations S.à.r.l.*, No. IPR2020-00129, 2021 WL 2524890 (P.T.A.B. June 17, 2021) (*'380 Decision*); *Medtronic, Inc. v. Teleflex Innovations S.à.r.l.*, No. IPR2020-00134, Paper No. 122 (P.T.A.B. June 7, 2021) (*'760 Decision*); *Medtronic, Inc. v. Teleflex Innovations S.à.r.l.*, IPR2020-00138, Paper No. 104 (P.T.A.B. June 7, 2021) (*'379 Decision*).[4,5] In addition, the Board granted Teleflex's contingent motion to amend certain claims of the '379 patent and determined the amended claims were not unpatentable. *'379 Decision*, at J.A. 133–64.

The parties organize the claims determined not unpatentable into three (overlapping) sets, a categorization we adopt for our analysis. The One-French Claims are claims 32 and 33 of the '380 patent; claims 48 and 51–53 of the '760 patent; and claims 46–51 of the '379 patent. The Double-Incline Claims are claim 27 of the '380 patent and claims 44, 46–48, and 51 of the '379 patent. Lastly, the Substitute Claims are claims 46, 47, and 49–51 of the '379 patent.

DISCUSSION

Medtronic appeals the Board's determination that Medtronic failed to prove the One-French and Double-Incline Claims would have been obvious. It also challenges the Board's decision granting Teleflex's motion to introduce

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[4] The *'760 Decision* is included in the Joint Appendix at J.A. 53–77.

[5] The *'379 Decision* is included in the Joint Appendix at J.A. 78–167.

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