United States Court of Appeals for the Federal Circuit

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

v.

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

2021-2357, 2021-2360, 2021-2364

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2020-00127, IPR2020-00130, IPR2020-00136.

Decided: June 5, 2023

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

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

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. 8,048,032; RE45,380; and RE45,776 (the patents-in-suit). Medtronic also appeals the Board's decisions granting Teleflex Innovation S.à.r.l's (Teleflex) motions to amend certain claims of the '032 and '380 patents. 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* '032 patent at 1:25–26.[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 1:15–29. 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 1:30–36. Interventional devices can then be inserted into the proximal opening of the

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[1] The patents-in-suit share a common specification. For simplicity, all citations to the written description will refer to the '032 patent.

catheter, advanced through the lumen of the catheter using a 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 1:36–40, 4:40–46. 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 1:36–44. 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 2:17–29; *see* J.A. 2172–76 (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. '032 patent at 2:28–44.

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 2:53–3:4, 4:33–5:3. In a preferred embodiment, the disclosed extension catheter includes three parts: (1) a proximal substantially rigid portion 20

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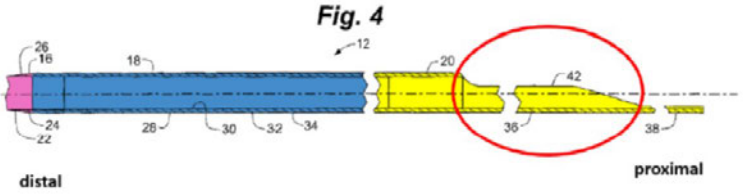
[2] The proximal and distal ends of a catheter respectively refer to the ends nearest to and farthest from the treating physician.

[3] One French is the standard unit of measurement for catheter diameters. One French equals one third of a millimeter. *See* J.A. 1886 ¶ 46.

(yellow); (2) a reinforced portion 18 (blue); and (3) a distal flexible tip 16 (pink). *See id.* at 6:9–54; *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 9:44–63. 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 3:5–20.



In 2009, Teleflex introduced a series of guide extension catheters embodying claims of the patents-in-suit and marketed as the GuideLiner V1, GuideLiner V2, and GuideLiner V3 (collectively, the GuideLiner). Those products enjoyed undisputed commercial success and industry praise and were eventually followed by multiple, competing guide extension catheters, including Medtronic's Telescope product, introduced in 2019.

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. 5,439,445 (Kontos), which discloses a support catheter for

delivering angioplasty balloons, in view of various combinations of secondary references. The secondary references included: (1) U.S. Patent Application Publication No. 2004/0010280 (Adams), disclosing a catheter assembly with a distal side opening for removing embolic debris while occluding blood flow during treatment; (2) U.S. Patent No. 7,604,612 (Ressemann), disclosing an evacuation sheath assembly with a distal side opening used to remove embolic material while occluding blood flow using sealing balloons; (3) U.S. Patent Application Publication No. 2005/0015073 (Kataishi), disclosing a suction catheter designed to remove thrombi in blood vessels; and (4) Takahashi.

The Board instituted each petition and issued final written decisions holding some claims unpatentable and others not. *See Medtronic, Inc. v. Teleflex Innovations S.à.r.l.*, No. IPR2020-00127, 2021 WL 2518685 (P.T.A.B. June 7, 2021) (*'032 Decision*); *Medtronic, Inc. v. Teleflex Innovations S.à.r.l.*, No. IPR2020-00130, 2021 WL 2524006 (P.T.A.B. June 17, 2021) (*'380 Decision*); *Medtronic, Inc. v. Teleflex Innovations S.à.r.l.*, No. IPR2020-00136, 2021 WL 2524191 (P.T.A.B. June 17, 2021) (*'776 Decision*). In addition, the Board granted Teleflex's contingent motions to amend certain claims of the '032 and '380 patents and determined the amended claims were not unpatentable.

The parties organize the claims determined not unpatentable into four (overlapping) sets, a categorization we adopt for our analysis. The Side Opening Claims are claims 3, 4, 9, 13, and 18 of the '032 patent; claims 3, 4, 9, 14, and 19 of the '380 patent; and claims 25–27, 29, 33, 35–37, 39, 41–49, and 52 of the '776 patent. The One-French Claims are claims 8 and 17 of the '032 patent; claims 8 and 18 of the '380 patent; and claims 30–32 and 53–56 of the '776 patent. The Double-Incline Claims are claims 52–56 of the '776 patent. Lastly, the Substitute Claims are claims

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