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Paper 9
Entered: February 24, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.,
Petitioner,

v.

TELEFLEX LIFE SCEINCES LIMITED,
Patent Owner.

IPR2020-01344
Patent RE46,116 E

Before SHERIDAN K. SNEDDEN, JAMES A. TARTAL, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

TARTAL, *Administrative Patent Judge*.

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

I. INTRODUCTION

Medtronic, Inc., and Medtronic Vascular, Inc. ("Petitioner") filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claims 25–55 ("the Challenged Claims") of U.S. Patent No. RE46,116 E (Ex. 1401, "the '116 patent"). Paper 1 ("Pet."). Teleflex Life Sciences Limited ("Patent Owner") filed a Preliminary Response. Paper 7 ("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 '116 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 '116 Patent

The '116 patent, titled "Coaxial Guide Catheter for Interventional Cardiology Procedures," issued August 23, 2016, from Application

No. 14/195,435, filed March 3, 2014. Ex. 1401, codes (21), (22), (45), (54). The '116 patent is a reissue of U.S. Patent No. 8,292,850 ("the '850 patent") from Application No. 13/359,059 ("the '059 application") filed on January 26, 2012, which the '116 patent states is a continuation of an application filed on November 1, 2013 (issued as U.S. Patent No. RE45,380), which is an application for the reissue of U.S. Patent No. 8,292,850, which is a division of an application filed on June 28, 2010 (issued as U.S. Patent No. 8,142,413), which is a division of an application filed on May 3, 2006 (issued as U.S. Patent No. 8,048,032). *Id.* codes (60), (64). The '116 patent is directed to "methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta." *Id.* at 1:38–40.

The '116 patent explains, as background, that in "[i]nterventional cardiology procedures," guidewires or other instruments, such as balloon catheters and stents, are often inserted through guide catheters into coronary arteries that branch off from the aorta. *Id.* at 1:44–50. In coronary artery disease, "the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions" in a phenomenon known as stenosis. *Id.* at 1:50–54. In treating the stenosis, "a guide catheter is inserted through the aorta and into the ostium of the coronary artery," sometimes with the aid of a guidewire, and is passed beyond the occlusion or stenosis. *Id.* at 1:59–65. However, "[c]rossing tough lesions can create enough backward force to dislodge the guide catheter from the ostium of the artery being treated," which can make it difficult or impossible for the interventional cardiologist to treat certain forms of coronary artery disease. *Id.* at 1:66–2:3.

The '116 patent discusses four categories of previous "attempts to provide support to the guiding catheter to prevent backward dislodgement from the coronary ostium (referred to as 'backup support')." *Id.* at 2:4–7. One category of guiding catheters "are configured to draw backup support from engaging the wall of the aortic arch opposing the ostium of the coronary artery that is being accessed." *Id.* at 2:8–11. A second category are "guiding catheters that include a retractable appendage. *Id.* at 2:25–26. A third category are "guide catheters that have a portion that seeks to expand laterally to grip the interior wall of the ostium." *Id.* at 2:36–41. A fourth category, or "technique," of the prior attempts "includes the placement of a smaller guide catheter within a larger guide catheter in order to provide added support for the crossing of lesions or for the distal delivery of balloons and stents." *Id.* at 2:50–53. The '116 patent states this fourth technique was described in Takahashi,[1] which uses a guide catheter inserted "more deeply into the ostium of the coronary artery than typically has been done before." *Id.* at 2:53–62. The '116 patent states that such "deep seating" by this technique "creates the risk that the relatively stiff, fixed curve, guide catheter will damage the coronary artery." *Id.* at 2:63–65.

The '116 patent purports to resolve issues identified with the prior procedures by using "a coaxial guide catheter that is deliverable through standard guide catheters by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter." Ex. 1401, 3:20–23. According to the '116 patent, the coaxial guide catheter "preferably includes a tapered inner catheter that runs over a standard 0.014 inch coronary

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[1] Saeko Takahashi, et al., *New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter*, 63 CATHETERIZATION AND CARDIOVASCULAR INTERVENTIONS 452–456 (2004) (Ex. 1410, "Takahashi").

guidewire to allow atraumatic placement within the coronary artery," and this feature allows removal of the tapered inner catheter after the coaxial guide catheter is in place. *Id.* at 3:23–28.

Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter in accordance with the invention described in the '116 patent:

Fig. 1

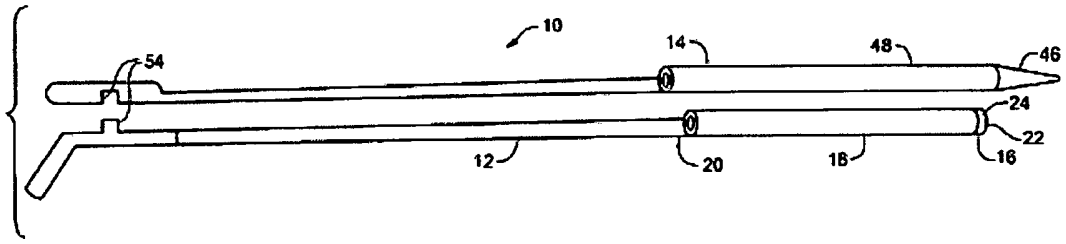

Fig. 2

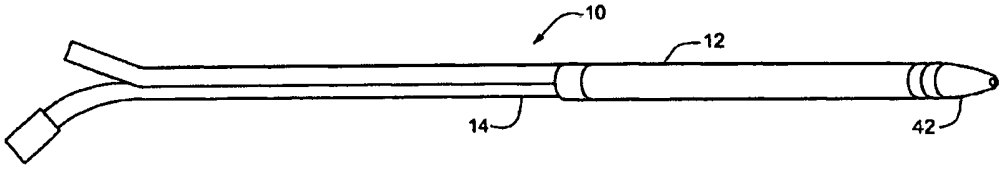

Figure 1 is a schematic depiction of the coaxial guide catheter and tapered inner catheter separately, and Figure 2 depicts those two elements assembled together. *Id.* at 5:51–56; Figs. 1 and 2. As shown above, "coaxial guide catheter assembly 10" includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* at 6:42–44. Coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:45–46. Tapered inner catheter 14 "includes tapered inner catheter tip 42." *Id.* at 7:26–27. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 7:30–31. Both tapered portion 46 and straight portion 48 are pierced by lumen 50 (not labeled in figures above). *Id.* at 7:31–32. "Tapered inner catheter 14 may also include

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