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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.,
Petitioner,

v.

NIAZI LICENSING CORPORATION,
Patent Owner.

Case IPR2018-00610
Patent 6,638,268 B2

Before JAMES A. TARTAL, GEORGE R. HOSKINS, and TIMOTHY J. GOODSON, *Administrative Patent Judges*.

HOSKINS, *Administrative Patent Judge*.

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

I. INTRODUCTION

Medtronic, Inc. ("Petitioner") has filed a Petition (Paper 1, "Pet.") pursuant to 35 U.S.C. §§ 311–319 to institute an *inter partes* review of claims 1, 10–14, 18, 19, and 23–26 of U.S. Patent No. 6,638,268 B2 ("the '268 patent"). Niazi Licensing Corporation ("Patent Owner") has filed a Preliminary Response (Paper 7, "Prelim. Resp."). Applying the standard set forth in 35 U.S.C. § 314(a), which requires demonstration of a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim, we institute, on behalf of the Director (37 C.F.R. § 42.4(a)), an *inter partes* review to determine whether Petitioner demonstrates by a preponderance of the evidence that claims 1, 10–14, 18, 19, and 23–26 of the '268 patent are unpatentable.

II. BACKGROUND

A. Real Parties in Interest and Related Proceedings

Petitioner identifies itself as the real party in interest for this proceeding. Pet. 2. Patent Owner identifies itself as the real party in interest for this proceeding. Paper 4, 1. The parties identify several U.S. District Court litigations as related to this proceeding. Pet. 2–3; Paper 4, 1. Petitioner additionally identifies another *inter partes* review proceeding concerning the '268 patent, filed on the same day as the present proceeding, which has been assigned the case number IPR2018-00609. Pet. 3.

B. The ’268 Patent

The ’268 patent discloses a double catheter that is useful to “cannulate[[1]] the coronary sinus without significant manipulation.” Ex. 1001, Title, Abstract. Figures 1 and 2 of the ’268 patent show a first embodiment, and are reproduced below:

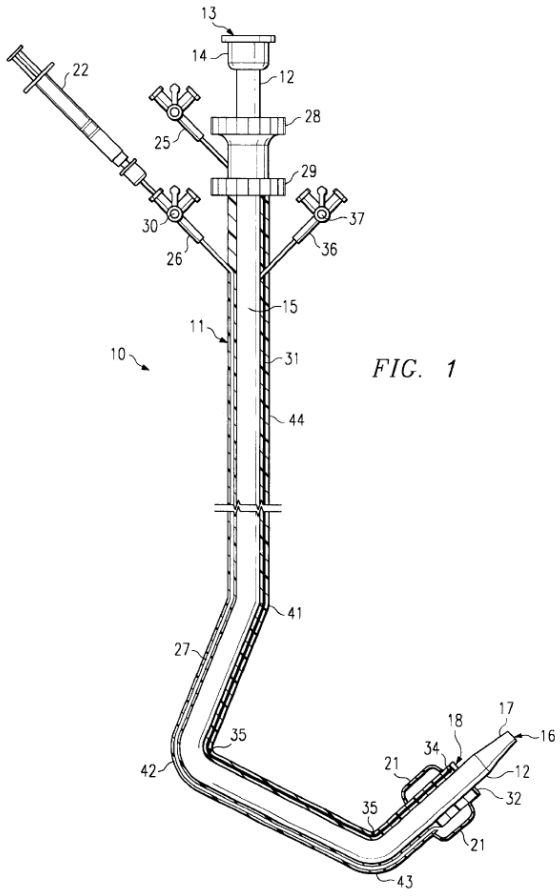

FIG. 1

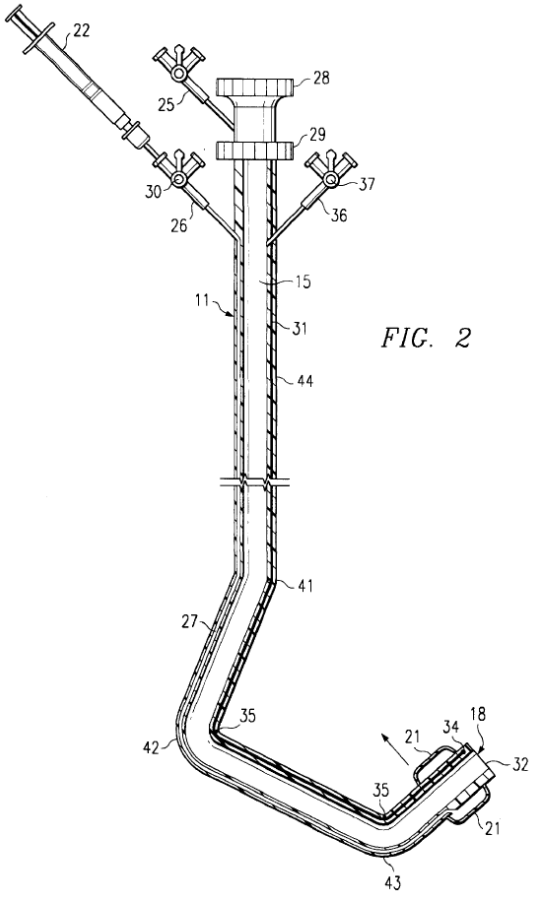

FIG. 2

[1] A “cannula” is “a tube . . . for insertion into body cavities or ducts, as for drainage; cf. CATHETER.” *Webster’s New World Dictionary of American English* (3rd College Ed., © 1988, Ed. Victoria Neufeldt), at 205. We, therefore, understand the term “cannulate,” in the context of the ’268 patent, to refer to insertion of a catheter into a patient, and manipulation of the catheter so that its distal end reaches a specified body cavity or duct within the patient, such as the coronary sinus. *See* Ex. 1001, 1:12–28.

Figure 1 is a side view of double catheter 10 comprising outer catheter 11 and inner catheter 12, and Figure 2 is a side view of outer catheter 11 without inner catheter 12. *Id.* at 2:62–63, 3:9–14.

A physician inserts distal end 16, 18 of double catheter 10 into the venous system of a patient, such as by surgically accessing a subclavian vein. *Id.* at 3:31–33, 3:43–44, 4:32–36. The physician advances double catheter 10 through the patient's venous system until distal end 16, 18 is positioned within the right atrium of the patient's heart. *Id.* at 4:36–38. The physician manipulates double catheter 10 so that at least inner catheter 12 exits the right atrium and enters the coronary sinus.[2] *Id.* at 4:38–55. The physician passes an electrical lead through and out of distal end 16 of inner catheter 12, to be placed on the heart wall proximate the left ventricle. *Id.* at 4:59–62, 1:29–38. The lead may then be used to control the contractions of the left ventricle, known as "pacing" the left ventricle. *Id.*

According to the '268 patent, "there are no presently available preformed catheters that will slip easily into the coronary sinus" (*id.* at 1:38–41), and "[t]he present invention provides a catheter especially adapted for use in the coronary sinus" (*id.* at 2:12–14). Thus, "[f]or optimum deployment in the coronary sinus, inner and outer catheters 11, 12 preferably have a predetermined shape . . . but [are] still flexible enough to bend when required." *Id.* at 4:4–8. The predetermined shape is illustrated in Figures 1–2 as a "hook-shaped distal end of outer catheter 11 [comprising]

[2] "The coronary sinus is a collection of veins joined together to form a large vessel that collects blood from the heart muscle," and "delivers less-oxygenated blood to the right atrium." *See* https://en.wikipedia.org/wiki/Coronary_sinus (last accessed Aug. 1, 2018); Ex. 1001, 1:12–18.

substantially straight segments spanning three bends 41, 42 and 43" having specified angular ranges. *Id.* at 4:8–19. That predetermined shape can be modified somewhat during a surgical procedure, to aid the entry of catheter 10 into the coronary sinus, by twisting torque screw 29 to wind or unwind cable 31 attached to anchor 34 near distal tip 32 of outer catheter 11. *Id.* at 3:55–4:1, 4:19–26.

A second embodiment of the '268 patent provides another method for modifying the predetermined shape of the distal end of the outer catheter, and is illustrated in Figure 3, reproduced below:

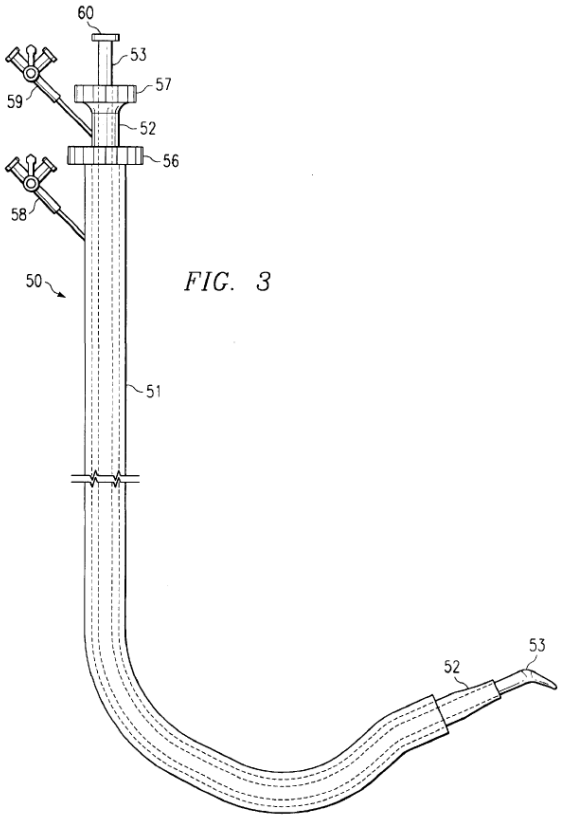

FIG. 3

Figure 3 is a side view of triple catheter 50 comprising outer catheter 51, inner catheter 52, and obturator 53. *Id.* at 2:64–65, 4:63–5:3. Instead of "rely[ing] on specialized miniature adjustment mechanisms" such as screw 29 and cable 31 in Figures 1–2, "[t]he angle of outer guide 51 can be

changed by inserting or withdrawing the inner guide 52," with or without also using obturator 53, "as needed to cannulate coronary sinuses of varying heights of origin." *Id.* at 4:63–67, 6:2–18.

C. The Challenged Claims

The '268 patent contains twenty-seven claims. Petitioner challenges claims 1, 10–14, 18, 19, and 23–26. Of the challenged claims, claims 1, 11, 13, 18, and 24 are independent. Claims 1, 11, and 13 are illustrative of the challenged subject matter. Claim 1 recites:

> 1. A double catheter, comprising:
>
> an outer, resilient catheter having shape memory and a hook shaped distal end configured for cannulation of the coronary sinus with at least one curved bend;
>
> an inner, pliable catheter slidably disposed in the outer catheter and of greater length than the outer catheter so that a distal end portion of the inner catheter can be extended or retracted from a distal end opening of the outer catheter to vary the overall length of the double catheter, the inner catheter having an internal lumen configured for the introduction of contrast media and a pacing lead into the coronary sinus; and
>
> a mechanism operable from the proximal end of the outer catheter for changing the curvature of the distal end of the outer catheter.

Ex. 1001, 6:61–7:9. Claim 11 recites:

> 11. A method for placing an electrical lead in a lateral branch of a coronary sinus vein using a double catheter including an outer catheter and an inner catheter slidably disposed inside the outer catheter, comprising:
>
> inserting the catheter into the coronary sinus;
>
> advancing a guide wire through the catheter into a coronary sinus lateral branch vein;

advancing the inner catheter out of a front end opening of the outer catheter along the guide wire into the branch vein;

inserting the lead through the outer and inner catheters to a target location in the branch vein; and

withdrawing the catheter leaving the lead in the branch vein.

Id. at 7:63–8:9. Claim 13 recites:

13. An outer catheter configured for use with an inner, pliable catheter which can be slidably disposed in the outer catheter and of greater length than the outer catheter so that a distal end portion of the inner catheter can be extended or retracted from a distal end opening of the outer catheter, the outer catheter comprising

a resilient tube having shape memory and sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus, and

having a hook-shaped distal end wherein

a first bend adjoining a straight, proximal portion of the outer catheter is in the range of 130° to 180°,

a second, intermediate bend is in the range of 75° to 100° in a direction opposite the first bend, and

a third bend nearest the distal end of the outer catheter in the same direction as the second bend is in the range of to 130° to 175°.

Id. at 8:13–28 (line breaks and indentations added).

D. Asserted Grounds of Unpatentability

Petitioner presents the following challenges to the ’268 patent in this proceeding. *See* Pet. 4–5.

Statutory Basis	References	Claim(s) Challenged
§ 103(a)	Auricchio[3]	11
§ 103(a)	Auricchio and Randolph[4]	12 and 24
§ 103(a)	Auricchio, Randolph, and Payne[5]	13, 14, 18, 19, 23, 25, and 26
§ 103(a)	Lurie[6] and Ockuly[7]	1 and 10
§ 103(a)	Lurie, Ockuly, and Blanc[8]	1 and 10

III. ANALYSIS

A. Claim Interpretation

The Board interprets claims of an unexpired patent using the broadest reasonable construction in light of the specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable construction standard); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,764 (Aug. 14, 2012).

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[3] Ex. 1019, U.S. Patent No. 5,935,160, iss. Aug. 10, 1999.

[4] Ex. 1017, U.S. Patent No. 5,775,327, iss. July 7, 1998.

[5] Ex. 1009, WO 99/49773, pub. Oct. 7, 1999.

[6] Ex. 1018, U.S. Patent No. 6,277,107 B1, iss. Aug. 21, 2001.

[7] Ex. 1020, U.S. Patent No. 5,833,673, iss. Nov. 10, 1998.

[8] Ex. 1015, Jean-Jacques Blanc, et al., *A Method for Permanent Transvenous Left Ventricular Pacing*, 21 Pacing and Clinical Electrophysiology 2021, 2021–24 (1998).

1. "a mechanism operable from the proximal end of the outer catheter for changing the curvature of the distal end of the outer catheter" (claims 1 and 23)

The parties disagree concerning the claim construction of the "mechanism" limitation recited in claims 1 and 23. Pet. 17–20; Prelim. Resp. 3–7. Claim 1 is representative of the issues presented, so we focus on that claim in our analysis.

Petitioner contends the "mechanism" limitation is a means-plus-function limitation, subject to construction under 35 U.S.C. § 112, ¶ 6. Pet. 17–20. Petitioner acknowledges that, because claim 1 does not use the term "means," a presumption arises that § 112, ¶ 6 does not apply. *Id.* at 17–18 (citing *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (en banc in part)). Petitioner contends the presumption is overcome in this case, because claim 1 fails to recite sufficiently definite structure for performing the claimed function of changing the curvature of the distal end of the catheter. *Id.* at 18. Petitioner further contends the '268 patent specification discloses three different structures corresponding to the claimed function, namely: "(1) a torque screw attached to a pull wire or cable anchored close to the tip of the outer catheter, (2) an inner guide [catheter], or (3) an inner guide [catheter] in combination with an obturator." *Id.* at 18–20 (citing Ex. 1001, 3:55–65, 6:2–12).

Patent Owner contends the "mechanism" limitation is not a means-plus-function limitation. Prelim. Resp. 3–7. In Patent Owner's view, the presumption that § 112, ¶ 6 does not apply has not been overcome, because claims 17 and 22 recite a "means for inflation," thereby demonstrating a deliberate attempt not to invoke § 112, ¶ 6 for claim 1. *Id.* at 4. Patent Owner also contends the '268 patent's disclosure of structures (1) and (2)

establishes the claimed mechanism "[has] a sufficiently definite meaning as the name for the structure that performs the function, even when the term covers a broad class of structures or identifies the structures by their function." *Id.* at 4–5 (citing MPEP § 2181). Patent Owner further points to the claim requirement for the mechanism to be "operable from the proximal end of the outer catheter" as indicating that § 112, ¶ 6 does not apply. *Id.* at 5–6. Patent Owner proposes that the mechanism limitation of claim 1 be interpreted as "a structure for changing the curvature of the outer catheter that must be operable from the proximal end of the outer catheter." *Id.* at 7.

We agree for purposes of this Decision with Petitioner's proposed construction of claim 1. Claim 1 does not use the term "means," so we presume § 112, ¶ 6 does not apply. *Williamson*, 792 F.3d at 1347–49. Nonetheless, that presumption is overcome where the claim fails to recite sufficiently definite structure for performing the claimed function. *Id.* That is the case here. The only structural term appearing in the "mechanism" limitation of claim 1 is the word "mechanism" itself, which is a "nonce word[] . . . used in a claim in a manner that is tantamount to using the word 'means' because [it] 'typically do[es] not connote sufficiently definite structure.'" *Id.* at 1350 (quoting *Mass. Inst. of Tech. & Elecs. for Imaging, Inc. v. Abacus Software*, 462 F.3d 1344, 1354 (Fed. Cir. 2006)). The claimed requirement for the mechanism to be "operable from the proximal end of the outer catheter" does not provide sufficiently definite structure for performing the function of changing the curvature of the distal end of the catheter.

Indeed, the '268 patent discloses at least two very different structures for changing the curvature of the distal end of the outer catheter. The first is

torque screw 29 attached to cable 31 anchored close to distal tip 32 of outer catheter 11. Ex. 1001, Fig. 2, 3:55–65, 7:31–40 (claim 4). The second is inner guide catheter 52 being inserted into or withdrawn from outer guide catheter 51, perhaps also using obturator 53 in a similar fashion. *Id.* at Fig. 3, 5:65–6:16, 7:10–15 (claim 2). The lack of structural commonality between those two embodiments belies the notion that a person of ordinary skill in the art would have understood claim 1 to recite sufficiently definite structure for performing the claimed function.

For the foregoing reasons, we determine the "mechanism" limitation of claims 1 and 23 is a means-plus-function limitation subject to construction under 35 U.S.C. § 112, ¶ 6. The parties agree that the corresponding structures include at least (1) a torque screw attached to a cable anchored close to the distal tip of the outer catheter, and (2) an inner guide catheter within the outer catheter. Pet. 18–19; Prelim. Resp. 4–5. We agree with Petitioner's additional citation to (3) an inner guide catheter in combination with an obturator, regarding which Patent Owner is largely silent. *See* Ex. 1001, Fig. 3, 5:65–6:16. Therefore, we construe the "mechanism" limitation of claims 1 and 23 to correspond to any one of those structures (1)–(3), and equivalents thereof. 35 U.S.C. § 112, ¶ 6.

2. "sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus" (claim 24)

Claim 24 recites a method for placing an electrical lead in a coronary sinus vein using a double catheter, and the preamble describes the outer catheter as having "sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus." Ex. 1001, 9:16–21. Petitioner contends that recitation does not breathe life and meaning into the claim, is

not necessary to understand the claim, and is a mere intended use, so it is not limiting. Pet. 20–21. The Preliminary Response does not address Petitioner's contentions in that regard. Based on the argument and evidence currently in the record, we agree with Petitioner's proposed construction.

3. "advancing a guide wire through the catheter" (claim 11)

The preamble of claim 11 recites three catheter terms: "*a double catheter* including *an outer catheter* and *an inner catheter*." Ex. 1001, 7:64–65 (emphases added). Claim 11 then recites "advancing a guide wire through *the catheter* into a coronary sinus." *Id.* at 8:1–2 (emphasis added).

Petitioner does not offer an express construction of "the catheter" in the advancing step. Petitioner instead provides alternative theories of obviousness depending on whether claim 11 requires (1) advancing the guide wire through *just one* of the outer and inner catheters (*see* Pet. 29–30), or (2) advancing the guide wire through *both* of the outer and inner catheters (*see id*. at 30–31). Patent Owner alleges "Petitioner interprets the term 'catheter' as 'double catheter,'" and states "Patent Owner believes this is the proper interpretation of this term." Prelim. Resp. 7.

We agree that the phrase "the catheter" in the guide wire advancing step refers back to "the double catheter" of the preamble. That by itself, however, does not answer the question of whether claim 11 requires advancing the guide wire through just one, or both, of the outer and inner catheters. The outer and inner catheters together form the double catheter, so advancing a guide wire through one of them may still be sufficient.

We determine, based on the argument and evidence currently in the record, that under a broadest reasonable construction the guide wire

advancing step of claim 11 encompasses advancing the guide wire through just one of the outer and inner catheters. The language of claim 11 itself demonstrates Patent Owner was able to limit the claim to performing actions with both the outer and inner catheters, in reciting "inserting the lead through the outer and inner catheters." Ex. 1001, 8:6–7. No such specific requirement is made in the guide wire advancing step.

Further, the '268 patent specification discloses at least one embodiment in which a guide wire is advanced through the outer catheter before the inner catheter is then advanced through the outer catheter along the guide wire:

> Referring to FIGS. 7 and 8, outer guiding catheter 51 is initially . . . inserted into the right atrium 80. The physician attempts to use it to cannulate the coronary sinus without the use of the other components. If this succeeds, an 0.038" hydrophillic-coated guide wire 81 is advanced through it, and used to cannulate the target lateral coronary sinus side-branch 56. (If the side branch 56 cannot be easily cannulated, the angled obturator 53 can be extended and used to direct the guide wire 81 as illustrated in FIG. 7.) The inner guide 52, with obturator 53 inside, is then passed through outer guide 52 over the 0.038" wire into the target side branch 56.

Ex. 1001, 5:46–58. The '268 patent specification also appears to contemplate other embodiments in which the guide wire is advanced through both of the outer and inner catheters. *See id.* at 4:32–43.

Based on the foregoing, we determine for purposes of this Decision that claim 11 requires advancing the guide wire through just one of the outer and inner catheters, or alternatively both of the outer and inner catheters.

4. "adjusting the curvature of the double catheter" (claim 12)

Claim 12 depends from claim 11, to add "adjusting the curvature of *the double catheter*." Ex. 1001, 8:10–12 (emphasis added). Petitioner implicitly contends the limitation of claim 12 is met by adjusting only the curvature of the outer catheter component of the double catheter. *See* Pet. 34–35 (discussing curvature of the outer guide catheter but not the inner support catheter of Auricchio). Patent Owner contends the limitation of claim 12 requires adjusting the curvature of both the outer and inner catheters. *See* Prelim. Resp. 16 (claim 12 limitation "requires inserting the inner catheter into the outer catheter before entry of the double catheter into the coronary sinus" such that "[o]nce assembled, the curvature of the catheter is adjusted").

We determine, based on the argument and evidence currently in the record, that under a broadest reasonable construction the curvature adjustment step of claim 12 encompasses adjusting the curvature of just one of the outer and inner catheters. The language of parent claim 11 demonstrates Patent Owner was able to limit the claim to performing actions with both the outer and inner catheters, in reciting "inserting the lead through the outer and inner catheters." Ex. 1001, 8:6–7. No such specific requirement is made in the curvature adjustment step of claim 12. Further, the '268 patent specification discloses at least one embodiment in which the coronary sinus is cannulated with the outer catheter before the inner catheter is then advanced through the outer catheter. Ex. 1001, 5:46–58. The '268 patent specification also appears to contemplate other embodiments in which the outer and inner catheters cannulate the coronary sinus at the same time. *See id.* at 4:32–43.

Based on the foregoing, we determine for purposes of this Decision that claim 12 requires adjusting the curvature of just one of the outer and inner catheters, or alternatively both of the outer and inner catheters.

5. Remaining Claim Terms

No further explicit interpretations of any claim terms are needed to resolve the issues presented by the arguments and evidence of record. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (per curiam) (claim terms need to be construed "only to the extent necessary to resolve the controversy") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

B. Obviousness over Auricchio

Petitioner asserts claim 11 of the '268 patent is unpatentable under 35 U.S.C. § 103(a) as having been obvious over Auricchio. Pet. 4, 27–33. We have reviewed the arguments and evidence of record. Given the evidence of record, Petitioner has demonstrated a reasonable likelihood of prevailing on its assertions as to claim 11. We, therefore, institute review of claim 11 as having been obvious over Auricchio. We begin our analysis with a brief summary of the law of obviousness, then we address the level of ordinary skill in the art, next we summarize the Auricchio disclosure, and finally we address Petitioner's and Patent Owner's contentions as to obviousness.

1. Law of Obviousness

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that

the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness, if made available in the record. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

2. Level of Ordinary Skill in the Art

Petitioner contends a person having ordinary skill in the art pertaining to the '268 patent "would have been a cardiologist, cardiac electrophysiologist, or interventional cardiologist having experience using catheters (or introducers or sheaths) in the heart, including catheters used for placement of, for example, leads." Pet. 16; Ex. 1005 ¶¶ 14–15. "Alternatively," such a person:

> would have been an engineer with a bachelor's degree in the relevant field (e.g., electrical, mechanical, or biomedical engineering) having at least three to five years of experience designing catheters of the type used in the heart, including catheters used for placement of, for example, leads, and an understanding of the heart and associated procedures.

Pet. 16; Ex. 1005 ¶ 15. The Preliminary Response does not take a position as to the level of ordinary skill in the art.

We determine on the current record that the level of ordinary skill proposed by Petitioner is consistent with the '268 patent and the asserted

prior art. We, therefore, adopt that level in deciding whether to institute trial.

3. Auricchio Disclosure

Auricchio is directed, principally, to the structure of an electrical lead for pacing the heart, which is "especially adapted to be advanced into a selected coronary vein." Ex. 1019, Title, Abstract. Auricchio also discloses methods for "advancing the [electrical] lead through both the coronary sinus and into a selected coronary vein." *Id.* at Abstract. One such method is as follows:

> [T]he physician may insert a guide catheter through the superior vena cava into the ostium of the coronary sinus. A guide wire is then inserted into the guide catheter and advanced to the desired position within in a preselected coronary vein. Once the guide wire is in position, a thin walled support catheter is advanced over the guide wire to the distal end of the guide wire. The guide catheter and guide wire are then removed, leaving the support catheter in place. Then, the coronary vein lead of the present invention is advanced through the support catheter to the desired site in the coronary vein.

Id. 3:22–32; *see also id.* at 8:49–53 (substantially same disclosure).

4. Claim 11

Petitioner provides detailed arguments and evidence, including the Declaration of Dr. Ronald David Berger (Ex. 1005), in support of contending that claim 11 would have been obvious over Auricchio. Pet. 27–33; Ex. 1005 ¶¶ 49–55.

Petitioner relies on the Auricchio passage quoted above (Ex. 1019, 3:22–32) as disclosing the method of claim 11, except perhaps for the steps of "advancing a guide wire through the catheter," and "inserting the lead

through the outer and inner catheters." Pet. 27–33; Ex. 1005 ¶¶ 49–55. The Preliminary Response addresses Petitioner's argument only as to those two claimed steps. We determine Petitioner's contentions as to the other claim limitations are supported in the present record sufficiently for us to institute review. In particular, we agree with Petitioner's argument that the claimed "outer catheter" may correspond to Auricchio's "guide catheter," and the claimed "inner catheter" may correspond to Auricchio's "support catheter," such that the claimed "double catheter" corresponds to the combination of Auricchio's outer guide catheter and inner support catheter. Pet. 27–28; Ex. 1005 ¶ 50. We, thus, turn to the presently disputed issues.

a) "advancing a guide wire through the catheter"

Concerning the guide wire advancing step, Petitioner first argues Auricchio discloses the step, because Auricchio "discloses advancing a guide wire through the [outer] guide catheter of Auricchio's double catheter into the lateral branch vein." Pet. 29–30 (citing Ex. 1019, 3:22–30, 8:49–52); Ex. 1005 ¶ 52.

Patent Owner agrees that "Auricchio discloses advancing a guide wire through a guide catheter (that is arguably analogous to the outer catheter of the '268 patent)." Prelim. Resp. 12. Patent Owner contends that disclosure, however, does not correspond to "advancing a guide wire through the catheter," because Auricchio's inner support catheter is not present within the outer guide catheter at the time the guide wire is advanced. *Id.* at 12–13.

Patent Owner's contention is not persuasive, because it relies on a claim limitation which is not found in claim 11. Under the construction we have adopted for purposes of this Decision, claim 11 encompasses

advancing the guide wire through just one of the outer and inner catheters. *See supra* Section III.A.3. Auricchio correspondingly discloses advancing a guide wire through its outer guide catheter, which is an outer catheter of a double catheter. *See* Ex. 1019, 3:22–26. Based on the present record, we therefore agree with Petitioner's contention that Auricchio discloses the guide wire advancing step.

Petitioner, alternatively, contends that if claim 11 is construed to require advancing the guide wire through Auricchio's outer guide catheter and inner support catheter, such a step would have been obvious to perform. Pet. 30–31. According to Petitioner, a person of ordinary skill in the art would have understood the benefits provided by "advancing a guide wire through both the guide catheter and support catheter, advancing a support catheter over it, and then using the support catheter to provide axial support as the guide wire is delivered to a desired position in the target vein." *Id.* at 30; Ex. 1005 ¶ 52. The identified benefit is that "[t]o the extent the guide wire was displaced during the procedure," a physician could "advance the guide wire relative to both the support catheter and the guide catheter in order to reposition the guide wire at the desired location." Pet. 30; Ex. 1005 ¶ 52. As a second basis for obviousness, Petitioner contends that, if a physician using Auricchio's double catheter "encounter[s] difficulties inserting the support catheter within the preselected coronary vein because of the tortuosity," the physician would have known to advance the guide wire through both of the outer and inner catheters "to position the guide wire in a second branch vein." Pet. 30; Ex. 1005 ¶ 52.

Patent Owner objects that Petitioner improperly attempts to substitute expert testimony for actual prior art disclosures. Prelim. Resp. 13–14 (citing

Motorola, Inc. v. Interdigital Tech. Corp., 121 F.3d 1461, 1473 (Fed. Cir. 1997)). Patent Owner accuses Dr. Berger of speculating with respect to what one might do with Auricchio's double catheter, in hindsight based on the '268 patent disclosure, and without support in the prior art. *Id.* Patent Owner, further, asserts Auricchio teaches away from advancing the guide wire through both of the outer and inner catheters, because Auricchio teaches advancing the guide wire through only the outer catheter. *Id.* at 14.

We determine that, based on the present record, Petitioner has provided a sufficiently persuasive reason for modifying Auricchio's method by advancing the guide wire through both of the outer guide catheter and the inner support catheter, as set forth above. This is not a case, as was *Motorola*, 121 F.3d at 1472–73, in which the prior art fails entirely to disclose a claim limitation. Auricchio discloses advancing a guide wire at least through an outer catheter, and also discloses advancing an inner catheter within the outer catheter over the guide wire. *See* Ex. 1019, 3:22–28. All that is (perhaps) missing is a timing requirement of claim 11, whereby the inner catheter is advanced within the outer catheter before the guide wire is then advanced through both catheters to help guide the inner catheter to a point of interest beyond the distal tip of the outer catheter. On the present record, Petitioner has provided sufficient reasons why one would implement such a timing sequence when using Auricchio's double catheter. *See also Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1335 (Fed. Cir. 2016) ("A claimed invention may be obvious even when the prior art does not teach each claim limitation, so long as the record contains some reason why one skill in the art would modify the prior art to obtain the claimed invention.").

Further, there is no teaching away in Auricchio from that proposed modification. Auricchio does appear to disclose only advancing the guide wire through the outer guide catheter. *See* Ex. 1019, 3:22–30. Nonetheless, Auricchio does not criticize, discredit, or discourage advancing the guide wire through the inner support catheter as well, or otherwise state a preference for limiting the method to advancing the guide wire through only the outer guide catheter. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (to teach away, a reference must criticize, discredit, or otherwise discourage the claimed solution); *see also Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1067–70 (Fed. Cir. 2018) (even in the absence of a teaching away, general preferences as stated in the prior art are still relevant to determining whether a skilled artisan would be motivated to combine the prior art in the manner claimed).

b) "inserting the lead through the outer and inner catheters"

Petitioner recognizes Auricchio does not disclose the lead insertion step of claim 11, because Auricchio discloses that the outer guide catheter is removed before the lead is advanced through only the inner support catheter. Pet. 31 (citing Ex. 1019, 3:28–32). Petitioner, nonetheless, contends it would have been obvious "to have kept the [outer] guide catheter in the coronary sinus while placing the lead, rather than removing it first," for several reasons. *Id.* at 31–32; Ex. 1005 ¶ 54.

Those reasons include that withdrawing the outer guide catheter risks displacing the inner support catheter from the preselected coronary vein, and leaving the outer guide catheter in place would avoid that risk. Ex. 1005 ¶ 54. Further, leaving the outer guide catheter in place would avoid the need

to recannulate the coronary sinus to exchange inner support catheters, if such exchange is needed. *Id.* Also, leaving the outer guide catheter in place would protect the patient's blood vessel walls as the inner support catheter is manipulated or withdrawn. *Id.* It would also permit the outer guide catheter to provide axial support to the inner support catheter, which is pliable, as the lead is advanced into a preselected coronary vein. *Id.*

Patent Owner objects that Petitioner improperly attempts to substitute expert testimony for actual prior art disclosures. Prelim. Resp. 14–16. Patent Owner accuses Dr. Berger of speculating with respect to what one might do with Auricchio's double catheter, in hindsight based on the '268 patent disclosure, and without support in the prior art. *Id.* at 15. Patent Owner, further, asserts Auricchio teaches away from inserting the lead through both of the outer and inner catheters, because Auricchio teaches inserting the lead through only the inner catheter. *Id.* at 15. Patent Owner also points to a statement by Dr. Roger Freedman that "telescoping sheaths would be 'too bulky to make the turn into the LV vein,'" as refuting Dr. Berger's testimony regarding obviousness. *Id.* (citing Ex. 2002, 2).

We determine that, based on the present record, Petitioner has provided a sufficiently persuasive reason for modifying Auricchio's method by inserting the lead through both of the outer guide catheter and the inner support catheter, as set forth above. We understand Dr. Freedman expressed doubt as to whether telescoping outer and inner catheters might be "too bulky" to extend through the coronary sinus to "one of the LV veins, and then distally in the LV vein." Ex. 2002, 2. However, claim 11 requires only that the inner catheter extends into the branch vein. *See* Ex. 1001, 8:3–5 ("advancing *the inner catheter* . . . into the branch vein") (emphasis added).

Auricchio correspondingly discloses that the outer guide catheter is small enough to be inserted "into the ostium of the coronary sinus," and the inner support catheter is small enough to be "advanced to the desired position within . . . a preselected coronary vein." Ex. 1019, 3:22–28. Dr. Freedman's statement does not address Auricchio's disclosure in that regard, and further is not pertinent to whether one would have modified Auricchio's method to insert the lead through both of the outer and inner catheters, which has little to do with catheter size.

Moreover, there is no teaching away in Auricchio from Petitioner's proposed modification. Auricchio does appear to disclose inserting the lead only through the inner support catheter. *See* Ex. 1019, 3:28–32. Nonetheless, Auricchio does not criticize, discredit, or discourage inserting the lead through both of the outer and inner catheters, or otherwise state a preference for limiting the method to inserting the lead through only the inner support catheter.

c) Secondary Considerations

Patent Owner additionally relies on two secondary considerations of nonobviousness: industry skepticism and long felt but unresolved need. *See* Prelim. Resp. 7–12.

As to industry skepticism, Patent Owner cites the statement of Dr. Freedman that telescoping outer and inner catheters might be too bulky to extend through the coronary sinus and into one of the LV veins. *Id.* at 8–10 (citing Ex. 2002, 2). As already discussed above, that statement has not been established to be pertinent to the subject matter recited in claim 11,

which requires only that the inner catheter, not both of the outer and inner catheters, extends into a branch vein.

As to long felt but unresolved need, Patent Owner contends that at the time of the ’268 patent’s invention, “the industry standard for implanting leads in the coronary sinus was to use a single catheter, which corroborates Dr. Freedman’s preference for a single catheter approach.” *Id.* at 10–11 (citing Exs. 1013, 1014, and 1022). Patent Owner further asserts prior art references also “generally recognize the need for improvements to the existing systems, yet none suggest using a telescoping system to implant leads.” *Id.* at 11–12 (citing Exs. 1015 and 1021). These contentions overlook that Auricchio is prior art to the ’268 patent, and discloses using a telescoping catheter to cannulate a coronary sinus branch vein, with the outer guide catheter being inserted “into the ostium of the coronary sinus,” and the inner support catheter being “advanced to the desired position within . . . a preselected coronary vein.” Ex. 1019, 3:22–28. Thus, the evidence presently of record does not support Patent Owner’s contention that there was an unresolved need for such a telescoping double catheter.

d) Conclusion as to Obviousness of Claim 11

For the foregoing reasons, based on the current record, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing on the challenge that claim 11 of the ’268 patent is unpatentable as having been obvious over Auricchio.

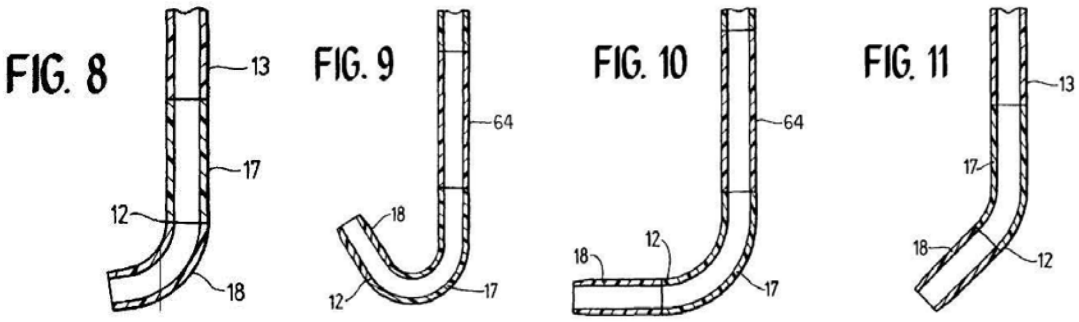
C. Obviousness over Auricchio and Randolph

Petitioner asserts claims 12 and 24 of the ’268 patent are unpatentable under 35 U.S.C. § 103(a) as having been obvious over Auricchio and

Randolph. Pet. 4, 33–40. We have reviewed the arguments and evidence of record. Given the evidence of record, Petitioner has demonstrated a reasonable likelihood of prevailing on its assertions as to claims 12 and 24. We, therefore, institute review of those claims as having been obvious over Auricchio and Randolph. We first summarize the Randolph disclosure, then we address Petitioner's and Patent Owner's contentions as to obviousness.

1. Randolph Disclosure

Randolph discloses "[a] guiding catheter for delivery of intravascular devices to a patient's coronary sinus." Ex. 1017, Abstract. Figures 8–11 of Randolph are reproduced below:



These Figures show "various conventional shapes for the distal extremity of" a catheter, including a Josephson type curve (Figure 8), a Damato type curve (Figure 9), an El Gamal type curve (Figure 10), and a hockey stick type curve (Figure 11). *Id.* at 3:57–59, 4:49–53. According to Randolph:

> The proximal or distal portions of the distal shaft section may be shaped before insertion into the patient's body . . . so that the distal extremity will keep [one of the shapes shown in Figures 8–11]. If desired, control lines (not shown) may be incorporated into the wall of the catheter and extend out the proximal end of the catheter shaft, whereby when tension is applied thereto after the catheter is inserted into the patient, the distal extremity of the catheter shaft is deflected or shaped in a desired manner.

Id. at 4:53–65. In this way, the "relatively flexible distal shaft section . . . is shapeable to a shape suitable for advancement within the patient's coronary sinus and particularly a branch vein thereof." *Id.* at 2:7–10.

2. Claim 12

Claim 12 depends from claim 11, to add "adjusting the curvature of the double catheter in order to enter the coronary sinus." Ex. 1001, 8:10–12.

Petitioner provides detailed arguments and evidence, including the Declaration of Dr. Berger, in support of contending that claim 12 would have been obvious over Auricchio and Randolph. Pet. 33–35; Ex. 1005 ¶ 56. Petitioner relies on the analysis of claim 11 and Auricchio, discussed above, in asserting the obviousness of claim 12 over Auricchio and Randolph. Pet. 33. Petitioner additionally relies on Randolph as disclosing the limitation of claim 12, in that Randolph discloses "control lines" which allow "the distal extremity of the catheter shaft [to be] deflected or shaped in a desired manner" for the purpose of "advancement within the patient's coronary sinus and particularly a branch vein thereof." *Id.* at 33–34 (quoting Ex. 1017, 4:60–65, 2:6–10); Ex. 1005 ¶ 56.

According to Petitioner, it would have been obvious in light of Randolph to use a deflecting catheter for Auricchio's outer guide catheter, to adjust its curvature "after it has been inserted into the patient's body to assist with navigating the anatomy around the coronary sinus ostium." Pet. 34–35; Ex. 1005 ¶ 56. Petitioner contends both references describe catheters for delivering a device into a branch vein of the coronary sinus, so a person of ordinary skill in the art "would have considered Randolph's complementary

teachings when designing an improved delivery system for LV lead placement" in Auricchio. Pet. 35; Ex. 1005 ¶ 56.

Patent Owner objects that "Auricchio does not disclose assembling the [outer] guide catheter and the [inner] support catheter prior to entering the coronary sinus," and instead discloses "first inserting the guide catheter [outer catheter] alone . . . into the ostium of the coronary sinus." Prelim. Resp. 16. Thus, Patent Owner's view is that Petitioner's proposed modification of Auricchio in light of Randolph would not lead to the invention of claim 12, because only the outer guide catheter shape would be adjusted to enter the coronary sinus, without the inner guide catheter. *Id.* at 16–17.

On the present record, Patent Owner's contention is not persuasive. Claim 12 encompasses adjusting the curvature of just one of the outer and inner catheters. *See supra* Section III.B.4. Auricchio correspondingly discloses entering the coronary sinus using the outer guide catheter. *See* Ex. 1019, 3:22–24.

Patent Owner additionally asserts the Petition lacks a rational underpinning for combining Auricchio with Randolph. Prelim. Resp. 32–34. In support, Patent Owner asserts Auricchio's catheter is "introduced through the subclavian vein (in the shoulder)," while Randolph's catheter is "introduced through the femoral vein." *Id.* at 32 (citing Ex. 1017, 2:40–41).[9] Patent Owner additionally asserts Auricchio's catheter is used to place an electrical lead in the coronary sinus, while Randolph's catheter is used to

[9] Patent Owner does not cite to any Auricchio disclosure which might indicate Auricchio's catheter is introduced through the subclavian vein. *See* Prelim. Resp. 32.

place a device for sensing electrical activity in the coronary sinus. *Id.* at 32–33 (citing Ex. 1017, Abstract). Based on these differences, Patent Owner contends Petitioner errs in asserting that the proposed combination of Auricchio and Randolph is "the predictable use of prior art elements according to their established functions," because their respective functions are different. *Id.* at 33. Patent Owner also contends the combination of Auricchio and Randolph would not have enabled the practice of claim 12 without undue experimentation. *Id.* at 34.

We determine that, based on the present record, Petitioner has provided a rational underpinning for modifying Auricchio's outer guide catheter to include a mechanism for adjusting the curve of the catheter to enter the coronary sinus, as set forth above. Auricchio and Randolph address a common problem of cannulating the coronary sinus to place a medical device in a coronary vein — an electrical pacing lead in Auricchio, and an electrical sensor in Randolph. *See* Ex. 1019, Abstract; Ex. 1017, Abstract. Even if Auricchio reaches the coronary sinus from a subclavian vein, and Randolph reaches the coronary sinus from a femoral vein, it appears from the evidence presently before us that both would benefit from being able to adjust the curvature of the catheter's distal end inside the patient to cannulate the coronary sinus. The evidence of record does not indicate that modifying Auricchio's outer guide catheter to include Randolph's control line would have required undue experimentation.

Patent Owner's reliance on secondary considerations has been addressed above in connection with claim 11, from which claim 12 depends.

Accordingly, based on the current record, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing on the

challenge that claim 12 of the '268 patent is unpatentable as having been obvious over Auricchio and Randolph.

3. Claim 24

Petitioner provides detailed arguments and evidence, including the Declaration of Dr. Berger, in support of contending that independent claim 24 would have been obvious over Auricchio and Randolph. Pet. 36–40; Ex. 1005 ¶¶ 57–63. Petitioner's analysis is substantially identical to the analysis discussed above concerning the obviousness of claim 11 over Auricchio, except Petitioner relies on Randolph as disclosing a catheter comprising "a resilient tube having shape memory" and "having a hook-shaped distal end," as recited in claim 24. Pet. 36–40. Petitioner cites Figures 8–11 of Randolph as disclosing resilient tubes having a shape memory, and a hook-shaped distal end. *Id.* at 37–38 (citing Ex. 1017, 2:20–31, 3:57–59, 4:49–65); Ex. 1005 ¶ 58.

According to Petitioner, it would have been obvious in light of Randolph to form the distal end of Auricchio's outer guide catheter out of a shape memory material and to have a hook shape, because this would "facilitate 'rapid advancement of an intravascular device into a patient's coronary sinus and particularly into a cardiac vein draining into the coronary sinus.'" Pet. 38 (quoting Ex. 1017, 1:61–63); Ex. 1005 ¶ 58. Petitioner further contends a person of ordinary skill in the art would have recognized that the preformed hook shapes illustrated in Randolph "generally match[] the anatomical pathway to the coronary sinus ostium . . . and would facilitate access to the coronary sinus." Pet. 38; Ex. 1005 ¶ 58. Moreover, Petitioner asserts both Auricchio and Randolph disclose catheters for cannulating the

coronary sinus, and "there were only a limited number of materials from which a guide catheter can be made, and selecting a guide catheter with physical properties that render the sheath resilient and having shape memory, like the guide catheter of Randolph, would have been a routine design choice." Pet. 38–39; Ex. 1005 ¶ 58.

Patent Owner asserts the Petition lacks a rational underpinning for combining Auricchio with Randolph, as already set forth above in connection with claim 12. Prelim. Resp. 32–34. We determine that, based on the present record, Petitioner has provided a rational underpinning for modifying Auricchio's outer guide catheter to be formed of a shape memory material and to have a hook-shaped distal end, as set forth above. Auricchio and Randolph address a common problem of cannulating the coronary sinus to place a medical device in a coronary vein. *See* Ex. 1019, Abstract; Ex. 1017, Abstract. Even if Auricchio reaches the coronary sinus from a subclavian vein, and Randolph reaches the coronary sinus from a femoral vein, it appears from the evidence presently before us that both would benefit from being formed of a shape memory material and having a hook-shaped distal end to cannulate the coronary sinus.

Patent Owner's reliance on secondary considerations has been addressed above in connection with claim 11, which like claim 24 requires only that the inner catheter, not both of the outer and inner catheters, extends into a branch vein. Moreover, Auricchio is prior art to the '268 patent, and discloses using a telescoping catheter to cannulate a coronary sinus branch vein. Ex. 1019, 3:22–28.

Accordingly, based on the current record, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing on the

challenge that claim 24 of the ’268 patent is unpatentable as having been obvious over Auricchio and Randolph.

D. Obviousness over Auricchio, Randolph, and Payne

Petitioner asserts claims 13, 14, 18, 19, 23, 25, and 26 of the ’268 patent are unpatentable under 35 U.S.C. § 103(a) as having been obvious over Auricchio, Randolph, and Payne. Pet. 4, 41–53. We have reviewed the arguments and evidence of record. Given the evidence of record, Petitioner has demonstrated a reasonable likelihood of prevailing on its assertions as to claims 13, 14, 18, 19, 23, 25, and 26. We, therefore, institute review of those claims as having been obvious over Auricchio, Randolph, and Payne. We first summarize the Payne disclosure, then we address Patent Owner’s argument that Payne is non-analogous art, and finally we address Petitioner’s and Patent Owner’s contentions as to obviousness.

1. Payne Disclosure

Payne discloses “[a] delivery catheter system for delivering a substance delivery member into a patient’s left ventricle.” Ex. 1009, Abstract. Figure 1 of Payne is reproduced below:

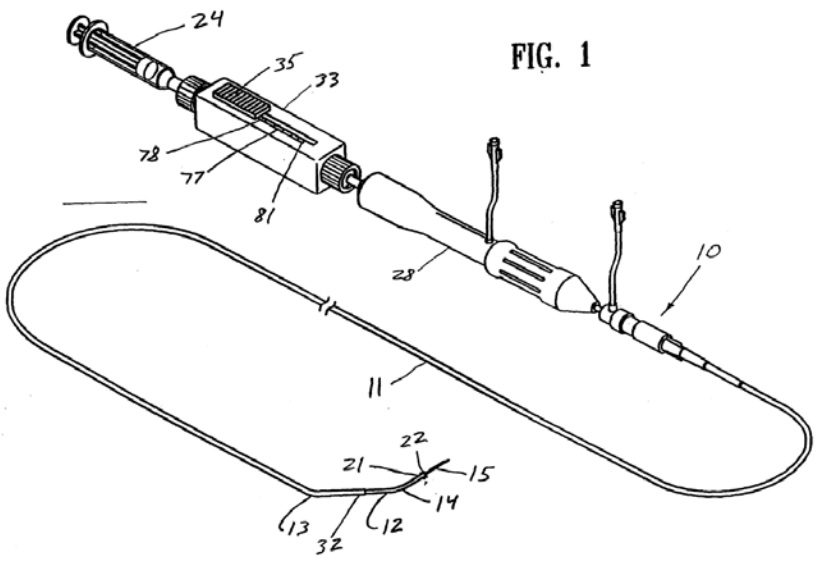


FIG. 1

Figure 1 is a perspective side view of delivery catheter system 10 including first delivery catheter 11 slidably and rotatably receiving second delivery catheter 12. *Id.* at 11:8, 12:12–15. System 10 is disclosed to be useful in "delivering an elongated therapeutic or diagnostic device [15] or agent *into the wall of a patient's heart*," particularly into the left ventricle wall from within the left ventricle chamber. *Id.* at Abstract, 5:13–6:10 (emphasis added), 12:12–27. To aid the user of system 10 to perform such a procedure, outer catheter 11 includes angled distal shaft section 13, which helps to place and hold device 15 in a perpendicular or near perpendicular orientation at the left ventricle wall. *Id.* at Abstract, 5:19–27, 9:22–32, 12:16, 14:17–28 (Fig. 3).

Figure 5 of Payne discloses one embodiment for the shape of distal shaft section 13, and is reproduced below:

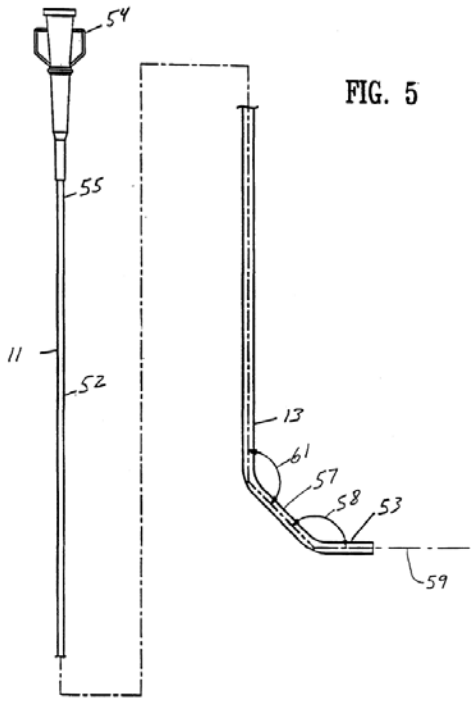


FIG. 5

Id. at 17:1–15. Figure 5 illustrates outer catheter 11 comprised of main shaft section 52 and distal shaft section 13, with the latter comprised of first and second segments 53, 57 forming angles 58 and 61. *Id.* Angle 58 can be from about 90° to about 160°, and angle 61 can be from about 95° to about 165°. *Id.* at 17:6–11.

2. Whether Payne is Analogous Art

Patent Owner argues Payne is non-analogous art to the claimed invention. Prelim. Resp. 17–28. For the following reasons, based on the present record, this argument is not persuasive.

> Two criteria have evolved for determining whether prior art is analogous: (1) whether the art is from the same field of endeavor [as the inventor's], regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.

In re Clay, 966 F.2d 656, 658–59 (Fed. Cir. 1992). We consider both criteria in turn.

a) Field of Endeavor of '268 Patent

Patent Owner contends the field of endeavor of the '268 patent is "catheters of the type used to cannulate the coronary sinus . . . through the right atrium." Prelim. Resp. 20 (citing Ex. 1001, 1:8–9, 3:39–41). Patent Owner asserts Payne is from the different field of "a 'delivery catheter system for delivering a substance delivery member into a patient's left ventricle.'" *Id.* at 19 (quoting Ex. 1009, Abstract). Patent Owner would limit the '268 patent's field of endeavor to cannulating the coronary sinus, and limit Payne's field of endeavor to cannulating the left ventricle, because "[t]he human body is highly complex and variable both in terms geometry and physiology," which "requires a high level of specialization in the design and use of medical instruments." *Id.* at 17–18.

We are not persuaded that the respective fields of endeavor of the '268 patent and of Payne may be parsed so finely. We determine, based on the present record, that both references fall within the same field of endeavor: catheter devices which are useful to cannulate a cardiac cavity or duct via the venous system, and place a device therein.

b) Reasonably Pertinent to Problem Involved in '268 Patent

A reference is reasonably pertinent to an inventor's problem if it is one that, because of the matter with which it deals, would have logically commended itself to the inventor's attention in considering his or her invention as a whole. *In re ICON Health and Fitness, Inc.*, 496 F.3d 1374, 1379–80 (Fed. Cir. 2007).

Patent Owner contends the problem addressed by the inventor of the '268 patent was "implanting pacing leads in a branch of the coronary sinus while navigating tortuous vessels and side branches." Prelim. Resp. 22–23 (citing Ex. 1001, 1:38–41, 1:61–2:14). We agree with that contention.

Patent Owner also contends Payne is not reasonably related to the problem addressed by the inventor of the '268 patent. *Id.* at 21–22, 23–28. Patent Owner asserts Payne addresses the different problem of using a catheter to place a substance delivery member proximate to the left ventricle wall, and maintain the member in a substantially perpendicular orientation with respect to the wall to administer therapy to the wall. *Id.* at 21–22 (citing Ex. 1009, 4:25–30, 5:19–22). Patent Owner asserts the '268 patent "does not involve administering therapy to the heart wall," or "maintaining the position of a therapeutic device" against the left ventricle wall, or "a catheter that is introduced through the femoral artery." *Id.* at 22.

Patent Owner's argument is not persuasive, because it effectively requires Payne to address the *same* problem with which the '268 patent inventor was involved. The test, instead, is whether Payne is *reasonably pertinent* to the '268 patent inventor's problem because it would have logically commended itself to the inventor's attention in considering his invention as a whole. *ICON*, 496 F.3d at 1379–80. That test is satisfied here. Payne discloses several catheter configurations which are useful for helping a physician to orient a catheter's distal end within the patient's left ventricle to place a device or substance on the wall. That design challenge, while different from orienting the catheter's distal end within the patient's coronary sinus to place a device therein, is nonetheless reasonably pertinent to that problem.

We are not persuaded by Patent Owner's argument that the facts presented in this case are similar to the facts presented in *Clay*, *supra*. *See* Prelim. Resp. 26–28. In that decision, the court stated Clay's gel was disclosed "to displace liquid product [specifically, refined hydrocarbons] from the dead volume of a storage tank." *Clay*, 966 F.2d at 659. Sydansk's gel was disclosed as useful in the "treatment of underground formations . . . to fill anomalies so as to improve flow profiles and sweep efficiencies" in the formation. *Id.* (footnote omitted). The court concluded Sydansk's "problem of recovering oil from rock" was not reasonably pertinent to Clay's problem of "preventing loss of stored product to tank dead volume." *Id.* at 659–60. By contrast, in this case, the respective catheters of the '268 patent and of Payne are meant for use in the same general location (the patient's cardiac region) and perform substantially the same function (placing a device at a specific cardiac wall location).

For the foregoing reasons, we determine Payne is reasonably pertinent to the problem addressed by the inventor of the '268 patent.

c) Conclusion

Based on the argument and evidence currently in the record, Petitioner has sufficiently shown that Payne is analogous art to the '268 patent under either one of the two criteria for establishing analogousness.

3. Claim 13

Petitioner provides detailed arguments and evidence, including the Declaration of Dr. Berger, in support of contending that claim 13 would have been obvious over Auricchio, Randolph, and Payne. Pet. 41–47; Ex. 1005 ¶¶ 64–67. Petitioner's analysis is substantially identical to the

analysis discussed above concerning the obviousness of claim 24 over Auricchio and Randolph, with two material differences.

The first difference is that Petitioner relies on Auricchio as disclosing that its outer guide catheter has "sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus," as recited in claim 13. Pet. 37, 41 (citing Ex. 1019, 3:11–37, 5:25–29, 8:28–53); Ex. 1005 ¶¶ 58, 66. The Preliminary Response does not dispute that contention. We determine the contention is supported in the present record sufficiently for us to institute review.

The second difference is that Petitioner relies on Payne as disclosing a hook-shaped catheter having three bends that overlap with the ranges specified in claim 13, as illustrated in Figure 5 of Payne. Pet. 42–45; Ex. 1005 ¶ 67. The Preliminary Response does not dispute that contention. We determine the contention is supported in the present record sufficiently for us to institute review.

According to Petitioner, it would have been obvious "to modify the outer guide catheter of the combination of *Auricchio* and *Randolph* in view of *Payne*." Pet. 46; Ex. 1005 ¶ 67. Petitioner finds an express motivation for this modification in Randolph's disclosure that catheters used to access the coronary sinus can have a variety of curved shapes. Pet. 46 (citing Ex. 1017, 4:49–55, Figs. 8–11); Ex. 1005 ¶ 67. Petitioner contends "selection of features such as outer catheter shape would have been an obvious design choice," given that "[a] variety of catheter shapes designed for use within the heart, including in the coronary sinus, were known" and it was "common practice" to adopt elements between such catheters. Pet. 46–47 (citing Exs. 1012 and 1016–1018); Ex. 1005 ¶ 67. Petitioner moreover

contends a person of ordinary skill in the art would have recognized that the catheter shape illustrated in Figure 5 of Payne "resembles a known shape that matches the anatomical pathway to the coronary sinus ostium," and hence would be useful in the combined catheter of Auricchio and Randolph. Pet. 47 (citing Ex. 1009, 9:22–25); Ex. 1005 ¶ 67.

Patent Owner contends Petitioner has failed to provide a rational underpinning for combining Randolph and Payne. Prelim. Resp. 28–31. According to Patent Owner, Petitioner's motivation analysis is not supported by the disclosure of Randolph cited by Petitioner. *Id.* at 28–29. Patent Owner additionally asserts Randolph already discloses preferred preformed bends for a catheter to cannulate the coronary sinus (Ex. 1017, Figs. 8–11), and Petitioner has failed to establish a rational underpinning for why those shapes would have been modified to be like Payne's Figure 5. *Id.* at 29–30. Patent Owner particularly cites the different purposes of the two references — Randolph's catheter being designed to enter the coronary sinus, and Payne's catheter being designed to enter the left ventricle. *Id.* Patent Owner moreover asserts Randolph teaches away from alternate curve designs, such as Payne's, in that Randolph provides for "control lines" operable to "deflect[] or shape[]" the distal end of Randolph's guide catheter, if such changes are desired. *Id.* at 30–31 (citing Ex. 1017, 4:60–65).

Upon consideration of the foregoing arguments and evidence, we conclude Patent Owner has mounted a credible challenge to Petitioner's case for obviousness, particularly concerning why one would have found Payne's catheter shape (meant to cannulate the left ventricle) useful in the catheter of Auricchio and Randolph (meant to cannulate the coronary sinus).

Nonetheless, based on the present record, Petitioner has set forth sufficient explanation and evidence of motivation for modifying the outer catheter of the combination of Auricchio and Randolph to have the shape of Payne's Figure 5, as set forth above, for us to institute review.

Further, there is no teaching away in Randolph from that proposed modification. Randolph does not criticize, discredit, or discourage changing the preformed shape of its outer guide catheter to ease advancing the outer guide catheter into the coronary sinus. Indeed, Randolph implicitly suggests such modifications might be useful, in disclosing four different but still suitable shapes. *See* Ex. 1017, Figs. 8–11, 4:49–55. Randolph describes the "control lines" as being useful in connection with any of the four disclosed shapes, and does not indicate that the use of control lines is limited to the four disclosed preformed shapes. *Id.* at 4:55–65.

Patent Owner's reliance on secondary considerations has been addressed above, in that claim 13 pertinently requires only that the outer catheter tube may be advanced "into a distal coronary sinus," not into a branch vein. Moreover, Auricchio is prior art to the '268 patent, and discloses an outer guide catheter being inserted "into the ostium of the coronary sinus." Ex. 1019, 3:22–28.

Accordingly, based on the current record, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing on the challenge that claim 13 of the '268 patent is unpatentable as having been obvious over Auricchio, Randolph, and Payne.

4. Claims 14, 18, 19, 23, 25, and 26

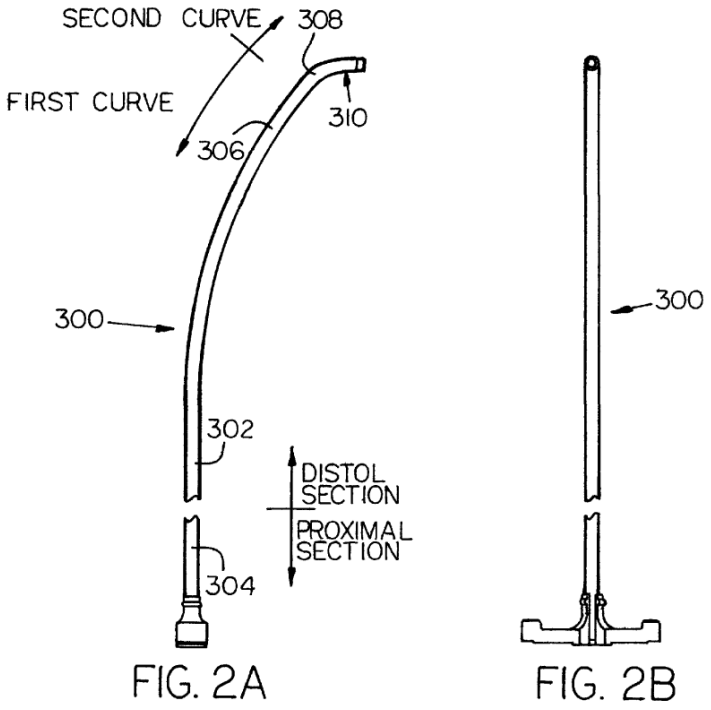
Petitioner provides detailed arguments and evidence, including the Declaration of Dr. Berger, in support of contending that claims 14, 18, 19, 23, 25, and 26 would have been obvious over Auricchio, Randolph, and Payne. Pet. 47–53; Ex. 1005 ¶ 68. The arguments presented against such obviousness in the Preliminary Response have all been addressed above. We have reviewed Petitioner's argument and contentions, and we conclude that Petitioner has demonstrated a reasonable likelihood of prevailing on the challenge that claims 14, 18, 19, 23, 25, and 26 are unpatentable as having been obvious over Auricchio, Randolph, and Payne.

E. Obviousness over Lurie and Ockuly

Petitioner asserts claims 1 and 10 of the '268 patent are unpatentable under 35 U.S.C. § 103(a) as having been obvious over Lurie and Ockuly. Pet. 5, 54–63. We have reviewed the arguments and evidence of record. Given the evidence of record, Petitioner has demonstrated a reasonable likelihood of prevailing on its assertions as to claims 1 and 10. We, therefore, institute review of those claims as having been obvious over Lurie and Ockuly. We first summarize the Lurie and Ockuly disclosures, then we consider our discretion under 35 U.S.C. § 325(d), next we address Patent Owner's argument that Ockuly is non-analogous art, and finally we address Petitioner's and Patent Owner's contentions as to obviousness.

1. Lurie Disclosure

Lurie discloses a coronary sinus introducer designed for inserting an electrical lead into the coronary sinus. Ex. 1018, Abstract, 2:58–62. Figures 2A and 2B of Lurie are reproduced below:



These Figures show two side views of introducer 300, differing from each other by a 90° rotation of the introducer. *Id.* at 3:58–62, 5:43–46. The Figures illustrate introducer 300 as having a "precurved" distal section 302 comprised of two separate curves 306 and 308. *Id.* at 5:55–6:18. That distal end section shape "permits ease in locating the ostium of the coronary sinus," so that introducer 300 may be "advanced as far as is required or desired into the coronary sinus." *Id.* at 10:5–17.

2. Ockuly Disclosure

Ockuly discloses a guiding introducer system comprised of outer introducer 30 receiving inner introducer 20. Ex. 1020, 6:31–43, Figs. 2A–2B and 3A–3B. Ockuly indicates that its system is particularly useful for treating ventricular tachycardia in the left ventricle by ablating or mapping the interior wall surface of the left ventricle. *Id.* at Abstract, 5:55–67.

"Being able to extend the inner guiding introducer within the outer guiding introducer and to rotate the inner guiding introducer within the outer guiding introducer permits a wide variety of overall shapes, which is particularly useful to medical practitioners." *Id.* at 8:43–64.

3. Discretion under 35 U.S.C. § 325(d)

Patent Owner urges us to invoke our discretion to deny review under 35 U.S.C. § 325(d). Prelim. Resp. 36–40. According to Patent Owner, Lurie and Ockuly are both "cumulative of art considered by the Examiner during original prosecution of the '268 patent." *Id.* at 36–39 (citing Exs. 2003–2006). Patent Owner contends that the Examiner's failure to reject claims 1 and 10 over any one of the cited references "demonstrates their marginal relevance." *Id.* at 36–37.

Even assuming that Lurie and Ockuly are cumulative of prior art cited to the Examiner during prosecution of the '268 patent, we decline to exercise our discretion to deny institution on that basis.

> In evaluating whether to exercise our discretion when the same or substantially the same prior art or arguments previously were presented to the Office under section 325(d), we have weighed some common non-exclusive factors, such as: (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art; (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts

> presented in the Petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson & Co. v. B. Braun Melsungen AG, Case IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) (informative).

We have assumed factors (a) and (b) favor denial of institution. However, factors (c) and (d) do not favor denial of institution. The record establishes only that Exhibits 2003–2006 were cited to the Examiner. Beyond that bare fact, Patent Owner does not point to any evidence in the record to reflect the extent to which the Examiner evaluated the references, or any particular reason why the references were not cited as the basis for a rejection. Thus, this case is different from the case cited by Patent Owner where the Board invoked § 325(d) to deny review. *See Nu Mark LLC v. Fontem Holdings 1, B.V.*, Case IPR2016-01309, Paper 11, at 7–8, 11–12 (PTAB Dec. 15, 2016) (Examiner had relied on one reference cited by Petitioner as the basis for an anticipation rejection, and additionally provided a statement of reasons for allowance over that reference in combination with other prior art that was cumulative of a second reference cited by Petitioner). Concerning factors (e) and (f), while Petitioner does not specifically address the citation of Exhibits 2003–2006 to the Examiner during prosecution, Petitioner has set forth various reasons supporting Petitioner's contention that claims 1 and 10 would have been obvious over Lurie and Ockuly. Weighing these considerations together as a whole, we decline to invoke our discretion under 35 U.S.C. § 325(d) to deny review in this case.

4. Ockuly is Analogous Art

Patent Owner argues Ockuly is non-analogous art to the claimed invention. Prelim. Resp. 40–44. Patent Owner's reasoning is substantially

the same as discussed above in connection with Payne, principally relying on the fact that Ockuly's catheter is used to cannulate the left ventricle to ablate the chamber wall, rather to cannulate the right atrium and the coronary sinus to implant an electrical lead. *See id.* For substantially the same reasons provided in connection with Payne, we conclude, based on the argument and evidence currently in the record, that Petitioner has sufficiently shown that Ockuly is analogous art the '268 patent under either one of the two criteria for establishing analogousness.

5. Claim 1

Petitioner provides detailed arguments and evidence, including the Declaration of Dr. Berger, in support of contending that claim 1 would have been obvious over Lurie and Ockuly. Pet. 54–62; Ex. 1005 ¶¶ 79–83. Petitioner cites Lurie as disclosing a catheter (i.e., introducer 300) having a distal end shape which assists in rapid placement of the catheter in the coronary sinus in order to place a pacing lead therein. Pet. 54 (citing Ex. 1018, Abstract, 1:14–19, 2:58–62, 3:12–15, 4:49–52, 4:62–66, 5:25–28); Ex. 1005 ¶¶ 80–81. Petitioner contends Lurie's catheter has a shape memory and a hook-shaped distal end, as illustrated in Figure 2A of Lurie. Pet. 57–58 (citing Ex. 1018, Abstract, 7:23–27, 8:31–33); Ex. 1005 ¶ 81.

Petitioner cites Ockuly as disclosing a double catheter, in which the inner catheter has a greater length than the outer catheter to be extended or retracted from the distal open end of the outer catheter, to form various shapes and thereby allow precise placement of the tip of the inner catheter at a specific location of the left ventricle wall. Pet. 54–55 (citing Ex. 1020, 3:54–62, 6:39–43, 8:60–64); Ex. 1005 ¶ 82. Petitioner asserts Ockuly's

inner catheter advantageously has a lumen configured to introduce a medical device into a patient's heart. Pet. 59 (citing Ex. 1020, 3:44–48, 6:50–53, 9:51–56); Ex. 1005 ¶ 82.

Petitioner contends it would have been obvious to use an inner catheter within Lurie's catheter 300, thereby forming a double catheter useful for inserting an electrical lead into the coronary sinus, in light of Ockuly. Pet. 54–57; Ex. 1005 ¶ 80. Petitioner finds an express motivation for this modification in Lurie's disclosure that accessing the coronary sinus can be "very difficult." Pet. 55 (citing Ex. 1018, 2:20–40); Ex. 1005 ¶ 80. Petitioner further asserts Lurie discloses telescoping a dilator or a shaped catheter within Lurie's catheter 300 to assist locating catheter 300 in the coronary sinus, and thereby would have motivated a person of ordinary skill in the art "to look to other introducer disclosures for details of the telescoping technique" such as Ockuly. Pet. 55–56 (citing Ex. 1018, 3:29–36, 8:30–32, and Ex. 1020, 3:42–43); Ex. 1005 ¶ 80. According to Petitioner, a person of ordinary skill in the art "would have been motivated to use a telescoping system, like the system described in *Ockuly*, for LV lead placement [as in Lurie] in order to reach a more distal portion of the coronary sinus vasculature, and would have recognized that the use of such a system would eliminate the need to exchange tools or withdraw tools from within the outer guiding introducer for placement of the lead." Pet. 56 (citing Ex. 1020, 3:33–35, 5:50–52, 6:36–39, 8:43–49, 8:60–64); Ex. 1005 ¶ 80.

Patent Owner objects that the Petition lacks a rational underpinning for combining Lurie and Ockuly. *See* Prelim. Resp. 44–48. Patent Owner accuses Petitioner of presenting "a classic hindsight analysis" including

"vague assertions" of obviousness. *Id.* at 44–45. Patent Owner additionally asserts Lurie's catheter 300 is already suitable for accessing the coronary sinus, and Petitioner has failed to establish a rational underpinning for why one would have added an inner catheter to Lurie for that purpose. *Id.* at 45–46. Patent Owner particularly cites the different purposes of the two references — Lurie's catheter being designed to enter the coronary sinus, and Ockuly's catheter being designed to enter the left ventricle. *Id.* at 46–47. Patent Owner also points to a statement by Dr. Roger Freedman that "telescoping sheaths would be 'too bulky to make the turn into the LV vein'" as refuting Dr. Berger's testimony as to obviousness. *Id.* at 47–48 (citing Ex. 2002, 2).

We determine that, based on the present record, Petitioner has provided a rational underpinning for using an inner catheter within Lurie's introducer 300, in light of Ockuly, as set forth above. In particular, it appears a person of ordinary skill in the art would have appreciated that using a telescoping double catheter instead of Lurie's single catheter 300 would have eased the physician's task of cannulating the coronary sinus to place an electrical lead therein. Ockuly supports that notion in disclosing that telescoping double catheters are "particularly useful to medical practitioners" because they "permit[] a wide variety of overall shapes" to be formed by the double catheter, and thereby reach desired points of interest in a patient's cardiac region. Ex. 1020, 8:43–64.

At the same time, we acknowledge Dr. Freedman's skepticism as to whether a telescoping double catheter might be too bulky to extend through the coronary sinus and into one of the LV veins. *See* Ex. 2002, 2. Also potentially pertinent is whether the industry standard was to cannulate the

coronary sinus with a single catheter, despite recognized difficulties in doing so. Nonetheless, the issue of secondary considerations is highly fact-specific, and at this stage of the proceeding, we have not heard evidence or argument from Petitioner on these issues. A more complete record after trial will facilitate our consideration of how they impact the obviousness analysis. The evidence of secondary considerations presented at this stage of the proceeding by Patent Owner is insufficient to support a denial of the Petition.

For the foregoing reasons, based on the current record, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing on the challenge that claim 1 of the '268 patent is unpatentable as having been obvious over Lurie and Ockuly.

6. Claim 10

Petitioner provides detailed arguments and evidence, including the Declaration of Dr. Berger, in support of contending that claim 10 would have been obvious over Lurie and Ockuly. Pet. 62–63; Ex. 1005 ¶ 84. The arguments presented against such obviousness in the Preliminary Response have all been addressed above. We have reviewed Petitioner's argument and contentions, and we conclude that Petitioner has demonstrated a reasonable likelihood of prevailing on the challenge that claim 10 is unpatentable as having been obvious over Lurie and Ockuly.

F. Obviousness over Lurie, Ockuly, and Blanc

Petitioner asserts claims 1 and 10 of the '268 patent are unpatentable under 35 U.S.C. § 103(a) as having been obvious over Lurie, Ockuly, and Blanc. Pet. 5, 63–64; Ex. 1005 ¶¶ 85–86. Petitioner relies on Blanc for

using an inner catheter to introduce a contrast media, in the event Lurie and Ockuly are deficient in that regard. Pet. 63–64 (citing Ex. 1015, at 2022); Ex. 1005 ¶¶ 85–86. The arguments presented against such obviousness in the Preliminary Response have all been addressed above. We have reviewed Petitioner's argument and contentions, and we conclude that Petitioner has demonstrated a reasonable likelihood of prevailing on the challenge that claims 1 and 10 are unpatentable as having been obvious over Lurie, Ockuly, and Blanc.

IV. CONCLUSION

For the above reasons, we determine the information presented establishes there is a reasonable likelihood that Petitioner would prevail with respect to at least one claim of the '268 patent challenged in the Petition. Accordingly, we institute an *inter partes* review. 35 U.S.C. § 314(a).

At this preliminary stage, the Board has not made a final determination with respect to the patentability of the challenged claims or any underlying factual and legal issues. The Board's final determination will be based on the record as developed during the *inter partes* review.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted for claims 1, 10–14, 18, 19, and 23–26 of the '268 patent on the following asserted grounds:

(1) Claim 11 under 35 U.S.C. § 103(a) as unpatentable over Auricchio;

(2) Claims 12 and 24 under 35 U.S.C. § 103(a) as unpatentable over Auricchio and Randolph;

(3) Claims 13, 14, 18, 19, 23, 25, and 26 under 35 U.S.C. § 103(a) as unpatentable over Auricchio, Randolph, and Payne;

(4) Claims 1 and 10 under 35 U.S.C. § 103(a) as unpatentable over Lurie and Ockuly; and

(5) Claims 1 and 10 under 35 U.S.C. § 103(a) as unpatentable over Lurie, Ockuly, and Blanc; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, which commences on the entry date of this decision.

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