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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 IPR2018-00609
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; 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 IPR2018-00610. 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:

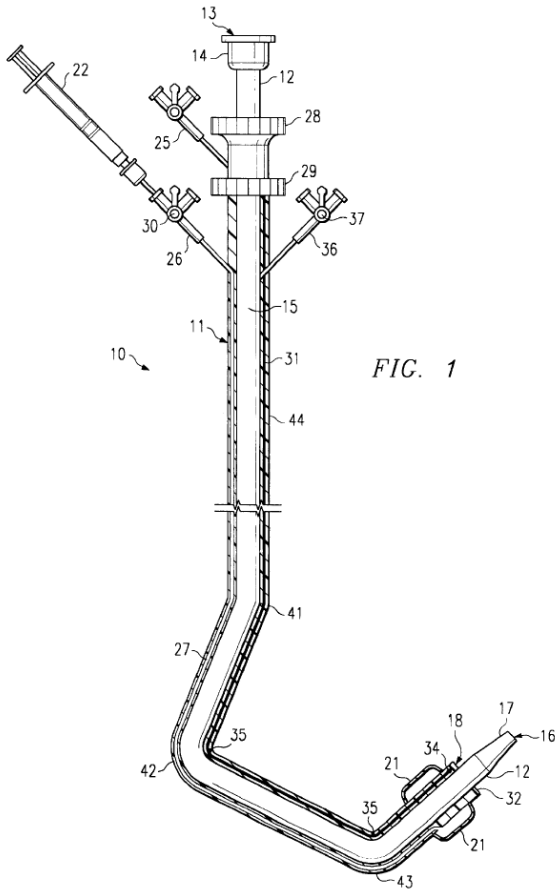

FIG. 1

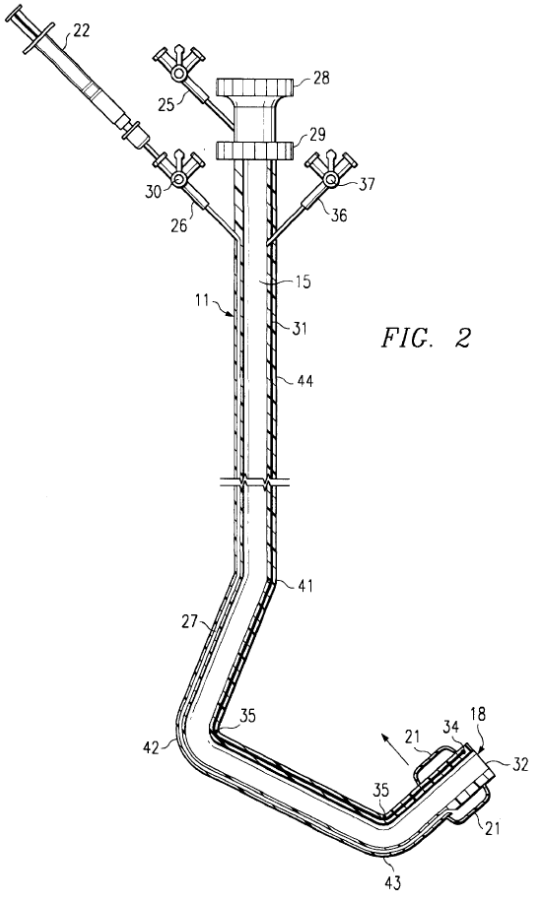

FIG. 2

[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:

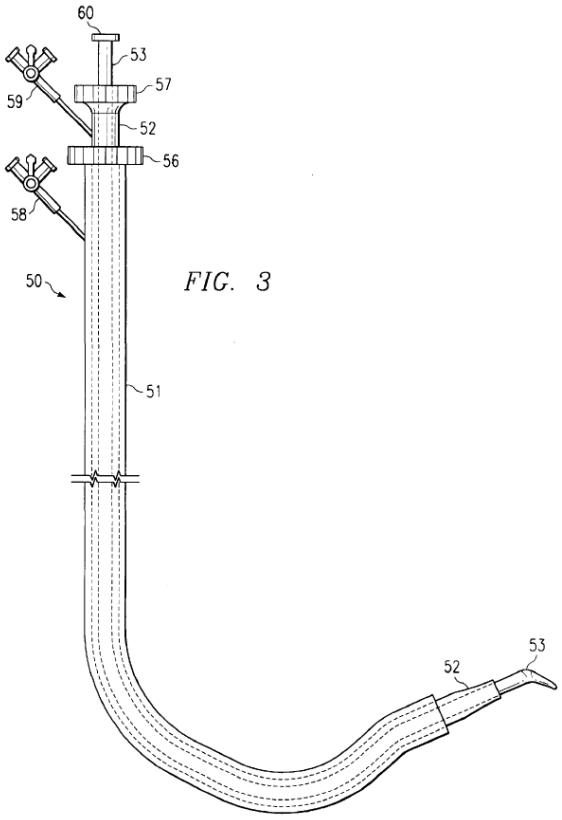

FIG. 3

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, 28.

Statutory Basis	Reference(s)	Claims Challenged
§ 102(e)	Norlander[3]	1, 10–12, and 24
§ 103(a)	Norlander	10 and 24
§ 103(a)	Norlander and Payne[4]	13, 14, 18, 19, 23, 25, and 26

III. ANALYSIS

A. Prior Art Status of Norlander

Petitioner asserts Norlander is prior art to the challenged claims of the '268 patent. Pet. 21–30. Patent Owner disagrees. Prelim. Resp. 4–29. For the following reasons, we conclude, based on the record at this preliminary stage of the proceeding, that Petitioner has sufficiently shown for purposes of institution that Norlander is effective as a prior art reference on March 1, 2000. Further, the earliest potential priority date for the challenged claims of the '268 patent is April 7, 2000. Therefore, Petitioner has shown, based on the present preliminary record, that Norlander is effective as a prior art reference against the challenged claims of the '268 patent, sufficiently for us to institute review in this proceeding.

1. Whether Norlander is Effective as a Prior Art Reference on March 1, 2000

The parties agree that the decision in *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015), governs our

[3] Ex. 1007, U.S. Patent No. 6,562,049 B1, iss. May 13, 2003 (hereafter "Norlander" or "the Norlander patent").

[4] Ex. 1009, WO 99/49773, pub. Oct. 7, 1999 (hereafter "Payne").

determination as to the date on which Norlander is effective as prior art. Pet. 28–30; Prelim. Resp. 4–10. The parties disagree, however, as to the holding and application of *Dynamic Drinkware* in that regard.

We concur that the facts presented in this case require application of *Dynamic Drinkware*. Norlander is a U.S. Patent that issued from a utility application filed on November 9, 2000. Ex. 1007, (22). The Norlander patent claims the benefit of March 1, 2000, as an effective filing date, based on a U.S. Provisional Application filed on that date. *Id.* at (60); Ex. 1008 (hereafter "the Norlander provisional"). Under *Dynamic Drinkware*, the Norlander patent is effective as a prior art reference under 35 U.S.C. § 102(e) on March 1, 2000, "if the disclosure of the [Norlander provisional] provides support for the claims in the [Norlander patent] in compliance with § 112, ¶ 1." *Dynamic Drinkware*, 800 F.3d at 1381–82 (citing *In re Wertheim*, 646 F.2d 527, 537 (CCPA 1981)). The parties dispute whether *Dynamic Drinkware* requires the Norlander provisional to support just one claim in the Norlander patent (Petitioner's contention), or to support all claims in the Norlander patent (Patent Owner's contention).

We agree with Petitioner's contention. We recognize that *Dynamic Drinkware* refers to "the claims" (plural) of a potential prior art patent having written description support in the patent's parent application. *Dynamic Drinkware*, 800 F.3d at 1381–82. However, in *Dynamic Drinkware*, the petitioner had not demonstrated written description support in the parent application for *any* claim of the potential prior art patent. *Id.* Thus, the specific issue presented here of whether just one claim or all claims of the potential prior art patent must have written description support in the parent application was not at issue in *Dynamic Drinkware*.

Indeed, *Dynamic Drinkware* discusses the circumstances under which a challenged patent is determined to have priority to a parent application's filing date, in order to antedate a potential prior art reference. *Id.* at 1379–81. That discussion refers to "the asserted claims" (plural) and "the invention claimed" (generally) in the challenged patent being entitled to priority to an earlier filing date of a parent application. *Id.* at 1380. Yet, in the context of a challenged patent's claims, the priority determination is made for each claim individually, not based on all claims. *See Lucent Techs., Inc. v. Gateway, Inc.*, 543 F.3d 710, 718 (Fed. Cir. 2008) ("Patent claims are awarded priority on a claim-by-claim basis based on the disclosure in the priority applications."); *Augustine Med., Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1302–03 (Fed. Cir. 1999). This suggests, in the context of a potential prior art patent's effective filing date, we should also apply an individual claim analysis rather than analyzing all claims.

We, thus, agree with our colleagues' decision in *Ex Parte Mann*, Appeal No. 2015-003571, 2016 WL 7487271 (PTAB Dec. 21, 2016), that *Dynamic Drinkware* does not specify whether support is required for all claims or only one claim. *Id.* at *6. We, further, concur with their assessment that requiring support for all claims (i.e., the approach advocated by Patent Owner here) does not make sense when one considers its application to other contexts, such as when a potential prior art reference claims priority to two different provisional applications respectively disclosing two different inventions X and Y. *See id.* ("If *Dynamic Drinkware* required that all claims be supported by a single provisional application, then a non-provisional child with one claim for X and a second

claim for Y would be unable to use the priority date for either provisional application.").

Thus, we determine *Dynamic Drinkware* requires the Norlander provisional to support just one claim in the Norlander patent for the Norlander patent to be effective as prior art on March 1, 2000. The Petition presents a claim chart in an effort to establish that claim 1 of the Norlander patent is supported by the Norlander provisional. Pet. 28–30. The Preliminary Response does not dispute Petitioner's contentions in that regard. *See, e.g.*, Prelim. Resp. 8–10 (contending that claims 12–15, 27, and 29–32 of the Norlander patent are not supported by the Norlander provisional, but not addressing claim 1 of the Norlander patent). We have reviewed the evidence cited by Petitioner, and we determine the present preliminary record establishes claim 1 of the Norlander patent is supported by the Norlander provisional.

Thus, for the foregoing reasons, and based on the present preliminary record in this proceeding, we conclude the Norlander patent is effective as prior art on March 1, 2000.

2. Whether Norlander is Prior Art to All Challenged Claims of the '268 Patent

The '268 patent issued from a utility application filed on April 6, 2001, and claims the benefit of an earlier filing date on April 7, 2000, based on a provisional application filed on that date. *See* Ex. 1001, (22), (60); Ex. 1002 (hereafter "the '268 provisional"). Thus, each challenged claim of the '268 patent has an earliest possible priority filing date of April 7, 2000. Patent Owner does not point to any evidence in the present record which might establish entitlement to a date of invention preceding that priority

date. Petitioner sufficiently contends that Norlander is effective as prior art on March 1, 2000. Therefore, based on the present preliminary record in this proceeding, Norlander is prior art to all challenged claims of the '268 patent.

3. Priority of the Challenged Claims of the '268 Patent

The parties present several disagreements concerning whether the challenged claims of the '268 patent have written description support in the '268 provisional. Pet. 21–27; Prelim. Resp. 10–24. For the reasons provided above, at the present time, Petitioner has sufficiently shown that Norlander is prior art to all challenged claims of the '268 patent, regardless of whether any given challenged claim has a priority date of April 7, 2000, or April 6, 2001. Nonetheless, we address here the parties' disputes concerning the effective filing date of the challenged claims. Challenged claims 1, 11, and 13 are representative of those disputes, as follows.

a) Claim 1: "a mechanism operable from the proximal end of the outer catheter for changing the curvature of the distal end of the outer catheter"

The parties first disagree whether the "mechanism" limitation of claim 1 is a means-plus-function limitation, subject to construction under 35 U.S.C. § 112, ¶ 6. For reasons provided in Section III.B.1 *infra*, we are persuaded for purposes of this Decision that this limitation is a means-plus-function limitation. Further, the corresponding structures in the '268 patent specification include: (1) a torque screw attached to a cable anchored close to the distal tip of the outer catheter; (2) an inner guide catheter within the outer catheter; and (3) an inner guide catheter in combination with an obturator. *See infra* Section III.B.1.

Petitioner asserts "*each* of" those corresponding structures must be disclosed in the '268 provisional for claim 1 to have benefit to the earlier priority date. Pet. 26–27 (emphasis added) (citing *Uniloc USA, Inc. v. Sega of Am., Inc.*, 711 Fed. App'x 986, 2017 WL 4772565 (Fed. Cir. 2017); *Lucent*, 543 F.3d at 719; and *Automotive Techs. Int'l, Inc. v. Delphi Corp.*, 776 F. Supp. 2d 469, 492 (E.D. Mich. 2011)). In Petitioner's view, that requirement is not satisfied by the '268 provisional, because it discloses corresponding structure (1), but not corresponding structures (2) and (3). *Id.* at 27.

Patent Owner takes the position that the '268 provisional needs only to disclose "sufficient" or "some" of the corresponding structures. Prelim. Resp. 19–23 (citing *EnOcean GmbH v. Face Int'l Corp.*, 742 F.3d 955, 961 (Fed. Cir. 2014) and *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1382 (Fed. Cir. 1999)). In Patent Owner's view, that requirement is satisfied by the '268 provisional, because it discloses corresponding structures (1) and (2), even if it is missing corresponding structure (3). *Id.* at 19–21.

We have reviewed the case law cited by the parties. The cited Federal Circuit cases do not resolve the legal issue presented here. That issue is whether the '268 provisional must disclose all corresponding structures (1), (2), and (3), or just one corresponding structure (1), (2), or (3), for claim 1 to have priority to the '268 provisional filing date.

The Federal Circuit cases cited by Petitioner concerned situations where *no* corresponding structure had been established to be present in a parent provisional application. *Uniloc*, 711 Fed. App'x at 990–93 (substantial evidence supported finding that provisional applications did not

disclose "a summation algorithm" corresponding structure); *Lucent*, 543 F.3d at 719–20 (district court had correctly "recognized that *none* of the corresponding structures appeared" in the parent application) (emphasis added).

The first case cited by Patent Owner appears to have involved only one corresponding structure, as opposed to the multiple corresponding structures at issue here. *EnOcean*, 742 F.3d at 961 (determining the claimed "signal reception means" was sufficiently described by a parent application's reference to "a single receiver" to establish possession of the claimed invention, without expressly identifying the corresponding structures of the patent application disclosure at issue). The second case cited by Patent Owner concerned the definiteness requirement of 35 U.S.C. § 112, ¶ 2, rather than the written description requirement of 35 U.S.C. § 112, ¶ 1 at issue here. *Atmel*, 198 F.3d at 1378–82 ("All one needs to do in order to obtain the benefit of that claiming device is to recite *some* structure corresponding to the means in the specification, as the statute states, *so that one can readily ascertain what the claim means* and comply with the particularity requirement of ¶ 2.") (emphases added).

Petitioner additionally cites a District Court decision, which is not binding precedent, but does squarely addressed the issue presented here. *See Automotive Techs.*, 776 F. Supp. 2d at 490–92. In that decision, the court reviewed four Federal Circuit cases, and concluded they collectively establish a parent application must disclose "each and every" corresponding structure of a means-plus-function limitation for priority to be found. *Id.*

In short, upon our review of the legal authorities cited by each party, we do not find a clear and binding resolution of the specific legal issue

presented here. We, therefore, defer further consideration of this issue, and will address the issue later in the event we ultimately conclude Norlander's effective prior art date falls after the '268 provisional filing date.

As suggested above, the parties also have a factual disagreement concerning whether corresponding structure (2), an inner guide catheter disposed within an outer catheter for changing the curvature of the distal end of the outer catheter, is adequately disclosed in the '268 provisional to demonstrate possession by the inventor. *See* Pet. 27; Ex. 1005 ¶ 50; Prelim. Resp. 16–19. The '268 provisional clearly discloses an inner catheter disposed within an outer catheter. *See* Ex. 1002, Figs. 1 & 8, 2:16–19. The dispute is whether the '268 provisional adequately links that structure to the claimed function under § 112, ¶ 6. Patent Owner contends claim 10 of the '268 patent provides the requisite linkage. Prelim. Resp. 17–19.

Patent Owner's contention is not persuasive. Claim 10 of the '268 patent is not found in the '268 provisional. Patent Owner asserts the addition of claim 10 during prosecution of the utility application that issued as the '268 patent is sufficient to demonstrate possession of the linkage on the date the '268 provisional was filed. *Id.* However, neither of the two decisions cited by Patent Owner supports that proposition. The cited *Medtronic* decision does not implicate whether dependent claims presented after a filing date may establish possession as of the filing date. *See Medtronic, Inc. v. Advanced Cardiovascular Sys., Inc.*, 248 F.3d 1303, 1313 (Fed. Cir. 2001). Moreover, the dependent claims at issue in *Medtronic* were presented via a Preliminary Amendment "filed . . . along with" the application, not after the application. *Id.* at 1307–08. The *B. Braun* decision held "*neither* the specification *nor* the prosecution history" disclosed a

linkage. *See B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1425 (Fed. Cir. 1997) (emphases added). Thus, the *B. Braun* decision does not suggest that new matter presented after a filing date may establish possession as of the filing date.

b) Claim 11: "advancing the inner catheter out of a front end opening of the outer catheter along the guide wire into the branch vein"

Petitioner contends the '268 provisional does not disclose advancing an inner catheter out of an outer catheter *along a guide wire*, as recited in claim 11 of the '268 patent. Pet. 23–24. In Petitioner's view, the '268 provisional instead discloses that the guide wire is removed before the inner catheter is advanced out of the outer catheter. *Id.* (citing Ex. 1002, 3–4). The Preliminary Response does not address Petitioner's argument. We have reviewed the evidence cited by Petitioner, and it appears to support Petitioner's position.

c) Claim 13: Outer Catheter Comprising "a first bend adjoining a straight, proximal portion of the outer catheter is in the range of 130° to 180°"

Petitioner contends the '268 provisional does not disclose a first bend of an outer catheter "that equals 180° (*i.e.*, no first bend)." Pet. 24–26; *see also* Ex. 1001, Fig. 2, 4:26–28 ("outer catheter 11 may be substantially J-shaped with no first bend (bend 41 = 180°)"). In Petitioner's view, the '268 provisional instead discloses a first bend having only a "range of 130° ***to 175***°." *Id.* at 25 (quoting Ex. 1002, claim 8). Petitioner acknowledges Figure 8 of the '268 provisional "depicts a curved, generally J-shaped double catheter." *Id.* Petitioner nonetheless contends Figure 8 is insufficient to establish possession of claim 13, because "it does not depict a catheter

with straight sections joined by bends or disclose the angles of any such bends." *Id.*

The Preliminary Response expressly "does not contend that claim [13] may claim priority" to the '268 provisional, and concedes a "5 degree difference between the range disclosed in the ['268] provisional and the '268 patent." Prelim. Resp. 24–25. Patent Owner's theory is that the '268 provisional establishes a constructive reduction to practice of the invention recited in claim 13 *except* for the first bend limitation. On the present record, that theory is not persuasive at least because it fails to establish that the '268 provisional discloses the other limitations of claim 13. *Id.* at 25–29. A patentee seeking to antedate prior art has a burden of production to establish entitlement to an earlier priority date. *Dynamic Drinkware*, 800 F.3d at 1379–80; *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 870–71 (Fed. Cir. 2010). Petitioner's silence concerning whether the '268 provisional discloses the other limitations of claim 13 is not an admission that it discloses those other limitations, and it also does not, by itself, satisfy Patent Owner's burden to show support for those limitations in the provisional in order to go forward on this issue.

We have reviewed the evidence cited by Petitioner, and it appears to support Petitioner's position that the '268 provisional does not demonstrate possession of the invention recited in claim 13. The best evidence to support a contrary view appears to be Figure 8 of the '268 provisional, which illustrates a J-shaped double catheter, and therefore perhaps a first bend of 180°. However, Figure 8 does not appear to disclose, based on the argument and evidence currently of record, second and third bends falling within the ranges specified in claim 13, in combination with a first bend of 180°.

B. 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).

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. 17–19; Prelim. Resp. 11–15. 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. 17–19. Petitioner acknowledges that, because claim 1 does not use the term "means," a presumption arises that § 112, ¶ 6 does not apply. *Id.* at 17 (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 17–18. 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 18–19 (citing Ex. 1001, 3:55–65, 6:2–12).

Patent Owner contends the "mechanism" limitation is not a means-plus-function limitation. Prelim. Resp. 11–15. 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 11–12. 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 12–13 (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 13–14. 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 14–15.

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. 12–13. 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. "adjusting the curvature of the double catheter" (claim 12)

Claim 12 depends from claim 11. 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 12 then recites "adjusting the curvature of *the double catheter*." *Id.* at 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. 50–51 (discussing curvature of outer sheath 11 but not inner sheath 12 of Norlander). Patent Owner implicitly contends the limitation of claim 12 requires adjusting the curvature of both the outer and inner catheters. *See* Prelim. Resp. 35.

We determine, 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:

> 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 outer and inner catheters cannulate the coronary sinus at the same time. *See id.* at 4:32–43.

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

4. 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)).

C. Anticipation by Norlander

Petitioner asserts claims 1, 10–12, and 24 of the '268 patent are unpatentable under 35 U.S.C. § 102(e) as anticipated by Norlander. Pet. 4, 28, 35–54. 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. Because Petitioner has demonstrated a reasonable likelihood of prevailing "with respect to at least 1 of the claims challenged," we institute review on all challenged claims. 35 U.S.C. §§ 314(a) & 318(a); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348 (2018).

We initially note that the Norlander provisional must disclose the subject matter from the Norlander patent relied upon by Petitioner as invalidating the challenged claims of the '268 patent. *See* 35 U.S.C. § 119(e)(1) ("An application for patent . . . for an invention *disclosed* in the manner provided by the first paragraph of section 112 of this title in a provisional application . . . shall have the same effect, as to such invention, as though filed on the date of the provisional application") (emphasis added); *In re Giacomini*, 612 F.3d 1380, 1383 (Fed. Cir. 2010) ("an

applicant is not entitled to a patent if another's patent discloses the same invention, which was *carried forward* from an earlier U.S. provisional application or U.S. non-provisional application") (emphasis added). In relation to that requirement, Petitioner's analysis cites pertinent disclosures from both the Norlander patent and the Norlander provisional. *See, e.g.*, Pet. 35–41 (representative analysis of claim 1 of the '268 patent, citing Exhibit 1007 and Exhibit 1008). The Preliminary Response does not assert Petitioner failed to meet its burden in this regard. We, therefore, do not address this issue further in the present Decision.

We begin our analysis with a brief summary of the law of anticipation, then we summarize the Norlander disclosure, and finally we address Petitioner's and Patent Owner's contentions as to anticipation.

1. Law of Anticipation

A patent claim is unpatentable as anticipated under 35 U.S.C. § 102 "if each and every limitation is found either expressly or inherently in a single prior art reference." *WhitServe, LLC v. Computer Packages, Inc.*, 694 F.3d 10, 21 (Fed. Cir. 2012) (quoting *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998)).

2. Norlander Disclosure

Norlander discloses an "introducer apparatus" designed to "provide quicker and easier placement of a pacing lead or other device through a complex tortuous path to a remote anatomical location." Ex. 1007, 2:8–15. For example, Figure 1 illustrates introducer apparatus 10, "which is particularly configured for navigating the subclavian vein and into the heart

to place a pacemaker or defibrillator lead into the coronary sinus vein." *Id.* at 5:26–30. Figure 1 is reproduced below:

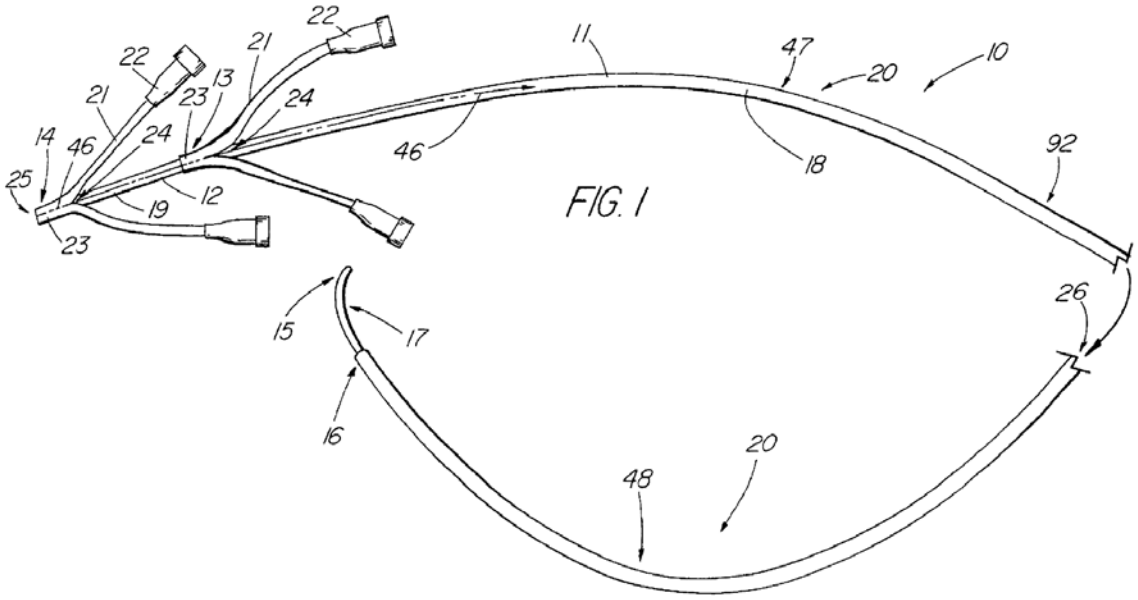

Figure 1 is a side view of introducer apparatus 10, which is composed of first introducer sheath 11 and second introducer sheath 12, with sheath 12 coaxially received within sheath 11. *Id.* at 4:8–9, 4:48–52, 5:20–23. Sheath 11 has preformed bend 20, comprised of proximal bend 47 and distal bend 48, that at least somewhat corresponds to the shape of a tortuous anatomical pathway to ease navigation of sheath 11 through the pathway to access the coronary sinus. *Id.* at 5:64–6:28, Figs. 3 & 3a.

3. Claims 1 and 10

Petitioner provides detailed arguments and evidence, including the Declaration of Dr. Ronald David Berger (Ex. 1005), in support of contending that Norlander discloses each and every limitation of independent claim 1 and its dependent claim 10. Pet. 35–43; Ex. 1005 ¶¶ 62–67.

Concerning the outer catheter having a "hook shaped distal end" as recited in claim 1 (Ex. 1001, 6:63–64), Petitioner contends Norlander's first sheath 11 is an outer catheter, which has a hook-shaped distal end. Pet. 36–37. Petitioner particularly relies on preformed bend 20 of sheath 11, including distal bend 48, as having the shape of a hook. *Id.* at 37 (citing Ex. 1007, Fig. 1, 6:12–16, 6:26–28); Ex. 1005 ¶ 64.

Patent Owner objects that Figure 1 of Norlander illustrates outer sheath 11 together with inner sheath 12, and therefore "does not show [outer sheath 11] in an undistorted state" as required to establish that outer sheath 11, by itself, has a hook-shaped distal end. Prelim Resp. 29–30. Patent Owner cites Norlander's disclosure that outer sheath 11 may have a variety of shapes, including a "straight" shape, as establishing the actual shape of outer sheath 11 in Figure 1 "is unknown." *Id.* at 30–31 (discussing Ex. 1007, 8:4–8). Patent Owner asserts Norlander's written description concerning preformed bend 20 is insufficient to establish that outer sheath 11 has a hook-shaped distal end. *Id.* at 31–32 (discussing Ex. 2007, 6:12–35).

Based on the arguments and evidence presently in the record, Petitioner has sufficiently shown that Norlander discloses the distal end of outer sheath 11 is hook-shaped. Specifically, Norlander indicates "it is desirable . . . to add at least one preformed bend 20 *to the outer introducer sheath 11*." Ex. 1007, 5:64–6:2 (emphasis added). That is, preformed bend 20 is a property of outer sheath 11, without the involvement of inner sheath 12. Norlander further describes how preformed bend 20 facilitates maneuvering outer sheath 11 into the coronary sinus (*id.* at 5:64–6:28), which may happen *before* inner sheath 12 is inserted into outer sheath 11 (*id.*

at 2:49–64, 6:35–40). Thus, Norlander describes preformed bend 20 as the shape assumed by outer sheath 11 in the absence of inner sheath 12. The Preliminary Response does not materially dispute that the curvature of preformed bend 20 corresponds to the "hook shape[]" recited in claim 1. *See* Prelim. Resp. 29–32; Ex. 1007, 6:12–28.

Although not specifically contested by Patent Owner at the present time, we have reviewed the arguments and evidence presented by Petitioner in support of contending that Norlander discloses all the other limitations of claims 1 and 10. Pet. 35–36, 38–43; Ex. 1005 ¶¶ 62–63, 65–67. We determine those contentions are supported in the present record sufficiently for us to institute review to determine whether claims 1 and 10 are anticipated by Norlander.

Accordingly, based on the current record, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing on the challenge that claims 1 and 10 of the '268 patent are unpatentable as anticipated by Norlander.

4. Claims 11 and 12

Petitioner provides detailed arguments and evidence, including the Declaration of Dr. Berger, in support of contending that Norlander discloses each and every limitation of independent claim 11 and its dependent claim 12. Pet. 43–51; Ex. 1005 ¶¶ 68–75. Concerning the step of "advancing a guide wire through the catheter" as recited in claim 11, Petitioner cites Norlander's disclosure that introducer apparatus 10, comprised of outer sheath 11 and inner sheath 12, "is normally *introduced over a wire guide*." Pet. 47 (emphasis added) (citing Ex. 1007, 7:15–16);

Ex. 1005 ¶ 71. Petitioner additionally cites the Norlander disclosure indicating that tip 69 of wire guide 45 is guided to a target site where either distal tip 16 of outer sheath 11 or distal tip 15 of inner sheath 12 "is to be placed." Pet. 47–49 (citing Ex. 1007, 7:21–24, 7:26–37); Ex. 1005 ¶ 71; Ex. 1007, 7:24, 7:26.

Patent Owner objects that "Norlander discloses *first* advancing a wire guide into the coronary sinus . . . *and then* advancing the introducers [11, 12] over the wire guide." Prelim. Resp. 32–33 (emphases added) (citing Ex. 1007, 7:15–35). Patent Owner contends that sequence of Norlander's method "is the opposite of" advancing a guide wire through introducer apparatus 10, as recited in claim 11. *Id.* at 33–34.

Based on the current record, the Norlander disclosure cited by Petitioner appears to disclose advancing the guide wire within a patient *before* insertion of either inner sheath 11 or outer sheath 12, and inserting inner sheath 11 or outer sheath 12 *only after* the guide wire is already in place. *See* Ex. 1007, 7:15–35. That is the opposite of advancing a guide wire through the catheter, as recited in claim 11. Dr. Berger testifies "[i]t was standard practice to insert the wire guide through an introducer apparatus distally into the vasculature before advancing the introducer apparatus over the wire guide." Ex. 1005 ¶ 71. However, that testimony is not accompanied by any citation to Norlander to establish that Norlander discloses such a practice, and so anticipates claim 11. *See id.*

Additionally concerning claim 12, Patent Owner asserts the limitation of "adjusting the curvature of the double catheter in order to enter the coronary sinus" is not disclosed in Norlander. Prelim. Resp. 35; Ex. 1001, 8:10–12. Patent Owner's view is that, in Norlander, "the outer introducer

sheath is already 'in place' within the coronary sinus when the inner introducer sheath is inserted over the guide wire." Prelim. Resp. 35. On the present record, Patent Owner's contention is not persuasive. Claim 12 encompasses adjusting the curvature of just one of the inner and outer catheters. *See supra* Section III.B.3. Norlander correspondingly discloses adjusting the curvature of outer sheath 11 to enter the coronary sinus. *See* Ex. 1007, 2:49–60, 5:64–6:28, 9:2–13.

5. Claim 24

Petitioner provides detailed arguments and evidence, including the Declaration of Dr. Berger, in support of contending that Norlander discloses each and every limitation of independent claim 24. Pet. 52–54; Ex. 1005 ¶¶ 76–82. Concerning the step of "advancing a guide wire through the catheter" as recited in claim 24, Petitioner relies on the contentions set forth above in relation to an identical limitation in claim 11. Pet. 53; Ex. 1005 ¶ 79. Patent Owner makes the same objection noted above. Prelim. Resp. 32–35.

6. Conclusion as to Anticipation by Norlander

Concerning Petitioner's assertions of anticipation by Norlander, Petitioner has demonstrated a reasonable likelihood of prevailing at least as to claims 1 and 10. We institute a review to proceed to a final written decision as to whether claims 1, 10–12, and 24 are unpatentable as anticipated by Norlander, based on a fully developed record.

D. Obviousness over Norlander

Petitioner asserts claims 10 and 24 of the ’268 patent are unpatentable under 35 U.S.C. § 103(a) as having been obvious over Norlander. Pet. 4, 54–57. 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 10. We begin our analysis with a brief summary of the law of obviousness, then we address the level of ordinary skill in the art, 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. 15–16; 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. 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 Norlander. Pet. 54–56; Ex. 1005 ¶ 83. Claim 10 depends from claim 1, to specify that the "mechanism" of claim 1 "comprises a portion of the inner catheter configured to reduce the curvature of the hook shaped distal end when inserted in the outer catheter." Ex. 1001, 7:58–62. According to Petitioner, even if Norlander does not disclose the limitation of claim 10 as set forth in Petitioner's Norlander anticipation ground, it would nonetheless have been obvious "to reduce the curvature of bend 48 forming the hook-shaped distal end 16 of outer introducer sheath 11

by inserting inner introducer sheath 11 [sic 12] through the outer introducer sheath 12 [sic 11]." Pet. 54; Ex. 1005 ¶ 83.

Petitioner contends Norlander already discloses inner sheath 12 may include "a generally straight shaft" (Ex. 1007, 6:32–35), and inner sheath 12 may be inserted into outer sheath 11 until the distal end of inner sheath 12 extends out of the distal end of outer sheath 11. Pet. 54–55; Ex. 1005 ¶ 83. In light of those disclosures, Petitioner concludes it would have been obvious to use Norlander's straight inner sheath 12 to adjust the curvature of outer sheath 11, because this would help to position the distal end of sheath 11 at the coronary sinus ostium in order to cannulate a vein proximate to the ostium. Pet. 55–56; Ex. 1005 ¶ 83.

The Preliminary Response does not address Petitioner's foregoing contentions as to the obviousness of claim 10. *See* Prelim. Resp. 48–49.

Based on the current record, we determine Petitioner has demonstrated a reasonable likelihood of prevailing on the challenge that claim 10 of the '268 patent is unpatentable as having been obvious over Norlander.

4. Claim 24

Petitioner provides detailed arguments and evidence, including the Declaration of Dr. Berger, in support of contending that claim 24 would have been obvious over Norlander. Pet. 56–57; Ex. 1005 ¶¶ 84–90. For the reasons discussed above in connection with Petitioner's Norlander anticipation ground, the Norlander disclosure cited by Petitioner as disclosing the claimed step of "advancing a guide wire through the catheter" does not appear to support Petitioner's contentions. Petitioner does not

present any obviousness rationale for modifying or supplementing Norlander's disclosure in that regard. *See* Pet. 56–57; Ex. 1005 ¶ 87. Patent Owner does not present any additional argument against instituting review of claim 24 on this ground. *See* Prelim. Resp. 48–49.

5. Conclusion as to Obviousness over Norlander

Concerning Petitioner's assertions of obviousness over Norlander, Petitioner has demonstrated a reasonable likelihood of prevailing as to claim 10. We institute a review to proceed to a final written decision as to whether claims 10 and 24 are unpatentable as having been obvious over Norlander, based on a fully developed record.

E. Obviousness over Norlander 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 Norlander and Payne. Pet. 4, 57–68. 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 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:

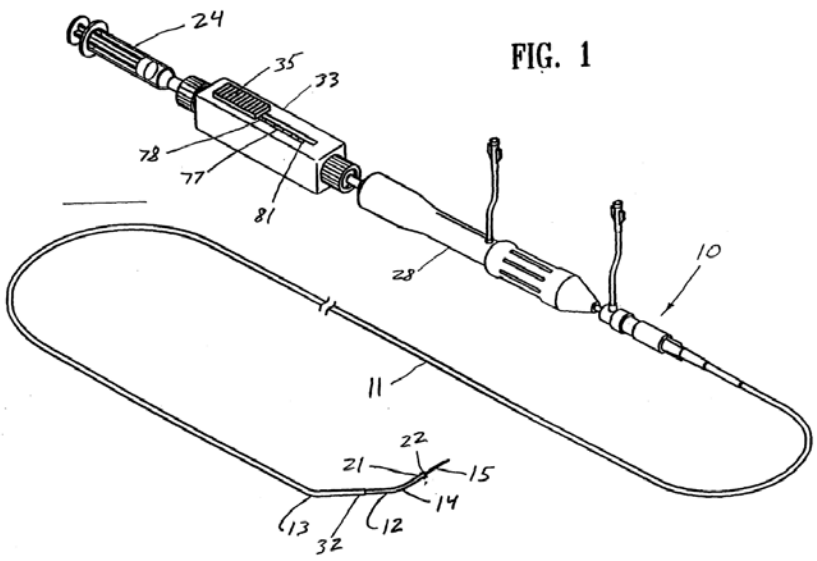

FIG. 1

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:

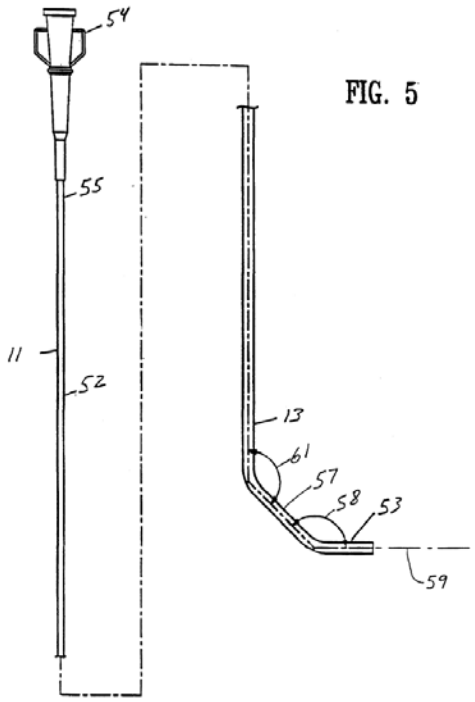

FIG. 5

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. 36–46. 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. 38 (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 37–38 (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 36.

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. 41–42 (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 40–41, 42–46. 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 40 (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 40.

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. 45–46. 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 Norlander and Payne. Pet. 57–63; Ex. 1005 ¶¶ 91–94.

Petitioner contends Norlander's outer sheath 11 discloses the outer catheter recited in claim 13, except outer sheath 11 is not disclosed as having "sufficient stiffness to permit advancement . . . into a *distal* coronary sinus," or as having three bends falling within the claimed ranges. Pet. 57–63 (emphasis added); Ex. 1005 ¶¶ 91–94. The Preliminary Response does not dispute that contention. We determine the contention is supported in the present record sufficiently for us to institute review.

In relation to the claimed "stiffness," Petitioner contends Norlander already discloses outer sheath 11 has "sufficient stiffness to navigate to and enter the coronary sinus ostium." *Id.* at 56–57 & 58 (citing Ex. 1007, 2:49–52); Ex. 1005 ¶¶ 85, 93. Dr. Berger opines that it would, additionally, have been obvious "that an outer introducer sheath having sufficient stiffness to navigate to and enter the coronary sinus ostium [such as Norlander's outer sheath 11], *could also be advanced distally into the coronary sinus to the distal coronary sinus*." Ex. 1005 ¶ 85 (emphasis added). For example, according to Dr. Berger: "It was a well-known technique at the time of the alleged invention to advance an outer sheath into the distal coronary sinus to provide support to a guide wire and/or inner catheter used to cannulate a branch vein for lead placement." *Id.* Indeed, Norlander itself indicates sheath 11 "is particularly configured for navigating the subclavian vein and into the heart to place a pacemaker or defibrillator lead *into the coronary sinus vein*." Ex. 1007, 5:26–30 (emphasis added).

In relation to the claimed bends, Petitioner relies on Payne as disclosing outer catheter 11 having three bend angles that overlap with the claimed ranges, as illustrated in Figure 5 of Payne. Pet. 58–62 (citing Ex. 1009, Fig. 5, 9:22–25, 12:12–15, 17:1–12); Ex. 1005 ¶ 94. According to

Petitioner, it would have been obvious "to modify the shape of outer introducer sheath 11 described in *Norlander* in view of *Payne*." Pet. 62; Ex. 1005 ¶ 94. Petitioner finds an express motivation for this modification in Norlander's disclosure that "outer . . . sheath 11 can be shaped with multiple bends to 'help[] in the navigation of the sheath to the target site.'" Pet. 62 (citing Ex. 1007, 5:65–6:5 and Ex. 1009, 9:22–25). Petitioner additionally contends "selection of features such as outer catheter shape would have been an obvious design choice," given that Norlander and Payne are both used in "cardiac procedures for navigating the coronary vessels." *Id.* at 62–63; Ex. 1005 ¶ 94. 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 Norlander. Pet. 63 (citing Ex. 1009, 9:22–25 and Ex. 1007, 6:10–12); Ex. 1005 ¶ 94.

Patent Owner contends Petitioner has failed to provide a rational underpinning for combining Norlander and Payne. Prelim. Resp. 46–48. Patent Owner contends Petitioner's motivation analysis is not supported by the disclosure of Norlander cited by Petitioner. *Id.* at 46–47. Patent Owner additionally asserts Norlander already discloses a preferred preformed bend 20 for outer sheath 11 to cannulate the coronary sinus, and Petitioner has failed to establish a rational underpinning for why that shape would have been modified to be like Payne's Figure 5. *Id.* at 47–48. Patent Owner particularly cites the different purposes of the two references — Norlander's catheter being designed to enter the coronary sinus, and Payne's catheter being designed to enter the left ventricle. *Id.*

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 Norlander (useful to cannulate the coronary sinus). Nonetheless, based on the present record, Petitioner has set forth sufficient explanation and evidence of motivation for modifying Norlander's outer sheath 11 to have the shape of Payne's Figure 5, as set forth above, for us to institute review. Accordingly, we institute a review to proceed to a final written decision as to whether claim 13 is unpatentable as having been obvious over Norlander and Payne, based on a fully developed record.

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 Norlander and Payne. Pet. 63–68; Ex. 1005 ¶¶ 95–105. Patent Owner's arguments as to these claims have all been addressed above. 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 Norlander and Payne.

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 or legal issue. 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 grounds:

(1) Claims 1, 10–12, and 24 under 35 U.S.C. § 102(e) as anticipated by Norlander;

(2) Claims 10 and 24 under 35 U.S.C. § 103(a) as unpatentable over Norlander; and

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