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Paper No. 40
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACCLARENT, INC.,
Petitioner,

v.

FORD ALBRITTON, IV,
Patent Owner.

Case IPR2017-00498
Patent 9,011,412 B2

Before JOSIAH C. COCKS, BEVERLY M. BUNTING, and RICHARD H. MARSCHALL, *Administrative Patent Judges*.

MARSCHALL, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

Neurent 1105
Neurent v. Foundry
IPR2024-00669

I. INTRODUCTION

Acclarent, Inc. ("Petitioner") filed a Petition for *inter partes* review of claims 1–7 and 14–20 of U.S. Patent No. 9,011,412 B2 (Ex. 1001, "the '412 patent"). Paper 1 ("Pet."), 19. Ford Albritton, IV ("Patent Owner") filed a Preliminary Response. Paper 11 ("Prelim. Resp."). We instituted trial as to all of the claims challenged by Petitioner, claims 1–7 and 14–20, and on all grounds set forth in the Petition. Paper 12 ("Institution Decision" or "Inst. Dec."). After institution of trial, Patent Owner filed a Patent Owner's Response (Paper 20, "PO Resp."), and Petitioner filed a Petitioner's Reply (Paper 22, "Pet. Reply"). Patent Owner further filed a Motion to Exclude Evidence (Paper 29), and Petitioner filed an Opposition to the Motion (Paper 32). Oral argument was conducted on April 24, 2018. Paper 39 ("Tr."). After oral argument, the parties submitted briefs on the issue of whether any challenged claims cover Figure 2 of the '412 patent. Papers 37, 38.[1]

We have jurisdiction under 35 U.S.C. §§ 6(b) and 318(a). Having considered the evidence and arguments of both parties, we conclude that Petitioner has not met its burden of showing, by a preponderance of the evidence, that any of claims 1–7 and 14–20 are unpatentable.

A. Related Matters

Petitioner and Patent Owner identify the following proceeding in the U.S. District Court for the Northern District of Texas as a related matter: *Dr. Ford Albritton IV v. Acclarent, Inc.*, No. 3:16-cv-03340-D (filed Dec. 1,

[1] We need not reach this issue, as the outcome in this Decision and analysis below in favor of Patent Owner remains the same even if the claims cover Figure 2 of the '412 patent, as alleged by Petitioner. Paper 37, 1–3.

2016). Pet. 5; Paper 6, 2. Another proceeding, filed by Acclarent on December 1, 2016 and alleging invalidity of the '412 patent, was dismissed without prejudice on December 2, 2016. Pet. 5; *Acclarent Inc. v. Ford Albritton IV*, No. 5:16-cv-06919 (N.D. Cal.). In addition, Petitioner filed IPR2018-00268, challenging claims 8–13 of the '412 patent, which are not at issue here. *Acclarent, Inc. v. Ford Albritton, IV*, IPR2018-00268 (filed Dec. 1, 2017) (Paper 1). We denied institution in IPR2018-00268 on May 31, 2018. *See id.* Paper 10. Petitioner filed a request for rehearing on June 18, 2018, which remains pending. *Id.* at Paper 11.

B. The '412 Patent

The '412 patent is titled "APPARATUS, SYSTEM AND METHOD FOR MANIPULATING A SURGICAL CATHETHER AND WORKING DEVICE WITH A SINGLE HAND." Ex. 1001, (54). The '412 patent describes the functions performed by the handle structure in the following manner:

> The handle has a structure to allow a position of the guide catheter to be controlled by some or all of three fingers of one hand of an operator of the handle. The structure of the handle is adapted to permit the operator to position a thumb and index finger of the hand to manipulate a working device inserted into the lumen of the guide catheter, where the working device is manipulable via a portion of the working device immediately adjacent to the handle.

Id. at Abstract.

Figure 3 of the '412 patent is reproduced below:

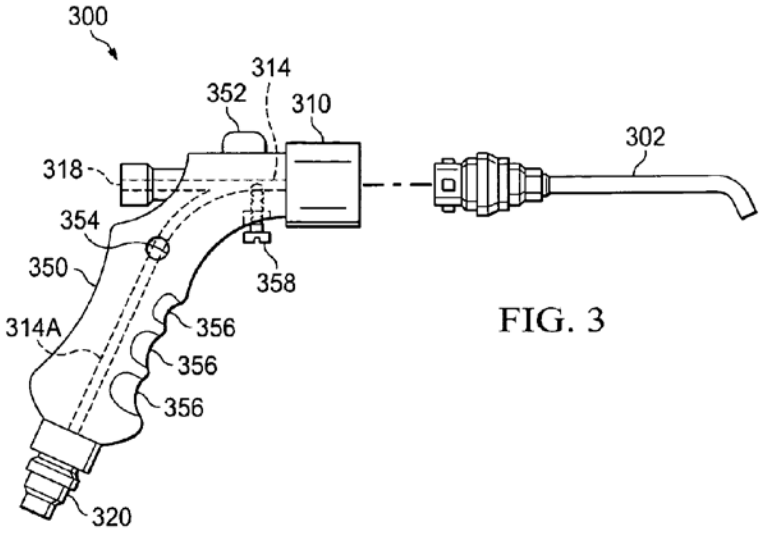


FIG. 3

Figure 3 shows surgical catheter 300 having handle 350 and guide 302. *Id.* at 3:51–56. Handle 350 includes opening 318, through which working devices, such as "an endoscope, guidewire or other working device, may be inserted." *Id.* at 4:4–9. Attaching a suction source at handle coupling 320 provides suction at the distal end of guide 302. *Id.* at 4:12–15. Opening 354 on handle 350 allows "the user to control the amount of suction present at the distal end of the guide 302." *Id.* at 4:18–21.

The specification explains that the user holds handle 350 using "some or all of the small finger, the ring finger and the middle finger," while "[t]he fore finger and thumb are left free to manipulate a working device into the opening 318." *Id.* at 4:62–5:3. The upper and lower portions of handle 350 form an angle that facilitates manipulation of the working device while simultaneously allowing the remaining fingers to control the position of guide 302. *Id.* at 5:8–18, 5:23–33.

C. Claims

Of the challenged claims, claims 1 and 14 are independent. Claim 1 is illustrative and is reproduced below:

> 1. A system, comprising:
>
> a guide catheter insertable through an external body passage of a subject, said guide catheter having a substantially rigid shaft, a proximal opening, a distal opening and a lumen extending between the proximal opening and the distal opening;
>
> a handle coupled to the guide catheter, the handle having a handle opening, a handle coupling and a structure, wherein the structure is configured to allow a position of the guide catheter to be controlled by some or all of three fingers of one hand of an operator of the handle, and wherein the handle coupling is configured to couple a source of suction to the lumen; and
>
> a working device adapted to be insertable through the handle opening into the lumen of the guide catheter,
>
> wherein the structure of the handle is adapted to permit the operator to position a thumb and index finger of the hand to manipulate the working device via a portion of the working device immediately adjacent to the handle opening and to control, by one of the thumb or index finger, an amount of suction coupled to the distal opening of the lumen.

Ex. 1001, 5:57–6:12.

D. Instituted Grounds of Unpatentability

We instituted *inter partes* review to determine whether claims 1–7 and 14–20 are unpatentable under the following grounds (Inst. Dec. 5, 28):

Ground No.	Reference(s)	Basis	Challenged Claims
1	Goldfarb[2]	§ 102	1–5, 7, 14–18, and 20
2	Goldfarb	§ 103	6 and 19
3	McCabe[3]	§ 102	1, 2, 4–7, 14, 15, and 17–20
4	Makower[4]	§ 102	1, 2, 7, 14, 15, and 20
5	Makower and Jones[5]	§ 103	4–6 and 17–19

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, a claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears. 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

[2] U.S. Patent No. 8,747,389 B2 issued to Goldfarb et al. on June 10, 2014 ("Goldfarb") (Ex. 1005).

[3] U.S. Patent No. 5,562,640 issued to McCabe et al. on October 6, 1996 ("McCabe") (Ex. 1006).

[4] U.S. Patent Pub. No. 2006/0063973 A1 issued to Makower et al., published on March 23, 2006 ("Makower") (Ex. 1009).

[5] U.S. Patent No. 4,915,691 issued to Jones et al. on April 10, 1990 ("Jones") (Ex. 1007).

reasonable interpretation standard). Consistent with the broadest reasonable construction, claim terms are presumed to have their ordinary and customary meaning as understood by a person of ordinary skill in the art in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

1. "configured to" and "adapted to"

Independent claims 1 and 14 each recite a handle "structure" that is: (1) "*configured to* allow a position of the guide catheter to be controlled by some or all of three fingers of one hand" ("the positioning limitation"); (2) "*adapted to* permit the operator to position a thumb and index finger of the hand to manipulate" a working device such as a guidewire ("the manipulating limitation"); and (3) "*adapted to* permit" (claim 1) or "*configured to* permit" (claim 14) the operator to control, by one of the thumb or index finger, an amount of suction" ("the suction control limitation"). Ex. 1001, 5:65–6:12, 7:13–8:1 (emphasis added). The claims refer to the fingers and thumb of the same "hand" throughout. *See id.* Both parties treat the limitations together, and do not argue for a construction for "configured to" that differs from "adapted to." *See* Pet. 24–25, 28–29; Pet. Reply 4–10; PO Resp. 5–10.

In the Institution Decision, and based on the record at that time, we applied "the implicit construction used by Petitioner" in the Petition, and construed the "configured to" and "adapted to" limitations "to require

structure that is capable of performing the claimed functions." Inst. Dec. 8.[6] Now, with the complete record before us, we revisit our initial construction.

a. Intended Use

Petitioner first argues that these limitations merely recite intended uses and "therefore cannot be used to differentiate the claimed apparatus from the prior art." Pet. 24–25; *see also id.* at 28, 43, 46, 57, 59; Pet. Reply 5–7. Petitioner contends that the claimed handle structure "allows" and "permits" certain functionality that amount to intended uses, and the handle structure is not further defined by the claims. Pet. Reply 6. Petitioner also contends that the claims are "limited to how a **user** would hold the device, and not to any specific function of the device itself." *Id.* According to Petitioner, the specification further supports the interpretation that the limitations amount to mere intended use because it "lacks any meaningful discussion of the handle structure." *Id.* at 7. Petitioner argues that the "specification fails to identify any particular structure that allows/permits the handle to be used in the claimed manner, and only discloses an intended use which cannot confer patentability to the claims." *Id.* (citing *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc*., 289 F.3d 801, 809 (Fed Cir. 2002); *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997)).

Patent Owner argues that terms such as "'configured to,' 'handle,' and 'adapted to' constitute structural limitations rather than an intended use."

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[6] Although Petitioner contended that these limitations are entitled to no patentable weight and appeared to use a "capable of" construction as a fallback position, neither party provided an express construction of these terms prior to the Institution Decision. Inst. Dec. 8. We invited the parties to address the issue further during trial, and cited to several potentially relevant cases that may bear on the construction of these terms. *Id.*

PO Resp. 8. Patent Owner also contends that the fact that the terms describe an interplay between components does not render the limitations intended use, and such terms can be used to differentiate the prior art. *Id.* at 8–10. According to Patent Owner, appearance of the limitations in the body of the claim, rather than the preamble, reinforces the conclusion that the limitations are not intended use and should not be rendered superfluous by not giving them patentable weight. *Id.* at 10.

We do not agree with Petitioner that these limitations should be given no patentable weight because they merely recite intended uses. First, we disagree with Petitioner's position that the claims simply relate to "how a **user** would hold the device," and not the structure or function of the device itself. Pet. Reply 6. Here, the claims specifically require a "handle . . . structure," not merely a user performing functions. The fact that the claims go on to specify functions that the structure enables, does not render the claims directed purely to user actions that provide no patentable weight to the claims. Second, we disagree with Petitioner's contention that the "specification fails to identify any particular structure that allows/permits the handle to be used in the claimed manner." Pet. Reply 7. The specification explains that the user holds handle 350 using "some or all of the small finger, the ring finger and the middle finger," while "[t]he fore finger and thumb are left free to manipulate a working device into the opening 318." *Id.* at 4:62–5:3. The specification also describes the angle formed between the upper and lower portions of handle 350 that facilitates manipulation of the working device while simultaneously allowing the remaining fingers to control the position of guide 302. *Id.* at 5:8–18, 5:23–33. The accompanying figures disclose the corresponding structure that achieves

these goals. *Id.* at Figs. 3–5. Petitioner's argument that the specification fails to disclose the structure that performs the claimed functions is unavailing because it overlooks these descriptions of the handle structure and their role in enabling the claim limitations. *See* Pet. Reply 7.

In addition, Petitioner does not direct us to cases addressing similar claim language to that at issue here that were not given patentable weight. The cases Petitioner relies on stand for the position that recitation of a new intended use for an old product does not make a claim to that old product patentable. *See* Pet. Reply 5–7; *Catalina Mktg.*, 289 F.3d at 809; *Schreiber*, 128 F.3d at 1477; *In re Swinehart*, 439 F.2d 210, 212 (CCPA 1971). Those cases do not support construing "configured to" and "adapted to," as a matter of claim construction, as having no patentable weight.

The language at issue here more closely tracks that at issue in *In re Giannelli*, 739 F.3d 1375, 1379 (Fed. Cir. 2014). In *Giannelli*, the claim required a "first handle portion *adapted to* be moved from a first position to a second position by a pulling force." *Id.* (emphasis added). The Board "noted that the recitation of a new intended use for an old product did not make a claim to that old product patentable," and determined that the claim contemplated a new use for a prior art product. *Id.* The Board also focused on whether the prior art was "capable of" performing the "adapted to" function. *Id.* The Federal Circuit reversed, holding that the Board erred in focusing on the "new intended use of the prior art apparatus" inquiry to conclude that "mere *capability*" of the prior art to perform the claimed function was sufficient to satisfy the claim limitation. *Id.* at 1380. The Federal Circuit did not construe the "adapted to" limitation as mere intended use that cannot differentiate the claim from the prior art, and instead

construed the "adapted to" language as meaning "made to, designed to, or configured to." *Id.* (quotation omitted).

Petitioner does not even cite to *Giannelli* much less distinguish it, even though we expressly invited the parties to address *Giannelli* in our Institution Decision. Inst. Dec. 8. Petitioner therefore provides no avenue to reconcile any tension between the "intended use" case law it relies upon and *Giannelli's* rejection of that approach in the context of the "configured to" and "adapted to" claim limitations at issue here.

Based on the foregoing, Petitioner's arguments and evidence do not persuade us that the "configured to"/"adapted to" limitations are mere intended use limitations, not entitled to patentable weight.

b. "Capable of" vs. "Made to, Designed to, or Configured to"

Petitioner argues another possible interpretation of these claim limitations—that the limitations should be construed as functional limitations that merely require structures "capable of" performing the claimed functions. Pet. Reply 4, 7–11. Petitioner acknowledges that phrases such as "adapted to" and "configured to" "can be given a broader meaning ('capable of' or 'suitable for') or a narrower meaning ('designed to' or 'constructed to')." *Id.* at 7. Petitioner contends that the complete claim limitations—"configured to allow" and "adapted/configured to permit"—"remove any doubt that if the Board construes them as functional, the terms should be given the broader constructions." *Id.* at 8. Petitioner further contends that neither the claims nor the specification "disclose any particular structure that allows a user to meet the functional language," and that the references such as the handle angle are too broad to provide adequate direction or guidance. *Id.* at 9. Petitioner also dismisses Patent Owner's

argument that the specification focuses on the advantages of single-handed use, finding those arguments failing "to reference any structure enabling such use." *Id.*

Patent Owner argues that both "configured to" and "adapted to" should be construed to mean "configured to" or "designed or configured to accomplish the specified objective, not simply that they can be made to serve that purpose." PO Resp. 5–6 (quotation omitted). According to Patent Owner, the claims are "configured to" accomplish single-handed operation by requiring the same hand to control the device as well as manipulate the working device. *Id.* at 6. Patent Owner also contends that the specification shows that the narrower definition controls because it emphasizes single-handed use over the prior art's two-handed operation. *Id.* at 6–7.

Patent Owner argues persuasively that the narrower construction, rather than the broad "capable of" construction advocated by Petitioner, applies. Controlling case law strongly supports this result here. First, in *Giannelli*, as discussed above, the Federal Circuit reversed the Board's construction of an "adapted to" limitation as requiring mere capability to perform the claimed function. *Giannelli,* 739 F.3d at 1379–80. The court looked to the specification, which made clear that the claimed rowing machine was "designed or constructed to be used" in the manner claimed. *Id.*

Similarly, in *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d. 1335, 1349 (Fed. Cir. 2012), the court considered whether to construe an "adapted to" limitation using the broader "capable of"/"suitable for" construction or the narrower "made to, designed to, or configured to" construction. *Id.* (quotation omitted). The court reasoned that "the phrase

'adapted to' is most naturally understood to mean that" the claimed structures "are designed or configured to accomplish the specified objective, not simply that they can be made to serve that purpose." *Id.* The court also viewed the specification as suggesting that the structures "are meant" to perform the claimed function, "not simply that they are capable of doing so." *Id.*

The Federal Circuit again construed "adapted to" in the narrower sense to mean "made or designed" to perform the claimed functions in *In re Man Machine Interface Technologies LLC*, 882 F.3d 1282, 1286 (Fed. Cir. 2016). In *Man Machine Interface*, the claim required "a body adapted to be held by the human hand." *Id.* at 1284. The court found that the specification supported the narrower interpretation by describing a "preferably elongated and rounded" body to be held in the hand, how the device is held in the hand, and how the hand-held device differed from prior art desk-bound devices. *Id.* at 1286; *see also In re Chudik*, 851 F.3d 1365, 1373 n.3 (Fed. Cir. 2017) (construing "arranged to" as "analogous to 'adapted to,' which means 'made to,' designed to,' or 'configured to.'" (quoting *Man Machine Interface*, 822 F.3d at 1286)).

The cases discussed above all construed the pertinent terms in the narrower sense. Petitioner did not cite to any controlling case law where either "configured to" or "adapted to" was construed in the broad manner advocated by Petitioner to mean "capable of." Petitioner also failed to cite to or address *Giannelli* or *Aspex Eyewear*, despite our invitation to do so, which speaks volumes regarding Petitioner's ability to distinguish those cases and escape their holdings, and supports applying the narrower construction to "configured to" and "adapted to" here. *See* Inst. Dec. 8.

Moreover, the facts here fit comfortably within the precedent rejecting the "capable of" construction in favor of the narrower construction. First, the claim language itself supports the narrower construction by using the "configured to" and "adapted to" language. The precedent makes clear that the "configured to" phrase itself connotes the narrower meaning and simply presumes this is the case—the closer issue under discussion was whether "adapted to" can be read more broadly. For example, in *Aspex Eyewear*, the court treated "configured to" as synonymous with the narrower "made to" and "designed to" phrases, and only left the possibility that "adapted to" could have a broader meaning. *Aspex Eyewear*, 672 F.3d at 1349 ("In common parlance, the phrase 'adapted to' is frequently used to mean 'made to,' 'designed to,' or 'configured to,' but it can also be used in a broader sense to mean 'capable of' or 'suitable for.'"); *see also Giannelli*, 739 F.3d at 1379 (same); *Man Machine Interface*, 882 F.3d at 1286 (same). Petitioner never adequately explains how "configured to" can be construed as requiring a mere capability under this precedent.[7] We agree with Patent Owner that the most natural reading of "configured to" in the claims at issue here requires structure designed to accomplish the claimed objectives.

In addition, although the cases note that "adapted to" can be read more broadly, they consistently hold the opposite view, and read "adapted to" as most naturally having the narrower meaning. *See id.* We see no reason to depart from that approach here. That is, the claims use

[7] Because Patent Owner argues "configured to" and "adapted to" together as if they have the same meaning, the failure of Petitioner to separately argue "adapted to" tends to support applying the same, narrower construction to "adapted to" that applies to "configured to."

"configured to" and "adapted to" in a manner that requires structure that performs specific functions (e.g., positioning the device, manipulating the working device, controlling suction) using the same hand. The claim language does not suggest that it covers a device not made to or designed to perform these functions, but rather that could be made to do so. *See Aspex Eyewear*, 672 F.3d at 1349 ("[T]he phrase 'adapted to' is most naturally understood to mean that" the claimed structures "are designed or configured to accomplish the specified objective, not simply that they can be made to serve that purpose.").

Finally, contrary to Petitioner's position, the specification supports the narrower construction by describing the structure necessary to perform the claimed functions and stressing the importance of the single-handed operation over the prior art. As noted above, the specification explains how the user holds handle 350 using "some or all of the small finger, the ring finger and the middle finger," while "[t]he fore finger and thumb are left free to manipulate a working device into the opening 318." *Id.* at 4:62–5:3. The specification also describes the structure necessary to allow these functions to be performed, including the angle formed between the upper and lower portions of handle 350, and the location of opening 318 used to insert a working device and opening 354 that controls suction. *Id.* at 4:61–5:33, Figs. 3–5. The orientation and size of the handle, combined with the location of openings 318, 354, allows the user to manipulate the working device with thumb and index finger and control suction using the same hand that positions the device. *Id.* The specification also distinguishes this improved, single-handed operation, from the two-handed operation necessary using prior art devices. *Id.* at 1:42–53, 5:23–33. The

specification's description of the structure required to perform the claimed functions and the importance of that structure to the goal of the claimed invention, reinforces a construction of "configured to" and "adapted to" that requires structure made to or designed to accomplish the claimed functions. *See Man Machine Interface*, 882 F.3d at 1286 (relying in part on distinction over prior art in the specification as reason to construed "adapted to" more narrowly).

Based on the foregoing, Patent Owner presents persuasive arguments and credible evidence to support a finding that "configured to" and "adapted to" should be construed narrowly. As such, we construe the terms "configured to" and "adapted to" as "requiring structure designed to or configured to accomplish the specified objective, not simply that they can be made to serve that purpose." PO Resp. 5–6 (quoting *Aspex Eyewear*, 672 F.3d at 1349).

2. Other Claim Terms

In addition, Petitioner proposes explicit constructions for several other terms, including "guide catheter," "handle coupling," "coupled," and "structure." Pet. 13–16. The parties also propose competing constructions for "external body passage." PO Resp. 4–5; Pet. Reply 11–12. We need not provide an explicit construction for these claim terms in order to resolve the issues presented in the Petition. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be

construed that are in controversy, and only to the extent necessary to resolve the controversy.").[8]

B. Person of Ordinary Skill in the Art

In our Institution Decision, we initially determined that "a person of ordinary skill in the art at the time of the invention would have had at least a bachelor's degree in either electrical engineering or mechanical engineering, or equivalent, with at least four years' experience designing surgical instruments *or* a doctor of medicine (MD) and at least 2 years of experience with laparoscopic or endoscopic surgical procedures." Inst. Dec. 9–10. Additionally, we noted that the prior art of record in this proceeding—namely, Goldfarb, McCabe, Makower, and Jones—is indicative of the level of ordinary skill in the art. *See id.; Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). The parties have not disputed this determination during trial. Thus, based on the full record, we find that the level of ordinary skill in the art used in addressing the issues in this Decision remains the same—namely a bachelor's degree in either electrical engineering or mechanical engineering, or equivalent, with at least four years' experience designing surgical

[8] Patent Owner argues that Petitioner's "capability" approach to claim construction leads to other problems. PO Resp. 10–16. We need not address these concerns given our rejection of the "capable of" construction advanced by Petitioner. Petitioner argues that we should not adopt the narrower construction because to do so would allow Patent Owner to advocate a broader construction for purposes of infringement in related litigation. Pet. Reply 10–11. We need not determine whether Patent Owner can reasonably advocate a broader construction than we adopt here in any future district court litigation, and our resolution of the claim construction dispute here should not be interpreted as sanctioning such an approach.

instruments or a doctor of medicine (MD) and at least 2 years of experience with laparoscopic or endoscopic surgical procedures.

C. Legal Principles

We analyze the instituted grounds of unpatentability in accordance with the below-stated principles in mind.

1. Burden of Proving Unpatentability

In *inter partes* reviews, petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to the patent owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail in this proceeding, Petitioner must support its challenges by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). Accordingly, all of our findings and conclusions are based on a preponderance of the evidence.

2. Anticipation

A claim is anticipated if each limitation of the claim is disclosed in a single prior art reference arranged as in the claim. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). "[A] reference can anticipate a claim even if it 'd[oes] not expressly spell out' all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would 'at once envisage' the claimed arrangement or combination." *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (quoting *In re Petering*, 301 F.2d 676, 681 (CCPA 1962)).

3. Obviousness

A claim is unpatentable under 35 U.S.C. § 103(a) 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 skill in the art; and (4) where in evidence, so-called secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

D. Petitioner's Arguments and Evidence Under the Controlling Claim Construction

As discussed above, we construe "configured to" and "adapted to" as "requiring structure designed to or configured to accomplish the specified objective, not simply that they can be made to serve that purpose." The Petition never addresses whether the prior art discloses the relevant limitations if those limitations are construed in this manner. Instead, the arguments and evidence in the Petition consider two possibilities. First, Petitioner argued in the Petition that the claim limitations were mere "intended use" limitations that did not confer patentable weight at all. Pet. 24–25, 28–29, 43, 46, 57, 59. Second, as a fallback position, Petitioner argued that "to the extent th[e] limitation[s] [are] given weight," the prior art discloses structure that is "configured to" or "capable of" performing the claimed functions. *See id.* at 26, 30, 44, 46–47, 57. Although the Petition uses the claim term "configured to" at times to allege that the prior art discloses the limitation, the use of that phrase did not comport with the narrower meaning consistent with our claim construction. *See id.* Instead, Petitioner took the position that the prior art discloses the limitations in

question if it "can be" or "could be" used in the manner suggested by the claim language—i.e., the Petition relied on the argument that mere capability to perform the claimed function sufficed. *See, e.g.*, *id.* at 30, 46 ("While McCabe does not teach holding the handle as required by claim 1, McCabe's handle certainly has a structure that is *capable* of permitting the operator to position a thumb and index finger of the hand to manipulate the working device . . . ."). Petitioner's approach was noted in our Institution Decision. Inst. Dec. 7–8.

Now, based on the entire record, because the Petition bases the grounds on either an "intended use" or "capable of" approach to claim construction, the Petition lacks sufficient argument and credible evidence to support a finding of unpatentability under the narrower construction that we adopt here. *See* Institution Decision 8. Petitioner's Reply continues to rely primarily on the "intended use" and "capable of" approaches, but Petitioner adds another fallback position in the event that we adopted the narrower construction proposed by Patent Owner: "[e]ven if these terms are somehow construed narrowly, the cited prior art is necessarily 'designed' or 'configured' to be held in the claimed manner, and would still inherently anticipate the claims." Pet. Reply 10. While Petitioner's new argument is in some sense responsive to arguments made in the Patent Owner's Response, allowing responsive arguments and evidence in a Petitioner's Reply does not permit a petitioner to address entirely new theories of unpatentability under a claim construction not contemplated in the Petition.

In any event, as discussed in more detail below, although Petitioner broadly asserted that it could carry its burden even under the narrow claim interpretation, its specific arguments with respect to the prior art references

often failed to make that allegation, much less establish by a preponderance of the evidence that the prior art discloses those limitations.

E. Ground 1 — Anticipation Based on Goldfarb

Petitioner asserts that Goldfarb anticipates claims 1–5, 7, 14–18, and 20. Pet. 19. With respect to claims 1 and 14, Petitioner relies on Goldfarb's disclosure and the expert declarations of Randy Kesten and Dr. Howard Levine in support of its allegation that Goldfarb discloses every limitation of claims 1 and 14. *See* Pet. 20–32, 35–36; Pet. Reply 12–18; Ex. 1004 ("Kesten Declaration"), ¶¶ 61–89; Ex. 1018 ¶¶ 41, 43, 45, 46 ("Levine Declaration"). Petitioner also relies on screenshots from a video of a surgery allegedly using Goldfarb's device, and related deposition testimony of Dr. Holmes, Patent Owner's declarant. *See* Pet. Reply 12–18; Ex. 1016 (Holmes deposition); Ex. 2023 (video).

1. Overview of Goldfarb

Goldfarb discloses devices for dilating passageways within the ear, nose, and throat. Ex. 1005, Abstract. Goldfarb discloses a "dilation catheter device . . . that facilitates ease of use by the operator and, in at least some cases, allows the dilation procedure to be performed by a single operator." *Id.* The dilation catheter may be used in conjunction with an endoscope, and "an optional handle may be used to facilitate grasping or supporting a [dilation catheter] as well as another device (e.g., an endoscope) with a single hand." *Id.*

Goldfarb's Figures 3A and 8A are reproduced below:

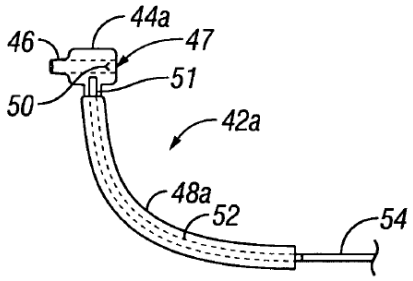


FIG. 3A

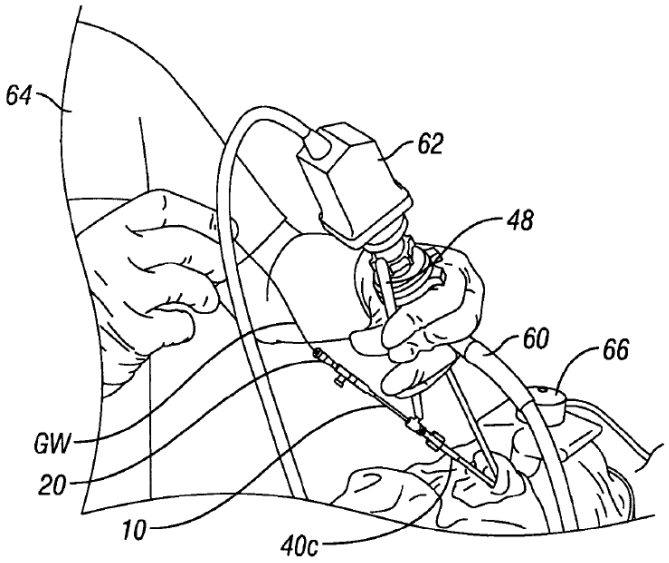


FIG. 8A

Figure 3A depicts handle 42a having fluid channel 52 extending from lumen 47 downwardly through head 44a and through handle member 48a. *Id.* at 11:14–17. "[I]rrigation and/or suction tube 54 may be attached" to handle member 48a. *Id.* at 11:19–21. Figure 8A depicts an example of how "handle 42 may be used to facilitate concurrent holding of an endoscope as well as the guide catheter" with a single hand of the operator. *Id.* at 11:50–54. In Figure 8A, an operator holds endoscope 60 and handle member 48 of guide catheter 40c in one hand, while manipulating the guidewire GW and dilation catheter 10 in the other hand. *Id.* at 11:58–12:3. An operator can bend malleable handle member 48 to form an angle between the shaft of guide catheter 40c and endoscope 60 to facilitate the operation. *Id.* at 12:17–32.

2. Discussion

a. Claims 1 and 14

i. "manipulating limitation"

Claims 1 and 14 require that the structure of the handle be "adapted to permit the operator to position a thumb and index finger of the hand to manipulate the working device . . . immediately adjacent to the handle opening" ("the manipulating limitation") Ex. 1001, 6:5–9, 7:17–21. Petitioner relies on Goldfarb's Figure 3A and its alleged similarity to the '412 patent's Figure 3 in contending that Goldfarb satisfies the manipulating limitation. *Id.* at 29 ("The relative positioning of the opening and the handle is what purportedly allows a user to engage a working device immediately adjacent to the opening using a thumb and index finger."). According to Petitioner, Goldfarb's similar handle is capable of performing the claimed function because it "is malleable and can be shaped to allow a user to position a thumb and index finger of the hand to manipulate a working device via a portion of the working device immediately adjacent to the handle opening." *Id*. at 30 (citing Ex. 1005, 10:54–57). Additionally, Petitioner asserts that one of ordinary skill in the art would "understand that the thumb and index finger could be positioned adjacent to the opening (adjacent arrow 47 [in Fig. 3A]) to grasp the working device, e.g., a guide wire GW and/or a dilation catheter 10." *Id.* (citing Ex. 1004 ¶ 83). In Petitioner's Reply, Petitioner again stresses that "the prior art need only be capable of being held in the claimed manner," and also stresses that the video showing Goldfarb's device in operation shows that it "has indeed been used in the claimed manner." Pet. Reply 12–13.

Patent Owner disputes whether Goldfarb discloses the manipulating limitation. PO Resp. 18–23. Patent Owner argues that Goldfarb "explicitly describes" and illustrates in Figures 8A and 8B that manipulation of the working device is not performed using the same hand that holds the handle. PO Resp. 20. According to Patent Owner, Goldfarb discloses the use of *two hands* to position the guide catheter and working device, while the claim requires the *same hand* to perform both functions. *Id.* at 19–22 (citing Ex. 1005, 10:67–11:2, 11:57–60, 12:1–3, 12:30–32, 13:39–40, 14:35–41, 15:38–44, Figs. 8A–8B; Ex. 2006 ¶¶ 20–21). Patent Owner also argues that videos do not show Goldfarb used in a manner consistent with the claims, and that it is not even capable of being used as claimed. *See id.* at 22–25 (citing Ex. 2020 ¶¶ 40, 42, 43, 45).

We find that Petitioner's arguments and evidence do not establish persuasively that Goldfarb's device discloses a handle structure "designed or configured to accomplish the specified objective"—here, permitting "the operator to position a thumb and index finger of the hand to manipulate the working device . . . immediately adjacent to the handle opening." Even in its Reply, Petitioner does not directly address how Goldfarb's device meets this limitation if construed narrowly as Patent Owner suggests, rather than requiring a mere capability to perform the claimed function as Petitioner proposes. *See* Pet. Reply 12–14 (stressing capability of Goldfarb). The parties dispute whether the videos allegedly showing the Goldfarb device in operation discloses the claimed single-handed operation. *See* Pet. Reply 12–14; PO Resp. 22–25. Even if the videos showed the devices used in the claimed manner, that would only establish the mere capability of Goldfarb's device to perform the claimed function. *See Aspex Eyewear*, 672 F.3d at

1349 (narrower construction does not cover structures that "can be made to serve the purpose" of the claimed functions).

More importantly, Goldfarb itself discloses in Figure 8A how its device was designed to be used, and does not show the device used in the claimed manner. Ex. 1005 Fig. 8A. Instead, Goldfarb shows its device used with *one hand* controlling the guide catheter (and endoscope), and *another hand, i.e., a second hand*, controlling the working device. *See, e.g.*, *id.* at 11:50–54, 11:58–12:3, 12:17–32. With two different hands used for these tasks, Goldfarb does not disclose a handle structure designed to "permit the operator . . . to manipulate the working device . . . immediately adjacent to the handle opening" using a thumb and index finger of the *same hand* used to position the device as required by the manipulating limitation.

ii. "suction control limitation"

As discussed above, claims 1 and 14 require "control, by one of the thumb or index finger, an amount of suction coupled to the distal opening of the lumen" ("the suction control limitation"). Ex. 1001, 6:9–11, 7:23–8:2. Petitioner relies on Goldfarb's disclosure of a "thumb/finger hole to control the suction force" to satisfy the controlling limitation, arguing that Goldfarb discloses a hole that "can be covered by the thumb of a user." *Id.* at 31; Ex. 1005, 11:6–12, 11:33–34. Because the '412 patent discloses that the forefinger and thumb are free to cover opening 318 to redirect suction, relying on the testimony of its declarant, Petitioner argues that "Goldfarb's handle opening 47 can similarly function to allow a user to cover the opening to control an amount of suction." *Id.* at 32 (citing Ex. 1004, ¶¶ 85–87). In Petitioner's Reply, Petitioner alleges that the claims do not require simultaneous suction control while controlling the guide catheter, and the

video shows that a user "could release the guide catheter and use the same hand to control suction." Pet. Reply 17. According to Petitioner, the claims do not require a location for suction control, and the "videos show the index finger positioned on the handle where a port could clearly be covered." *Id.*

Patent Owner raises arguments with respect to the suction control limitation that are similar to those made with respect to the manipulating limitation. PO Resp. 26–27 (citing Ex. 1005, 10:66–11:12, Figs. 8A–8B). Specifically, Patent Owner contends that the claim requires the thumb and index finger of the same hand to both manipulate the working device and control suction, and Goldfarb discloses the use of two different hands to perform these tasks. *Id.* at 27 (citing Ex. 2020 ¶ 49).

We find that Petitioner does not present sufficient arguments and credible evidence to support a finding that Goldfarb discloses a handle structure "designed or configured to accomplish the specified objective"—here, permitting the operator "to control, by one of the thumb or index finger, an amount of suction." Again, even in its Reply, Petitioner does not directly address how Goldfarb's device meets this limitation if construed narrowly as Patent Owner suggests, rather than requiring a mere capability. *See* Pet. Reply 16–18 (stressing capability of Goldfarb: "one *could* release the guide catheter and use the same hand to control suction"; "thumb . . . *can* certainly cover a suction port on the device"; "index finger positioned on the handle where a port *could* clearly be covered" (emphasis added)). Therefore, Petitioner does not even allege, much less establish, that Goldfarb was *designed* to accomplish the goal of permitting suction control using the same thumb and index finger used to manipulate the working device. Petitioner does not direct us to any passage in Goldfarb specifying the

location of any suction control hole with any particularity, or indicating which fingers are used to control suction. *See* Ex. 1005, 11:6–44, Figs. 3–3C, 8A–8B. Again, to the extent that Goldfarb discloses how it was designed to be used, it discloses different hands positioning the guide catheter and working device, and even the addition of suction control would not result in disclosing the use of the same hand to perform all three functions as claimed (positioning the guide catheter, manipulating the working device, and controlling suction).

Based on the foregoing, we find that Petitioner has not established by a preponderance of the evidence that Goldfarb discloses the manipulating limitation or the suction control limitation of claims 1 and 14.

b. Claims 2–5, 7, 15–18, and 20

Each of claims 2–5, 7, 15–18, and 20 depend directly or indirectly from claims 1 and 14, and recite additional limitations. Because we find that Petitioner has not established by a preponderance of the evidence that independent claims 1 or 14 are unpatentable as anticipated by Goldfarb, we similarly find that dependent claims 2–5, 7, 15–18, and 20 are not anticipated for the same reasons.

3. Summary

Based on the complete record, we conclude that Petitioner has not established by a preponderance of the evidence that Goldfarb anticipates claims 1–5, 7, 14–18, and 20.

F. Ground 2 — Obviousness Based on Goldfarb

Petitioner alleges dependent claims 6 and 19, which depend indirectly from claims 1 and 14, respectively, are unpatentable based on Goldfarb under 35 U.S.C. § 103(a). Pet. 36–37. Petitioner does not rely on

obviousness with respect to claims 6 and 19 in a manner that addresses the deficiencies noted above with respect to claims 1 and 14. Pet. 37 (alleging that attaching a suction tube in a manner that allows movement would have been obvious); Pet. Reply 18. Thus, based on the complete record, we conclude that Petitioner has not established by a preponderance of the evidence that claims 6 and 19 are unpatentable as obvious based on Goldfarb.[9]

G. Ground 3 — Anticipation Based on McCabe

Petitioner alleges that McCabe anticipates claims 1, 2, 4–7, 14, 15, and 17–20. Pet. 19. With respect to claims 1 and 14, Petitioner relies on McCabe's disclosure and the Kesten Declaration and Levine Declaration in support of its allegation that McCabe discloses every limitation of claim 1. *See* Pet. 38–48, 51–52; Ex. 1004, ¶¶ 112–42; Pet. Reply 18–20; Ex. 1018 ¶ 57. Petitioner also relies on videos of a surgery allegedly using devices similar to that of McCabe, and related deposition testimony of Dr. Holmes, Patent Owner's declarant. *See* Pet. Reply 18–19; Ex. 1016 (Holmes deposition); Ex. 2026 (video).

1. Overview of McCabe

McCabe discloses "[a]n endoscopic surgical instrument for aspiration and irrigation of a surgical site." Ex. 1006, Abstract. The device includes ports for irrigation and suction that communicate with a "single lumen cannula" that transports fluid and suction pressure to a surgical site. *Id.*

[9] Patent Owner contends that certain "objective indicia" support the nonobviousness of the claims. *See* PO Resp. 57–63. We need not reach these issues in order to resolve the obviousness challenges presented by Petitioner in this matter.

McCabe's Figure 9 is reproduced below.

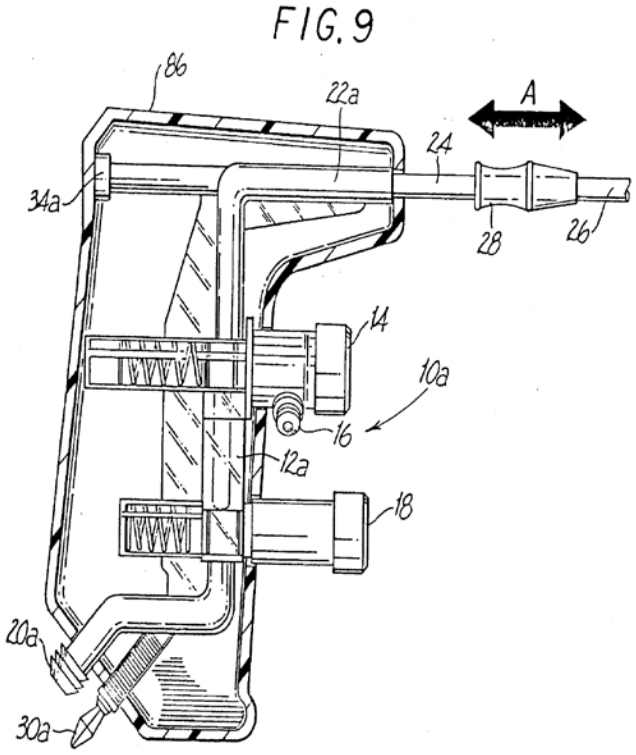


Figure 9 depicts "surgical instrument 10a enclosed in housing 86." *Id.* at 6:45–46. Coupling member 22a engages body portion 12a and single lumen cannula 24. *Id*. at 6:48–49. Optical fiber port 34a provides direct axial communication with single lumen cannula 24. *Id.* at 6:50–51.

2. Discussion

Petitioner relies on McCabe's "pistol-type housing 86" as disclosing the claimed "handle," and port 34a as disclosing the claimed "opening." Pet. 41. For the manipulating limitation, Petitioner alleges similarity between the handle shown in McCabe's Figure 9 and in the '412 patent's Figure 3, which is configured to allow the claimed manipulation. *Id.* at 46–47. According to Petitioner, "[w]hile McCabe does not teach holding the handle as required by claim 1, McCabe's handle certainly has a structure that is *capable* of permitting the operator to position a thumb and index finger of the hand to

manipulate the working device." *Id.* at 46. Relying on the Kesten Declaration, Petitioner contends that McCabe's structure is not only capable of allowing the thumb and index finger to engage a working device adjacent the port 34a; it would actually "be more conducive" for that purpose than the handle disclosed in the '412 patent. *Id.* at 47 (citing Ex. 1004 ¶¶ 136–38). In its Reply, Petitioner asserts that "there would have been nothing precluding" one of ordinary skill in the art "from stabilizing the McCabe device while manipulating the working device with the same hand that was holding McCabe's handle." Pet. Reply 19. Petitioner also alleges that Patent Owner's doubts about the ability of McCabe to perform the claimed functions based on size are unfounded because McCabe "contains no such teachings regarding size" and the '412 patent "contains no teachings regarding a specific size required of the claimed handle structure." *Id.* at 20.

Patent Owner argues that McCabe fails to disclose the manipulating limitation. PO Resp. 35–38 (citing Ex. 1004 ¶¶ 136–37; Ex. 2020 ¶¶ 66–68).[10] According to Patent Owner, Petitioner's arguments lack adequate support, and that arguments regarding the capabilities of McCabe miss the mark because they are not based on the correct claim construction. *Id.* at 35–36. Patent Owner also contends that "the McCabe device is not configured for a single hand to both hold the handle and manipulate the working device" and that it "is too wide" to allow three fingers to hold the handle while the remaining fingers manipulate the working device. *Id.* at

[10] Patent Owner also alleges that McCabe fails to disclose a "guide catheter insertable through an external body passage." PO Resp. 31–35. We need not reach that issue to conclude that Petitioner has not established that McCabe anticipates the challenged claims of the '412 patent.

36–37. Finally, Patent Owner argues that McCabe's handle angle, combined with its thickness, prevents performance of the manipulating limitation. *Id.* at 37.

Based on further review of the trial record, Petitioner does not present sufficient arguments and credible evidence to support a finding that McCabe's device discloses a handle structure "designed or configured to accomplish the specified objective"—here, permitting "the operator to position a thumb and index finger of the hand to manipulate the working device . . . immediately adjacent to the handle opening." As with Goldfarb, even in its Reply, Petitioner does not directly address how McCabe's device meets this limitation if construed narrowly as Patent Owner suggests, rather than requiring a mere capability. *See* Pet. Reply 18–20. Petitioner's argument that there would have been "nothing precluding" one to use McCabe's device in a particular manner does not address the salient issue—what McCabe was *designed* to do. *See Aspex Eyewear*, 672 F.3d at 1349.

Petitioner notes McCabe's silence regarding how a user holds its device, as well its size. *See* Pet. 46 ("While McCabe does not teach holding the handle as required by claim 1, McCabe's handle certainly has a structure that is *capable* of permitting the operator . . . to manipulate . . . ."); Pet. Reply 20. This silence, however, does not aid Petitioner's cause. Without any guidance in McCabe regarding how it is designed to be held or used, Petitioner is left with little to work with in support of its position that McCabe is designed to perform the claimed functions, assuming Petitioner had made that allegation. In addition, the lack of size information in McCabe undermines Petitioner's position that the structural similarity between McCabe and the device disclosed in the figures of the '412 patent

establishes that McCabe can be used in the same way as the device disclosed in the '412 patent. *See* Pet. 46–47 (citing Ex. 1004 ¶¶ 136–38); Pet. Reply 19. The '412 patent specification may not provide specific dimensions, but it describes a device having a size that allows a user to position the device with three fingers while manipulating a working device with a thumb or index finger of the same hand near an opening in the handle. *See*, *e.g.*, Ex. 1001, 4:62–5:3. Without size information regarding the thickness of McCabe's handle and distances necessary to reach the working device, those arguments and related declarant opinions are speculative. *See id.* Again, because Petitioner does not offer sufficient arguments or credible evidence that McCabe is anything more than "capable of" meeting the manipulating limitation, we are not persuaded that McCabe discloses the limitation.

Based on the foregoing, the explanations and supporting evidence presented by Petitioner are not sufficient to support a finding that either of claims 1 or 14 are anticipated by McCabe. Each of dependent claims 2, 4–7, 15, and 17–20 depends directly or indirectly from claims 1 and 14, and recite additional limitations. Because we determine that Petitioner has not established that independent claims 1 or 14 are unpatentable as anticipated by McCabe, we similarly find that dependent claims 2, 4–7, 15, and 17–20 are not anticipated for the same reasons.

Based on the complete record, we conclude that Petitioner has not established by a preponderance of the evidence that McCabe anticipates claims 1, 2, 4–7, 14, 15, and 17–20.

H. Ground 4 — Anticipation Based on Makower

Petitioner alleges that Makower anticipates claims 1, 2, 7, 14, 15, and 20. Pet. 19. With respect to claims 1 and 14, Petitioner relies on Makower's

disclosure and the Kesten and Levine Declarations in support of its allegation that Makower discloses every limitation of claims 1 and 14. *See* Pet. 53–60, 62–63; Ex. 1004, ¶¶ 158–86; Pet. Reply 20–25; Ex. 1018 ¶¶ 63–64. Petitioner also relies on photos and a video of a device allegedly similar to Makower's device. Pet. Reply 21; Ex. 1020; *see also* Pet. Reply 24 (citing videos relied on by Patent Owner at Exs. 1022–1023).

1. Overview of Makower

Makower discloses devices "for treating disorders of the ear, nose, throat, and paranasal sinuses" and "hand held devices having pistol type grips and other handpieces." Ex. 1009, Abstract. Makower's Figure 8A is reproduced below.

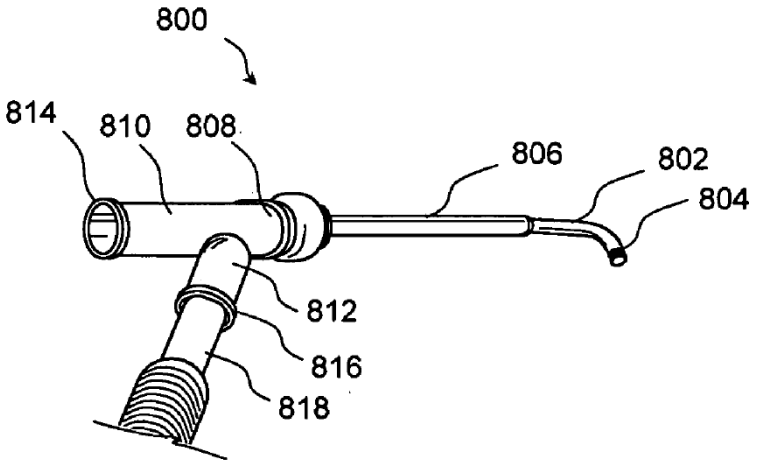


Figure 8A depicts guide catheter 800 having elongate tube 802 and branched or Y-connector 808. *Id.* ¶ 167. The proximal region of Y-connector 80 includes straight arm 810 and side arm 812. *Id.* The proximal end of straight arm 810 includes hub 814, which can be a female luer hub or rotating valve. *Id.* The proximal end of side arm 812 includes hub 816, which is attached to suction tube 818 to provide suction to guide catheter 800, and may include a rotating valve that adjusts the amount of suction. *Id.*

Guide catheter 800 may be used to provide suction or introduce devices into the anatomy. *Id.*

2. Discussion

a. Positioning and Manipulating Limitations

Petitioner relies on Makower's branched Y-connector as disclosing the claimed "handle" and hub 814 as disclosing the claimed "opening." Pet. 55. For the positioning limitation, Petitioner contends that Makower's structure allows an operator to position three fingers around the straight arm, while allowing the thumb and index finger to remain free. *Id.* at 57. To support this position, Petitioner relies on a hand drawing prepared by its expert, showing where the fingers would be located if held in this manner, and showing how the thumb and index finger remain free to manipulate a working device adjacent hub 214. *See id.*; Ex. 1004, ¶¶ 172–73. In its Reply, Petitioner further relies on a video and screenshot showing a device allegedly similar to that of Makower in use, with a thumb and index finger of the same hand free to manipulate the working device. Pet. Reply. 21 (citing Ex. 1020; Ex. 1021, 70:4–14). Petitioner also argues that because "Makower and [Figure 2 of the '412 patent] are structurally identical, Makower is necessarily capable of being held in the claimed manner." *Id.* at 22.

For the manipulating limitation, Petitioner contends that "Makower's device would be held by grasping the straight arm 810 with the pinky, ring, and middle fingers," allowing the thumb and index finger of the same hand to grasp the working device. Pet. 59 (citing Ex. 1004 ¶¶ 179–80). In its Reply, Petitioner argues that because "Makower allows a user to control the working device with the thumb and index finger, Makower anticipates the

claims." Pet. Reply 23. Petitioner also argues that Makower's support devices, which may interfere with performing the claimed function, are not required. *Id.* (citing Makower ¶ 139).

Patent Owner argues that Makower fails to disclose the positioning and manipulating limitations. PO Resp. 44–50. Regarding the positioning limitation, Patent Owner argues that Petitioner's evidence lacks adequate support, and the after-the-fact hand drawing and photos do not show how one of skill in the art would actually hold Makower's device. *Id.* at 45–48 (citing Ex. 1004 ¶¶ 172–173; Ex. 1009 ¶¶ 149, 239; Ex. 2020 ¶¶ 83, 85; Ex. 2021, 61:4–62:14, 74:18–76:3).[11] Regarding the manipulating limitation, Patent Owner argues that "capability" is not the correct construction, and Petitioner's expert opinion that "Makower can allegedly be held as claimed" is insufficient. *Id.* at 48–49. Patent Owner also argues that Makower discloses a support mechanism, as shown in Makower's Figure 2D, that prevents a surgeon from holding the guide catheter and manipulating the working device as required by the claims. *Id.* at 49–50 (citing Ex. 1009 ¶¶ 147, 149, 239; Ex. 2020 ¶¶ 87, 88).

[11] Patent Owner suggests throughout its Patent Owner's Response that Petitioner's "capability" argument is not only incorrect, but that inherency, in this context, requires Petitioner to show that the prior art such as Makower's device is "necessarily or always" held in the claimed manner. *See, e.g.*, PO Resp. 45–46. We do not adopt that interpretation of the relevant case law. The fact that Makower or the other prior art may be held in a manner not required by the claims would not automatically doom Petitioner's grounds. Petitioner could have shown that the prior art was designed to perform the functions required by the claim limitations even if those devices could have been used in other ways.

We are not persuaded by Petitioner's arguments and evidence that Makower discloses either the positioning limitation or the manipulating limitation because Petitioner does not even allege in its Petition or Petitioner's Reply that Makower's device is designed to perform the functions required by those claims. *See* Pet. 57, 59; Pet. Reply 20–24. Instead, even in its Reply, Petitioner repeatedly asserts that "Makower only needs to be capable of being held in the claimed manner, regardless of whether it would be desirable or not." Pet. Reply 22–23; *see also id.* at 22 ("Makower is necessarily capable of being held in the claimed manner."). Petitioner broadly asserts on page 10 of its Reply, that "[e]ven if these terms are somehow construed narrowly, the cited prior art is necessarily 'designed' or 'configured' to be held in the claimed manner, and would still inherently anticipate the claims." Pet. Reply 10. That broad assertion early in Petitioner's Reply, however, does not convert all of its more specific "capability" arguments regarding the prior art references into an argument, with supporting evidence, that the prior art is "designed to" perform the claimed functions. Further, even if we were to infer the assertion that Makower is designed to perform the positioning and manipulating limitations, Makower is either silent on how a user may position its device or manipulate its working device, or it discloses a support mechanism (in Figure 2D) that undermines a reading of Makower consistent with these limitations. *See* PO Resp. 49. Under these circumstances, we find that Petitioner has failed to provide sufficient arguments and credible evidence establishing that Makower discloses the positioning or manipulating limitations of claims 1 or 14.

b. Suction Control Limitation

Regarding the suction control limitation, Petitioner alleges that "Makower teaches that hub 816 can comprise a rotating hemostasis valve 'to adjust the amount of suction.'" Pet. 60 (quoting Ex. 1009 ¶ 167). Petitioner further argues that hub 816 "would be controlled by one of a thumb or finger" and that "hub 814 . . . can also be used to control, by one of the thumb or index finger, an amount of suction." *Id.* at 60 (citing Ex. 1004 ¶¶ 181–85). In its Reply, Petitioner stresses that the claims do not require simultaneous control of the suction and guide catheter, and the user could simply rotate Makower's hub to control suction. Pet. Reply 24 (citing Ex. 1018 ¶ 63). Petitioner also asserts that controlling any amount of suction satisfies the claim, and concludes by asserting that Patent Owner's contentions to the contrary prove that Makower "is capable of being used in the claimed manner." *Id.* at 24–25.

Patent Owner argues that Petitioner's allegations lack support, because Makower does not even disclose finger placement and the drawings showing Makower's device in use do not even show control of suction. PO Resp. 50–51. Patent Owner also argues that Makower's structure "is not capable of controlling suction by one of the thumb or index finger of the same hand that holds Y-connector and it certainly was not configured to do so for these same reasons." *Id.* at 51. Patent Owner takes issue with Petitioner's expert, arguing that Mr. Kesten fails to show "how a surgeon could maneuver his/her index finger and thumb to hubs 814 and 816 to control suction." *Id.* (citing Ex. 1004 ¶¶ 181–82, 184; Ex. 1009 ¶ 167; Ex. 2020 ¶ 92). Patent Owner also asserts that it is not even possible to control suction via Makower's hub 816. *Id.* at 52 n.9.

As discussed above, Petitioner does not even assert explicitly that Makower discloses the suction control limitation under the proper construction. Instead, Petitioner continues to rely upon the "capable of" construction we rejected above. *See id.* at 25. To the extent that Makower discloses how it was designed to be used, the suggested use of a support potentially undermines any assertion that one could control suction with the thumb or index finger of the same hand that positions the guide catheter and manipulates the working device. *See* Ex. 1009 Fig. 2D; PO Resp. 49. Further, Makower itself identifies Makower's hub 816 as the hub used to control suction. *See* Ex. 1009 ¶ 167. Because Makower expressly discloses control of suction via hub 816, not hub 814, Petitioner's allegations fail to explain sufficiently how Makower is designed to control suction through hub 816 if held with the hand as Petitioner proposes in its drawings and photos. *See* Ex. 1009 ¶ 167; Pet. 60 (noting that Makower discloses control of suction via hub 816); Ex. 1004 ¶ 181.

While we agree with Petitioner that claims 1 and 14 do not require *simultaneous* control of the position of the guide catheter, manipulation of the working device, and suction control, Petitioner must still establish that Makower discloses that it is *designed* to perform the suction control function. In the context of Makower, that requires showing the use of the thumb or index finger on hub 816, which Makower discloses as the hub used to control suction. Ex. 1009 ¶ 167. Petitioner's arguments and evidence do not establish adequately that Makower was designed to be used in that manner. Moreover, its Reply does not even refer to hub 816 or show it in use in photographs, and instead generally alleges that "the hub" could be rotated to control suction. Pet. Reply 24 (citing Ex. 1018 ¶ 63 (referring to

"Makower's hub" and seemingly referring to hub 814, not hub 816; focuses on what a user "could" do). Based on the complete record, we find that Petitioner has failed to establish that Makower discloses the suction control limitation of claims 1 or 14.

Based on the foregoing, we find that Petitioner has not provided sufficient arguments and credible evidence establishing by a preponderance of the evidence that Makower discloses the suction control limitation of claims 1 and 14.

Based on the complete record, we conclude that Petitioner has not established by a preponderance of the evidence that Makower anticipates claims 1 and 14.

c. Claims 2, 7, 15, and 20

Each of claims 2, 7, 15, and 20 depend directly from claims 1 and 14, and recite additional limitations. Because we conclude that Petitioner has not established by a preponderance of the evidence that independent claims 1 or 14 are unpatentable as anticipated by Makower, we similarly conclude that dependent claims 2, 7, 15, and 20 are not anticipated for the same reasons.

4. Summary

Based complete record, we conclude that Petitioner has not established by a preponderance of the evidence that Makower anticipates claims 1, 2, 7, 14, 15, and 20.

I. Ground 5 — Obviousness Based on Makower and Jones

With respect to Ground 5, Petitioner alleges obviousness of claims 4–6 and 17–19, which depend directly or indirectly from claims 1 and 14, based on Makower and Jones. Pet. 63–66. Petitioner does not rely on Jones

with respect to these dependent claims in a manner that addresses the deficiencies based on Makower alone noted above with respect to claims 1 and 14. *Id.*; Pet. Reply 25–26. Accordingly, we are not persuaded that Petitioner has established by a preponderance of the evidence that claims 4–6 and 17–19 are unpatentable as obvious based on Makower and Jones.

J. Patent Owner's Motion to Exclude

Patent Owner seeks to exclude certain paragraphs from Petitioner's expert reports and a video. Paper 29, 2. All of the evidence relates to Petitioner's attempt to show that some actual devices—which allegedly correspond to structures in the prior art—can be used to meet the functional requirements of the claim. *See, e.g.*, Pet. Reply 21.

After considering this evidence and testimony purportedly in Petitioner's favor, we have concluded, as discussed above, that Petitioner has not established by a preponderance of the evidence that any of the claims are unpatentable. Accordingly, whether this testimony and evidence is excluded would have no effect on the outcome of this proceeding or on any aspect of the present Decision. As a result, we *dismiss* Patent Owner's Motion to Exclude as moot.

III. CONCLUSION

Having considered the entire record before us, we determine that Petitioner has not shown by a preponderance of the evidence that any of claims 1–7 and 14–20 are unpatentable.

IV. ORDER

It is

ORDERED that claims 1–7 and 14–20 are not held unpatentable based on the record in this proceeding;

FURTHER ORDERED that Patent Owner's Motion to Exclude (Paper 29) is *dismissed* as moot; and

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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