

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*.

DECISION
Instituting *Inter Partes* Review
37 C.F.R. § 42.108

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.”). Institution of an *inter partes* review is authorized by statute only when “the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a); *see* 37 C.F.R. § 42.108. For the reasons set forth below, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner will prevail in showing the unpatentability of claims 1–7 and 14–20. Accordingly, we institute an *inter partes* review as to those claims.

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, 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.).

B. The ’412 Patent

The ’412 patent is titled “APPARATUS, SYSTEM AND METHOD FOR MANIPULATING A SURGICAL CATHETER 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:

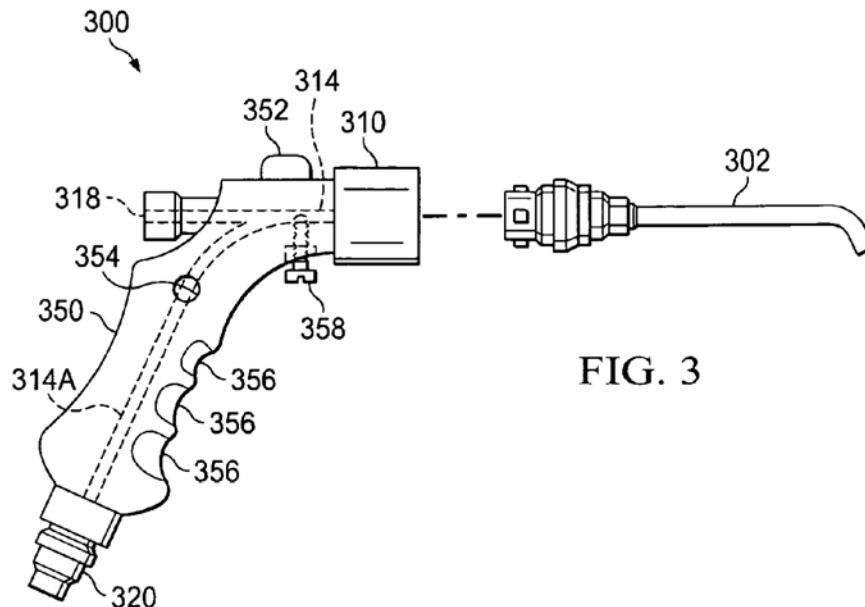


FIG. 3

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. The Prior Art

Petitioner relies on the following prior art references:

Reference	Date	Exhibit No.
U.S. Patent No. 8,747,389 B2 issued to Goldfarb et al. (“Goldfarb”)	June 10, 2014	1005
U.S. Patent No. 5,562,640 issued to McCabe et al. (“McCabe”)	Oct. 8, 1996	1006
U.S. Patent No. 4,915,691 issued to Jones et al. (“Jones”)	Apr. 10, 1990	1007
U.S. Patent Pub. No. 2006/0063973 A1 issued to Makower et al. (“Makower”)	Mar. 23, 2006	1009

E. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–7 and 14–20 based on the following grounds (Pet. 19):

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

II. ANALYSIS

A. *Proposed Denial Under 35 U.S.C. § 325(d)*

As an initial matter, we consider Patent Owner’s argument that we reject the Petition because it raises “the same or substantially the same prior art and arguments that were already considered and rejected by the Patent Office during prosecution of the ’412 patent.” Prelim. Resp. 16. Under § 325(d), in exercising our discretion to reject the Petition, we “may take into account whether . . . the same or substantially the same prior art or arguments were presented to the Office.” 35 U.S.C. § 325(d). Here, Patent Owner presents evidence that two of the four references Petitioner relies upon (Goldfarb and Makower), were before the Examiner during prosecution of the ’412 patent. Prelim. Resp. 16–17. Patent Owner acknowledges, however, that the Examiner did not rely on Goldfarb to reject any claims during prosecution, and Patent Owner does not explain the relevance of the Examiner’s rejection involving Makower of certain dependent claims to the issues raised by the Petition. *See id.* Under these circumstances, we are not persuaded that the issues raised by the Petition are so similar to those considered during prosecution of the ’412 patent that we should exercise our discretion to deny institution of the Petition, in whole or in part, under 35 U.S.C. § 325(d).

B. *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 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. “*guide catheter*,” “*handle coupling*,” “*coupled*,” and “*structure*”

Petitioner proposes explicit constructions for several terms, including “*guide catheter*,” “*handle coupling*,” “*coupled*,” and “*structure*.” Pet. 13–16. Patent Owner contends that none of these terms requires construction. Prelim. Resp. 10. At this point in the proceedings, we need not provide an explicit construction for the claim terms identified by Petitioner 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.”).

2. “*configured to*” and “*adapted to*”

Petitioner proposes a number of additional implicit constructions as part of its contentions regarding the prior art. For example, as to functional language such as “*configured to*” and “*adapted to*,” Petitioner argues that these limitations merely recite intended uses and “therefore cannot be used to differentiate the claimed apparatus from the prior art.” Pet. 24; *see also id.* at 28, 43, 46, 57, 59.

Patent Owner counters that Petitioner cannot disregard these limitations. Prelim. Resp. 10–11, 22–23. To the extent that Petitioner contends that the limitations containing “*configured to*” and “*adapted to*” language have no limiting effect at all on the claims, we disagree. Petitioner does not support its assertion with any authority or persuasive argument

suggesting that such phrases must be given no weight as a matter of claim construction or in the analysis of the prior art. Pet. 24–25.

Petitioner also argues 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. Petitioner does not set forth a specific construction for “configured to” or “adapted to,” and seems to take 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., mere capability to perform the claimed function suffices. *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”). Patent Owner does not directly address this issue, nor does Patent Owner argue that these limitations require more than a structure that is capable of performing the claimed functions. Prelim. Resp. 9–11.

For purposes of this decision, we will apply the implicit construction used by Petitioner and construe the “configured to” and “adapted to” limitations to require structure that is capable of performing the claimed functions. We invite both parties to address this issue further during the trial phase. *See, e.g., In re Man Machine Interface Techs. LLC*, 882 F.3d 1282, 1286 (Fed. Cir. 2016) (noting that “‘adapted to’ generally means ‘made to,’ ‘designed to,’ or ‘configured to,’ though it can also be used more broadly to mean ‘capable of’ or ‘suitable for’”); *see also In re Gianelli*, 739 F.3d 1375, 1379 (Fed. Cir. 2014); *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1349 (Fed. Cir. 2012).

C. Person of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art “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.” Pet. 12. Patent Owner argues that Petitioner’s definition “fails for three reasons”: (1) it excludes the inventor, Dr. Albritton; (2) “it ignores the medical education and training necessary to understand the use” of surgical instruments; and (3) it improperly equates “surgical instruments” generally with experience related to laparoscopic and endoscopic instruments. Prelim. Resp. 7. Patent Owner proposes the following definition for a person of ordinary skill in the art:

(1) a doctor of medicine (MD) and at least 2 years of experience with laparoscopic or endoscopic surgical procedures; or (2) a bachelor’s degree in mechanical engineering or a related discipline and at least four years of experience designing laparoscopic or endoscopic surgical instruments, while working in consultation with a medical doctor familiar with use of laparoscopic or endoscopic surgical instruments.

Prelim. Resp. 6–7.

Our determination does not turn on the differences between these definitions. In particular, we are not convinced, based on the current record, that a person of ordinary skill in the art must have at least 2 years of experience with laparoscopic or endoscopic surgery or instruments. We agree with Patent Owner, however, that a person of ordinary skill in the art, in this case, should include the inventor. For purposes of this decision only, we adopt Petitioner’s proposed definition, with the addition of Patent Owner’s identification of the inventor within its scope. Accordingly, for purposes of this decision, 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. Additionally, we note 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 Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995).

Patent Owner contends that Petitioner's expert Mr. Kesten fails to meet its proposed level of ordinary skill in the art, but does not argue that Mr. Kesten fails to meet Petitioner's proposed level of ordinary skill in the art. Prelim. Resp. at 11–14. Because we have adopted Petitioner's proposed level of ordinary skill as part of our own at this stage, we decline Patent Owner's request to disqualify Mr. Kesten as an expert at this time.

D. Ground 1 – Anticipation Based on Goldfarb

Petitioner asserts that Goldfarb anticipates claims 1–5, 7, 14–18, and 20. Pet. 19.

1. Principles of Law

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) (citing *In re Petering*, 301 F.2d 676, 681 (CCPA 1962)).

2. 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:

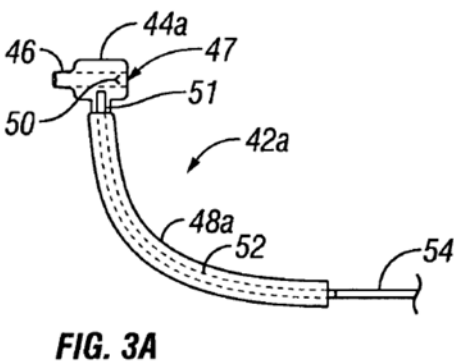


FIG. 3A

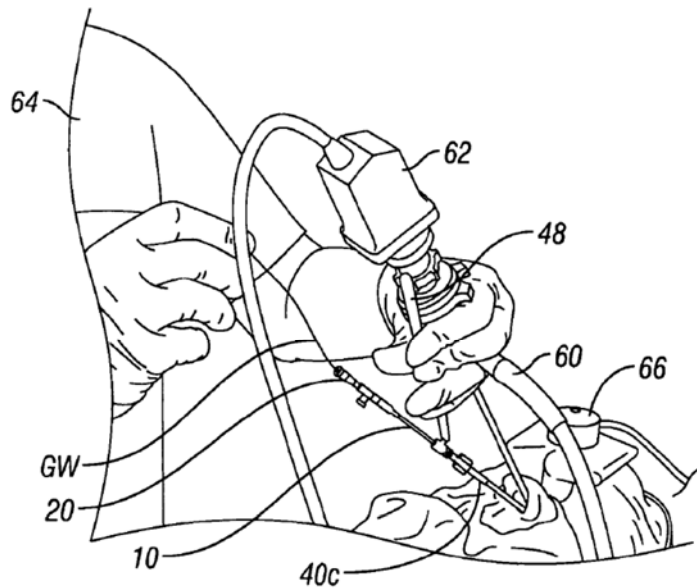


FIG. 8A

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 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.

3. Discussion

a. Claims 1 and 14

With respect to claims 1 and 14, Petitioner relies on Goldfarb’s disclosure and the expert declaration of Randy Kesten in support of its allegation that Goldfarb discloses every limitation of claims 1 and 14. *See* Pet. 20–32, 35–36; Ex. 1004 (“Kesten Declaration”), ¶¶ 61–89. For example, Petitioner relies on Goldfarb’s guide catheter 40c as disclosing the claim element of a “guide catheter insertable through an external body passage,” and Goldfarb’s handle 42 and lumen 47 as disclosing the claim element of a “handle having a handle opening.” Pet. 20–22. Additionally, claims 1 and 14 recite that the handle structure is “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”). Ex. 1001, 5:65–67, 7:12–15. Petitioner notes the similarity in structure between the handle shown in Goldfarb’s Figure 3A and in the ’412 patent’s Figure 3, and argues that Goldfarb’s handle is configured to allow the claimed control. *Id.* at 25–26. Petitioner also relies on Goldfarb’s description of controlling the guide

catheter using the handle and the malleability of the handle's shape. *Id.* at 26 (citing Ex. 1005, 10:54–57, 10:63–67, Abstract). Relying on the testimony of its declarant, Petitioner asserts that “[a] POSA would also recognize that Goldfarb’s one-handed handle design is meant to be held by the pinky, ring, and middle fingers positioned around the handle 42 to control movement of the guide catheter 40a-40d coupled thereto, thus leaving the index finger and thumb free to perform other functions, such as controlling suction or the working device.” *Id.* (citing Ex. 1004, ¶¶ 73–77). On this record, Petitioner demonstrates sufficiently how the disclosure in Goldfarb satisfies these claim limitations.

In Patent Owner’s Preliminary Response, Patent Owner disputes specifically whether Goldfarb discloses two claim limitations. Prelim. Resp. 18–26. First, claims 1 and 14 further 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 again 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).

Patent Owner argues that Goldfarb fails to disclose a handle structure that meets the manipulating limitation. Prelim. Resp. 19. Patent Owner contends that Goldfarb merely discloses one-handed operation of the *endoscope* and guide catheter, not the *working device* and guide catheter as required by the claim. Prelim. Resp. 19–20. According to Patent Owner, Goldfarb discloses the use of two hands to position the guide catheter and working device. *Id.* at 21 (citing Ex. 1005, 10:67–11:2).

Although Goldfarb’s figures disclose two different hands for controlling the guide catheter and working device as Patent Owner asserts, Petitioner’s allegations are not so limited. On the present record, Petitioner demonstrates sufficiently how Goldfarb’s handle is capable of performing the claimed function due to the structural similarities between the structure in the ’412 patent and Goldfarb’s handle. Pet. 29–30. Indeed, Petitioner demonstrates sufficiently how one using Goldfarb’s device “could” position the thumb and index finger adjacent to the opening to grasp the working device, such as a guidewire. *Id.* at 30.

Thus, based on the current record, Petitioner demonstrates sufficiently that Goldfarb discloses structure at least capable of permitting the operator to use a thumb and index finger to manipulate a working device immediately adjacent the opening of the handle.

Second, claims 1 and 14 also require “control, by one of the thumb or index finger, an amount of suction coupled to the distal opening of the

lumen” (“the controlling 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).

Patent Owner raises arguments with respect to the controlling limitation that are similar to those discussed above with respect to the manipulating limitation. Prelim. Resp. 24–25. Specifically, Patent Owner contends that the claim requires the same thumb and index finger to both manipulate the working device and control suction, and Goldfarb discloses two different hands to perform these tasks. *Id.* Patent Owner’s contentions again fail to address adequately whether Goldfarb discloses “a hole that can be covered by the thumb of a user to control suction” as Petitioner alleges. *See* Pet. 31. Goldfarb discloses a pinch valve or hole in a handle to control suction. Ex. 1005, 11:6–12, 11:33–34. Once an operator uses a single hand to control the guide catheter and manipulate a working device with a thumb and index finger, nothing in Goldfarb prohibits use of that same thumb or index finger from selectively covering the hole to control suction. Based on the current record, Petitioner demonstrates sufficiently that Goldfarb discloses structure at least capable of permitting the operator to use a thumb or index finger to control an amount of suction.

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. Patent Owner does not otherwise challenge Petitioner’s explanations and supporting evidence as to these claims. Prelim. Resp. 25. Petitioner explains sufficiently how the disclosure in Goldfarb satisfies the limitations recited in these claims. Pet. 32–35, 36.

4. Summary

Based on the evidence in the present record, Petitioner demonstrates sufficiently, for purposes of this decision, a reasonable likelihood of success in its challenge to claims 1–5, 7, 14–18, and 20 as anticipated by Goldfarb.

E. Ground 2 – Obviousness Based on Goldfarb

Petitioner alleges claims 6 and 19 are unpatentable based on Goldfarb under 35 U.S.C. § 103(a). Pet. 36–37. We are persuaded that Petitioner has established a reasonable likelihood of prevailing on its asserted ground as to claims 6 and 19 for the reasons explained below.

1. Principles of Law

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. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966). We analyze this ground based on obviousness in accordance with the above-stated principles.

2. Discussion

Claims 6 and 19 both require a handle coupling “adapted to allow movement of the source of suction relative to the handle.” Ex. 1001, 6:28–30, 8:19–21. Petitioner alleges that rotating “female luer locks” provide the claimed functionality, were well known in the art, and it would have been obvious to attach either Goldfarb’s guide catheter to handle 42 or the suction tube to Goldfarb’s handle 42 “to allow movement of the source of suction relative to the handle.” Pet. 37. According to Petitioner, one of ordinary skill in the art “would have recognized that such a configuration would prevent kinking or twisting of the suction tube or would otherwise avoid other interference with use of the device, providing the requisite motivation to employ the same in combination with Goldfarb.” *Id.* (citing Ex. 1004, ¶¶ 107–111).

Patent Owner argues that Petitioner’s allegations are too conclusory. Prelim. Resp. 26–27. Patent Owner also argues that “Goldfarb teaches away from controlling suction with the same hand that manipulates the working device,” and therefore “one of skill in the art would not modify Goldfarb to arrive at the invention as recited in claims 6 and 19.” *Id.* at 28.

At this juncture in the proceeding, Petitioner demonstrates sufficiently that the proffered rationale for adding a rotating coupling to Goldfarb is supported by rational underpinnings. Namely, that the addition of such known couplings that allow the claimed relative movement “would prevent kinking or twisting of the suction tube or would otherwise avoid other

interference with use of the device.” Pet. 37. Further, although Goldfarb may teach a different type of one-handed operation involving the endoscope and guide catheter in a single hand, we are not convinced that such a disclosure teaches away from other potential one-handed operations involving the guide catheter and working device.

We are satisfied, on the present record, that Petitioner demonstrates sufficiently a reasonable likelihood that it would prevail in its challenge that claims 6 and 19 are unpatentable over Goldfarb under 35 U.S.C. § 103.¹

F. Ground 3 – Anticipation Based on McCabe

Petitioner alleges that McCabe anticipates claims 1, 2, 4–7, 14, 15, and 17–20.

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.*

¹ Patent Owner contends that certain “objective indicia” support the nonobviousness of the claims. *See* Prelim. Resp. 49–54. Patent Owner argues that the ’412 patent “met a long felt, but unresolved need, and was subsequently praised and copied by others.” *Id.* at 50. Petitioner did not address “objective indicia” and Patent Owner’s evidence and argument are currently untested. Rather than make any preliminary findings on an incomplete record, we invite the parties to further address and submit evidence and argument on these issues during the trial phase.

McCabe's Figure 9 is reproduced below.

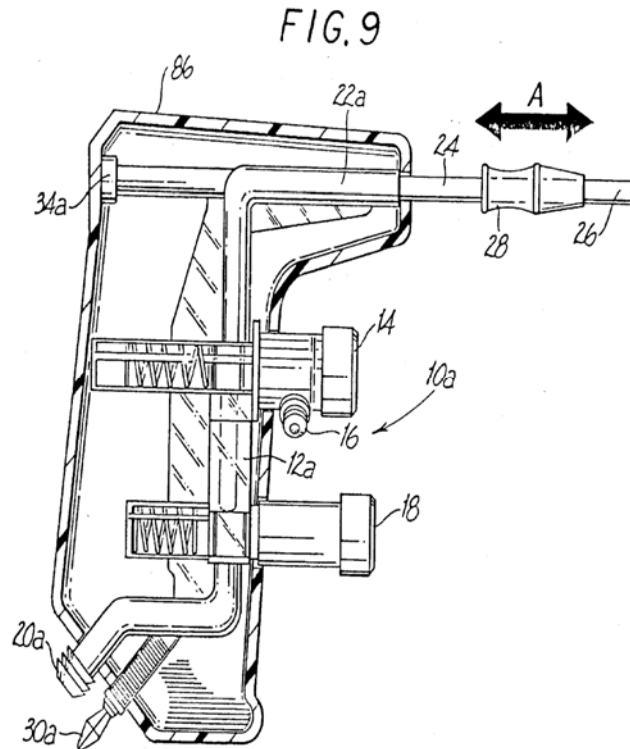


Figure 9 depicts “surgical instrument 10a enclosed in housing 86.” *Id.* at 6:45–46. Coupling member 22a engages body portion 12a and single lumen cannula 24. *Id.* at 6:48–49. Optical fiber port 34a provides direct axial communication with single lumen cannula 24. *Id.* at 6:50–51.

2. Discussion

With respect to claims 1 and 14, Petitioner relies on McCabe's disclosure and the Kesten Declaration in support of its allegation that McCabe discloses every limitation of claim 1. *See* Pet. 38–48, 51–52; Ex. 1004, ¶¶ 112–142. For example, 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 notes the similarity in structure between the handle shown in McCabe's Figure 9 and in the '412 patent's Figure 3, which is configured to allow the

claimed positioning. *Id.* at 45–47. 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 manipulated 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 ¶ 136–138). On this record, Petitioner demonstrates sufficiently how the disclosure in McCabe satisfies these claim limitations.

In Patent Owner’s Preliminary Response, Patent Owner disputes specifically whether Goldfarb discloses two claim limitations. Prelim. Resp. 28–38. First, claims 1 and 14 recite, in relevant part, “a guide catheter insertable through an external body passage of a subject” (“guide catheter limitation”). Ex. 1001, 5:58–59, 7:6–7. Petitioner relies on McCabe’s single lumen cannula 24 as disclosing the guide catheter limitation. Pet. 39. Patent Owner argues that McCabe fails to disclose the guide catheter limitation because McCabe discloses a device “insertable through an incision into an **internal** body passage . . . after the body is ‘penetrated by a trocar assembly.’” Prelim. Resp. at 29. Based on the current record, we are not persuaded by Patent Owner’s argument. Patent Owner suggests that “insertable through an external body passage” excludes passing through the body via an incision, but nothing in the claim language suggests that claims are so limited. Patent Owner relies on McCabe’s Figure 11 for support, but that figure shows the device inserted through body wall 90, which seems to

support Petitioner’s position rather than Patent Owner’s. *See id.* at 30. To the extent that Patent Owner relies on the presence of cannula 88 inserted prior to the device, the claims again do not indicate that “insertable through an external body passage” precludes insertion via another device such as cannula 88, and Patent Owner has not proposed a construction to that effect.

Second, Patent Owner argues that McCabe fails to disclose the manipulating limitation. *Id.* at 30–34. According to Patent Owner, Petitioner admitted McCabe does not disclose this limitation when Petitioner stated that “McCabe does not teach holding the handle as required by claim 1.” *Id.* at 31. Patent Owner also argues that McCabe fails to enable the limitation without any disclosure regarding how the handle is used. *Id.* These arguments fail to acknowledge Petitioner’s assertion that despite the lack of express disclosure in McCabe regarding its use, McCabe nevertheless discloses structure at least *capable* of permitting the operator to place the thumb and index finger adjacent port 34a to manipulate a working device. *See* Pet. 46. This does not amount to an admission of no anticipation, and Patent Owner’s enablement argument does not take into account that disclosure of a structure merely capable of performing the claimed function satisfies the claim limitation.

Patent Owner further contends that Mr. Kesten lacks the requisite experience to opine on how McCabe’s device would be used, and that “placement of valve members 14 and 18 in McCabe . . . preclude a user from controlling the position of the guide catheter and manipulating the working device with the same hand.” Prelim. Resp. at 32–33. As stated above, we are not rejecting Mr. Kesten’s declaration because he is not one of ordinary skill in the art, nor do we reject out of hand Mr. Kesten’s assertion that

McCabe's device is capable of being used in the manner claimed. Patent Owner submits its own expert declaration to support the argument that McCabe's structure prevents the claimed functionality. *See id.* at 32–33; Ex. 2006 (Declaration of Dr. Douglas K. Holmes), ¶¶ 23–24. We view the conflicting expert testimony on this central issue as creating a genuine issue of material fact, requiring us to view the testimony in the light most favorable to Petitioner for purposes of this decision. *See* 37 C.F.R. § 42.108(c). Accordingly, we decline to deny institution based on Patent Owner's argument with respect to this limitation.

Based on the foregoing, the explanations and supporting evidence presented by Petitioner sufficiently demonstrate that claims 1 and 14 are anticipated by McCabe.

Each of dependent claims 2, 4–7, 15, and 17–20 recites additional limitations. We determine at this juncture of the proceeding that the explanations and supporting evidence presented by Petitioner sufficiently demonstrate how dependent claims 2, 4–7, 15, and 17–20 are anticipated by McCabe.

Thus, based on the arguments and evidence of record, Petitioner demonstrates sufficiently, for purposes of this decision, a reasonable likelihood that it would prevail with respect to its contention that claims 1, 2, 4–7, 14, 15, and 17–20 of the '412 patent would have been anticipated by McCabe.

G. Ground 4 – Anticipation Based on Makower

Petitioner alleges that Makower anticipates claims 1, 2, 7, 14, 15, and 20.

1. Overview of Makower

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

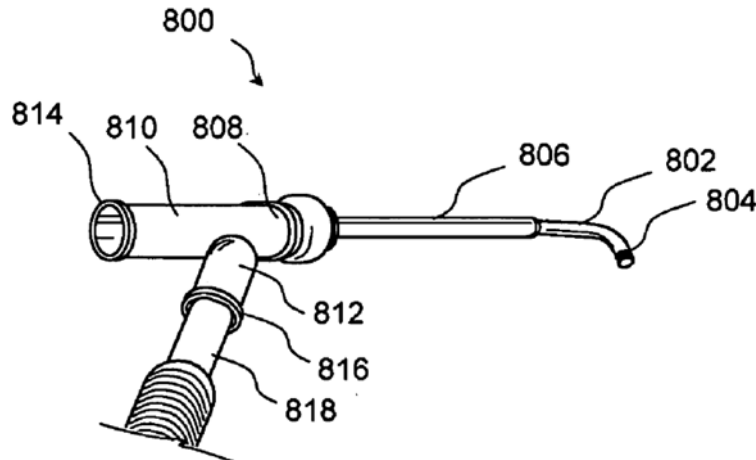


Figure 8A depicts guide catheter 800 having elongate tube 802 and branched or Y-connector 808. *Id.* at ¶ 167. The proximal region of Y-connector 80 includes straight arm 810 and side arm 812. *Id.* The proximal end of straight arm 810 includes hub 814, which can be a female luer hub or rotating valve. *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

With respect to claims 1 and 14, Petitioner relies on Makower’s disclosure and the Kesten Declaration in support of its allegation that Makower discloses every limitation of claims 1 and 14. *See* Pet. 53–60,

62–63; Ex. 1004, ¶¶ 158–186. For example, 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 controlling 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, ¶¶ 172–173; *see also* Pet. 59.

Patent Owner argues that Makower fails to disclose the controlling, manipulating, and “control[ling] . . . an amount of suction” limitations. Prelim. Resp. 38–43. Patent Owner’s arguments with respect to Makower are similar to those discussed above with respect to McCabe—i.e., 1) Makower fails to discuss how to hold its Y-connector or control suction; 2) Makower’s lack of disclosure renders it non-enabling; 3) Mr. Kesten is not qualified to opine on the issue; and 4) Patent Owner’s experts contradict Mr. Kesten’s opinions. *See id.*

For similar reasons to those discussed above in the context of McCabe, we are not persuaded by Patent Owner’s arguments. Instead, we are more persuaded that the arguments in the Petition, in combination with Mr. Kesten’s opinions, demonstrate sufficiently that Makower discloses the limitations recited in claim 1. Makower’s lack of express teaching as to how its structure is held is not fatal because Petitioner shows sufficiently that the structure can be held and operated in the manner required by claims 1 and 14. *See* Pet. 57, 59; Ex. 1004, ¶¶ 172, 173, 179, 180–184. Moreover, at this

stage, Patent Owner's expert declarations disagreeing with Mr. Kesten's opinions create genuine issues of fact that must be viewed in a light most favorable to Petitioner. *See* 37 C.F.R. § 42.108(c).

Based on the foregoing, the explanations and supporting evidence presented by Petitioner sufficiently demonstrate that claims 1 and 14 are anticipated by Makower.

Each of dependent claims 2, 7, 14, 15, and 20 recite additional limitations. We determine at this juncture of the proceeding that the explanations and supporting evidence presented by Petitioner sufficiently demonstrate how dependent claims 2, 4–7, 15, and 17–20 are anticipated by McCabe.

Thus, based on the arguments and evidence of record, Petitioner demonstrates sufficiently, for purposes of this decision, a reasonable likelihood that it would prevail with respect to its contention that claims 1, 2, 7, 14, 15, and 20 of the '412 patent would have been anticipated by Makower.

H. Ground 5 – Obviousness Based on Makower and Jones

With respect to Ground 5, Petitioner alleges obviousness of claims 4–6 and 17–19 based on Makower and Jones. Pet. 63–66. Claim 4 depends from claim 1 and further requires “a second opening in the handle adapted to permit control of the amount of suction coupled to the distal opening of the lumen.” Ex. 1001, 6:21–24. As discussed above, Petitioner has established a reasonable likelihood of success that Makower discloses all of the limitations of claim 1. Petitioner alleges that using “opening or vents to control the amount of suction were well known to a [person of ordinary skill in the art] and common in the field.” Pet. 63. Petitioner also contends that

Jones discloses such an opening in the form of thumb control hole 28 that “may be partially closed off with one’s thumb or fully closed off to vary the amount of suction that is applied through the catheter 11.” *Id.* at 64 (quoting Ex. 1007, 4:35–38). According to Petitioner, Jones discloses the limitation required by claim 4, the second “opening,” as well as the reason for the modification, “to selectively control the suction with a single hand.” *Id.* at 65. Patent Owner repeats arguments similar to those with respect to Ground 2—that Mr. Kesten is not qualified to opine on obviousness issues and Makower teaches away from the claimed single-handed operation.

Based on our review of the current record including Makower, Jones, the Petition, and Kesten Declaration, we conclude that Petitioner has shown that the combination of Makower and Jones discloses all of the limitations of claim 4 and Petitioner provided an adequate rationale for the proposed modification. We have considered Patent Owner’s additional arguments against the combination of Makower and Jones and we are not persuaded that institution should be denied for the reasons stated by Patent Owner. *See* Prelim. Resp. 45–48.²

Based on the foregoing, the explanations and supporting evidence presented by Petitioner sufficiently demonstrate that claim 4 is unpatentable over Makower and Jones.

Each of dependent claims 5, 6, and 17–19 recite additional limitations. Patent Owner does not otherwise challenge Petitioner’s explanations and

² As stated above, Patent Owner contends that certain “objective indicia” support the nonobviousness of the claims. *See* Prelim. Resp. 49–54; *supra* note 1. The parties are free to submit evidence and argument on these issues during the trial phase.

supporting evidence as to these claims. Prelim. Resp. 45–49. We determine at this juncture of the proceeding that the explanations and supporting evidence presented by Petitioner sufficiently demonstrate how dependent claims 5, 6, and 17–19 are unpatentable over Makower and Jones.

Thus, based on the arguments and evidence of record, Petitioner demonstrates sufficiently, for purposes of this decision, a reasonable likelihood that it would prevail with respect to its contention that claims 4–6 and 17–19 of the '412 patent would have been obvious and unpatentable over Makower and Jones.

III. CONCLUSION

Having evaluated the Petition, its underlying supporting evidence, and Patent Owner's Preliminary Response, we determine that Petitioner has shown a reasonable likelihood of success in its challenge to claims 1–7 and 14–20 as set forth in the Petition and discussed above.

At this stage of the proceeding, the Board has not made a final determination as to the construction of any claim term or the patentability of claims 1–7 and 14–20 of the '412 patent.

IV. ORDER

It is ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted to determine whether claims 1–7 and 14–20 are unpatentable based on the statutory grounds of anticipation under 35 U.S.C. § 102 and obviousness under 35 U.S.C. § 103 as asserted in the Petition and identified in section I.E. above;

FURTHER ORDERED that *inter partes* review is not instituted in this proceeding on any other grounds; 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. The trial will commence on the entry date of this decision.

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