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Paper No. 16
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AURIS HEALTH, INC.,
Petitioner,

v.

INTUITIVE SURGICAL OPERATIONS, INC.,
Patent Owner.

IPR2019-01173
Patent No. US 8,801,601 B2

Before ULRIKE W. JENKS, TINA E. HULSE, and JAMES A. WORTH, Administrative Patent Judges.

JENKS, *Administrative Patent Judge.*

DECISION

Granting Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

Auris Health Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–18 of Patent No. US 8,801,601 B2 (Ex. 1001, "the '601 patent"). Paper 1 ("Pet."). Intuitive Surgical Operations, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 8 ("Prelim. Resp.").

We have authority, acting on the designation of the Director, to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). *Inter partes* review may not be instituted unless "the information presented in the petition filed under section 311 and any response filed under section 313 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). The Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

For the reasons set forth below, upon considering the Petition and supporting evidence of record, we determine that the information presented in the Petition establishes a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims. Accordingly, we institute *inter partes* review on all of the challenged claims based on the all of the grounds identified in the Petition.

Our findings of fact and reasoning discussed below are based on the evidentiary record developed thus far, and made for the sole purpose of determining whether the Petition meets the threshold for initiating review. This decision to institute trial is not a final decision as to the patentability of

any challenged claim or the construction of any claim limitation. Any final decision will be based on the full record developed during trial.

A. Real Parties-in-Interest

Petitioner identifies itself, Ethicon, Inc., and Johnson & Johnson as real parties-in-interest to this proceeding. Pet. 1. Patent Owner identifies itself and Intuitive Surgical, Inc. as real parties-in-interest. Paper 4, 1.

B. Related Proceedings

Petitioner identifies that the '601 patent has been asserted in: *Intuitive Surgical, Inc. v. Auris Health, Inc.*, Action No. 18-1359-MN (D. Del.) (pending). Pet. 1; Paper 4.

C. The '601 Patent (Ex. 1001)

The '601 patent issued on Aug. 12, 2014 from Application No. 13/678,917 ("the '917 application"), filed Nov. 16, 2012, which claims priority to U.S. Application No. 12/411,515, filed on Mar. 26, 2009, now U.S. Patent No. 8,337,397.

The '601 patent is titled "Method and System for Providing Visual Guidance to an Operator for Steering a Tip of an Endoscopic Device Toward One or More Landmarks in a Patient." Ex. 1001, (54). The '601 patent discloses an endoscope, a medical device that is inserted into the body and allows a physician to diagnose problems with internal body organs. *Id.* at 1:52–54. The endoscope includes an image capturing device, such as a camera, as well as "surgical tools, such as those used for cutting, grasping, cauterizing, etc., [that] may extend out of the endoscope's distal tip." *Id.* at 1:59–65. The device includes an "endoscopic navigation tool, [that

provides] graphical indications showing steering directions to previously defined landmarks." *Id.* at 8:51–53.

The object is to provide "visual guidance to an operator for steering an endoscopic device towards one or more landmarks in a patient." *Id.* at 2:56–58.

> [T]he operator of the steerable endoscope 110 is provided a view of the current shape of the endoscope 110 relative to the patient's body in order to provide guidance to the operator for navigating the endoscope 110 to a target site within the patient. A visual indication of the target site may also be displayed as well as computer models or other indications of any anatomic structures or body lumens that the endoscope 110 may encounter or pass through in its path to the target site.

Id. at 7:21–29. Graphical indications showing steering directions to previously defined landmarks are provided. *Id.* at 8:51–54. There are two types of graphical indications disclosed. "[A] primary display screen displaying an image captured by a steerable endoscope as viewed in a system." *Id.* at 3:46–48. This is the display that is captured by the camera at the tip of the endoscope. *See id.*, Figures 6, 10, and 11. This image can include directional guidance in the form of arrows indicating the position of landmarks. *See id.*, Figure 15. "The directions of the 3-D arrows are referenced to the endoscope tip's reference frame so that they correspond to directions that the operator should steer the endoscope's tip 112 using the handle or electromechanical interface 116." *Id.* at 10:10–15.

The other type of graphical displays provide a view of the patient including "anterior-posterior view 750 of the patient computer model 720 and endoscope computer model 710 is shown along with indications of various landmarks along the endoscope's path (e.g., mouth entry, esophagus,

stomach entry, and colon) on the auxiliary display screen 160." *Id.* at 7:42–46 (citing Figure 7). The position of landmarks within the patient may be registered with preoperative measurements such as Magnetic Resonance Imaging (MRI), Computer Axial Tomography (CAT), or X-rays. *Id.* at 9:51-63. The position of the endoscope tip is determined using a fixed reference frame. *Id.* at 9:26–27.

> [A] vector connecting the current position of the endoscope tip 112 to the position of each landmark to which guidance indications are to be provided is determined by the display processor 150 using the endoscope tip position determined in 1202 and landmark positions stored in the memory device 155.

Id. at 9:35–40. This allows for "directional guidance to landmarks in front of the endoscope tip 112 (i.e., between the current position of the endoscope tip and the target site), not just behind it (i.e., between the entry point into the patient and the current position of the endoscope tip)." *Id.* at 9:66–10:3.

D. Illustrative Claims

Claims 1 and 10 of the '601 patent are illustrative and reproduced below:

> 1. A method for navigating a steerable instrument in a patient anatomy, the method comprising:
>
> receiving a first landmark establishment request;
>
> responsive to receiving the request, recording information about a reference portion of the steerable instrument located at a first anatomic landmark in the patient anatomy;
>
> referencing the recorded information as first landmark information;
>
> registering the first landmark information to a model of the patient anatomy; and

providing guidance for navigating the steerable instrument along a path through a plurality of anatomic landmarks, including the first anatomic landmark, to a target location within the patient anatomy.

Ex. 1001, 13: 2–16.

10. A method for navigating a steerable instrument in a patient anatomy, the method comprising:

recording first information about a reference portion of the steerable instrument located at a first anatomic landmark in the patient anatomy;

referencing the recorded first information as first landmark information, the recorded first information including position information for the reference portion located at the first anatomic landmark and including an image captured by the steerable instrument while the reference portion is located at the first anatomic location;

recording second information about the reference portion of the steerable instrument located at a second anatomic landmark in the patient anatomy;

referencing the recorded second information as second landmark information, the recorded second information including position information for the reference portion located at the second anatomic landmark and including an image captured by the steerable instrument while the reference portion is located at the second anatomic location; and

providing guidance for navigating a guided instrument along a path through the first and second anatomic landmarks.

Id. at 13:37–14:18.

E. Prior art

Petitioner relies upon the following prior art references (Pet. 15–74):

References	Patent / Reference	Date	Exhibits
Ganatra	US 2009/0227861 A1	Sept. 10, 2009	Ex. 1004
Larkin	US 2007/0156019 A1	July 5, 2007	Ex. 1005
Soper	US 7,901,348 B2	Mar. 8, 2011	Ex. 1007

Petitioner also relies upon the Declaration of Blake Hannaford, Ph.D. (Ex. 1003) to support its contentions.

F. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–18 of the '601 patent on the following grounds. Pet. 15–74.

Claim(s Challenged	**Basis[1,2]**	**References**
1, 2, 5–9	§ 102(a)	Ganatra
1–3, 5–18	§ 103(a)	Ganatra, Soper
4, 18	§ 103(a)	Ganatra, Larkin
4, 18	§ 103(a)	Ganatra, Larkin, Soper

II. ANALYSIS

A. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art would have had at least "an undergraduate education in electrical engineering, mechanical engineering, robotics, biomedical engineering, or a related field

[1] The relevant sections of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (Sept. 16, 2011), took effect on March 16, 2013. Because the application from which the '601 patent issued was filed before that date, our citations to Title 35 are to its pre-AIA version.
[2] We view each instance of Petitioner's use of the phrase "and/or" in its discussion of the grounds as raising two separate grounds. *See, e.g.*, Pet. 70 ("Ganatra and Larkin, with or without Soper"). Therefore, we include each in our listing of the grounds. *Compare id.* at 3 (identifying three grounds) *with* Section I.E. above (identifying four grounds).

of study, along with about two years of experience in academia or industry." Pet. 9 (citing Ex. 1003 ¶ 30).

On this record, and absent opposition from Patent Owner, we adopt Petitioner's definition of the level of ordinary skill in the art. We also note that the prior art itself demonstrates the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 163 (Fed. Cir. 1985)).

B. Principles of Law

To prevail in its challenge to Patent Owner's claims, Petitioner must demonstrate by a preponderance of the evidence[3] that the claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). To establish anticipation under 35 U.S.C. § 102, each and every element in a claim, arranged as recited in the claim, must be found in a single prior art reference. *See Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008); *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). Although the elements must be arranged or combined in the same way as in the claim, "the reference need not satisfy an *ipsissimis verbis* test," i.e., identity of terminology is not required. *In re Gleave*, 560 F.3d

[3] The burden of showing something by a preponderance of the evidence requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before the trier of fact may find in favor of the party who carries the burden. *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Tr. for S. Cal.*, 508 U.S. 602, 622 (1993).

1331, 1334 (Fed. Cir. 2009) (accord *In re Bond*, 910 F.2d 831, 832–33 (Fed. Cir. 1990)).

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 of the invention to a person having ordinary skill in the art. *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 "the scope and content of the prior art"; "differences between the prior art and the claims at issue"; and "the level of ordinary skill in the art." *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

A patent claim "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. An obviousness determination requires finding "both 'that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016) (citation omitted); *see KSR*, 550 U.S. at 418 (for an obviousness analysis, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does"). Further, an assertion of obviousness "cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)); *In re NuVasive, Inc.*, 842

F.3d 1376, 1383 (Fed. Cir. 2016) (a finding of a motivation to combine "must be supported by a 'reasoned explanation'" (citation omitted)).

C. Claim Construction

In an *inter partes* review for a petition filed on or after November 13, 2018, "[claims] of a patent . . . shall be construed using the same claim construction standard that would be used to construe the [claims] in a civil action under 35 U.S.C. § 282(b), including construing the [claims] in accordance with the ordinary and customary meaning of such claims as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b); *see* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (codified at 37 C.F.R. § 42.100(b) (2019)) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018). A term's ordinary and customary meaning "is its meaning to the ordinary artisan after reading the entire patent." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005) (en banc). Nevertheless, "it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning," because "[t]he specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

Petitioner requests construction of the terms "anatomic landmark," "a path through," and "fixed reference frame." Pet. 10–15. Patent Owner does not dispute Petitioner's proposed construction of "a path through" or a

"fixed reference frame." Prelim Resp. 3. Patent Owner, however, disputes the construction of "anatomic landmark" as a "user established anatomical feature." *Id*. at 4. Patent Owner suggests that "guidance" could benefit from construction. *Id*. at 5. For purposes of this decision on institution, we provide a construction of the term "anatomic landmark" and "guidance."

1 "anatomic landmark"

The term "anatomic landmark" appears in independent claims 1 and 10, and therefore by virtue of dependency effectively appears in claims 2–9 and 11–18 as well. Petitioner, for the purpose of this proceeding, proposes that the term "'anatomic landmark' [refers] to a user established anatomical feature." Pet. 11 (citing Ex. 1003 ¶ 48).

Patent Owner contends that there is nothing in the '601 patent that suggests such a special definition. Prelim. Resp. 4. "The specification of the '601 patent supports a plain meaning of the term 'anatomic landmark' as any anatomic structure within a patient." *Id.* (citing Ex. 1001, Abstract, 10:24–36, 11:58–12:1, 12:41–58).

The '601 specification describes, "providing visual guidance to an operator for steering an endoscopic device towards one or more landmarks in a patient." Ex.1001, 2:56–58. Landmarks as understood in light of the '601 specification are known structures that can be used for positioning purposes and are not limited to user-defined structures. This understanding is supported by the '601 specification's explanation that the computer model can show "indications of various landmarks along the endoscope's path (e.g., mouth entry, esophagus, stomach entry, and colon) on the auxiliary display screen." *Id.* 7:43–46, *see also id.* 12:45–51 ("the establishment of landmarks while navigating the endoscope [] towards a target site within the

patient, anatomic structures (such as the esophagus, stomach, colon, etc.) may be measured using position information of the endoscope tip [] as it moves from one end of the anatomic structure to the other.").

A Markman Hearing was held in the related district court proceeding in *Intuitive Surgical, Inc. v. Auris Health, Inc.*, Action No. 18-1359-MN (D. Del.) and a ruling entered with respect to the construction of the terms "anatomical landmark" a term also at issue in the present Petition. Ex. 1018, 131:2–132:7. We authorized Petitioner to file the transcript of the hearing as an exhibit (Ex. 1018) and granted additional briefing to explain the relevance of the court's claim construction to this proceeding. Paper 11.

The district court construed the term "anatomic landmark" to mean "anatomic structure that is or has been registered and recorded." Ex. 1018, 131:8–9. Patent Owner agreed to the construction "provided no user action is required to establish an anatomic structure as a landmark." Paper 13 (citing Ex. 1018, 88:11-89:8). At this stage of the proceeding, having considered the parties' respective arguments and the district court's claim construction, we construe "anatomic landmark" as encompassing any anatomic structure that has been registered and recorded (not necessarily by the user), examples of which include, but are not limited to, the esophagus, stomach, colon, etc.

2. "guidance"

In the Preliminary Response, Patent Owner notes that the term "guidance" could benefit from construction if trial is instituted but does not provide a definition. Prelim. Resp. 5; Paper 13, 2–3. Petitioner did not provide a proposed construction for "guidance" in the Petition.

The district court did not construe the term "guidance" beyond its plain and ordinary meaning. Ex. 1018, 130:22–25; *see id.* 97:3–16. Petitioner contends that "guidance" is not limited to "directional guidance" as argued by Patent Owner. Paper 15, 2 ("Limiting the term [guidance] to 'which direction [] to navigate the instrument' requires both directional and steering information, which are exactly what the court rejected."). Patent Owner argues that although it proposed that "guidance" should be construed as "directional steering information" in the district court case, Patent Owner applied the plain and ordinary meaning of the term in the Preliminary Response. Paper 13, 3. Patent Owner notes, however, that Petitioner acknowledges that "guidance for navigating . . . to a target location" requires some directional information in the form of visual indicators. *Id.* The dispute, therefore, is whether guidance in the context of the '601 specification and more importantly in the context of the claims, includes more than directional information.

The '601 specification teaches "providing visual guidance to an operator for steering an endoscopic device towards one or more landmarks in a patient." Ex. 1001, 2:56–58. According to the '601 specification, guidance to steer the endoscope requires "determining a current position of a reference point on the endoscopic device relative to a reference frame [and] determining a first vector from the current position of the reference point to a position of a first landmark relative to the reference frame." *Id.* 2:63–67, *see also id.* 4:4–7 ("FIG. 12 illustrates a flow diagram of a computer implemented method of providing directional guidance to maneuver an endoscopic device to one or more landmarks, utilizing aspects of the present invention."), *id.* at 4:216–19 ("FIG. 15 illustrates a primary display screen

displaying a current image captured by an endoscopic device and graphical representations of various vectors indicating directions to corresponding landmarks."). The '601 specification further describes the use of "a vector connecting the current position of the endoscope tip 112 to the position of each landmark to which guidance indications are to be provided is determined by the display processor 150 using the endoscope tip position determined in 1202 and landmark positions stored in the memory device 155." *Id.* at 9:35–40.

On this record at this stage of the proceeding, we construe "guidance" as graphical indicators, such as for example vectors or arrows, that point in the direction the endoscope is to travel. The parties are invited to brief this issue further at trial, if deemed necessary.

3. Remaining Claim Terms

At this stage of the proceeding, we determine that it is unnecessary to expressly construe any remaining claim terms for purposes of this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

D. Ground 1: Anticipation of Claims 1, 2, and 5–9 by Ganatra

Petitioner contends that claims 1, 2, and 5–9 are unpatentable as anticipated by Ganatra. Pet. 15–43. Patent Owner opposes. Prelim. Resp. 9–21.

1. Overview of Ganatra (Ex. 1004)

Ganatra teaches "systems and methods for navigating a medical instrument within a branched structure of a body." Ex. 1004 ¶ 1. The method uses predetermined points for defining a pathway along the branches of a body structure. *Id.* Abstract. Figures 3A and 3B of Ganatra, reproduced below, show the navigation system in operation.

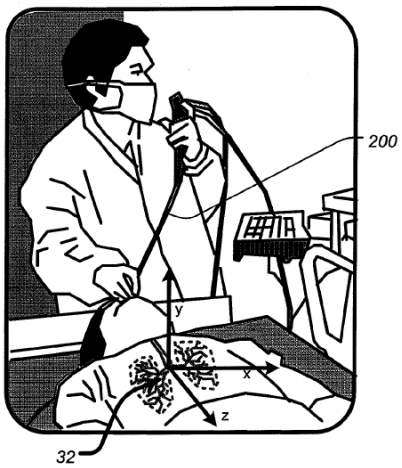

FIGURE 3A

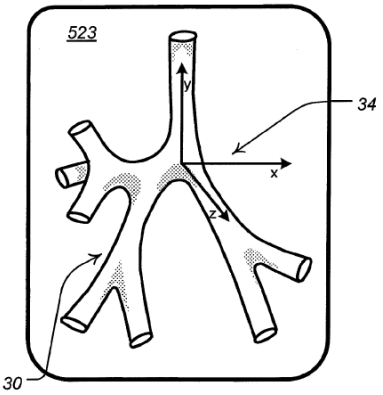

FIGURE 3B

Figure 3 shows a patient and an operator positioning a bronchoscope as well as an external reference frame.

> Those skilled in the art will appreciate that tracked locations of bronchoscope 200 will be reported by the tracking system as coordinates with respect to a coordinate system 32, which is in a frame of reference of the tracking system and the patient's body, which is within the field of the tracking system, and that the model has a separate frame of reference and a corresponding coordinate system 34, to which tracking coordinate system 32 needs to be registered in order to accurately display representations of locations of bronchoscope 200 on display 30.

Id. ¶ 19.

> [T]he operator of bronchoscope 200 may sequentially position bronchoscope 200 within the actual bronchial tree of the patient so that sensor X is located at multiple reference, or fiduciary points, which correspond to known points of the model, and then the coordinates for corresponding points may be used to find a mathematical transformation, for example, an affine transformation, which relates the two frames of reference to one another, thereby registering tracking coordinate system 32 with model coordinate system 34.

Id. ¶ 20. The problem with having the clinician/operator locate fiduciary points for registration is that the process is time consuming. *Id.* Instead, Euclidean distance from a reference point can be used to facilitate the collection of additional fiduciary points. *Id.*

Figure 4, reproduced below, shows a bronchial tree model that serves as reference points in the model coordinate system. *Id.* ¶ 21.

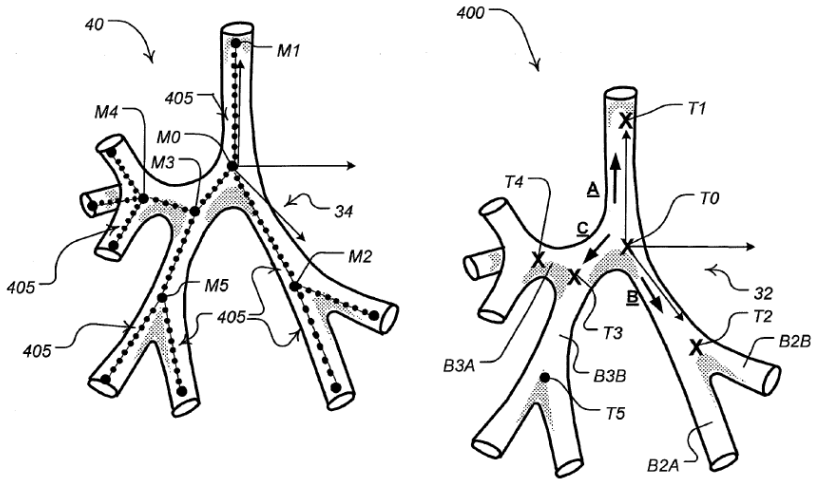

FIGURE 4A

FIGURE 4B

> FIG. 4A illustrates predetermined points 405 including the subset of designated points identified as M0, M1, M2 and M3; designated point M0, which serves as a reference point of model coordinate system 34, is shown located at a first branching point of a main airway, or trachea, of the tree, in

> proximity to the carina of the bronchial tree. . . . According to a first step of a method of the present invention, the bronchoscope operator locates bronchoscope 200 in proximity to the carina of the actual bronchial tree 400, so that tracking sensor X is located at a point T0, which corresponds to designated point M0 of model 40, and then instructs processor 522 to establish point T0 as an anchor point of tracking coordinate system 32.

Id. ¶ 21. "[I]t may be appreciated that the operator of bronchoscope need not look for [all] fiduciary points along the branches of tree 400 because spatial information . . . is compared with positional information provided by tracking system 51 to automatically collect the fiduciary points." *Id.* ¶ 23.

Figures 4C–4E, reproduced below, show the pre-determined or pre-programed instructions for the registration process.

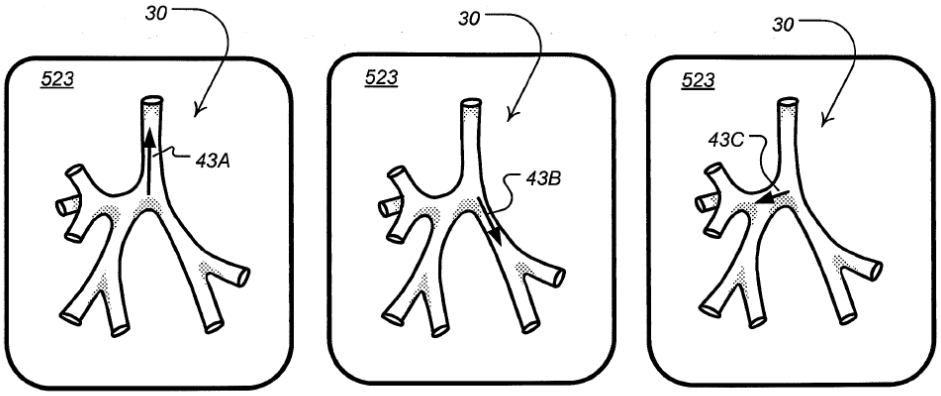

FIGURE 4C FIGURE 4D FIGURE 4E

Figures 4C–4E show "an exemplary visual indicator [in the form of arrows] 43A, 43B, 43C is shown overlaid on each displayed representations 30 of the model; indicators 43A, 43B, 43C may provide guidance to a user of the navigation system for carrying out the above-described registration process according to a particular sequence." *Id.* ¶ 24. The indictors show the

sequential positioning of the bronchoscope in the various branches in order to find points T1, T2, and T3 as shown above in Figure 4B. *Id.*

> [A]dditional indicators may also be displayed along each branch, to direct the operator to backtrack the bronchoscope back to anchor point T0, following travel to each of points T1, T2 and T3. Although arrows are illustrated as indicators 43A, 43B, 43C, it should be appreciated that other forms of indicator may be used in alternate embodiments of the invention in order to provide similar guidance in the movement of the bronchoscope, and for providing an indication, or feedback that the bronchoscope has been advanced far enough in each branch; examples of the other forms of indicators include, without limitation, color coding of branches and blinking or flashing points or Zones along each branch; alternately words may be used to provide written, explicit instructions and feedback on display 30.

Id.

After initial registration, the system can then track the medical instrument position on the display.

> According to the illustrated embodiment a sphere 52, which is superimposed on display 30, represents a location of the medical instrument that corresponds to a collected registered set of coordinates, which is reported to display element 523 by processor 522 as the medical instrument is moved through the branched structure of the patient.

Id. ¶ 25. Ganatra uses "a tracking sphere 52 on displayed representation 30 of the model, to mark a current position of the bronchoscope." *Id.* ¶ 28.

Figure 6C, reproduced below, shows a site 620 a point of interest in the patient.

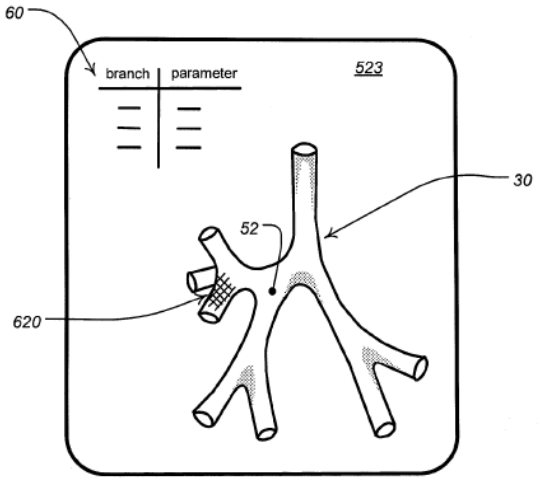

FIG. 6C illustrates tracking sphere 52 as a indicator of a current location of the medical instrument after having been moved away from site 620, upon completion of a procedure at site 620. According to the illustrated embodiment, the indicator at site 620, which may be displayed in any suitable manner and is not limited to the illustrated cross hatching, serves as a key reference for the operator of the medical instrument, as he or she continues to move the instrument through the branched structure of the patient, for example, to perform another procedure at another site.

Id. ¶ 29.

2. Analysis

Petitioner asserts that Ganatra discloses every limitation of the ’601 patent. Pet. 15–43.

a. Claim 1: “A method for navigating a steerable instrument in a patient anatomy”

Petitioner asserts that Ganatra teaches a method of navigating a bronchoscope through the bronchial tree structures of a patient’s anatomy. Pet. 20–21. The exemplary bronchoscope “includes a tracking sensor X near a distal end 202 of the bronchoscope and that is steered by an operator.” Pet. 20–21 (citing Ex. 1004 ¶ 18–20, Figure 2; Ex. 1003 ¶¶ 86–87).

Patent Owner does not contest that Ganatra's instrument is steerable. *See* Prelim Resp. 10. Instead, Patent Owner argues that Ganatra's disclosure is limited to a tracking-only navigation system and that the registration process disclosed in Ganatra is not a guidance system. *Id.*

We determine that Ganatra discloses a method for navigating a steerable instrument.

b. "receiving a first landmark establishment request"

Petitioner asserts that Ganatra's registration method requires that

> the operator navigates the bronchoscope through (in one side and out the other) the designated points in the patient's anatomy, and when the bronchoscope is located at each designated point, the system registers the tracking system coordinates (one of T0, T1, T2, T3, T4, and T5) to the model system coordinates (one of M0, M1, M2, M3, M4, and M5).

Pet. 22 (citing Ex. 1004 ¶¶ 20, 22, 23; Ex. 1003 ¶ 93). Because Ganatra describes performing these initial registration steps at the start of the procedure, the step of "receiving a first landmark establishment request" is included in the process. Pet. 23 (citing Ex. 1004 ¶ 21).

Patent Owner does not contest this limitation. *See* Prelim. Resp. 10.

We determine that Ganatra's registration process includes receiving a landmark establishment request.

c. "responsive to receiving the request, recording information about a reference portion of the steerable instrument located at a first anatomic landmark in the patient anatomy"

Petitioner asserts that "Ganatra explains that the operator navigates the bronchoscope so that [when] 'tracking sensor X is located at a point T0, which corresponds to designated point M0 of model 40'" and the operator

instructs the processor to establish an anchor point in the tracking coordinate system that is then recorded. Pet. 25 (citing Ex, 1004 ¶¶ 21, 22). "[T]he instruction to register M0/T0 meets this claim element." *Id.* at 26 (citing Ex. 1003 ¶¶ 99–100).

Patent Owner does not contest this limitation. *See* Prelim. Resp. 10.

We determine that Ganatra's registration process records and obtains information from the coordinate system that is in a frame of reference with the patient's body using the tracking sensor at the tip of the endoscope and registering that location within the computer model coordinate system marking the various designated points. Ex. 1004 ¶¶ 19–24, Figures 4A–E. Accordingly, we determine that Ganatra meets this limitation.

d. "referencing the recorded information as first landmark information"

Petitioner asserts that "the processor continuously references anchor point M0/T0 to calculate Euclidean distances between sensor X and anchor point T0." Pet. 27 (citing Ex. 1004 ¶ 22; Ex. 1003 ¶¶ 101–03).

Patent Owner does not contest this limitation. *See* Prelim. Resp. 10.

We determine that Ganatra's registration process includes referencing the recorded information as landmark information.

e. "registering the first landmark information to a model of the patient anatomy"

Petitioner asserts that "Ganatra registers the location information it records for each designated point to the coordinates of that designated point in the computer model." Pet. 27 (citing Ex. 1004 ¶ 21). Petitioner asserts that T0/M0 point registered in Ganatra meets the limitation of "registering the first landmark information to a model of the patient anatomy." Pet. 28 (citing Ex. 1003 ¶¶104–05).

Patent Owner does not contest this limitation. *See* Prelim. Resp. 10.

We determine that Ganatra's registration process includes assigning coordinates from the tracking sensor onto the computer model of the patient's anatomy, which meets this limitation.

f. "providing guidance for navigating the steerable instrument along a path through a plurality of anatomic landmarks, including the first anatomic landmark, to a target location within the patient anatomy"

Petitioner asserts that "Ganatra's navigation system 50 provides navigation guidance to the operator to assist in the initial registration process and in navigating the instrument to a target site." Pet. 28 (citing Ex. 1004 ¶ 22; Ex. 1003 ¶106). Petitioner asserts that Ganatra "superimposes arrows on the displayed model to inform the operator in which direction the bronchoscope should be navigated to reach each of M1/T1, M2/T2, and M3/T3." *Id.* (citing Ex. 1004 ¶ 21, Figures 4C–4E). Petitioner asserts that because each designated point is an '"anatomic landmark' . . . the path through, M0/T0, M1/T1, M2/T2, and M3/T3 runs through a plurality of anatomic landmarks." *Id.* at 30 (citing Ex. 1003 ¶ 108).

Petitioner further asserts that Ganatra teaches other types of visual indicators that may be marked on the display and are used for navigating the medical instrument to the target site. Pet. 32 (citing Ex. 1004 ¶ 29). Petitioner asserts that Ganatra "shows how arrows can be used, showing use of arrows to guide the operator along a path to designated points in the context of the initial registration process." *Id.* (citing Ex. 1004 ¶ 24). "As [Petitioner's expert] Dr. Hannaford explains, Ganatra generally discloses using such arrows to guide a user to an intended destination, even though Ganatra only illustrates these arrows in the context of the initial registration

process." *Id.* at 32 (citing Ex. 1003 ¶¶ 114–15). Dr. Hannaford further concludes that the use of arrows disclosed in Ganatra for guiding the registration process could similarly be "used in the same manner to guide the operator to cite 620 to perform the procedure." *Id.* at 33 (citing Ex. 1003 ¶¶ 115–16).

Patent Owner contends that Petitioner concedes that Ganatra only discloses using arrows on the visual display during the initial registration process and "that Ganatra does not 'explicitly illustrate' using 'additional visual indicators' to navigate to target site 620 (Pet., 32)." Prelim Resp. 10. Patent Owner contends that Dr. Hannaford's testimony cannot be used to fill in gaps in Ganatra's disclosure. *Id.* at 12 (citing *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (citing *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) (anticipation is not proven by "multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention")). Patent Owner contends that Ganatra explains that the model coordinate system and the tracking coordinate system need to be registered in order to accurately display representation of locations of bronchoscope on the display. Prelim Resp. 18 (citing Ex. 1004 ¶ 19). Patent Owner contends that it is only after the registration process is complete that Ganatra's system can "track the position of bronchoscope 200 . . . on display 30." *Id.* (citing Ex. 1004 ¶ 25). Patent Owner contends that Ganatra's guidance during the registration process is not "navigation guidance 'to a target location'" as required by claim 1. *Id.* at 20.

On this record, we find that Ganatra teaches a registration process that plots the fiducial points and marks the path the endoscope needs to traverse in order to register the computer model with the coordinate tracking system.

Ex. 1004 ¶¶ 19– 24, Figures 4A–4E. Ganatra explains that the operator "selects a registration path, for example, a sequence of directions, or branches along which to move sensor X and inputs this information into workstation 500." *Id.*¶ 22. Ganatra's visual display allows the operator to establish whether the bronchoscope moves towards or away from the point of interest 620 by following movement of tracking sphere 52. *See* Ex. 1004 ¶ 29 ("tracking sphere 52 as a indicator of a current location of the medical instrument after having been moved away from site 620"), Figure 6C. We agree with Patent Owner, however, that Ganatra does not disclose the use of guidance in the form of vectors or arrows for plotting a path for navigating the bronchoscope to reach a particular target site.

The burden is on Petitioner to prove unpatentability by a preponderance of the evidence. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378–80 (Fed. Cir. 2015). We determine that Petitioner has not established a reasonable likelihood of prevailing on its contentions that Ganatra anticipates the subject matter of independent claim 1.

g. Claims 2 and 5–9

For the same reasons discussed above (*see* II.D.2.f) for claim 1, we determined that the evidence presented by Petitioner does not establish a reasonable likelihood of prevailing at trial for dependent claims 2 and 5–9.

h. Alleged Obviousness Ground over Ganatra Alone

Petitioner asserts that "[e]ven if the Board were to determine Ganatra does not disclose this navigation technique, it would have been obvious for the same reasons, as described below." Pet. 35. Patent Owner interprets Petitioner's assertion as contending that claim 1 is obvious based on Ganatra

alone. Prelim. Resp. 20–21. In view of that interpretation, Patent Owner argues that Petitioner's one sentence alternative obviousness ground based on Ganatra alone is legally insufficient. *Id.*

Because Petitioner states the claims would have been obvious over Ganatra "for the same reasons, as described below," we do not believe Petitioner intended to include an obviousness ground based on Ganatra alone. *See* Pet. 35. Rather, we interpret Petitioner's statement as referring to the obviousness argument related to the combination of Ganatra and Soper following the anticipation argument in the Petition (i.e., "below" the anticipation ground).

E. Ground 2: Obviousness of Claims 1–3 and 5–18 over Ganatra and Soper

Petitioner contends that claims 1–3 and 5–18 are unpatentable as obvious over Ganatra and Soper. Pet. 15–43. Patent Owner opposes. Prelim. Resp. 21–26. Based on the current record, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing that at least one challenged claim is unpatentable as obvious over Ganatra and Soper.

1. Overview of Soper (Ex. 1007)

Soper teaches "a method and apparatus for providing three-dimensional (3-D) guidance to a catheter-scope or flexible endoscope that is being advanced through a branching lumen in a patient's body." Ex. 1007, 1:13–16.

> A position sensor on the endoscope produces a signal indicating the position (and orientation) of the distal tip of the endoscope in a Cartesian coordinate system during the procedure. A visual display is continually updated, showing the present position and

> orientation of the marker in a 3-D graphical surface model of the airways that is generated through segmentation of medical images.

Id. at 3:1–7. Identification by the clinician of bifurcations on video images allows for recalibration of the scope head within the 3-D model. *See id.* at 3:30–36.

> The system relies on the visual identification of branch points by a physician, to continually recalibrate the current position of the flexible endoscope to the corresponding branch point on the static 3-D model. This methodology uses measurements of absolute position relative to a sensor, in order to generate positional data comprising a device "history" that simplifies the position of the flexible endoscope to a series of choices made along a binary decision tree in which the decisions determine which branch to take with the flexible endoscope at each junction of the bronchial tree.

Id. at 8:27–36.

> A graphic marker 192 is displayed in the user interface . . . to show the position of the catheter in airways 190, *and the intended navigation routes 204 to the points of biopsy are shown in a static 3-D airway surface model 200* . . . along with a current position 202 of the flexible endoscope.

Id. at 13:62–67 (emphasis added). Soper explains that "[a]s the scope traverses the airways, the graphical interface is continually updated, charting progress from both global and fly-through perspectives." *Id.* at 14:2–4. Before steering the scope down a branch point, the clinician must verify the position of the endoscope either via touch sensor or by visual assessment. *Id.* at 14:9–12. "Based on the chosen route and the known position and orientation of the catheter tip, a visual graphic is presented on a video monitor to instruct the clinician on how to proceed." *Id.* at 14:23–25.

2. Analysis

In its Petition, Petitioner sets forth how the limitations of the claims are rendered obvious over Ganatra and Soper. Pet. 43–50. According to Petitioner, Ganatra and Soper are analogous art because "[b]oth are directed to systems for providing navigation guidance to an operator steering an endoscope through a patient's airways." Pet. 45 (citing Ex. 1003 ¶¶ 80–81). Petitioner asserts that both combine information from 3-D computer models of a patient's anatomy with the position of a tracking sensor at the tip of an endoscope in order to register the location of the endoscope tip on the computer model. *Id.* Petitioner relies on the declaration of Dr. Hannaford (Ex. 1003) to support its contentions.

Patent Owner opposes. Prelim Resp. 21–26.

a. Independent Claim 1

As discussed above (*see* II.D.2.a– II.D.2.e), Petitioner contends that Ganatra meets most of the elements recited in claim 1. Patent Owner does not dispute these limitations. *See* Prelim. Resp. 10, 21–26. Instead, the dispute lies with the limitation of "*providing guidance for navigating the steerable instrument along a path through a plurality of anatomic landmarks, including the first anatomic landmark, to a target location within the patient anatomy*" as recited in claim 1 of the '601 patent.

Petitioner acknowledges that Ganatra uses arrows "to guide the operator along a path to designated points [only] in the context of the initial registration process." Pet. 32 (citing Ex. 1004 ¶ 24). Petitioner asserts that Ganatra "describe[s] a process for using arrows to guide a user through landmarks" and the same process could similarly be applied for guiding the endoscope to a target location. *Id.* at 46; *see also id.* at 32 (Ganatra "shows

how arrows can be used, showing use of arrows to guide the operator along a path to designated points in the context of the initial registration process.")).

Petitioner also acknowledges that "Ganatra does not explicitly describe the details how its system provides 'another type of visual indicator' 'on display 30' for use 'as a reference for navigating the medical instrument to site 620.' Pet. 46 (Ex. 1004 ¶ 29). "Ganatra does not, for example, include any figures that explicitly illustrate both site 620 and additional visual indicators (e.g., arrows) that assist in navigating to that site." *Id.* (citing; Ex. 1003 ¶ 123). According to Petitioner's expert, Dr. Hannaford, it would have been obvious to one of ordinary skill in the art to also use "arrows to guide a user to an intended destination, even though Ganatra only illustrates these arrows in the context of the initial registration process." *Id.* at 33 (citing Ex. 1003 ¶¶ 114–15). Petitioner contends that a person of ordinary skill in the art would have looked to analogous art, such as Soper (*see* Pet. 47 (citing Ex. 1003 ¶¶ 80, 81, 122–125; Ex. 1007, 13:58–66)), to provide guidance with respect to visual navigation a concept already introduced in Ganatra but not explicitly described. *Id.* at 46 (citing Ex. 1004 ¶ 29 ("Ganatra describes the using "cross-hatching, to mark a site 620 at which the medical instrument performed a procedure. . . . [Ganatra also suggests using] another type of visual indicator, as a reference for navigating the medical instrument to site 620 to perform the procedure, once the registration process is completed.")).

Patent Owner contends that Petitioner has not provided sufficient reasons – other than generalized improvement – to pick Ganatra and Soper. Prelim. Resp. 22. Patent Owner contends that relying on "generalized improvement" is improper hindsight reasoning because Petitioner's

obviousness analysis relies on the ’601 patent disclosure as a blueprint to arrive at the combined elements. *Id.* at 24. Patent Owner contends that Petitioner has not provided an explanation of “why and how one [of ordinary skill] would have combined those prior art elements” to arrive at the claims. *Id.* at. 26. Specifically, Patent Owner contends that Petitioner has not “explain[ed] how a skilled artisan would have combined Soper’s teachings with Ganatra’s tracking-only navigation system and how that unarticulated combination would work.” *Id.* at 25.

On the record at this stage of the proceeding, we are not persuaded by Patent Owner’s contention that Petitioner relied on improper hindsight when articulating the grounds of unpatentability based on Ganatra and Soper. Patent Owner has not directed us to any evidence that would suggest that Petitioner relied on information gleaned only from the ’601 specification and not available in the cited references. *See In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971) (“Any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it . . . does not include knowledge gleaned only from applicant’s disclosure, such a reconstruction is proper.”).

Here, Ganatra discloses that after the registration process is complete the system can be used to navigate to a site of interest in order to perform a medical procedure. Ex. 1004 ¶ 29. Specifically, Ganatra indicates following tracking sphere 52 to determine the current location of the medical instrument. *Id.*

Soper discloses a road-map decision model that “[b]ased on the chosen route and the known position and orientation of the catheter tip, a visual graphic is presented on a video monitor to instruct the clinician on

how to proceed." Ex. 1007, 14:23–25; 20:15–18 ("from the current position, a step [] will then provide an arrow on the virtual interface that indicates a direct path and the distance to the intended destination.").

Petitioner's expert avers that Ganatra uses visual indicators to navigate the endoscope to site 620, but acknowledges that Ganatra does not provide any details on how to achieve this. Ex. 1003 ¶ 122. Petitioner's expert attests that equipped with this knowledge of being guided to a point of interest as taught in Ganatra one of ordinary skill in the art would have been motivated to "to look to other references for additional details on how such indications could be implemented." *Id.* Petitioner's expert explains that Soper provides visually assisted guidance for a thin flexible endoscope. *Id.* ¶¶ 73–77. Specifically, Soper describes two ways of using visual indicators to assist in navigating to a point in a patient's body to conduct a biopsy. *Id.* ¶ 124. One way Soper provides visual indicators is to plot intended navigation routes. *Id.* The second method disclosed in "Soper explains that its system can 'provide an arrow on the virtual interface that indicates a direct path and the distance to the intended destination.'" *Id.* ¶ 125.

We are not persuaded by Patent Owner's contention that Petitioner has not sufficiently articulated a reason for combining Ganatra and Soper. *See KSR*, 550 U.S. at 418 (quoting *In re Kahn*, 441 F.3d at 988 ("A conclusion of obviousness must include "articulated reasoning with some rational underpinning to support the legal conclusion.")). Here, Petitioner directs us to teachings in Ganatra that suggest using the system to navigate to a site of interest. Pet. 18 ("it displays the computer model and superimposes a visual indicator 52 on the model to identify the current

location of the bronchoscope." (citing Ex. 1004 ¶ 29)), *see id.* at 30–31, 33, 35, 46. Soper discloses an analogues bronchoscope system that contains similar features to Ganatra's system (Pet. 45), and provides two different visual guidance processes to direct an operator of a bronchoscope to a site of interest. Pet. 46–47 (Ex. 1007, 13:58–66, 20:15–18; Ex. 1003 ¶¶ 80, 81, 122–25). On this record, at this stage of the proceeding we find that Petitioner has directed us to sufficient evidence in the record from which to reasonably conclude that there is a reason to combine the references to arrive at all the limitations as set out in claim 1 of the '601 patent.

Summary

For the preceding reason, we determine that Petitioner has established a reasonable likelihood of prevailing on its contentions that the combination of Ganatra and Soper would have rendered obvious the subject matter of independent claim 1.

b. Claim 2

Claim 2 depends from claim 1, and further recites "wherein the first landmark information includes position information." Ex. 1001, 13:17–18. Petitioner asserts that "Ganatra discloses that it stores both the tracking system coordinates and the model system coordinates (each "position information") in a database." Pet. 36 (citing Ex. 1004 ¶¶ 22, 23, 26, 28, 31; Ex. 1003 ¶¶ 130–31.), *id.* at 51. Patent Owner does not separately dispute this limitation. We determine that Petitioner has made an adequate showing, at this stage of the proceeding that the art teaches the elements recited in claim 2.

c. Claim 3

Claim 3 depends from claim 1, and further recites "wherein the first landmark information includes an image from the reference portion of the steerable instrument captured by an image capture device." Ex. 1001, 13:19–21. Petitioner relies on Ganatra for teaching that the bronchoscope can include a video camera that can help the operator find fiduciary points. Pet. 51 (citing Ex. 1004 ¶¶ 20, 30; Ex. 1003 ¶ 135). Petitioner acknowledges that "Ganatra does not explicitly state that the images collected at each designated point are stored." *Id.* at 52. Petitioner relies on Soper for teaching "a bronchoscope that captures and saves images of branching points and other features of the bronchial passages as it passes through them." *Id.* at 53 (citing Ex. 1007, 18:30-35, 19:1-5, 19:21-32; Ex.1003 ¶140). "Soper explains that annotating the images aids the system in 'provid[ing] a data record of each of the bronchial passages that was traversed.'" *Id.* at 54 (citing Ex. 1007, 19:15–21). Ganatra similarly keeps track of the passageways that have been traversed. *Id.* (citing Ex. 1004 ¶ 26). Based on this similarity between Ganatra and Soper, Petitioner concludes that one or ordinary skill in the art would have understood that keeping notes in Ganatra's system would provide the same benefit of annotating the traversed passageways. *Id.* (citing Ex. 1003 ¶ 144). Patent Owner does not separately dispute this limitation. We determine that Petitioner has made an adequate showing, at this stage of the proceeding that the art teaches the elements recited in claim 3.

d. Claim 5

Claim 5 depends from claim 1, and further recites "wherein the first landmark information includes a timestamp." Ex. 1001, 13:24–25.

Petitioner relies on Ganatra for teaching recording movement and time of travel of the endoscope. Pet. 36–37 (citing Ex. 1004 ¶¶ 27–28; Ex. 1003 ¶ 155), *id.* at 51. Patent Owner does not separately dispute this limitation. We determine that Petitioner has made an adequate showing, at this stage of the proceeding that the art teaches the elements recited in claim 5.

e. Claim 6

Claim 6 depends from claim 1, and further recites "wherein the first landmark information includes a graphical representation." Ex. 1001, 13:26–27. Petitioner relies on Ganatra for teaching "a displayed image of the computer model using a circle or dot as a visual indicator". Pet. 38–40 (citing Ex. 1004 ¶ 28, Figure 6A; Ex. 1003 ¶ 158–163), *id.* at 51. Patent Owner does not separately dispute this limitation. We determine that Petitioner has made an adequate showing, at this stage of the proceeding that the art teaches the elements recited in claim 6.

f. Claim 7

Claim 7 depends from claim 6 and ultimately from claim 1, and further recites "further comprising displaying the model of the patient anatomy registered with the graphical representation." Ex. 1001, 13:28–30. Petitioner relies on Ganatra for teaching "that a visual indicator identifying a designated point or the space between designated points can be superimposed on the computer model and displayed to a user". Pet. 38–39 (citing Ex. 1004 ¶ 28, Figure 6A; Ex. 1003 ¶ 166–168), *id.* at 51. Patent Owner does not separately dispute this limitation. We determine that Petitioner has made an adequate showing, at this stage of the proceeding that the art teaches the elements recited in claim 7.

g. Claim 8

Claim 8 depends from claim 1, and further recites "wherein the guidance includes a model of the path between the plurality of anatomic landmarks." Ex. 1001, 13:31–33. Petitioner relies on Ganatra for teaching an initial registration process that uses arrows to guide the operator to navigate through designated points. Pet. 41–42 (citing Ex. 1004 ¶ 29, Figure 6C; Ex. 1003 ¶¶ 173–75), 51. Patent Owner does not separately dispute this limitation. We determine that Petitioner has made an adequate showing, at this stage of the proceeding that the art teaches the elements recited in claim 8.

h. Claim 9

Claim 9 depends from claim 8 and ultimately from claim 1, and recites "further comprising displaying the model of the path registered with the model of the patient anatomy." Ex. 1001, 13:17–18. Petitioner relies on Ganatra for superimposing on the computer model of the patient's anatomy arrows to guide the operator to designated points for registration. Pet. 41–43 (citing Ex. 1004 ¶ 29, Figure 6C; Ex. 1003 ¶¶ 173–75, 181), *id.* at 51. Patent Owner does not separately dispute this limitation. We determine that Petitioner has made an adequate showing, at this stage of the proceedings that the art teaches the elements recited in claim 9.

i. Independent Claim 10

Petitioner contends that Ganatra teaches a steerable instrument, that records information about anatomic landmarks, and that references the recorded information. Pet. 56–59 (citing Ex. 1004 ¶¶ 22, 23, 24, 26; Ex 1003 ¶¶ 187–92). Petitioner contends that Ganatra discloses the use of a video camera coupled to the imaging system, and that such images can help

the operator find fiducial points. *Id.* at 51 (citing Ex. 1004 ¶¶ 20, 30). Petitioner concedes that "Ganatra does not explicitly state that the images collected at each designated point are stored." *Id.* at 52. Petitioner relies on Soper for teaching "a bronchoscope that captures and saves images of branching points and other features of the bronchial passages as it passes through them." *Id.* at 53 (citing Ex.1007, 18:30-35, 19:1-5, 19:21-32; Ex.1003 ¶ 140). Petitioner contends that Soper's annotations allows the clinician to record notes with model. *Id.* at 54–55 (citing Ex. 1007, 22:40–45 ("Annotations could be logged in a textual or audible form for comparison at a later date. Regions that could not be accessed in previous examinations would have some visual indicator that links to a set of comments or notes made by the same or different physician at an earlier date."). Petitioner contends that one of ordinary skill in the art would have understood that adding such an annotation scheme to Ganatra's system would provide the same benefit. *Id.* at 55 (citing Ex. 1003 ¶ 144). Petitioner asserts that Ganatra teaches an initial registration process and that "the registration continues to be refined throughout the procedure as the operator navigates the bronchoscope through additional designated points," and that can be used to refine the registration process. *Id.* at 58–59 (citing Ex. 1004 ¶¶ 23, 26; Ex. 1007, 22:40–45; Ex. 1003 ¶¶ 144, 190–92, 195–96). Petitioner contends that because "Ganatra calculates the distance between the two points, . . . Ganatra references the recorded information for each designated point." *Id.* at 62 (citing Ex. 1004 ¶ 28; Ex. 1003 ¶¶ 204-6). Finally, Petitioner contends that the combination of "Ganatra and Soper teach providing navigation guidance on path from M0/T0 to M3/T3 to

M4/T4 (a 'plurality of anatomic landmarks') to target site 620." *Id.* at 64 (citing Ex. 1003 ¶¶ 211–12).

Patent Owner does not provide a separate argument with respect to claim 10, instead relying on those presented for claim 1. For the same reasons discussed above (*see* II.E.2.a), we determine that Petitioner has established a reasonable likelihood of prevailing on its contention that the combination of Ganatra and Soper renders the subject matter of independent claim 10 unpatentable.

j. Claim 11

Claim 11 depends from claim 10, and further recites "wherein the position information of the first and second landmark information is recorded with respect to a fixed reference frame." Ex. 1001, 14:19–21. Petitioner asserts that "Ganatra explains that the tracking system coordinates 32 are 'in a frame of reference of the tracking system and the patient's body, which is within the field of the tracking system.'" Pet. 65 (citing Ex. 1004 ¶¶ 18–19, Figure 3A; Ex. 1003 ¶¶ 216–17.). Patent Owner does not separately dispute this limitation. We determine that Petitioner has made an adequate showing, at this stage of the proceeding that the art teaches the elements recited in claim 11.

k. Claim 12

Claim 12 depends from claim 10, and further recites "further comprising registering the first and second landmark information to a model of the patient anatomy." Ex. 1001, 14:22–24. Petitioner asserts that Ganatra teaches registering the tracking system with the coordinate system. Pet. 68 (citing Ex. 1004 ¶ 21, Figure 3A; Ex. 1003 ¶¶ 104–05, 223.). Patent Owner does not separately dispute this limitation. We determine that Petitioner has

made an adequate showing, at this stage of the proceeding that the art teaches the elements recited in claim 12.

l. Claim 13

Claim 13 depends from claim 12 and ultimately from claim 10, and further recites "further comprising displaying the model of the patient anatomy registered with graphical representations of the first and second landmark information." Ex. 1001, 14:25–27. Petitioner asserts that Ganatra teaches registering the tracking system with the coordinate system. Pet. 38–41 (citing Ex. 1004 ¶¶ 28–29, Figures 6A–B; Ex. 1003 ¶¶ 159–68.), 68–69. Patent Owner does not separately dispute this limitation. We determine that Petitioner has made an adequate showing, at this stage of the proceeding that the art teaches the elements recited in claim 11.

m. Claims 14–16 and 18

For claims 14–18 Petitioner relies on the same rationale presented above for claims 3, 5, 8, 9. Pet. 69. Patent Owner does not separately dispute these limitations. We determine that Petitioner has made an adequate showing, at this stage of the proceedings, for institution purposes only, that the art teaches the elements recited in claims 14–16 and 18.

n. Claim 17

Claim 17 depends from claim 12 and ultimately from claim 10, and further recites "wherein the guided instrument is the steerable instrument." Ex. 1001, 14:37–38. Petitioner contends that Ganatra teaches that the bronchoscope is guided by an operator. Pet. 60 (citing Ex. 1004 ¶¶ 18–20) Patent Owner does not separately dispute this limitation. We determine that Petitioner has made an adequate showing, at this stage of the proceeding that the art teaches the elements recited in claim 17.

F. Ground 3: Obviousness of Claims 4 and 18 over Ganatra and Larkin

Claim 4 depends from claim 1, and further recites "wherein the first landmark information includes shape information." Ex. 1001, 13:22–23. And claim 18 depends from claim 10, and further recites "wherein the first and second landmark information includes shape information landmark information each include at least one of: information about a shape of the steerable instrument; a timestamp, and a graphical representation." Ex. 1001, 14:38–42.

Petitioner contends that claims 4 and 18 are rendered obvious based on the combination of Ganatra and Larkin. Pet. 70–71. Patent Owner opposes. Prelim. Resp. 26.

For the reasons discussed above with respect to the anticipation rejection of claim 1 based on Ganatra (*see* II.D.2.f), we agree with Patent Owner that Petitioner has not established a reasonable likelihood of prevailing on its contentions that Ganatra in conjunction with Larkin would render the subject matter obvious. Here, Petitioner is not relying on Larkin for providing guidance for navigating to a target location as recited in claim 1, an element missing from Ganatra. Accordingly, the combination with Larkin is not sufficient to establish a reasonable likelihood of prevailing at trial based on this combination.

G. Ground 4: Obviousness of Claims 4 and 18 over Ganatra, Larkin, and Soper

Petitioner contends that claims 4 and 18 are rendered obvious based on the combination of Ganatra, Larkin, and Soper. Pet. 70–71. Patent Owner opposes. Prelim. Resp. 26.

For the reasons discussed above with respect to the obviousness rejection of claims 1 and 10 based on Ganatra and Soper (see II.F.2.a and II.F.2.i). Petitioner asserts that Ganatra teaches determining contours or trajectories of a passageway. Pet. 72 (citing Ex. 1004 ¶ 31; Ex. 1003 ¶¶ 79, 147–49). Petitioner relies on Larkin for teaching a Fiber Bragg Grating sensor. Pet. 72–74 (Ex. 1004 ¶ 42 ("[a]n optical fiber bend sensor comprising one or more optical fibers is provided in the bendable region of the body. Each of these optical fibers includes a Fiber Bragg Grating, preferably a collinear array of Fiber Bragg Gratings."), ¶¶ 44, 95, 99; Ex. 1003, 150–51). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). Petitioner concludes that it would have been obvious to include Larkin's sensor in Ganatra's endoscope to assist in "determining the 'characteristic curvatures, or contours' of the airways." Pet. 73 (citing Ex. 1003 ¶¶ 150–51).

Patent Owner does not separately dispute these limitations, instead relying on arguments presented with respect to claims 1 and 10. Prelim. Resp. 26–27.

We determine that Petitioner has made an adequate showing, at this stage of the proceeding, that the combination of Ganatra, Larkin, and Soper teaches all the elements recited in claims 4 and 18 in order to establish a reasonable likelihood of prevailing in demonstrating that the subject matter of claims 4 and 18 is unpatentable.

III. CONCLUSION

We conclude that Petitioner has established a reasonable likelihood of prevailing in its assertions that at least one of claims 1–18 of the ’601 patent is unpatentable under 35 U.S.C. § 103(a).

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or the construction of any claim term.

IV. ORDER

It is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–18 of the ’601 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the ’601 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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