UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AURIS HEALTH, INC.,
Petitioner,

v.

INTUITIVE SURGICAL OPERATIONS, INC.,
Patent Owner.

Case No. IPR2019-01173
Patent No. 8,801,601

PATENT OWNER'S NOTICE OF APPEAL

Pursuant to 35 U.S.C. §§ 141, 142 and 319, and 37 C.F.R. §§ 90.2 and 90.3, Patent Owner Intuitive Surgical Operations, Inc. ("Intuitive") hereby provides notice that it appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision entered December 11, 2020, (Paper 34), and from all underlying orders, decisions, rulings, and opinions regarding Intuitive's U.S. Patent No. 8,801,601 ("the '601 patent") set forth in *Inter Partes* Review IPR2019-01173.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), the issues on appeal include, but are not limited to:

- The Board's determination that claims 1-18 of the '601 patent are unpatentable under 35 U.S.C. § 103 over Ganatra[1] and Soper[2], or Ganatra, Larkin[3] and/or Soper, including issues related to claim construction, substantial evidence, establishing obviousness under § 103, and the standard for evaluating nexus to evidence of secondary considerations of nonobviousness under § 103 and its related application; and
- Appointments Clause issues relevant to this proceeding and raised in the petitions for writ of certiorari to the U.S. Supreme Court in *Arthrex, Inc. v. Smith & Nephew, Inc.*, No. 19-1458 (filed June 30, 2020), *Smith &*

[1] U.S. Patent Pub. No. 2009/0227861
[2] U.S. Patent No. 7,901,348
[3] U.S. Patent Pub. No. 2007/0156019

Nephew, Inc. v. Arthrex, Inc., No. 19-1452 (filed June 29, 2020), *United States v. Arthrex, Inc.*, No. 19-1434 (filed June 25, 2020), and any other petitions for certiorari that similarly raise Appointments Clause issues, and the Supreme Court's grant of certiorari on this Appointments Clause issue in *United States v. Arthrex Inc.*, No. 19-1434, 2020 WL 6037206, at *1 (U.S. Oct. 13, 2020); and

- All other issues decided adversely to Intuitive in any order, decision, ruling or opinion underlying or supporting the Final Written Decision.

A copy of the decision being appealed is attached to this Notice.

Pursuant to 35 U.S.C. § 142 and 37 C.F.R. § 90.2(a), this Notice is being filed with the Director of the United States Patent and Trademark Office, and a copy of this Notice is being concurrently filed with the Patent Trial and Appeal Board. In addition, a copy of this Notice and the required docketing fees are being filed with the Clerk's Office for the United States Court of Appeals for the Federal Circuit via CM/ECF.

Respectfully submitted,

Dated: December 22, 2020

By: */Erika H. Arner/*

Erika H. Arner, Reg. No. 57,540
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Counsel for Patent Owner
Intuitive Surgical Operations, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on December 22, 2020, a copy of the foregoing **Patent Owner's Notice of Appeal** was filed and served electronically through the Board's E2E system, and a copy was also filed by hand with the Director of the United States Patent and Trademark Office, at the following address:

Director of the United States Patent and
Trademark Office
c/o Office of the General Counsel, 10B20
Madison Building East
600 Dulany Street
Alexandria, VA 22314

I also hereby certify that on December 22, 2020, a copy of the foregoing **Patent Owner's Notice of Appeal** and the filing fee, were filed with the Clerk's Office of the United States Court of Appeals for the Federal Circuit, via CM/ECF.

I also hereby certify that on December 22, 2020, a true and correct copy of the foregoing **Patent Owner's Notice of Appeal** was served via email on counsel of record for the Petitioner at the following:

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Paper No. 34
Entered: December 11, 2020

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 8,801,601 B2

Before ULRIKE W. JENKS, ZHENYU YANG, and JAMES A. WORTH, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge.*

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

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."). With our authorization, Petitioner and Patent Owner filed supplemental briefing addressing claim construction. Papers 13, 15. On December 16, 2019, we instituted an *inter partes* review of claims 1–18 of the '601 patent. Paper 16 ("Dec. Inst."), 40.

Patent Owner filed a Response to the Petition. Paper 18 ("PO Resp."). Petitioner filed a Reply. Paper 22 ("Pet. Reply"). Patent Owner filed a Sur-reply (Paper 24, "PO Sur-reply").

An oral hearing was held on September 15, 2020, a transcript of which has been entered in the record. Paper 33 ("Tr.").

Pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73, we issue this Final Written Decision. Having considered the record before us, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–18 of the '601 patent are unpatentable. *See* 35 U.S.C. § 316(e) (2018).

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). A recognized difficulty when operating a steerable endoscope is that the tip may wind up looping around itself disorienting the operator when the captured image of the endoscope tip fails to clearly indicate the direction of the endoscope in relation to the target site. *Id.* at 2:31–39.

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 objective disclosed in the ’061 patent 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. The first type is “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 second 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 . . . 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:
> [(1a)] receiving a first landmark establishment request;
> [(1b)] 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;
> [(1c)] referencing the recorded information as first landmark information;
> [(1d)] registering the first landmark information to a model of the patient anatomy; and
> [(1e)] 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 (bracketing and numbering added for reference convenience).

> 10. A method for navigating a steerable instrument in a patient anatomy, the method comprising:
>
> [(10a)] recording first information about a reference portion of the steerable instrument located at a first anatomic landmark in the patient anatomy;
>
> [(10b)] 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;
>
> [(10c)] recording second information about the reference portion of the steerable instrument located at a second anatomic landmark in the patient anatomy;
>
> [(10d)] 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
>
> [(10e)] providing guidance for navigating a guided instrument along a path through the first and second anatomic landmarks.

Id. at 13:37–14:18 (bracketing and numbering added for reference convenience).

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

References	Patent / Reference	Date	Exhibits
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. Patent Owner relies upon the Declarations of Vincent Duindam, Ph.D. (Ex. 2007) and Kevin Cleary, Ph.D. (Ex. 2010) to support its opposition to the Petition.

F. The Instituted Grounds of Unpatentability

We instituted trial to review the patentability of claims 1–18 of the ’601 patent on the following grounds. Dec. Inst. 40.

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

[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).

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

Patent Owner contends that a person of ordinary skill in the art would either have (a) a master's or doctoral degree or (b) a bachelor's degree in mechanical engineering, electrical engineering, biomedical engineering, robotics or similar discipline. PO Resp. 6 (citing Ex. 2010 ¶ 28). Patent Owner acknowledges that "[s]ignificant experience in the relevant field could substitute for formal education." *Id.*

On this record, we determine that the ordinary artisan is a person having at least at a bachelor's level educational experience in either mechanical engineering, electrical engineering, biomedical engineering, or robotics, in addition to at least two years' experience in the field of medical robotics or image-guided navigation. This definition is consistent with the level of skill in the art at the time of the invention as reflected by the prior art. *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))). Furthermore, the panel does not perceive that any differences between the definition adopted by the

panel and either of the definitions suggested by the parties would impact our Decision.

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 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

[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).

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.

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).

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.* at 7:43–46, *see also id.* at 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.”).

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. *See* Dec. Inst. 11–12. Neither Petitioner not Patent Owner contest this construction. Pet. 11–12; PO Resp. 7 (citing in support Ex. 1001, Abstract, 9:41–52, 10:25–11:3, 11:59–12:63, Fig. 13; Ex. 2010 ¶ 33).

2. “guidance”

The term “guidance” appears in independent claims 1 and 10, and therefore by virtue of dependency effectively appears in claims 2–9 and 11–18 as well. For the reasons provided in our Institution Decision, we construe “guidance” as graphical indicators such as vectors or arrows that point in the direction the endoscope is to travel. Dec. Inst. 14. Neither Petitioner nor Patent Owner contest this construction. Pet. Reply 2; PO Resp. 9–13 (citing in support Ex. 1001, Title, *id.* at Abstract, *id.* at 1:21–25, *id.* at 2:59-3:23, *id.* at 2:63-67, *id.* at 8:51-54, *id.* at 9:35–40, *id.* at Fig. 12, *id.* at Fig. 15; Ex. 2008, 81).

3. "a path through"

The term "a path through" 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 contends the term "should be construed to mean a path that runs in one side of the anatomic landmark and out of another." Pet. 12–13 (citing Ex. 1003 ¶¶ 53–57; Ex. 1001, 1:33–36, *id.* at 1:52–56, *id.* at 2:18–19; *id.* at 9:44–48; Ex. 1002, 303).

Patent Owner contends that no construction is necessary and the plain and ordinary meaning should apply. PO Resp. 7. However, if construction is needed Patent Owner contends that "a path through" does not have to enter and exit through an anatomic landmark but may be present along the path and the endoscope may encounter an anatomic landmark along the way to the target. *Id.* at 8 (citing Ex. 1001, 7:25–29 ("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 9:41–43 ("the landmarks are established by the operator as he or she guides the steerable endoscope 110 along its path from an entry point to a target site in the patient.")).

We agree with Patent Owner that "a path through" is not limited to situations in which an endoscope has to enter and exit through a physical structure. Therefore, we construe "a path through" as a path traveled by the endoscope to a final destination that encounters landmarks along the way, and encompasses situations in which the endoscope travels in on one side of the landmark and out on the other side as well as situations where the endoscope only passes in close proximity to the landmark.

4. "guidance for navigating . . . along a path through . . . anatomic landmarks"

The phrase "guidance for navigating . . . along a path through . . . anatomic landmarks" 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 contends that the ordinary meaning of "guidance for navigating . . . along a path through" encompass providing guidance only when decisions about which way to go need to be made. Pet. Reply. 16–17. "Just like directions for driving to a destination might provide instructions only for what to do at intersections (*e.g.*, go straight, turn left, take the exit ramp), a system can provide guidance to a target by instructing the operator what to do at each branching point." *Id.* at 17 (citing Ex. 1007, 13:53–56).

Patent Owner contends that guidance along a path requires the arrows to continuously point the operator in the direction of travel. *See* PO Sur-reply 15 (arguing that Petitioner provides "no explanation *why* or *how* a skilled artisan would have applied [Ganatra's] arrows 'along a path' to continuously point the operator 'in the direction to travel' as required by the claims.") Patent Owner contends that both parties' experts agree that "guidance for navigating . . . along a path through" requires continuous guidance that spans a path from starting point to target. PO Sur-reply 21 (citing Ex. 1003 ¶ 118). Patent Owner contends that the limitation of "guidance for navigating . . . along a path through . . . anatomic landmarks" does not encompass intermittent guidance because it requires continuous steering instructions. *See* Tr. 42:20–23; 56:14–57:2.

The claim requires "guidance for navigating . . . along a path through . . . anatomic landmarks." The '601 specification discloses two types of guidance,[4] the first guidance is in the form of a patient model that shows a "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." Ex. 1001, 7:42–46, Figure 7. In addition to the patient model, the computer screen can also show a view of the endoscope's captured image. *Id.* at 7:47–61, Figure 6. The '601 specification describes the second type of guidance as "an additional endoscopic navigation tool [a landmark direction guidance mode], [as] graphical indications showing steering directions to previously defined landmarks in the patient are also provided as an aspect of the present invention." *Id.* at 8:51–54, *see also id.* at 11:16–26 ("FIG. 15 shows . . . a current image 1501 (i.e., an image currently captured by the endoscope 110 . . .) displayed on it along with arrows 1511, 1512 and 1513 respectively providing directional guidance to the mouth entry, stomach entry and colon entry landmarks."). The '601 specification describes that the landmark direction guidance mode can be turned on and off by the operator. *Id.* at 8:61–62. The specification discloses that even when the landmark directional guidance mode is turned off the operator can still guide the endoscope to the target site. *Id.* at 11:48–54. Thus, neither the '601 specification nor the claims require that the graphical indicators need to be continuously displayed.

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[4] Patent Owner acknowledges that guidance in the claims is not limited to the display view from the point of the tip of the endoscope. *See* Tr. 37:3–38:23.

Based on these disclosures in the specification, we do not read the phrase "guidance for navigating . . . along a path through . . . anatomic landmarks" as requiring a continuous visual guide, as argued by Patent Owner. *See* PO Sur-reply 15; *see* Tr. 42:20–23; 56:14–57:2. As discussed above, we construe guidance as graphical indicators in the form of vectors or arrows that point in the direction the endoscope is to travel. *See supra* § II. C.2. Nothing in that construction requires that the indicators need to be continuously displayed and updated. We agree with Petitioner and determine that intermittent guidance provides sufficient information to maneuver the endoscope to a desired destination. For example, when guiding an endoscope through lumens such as those associated with the lung, guidance at bifurcations provides sufficient information for the operator to thread the endoscope through the lumens to a final destination. Once an endoscope is inserted into a lumen there is no need for instructions until an intersection (branch point) is reached. Accordingly, we construe the phrase "guidance for navigating . . . along a path through . . . anatomic landmarks" as encompassing either intermittent or continuous guidance.

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. PO Resp. 22–30.

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.

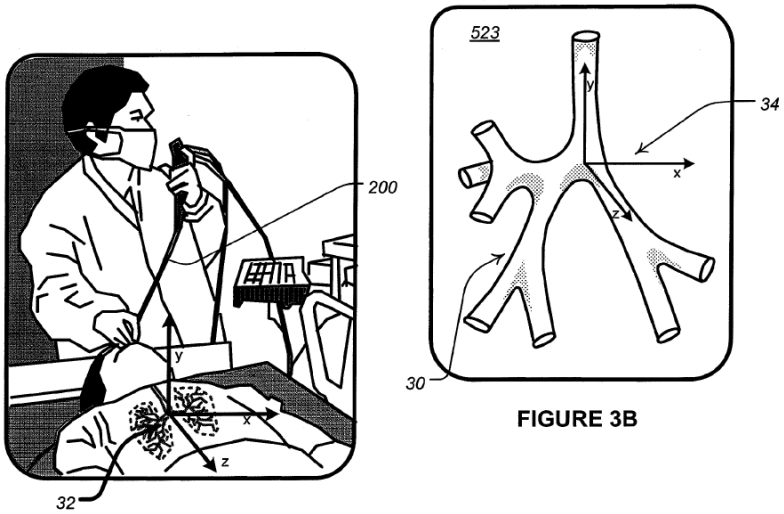


FIGURE 3A

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.

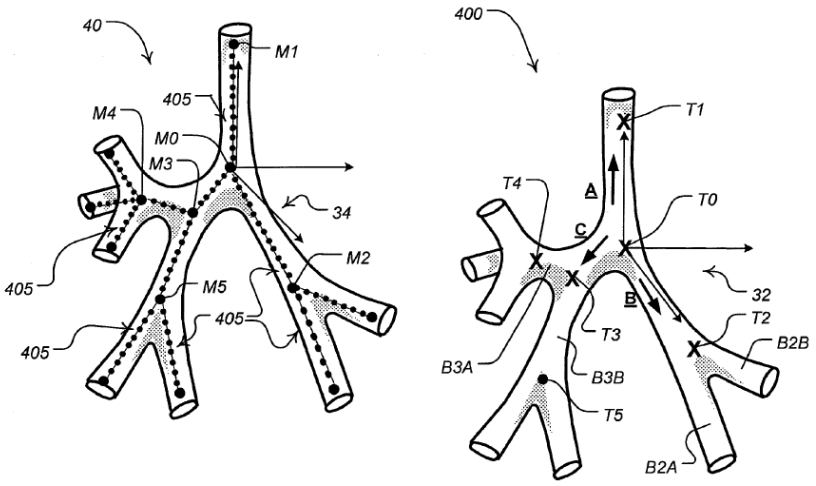


FIGURE 4A

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.

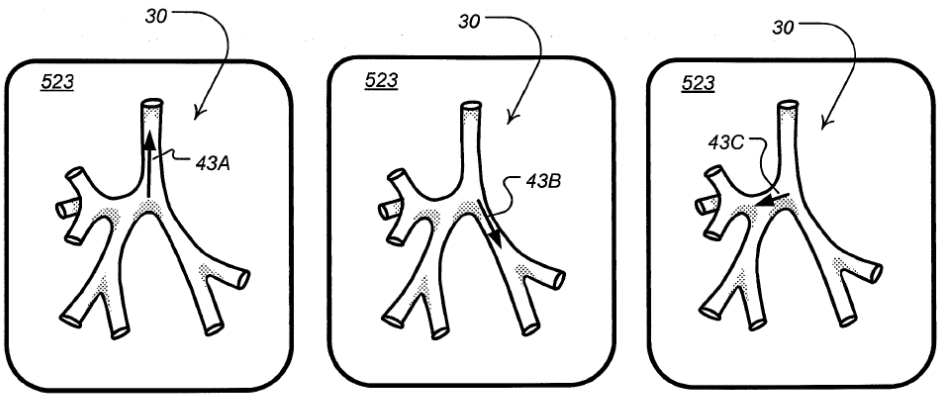


FIGURE 4C FIGURE 4D FIGURE 4E

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.

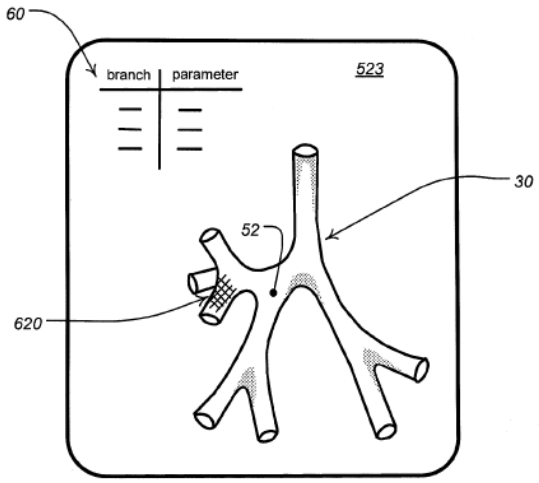
Id.

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[n] 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. Patent Owner opposes. PO Resp. 22–30.

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." *Id.* at 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* PO Resp. 22–30.

Preamble language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim. *See Boehringer Ingelheim Vetmedica, Inc. v. Schering–Plough Corp.*, 320 F.3d 1339, 1345, (Fed. Cir. 2003). Regardless of whether the preamble is limiting, we determine that Petitioner has shown that the recitation in the preamble is satisfied by Ganatra. *See* Ex. 1004 ¶¶ 18–20.

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. *Id.* at 23 (citing Ex. 1004 ¶ 21).

Patent Owner does not contest this limitation. *See* PO Resp. 22–30.

We determine that Ganatra's registration process includes receiving a landmark establishment request thereby meeting the recited limitation. *See* Ex. 1004 ¶¶ 20, 22, 23.

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* PO Resp. 22–30.

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* PO Resp. 22–30.

We determine that Ganatra's registration process includes referencing the recorded information as landmark information. *See* 1004 ¶ 22.

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*." *Id.* at 28 (citing Ex. 1003 ¶¶104–05).

Patent Owner does not contest this limitation. *See* PO Resp. 22–30.

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. *See* Ex. 1004 ¶ 21.

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" about the direction to move bronchoscope in order to "reach each of M1/T1, M2/T2, and M3/T3" targets. *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 33 (citing Ex. 1003 ¶¶ 114–15). Dr. Hannaford further concludes that the use of arrows disclosed in Ganatra for guiding the registration process would similarly work "in the same manner to guide the

operator to [c]ite 620 to perform a procedure." *Id.* at 33 (citing Ex. 1003 ¶¶ 115–16).

Patent Owner contends that "Petitioner concedes that Ganatra illustrates using arrows ('visual indicators' 43A, 43B, and 43C) only during the initial registration process (Pet. 33) and that Ganatra does not "explicitly illustrate" using 'additional visual indicators' to navigate to target site 620 (Pet., 32)." PO Resp. 23–24. Patent Owner contends that Dr. Hannaford's testimony cannot be used to fill in gaps in Ganatra's disclosure. *Id.* at 24–25 (citing *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (to establish anticipation, "it is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole.")); *see also Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991)). 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. PO Resp. 27 (citing Ex. 1004 ¶ 19; Ex. 2010 ¶ 56). 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 28 ("one skilled in the art would have concluded that initial registration and guidance for navigation to a target were distinct and separate concepts. *See* Ex. 2010, ¶¶52–56.").

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).

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 registration path and registration targets are thereby preplanned before the procedure begins. After registration is complete, 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[n] 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 when navigating the bronchoscope to reach a particular target site, such as site 620. In other words, Ganatra does not disclose using a pre-procedural path to a target site, such as site 620, for the endoscope to follow in order to reach the target location within the patient. Accordingly, we determine that Petitioner has not established that Ganatra anticipates the subject matter of independent claim 1.

g. Claims 2 and 5–9

For the same reasons discussed above (*see supra* § II.D.2.f) for claim 1, we determined that the evidence presented by Petitioner does not establish anticipation for dependent claims 2 and 5–9.

h. Alleged Obviousness Ground over Ganatra Alone

Petitioner states the claims would have been obvious over Ganatra alone. *See* Pet. 35 ("Even 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."), 46; *see also* Tr. 12:4–5 ("In the petition, petitioner also has grounds asserting that Ganatra alone suggested implementing its navigation guidance using arrows.").

Patent Owner argues that Petitioner's alternative obviousness ground based on Ganatra alone is legally insufficient. PO Resp. 29–30 (citing *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (The obviousness inquiry is "whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention.") (emphases in original)).

We agree with Patent Owner that Petitioner's single sentence obviousness ground based on Ganatra alone (*see* Pet. 35 and 46) does not meet the burden of identifying the specific evidentiary support from which to reach a conclusion of obviousness. As the Federal Circuit has explained, "[i]n an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (emphasis added) (citing 35 U.S.C. § 312(a)(3)); *see also Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) ("It is of the utmost

importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify 'with particularity' the 'evidence that supports the grounds for the challenge to each claim.'" (quoting 35 U.S.C. § 312(a)(3)); *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016) ("To satisfy its burden of proving obviousness, a petitioner cannot employ mere conclusory statements. The petitioner must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.").

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. PO Resp. 30–60.

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 references 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. PO Resp. 30–60.

a. Independent claim 1

As discussed above (*see* II.D.2.a– II.D.2.e), Petitioner contends that Ganatra meets elements (1a)–(1d) as recited in claim 1. *See* Pet. 20–28. Patent Owner does not dispute these limitations. *See* PO Resp. 22–30. Instead, the dispute lies with the element (1e) of the '601 patent, which recites "*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 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 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.'" *Id.* at 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). Petitioner asserts that Ganatra "describe[s] a process for using arrows to guide a user through landmarks to a target location" during the registration process and reasons that the same process would similarly be applied for

navigating the endoscope along a path to a target location. *Id.* at 46 (citing Ex. 1003 ¶ 125); *see also id.* at 50 (citing Ex. 1003 ¶ 125 (A person of ordinary skill in the art would "configure the system [of Ganatra] to use a line (instead of or in addition to arrows) to display the entire path from M0/T0 to target site 620 as taught by Soper (*see* [Ex. 1007] Figs. 4A and 4D, above).")); Tr. 15:6–8 (Petitioner asserts that "the same navigation system that was used during registration process [in Ganatra] to provide the arrows. So this [same] system is available to Ganatra during navigation.").

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. Ganatra provides guidance in the form of arrows for "registering tracking coordinate system 32 with model coordinate system 34." *Id.* ¶ 20. Ganatra's figures 4A-4E are reproduced below:

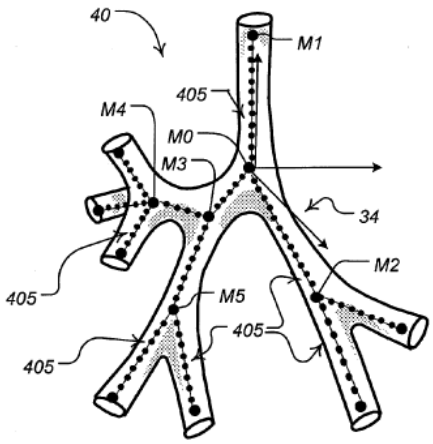


FIGURE 4A

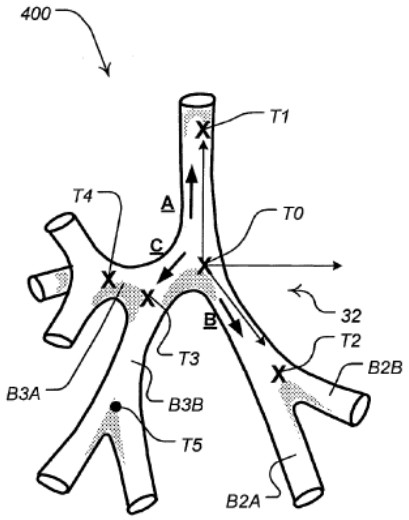


FIGURE 4B

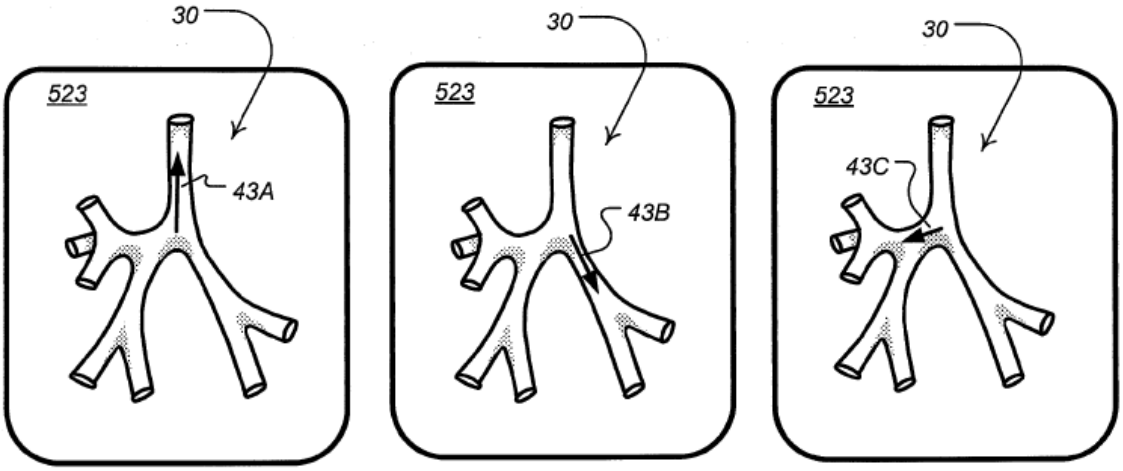


FIGURE 4C FIGURE 4D FIGURE 4E

"FIG. 4A is a schematic representation of a model of the bronchial tree structure of the patient, the model including predetermined points defining a pathway along branches of the tree, and some designated points of the predetermined points" *Id.* ¶ 10. "FIG. 4B is a schematic representation of an actual bronchial tree structure of the patient." *Id.* ¶ 11.

"FIGS. 4C-E are schematics of the display element of the navigation system presenting a representation of the model of the bronchial tree structure and including indicators for providing instructions to a user of the navigation system." *Id.* ¶ 12.

> [Visual] indicators 43A, 43B, 43C [in the form of arrows] may provide guidance to a user of the navigation system for carrying out the above-described registration process according to a particular sequence. . . . FIGS. 4C-E[, reproduced above,] illustrate a sequential series of displays 30, presented by display element 532, to guide the bronchoscope operator to move the bronchoscope along branches of the patient's bronchial tree, according to indicators 43A, 43B and 43C, in order to sequentially find points T1, T2 and T3 (FIG. 4B), which correspond to designated points M1, M2 and M3 [in the model]

> (FIG. 4A[, reproduced above]). According to some embodiments, once the operator has moved the bronchoscope far enough in direction A (FIG. 4B[, reproduced above]), for example to point T1, such that processor 522 has matched the Euclidean distance for sensor X to that of designated point M1, indicator 43A disappears from display 30 and then indicator 43B appears, as shown in FIG. 4D; likewise, once the operator has moved the bronchoscope far enough in direction B, for example to point T2, such that processor 522 has matched the Euclidean distance for sensor X to that of designated point M2, indicator 43B disappears from display 30 and indicator 43C appears, as shown in FIG.4E, and likewise for movement in direction C. It should be appreciated that additional 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.

Ex. 1004 ¶ 24; *see* Pet. 29. Thus, Ganatra exemplifies using arrows during the registration process, and acknowledges other types of indicators for providing similar guidance with the movement of the bronchoscope. Ex. 1004 ¶ 24. Ganatra explains that during the registration process, once the designated points are reached with the bronchoscope (i.e. T1, T2, T3, . . .), then the arrow disappears from the display and the next arrow guiding to the next registration point in the sequence appears. *Id.*

[D]esignated points M2 and M3 of predetermined points 405 of

> model 40, are preferably located at branching points, and it may be appreciated that downstream designated points, such as M4 and M5, are also preferably located at branching points, since branching points can serve as effective demarcations for the initiation and termination of each subsequent set of distance calculations, so that, as the bronchoscope is moved deeper into the branching structure 400, and continues to encounter new branching points (this detail is not shown in FIGS. 4A-B, but may be appreciated with reference to FIGS. 1 and 3C), the registration of coordinate systems 32 and 34 can be automatically refined throughout the bronchoscopy procedure, without interruption of navigation guidance provided by navigation system 50 to the operator, for example, via movement of tracking sphere 52 along display 30.

Ex. 1004 ¶ 26.

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." Pet. 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 details with respect to visual navigation introduced in Ganatra but not explicitly described in the context of reaching the target. Pet. 46 (citing Ex. 1004 ¶ 29 ("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.'")).

Soper discloses a road-map decision model that is "[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, *see also id.* at 20:15–18 (An extended model to navigate beyond the 3D model "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.").

Figures 4A and 4D of Soper are reproduced below:

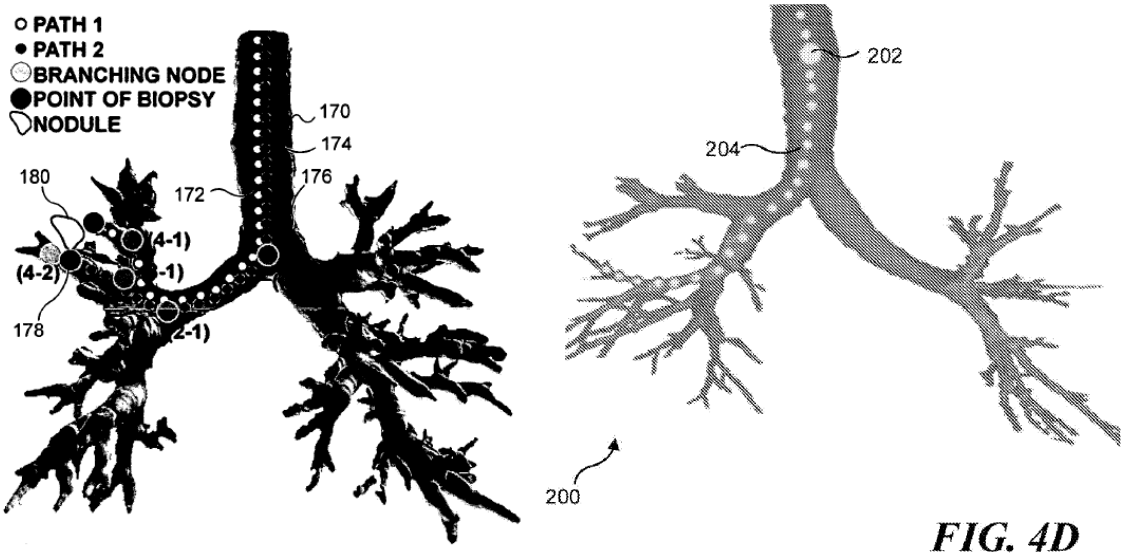


FIG. 4A

FIG. 4D

Figure 4A shows a display in the user interface of the 3-D lung surface model and pre-procedural path planning (Ex. 1007, 13:58–60) including "selected points targeted for a biopsy, and an automated course planning through the lung passages (where the generation index of each branch point is indicated)." *Id.* at 5:56–60. Figure 4D shows the static 3D airway surface model along with navigation route 204 and the current position of the flexible endoscope. *Id.* at 13:65–68.

Based on the combination of Ganatra and Soper, Petitioner concludes that it would have been obvious to a person of ordinary skill in the art at the time of the invention "to illustrate the navigation path to the operator using arrows and/or a line superimposed on the computer model of the patient's

lungs as taught by Soper." Pet. 48 (citing Ex. 1003 ¶ 125). In other words, Petitioner is relying on Soper's teaching of providing a preplanned navigation route to a target point of interest and Petitioner explains that one of ordinary skill in the art would use Ganatra's arrows in the same manner that Ganatra applies the arrows to a preplanned route during the initial registration process. *See* Pet. Reply 18 (citing Pet. 48–49; Ex. 1003 ¶¶ 125–126); *see also* Pet. 47 ("Soper explains that its user interface includes 'windows displaying the 3-D lung surface model and pre-procedural path planning (Fig. 4A)' and displaying 'the intended navigation routes to the points of biopsy are shown in FIG. 4D.' Ex.1007, 13:58-66."); 50 (arguing that a person of ordinary skill in the art would "configure the system [of Ganatra] to use *a line (instead of or in addition to arrows)* to display the entire path from M0/T0 to target site 620 as taught by Soper (*see* Figs. 4A and 4D, above)." (emphasis added)), 56 ("As integrated into Ganatra, these lines [of Soper] are a model of the path through the '*plurality of anatomic landmarks*' and are displayed on the model of the patient's anatomy."); Ex. 1003 ¶ 126 (Petitioner's expert Dr. Hannaford avers: "[A] person of ordinary skill in the art could configure the system to use a dotted line (instead of or in addition to arrows) to display the entire path from M0/T0 to target site 620 as shown by Soper (*see* Soper Figs. 4A and 4D []) or both a dotted line and arrows.").

A person of ordinary skill in the art is not an automaton and can fit teaching of multiple patents together like pieces of a puzzle. *KSR*, 550 U.S. at 420, 421; Pet. Reply 18. Here, Petitioner's combination[5] does not rely on

[5] Petitioner presents three reasons of unpatentability based on obviousness:

the incorporation of Soper's arrows into Ganatra's navigation but instead is looking to Soper for providing a preplanned route, i.e. a model path, for reaching an intended target and then applying Ganatra's arrows just like in the registration process. Pet. Reply 18 (A person of ordinary skill in the art "configuring Ganatra to use arrows to provide navigation guidance to target site 620, as suggested by Soper, would have done so in the same manner that Ganatra uses arrows in the registration process. Pet., 48–49; Ex.1003, ¶¶125–26."); Pet. 56 ("As integrated into Ganatra, these lines [of Soper] are a model of the path through the "*plurality of anatomic landmarks*" and are displayed on the model of the patient's anatomy.").

Patent Owner contends that the Petition fails because the combination of Ganatra and Soper lacks an element as claimed, lacks motivation to combine the references, lacks a reasonable expectation of success, and hindsight. PO Resp. 30–55. Additionally, Patent Owner also contends that even if the Board finds that the combination renders the claims obvious,

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(1) Ganatra renders guidance for navigating obvious: "[A person of ordinary skill in the art] would have understood Ganatra to describe a process for using arrows to guide a user through landmarks to a target location" (Pet. 46); (2) Soper renders guidance obvious: "A [person of ordinary skill in the art] considering how to provide additional indicators to help guide an operator to the target site as taught by Ganatra would have looked to other references [such as Soper] for examples of how others in the field had provided such guidance" (Pet. 47); and (3) The combination of Ganatra and Soper renders guidance obvious: a person of ordinary skill in the art would "configure the system [of Ganatra] to use a line (instead of or in addition to arrows) to display the entire path from M0/T0 to target site 620 as taught by Soper (*see* Figs. 4A and 4D, []).." Pet. 50. We agree with Patent Owner that individually, neither Ganatra nor Soper renders the claimed guidance obvious. However, for the reasons discussed in this decision we determine that the combination of Ganatra and Soper renders the claims obvious.

secondary considerations should rebut any showing of obviousness. *Id.* at 55–60. We address Patent Owner's contentions below.

1. Missing element

i. "guidance"

Patent Owner contends that "Soper's planned paths or intended navigation routes are not updated based on a current position or orientation of the bronchoscope," therefore Soper does not provide "guidance" as required by independent claim 1. PO Resp. 33–34.

We are not persuaded by Patent Owner's contention that Soper does not update the display. Petitioner explains that Soper describes the use of visual indicators in the form of a preprocedural path for navigating to a point of biopsy. Pet. 47 (citing Ex. 1003 ¶¶ 125–125). Soper's user interface includes "windows displaying the 3-D lung surface model and pre-procedural path planning (Fig. 4A)" and displaying "the intended navigation routes to the points of biopsy [as] shown in FIG. 4D." Pet. 47 (citing Ex. 1007, 13:58–66). Soper includes:

> A position sensor on the endoscope [that] 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.

Ex. 1007, 3:1–7, *see also id.* at 10:1–10. Based on these disclosures in Soper, we agree with Petitioner and are not persuaded by Patent Owner's contention that Soper does not update the current position or orientation of the endoscope.

We are also not persuaded by Patent Owner's contention that Soper does not provide "guidance" because Petitioner is not solely relying on Soper for this limitation. Petitioner is relying on Ganatra's arrows for directing the endoscope along a path such as the path disclosed in Soper. *See* Pet. 48 ("[A person of ordinary skill in the art] considering Ganatra would have found it obvious to illustrate the navigation path to the *operator using arrows and/or a line* superimposed on the computer model of the patient's lungs as taught by Soper. Ex. 1003, ¶ 125." (emphasis added)), 50 (A person of ordinary skill in the art would "configure the system to use a line (instead of or in addition to arrows) to display the entire path from M0/T0 to target site 620 as taught by Soper (*see* Figs. 4A and 4D, []). [Ex. 1003] ¶ 126"). In other words, Petitioner is relying on the combination of Ganatra's arrows in conjunction with the line of the pre-procedural path superimposed on the computer model to a target location as described in Soper to arrive at the limitations recited in claim 1(e).

We determine that the evidence of record supports Petitioner's position that the combination of Ganatra and Soper teaches the "guidance" limitation of claim 1(e). As discussed above (*see supra* § II.C.2), we construe guidance as graphical indicators in the form of vectors or arrows that point in the direction the endoscope is to travel. We further determined that guidance can be either continuous or intermittent as long as it provides the operator sufficient information to reach the final destination (*see supra* § II.C.4). We next determine whether the combination of Ganatra and Soper teaches reaching a target of interest by navigating through anatomic landmarks.

ii. "guidance for navigating . . . along a path through . . . anatomic landmarks"

Patent Owner contends that Soper does not overcome the deficiencies of Ganatra, arguing, specifically, that the combination lacks "guidance for navigating . . . along a path through . . . anatomic landmarks" as recited in claim 1(e). PO Resp. 30. Patent Owner contends that "[a] plot of the planned path or intended route to the target, as shown in Soper's Figures 4A and 4D (annotated below), does not constitute 'graphical indicators' that 'point in the direction the endoscope is to travel.'" *Id.* at 32. "Soper's displays of static, preplanned paths or intended navigation routes (or a mere showing of current position of the bronchoscope relative to an intended route) are not sufficient to meet the 'guidance' limitation of claim[] 1." *Id.* at 34.

We agree with Petitioner, that Patent Owner's focus on Soper alone is unpersuasive when the proposed grounds of unpatentability are premised on the combination of Ganatra and Soper. Pet. Reply. 18–20 (citing *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986); *see also In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (the test for obviousness is "what the combined teachings of the references would have suggested to those of ordinary skill in the art")). According to Petitioner, one of ordinary skill in the art based on the teachings of Ganatra would have found it obvious to illustrate the navigation path to the operator using arrows in conjunction with Soper's line superimposed on the computer model of the patient's lung. *See* Pet. 50 (A person of ordinary skill in the art would "configure the system [of Ganatra] to *use a line (instead of or in addition to arrows)* to display the entire path from M0/T0 to target site 620 as taught by Soper (*see* Figs. 4A and 4D, []). [Ex.1003] ¶ 126." (emphasis added)).

Petitioner acknowledges that Ganatra only provides guidance arrows during registration but finds that a person having ordinary skill in the art would nevertheless have reasonably inferred "Ganatra to generally disclose that the[] arrows can be used to guide a user to a destination" and that the same technique would apply during the navigation to a target of interest. Pet. Reply 4–5 (citing Ex. 1003 ¶¶ 114–115, 122; Pet. 46, 48). Ganatra explains that once the operator has moved the endoscope far enough from one registration target to the next registration target, the indicator (an arrow) disappears from the display and the next indicator (an arrow) for the next registration target appears on the display. Ex. 1004 ¶ 24; Fig. 4. Both Petitioner's expert and Patent Owner's expert agree that Ganatra's arrows direct the endoscope to registration points during the registration process. *See* Ex. 1003 ¶ 114 (Petitioner's expert, Dr. Hannaford testifying: "Ganatra shows how arrows can be used to guide the operator along a path to the appropriate designated points in the context of the initial registration process."); Ex. 1020, 42:21–24 (Patent Owner's expert, Dr. Cleary testifying: "Yes, I would think that the arrows, you know, would be useful to helping an operator move the scope to the registration points."), 50:2–7 (Patent Owner's expert, Dr. Cleary further testifying: "In this case, Ganatra is using the arrows for the registration process to show the operator where to move the scope in order to get to the next registration point, that is correct."). Petitioner additionally points out that it is the same system in Ganatra that is used during the registration process is also used in the navigation process. Tr. 15:6–8 ("[The] same navigation system that was used during registration process [in Ganatra] to provide the arrows. So this [same] system is available to Ganatra during navigation."). The evidence

supports the position that Ganatra's arrows point in the direction the endoscope is to travel and thereby guide the endoscope movement even if this guidance is only expressly taught in connection with the registration process.

Soper provides a preplanned path through the bronchial passages to reach a desired biopsy point. "The layout of this course is analogous to a roadmap where navigation relies on a series of decisions or turns one would make in route to reach a desired destination." Ex. 1007, 13:53–56. "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 14:23–35. "[T]he 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 13:64–67, Figure 4D. The evidence supports the position that Soper teaches a preplanned route to a designated biopsy target.

The obviousness analysis "can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR,* 550 U.S. at 418. "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 421.

We agree with Petitioner that it is reasonable to infer from the teachings of Ganatra that arrows used for guiding the endoscope from one registration target to the next registration target along a preplanned route would similarly guide the endoscope to a target of interest along a preplanned route as taught by Soper. *See* Pet. 48 (citing Ex. 1003 ¶ 125), 50

(citing Ex. 1003 ¶ 126); Pet. Reply 4–5.[6] Based on the combined teachings of Ganatra and Soper, we determine that the preponderance of evidence of record supports Petitioner's position that the combination of Ganatra and Soper teaches the limitation of "guidance for navigating . . . along a path through . . . anatomic landmarks" of claim 1(e).

2. Motivation to combine

Patent Owner contends that Petitioner fails to adequately explain the motivation to modify Ganatra in view of Soper. PO Resp. 47–50.

We are not persuaded by Patent Owner's contention that Petitioner has not sufficiently articulated a reason for combining Ganatra and Soper. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR,* 550 U.S. at 416. "[T]he analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id*. at 418. "[E]vidence of a motivation to combine need *not* be found in the prior art references themselves, but rather may be found in 'the knowledge of one of ordinary skill in the art or, in some cases, from the nature of the problem to be solved.'" *Dystar Textilfarben Gmbh & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1366 (Fed. Cir. 2006) (citation omitted).

[6] Indeed, in the next section, we conclude that a person of ordinary skill would have sought to apply Ganatra's arrows used for guiding the endoscope during registration to the preplanned route taught as by Soper for purposes of navigation.

Here, Petitioner directs us to teachings in Ganatra that suggest using the system to navigate to a site of interest. Pet. 18 ("[Ganatra] 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.

> As Dr. Hannaford explained, Ganatra's lack of explicit detail on providing navigation guidance to a target "provides a specific motivation to the [person of ordinary skill in the art] to look to other references for additional details on how such indications could be implemented." [] Thus, Ganatra provides an explicit motivation or suggestion for a [person of ordinary skill in the art] to look to other references for ways to implement navigation guidance.

Pet. Reply 8 (citing Ex. 1003 ¶ 122). Patent Owner's expert, Dr. Cleary testified:

> Q. So does Ganatra have any figures depicting all the different forms of navigation guidance that can be provided to the operator during the procedure?
>
> A. No, I would not agree with that statement because I would imagine there are many different types of guidance that can be provided, so I would not think that all those different types are shown in the figures in Ganatra.

Ex. 1020, 63:9–18. We agree with Petitioner's articulated motivation that Ganatra's lack of detail of how to traverse through the bronchial passages to arrive at an intended target, i.e. a biopsy site, would have motivated one of ordinary skill in the art to consult similar references for such teachings.

Petitioner identifies Soper as disclosing an analogous bronchoscope system that contains similar features to Ganatra's system (Pet. 45), and teaching use of a preplanned path to direct an operator of a bronchoscope to a site of interest. Pet. 46–48 (Ex. 1007, 13:58–66, 20:15–18; Ex. 1003 ¶¶ 80,

81, 122–25). Petitioner contends that "Soper also describes the benefits of navigation guidance, which provides additional motivation to incorporate such features into Ganatra." Pet. Reply 10 (citing Ex. 1003 ¶¶ 80–81).

Soper discloses that the benefit of providing instructions for navigating through a complex structure such as the lung using its navigation system is that it avoids the use of more specialized equipment such as C-arm fluoroscopy units, CT, or MRI scanners during the examination. Ex. 1007, 7:51–52. Soper explains that navigation of endoscope devices

> typically relies on an optical view from the head of the scope, this does not necessarily aid in directing the catheter through a system where there is extensive branching. The exponential increase in complexity underscores the need for some means of visually tracking the position of this endoscope on a [high-resolution computed tomography] HRCT generated 3-D model so that it may effectively guide the physician at each branch point as well as recording the regions that have been inspected.

Id. at 7:39–47. Soper discloses displaying intended navigation routes to the point of biopsy in a static 3D airway surface model along with a current position of the flexible endoscope. *Id.* at 13:62–67.

We determine that the evidence of record supports Petitioner's position that there is sufficient motivation to arrive at the combination of Ganatra and Soper.

3. Reasonable expectation of success

Patent Owner contends that Petitioner fails to establish that there would have been a reasonable expectation of success in combining Ganatra and Soper. PO Resp. 52–55.

"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.'" *CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (quoting *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–1368 (Fed. Cir. 2016)). "The reasonable expectation of success requirement refers to the likelihood of success in combining references to meet the limitations of the claimed invention." *Intelligent Bio-Sys., Inc.,* 821 F.3d at 1367. A reasonable expectation of success "does not require a *certainty* of success." *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006).

We already determined that there is sufficient motivation to combine Ganatra and Soper (*see supra* § II.E.2.a.3), we next address whether there is also a reasonable expectation of successfully navigating to a biopsy site based on the combination.

Ganatra shows how arrows are used "to guide the operator along a path to designated points in the context of the initial registration process." Pet. 32 (citing Ex. 1004 ¶ 24, Figures 4C–4E), 49. Both Petitioner's expert and Patent Owner's expert agree that Ganatra's arrows direct the endoscope to registration points during the registration process. *See* Ex. 1003 ¶ 114, *Id.* (Petitioner's expert, Dr. Hannaford testifying: "Ganatra also shows how arrows can be used, showing use of arrows to guide the operator along a path designated points in the context of the initial registration process."); Ex. 1020, 42:21–24 (Patent Owner's expert, Dr. Cleary testifying: "Yes, I would think that the arrows, you know, would be useful to helping an operator move the scope to the registration points."), 50:2–7 (Patent Owner's expert, Dr. Cleary further testifying: "Ganatra is using the arrows for the registration

process to show the operator where to move the scope in order to get to the next registration point, that is correct."). We find that Ganatra's arrows can reasonably guide the movement of the endoscope from one target point to the next target point.

Soper discloses an analogous bronchoscope system that contains similar features to Ganatra's system (Pet. 45), and provides a preplanned path to direct an operator of a bronchoscope to a site of interest. Pet. 46–48 (Ex. 1007, 13:58–66, 20:15–18; Ex. 1003 ¶¶ 80, 81, 122–25). Soper teaches that regions of interest are selected as intended points of biopsy. *See* Ex. 1007, 13:45–56. Soper's method plots a series of paths through the bronchial passages leading to the points of biopsy. "The layout of this course is analogous to a roadmap where navigation relies on a series of decisions or turns one would make in route to reach a desired destination." *Id.* at 13:53–56.

Based on the combination of Ganatra and Soper, Petitioner concludes that it would have been obvious to a person of ordinary skill in the art "to illustrate the navigation path to the operator using *arrows and/or a line* superimposed on the computer model of the patient's lungs as taught by Soper." Pet. 48 (citing Ex. 1003 ¶ 125) (emphasis added). In other words, Petitioner is relying on Soper's teaching of providing a preplanned navigation route to a target point of interest and explains that one of ordinary skill in the art would similarly use Ganatra's arrows in the same manner that Ganatra applies these arrows to following a preplanned route during Ganatra's registration process. *See* Pet. Reply 18 (citing Pet. 48–49; Ex. 1003 ¶¶ 125–126); *see also* Pet. 50 (A person of ordinary skill in the art would "configure the system [of Ganatra] to use *a line (instead of or in*

addition to arrows) to display the entire path from M0/T0 to target site 620 as taught by Soper (*see* Figs. 4A and 4D []).”), 56 (“As integrated into Ganatra, these lines [of Soper] are a model of the path through the ‘*plurality of anatomic landmarks*’ and are displayed on the model of the patient’s anatomy.”). We agree with Petitioner that there is a reasonable expectation of success in using Ganatra’s arrows to provide navigation guidance along a preplanned path because “Ganatra already teaches how arrows can be used to provide guidance to a user during the registration process.” Pet. Reply 14 (citing Ex.1004 ¶ 29; Ex.1003 ¶¶115–119). Accordingly, we are not persuaded by Patent Owner’s contention that the combination of references lacks a reasonable expectation of success.

Patent Owner also contends that “Petitioner has not identified any prior art that discloses dynamic navigation guidance[7] using graphical indicators along a path to a target site, as disclosed and claimed in the ’601 patent.” PO Resp. 54. Patent Owner contends that in order “to provide ‘guidance’ all along a path, the system has to continuously track not just the position but also the orientation of the endoscope within the patient’s anatomy, and use the current position and orientation information to generate a continuously-updated ‘roadmap’ in the form of arrows or other graphical indicators.” *Id.* at 53.

We are not persuaded by Patent Owner’s contention. We do not construe “guidance for navigating . . . along a path through . . . anatomic

[7] We note that “guidance” in the claims is not limited to the perspective of the endoscope camera, i.e. the camera view, but also encompasses tracking the movement of the endoscope on a model display of the patient’s anatomic structure. *See supra* § II.C.4; Tr. 37:3–38:23.

landmarks" to require graphical indicators to be continuously updated. *See supra* § II.C.4. As explained above (*see* § II.C.4), the phrase encompasses *either* intermittent or continuous guidance in the form of arrows or vectors. Because our construction of the claim does not require continuous guidance, we are not persuaded by Patent Owner's arguments that address dynamic or continuous updating requirement with respect to guidance. *See* PO Resp. 54 ("a continuously-updated 'roadmap' in the form of arrows or other graphical indicators." (citing Ex. 2010 ¶ 94)).[8] Here, the claims are broad enough to encompass either continuous or intermittent guidance. Arguments focusing on continuous or dynamic guidance when the combination as proposed by Petitioner encompasses intermittent guidance does not persuade us that there is a lack of reasonable expectation of success in combining the teachings of Ganatra and Soper.

4. Hindsight

Patent Owner contends that Petitioner's motivation for the combination is tainted by hindsight. PO Resp. 50–52. "Neither Ganatra nor Soper recognizes the scope disorientation problem explained in the '601 patent, let alone suggest solutions to overcome that problem." *Id.* at 50 (citing Ex. 2010 ¶ 92). Absent hindsight, "there is still no explanation *why* or *how* a skilled artisan would have applied the arrows 'along a path' to continuously point the operator 'in the direction to travel' as required by the claims." PO Sur-Reply 15.

The '601 patent specification provides two types of displays, a computer model and a captured image display. A computer model display

[8] We note that the burden of proof rests with Petitioner. 35 U.S.C. § 316(e).

"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." *Id.* at 7:43–46, Fig. 7. The same auxiliary screen can also show images captured by the endoscope. *Id.* at 7:47, Fig. 6. The endoscope image can additionally contain superimposed images of steering directions. *Id.* at 10: 27–28, Fig. 15.

Patent Owner's argument with respect to continuously pointing the operator in the direction of travel, however, are directed to limitations that are not in the claims and therefore not persuasive.

Petitioner's analysis does not suffer from the hindsight selectivity because Petitioner proposes the incorporation of a model path as disclosed in Soper into Ganatra's navigation system. *See* Pet. 50 ("Alternatively, a [person of ordinary skill in the art would] configure the system [of Ganatra] to use a line (instead of or in addition to arrows) to display the entire path from M0/T0 to target site 620 as taught by Soper (*see* Figs. 4A and 4D, []). [Ex. 1003] ¶126."); *KSR*, 550 U.S. at 416 ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."). Petitioner explains that Ganatra's arrows shown to be used for guidance during the registration process can similarly be used to guide an operator along a path to a destination during a procedure. Pet. 32 (citing Ex. 1003 ¶ 114–115); Pet. Reply 18 ("[A person of ordinary skill in the art] configuring Ganatra to use arrows to provide navigation guidance to target site 620, as suggested by Soper, would have done so in the same manner that Ganatra uses arrows in the registration process. Pet., 48-49; Ex.1003, ¶¶ 125-26."). Petitioner supports its reasoning that a person of skill in the art would have found it obvious to implement

Ganatra's arrows not just during the registration process but also during navigation with testimony from Dr. Hannaford, which we credit. *See* Ex. 1003 ¶¶ 114–115, 125–126 (explaining how that same process used during registration can similarly be implemented to reach a target of interest).

5. Secondary considerations

We must consider any evidence of objective indicia of non-obviousness before reaching our conclusion on obviousness *vel non*. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016). Notwithstanding what the teachings of the prior art would have suggested to one of ordinary skill in the art at the time of the invention, the totality of the evidence submitted, including objective evidence of non-obviousness, may lead to a conclusion that the challenged claims would not have been obvious to one of ordinary skill. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984). Patent Owner presents the following objective indicia of non-obviousness: (1) unexpected results and (2) long-felt need. PO Resp. 55–60; PO Sur-Reply 21–25.

i. Unexpected results

Patent Owner argues that they have "shown nexus by showing the secondary considerations are a 'direct result of the unique characteristics of the claimed invention,' i.e., the 'guidance' element" by showing that the Ion system is "essentially the same invention" as claimed in the '601 patent. PO Sur-Reply 23 (citing *FOX Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373–74, 1377–78 (Fed. Cir. 2019)). Patent Owner explains that "the Ion™ System supplements the[] standard navigation views with a simulated endobronchial view of the airways superimposed with a graphical indicator in the form of a 3D line." PO Resp. 57 (citing Ex. 2007 ¶ 18; Ex. 2009 (Ion

Manual) at 8-3 (Figure 8.4)). According to Patent Owner, "the closest prior art methods (such as those disclosed in Ganatra and Soper) only track a position of the bronchoscope tip, provide some form of visual indication at the target location, and/or provide select directional guidance at airway bifurcations." *Id.* at 58.

Patent Owner's expert, Dr. Duindam, explains that "[t]he lung tree is a complex anatomical space, which makes it difficult to navigate to a target biopsy location." Ex. 2007 ¶ 21. Dr. Duindam avers that the Ion system navigation method embodies the methods of claims 1 and 10 of the '601 patent. *Id.* ¶¶ 17–22. Dr. Duindam explains that the system provides "a graphical indicator in the form of a 3D line that is superimposed on a simulated endobronchial view of the airways, as depicted in the image below (the blue 3D line in the bottom-left image)." *Id.* ¶ 18. Figure 8.4 from the Ion User manual is reproduced below.

Id. (citing Ex. 2009 at 8-3). Figure 8.4 is an illustration of an example of a planned pathway to target. Ex. 2009 at 8-3. Patent Owner explains that "there was concern at Intuitive that bronchoscopist, who are mainly

accustomed to viewing only CT scans or airway tree models, would not be able to understand and follow the real-time, dynamic navigation guidance provided by the Ion™ System," and that the commercial embodiment "provides surprisingly effective guidance to the operators when navigating to a target in the far periphery of the lung." PO Reply 57–58 (citing Ex. 2007 ¶ 19). Dr. Duindam explains that "the Ion system provides continuous visual guidance for steering the bronchoscope, which operators are easily able to follow and use when traversing the lung airways. In particular, the virtual rendering from inside the patient (i.e., the endobronchial view), superimposed with the continuously updated 3D graphical line, provides surprisingly effective guidance to the operators when navigating to a target in the far periphery of the lung." Ex. 2007 ¶ 19.

Petitioner argues that Patent Owner has not established the requisite nexus. Pet. Reply 21 (citing *Nevro Corp. v. Boston Sci. Neuromodulation Corp.*, IPR2017-01812, Paper 79 at 55-57 (Feb. 1, 2019)). Specifically, Petitioner contends that a solid line is not directional guidance in the form or arrows or vectors as required by the claim. "Dr. Duindam maps a solid, 3-D line that 'represents the planned pathway' to the '*guidance*' limitation, but he fails to show that the line meets the construction of that term. Ex.2007, ¶ 18. A line alone has no directionality, and does not point in any direction." Pet. Reply 21. Petitioner further contends that the "use of the line was known in the art, and therefore, cannot be used to demonstrate a nexus between any secondary consideration and the claimed invention." Pet. Reply. 22 (citing Ex. 1007, 13:58–67). "Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed

invention." *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011); *see also Fox Factory,* 944 F.3d at 1373 ("In order to accord substantial weight to secondary considerations in an obviousness analysis, the evidence of secondary considerations must have a nexus to the claims, *i.e.*, there must be a legally and factually sufficient connection between the evidence and the patented invention.") (internal quotations omitted).

We construe "guidance" as graphical indicators such as vectors or arrows that point in the direction the endoscope is to travel. *See supra* § II.C.2. As disclosed above, we are not persuaded that the phrase "guidance for navigating . . . along a path through . . . anatomic landmarks" requires continuous visual guidance along the route to the final destination. *See supra* § II.C.4. We determine that intermittent guidance provides sufficient information to maneuver the endoscope to a desired destination. *See id.* Dr. Duindam attributes the success of ION system to its ability to continuously provide visual guidance by superimposing the 3D graphical line onto the virtual rendering of the endobronchial view. Ex. 2007 ¶ 19. Because the claim does not require the guidance to be continuous, we are not persuaded by Patent Owner's expert's evidence of unexpected results. *See* Ex. 2007 ¶¶ 17–19. Specifically, Dr. Duindam's declaration shows a "3D line that is superimposed on a simulated endobronchial view of the airways . . . The 3D line represents the planned pathway and it updates continuously in real-time relative to the position and orientation of the bronchoscope." *See* Ex. 2007, ¶ 18. The Declaration, therefore, establishes the need for a simulated endobronchial view, that is different from the navigation view, i.e. the view from the endoscope camera, and different from the bronchial tree view. *See* Ex. 2007, Exhibit A, 5. The simulated endobronchial view also requires

continuous updating in-real time, again a requirement that is not claimed. *See* Ex. 2007, ¶¶ 18–19. Because these features materially impact the functionality of the product and are not recited in the claims we determine that there is no nexus, and therefore, these features cannot form a basis for a finding of non-obviousness.

Furthermore, as Petitioner points out, and we agree, "[a] line alone has no directionality, and does not point in any direction." Pet. Reply 21; *see also* PO Resp. 32 ("A plot of the planned path or intended route to the target, as shown in Soper's Figures 4A and 4D . . . , does not constitute 'graphical indicators' that 'point in the direction the endoscope is to travel.' Ex. 2010 ¶ 72; *see also* Ex. 2007 ¶ 13."). Patent Owner, therefore, has not established a connection between the evidence presented and the claims of the '601 patent.

For the foregoing reasons, we agree with Petitioner and find that Patent Owner has failed to establish a nexus between the claimed invention and the purported unexpected results. Accordingly, we find that the evidence of unexpected results that Patent Owner has provided is entitled to no weight and that Patent Owner has failed to establish unexpected results.

ii. Long-felt need

Patent Owner's expert, Dr. Duindam avers that the lung tree is a complex anatomical space and there is a persistent need for improved navigation systems. Ex. 2007 ¶¶ 20–22. According to Dr. Duindam, "bronchoscopists were largely relying on their knowledge of anatomy and CT scans to find their way in the lung tree, but that required specialized training and some trial-and-error to reach the target." *Id.* ¶ 22.

Petitioner argues that Patent Owner has not provided an evidentiary basis to establish long-felt need or evidence to establish how persons in the market place would have viewed the method as claimed. *See* Pet. Reply 23 (citing *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332 (Fed. Cir. 2009)).

We agree with Petitioner that Patent Owner has not provided a sufficient evidentiary basis from which to conclude that there was a long-felt need. To establish long-felt need Patent Owner must establish that the product that is the subject to secondary considerations is coextensive with the claims. We understand that "the mere existence of one or more unclaimed features does not necessarily mean presuming nexus is inappropriate." *See Fox Factory*, 944 F.3d at 1376. However, reliance on features not claimed that materially impact the functionality of the product means that nexuses cannot be presumed. *Id.* Dr. Duindam's declaration attributes the success of ION system to its ability to continuously provide visual guidance by superimposing the 3D graphical line onto the continuously updated virtual rendering of the endobronchial view. *See* Ex. 2007 ¶¶ 18–19. The Declaration, therefore, establishes the need for a simulated endobronchial view, that is different from the navigation view, i.e. the view from the endoscope camera, and different from the bronchial tree view. *See* Ex. 2007 ¶ 18, Exhibit A, 5. Because these features materially impact the functionality of the product and are not recited in the claims we determine that there is no nexus, and therefore, these features cannot form a basis for a finding of non-obviousness.

"A finding that a presumption of nexus is inappropriate does not end the inquiry into secondary considerations. . . . [patent owner may still show]

that the evidence of secondary considerations is the 'direct result of the unique characteristics of the claimed invention.'" *Fox Factory*, 944 F.3d at 1373–74 (citing *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996). Patent Owner explains that that the commercial embodiment of the Ion system "solves the limitations of previous navigation systems by providing step-by-step visual guidance for steering the bronchoscope, and thereby helps bronchoscopists find their way through the lung tree more efficiently and in shorter time, which in turn may lead to better patient outcomes." PO Reply 59–60 (citing Ex. 2007 ¶¶ 18, 22). Dr. Duindam's declaration attributes the success of ION system to its ability to continuously provide visual guidance by superimposing the 3D graphical line onto the continuously updated virtual rendering of the endobronchial view. *See* Ex. 2007 ¶¶ 18–19. Because these features materially impact the functionality of the product but are not recited in the claims, these features can not form a basis for finding non-obviousness based on unique characteristics of the claimed method. For the foregoing reasons, we agree with Petitioner and find that Patent Owner has failed to establish a nexus between the claimed invention and the purported long-felt need. Accordingly, we find that the evidence of long-felt need that Patent Owner has provided is entitled to no weight and that Patent Owner has failed to establish unexpected results.

6. Summary

Having considered the arguments and evidence presented at trial, we determine that Petitioner has shown by a preponderance of the evidence that claim 1 is unpatentable under 35 U.S.C. § 103(a). We also find that Patent Owner has failed to persuasively show secondary considerations of non-obviousness because the Intuitive's Ion Endoluminal System is not shown to

be coextensive with the "guidance" of claim 1, and because Patent Owner has not established that the alleged unexpected results and satisfaction of long felt need were the direct result of the unique characteristics of the claimed method. We are therefore unable to accord Patent Owner's evidence any weight. *Fox Factory*, 944 F.3d at 1373.

b. 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 allow the clinician to record notes with the 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 can be used to further 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 arguments presented for claim 1. For the same reasons discussed above (*see supra* § II.E.2.a), after considering the arguments and evidence, we determine that Petitioner has shown by a preponderance of the evidence that the combination of Ganatra and Soper teach each limitation of claim 10 of the '601 patent. We conclude that claim 10 is unpatentable under 35 U.S.C. § 103(a) over Ganatra and Soper.

c. Claims 2, 3, 5–7, 11–13, and 16–18

With respect to dependent claims 2, 3, 5–7, 11–13, and 16–18, we find that Petitioner has shown by a preponderance of the evidence that Ganatra and Soper account for the limitations in these claims. Pet. 59–65, 67–70. We reviewed all the arguments and evidence of record, including Dr. Hannaford's testimony and find that a preponderance of the evidence

supports the contention that the cited references collectively disclose or suggest each and every limitation of claims 2, 3, 5–7, 11–13, and 16–18.

Patent Owner does not present separate and specific arguments for any of these dependent claims. *See* PO Resp. 53–57. We, therefore, adopt the teachings set forth in the Petition and in Dr. Hannaford's Declaration as mapped to the limitations of the challenged claims as our own findings. *See In re NuVasive, Inc.*, 841 F.3d 966, 974 (Fed. Cir. 2016) (explaining that the Board need not make specific findings about claim limitations that a patent owner does not dispute are disclosed in the prior art).

d. Claims 8, 9, 14, and 15

Patent Owner contends that dependent claims 8 and 14 recite that the "guidance" recited in claim 1 includes "a model of the path," and dependent claims 9 and 15 further recite "displaying the model of the path registered with the model of the patient anatomy" and, therefore, based on "[t]he doctrine of claim differentiation . . . Soper's display of preplanned paths or intended navigation routes cannot be equated to the claimed 'guidance' in independent claims 1 and 10." PO Resp. 34; PO Sur-reply 20 (citing Ex. 2011 ¶¶ 577–578). "That is, interpreting the 'model of the path' recited in the dependent claims as the 'guidance' recited in claims 1 and 10 would vitiate any substantive claim differences between the independent claims (1 and 10) and the dependent claims." *Id.* at 35.

"Under the doctrine of claim differentiation, dependent claims are presumed to be of narrower scope than the independent claims from which they depend" and, thus, independent claims are presumed to be "at least as broad as the claims that depend from them." *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1242 (Fed. Cir. 2003); *see Alcon Research, Ltd. v. Apotex Inc.*,

687 F.3d 1362, 1367 (Fed. Cir. 2012) (holding that where a dependent claim recited a specific range of concentrations, the independent claim "must cover at least that range"). Here, we do not find that claim 8 is adding a new limitation but instead is narrowing an already recited limitation in claim 1. In other words, claim 1 defines the genus "guidance," while claim 8 specifies that the genus includes the species "a model of the path." Claims 9, 14, and 15 similarly recite species of guidance. A determination that a combination of references teaches a claimed species means that the same combination will also meet the limitations of the genus.

Here, Petitioner is not relying on Soper's preplanned path alone as providing the guidance limitation of claim 1. *See* Pet. 46–50, 55–56. Petitioner is instead relying on the teaching of Soper's lines that include a preplanned path or model path to a designated point of biopsy within the patient in conjunction with arrows disclosed in Ganatra. *See* Pet. 48 (citing Ex. 1003 ¶ 125). Petitioner contends that in addition to a line taught by Soper, the system additionally includes arrows taught by Ganatra to display the entire path to the target site of interest. *Id.* at 50 (citing Ex. 1003 ¶ 126). In other words, a person of ordinary skill in the art would have understood that the arrows of Ganatra would "be used in the same manner [as used in the registration process] to guide the operator to site 620 to perform a procedure" following the preplanned path or model path taught in Soper. *Id.* at 33 (citing Ex. 1003 ¶¶ 115–116), 49, 50 ("[A person of ordinary skill in the art would] configure the system to use a line (instead of or in addition to arrows) to display the entire path from M0/T0 to target site 620 as taught by Soper (*see* Figs. 4A and 4D, []). [Ex. 1003] ¶126."). Thus, "guidance" based on the combination of Ganatra and Soper as proposed by Petitioner, includes

the line to the designated point of interest (i.e. a model path) as taught by Soper in addition to the arrows for navigation as taught by Ganatra. Petitioner's "guidance" as proposed by the combination of Ganatra and Soper encompasses the narrower limitation of "guidance includes a model of the path between the plurality of anatomic landmarks" as recited in claim 8. For the same reasons just discussed for claim 8, the combination of Petitioner's "guidance" as proposed by the combination of Ganatra and Soper similarly encompasses the narrower limitation of "guidance includes a model of the path between the plurality of anatomic landmarks" as recited in claim 14.

Petitioner is relying on the combination of Soper and Ganatra to teach the limitation of reaching a designated point of interest along a model of a path that is registered with the model of the patient anatomy as set out in claims 9 and 15. *See* Pet. 56 ("As integrated into Ganatra, these lines are a model of the path through the '*plurality of anatomic landmarks*' and are displayed on the model of the patient's anatomy."), *see also id.* at 55–56 ("Soper teaches superimposing on the computer model of the lungs both the 'preprocedural path planning' to a user . . . as well as 'the intended navigation routes 204.". . . . These paths are depicted as dotted lines . . . that extend from the entrance way of the trachea, though branching points in the lungs, to various points of biopsy. " (citing Ex.1007, 13:58–66, Fig. 4A, Fig. 4D; Ex. 1003 ¶ 177)). Here, the combination of Soper and Ganatra as proposed by Petitioner teaches a model path that is mapped to a model of the patients anatomy, thereby meeting the narrower limitation of "guidance" that encompasses "displaying the model of the path registered with the model of the patient anatomy" as set out in claims 9 and 15.

Because independent claims are presumed to be at least as broad as the claims that depend from them, we are not persuaded by Patent Owner's contention that that Petitioner's identification of a species of guidance based on the combination of Ganatra and Soper vitiates any differences between independent and depend claims. Accordingly, we are not persuaded by Patent Owner's contention that Petitioner's recited ground of unpatentability violates the doctrine of claim differentiation.

e. Conclusion as to obviousness

In sum, we find that the combination of Ganatra and Soper teaches or suggests each and every element of claims 1–3 and 5–18. We find that an ordinarily skilled artisan would have been motivated to combine Ganatra and Soper, and would have had a reasonable expectation of success in achieving the claimed invention. We also find that Patent Owner has failed to persuasively show secondary considerations of non-obviousness for failure to show persuasively that the Intuitive's Ion Endoluminal System is coextensive with the "guidance" of claim 1. We are therefore unable to accord Patent Owner's evidence any weight. *Fox Factory*, 944 F.3d at 1373.

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

Petitioner contends that claims 4 and 18 are rendered obvious based on the combination of Ganatra and Larkin. Pet. 70–71. Patent Owner opposes. PO Resp. 60–61.

For the reasons discussed above with respect to the anticipation rejection of claim 1 based on Ganatra alone (*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 that the claims are unpatentable.

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

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 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, Larkin, and Soper. Pet. 70–71. Patent Owner opposes. PO Resp. 60–61 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. 1005 ¶¶ 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,* 550 U.S. at 416. 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 deficiencies set out in the prior art and in Petitioner's obviousness theories of claims 1 and 10. PO Resp. 60–61. Because a preponderance of the evidence supports Petitioner's arguments relating to the teachings of the prior art, we adopt Petitioner's arguments as our own. *See* Pet. 71–74; *see also In re Nuvasive*, 841 F.3d 966, 974 (Fed. Cir. 2016) (explaining that the Board need not make specific findings as to claim limitations that Patent Owner does not dispute are disclosed in the prior art).

For the reasons discussed above (*see supra* § II.E.2), we determine that Petitioner has sufficiently shown, that the combination of Ganatra and Soper teaches all the elements recited in claims 1 and 10. We find that Petitioner has provided a sufficiently articulated rationale for making the combination with respect to Larkin. For the same reasons as discussed above (see *supra* § II.E.2), we are not persuaded by Patent Owner's argument that a person of ordinary skill would not have combined Ganatra with Soper. *See* PO Br. 60–61.We determine Petitioner has shown by a preponderance of the evidence that claims 4 and 18 are unpatentable.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has established by a preponderance of the evidence that claims 1–18 of the '601 patent are unpatentable as obvious over the cited prior art.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has proved by a preponderance of the evidence that claims 1–18 of the ’601 patent are unpatentable; and

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

In summary:

Claims	**35 U.S.C §**	**Reference(s)/Basis**	**Claims Shown Unpatentable**	**Claims Not Shown Unpatentable**
1, 2, 5–9	102(a)	Ganatra		1, 2, 5–9
1–3, 5–18	103(a)	Ganatra, Soper	1–3, 5–18	
4, 18	103(a)	Ganatra, Larkin		4, 18
4, 18	103(a)	Ganatra, Larkin, Soper	4, 18	
Overall Outcome			1–18	

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