UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AURIS HEALTH, INC.
Petitioner,

v.

INTUITIVE SURGICAL OPERATIONS, INC.
Patent Owner.

Patent No. 8,801,601

Inter Partes Review No. IPR2019-01173

Petition for *Inter Partes* Review of
U.S. Patent No. 8,801,601

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1006	Hannaford CV
1007	U.S. Patent No. 7,901,348 to Soper
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Petitioner's Mandatory Notices

I. REAL PARTY IN INTEREST (§42.8(B)(1))

Auris Health, Inc. is a real party in interest pursuant to § 42.8(b)(1). Auris Health, Inc. is a wholly owned subsidiary of Ethicon, Inc., which is a wholly owned subsidiary of Johnson & Johnson. Both Ethicon, Inc. and Johnson & Johnson also are real parties in interest.

II. OTHER PROCEEDINGS (§42.8(B)(2))

A. Patents and Applications

U.S. Patent No. 8,801,601 ("'601 patent") is related to following issued patents or pending applications:

- U.S. Patent No. 8,337,397
- U.S. Appl. No. 14/452,302

B. Related Litigation

The '601 patent has been asserted in the following litigations:

- *Intuitive Surgical, Inc. v. Auris Health, Inc.*, Action No. 18-1359-MN (D. Del.) (pending).

C. Patent Office Proceedings

The '601 patent is not subject to any proceedings filed in the Patent Office.

III. LEAD AND BACKUP LEAD COUNSEL (§42.8(B)(3))

Lead Counsel is: Ching-Lee Fukuda (Reg. No. 44,334), clfukuda@sidley.com, (212) 839-7364. Back-Up Lead Counsel are: Thomas A. Broughan III (Reg. No. 66,001), tbroughan@sidley.com, (202) 736-8314, Sharon Lee, sharon.lee@sidley.com, (202) 736-8510) and Ketan Patel, ketan.patel@sidley.com, (212) 839-5854.[1]

IV. SERVICE INFORMATION (§42.8(B)(4))

Service on Petitioner may be made by e-mail (at the email addresses above & SidleyAurisTeam@sidley.com). Petitioner's mail or hand delivery address is: Sidley Austin LLP, 1501 K Street, N.W., Washington, D.C. 20005. The fax number for lead and backup lead counsel is (202) 736-8711.

[1] Petitioner will file motions for Sharon Lee and Ketan Patel to appear *pro hac vice* according to the Board's orders and rules.

I. INTRODUCTION

The ’601 patent is directed toward a well-known method for providing navigation guidance to an operator of an endoscope while it is being navigated inside of a patient. The endoscope includes a sensor that can determine its position in three-dimensional space, and the method uses this information to correlate the endoscope’s position within a patient with a computer model of the patient’s anatomy. The ’601 patent claims are directed to methods for registering the patient’s anatomy to the computer model using anatomic landmarks, and then displaying on a screen both the computer model and navigation guidance to assist the operator in steering the endoscope to a target site.

This type of navigation for a steerable instrument was well-known before the priority date of the ’601 patent. For example, U.S. Patent Publication No. 2009/0227861 to Ganatra (“Ganatra” (Ex.1004)) teaches “method[s] for navigating a medical instrument within a branched structure of a body” that includes steps for registering anatomic landmarks to a computer model of the patient’s anatomy and providing navigation guidance to the user in the form of arrows and other indicators on a screen showing a computer model of the anatomy. The Ganatra reference discloses or teaches all of the elements of the independent claims, and most dependent claims, and was not considered during prosecution of the ’601 patent. To the extent Ganatra does not teach every limitation of the claims, the

claims would have been obvious to a person of ordinary skill in the art ("POSA") based on Ganatra in view of additional references.

Petitioner respectfully requests the Board to institute *inter partes* review of the '601 patent claims.

II. Regulatory Information

A. Certification that Petitioner May Contest the '601 Patent (§ 42.104(a))

Petitioner certifies that the '601 patent is available for *inter partes* review (IPR), and that Petitioner is not barred or estopped from requesting an IPR of the '601 patent claims. Neither Petitioner, nor any party in privity with Petitioner, has filed a civil action challenging the validity of any claim of the '601 patent. The '601 patent has not been the subject of a prior IPR by Petitioner or a privy of Petitioner.

Petitioner also certifies this IPR petition is timely filed as this petition was filed less than one year after September 4, 2018, the date Petitioner was first served with a complaint alleging infringement of a claim of the '601 patent. *See* 35 U.S.C. § 315(b); Ex.1014.

B. Identification of Claims Being Challenged (§ 42.104(b))

Claims 1-18 are unpatentable based on the following art and grounds.

Prior Art Reference	Abbreviation
U.S. Patent Publication No. 2009/0227861 to Ganatra	"Ganatra" (Ex.1004)
U.S. Patent No. 7,901,348 to Soper	"Soper" (Ex.1007)

U.S. Patent Publication No. 2007/0156019 to Larkin	"Larkin" (Ex.1005)

Ground	35 U.S.C. §	Claims	Prior Art Reference(s)
1	102	1-2, 5-9	Ganatra
2	103(a)	1-3, 5-18	Ganatra and Soper
3	103(a)	4, 18	Ganatra and Larkin, with or without Soper

Petitioner's positions are supported by the Declaration of Blake Hannaford, Ph. D. (Ex.1003), an expert in telerobotic surgical systems who has over 20 years of experience in the field. Ex.1003, ¶¶2-8.

C. Fee for *Inter Partes* Review (§ 42.15(a))

The Director is authorized to charge the fee specified by 37 C.F.R. § 42.15(a) to Deposit Account No. 50-1597.

III. Background

A. Background Technology

Steerable medical instruments such as endoscopes have long been used in diagnostic procedures such as colonoscopies and bronchoscopies. *See, e.g.*, Ex.1004, ¶¶[0002], [0017]-[0018]; Ex.1010, Abstract, 1:11-3:35 (describing art known prior to 1998); Ex.1011, 1:60-2:11; Ex.1013, ¶¶[0113]-[0120]; Ex.1003, ¶38. In a bronchoscopy procedure, an endoscope may be navigated through the passageways of a person's lungs to access a target site where a physician could take images of the site, harvest a tissue sample, or perform surgery. Ex.1004, ¶¶[0019], [0030]; Ex.1010, Abstract; Ex.1013, ¶¶[0002], [0178]; Ex.1003, ¶38.

Prior to the procedure, a target location (such as the location of possibly abnormal tissue) can be identified by imaging the patient's anatomy (*e.g.*, using a CAT scan or MRI) and then creating a computer model of the anatomy that can be used to determine a path to the target location. Ex.1010, Abstract ("[A]n endoscope equipped with a biopsy needle is guided to a target in … the respiratory system. The position of the probe is monitored and a representation of the probe is superposed on a previously acquired image of the respiratory system …."); Ex.1013, Abstract ("The catheter (30 is navigated to the target which [sic] tracking the distal tip (34) of the guide (32) in the reference coordinate system."); Ex.1003, ¶39.

The computer model can be used during a procedure to assist the operator in navigating the instrument through a patient's anatomy to the target site. Ex.1004, ¶[0003] ("[P]atient-specific data defining a geometric model of the bodily structure may be employed to provide a representation of the structure, onto which the positional information of the sensor may be mapped, in order to provide guidance in navigating the medical instrument."); Ex.1010, Abstract ("The position of the probe is monitored and a representation of the probe is superposed on a previously acquired image of the respiratory system"); Ex.1013, ¶[0143] ("CT data is used to construct a virtual model of airways within the body tissue …"); Ex.1003, ¶40. To use the model to provide guidance, the system needs to determine location of the

instrument within the patient's anatomy (*e.g.*, by using an electromagnetic field to determine 3D coordinates of the tip of the endoscope) and then that position needs to be correlated to the coordinates of the computer model. *See, e.g.*, Ex.1004, ¶[0021]; Ex.1011, 4:10-16, 4:54-65; Ex.1012, ¶¶[0070]-[0110]. A well-known technique correlating an endoscope's actual position to a computer model is by navigating the endoscope to identifiable portions of the patient's anatomy, measuring the coordinates at those locations based on an external electromagnetic field, and then "registering" those external coordinates to the corresponding coordinates in the computer model. *See, e.g.*, Ex.1004, ¶¶[0018], [0021]; Ex.1011, Abstract, 2:63-66, 4:27-32, 5:42-49; Ex.1003, ¶41. Various mathematical transformations can then be used to map the endoscope's position to locations on the model. *See, e.g.*, Ex.1004, ¶¶[0021]-[0023]; Ex.1011, 7:1-40. During the procedure, a display can be used to depict the computer model, the location of the endoscope's tip, and other information to assist in navigation. Ex.1004, Fig. 5, ¶[0025]; Ex.1005, 3:1-12.

The basic technology for guiding a user from a source to target destination using models (*e.g.*, maps) and positioning systems was well-known. Ex.1017, 60:8-19; Ex.1016, Abstract. Navigation techniques have long used models, such as digital maps that include road and intersection data, to guide navigation between two specified points. Ex.1016, 6:37-59; Ex.1017, 8:32-9:13; 68:20-69:26. These

techniques includes sensors, such as a GPS receiver that detects the current position of mobile unit and a distance sensor to detect a distance. Ex.1017, 8:1-9; Ex.1016, 6:62-7:2. They also used display and voice output apparatus to provide navigational guidance to a user, (Ex.1017, 12:1-3; Ex.1016, 7:2-6), for example by displaying on the model the current position of the mobile unit and the path traveled. Ex.1016, 2:11-19.

B. Summary of the ’601 Patent

The ’601 patent is directed to methods for navigating an endoscope in a patient’s anatomy by establishing anatomic landmarks and providing visual guidance to assist an operator in steering an endoscope device through a plurality of anatomic landmarks to a target site. Ex.1001, 1:21-25.

The ’601 patent states that, prior to starting the procedure, a computer model of the relevant anatomy is created. Ex.1001, 9:41-10:3. To use the computer model during the procedure for navigation guidance, the ’601 patent states that an operator can establish anatomic landmarks in two ways. Ex.1001, 9:41-10:3. First, the operator can establish them prior to the procedure using preoperative images or models. Ex.1001, 9:53-63. Second, the operator also can establish them while guiding the endoscope along its path from an entry point to a target site in the patient. Ex.1001, 9:41-52. Either way, the landmarks are established by the operator. Ex.1003, ¶¶32-33.

Figure 13, reproduced below, provides a flow chart for establishing anatomic landmarks as the endoscope is guided through a patient's body. Ex.1001, 11:65-12:1.

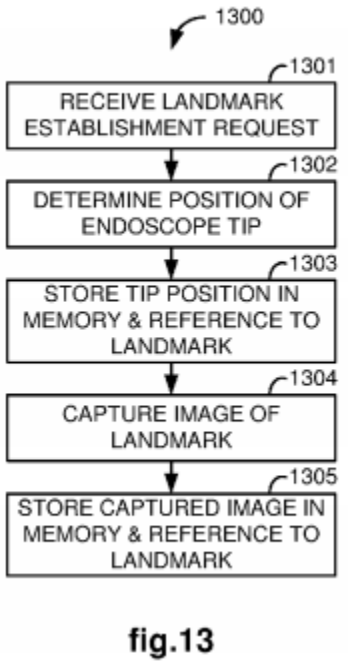


fig.13

First, a landmark establishment request is received from the operator. *Id.*, 12:9-14. In response, the current position of the endoscope tip in a fixed reference frame and an image captured at the endoscope tip can be recorded, stored in memory, and referenced as the landmark's position and image in the computer model. *Id.*, 12:15-30; *see* Ex.1003, ¶¶34-35.

To guide the operator in steering an endoscope through a plurality of anatomic landmarks to a target site, the '601 patent describes displaying 3-D arrows (or other graphical representations) to provide steering directions towards each of the plurality of anatomic landmarks. Ex.1001, 9:18-40; Ex.1003, ¶36. For

example, Figure 15, reproduced below, illustrates 3-D arrow 1511 indicating a steering direction towards the mouth entry, 3-D arrow 1512 indicating a steering direction towards the stomach entry, and 3-D arrow 1513 indicating a steering direction towards the colon entry. Ex.1001, 11:15-26.

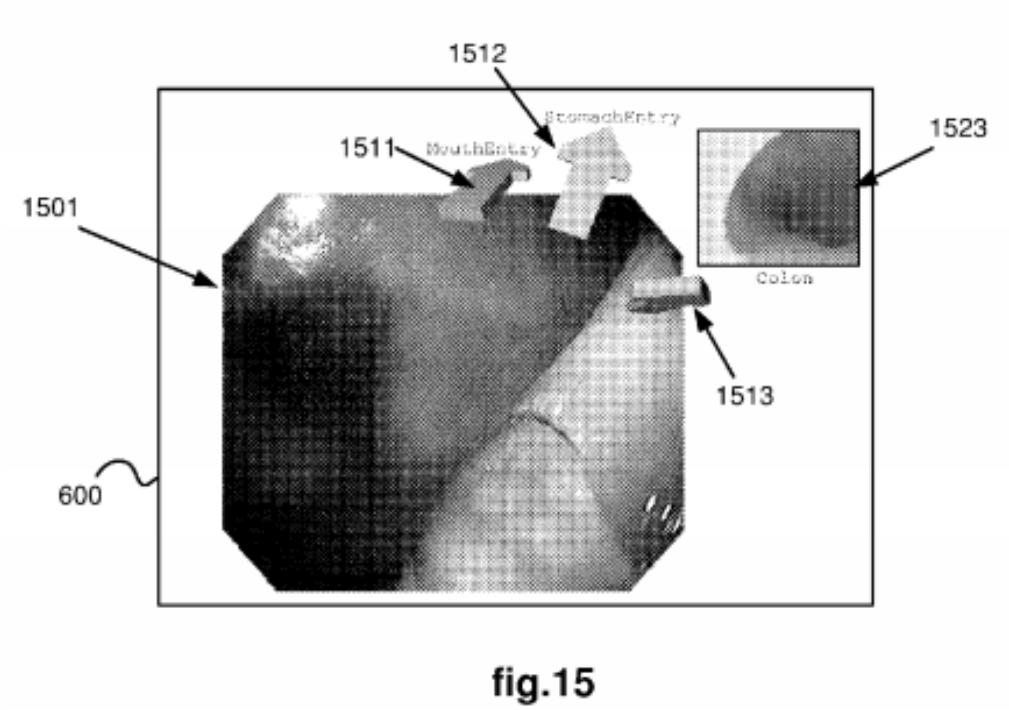


fig.15

Ex.1001, Fig. 15.

C. Prosecution History

The ’601 patent issued from Application No. 13/678,917, filed on November 16, 2012. During prosecution, the Examiner rejected the sole pending independent claim as anticipated. Ex.1002, 230-36. In response, the applicant amended that claim to specify “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." *Id.*, 300. The applicant explained that the cited prior art did not disclose "navigating the steerable instrument along a path through a plurality of anatomic landmarks" because the art disclosed use of "external anatomical markers [] located on the surface of the patient anatomy." *Id.*, 303. The Examiner allowed the claims, stating that "the prior art of record fails to explicitly teach or fairly suggest, alone or in combination, to additionally provide 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." *Id.*, 314.

D. Person of Ordinary Skill in the Art

A person of ordinary skill in the art would have been a person with a good working knowledge of robotics and medical devices such as endoscopes. That knowledge would have been gained by 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 studying or developing robotics or medical devices such as robotic surgical systems or endoscopes. Ex.1003, ¶30. This description is approximate; varying combinations of education and practical experience also would be sufficient. *Id.*

IV. CLAIM CONSTRUCTION

Claims "shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim 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 Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). Claim construction requires consideration of "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Phillips*, 415 F.3d at 1314 (citation omitted). The specification is "usually" dispositive and "the single best guide to the meaning of a disputed term." *Id.* at 1315 (citation omitted).

Auris proposes constructions for several terms below. However, because the teachings of the prior art references are squarely within the scope of the challenged claims, the Board likely will not need to adopt specific constructions. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (claim terms need only be construed to the extent necessary to resolve the case).

A. "anatomic landmark"

The '601 patent uses the term "anatomic landmark" to refer to a user established anatomical feature. Ex.1003, ¶48. Anatomic landmarks are associated with "anatomic structures in a patient," Ex.1001, Abstract, that are established by an operator "as the steerable endoscope 110 is being guided through a patient's body." *Id.*, 11:65-12:1. The '601 patent discloses an alternative embodiment where the operator establishes the landmark before the procedure using CT data. *Id.*, 9:52-10:3. The '601 patent states that an "operator may interactively establish landmarks for which directional guidance is to be provided at any time while guiding the steerable endoscope 110 towards the target site." *Id.*, 11:59-62, 9:41:43. The patent states that "a landmark establishment request is received from the operator." *Id.*, 12:8-9, Fig. 13 (1301). The patent further explains that after the request is received from the operator, "the current position of the endoscope tip 112 in the fixed reference frame is determined." *Id.*, 12:15-16, Fig. 13 (1302). After the current position of the endoscope tip 112 is determined, it "is then stored in the memory device 155 and referenced as the position of the landmark whose establishment has been requested." *Id.*, 12:23-25, Fig. 13 (1303). The patent states that additional information is stored and associated with "the landmark whose establishment has been requested." *Id.*, 12:26-31, Fig. 13 (1304-05); *see also id.*, 10:65-11:3. The patent uses the term "anatomic landmark" to refer to an anatomic

feature that the user requests to establish as a landmark. Ex.1003, ¶¶49-52. Thus, to the extent the term "anatomic landmark" needs to be construed for this petition, it should be construed to be a user established anatomical feature.

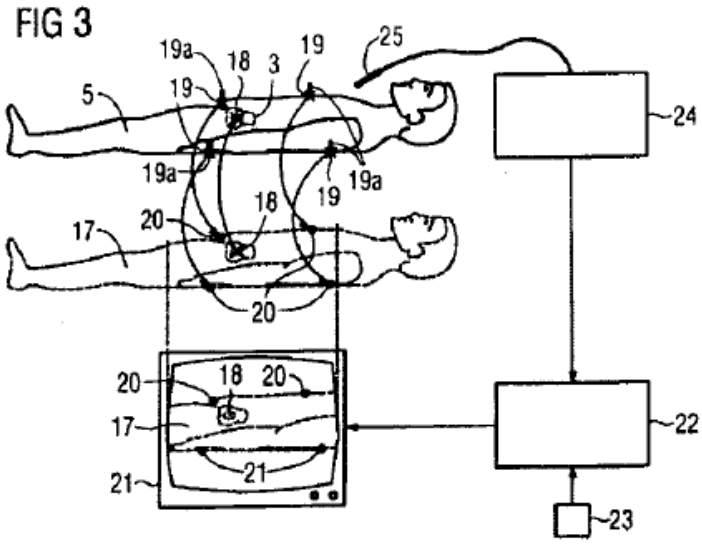
B. "a path through" [a plurality of | the first and second] anatomic landmarks, including the first anatomic landmark

To the extent the term "a path through" an anatomic landmark needs to be construed for the petition, it should be construed to mean a path that runs in one side of the anatomic landmark and out of another. Ex.1003, ¶53. The '601 patent consistently describes "through" to mean entry from one side of an anatomic landmark and out of another. Ex.1003, ¶54. In the background section, the patent states that to perform minimally invasive surgical procedures, "entry into the patient may be made through an incision or a natural body orifice." Ex.1001, 1:33-36. The patent further describes an endoscope as a medical device that is inserted "either through a natural orifice or a surgeon created opening and guid[ed] … to a target site within a patient." *Id.*, 1:52-56. As an example, the '601 patent states "in 'transgastric' surgery, instruments are passed through the mouth and into the stomach." *Id.*, 2:18-19.

In context of steering a tip of an endoscopic device toward a landmark in a patient, the patent describes a path through an anatomic landmark as running in one side of a landmark and out of another. As an example, in Figure 14, the patent shows that a steerable endoscope 110 "has entered through the patient's mouth and

its tip 112 guided to a target site." Ex.1001, 9:44-46. The endoscope 110 is then "guided through the esophagus to the patient's stomach." *Id.*, 9:47-48. A "path through" an anatomic landmark (*e.g.*, the mouth or esophagus) thus runs in one side and out the other, and it is not one that merely runs near an anatomic landmark or next to an anatomic landmark. Ex.1003, ¶¶55-57. The patent distinguishes between a "pass through" and "encountering" or running near an anatomic landmark: "A visual indication … may also be displayed … of any anatomic structures or body lumens that the endoscope 110 *may encounter or pass through in its path to the target site*." *Id.*, 7:25-29 (emphasis added).

This is consistent with the file history. Ex.1003, ¶57. During prosecution, the applicant distinguished prior art because the art disclosed use of "external anatomical markers [] located on the surface of the patient anatomy" and therefore the art did not disclose "navigating the steerable instrument along a path through a plurality of anatomic landmarks." Ex.1002, 303. The applicant reproduced an image from that reference showing the markers on the outside:



Id.

The patent's use of the word "through" is consistent with its plain meaning: moving in one side and out of the other side of (an opening, channel, or location). Ex.1015; Ex.1003, ¶58.

Therefore, a POSA would have understood that "a path through" an anatomic landmark is a path that runs in one side of the anatomic landmark and out of another.

C. "fixed reference frame"

The term "*fixed frame of reference*" in dependent claim 11 should be construed to mean "a reference frame that does not move during a medical procedure to be performed using a medical instrument."

The '601 patent states that "a patient computer model stored in memory 155 is referenced to ***a fixed reference frame (i.e., one that does not move during the***

medical procedure to be performed using the endoscope 110)." Ex.1001, 5:53-56 (emphasis added); *accord id.*, 9:18-21. Thus, the patent defines a "fixed reference frame" to mean "one that does not move during the medical procedure to be performed using the endoscope." *Id.*, 5:53-56; 9:18-21. In the context of the claims, which recite a "medical instrument" and not an "endoscope" specifically, the term "*fixed reference frame*" means "a reference frame that does not move during a medical procedure to be performed using a medical instrument."

V. Analysis of the Patentability of the Claims

A. Ground 1 – Anticipation Based on Ganatra

1. Summary of Ganatra

Ganatra was filed on March 6, 2008 and published on September 10, 2009. Ganatra is therefore prior art to the '601 patent under at least 35 U.S.C. § 102(e).[2]

Ganatra is directed to methods for navigating a medical instrument such as a bronchoscope through a patient's anatomy. Ex.1004, Abstract; Ex.1003, ¶64. Ganatra describes a system where a computer model of the patient's anatomy (*e.g.*, of the passageways of the lungs) is used to provide navigation guidance to the operator during a procedure. Ex.1004, ¶[0018]. Prior to the procedure, a user can select on the computer model different branching points and other parts of the

[2] The '601 patent's earliest possible effective priority date is March 26, 2009, which is over a year after Ganatra was filed.

bronchial tubes as "designated points" that will be used for a registration process and for navigation during the procedure. *Id.*, ¶[0022] ("the operator subsequently 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" and "each of the designated points may be established at any location within tree"); Ex.1003, ¶64. Figures 4A and 4B, reproduced below, show exemplary designated points which are labeled M0 to M5 in the computer model (Fig. 4A) and T0 to T5 in the patient's anatomy (Fig. 4B).

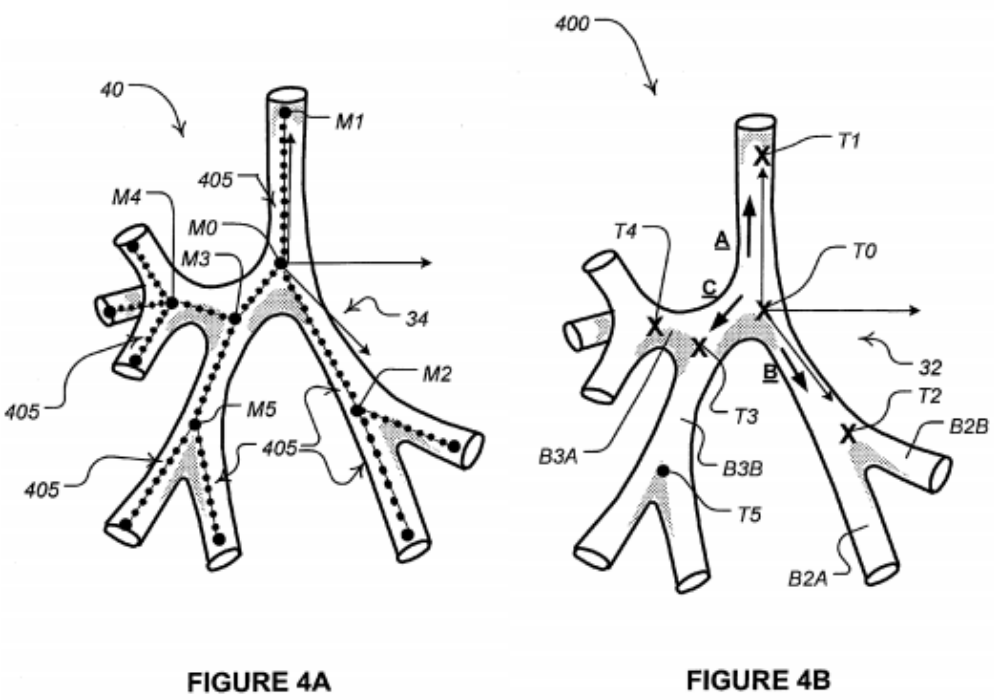


FIGURE 4A FIGURE 4B

The computer model will be depicted on a display during the procedure to assist the operator in navigating the instrument. *Id.*, ¶[0019]; Ex.1003, ¶65.

During the procedure, the position of the bronchoscope and other information are superimposed on the computer model. Ex.1004, ¶¶[0024]-[0025], [0028], Figs. 4A-E, 6A-C. The location of the bronchoscope is determined by creating an externally-generated magnetic field around the patient, which interacts with a tracking sensor near the distal end of the bronchoscope to allow the scope to determine its position in 3-dimensional space. *Id.*, ¶¶[0018]-[0020]; Ex.1003, ¶66. To enable use of the computer model in navigation, the coordinates of the patient's anatomy (tracking coordinate system 32) must be registered to the coordinates of the model (model coordinate system 34). Ex.1004, ¶¶[0022]-[0023]; Ex.1003, ¶67. The two coordinate systems are depicted in Figures 3A (the patient) and 3B (the computer model), reproduced below.

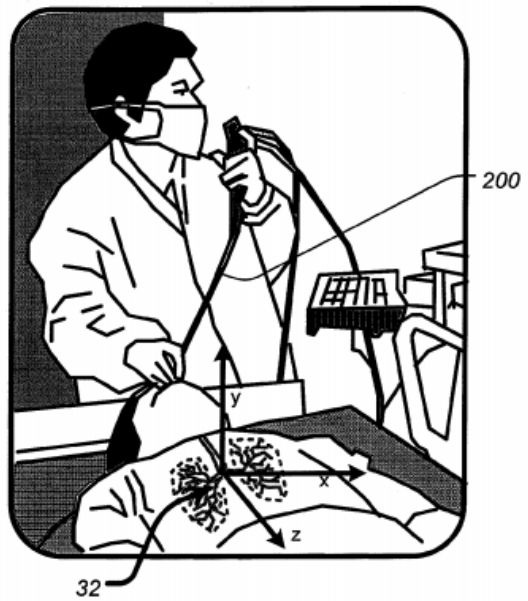


FIGURE 3A

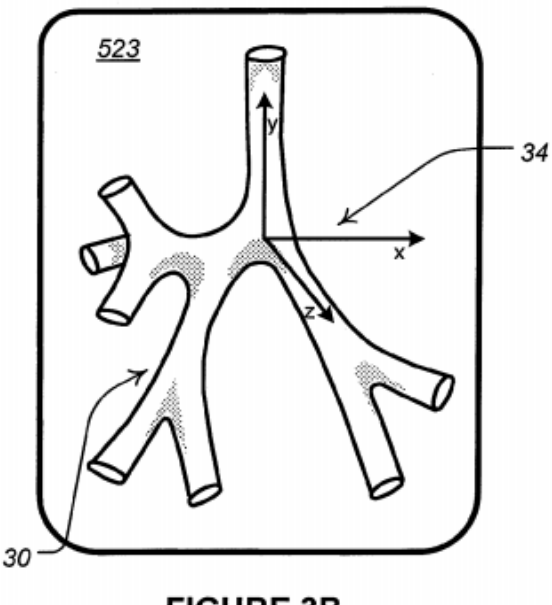


FIGURE 3B

To register the two coordinate systems, Ganatra describes an initial registration process where the bronchoscope is navigated through several of the preselected designated points within the patient. Ex.1004, ¶[0020]. At each designated point, the system records the 3D coordinates of the sensor and uses them to find a mathematical transformation that relates those coordinates to the coordinates of the model system, thereby registering tracking coordinate system 32 with model coordinate system 34. *Id*. Throughout the procedure, the registration can be refined when the bronchoscope navigates through additional designated points. *Id.*, ¶[0026]; Ex.1003, ¶68.

Ganatra's navigation system 50 provides navigation guidance on the display to assist the operator in the initial registration process and to assist the operator in navigating the bronchoscope to, *e.g.*, a target site 620. Ex.1004, ¶[0026]. The navigation system can provide several forms of guidance to the operator. For example, it displays the computer model and superimposes a visual indicator 52 on the model to identify the current location of the bronchoscope. *Id.*, ¶[0029]. As another example, a target site 620 can be identified using hatch marks on the model to assist the operator in navigating to that site. *Id*.; Ex.1003, ¶69. These two visual indicators are depicted in Figure 6C, below.

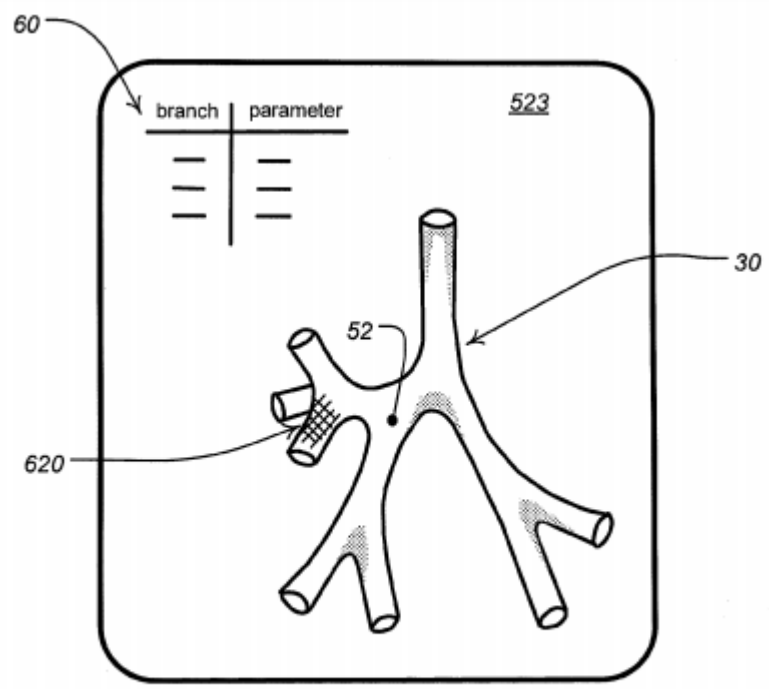


FIGURE 6C

Other types of "visual indicator[s]" can be overlaid on the display "as a reference for navigating the medical instrument to site 620." Ex.1004, ¶[0029]. Ganatra generally teaches that such visual indicators include "arrows," "color coding of branches, and blinking or flashing points or zones along each branch." *Id.*, ¶[0024]. Ganatra also teaches that the display can color in any passageways that have already been navigated through. *Id.*, ¶[0028].

Ganatra illustrates these visual indicators in an example as arrows (43A, 43B, 43C) on the model to instruct the operator in which direction to navigate the instrument during the initial registration process. *See* Ex.1004, ¶¶[0022]-[0024]; Ex.1003, ¶¶70-71.

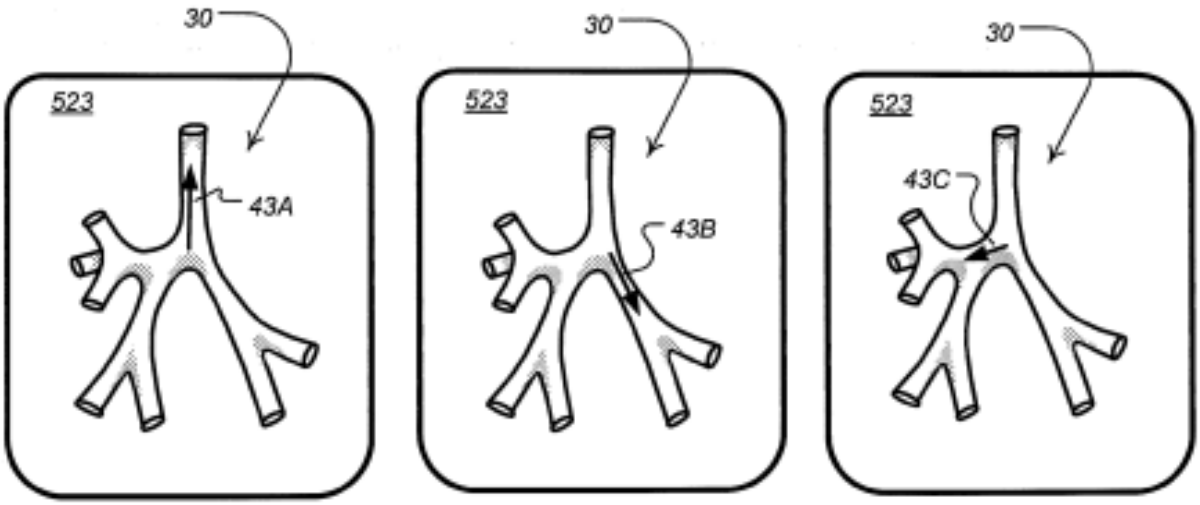


FIGURE 4C FIGURE 4D FIGURE 4E

Although these exemplary illustrations of the visual indications are shown as arrows used in the initial registration process, Ex.1004, ¶¶[0022]-[0024], Ganatra teaches that other types of visual indicators can be used and that the visual indicators can be used after the initial registration process to provide navigation guidance to the operator during the procedure. *Id.*, ¶¶[0028], [0029]; Ex.1003, ¶¶70-72.

2. Ganatra Anticipates Claims 1-2 and 5-9

As set forth below, Ganatra discloses all the elements in claims 1-2 and 5-9.

a) Claim 1

(1) "A method for navigating a steerable instrument in a patient anatomy"

Ganatra describes "methods for navigating a medical instrument within a branched structure of a body." Ex.1004, ¶[0001]. These medical instruments "include, without limitation, diagnostic instruments, such as biopsy tools and

bronchoscopes, and treatment instruments, such as tools for deploying stents or valves, or tools that apply ablation energy, for example, for bronchial thermoplasty." *Id.*, ¶[0018]. Figure 2 illustrates an exemplary bronchoscope 200 that includes a tracking sensor X near a distal end 202 of the bronchoscope and that is steered by an operator through the bronchial tree structure of a patient's anatomy. *Id.*, ¶¶[0018]-[0020]; Ex.1003, ¶¶86-87.

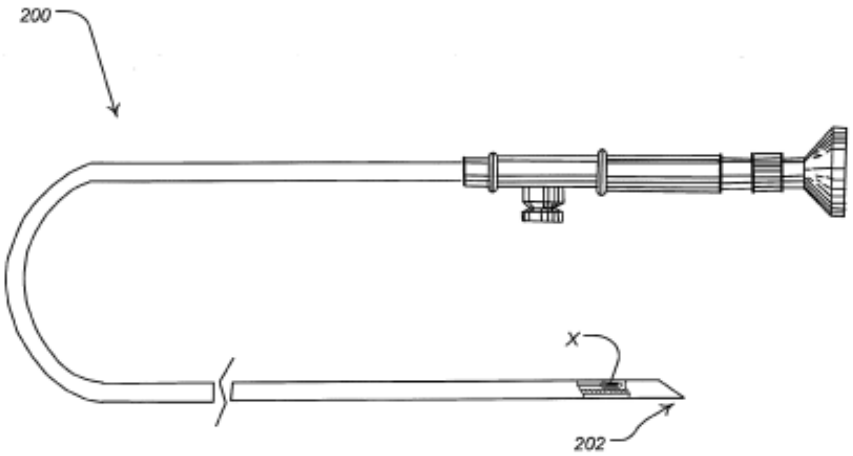


FIGURE 2

Thus, to the extent the preamble is limiting, Ganatra discloses "*a method for navigating a steerable instrument in a patient anatomy*." Ex.1003, ¶¶88-89

(2) "receiving a first landmark establishment request"

Ganatra discloses that to accurately display the bronchoscope's location within the patient on the computer model, the tracking coordinate system 32 of the patient needs to be registered with the model coordinate system 34. Ex.1004,

¶¶[0019]-[0020]. Ganatra discloses that an operator identifies a number of designated points (each a "*landmark*" or "*anatomic landmark*") in the model, labeled M0 to M5, prior to a procedure. *Id.*, ¶[0017] ("A subset of the predetermined points defining the pathway, which will be called designated points"), ¶[0018] ("the designated points…, which define the pathway, facilitate mapping, onto a display of the model of the tree structure, a tracked location of a medical instrument, in the corresponding actual bronchial tree structure, in real time, during a procedure, in order to provide navigation guidance for the medical instrument"), ¶[0022] ("the operator subsequently selects a registration path… and inputs this information into workstation 500" and "each of the designated points may be established at any location within tree"). Thus, the designated points are user-defined. Ex.1003, ¶¶90-91.

Throughout the procedure, 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). Ex.1004, ¶[0020] (to register the tracking coordinate system with the model coordinate system, an "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"), ¶[0023]; Ex.1003, ¶93.

Ganatra describes performing an initial registration process at the start of the procedure that includes the step of "*receiving a first landmark establishment request*." In the first step of the initial registration process, the operator navigates the bronchoscope to the first point within the patient, T0, and then instructs the system to start the registration process. Ex.1004, ¶[0021] ("the bronchoscope operator… then ***instructs*** processor 522 to establish point T0 as an anchor point of tracking coordinate system 32, ***via input into workstation 500, for example, at a user interface 524***, and, thus, initiates the registration process") (emphases added). The designated point M0[3] of the model coordinate system is "located at a first branching point of a main airway, or trachea, of the tree, in proximity to the carina of the bronchial tree" (*Id.*, ¶[0021]) which "corresponds to an anatomical landmark of the branched structure" (*Id.*, Claims 5, 37). Designated point M0 is shown in Figure 4A reproduced below. *Id.*, ¶[0021].

[3] Ganatra also calls M0 the reference point.

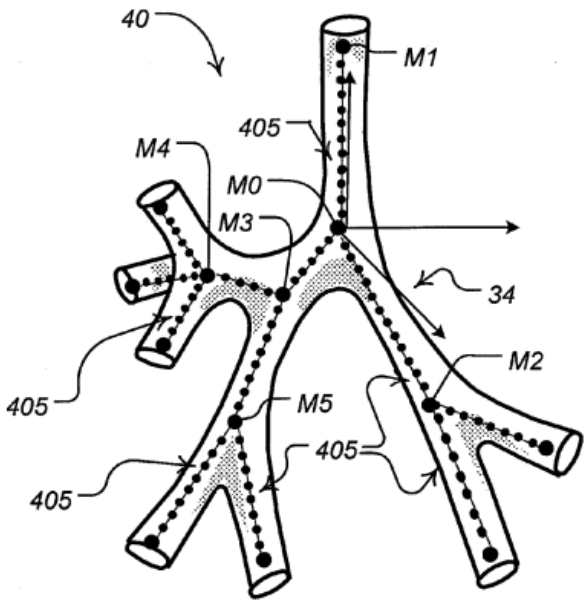


FIGURE 4A

The instruction to register M0/T0 meets the step of "*receiving a first landmark establishment request*," and thus Ganatra discloses this element. Ex.1003, ¶94.

(3) "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"

As explained above, the instruction to register M0/T0 corresponds to the "*first landmark establishment request*." In response to this instruction ("*responsive to receiving the request*"), Ganatra records information about the position of the tracking sensor X that is near a distal end of the bronchoscope ("*recording information about a reference portion of the steerable instrument*"). Ex.1004,

¶¶[0018], [0021], Fig.2; Ex.1003, ¶95. Ganatra explains that the operator navigates the bronchoscope so that "tracking sensor X is located at a point T0, which corresponds to designated point M0 of model 40" ("*a reference portion of the steerable instrument located at a first anatomic landmark in the patient anatomy*"), "and then instructs processor 522 to establish point T0 as an anchor point of tracking coordinate system 32" ("*recording information*"). Ex.1004, ¶[0021]; *see id.*, ¶[0022] (calculating distances from T0, showing T0 is stored in the system). Ganatra explains that "designated point M0 … 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." Ex.1004, ¶[0021]; *see id.*, Fig. 4A (below).

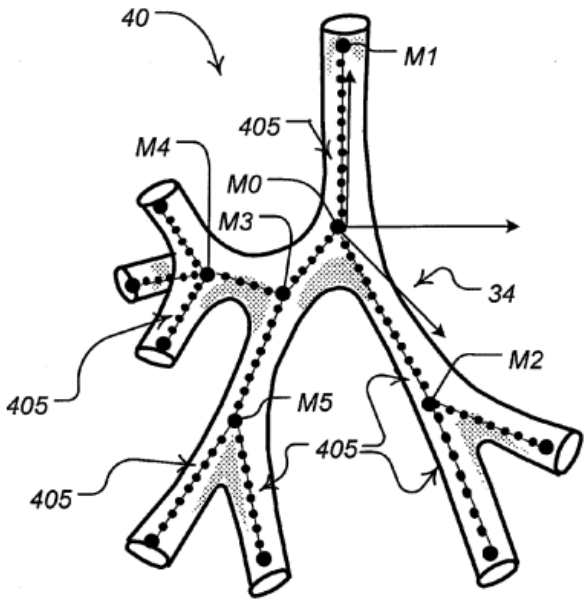


FIGURE 4A

In Fig. 4A (shown above), Ganatra shows an example where each designated point, including M0/T0, corresponds to branching point in the airway. Ex.1003, ¶¶96-98. Ganatra explains that each designated point is specified by a user, and that a user may specify any portion of the airway tree as a designated point. Ex.1004, ¶[0022] ("the operator … selects a registration path, for example, a sequence of directions, or branches … and inputs this information into workstation 500" and "although branching points are suitable, and even preferable, locations for designated points … each of the designated points may be established at any location within [the] tree"). Thus, M0/T0, like all branching points, is user-defined. Ex.1003, ¶99.

A POSA would have understood that during a bronchoscopy procedure, the bronchoscope is navigated into one side of each designated point and out another. Ex.1003, ¶¶98-99. This is depicted in Figure 4A, above, which shows a path as a dotted line that goes into one side of each designated point (*e.g.*, M0, M3, M4) and out another side. *Id.*, ¶98.

Each branching point thus meets Auris's construction of the term "*anatomic landmark*." Therefore, designated point M0/T0 corresponds to a "*first anatomic landmark*." Ex.1003, ¶¶91, 93-94.

Thus, the instruction to register M0/T0 meets this claim element. Ex.1003, ¶¶99-100.

(4) "referencing the recorded information as first landmark information;"

Ganatra describes several processes where the tracking system references the recorded position of the designated points and uses that information for various purposes. Ex.1003, ¶101.

Throughout the procedure, the processor continuously references anchor point M0/T0 to calculate Euclidean distances between sensor X and anchor point T0. Ex.1004, ¶[0022] ("[W]hen a Euclidean distance of sensor X, from anchor point T0, matches that of a corresponding designated point M1, M2 or M3, from reference point M0, which is stored in database 521 and communicated to processor 522 …."). Thus, Ganatra "*referenc[es] the recorded information*" for M0/T0. Ex.1003, ¶¶102-03.

(5) "registering the first landmark information to a model of the patient anatomy"

Ganatra registers the location information it records for each designated point to the coordinates of that designated point in the computer model. For T0/M0, Ganatra registers the measured tracking system coordinates for T0 to point M0 of the model. Ex.1004, ¶[0021] ("the bronchoscope operator locates bronchoscope 200 … 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 … and,

thus, ***initiates the registration process***") (emphases added). Thus for designated point T0/M0, Ganatra "*register[s] the first landmark information to a model of the patient anatomy*." Ex.1003, ¶¶104-05.

(6) "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."

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. Ex.1004, ¶[0026]. Each of these processes meets the "*providing guidance…*" step of the claim. Ex.1003, ¶106.

(a) Ganatra's Initial Registration Process Meets This Element

Ganatra describes an initial registration process that "is communicated to the operator via display." Ex.1004, ¶[0022]. The process begins when the operator registers M0/T0 (a "*first anatomic landmark*"). *Id.*, ¶[0021]. Ganatra then superimposes arrows on the displayed model to inform the operator in which direction the bronchoscope should be navigated to reach each of M1/T1, M2/T2, and M3/T3. These are illustrated as arrows 43A, 43B, and 43C in Figures 4C-E reproduced below:

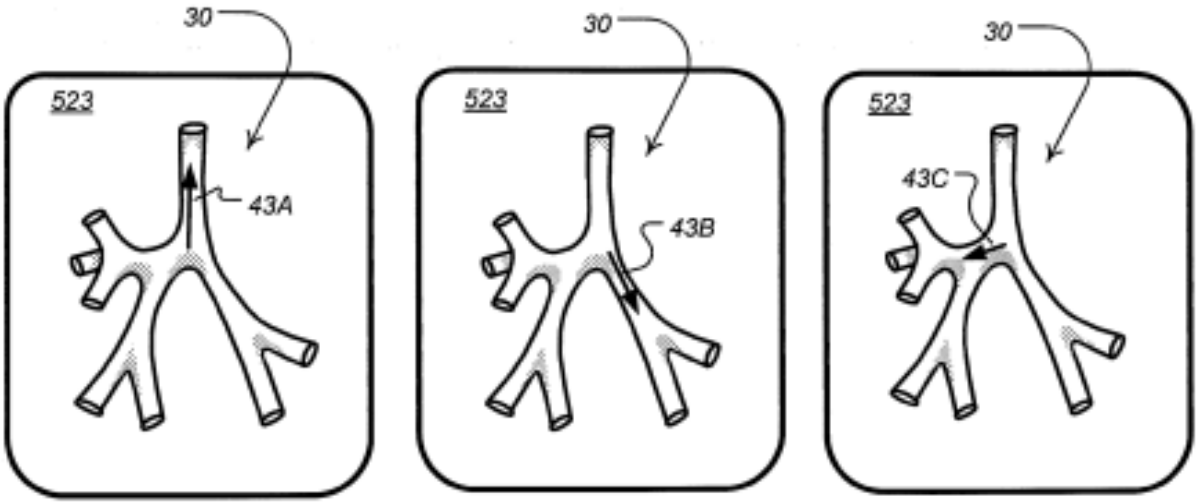


FIGURE 4C FIGURE 4D FIGURE 4E

"FIGS. 4C-E 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) …." Ex.1004, ¶[0024]. Though not shown in the figures, Ganatra explains 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." *Id*.; Ex.1003, ¶¶107-08. These arrows provide guidance for navigating the bronchoscope along a path through a plurality of designated points, including through M0/T0 (the "*first anatomic landmark*"), M1/T1, M2/T2, and M3/T3 ("*providing guidance for navigating the steerable instrument along a path through a plurality of anatomic landmarks, including the first anatomic landmark*"). As explained in §V.A.a.3, above, each designated point is an

"*anatomic landmark*." Therefore the path through, M0/T0, M1/T1, M2/T2, and M3/T3 runs through a plurality of anatomic landmarks. Ex.1003, ¶108.

After the initial registration process is complete, the navigation system continues to provide guidance to the operator to assist in navigating the bronchoscope to site 620 ("*a target location within the patient anatomy*"). Ex.1004, ¶[0026] ("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"), ¶[0029] ("one of predetermined points 405 of model 40… may be designated, to correspond with site 620, and marked on display 30, with another type of visual indicator, as a reference for navigating the medical instrument to site 620 to perform the procedure, once the registration process is completed"). This is one way in which Ganatra discloses the "*providing guidance*…" step. Ex.1003, ¶¶109-10.

(b) Ganatra's Navigation Guidance to Target Site 620 Independently Meets This Element

Ganatra explains that, after the initial registration process is complete, navigation guidance can be provided to assist the operator in navigating to a target site 620. Ex.1004, ¶¶[0026], [0029]. At the end of the initial registration process, the bronchoscope will be located near designated point M0/T0 because the system

"direct[s] the operator to backtrack the bronchoscope back to anchor point T0, following travel to each of points T1, T2 and T3." Ex.1004, ¶[0024]; Ex.1003, ¶¶111-12. The operator thus must navigate from M0/T0 to site 620, a path that runs through both M3/T3 and M4/T4. As explained in §V.A.a.3, above, each designated point is an "*anatomic landmark*." Therefore the path through, M0/T0, M3/T3, and M4/T4 runs through a plurality of anatomic landmarks. Ex.1003, ¶111.

Ganatra explains that a target site 620 can be identified on the displayed model using hatch marks and that additional visual indicators may be included to assist the operator in navigating to the site. Ex.1004, ¶[0029] ("[O]ne of predetermined points 405 of model 40 …, ***may be designated, to correspond with site 620, and marked on display 30, with another type of visual indicator, as a reference for navigating the medical instrument to site 620*** to perform the procedure, once the registration process is completed.") (Emphasis added). The hatch marks are depicted in Figure 6C, below. Also shown is Figure 4A, which depicts the designated points. Blue annotations have been added.

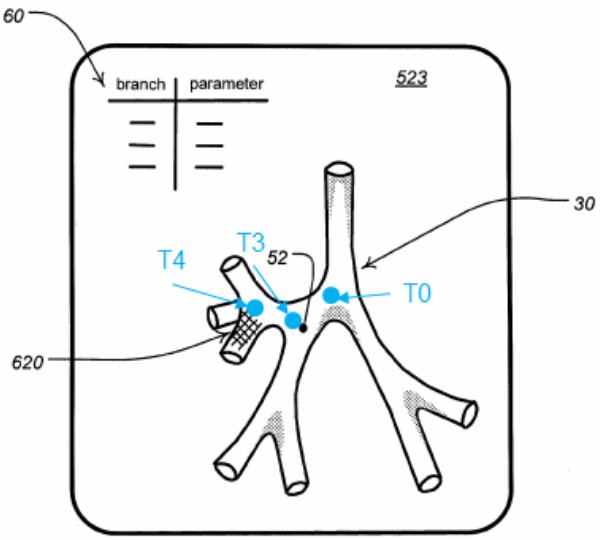


FIGURE 6C

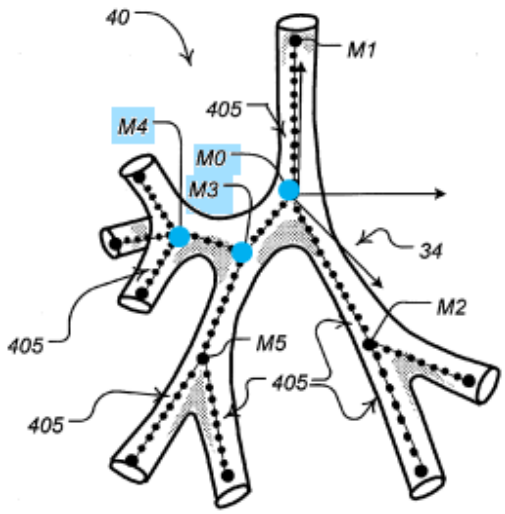


FIGURE 4A

Ex.1003, ¶112.

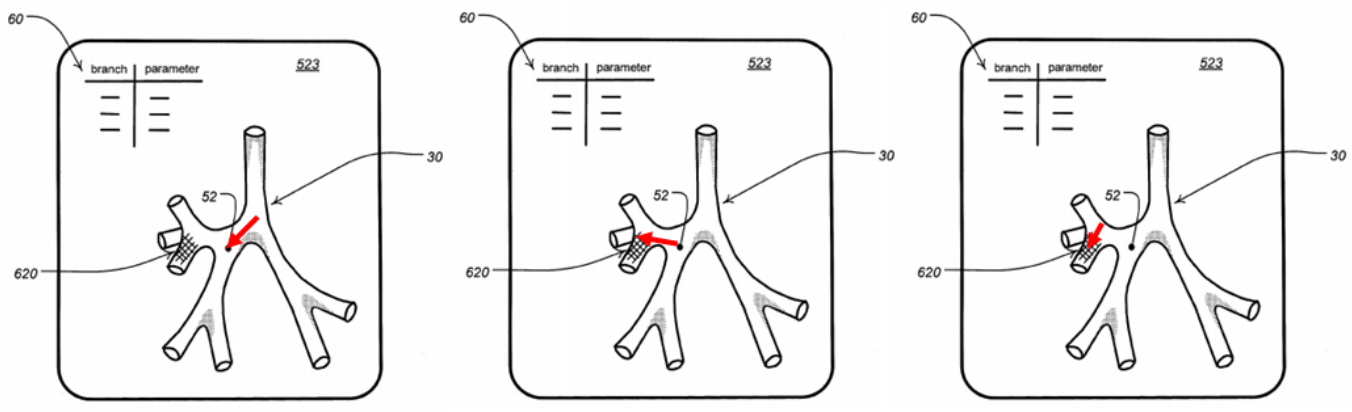
Ganatra states that "another type of visual indicator" may be "marked on display 30" for use "as a reference for navigating the medical instrument to site 620." Ex.1004, ¶[0029]. Ganatra does not include any figures that explicitly illustrate both site 620 and additional visual indicators used to assist in navigating to that site. Ex.1003, ¶¶113-14. As Dr. Hannaford explains, a POSA would have understood that any of the visual indicators described in Ganatra could be used for this process. *Id.*, ¶¶114-15. For example, Ganatra teaches using various types of visual indicators, such as "arrows," "color coding of branches and blinking or flashing points or zones along each branch." Ex.1004, ¶[0024]. Ganatra also 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.*,

Figs. 4C-4E, ¶[0024]. As 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. Ex.1003, ¶¶114-15. Thus, a POSA would have understood that arrows could be used in the same manner to guide the operator to site 620 to perform a procedure. *Id.*, ¶¶115-16.

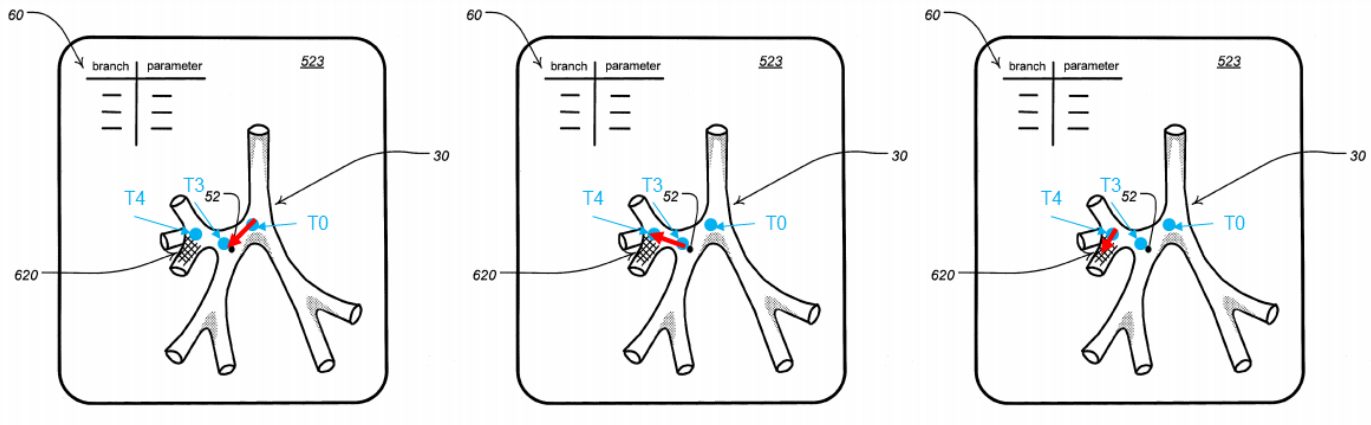
Dr. Hannaford describes how a POSA would have understood Ganatra to disclose providing a "visual indicator" to an operator "as a reference for navigating the medical instrument to site 620." Ex.1003, ¶¶112-13 (quoting Ex.1004, ¶[0029]). Ganatra provides that at the end of the initial registration process, the bronchoscope is located at T0. Ex.1003, ¶111. Thus, the path to target site 620 starts at M0/T0, runs through M3/T3 and M4/T4, and then reaches target site 620. Using arrows in the same way that Ganatra shows for the initial registration process, an arrow first would guide the user from M0/T0 to M3/T3. *Id.*, ¶¶111-12, 115. After the bronchoscope reaches M3/T3, a new arrow would appear directing the operator to M4/T4. *Id.*, ¶¶115-16. After the bronchoscope reached M4/T4, another arrow would guide the user from M4/T4 to site 620. *Id*. As Dr. Hannaford explains, this is how Ganatra uses the arrows during the registration process. *Id.*, ¶¶115-16; Ex.1004, ¶[0024] ("once the operator has moved the bronchoscope far

enough in direction B, for example to point T2…, indicator 43B disappears from display 30 and indicator 43C appears").

Dr. Hannaford illustrated how this guidance would be provided to the user in versions of Figure 6C that he annotated using colored arrows below.



Ex.1003, ¶116. The arrows could be displayed sequentially as the operator navigates through each designated point, or all three could be displayed at the same time. *Id.*, ¶¶116-17. This path runs through a plurality of designated points (T0, T3, and T4) to target site 620, as Dr. Hannaford illustrates in the figures below:



Ex.1003, ¶118.

Accordingly, if an operator's medical device is located at anchor point T0 and the target location for a procedure in the patient's bronchial tree is at target site 620 (just past point T4), Ganatra's system uses visual indicators to provide "*guidance for navigating the medial instrument along a path through a plurality of anatomic landmarks*" (*e.g.*, through T0, T3, and T4 shown in Figure 4B), "*including the first anatomic landmark*" (*e.g.*, T0), "*to a target location within the patient anatomy*" (target site 620). Ex.1004, ¶[0029], Figs. 4A-B, 5C; Ex.1003, ¶119. Thus, this is a second way in which Ganatra discloses the "*providing guidance*…" step. Ex.1003, ¶120.

For this second mapping, Petitioner has framed the analysis in terms of anticipation because as Dr. Hannaford explains, a POSA would have understood Ganatra to explicitly teach using these navigation methods to guide an operator to target site 620 even though they are not explicitly illustrated. Ex.1003, ¶¶115-20. 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.

Ganatra therefore anticipates claim 1.

b) Claim 2

Claim 2 depends from claim 1 and specifies that "*the first landmark information includes position information*."

For each designated point (which includes "*the first landmark*" M0/T0), Ganatra discloses that it stores both the tracking system coordinates and the model system coordinates (each "*position information*") in a database. Ex.1004, ¶[0022] ("[P]rocessor 522 receives a stream of positional information from tracking system 51."); Abstract ("A system and method . . . for collecting positional information for the medical instrument …."); ¶[0023] ("positional information provided by tracking system 51 to automatically collect the fiduciary points."); ¶[0026] ("[P]rocessor 522 receives a stream of positional information from tracking system 51 …."); ¶[0028] ("[A]s the bronchoscope was moved through branch B3B, registered sets of coordinates were collected for positions of the bronchoscope therein …."); ¶[0031] ("tracking system 51 collects positional information for sensor X"); ¶[0031] ("[T]he registration may be automatically updated, or refined, by processor 522 using positional information for tracking sensor X …."); Ex.1003, ¶¶130-31.

Accordingly, Ganatra anticipates claim 2.

c) Claim 5

Claim 5 depends from claim 1 and specifies that "*the first landmark information includes a timestamp*."

Ganatra discloses that the processor measures "a ***time*** that the medical instrument is moved within a particular branch of the branched structure," that the

time is "associated with a group of collected registered sets of coordinates," and that the time "***may be stored within database 521*** for future reference." Ex.1004, ¶[0027] (emphases added); *see also id.*, ¶[0028] ("***A time of travel within branch B3B may also be measured, stored and recorded/displayed*** …. ***[T]he time between collection of the coordinates for points T3 and T5 may be measured, stored and recorded/displayed***.") (emphasis added). Although Ganatra provides an example for measuring the time of travel within branch B3B and then storing that time, a POSA would have understood Ganatra to disclose measuring and storing the time of travel between any two designated points (*e.g.*, T0 and T3). Ex.1003, ¶155.

Accordingly, Ganatra anticipates claim 5.

d) Claim 6

Claim 6 depends from claim 1 and specifies that "*the first landmark information includes a graphical representation*."

The '601 specification states that "landmarks may be indicated, for example, by ... a small graphic icon related to the type of landmark." Ex.1001, 10:63-11:3 ("The landmarks may be indicated, for example, by a text label with the landmark name, a thumbnail image with the stored endoscope image captured with the landmark, a small graphic icon related to the type of landmark, or with an approximate 3-D model of the landmark."). A POSA would understand that a

graphic icon used to identify a landmark on a display is one example of "*first landmark information*" that is "*a graphical representation*." Ex.1003, ¶¶158-59.

Ganatra discloses several visual indicators ("*a graphical representation*") that can be associated with each designated point ("*first landmark information*") and displayed to an operator. Ex.1003, ¶¶160-63.

Ganatra explains that "FIGS. 6A-B are schematics of display element 523 presenting alternative displays of measured parameters." Ex.1004, ¶[0028]. Figure 6A (reproduced below) shows that designated point T3 is identified on a displayed image of the computer model using a circle or dot as a visual indicator ("*a graphical representation*").

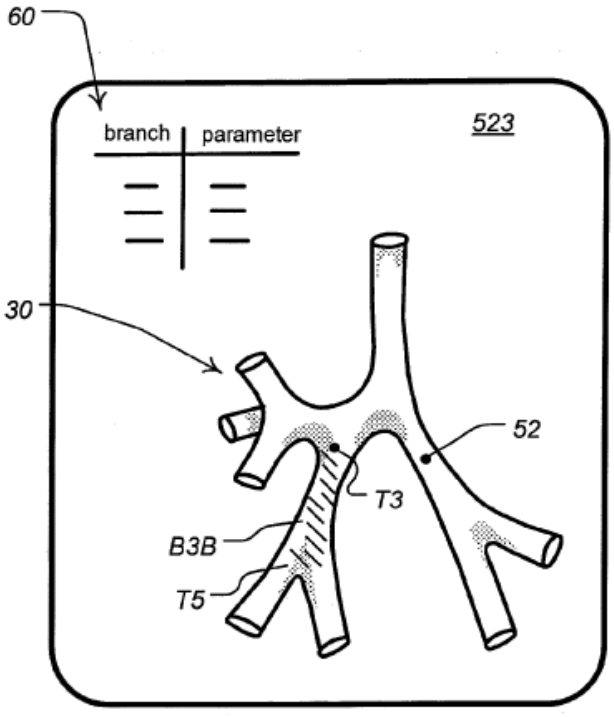


FIGURE 6A

Figure 6A also shows "hatch marks superimposed over branch B3B, as a visual indicator of a distance over which the bronchoscope has previously been moved." *Id*. Ganatra explains that the hatch marks are associated with designated points T3 and T5:

> [A]s the bronchoscope was moved through branch B3B, registered sets of coordinates were collected for positions of the bronchoscope therein, at least corresponding to branching points T3 and T5, ***so that processor 522 could calculate, or measure a distance between points T3 and T5***, store the distance in database 521, and send the information to display element 523 for recording in table 60 and/or ***for marking branch B3B***.

Id. (Emphases added).

Ganatra teaches that visual indicators such as dots or hatch marks may be associated with each designated point. Ex.1003, ¶¶159-62. Although Ganatra shows examples where visual indicators are associated with T3 and T5, a POSA would have understood that these visual indicators could be associated with any designated point (*e.g.*, any of T0 to T5). *Id.*, ¶162.

Thus, a POSA would have understood Ganatra to disclose that when its system records coordinate/position information for anchor point T0, it also associates a visual indicator with anchor point T0 so that it can be marked on the

display for the operator during navigation of the bronchoscope. Ex.1003, ¶163; Ex.1004, ¶[0029].

Therefore, Ganatra anticipates claim 6.

e) Claim 7

Claim 7 depends from claim 6 and recites "*further comprising displaying the model of the patient anatomy registered with the graphical representation.*"

As explained above with respect to claim 6, Ganatra discloses that a visual indicator identifying a designated point or the space between designated points can be superimposed on the computer model and displayed to a user. *See* §V.A.2.d, *above*. An example of this is depicted in Figure 6A:

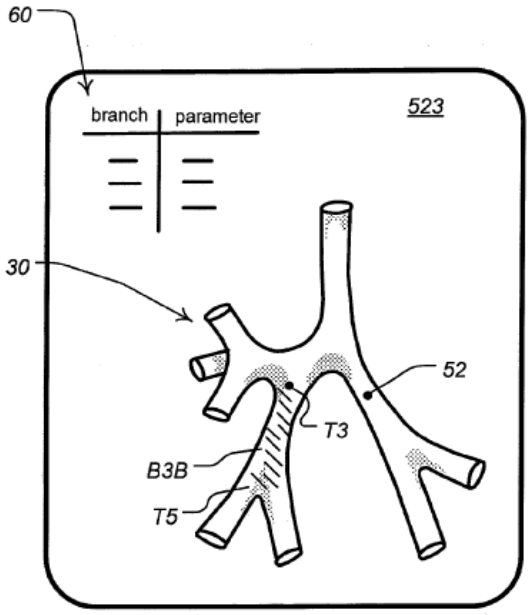


FIGURE 6A

As explained above with respect to claim 6, although Ganatra illustrates this with respect to designated points T3 and T5, a POSA would have understood

Ganatra to describe using these visual indicators with respect to any of the desgnated points. *See* §V.A.2.d, *above*; Ex.1003, ¶¶166-68.

Accordingly, Ganatra anticipates claim 7.

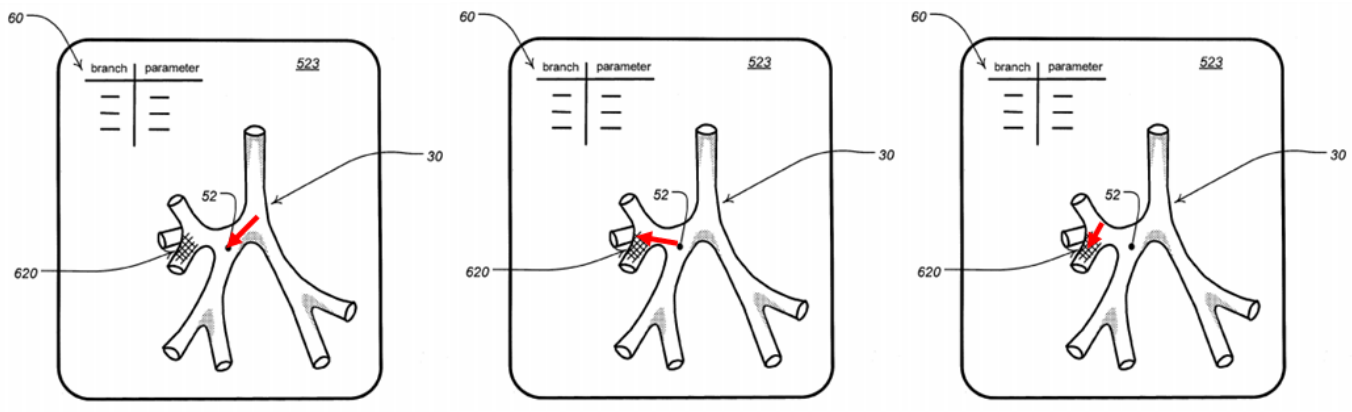
f) Claim 8

Claim 8 depends from claim 1 and further states that "*the guidance includes a model of the path between the plurality of anatomic landmarks*." As explained with respect to claim 1, two processes in Ganatra each independently meet the "*providing guidance*…" element. Each process meets claim 8 as well.

Ganatra's Initial Registiration Process. As explained above with respect to claim 1, Ganatra discloses an initial registration process where arrows guide a user through designated points T0/M0 to T3/M3. The arrows are displayed sequentially as the operator navigates through each of the four designated points M0/T0, M1/T1, M2/T2, and M3/T3 ("*the plurality of anatomic landmarks*"). Ex.1003, ¶172.

Ganatra's Guidance to Target Site 620. As explained above with respect to claim 1, a POSA would have understood Ganatra to disclose providing a "visual indicator" to an operator "as a reference for navigating the medical instrument to site 620," (Ex.1003, ¶173 (quoting Ex.1004, ¶[0029])), and that a POSA would have understood that could be done using arrows as Ganatra describes in the context of the initial registration process, (Ex.1003, ¶173). Dr. Hannaford

illustrated how this guidance would be provided to the user in the annotated versions of Figure 6C below.



Ex.1003, ¶¶173-74. The arrows could be displayed sequentially as the operator navigates through each designated point, or all three could be displayed at the same time. *Id.* As explained with respect to claim 1, this path runs through designated points M0/T0, M3/T3, and M4/T4 ("*the plurality of anatomic landmarks*").

As Dr. Hannaford explains for both of these processes, the arrows are a "*a model of the path between the plurality of anatomic landmarks*." Ex.1003, ¶175. The arrows depict the path over which the operator needs to guide the bronchoscope, and therefore they "*model*" the path. *See* §V.A.2.a.6, *above*. This path is superimposed on an image depicting the computer model of the patient's anatomy to provide navigation guidance to the operator in navigating the bronchoscope to a target location in the patient. Ex.1003, ¶175.

Ganatra therefore anticipates claim 8.

g) Claim 9

Claim 9 depends from claim 8 and recites "*further comprising displaying the model of the path registered with the model of the patient anatomy*."

As explained above with respect to claim 8, Ganatra teaches superimposing on the computer model of the patient's anatomy ("*displaying… the model of the patient anatomy*") arrows that guide the operator though a plurality of designated points to a target site ("*displaying the model of the path registered*"). Ex.1003, ¶181.

Ganatra therefore anticipates claim 9.

B. Ground 2: Ganatra and Soper Render Claims 1-3 and 5-18 Obvious

1. Summary of Soper

Soper was filed on December 10, 2004, published on August 18, 2005, and issued on March 8, 2011. Larkin is therefore prior art to the '601 patent under at least 35 U.S.C. § 102(a), (b), and (e).

Soper describes systems and methods for providing "visually-assisted guidance of an ultra-thin flexible endoscope to a predetermined region of interest through a lumen in a patient's body." Ex.1007, 2:63-65, Abstract ("Visual-assisted guidance of an ultra-thin flexible endoscope to a predetermined region of interest within a lung during a bronchoscopy procedure."), 7:42-52; Ex.1003, ¶74. Prior to a procedure, a computer model of the patient's anatomy, *e.g.*, of the airway tree, is

created, and biopsy points are selected. Ex.1007, 3:13-23; *see also id.*, 3:60-65, 12:16-33. The system then "automatically plot[s] [a series of courses] in the model tree to effectively steer the physician at each branching [point]." *Id.*, 3:23-29; *see also id.*, 13:49-56. For the procedure, Soper uses an endoscope with a sensor on its tip that interacts with an external electromagnetic field to determine the tip's position in space within the patient. *Id.*, 3:1-4, 7:54-59; Ex.1003, ¶75. The position information is used to determine the location of the endoscope on a 3-D computer model of the patient's anatomy. Ex.1007, 3:4-7, 10:1-10. Soper's system uses a registration process to map correlate the 3-D position of the sensor to the computer model. *Id.*, 3:34-36, 8:27-30. Soper uses branching points in the airways as registration points. *Id.*, 18:48-54, 18:63-19:1; Ex. 1003, ¶76. At each branching point, Soper takes an endoscopic image of the anatomy and stores it "for annotation or later inspection and saved in a library of images 336 within the lung model." Ex.1007, 19:1-5; *see also id.*, 19:15-23.

During a procedure, Soper provides visual guidance to the operator of the endoscope by superimposing graphic images on the computer model. Ex.1003, ¶77. For example, Soper's user interface displays the computer model and superimposes on it a "graphic marker 192 … to show the position of the catheter in airways 190" as well as "the intended navigation routes to the points of biopsy." Ex.1007, 13:63-67. The navigation route can be depicted as a path through the

airways, (*Ex.*1007, 13:64-67, Fig. 4D), and further navigation guidance can be provided by "provid[ing] an arrow on the virtual interface that indicates a direct path and the distance to the intended destination," *id.*, 20:15-18.

2. A POSA Would Have Considered Ganatra and Soper Together

The systems described in Ganatra and Soper are highly analogous and contain similar features. Both are directed to systems for providing navigation guidance to an operator steering an endoscope through a patient's airways. Ex.1003, ¶81. Both create a 3-D computer model of the patient's anatomy prior to the procedure, use an endoscope with a tracking sensor at its tip, use a registration process, and provide visual guidance to an operator including guidance to a target location. *Id.*

A POSA following his or her ordinary design process would consider and evaluate techniques used in analogous systems that could improve the performance of the system the POSA was trying to design. Ex.1003, ¶80. A POSA considering Ganatra would have looked to other references describing processes for providing navigation guidance for steering a medical instrument within a patient to determine whether any features of those systems could improve Ganatra's operation. Ex.1003, ¶¶80, 82. Soper was one such reference, and a POSA would have considered its teachings together with Ganatra. *Id.*, ¶¶80, 122. When implementing the various features of Ganatra, the POSA would refine that

feature's implementation based on Soper's implementation of analogous features. *Id.*, ¶80.

3. Claims 1-3, 5-18 Are Obvious Based on Ganatra and Soper

a) Claim 1

Patent Owner may contend that Ganatra does not disclose the step of "*providing guidance for navigating the steerable instrument along a path through a plurality of anatomic landmarks, including the first anatomic landmark, to a target location within the patient anatomy*" because 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." Ex.1004, ¶[0029]. 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. Ex.1003, ¶123. Even if such a distinction between Ganatra and the claims were accepted, the claims would still be unpatentable as obvious for at least two reasons.

First, as explained above, a POSA would have understood Ganatra to describe a process for using arrows to guide a user through landmarks to a target location. If the Board were to find that Ganatra's disclosure is insufficient to anticipate that process, that process at least would have been obvious for the same reasons set forth above.

Second, a POSA would have found that Ganatra and Soper together teach this limitation. A POSA 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 for examples of how others in the field had provided such guidance. Ex.1003, ¶¶80, 122. That person would have looked to Soper, which as described above, describes a system that is analogous to Ganatra. *Id.*, ¶81. In particular, the POSA would look to how Soper provides visual navigation guidance to an operator. *Id.*, ¶¶81, 123.

Soper explicitly describes two ways for providing visual indicators to a user to assist in navigating to a point of biopsy (a "*target location within the patient anatomy*"). Ex.1003, ¶¶124-25. First, 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. The intended navigation routes are the dotted lines shown in Figures 4A and 4D below, which extend from the entrance way of the trachea, though branching points in the lungs, to various points of biopsy:

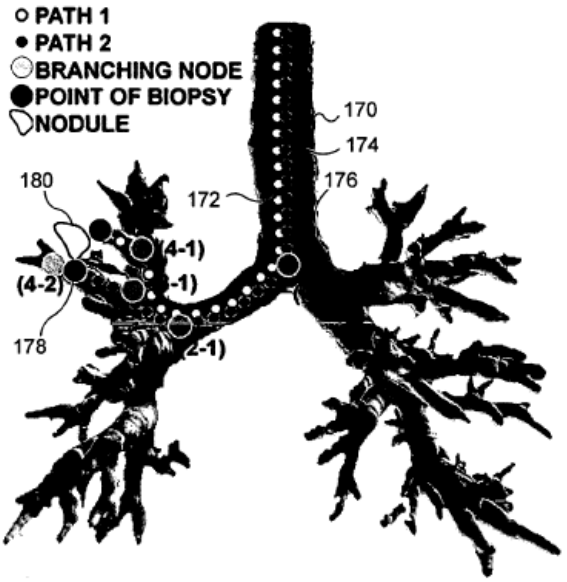


FIG. 4A

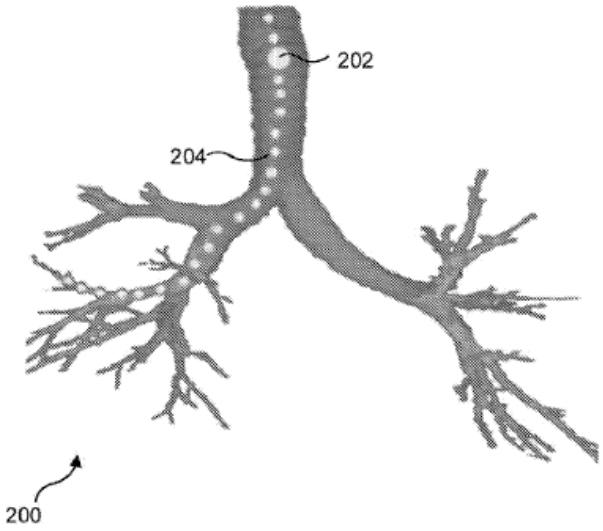
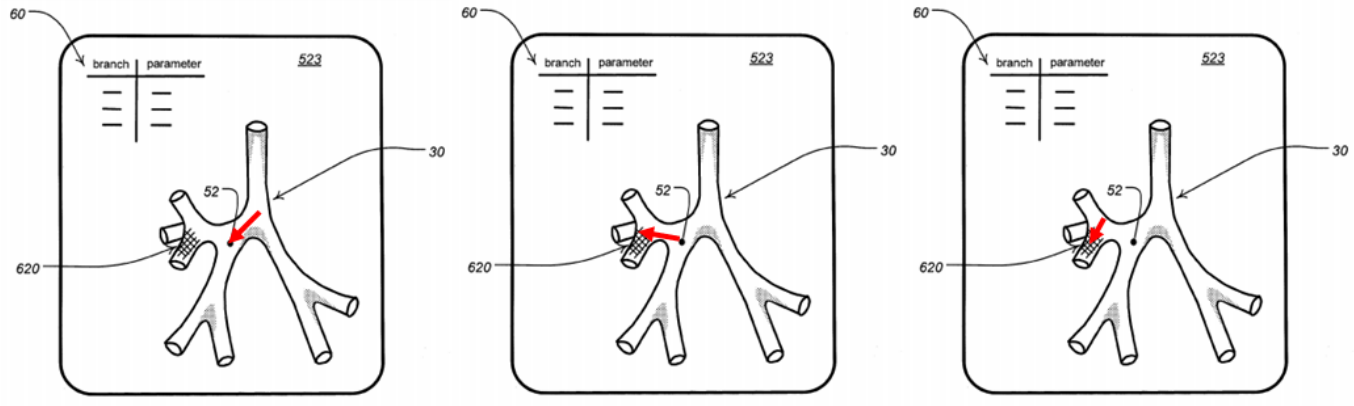


FIG. 4D

Second, Soper describes another way to provide visual guidance to the operator. Soper explains that its system can "provide an arrow on the virtual interface that indicates a direct path and the distance to the intended destination." Ex.1007, 20:15-18.

The POSA 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. This is consistent with Ganatra's own teaching, which show using arrows to depict a navigation path to an operator during the registration process. *Id.* Using arrows or a line to provide guidance for navigating to target site 620 would have been an obvious configuration of Ganatra, and implementing it would be a predictable and routine engineering task. *Id.*

As Dr. Hannaford explains, where arrows are used to provide guidance to an operator "as a reference for navigating the medical instrument to site 620," the path to target site 620 starts at M0/T0, runs through M3/T3 and M4/T4, and then reaches target site 620. Ex.1003, ¶¶111-12, 115 (quoting Ex.1004, ¶[0029]). In this configuration, an arrow first would guide the user from M0/T0 to M3/T3. Ex.1003, ¶¶111-12, 115. After the bronchoscope reaches M3/T3, a new arrow would appear directing the operator to M4/T4. *Id.*, ¶¶115-16. After the bronchoscope reached M4/T4, another arrow would guide the user from M4/T4 to site 620. *Id*. This is how Ganatra shows the arrows being used during the registration process. *Id.*, ¶¶115-16, 126; Ex.1004, ¶[0024] ("[O]nce the operator has moved the bronchoscope far enough in direction B, for example to point T2 …, indicator 43B disappears from display 30 and indicator 43C appears …."). Dr. Hannaford illustrated how this guidance would be provided to the user in the annotated versions of Figure 6C below.



Ex.1003, ¶126. The arrows could be displayed sequentially as the operator navigates through each designated point, or all three could be displayed at the same time. *Id.*, ¶¶116-17, 126. Alternatively, a POSA could 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, above). *Id.*, ¶126. As explained above (§V.2.a.6), this path, however it is depicted, runs through a plurality of designated points (T0, T3, and T4) to target site 620. *See id.*, ¶¶125-26.

Accordingly, if an operator's medical device is located at anchor point T0 and the target location for a procedure in the patient's bronchial tree is at target site 620 (just past point T4), it would have been obvious based on Soper to configure Ganatra's system to use visual indicators (*e.g.*, arrows or a line) to provide "*guidance for navigating the medial instrument along a path through a plurality of anatomic landmarks*" (*e.g.*, through T0, T3, and T4 shown in Ganatra Figure 4B), "*including the first anatomic landmark*" (*e.g.*, T0), "*to a target location within the patient anatomy*" (target site 620). Ex.1004, ¶[0029], Figs. 4A-B, 5C; Ex.1003, ¶127. Thus, Ganatra alone or the combination of Ganatra and Soper teach the "*providing guidance…*" step.

b) Claims 2, 5-7

Ganatra alone discloses the elements of claims 2, 5-7, and therefore those claims are obvious based on Ganatra alone or the combination of Ganatra and Soper.

c) Claim 3

Claim 3 depends from claim 1 and specifies that "*the first landmark information includes an image from the reference portion of the steerable instrument captured by an image capture device*."

Ganatra discloses that the "bronchoscope 200 may include a video camera coupled to an imaging system for displaying images of the local environment around distal end 202 of bronchoscope 200, as it is advanced through the bronchial tree of the patient." Ex.1004, ¶[0020]. Ganatra explains that "images collected by bronchoscope 200 can help the operator to find the fiduciary points." *Id*. Ganatra explains:

> As described above, bronchoscope 200 may include a video camera, and … ***a stream of images is collected from bronchoscope and matched, by processor 522, to virtual endoluminal views***, which are also generated from the volumetric data set of the images collected via CT scanning and stored in database 521 …. ***This image matching may further refine any of the approaches for registration and/or subsequent navigation***, which are described herein, and may help to distinguish between patient motion and bronchoscope motion.

Ex.1004, ¶[0030] (emphases added). Thus, Ganatra teaches that its distal end portion of the bronchoscope may include an image capture device (*e.g.*, a video camera) "[to] help the operator to find the fiduciary points [such as designated points T0 to T5] within [a] patient's bronchial tree" to assist in registering the tracking coordinate system to the model coordinate system. Ex.1004, ¶[0020]; *see also id.*, ¶[0030].

Ganatra discloses that its process can collect images when the bronchoscope is located at any of the designated points (each an "*anatomic landmark*") to help the operator identify the proper points for registration and help to distinguish between patient motion and bronchoscope motion. Ex.1004, ¶¶[0020], [0030]; Ex.1003, ¶135. Ganatra does not explicitly state that the images collected at each designated point are stored. A POSA would have found doing so obvious based on Ganatra's own teachings. *Id.*, ¶136. Ganatra states that the images can be used to "refine any of the approaches for registration and/or subsequent navigation." Ex.1004, ¶[0030]. The skilled person would have understood that storing the images would allow the bronchoscope operator to manually adjust the registered location to more accurately correspond to the designated point. Ex.1003, ¶136.

Even if Ganatra itself were found not suggest storing and retrieving the images as associated with a designated point, configuring Ganatra to store and retrieve those images would have been obvious based on Soper.

Ganatra states that its bronchoscope includes a camera and that "a stream of images is collected from [the] bronchoscope and matched … to virtual endoluminal views" and that this "image matching may further refine any of the approaches for registration and/or subsequent navigation … and may help to distinguish between patient motion and bronchoscope motion." Ex.1004, ¶[0030]. Ganatra does not, however, explain the details of the image matching process or how it actually achieves the stated goals. Ex.1003, ¶139. A POSA would have looked to other references for additional information on how the images could be used. *Id.*

Soper describes a bronchoscope that captures and saves images of branching points and other features of the bronchial passages as it passes through them. Ex.1007, 18:30-35, 19:1-5, 19:21-32; Ex.1003, ¶140. At each branching point, Soper takes an endoscopic image of the anatomy and stores it "for annotation or later inspection and saved in a library of images 336 within the lung model." Ex.1007, 19:1-5; *see also id.*, 19:15-23. Soper explains that the captured images are used to create a "dynamic airway tree model 340 that is more accurate and compensates for the effects of bodily functions, such as breathing." Ex.1007, 19:24-29. Soper explains that motion can be detected, for example, "when the difference image computed by subtracting an acquired endoscopic image and the

endoscopic image stored during the last reregistration exceed some threshold." *Id.*, 20:30-33, Fig. 8D.

A POSA considering Ganatra and Soper would have been motivated to configure Ganatra to save captured images to enable the sytem to create a dynamic airway tree model to identify and compensate for patient motion such as breathing. Ex.1003, ¶141. Ganatra states that an imaging mapping process may be used to identify patient motion without explaining how, and Soper teaches how the images can be used to do so. *Id*. A POSA would have found it to be a matter of routine to configure Ganatra to use Soper's process for identifying motion, and doing so would have been predictable. *Id*.

In addition, Soper explains that annotating the images aids the system in "provid[ing] a data record of each of the bronchial passages that was traversed." Ex.1007, 19:15-21. The annotations can be "logged in a textual or audible form" and "[r]egions 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." *Id.*, 22:40-45; Ex.1003, ¶¶142-43. Like Soper, Ganatra also teaches that it is beneficial to track which passageways have been traversed to assist in navigation. Ex.1004, ¶[0026]. Soper teaches that capturing and annotating images of the airway passages can provide benefits by allowing a clinician to record notes about what was observed in the passage.

Ex.1007, 22:40-45. A POSA would have understood that configuring Ganatra's system to record images and notes from a physician would provide the same benefits in Ganatra's system. Ex.1003, ¶144. This is a second reason that a POSA would have configured Ganatra to store and retrieve images of the patient's anatomy. *Id.* A POSA would have found it to be a matter of routine to configure Ganatra to use Soper's image annotation process, and doing so would have been predictable. *Id*.

Thus, Ganatra alone or the combination of Ganatra and Soper render claim 3 obvious.

d) Claims 8 and 9

Claim 8 depends from claim 1 and further states that "*the guidance includes a model of the path between the plurality of anatomic landmarks*." Claim 9 depends from claim 8 and recites "*further comprising displaying the model of the path registered with the model of the patient anatomy*."

Patent Owner may contend these claims are not met by Ganatra alone because the arrows depicting the path to target site 620 are not a "*model of the path*." Even if such a distinction were accepted, these claims would have been obvious based on the combination of Ganatra and Soper. Ex.1003, ¶¶176-77. Soper teaches superimposing on the computer model of the lungs both the "pre-procedural path planning" to a user, (Ex.1007, 13:58-62, Fig. 4A), as well as "the

intended navigation routes 204," (Ex.1007, 13:64-66, Fig. 4D). These paths are depicted as dotted lines (*see* Figs. 4A and 4D above) that extend from the entrance way of the trachea, though branching points in the lungs, to various points of biopsy. Ex.1003, ¶177. 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. *Id*. Thus, Ganatra and Soper render claims 8 and 9 obvious.

e) Claim 10

(1) "A method for navigating a steerable instrument in a patient anatomy"

Ganatra discloses the preamble of claim 10 for the same reasons as claim 1. *See* §V.A.2.a.1, *above*.

(2) "recording first information about a reference portion of the steerable instrument located at a first anatomic landmark in the patient anatomy"

For the same reasons explained above for the step of "*responsive to the request, recording information*…" in claim 1, Ganatra's initial registration of M0/T0 meets this claim element. *See* §V.A.2.a.2, *above.*

In addition, Ganatra discloses two additional processes that also independently meet the step of "*recording first information.*…." Ex.1003, ¶¶187-92.

First, after M0/T0 is registered, the operator navigates the bronchoscope to each of T1, T2, and T3 to complete the registration process. Ex.1004, ¶¶[0023], [0024] (the navigation system "guide[s] 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 (FIG. 4A)"). As Ganatra explains, "processor 522 receives a stream of positional information from tracking system 51" and when the system determines that the position of sensor X corresponds to a reference point ("*a reference portion of the steerable instrument located at a first anatomic landmark*"), then "***processor 522 records***, or identifies ***a set of coordinates***, in tracking coordinate system 32, for sensor X … ***as points T1, T2, and T3***" ("*recording first information…*"). *Id.*, ¶[0022] (emphases added); *see also id.*, ¶[0023] ("deriving the mathematical transformation relating the model frame of reference to the tracking system frame of reference ***using the coordinates for each of points T1, T2, T3*** and the corresponding coordinates for points M1, M2, M3") (emphasis added); Ex.1003, ¶188.

As explained in §V.A.2.a.2, above, for claim 1, each designated point is an "*anatomic landmark*." Therefore, the initial registration of M1/T1, M2/T2, and M3/T3 each meets the step of "*recording first information … at a first anatomic landmark*." Ex.1003, ¶189.

Second, Ganatra explains that after the initial registration process, the registration continues to be refined throughout the procedure as the operator navigates the bronchoscope through additional designated points. Ex.1004, ¶[0026] ("[A]s 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 …), ***the registration … can be automatically refined*** …." (Emphases added); Ex.1003, ¶190.

When the position of sensor X in the bronchoscope matches the position of a previously unseen designated point (*e.g.*, T4 or T5) ("*a reference portion of the steerable instrument located at a first anatomic landmark*"), the system performs a re-registration or update step to record the new coordinate information ("*recording first information.*…"). Ex.1004, ¶[0026] (if the system determines the instrument is at designated point M4, "***the coordinates for sensor X, at point T4, along with the coordinates for point M4 are added*** to the sets of coordinates used for the initial registration … in order to re-register, or update the previous registration") (emphasis added), (the system "look[s] for a match with a distance of a designated point M5 of model 40 from reference point M0"). The step of performing a re-registration or an update is another way that Ganatra satisfies the step of "*recording first information … at a first anatomic landmark*." Ex.1003, ¶¶190-92.

(3) "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"

As explained with respect to claim 1, Ganatra discloses referencing the recorded information about designated point M0/T0. *See* §V.A.2.a.4, *above*. That information includes "*position information*" – both the model and tracking coordinates for M0/T0. Ex.1004, ¶[0023]; Ex.1003, ¶195.

As explained below with respect to the "*referencing the recorded second information as second landmark information*" element, Ganatra also discloses referencing the recorded information for M1/T1, M2/T2, and M3/T3. Ex.1003, ¶196.

As explained with respect to claim 3, Ganatra alone or the combination of Ganatra and Soper renders obvious capturing an image for each designated point, which can be used to refine the registration process (*the recorded first information including … an image captured … at the first anatomic location*"). *See* §V.B.3.c, *above*; Ex.1003, ¶197.

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

As explained for the "*recording first information.…*" element, Ganatra records information about each designated point M0/T0 to M5/T5. *See* §V.A.2.i.2, *above*. As explained in §V.A.2.a.3, above, for claim 1, each designated point is an "*anatomic landmark.*"

Ganatra discloses registration of six designated points: each of M0/T0 to M5/T5. Thus, Ganatra discloses both "*recording first information … at a first anatomic landmark*" and "*recording second information … at a second anatomic landmark.*" Ex.1003, ¶¶200-01.

(5) "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"

As explained with respect to claim 1, Ganatra discloses referencing the recorded information about designated point M0/T0. *See* §V.A.2.a.3, *above*. That information includes "*position information*" – both the model and tracking coordinates for M0/T0. Ex.1004, ¶[0023]; Ex.1003, ¶203.

Ganatra also discloses referencing recorded information for each of the other designated points (*e.g.*, M1/T1 to M5/T5). This information includes stores both the tracking system coordinates and the model system coordinates (each "*position information*") Ganatra stores for each designated point in a database. Ex.1004, ¶[0022] ("[P]rocessor 522 receives a stream of positional information from tracking system 51 …."); Abstract ("A system and method . . . for collecting positional information for the medical instrument …."); ¶[0023] ("positional information provided by tracking system 51 to automatically collect the fiduciary points."); ¶[0026] ("[P]rocessor 522 receives a stream of positional information from tracking system 51 …."); ¶[0028] ("[A]s the bronchoscope was moved through branch B3B, registered sets of coordinates were collected for positions of the bronchoscope therein …."); ¶[0031] ("tracking system 51 collects positional information for sensor X"); ¶[0031] ("[T]he registration may be automatically updated, or refined, by processor 522 using positional information for tracking sensor X ….").

Ganatra describes two processes that reference the stored location information for each designated point. First, Ganatra explains that its system can determine when the bronchoscope is navigated through a designated point (*e.g.*, through T2 or T3) and then monitor whether the bronchoscope is retracted back through that point. Ex.1004, ¶[0026] ("If point T4 is not reached, and the operator

decides to backtrack along branch B3A in order to travel down branch B3B instead, the initial registration will be effective ***for detecting the new direction from point T3 ….***") (emphasis added), ¶[0028] ("A time of travel within branch B3B may also be measured, stored and recorded/displayed, for example, by starting a timer, or clock when the registered set of coordinates, which corresponds to branching point T3, is collected … and, if branching point T5 is not passed …, ***stopping the timer when a subsequent collection of a set of coordinates, which also corresponds to point T3, takes place***.") (emphasis added). Thus, Ganatra references the recorded information for that designated point (*e.g.*, M1/T1 to M5/T5) to track whether the bronchoscope is retracted back through it. Ex.1003, ¶204.

Second, if the bronchoscope is navigated through a designated point and reaches a downstream designated point, Ganatra calculates the distance between the two points, such as the distance between T3 and T5. Ex.1004, ¶[0028] ("[A]s the bronchoscope was moved through branch B3B, registered sets of coordinates were collected… at least corresponding to branching points T3 and T5, so that processor 522 could calculate… a distance between points T3 and T5, store the distance in database 521, and send the information to display element 523 for recording in table 60 and/or for marking branch B3B"). Thus, Ganatra references the recorded information for each designated point (*e.g.*, M1/T1 to M5/T5) to

calculate the distance between them. Ex.1003, ¶¶204-06. These are two an additional ways in which Ganatra "*referenc[es] the recorded information*" for each designated point as first landmark information.

These disclosures in Ganatra are consistent with the '601 specification. The '601 patent describes an example where a landmark is referenced by accessing its stored position information. *See* Ex.1001, 12:23-30 ("[T]he current position of the endoscope tip 112 is then stored in the memory device 155 and referenced as the position of the landmark …."). The '601 patent also describes examples where the position information of multiple landmarks is used to calculate the distance between them and to scale the computer model to the patient's anatomy. *Id.*, 12:46-61 (the '601 patent describing an analogous process where "anatomic structures … may be measured using position information" and "the measured positions of the mouth and stomach entry landmarks have been used … to align and size a 3-D model"); Ex.1003, ¶207.

As explained with respect to claim 3, Ganatra alone or the combination of Ganatra and Soper render obvious capturing an image for each designated point, which can be used to refine the registration process (*the recorded second information including … an image captured … at the second anatomic location*"). *See* §V.B.3.c, *above*.

Therefore, Ganatra alone or the combination of Ganatra and Soper render obvious this element.

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

As explained with respect to claim 1, Ganatra "*provid[es] 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*." *See* §V.A.2.a.6, *above*.

With respect to the initial registration process, Ganatra alone or the combination of Ganatra and Soper teach providing navigation guidance on path from M0/T0 though M1/T1, M2/T2, and M3/T3 (a "*plurality of anatomic landmarks*") to target site 620. Ex. 1003, ¶¶211-12.

With respect to the navigation process, Ganatra alone or 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. Ex. 1003, ¶¶211-12. Each of M0/T0, M3/T3, and M4/T4 meet the "*anatomic landmark*" limitations, and thus together meet the "*first*" and "*second*" limitations. *See* §V.A.2.a.3.

Thus, Ganatra alone or the combination of Ganatra and Soper provide guidance for navigating an instrument along a path through a "*first*" and "*second*" anatomic landmark. *See* Ex. 1003, ¶212.

f) Claim 11

Claim 11 depends from claim 10 and recites that "*the position information of the first and second landmark information is recorded with respect to a fixed reference frame*."

As explained in the Claim Construction section above, the '601 patent defines the term "fixed reference frame" to mean "a reference frame that does not move during a medical procedure to be performed using a medical instrument."

As explained above with respect to claims 1 and 10, Ganatra discloses recording the tracking system coordinates 32 ("*position information*") for each designated point (a "*first*" and "*second*" landmark). *See* §§V.A.2.a.3, V.B.3.1.e.2&4. Ganatra explains that the tracking system coordinates 32 are "in a frame of reference of the tracking system and the patient's body, which is within the field of the tracking system." Ex.1004, ¶[0019]. Ganatra depicts this frame of reference in Figure 3A, which shows the axes of the tracking system coordinates as fixed with respect to the patient.

FIGURE 3A

A POSA would have understood that Ganatra's tracking system frame of reference does not move during the procedure, and thus, it is a "*fixed reference frame*." Ex.1003, ¶¶216-17.

Ganatra also discloses that its tracking system can use "the microBIRD™ system provided by Ascension Technology Corporation (Burlington, Vt.)" to created the external field. Ex.1004, ¶[0018]. As shown in the figure below, the microBIRD™ system includes an electromagnetic field-generating base and a magnetic field detector or sensor used for electromagnetic tracking. Ex.1008, 3-4; *see also* Ex.1009.

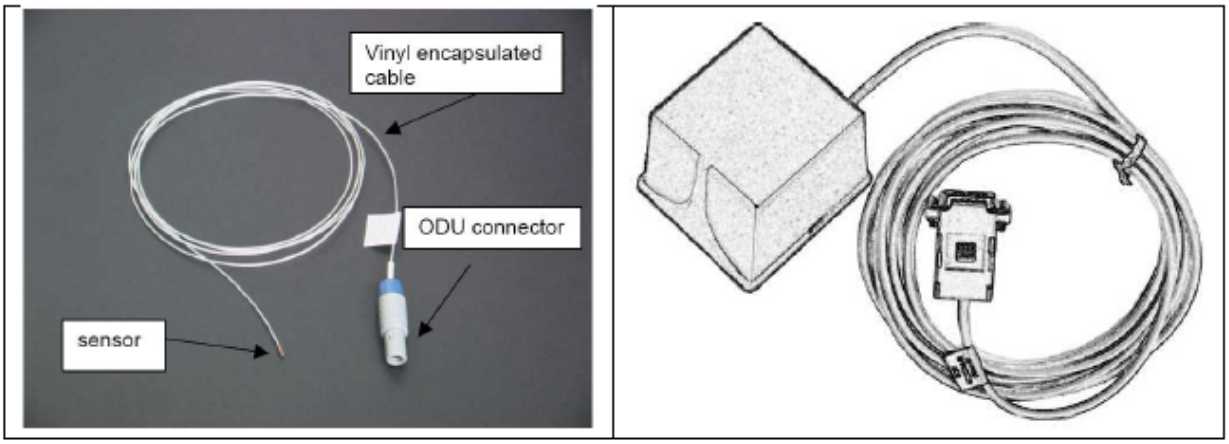


Figure 4. Left: MicroBird tracker from Ascension Corp. Right: tracker base.

The microBIRD™ base produces oscillating magnetic fields in 3D space and the microBIRD™ sensor picks up the field strength, which is used to determine the sensor's position in space relative to the base. Ex.1004, ¶[0018]. The reference frame associated with the microBIRD™ base is static/fixed becaues it does not move during the procedure. Ex.1008, 3-5 (stating that "[t]wo of the reference frames (associated with the tracker base and the calibration grid) are static" and that the tracker base coordinate system is "stationary"). Accordingly, the microBIRD™ system determines position information of the tracking sensor with respect to a fixed reference frame of the tracker base. This is an additional reason a POSA would have understood that Ganatra's tracking system operates with a fixed frame of reference. Ex.1003, ¶¶218-19.

Ganatra alone or the combination of Ganatra and Soper therefore render claim 11 obvious.

g) Claim 12

Claim 12 depends from claim 10 and specifies "*further comprising registering the first and second landmark information to a model of the patient anatomy*."

As explained with respect to claim 1 above, Ganatra teaches that registering the tracking system coordinates of each designated point with the model system coordinates for that point. *See* §V.A.2.a.5, *above*. The computer model (and the corresponding model system coordinates) is "*a model of the patient anatomy*." Ex.1003, ¶222.

As explained with respect to claim 10, Ganatra registers each M0/T0, M1/T1, M2/T2, M3/T3, M4/T4, and M5/T5, and thus, Ganatra registers both a "*first*" and "*second*" anatomic landmark to a model of the patient anatomy. *See* §§V.B.3.e.2&4, *above*; Ex.1003, ¶223.

Accordingly, Ganatra alone or the combination of Ganatra and Soper render claim 12 obvious.

h) Claim 13

Claim 13 depends from claim 12 (which depends from claim 10) and specifies "*further comprising displaying the model of the patient anatomy registered with graphical representations of the first and second landmark information*."

Ganatra alone or the combination of Ganatra and Soper teach this limitation for the same reasons they teach claims 6 and 7. *See* §§V.A.2.d, V.A.2.e, *above*.

i) Claim 14

Claim 14 depends from claim 12 and specifies "*wherein the guidance includes a model of the path between the first and second anatomic landmarks*."

Ganatra alone or the combination of Ganatra and Soper teach this limitation for the same reasons they teach claim 8. *See* §V.A.2.f, *above*.

j) Claim 15

Claim 15 depends on claim 14 and specifies "*further comprising displaying the model of the path registered with the model of the patient anatomy*."

Ganatra alone or the combination of Ganatra and Soper teach this limitation for the same reasons they teach claim 9. *See* §V.A.2.g, *above*.

k) Claim 16

Claim 16 depends from claim 10 and specifies that "*the steerable instrument includes an image capture device*." Ganatra alone or the combination of Ganatra and Soper render this claim obvious for the same reasons as claim 3. *See* §V.A.2.b, *above*.

l) Claim 17

Claim 17 depends from claim 10 and specifies that "*the guided instrument is the steerable instrument*."

As explained above, Ganatra's bronchoscope is steered and guided by an operator throughout the bronchial tree structure of a patient's anatomy. Ex.1004, ¶¶[0018]-[0020]. As such, Ganatra's bronchoscope is both a guided and steerable instrument. Ganatra alone or the combination of Ganatra and Soper therefore render claim 17 obvious.

m) Claim 18

Claim 18 depends from claim 10 and recites that "*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*."

Ganatra alone or the combination of Ganatra and Soper render this claim obvious for the same reasons they render claims 5 and 6 obvious. *See* §§V.A.2.c, V.A.2.d, *above*.

C. Ground 3: Ganatra and Larkin, with or without Soper

1. Summary of Larkin

Larkin was filed on July 20, 2006 and published on July 5, 2007, more than one year before the '601 patent's earliest effective priority date. Larkin is therefore prior art to the '601 patent under at least 35 U.S.C. § 102(b).

Larkin is directed to determining an endoscope's position and bending using optical fibers that include Fiber Bragg Gratings ("FBG"). Ex.1005, ¶[0042]. Specifically, Larkin explains that a medical instrument can include a strain sensor system "to measure strain in the optical fibers in order to determine a position and

shape of the body" of the medical instrument. *Id*. "This shape and position information can be used to assist in controlling movement of the robotic manipulator and/or surgical instrument." *Id.*; Ex.1003, ¶79.

2. A POSA Would Have Considered Ganatra and Larkin Together

It would have been obvious to a POSA at the time of the invention to combine the strain sensor system taught by Larkin with Ganatra's bronchoscope. Ex.1003, ¶84. Larkin and Ganatra are both directed to the same subject matter of determining position information of medical instruments in a patient's anatomy. A POSA following his or her ordinary design process would consider and evaluate techniques and structures used in analogous systems that could improve the performance of the system the POSA was trying to design. Ex.1003, ¶¶80, 85. A POSA considering Ganatra would have looked to other references describing processes for tracking or steering a medical instrument within a patient to determine whether any features of those systems could improve Ganatra's operation. Ex.1003, ¶85. Larkin was one such reference, and a POSA would have considered its teachings together with Ganatra. *Id*.

3. Claims 4 and 18 Are Obvious Based on Ganatra and Larkin, with or without Soper

As set forth below, Ganatra and Larkin teach all the elements of claims 4 and 18 and render those claims obvious.

a) Claim 4

Claim 4 depends from claim 1 and recites that "*the first landmark information includes shape information*." Ganatra does not explicitly state that its system stores shape information. However, Ganatra describes an embodiment where "contours, or trajectories, of actual pathways through the bronchial tree, over which bronchoscope 200 is advanced, are calculated from the positional information provided by tracking system 51 and then matched to characteristic curvatures, or contours, of corresponding portions, or branches, of the pathway defined by predetermined points 405 of model 40." Ex.1004, ¶[0031]. A POSA would have understood that to better track the curvature and contours of the bronchial tree, it would be advantageous to include shape sensing functionality within the bronchoscope. Ex.1003, ¶¶79, 147-49. One well-known technique for detecting the shape of an endoscope is described in Larkin. *Id*.

As Dr. Hannaford explains, such shape sensing functionality was well-known in the art at the time, had known benefits, and could have readily been integrated into an endoscopic system such as Ganatra's bronchoscope. Ex.1003, ¶150.

Larkin discloses that a medical instrument may include a "strain sensor system comprising a light source and a light detector [] to measure strain in the optical fibers in order to determine a position and ***shape of the body***" of the

medical instrument. Ex.1005, ¶[0042] (emphasis added). Specifically, "an optical fiber ... [can be] utilized … for monitoring the shape and relative position of each body segment 212 in the instrument 200." Ex.1005, ¶[0045]; *see also id.*, ¶[0044]. "This shape and position information can be used to assist in controlling movement of the robotic manipulator and/or surgical instrument." *Id.*, ¶[0042]. In addition, "the fiber including FBG bend sensors may be provided along the entire length of the instrument []." *Id.*, ¶[0095]. Furthermore, these "FBG sensors may be used to locate a portion of a surgical instrument (e.g., the tip of the instrument) in a fixed external coordinate system in order to combine external data ... with the positioning information to assist the operator in performing the surgical procedure." *Id.*, ¶[0099]. As such, a POSA would have been motivated to include Larkin's strain sensor system in the distal end of Ganatra's bronchoscope in order to determine the shape or bend of the distal end of the bronchoscope at certain points on its registration path to assist in controlling movement of the bronchoscope, particularly to assist in Ganatra's process for determining the "characteristic curvatures, or contours" of the airways. Ex.1003, ¶¶150-51; Ex.1004, ¶[0031].

Consequently, after the operator in Ganatra instructs the processor to establish point T0 as an anchor point of the tracking coordinate system, it would have been obvious for the processor to collect and record shape information from

Larkin's strain sensor system in the distal end portion of the bronchoscope that is located at a first branching point or anatomic landmark of the patient's bronchial tree to assist in registering the tracking coordinate system to the model coordinate system as well as controlling movement of the bronchoscope in the patient during use. *See* Ex.1004, ¶[0021]; Ex.1005, ¶¶[0042]-[0044], [0095], [0099]; Ex.1003, ¶¶150-51.

Accordingly, Ganatra and Larkin, with or without Soper, render claim 4 obvious.

b) Claim 18

Claim 18 depends from claim 10 and recites that "*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*."

As explained above, Ganatra alone or the combination of Ganatra and Soper render this claim obvious. If claim 18 were to require recording "information about *a shape of the steerable instrument*," it would have been obvious in view of Ganatra and Larkin for the same reasons those references render claim 4 obvious.

Accordingly, Ganatra and Larkin, with or without Soper, render claim 18 obvious.

VI. CONCLUSION

For the reasons set forth above, Auris respectfully asks the Board to initiate *inter partes* review and find claims 1-18 to be unpatentable.

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Respectfully submitted,

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Certification of Word Count (37 C.F.R. § 42.24)

I hereby certify that this Petition for *Inter Partes* Review has 13,903 words (as counted by the "Word Count" feature of the Microsoft Word™ word-processing system), exclusive of "a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing."

Dated: June 12, 2019 By /Thomas A. Broughan III/

Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached Petition for *Inter Partes* Review and supporting materials were served as of the below date by Federal Express on the Patent Owner at the correspondence address in PAIR indicated for U.S. Patent No. 8,801,601 as well as at other addresses.

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