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Paper No. 15
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.,
Petitioner,

v.

NEUROVISION MEDICAL PRODUCTS, INC.,
Patent Owner.

Case IPR2015-00502
Patent 8,634,894 B2

Before MEREDITH C. PETRAVICK, WILLIAM V. SAINDON, and BENJAMIN D. M. WOOD, *Administrative Patent Judges*.

PETRAVICK, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

NuVasive, Inc. ("Petitioner") filed a Petition requesting *inter partes* review of claims 1–19 of U.S. Patent No. 8,634,894 B2 (Ex. 1001, "the '894 patent") pursuant to 35 U.S.C. §§ 311–319. Paper 1 ("Pet."). Neurovision

Medical Products, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 14 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

We conclude that Petitioner has demonstrated that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. For the reasons described below, we institute an *inter partes* review as to claims 4, 6–11, and 14–19 of the '894 patent.

B. Related Proceedings

Both Petitioner and Patent Owner state that it is not aware of any civil action, other *inter partes* review, or pending prosecution concerning the '894 patent, but identify *Neurovision Medical Products v. NuVasive, Inc*., San Diego Superior Court Case No. 37-2014-00009821-CU-BT-CTL as a proceeding that may be affected by this proceeding. Pet. 3; Paper 10, 1. The San Diego Superior Court case is a trademark infringement and trade secret action.

C. The '894 patent

The '894 patent is titled "Electrode for Prolonged Monitoring of Laryngeal Electromyography" and issued on January 21, 2014. Ex. 1001, 1. The '894 patent discloses a laryngeal electromyography tube having electrodes, electrical traces, and conductive pads directly imprinted on the surface of, and thus substantially flush with, the surface of the tube, which permits the tube to be used for prolonged monitoring, in excess of eight

hours. *See id*. at col. 1, l. 45–col. 2, l. 2; col. 6, ll. 30–58. The electrodes, electrical traces, and conductive pads are imprinted on the surface of the tube by "painting, screen printing, transfer printing, gravure, flexographic or offset printing, as well as inkjet or electrostatic printing methods." *Id*. at col. 6, ll. 4–7. The electrodes, electrical traces, and conductive pads are formed with conductive ink or paint that comprises a mixture of conductive materials dissolved or suspended in a liquid carrier. *See id.* at col. 4, l. 49–col. 5, l. 16.

The '894 patent discloses various embodiments, in which the number and placement of the electrodes vary. *See id.* at Figs. 1, 2, 4, 7. Figure 7 depicts an embodiment in which two electrodes are placed on the tube such that an electrode is in contact with the vocal cords and another is in contact with the tongue when the tube is in use. *Id.* at col. 4, ll. 43–46. Figure 7 is reproduced below.

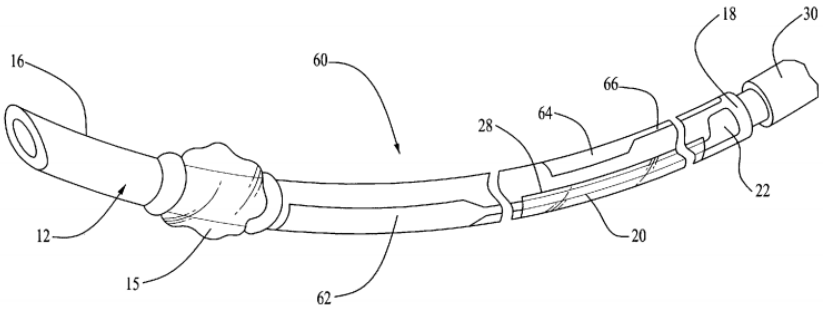

FIG. 7

Figure 7 depicts an embodiment having two electrodes, one of which rests against the vocal cords and the other rests against the tongue in use.

Figure 7 depicts laryngeal electromyography tube 60 having an endotracheal tube 12 imprinted with two electrode plates 62 and 64. *Id*. at col. 4, ll. 43–46. Electrode plate 62 is positioned to contact the vocal cords,

and electrode plate 64 is positioned to contact the tongue. *Id*. Conductive traces 20 connect the electrode plates to conductive pads 22, which attach to lead wires of an external device. *Id*. at col. 4, ll. 2–13, 46–48. Tube 60 also has an endotracheal tube balloon 15, which, when inflated, holds tube 60 in a desired position when in use. *See id*. at col. 4, ll. 2–3; Fig. 8. Figure 8 depicts tube 60 in use and is reproduced below.

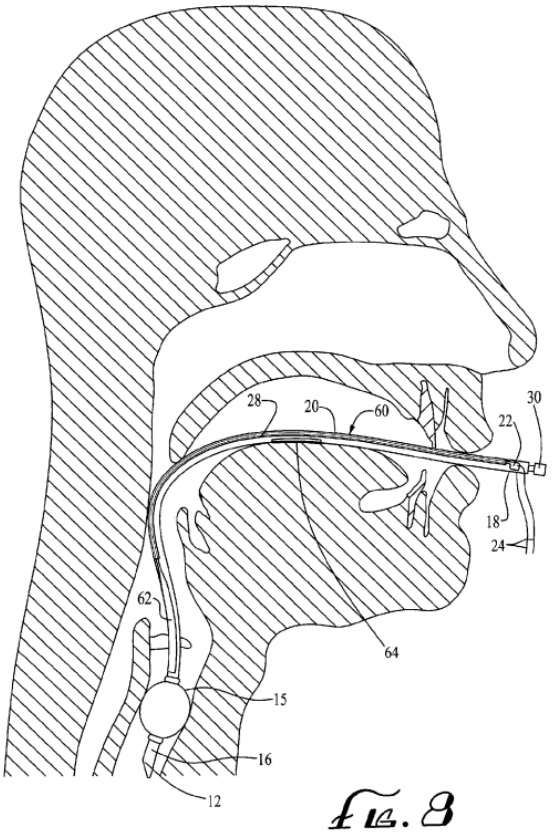

FIG. 8

Figure 8 depicts tube 60 placed within the trachea with one electrode plate adjacent the vocal cords and one electrode contacting the tongue.

Claim 1, reproduced below, is illustrative of the claimed subject matter.

> 1. A device for use in monitoring electrical signals during laryngeal electromyography comprising:

an endotracheal tube having a retention balloon at or adjacent a distal end thereof, said tube having on its outer surface first and second electrically conductive electrodes applied proximal of the balloon directly to the surface of the tube, without the inclusion of a carrier film between the tube surface and the electrodes, said first and second electrodes electrically isolated from each other, at least one of said electrically conductive electrodes positioned to contact the vocal cords, the second electrode positioned to contact tissue, nerves and muscle in the trachea or the tongue when the tube is positioned in the trachea,

said tube having on its surface first and second electrically conductive traces, said traces electrically isolated from each other, each trace connected to or integral with an electrode, the traces applied directly to the tube surface and running along the length of the endotracheal tube to a proximal portion of the tube,

a proximal connection point connected to or integral with each of the conductive traces, the connection points applied directly to the tube surface at a proximal end of the traces on the endotracheal tube, and

electrical leads connected to the connection points, said leads adapted for connection to monitoring equipment,

the electrically conductive traces covered by an insulating material along their length from a point adjacent the electrodes to a point adjacent the connection points.

D. Asserted Grounds of Unpatentability

For all of the challenged claims, Petitioner asserts the following grounds of unpatentability:

Ground	Claims	Prior Art
§ 103	1–19	Goldstone[1], Cook[2], and Hutchings[3]
§ 103	1–19	Lowery[4], Goldstone, and Hutchings

To support its Petition, Petitioner proffers a Declaration of Dr. Andrew Goldstone (Ex. 1011, "Decl. Goldstone") and a Declaration of Dr. Raymond Schettino (Ex. 1013, "Decl. Schettino"). Dr. Goldstone and Dr. Schettino are the inventors of the Goldstone patent. *See* Decl. Goldstone ¶ 1; Decl. Schettino ¶ 1. Petitioner also proffers a Declaration of Prof. Ian Hutchings (Ex. 1010, "Decl. Hutchings"), co-author of the Hutchings reference, and a Declaration of Mr. Guy R. Lowery (Ex. 1018, "Decl. Lowery"), a named inventor of the Lowery application. *See* Decl. Hutchings ¶ 7; Decl. Lowery ¶ 13.

II. ANALYSIS

A. 35 U.S.C. § 325(d)

Patent Owner requests that we exercise our discretion under 35 U.S.C. § 325(d) to deny the Petition because it relies upon prior art and arguments

[1] Goldstone et al., U.S. Patent No. 5,024,228 (issued June 18, 1991) (Ex. 1003).
[2] Cook et al., U.S. Patent No. 4,890,623 (issued Jan. 2, 1990) (Ex. 1004).
[3] K.K. B. Hon, L. Li, and I.M. Hutchings, *Direct Writing Technology — Advances and Developments*, 57 CIRP ANNUALS – MANUFACTURING TECHNOLOGY 601–620 (2008) (Ex. 1005) .
[4] Lowery et al., U.S. Patent App. Pub. No. 2009/0227885 A1 (published Sept. 10, 2009) (Ex. 1002).

that are the same or substantially the same as considered during the prosecution of the '894 patent. Prelim. Resp. 26–42. According to Patent Owner, the examiner considered Goldstone, Lowery, and Cook during prosecution. *Id*. at 30–34. Patent Owner states that Hutchings was not before the examiner, but that the technology disclosed by Hutchings was considered by the examiner because Hutchings is merely cumulative of Lowery. *Id*. at 34–35. Patent Owner also argues that Petitioner's proffered declarations do not properly add new material or argument. *Id*. at 35–42.

Petitioner acknowledges that Goldstone, Cook, and Lowery were considered by the examiner during prosecution of the '894 patent, but argues that the examiner did not consider these reference in the manner set forth in the Petition or in the combination set forth in the Petition. Pet. 6–7.

Section 325(d) of Title 35 U.S.C.[5] states: "In determining whether to institute or order a proceeding . . . , the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office."

During prosecution, the examiner relied upon Lowery to teach the claimed element that the electrical traces can be applied directly to the tube's surface without an underlayer (*see* Ex. 2005, 303), and Patent Owner responded by arguing that neither Lowery nor the other references taught such an element (*id*. at 319–23). In this proceeding, Petitioner proffers Hutchings, in both proposed grounds, as teaching this element. *E.g.*,

[5] Although this provision appears in Chapter 32 of the Patent Act, which is directed to post-grant reviews, by its terms it is applicable also to proceedings under Chapter 31, which covers *inter partes* review proceedings.

Pet. 22–23. Hutchings was not considered by the examiner during prosecution.

We, thus, are not persuaded by Patent Owner that the same or substantially the same prior art or argument were previously presented to the Office and decline to exercise our discretion under 35 U.S.C. § 325(d) to deny the Petition.

B. Claim Construction

A determination of obviousness over prior art begins with claim construction. *See In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998). We interpret claims using the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech. Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). However, a "claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history." *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). Any special definition for a claim term must be set forth in the specification with "reasonable clarity, deliberateness, and precision." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

i. "tissue, nerves and muscle in the trachea"

Petitioner contends that "tissue, nerves and muscle in the trachea" should be construed as encompassing the tissue, nerves, and muscle in the larynx, including the vocal cords. Pet. 8–9. Petitioner, however, admits that

considering the larynx and vocal cords as part of the trachea is "wrong as a matter of human anatomy," because the trachea is below the larynx and vocal cords. *Id*. at 9 (citing Decl. Schettino ¶¶ 22–23). Nonetheless, Petitioner argues that we should give "tissues, nerves and muscle in the trachea" a construction contrary to human anatomy because Patent Owner allegedly considered the vocal cords as part of the trachea during prosecution. *Id.* at 9.

Patent Owner disputes that the Specification and prosecution history define "tissue, nerves and muscle in the trachea" as encompassing the vocal cords. Prelim. Resp. 24–28. Patent Owner argues that the Petitioner is taking portions of the Specification and portions of the prosecution history out-of-context and that neither of the cited portions shows that Patent Owner clearly set forth a lexicographic definition of "tissue, nerves and muscle in the trachea," let alone, a definition that is contrary to human anatomy. *Id.*

Petitioner cites to column 4, lines 19–23 of the Specification of the '894 patent to support its position that Patent Owner defined "tissues, nerves and muscle in the trachea" as including vocal cords. Column 4, lines 19–23 states:

> A second embodiment of the laryngeal electromyography tube 40 shown in FIGS. 4 and 5 has the electrodes placed on the concave (inner surface of the curve) for picking up signal generated from *the vocal cord located on the front surface of the trachea.*

Emphasis added. Petitioner also cites to the following statement made in a Response to Office Action, filed on October 25, 2013:

> Based on the teachings of the various embodiments, one skilled in the art can appropriately vary the electrode positioning so as to provide electrode placements in contact with the vocal cord from the posterior or anterior side as well as in contact with the

> *trachea wall proximal of the vocal cords, such as closer to the tongue*, for example the epiglot[ti]s as shown in prior art disclosures, or in contact with the tongue. The claims now cover such placements as are supported in the specification.

Ex. 1014, 7; Ex. 2005, 319 (emphasis added).

Upon review of these portions of the Specification and prosecution history, we agree with Patent Owner that the portions do not define the trachea as including the vocal cords, but the portions merely orient the curve of the tube in the embodiment of Figures 4 and 5 and orient the position of the electrode on the trachea wall with reference to the vocal cords. *See* Prelim. Resp. 27. We, thus, are not persuaded by Petitioner that the Specification and prosecution history define, with reasonable clarity, deliberateness, and precision, "tissue, nerves and muscle in the trachea" as encompassing the vocal cords. On this record, we decline to give "tissue, nerves and muscle in the trachea" a meaning other than its ordinary and customary meaning, let alone one that is contrary to human anatomy (*see* Decl. Schettino ¶ 23).

ii. Other Terms

Petitioner proposes constructions for various other claim terms. Pet. 10. Based upon our review of the record before us, however, no explicit construction of any other claim term is needed at this time.

C. Grounds Under 35 U.S.C. § 103

> Section 103(a) forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, and (3) the level of skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); *see KSR*, 550 U.S. at 407 ("While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.").

i. Overview of Prior Art

a. Goldstone

Goldstone is a U.S. patent, which issued on June 18, 1991, and is titled "Electrode Endotracheal Tube." Ex. 1003, 1. Goldstone discloses an endotracheal tube having electrodes for detecting electromyographic signals of the laryngeal muscles. *Id.* at Abstract. Figure 1 of Goldstone is reproduced below.

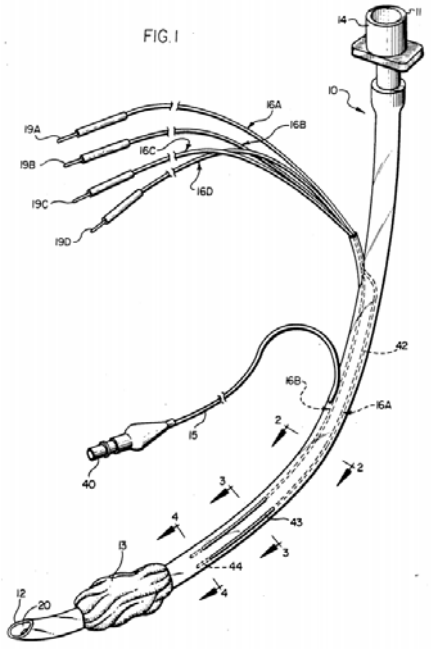

Figure 1 depicts Goldstone's electrode endotracheal tube.

The electrode endotracheal tube comprises flexible, non-electrically conducting tube 10 having fitting 14 on proximal end 11 and inflatable cuff 13 near distal end 12. *Id*. at col. 4, l. 64–col. 5, l. 13. Four electrode wires 16A, 16B, 16C, and 16D run between proximal end 11 and distal end 12. *Id*. at col. 5, ll. 14–18. Each electrode has first portion 42 that is insulated against electrical contact; second portion 43 that is on outer surface 23 of the tube, is uninsulated, and is capable of forming electrical contact; and optional third portion 43 that is embedded into the tube. *Id*. at col. 5, ll. 22–36. Electrical connecting plugs 19A, 19B, 19C, and 19D connect wires 16A–D to an external processing machine and may be "ports, alligator clips or insulated wires with bared ends." *Id*. at col. 5, ll. 58–63.

Goldstone discloses that the insulated wires could be "any type of electrically conducting lead suitable for use as an electrode, including metal paint, metallic tape or metal strips." *Id*. at col. 5, ll. 18–21.

In use, exposed second portion 43 is "positioned on the tube so that the uninsulated portion contacts a set of laryngeal muscles, particularly a vocal cord of that set, when the endotracheal tube is properly positioned." *Id*. at col. 3, ll. 40–44; col. 65, l. 65–col. 6, l. 9; Fig. 6.

b. Lowery

Lowery is a U.S. patent application publication, which published on September 10, 2009, and is titled "Apparatus and Methods for the Measurement of Cardiac Output." Ex. 1002, 1. Lowery discloses an endotracheal tube with an array of electrodes on an inflatable cuff that is used to measure cardiac output. *Id*. at Abstract.

Figure 1 is reproduced below.

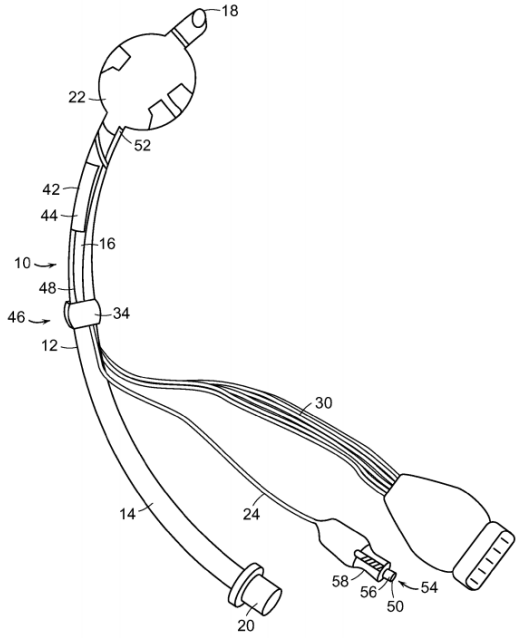

FIG. 1

Figure 1 depicts Lowery's endotracheal tube.

Endotracheal tube 12 has proximal portion 14 having coupler member 20 and distal portion 16 having inflatable cuff 22. *Id*. ¶ 26. Inflatable cuff 22 includes electrode patches 26, which contact the wall of the trachea in use and are connected to electrode runners 28. *Id*. ¶¶ 27, 31; Fig. 2. Tube 12 also has current electrode 42, which contacts the trachea and is connected to electrode runner 48. *Id*. ¶ 34. Electrode runners 28, 48 are connected to external wires 30 by traced conductive circuit material 70. *Id*. ¶¶ 27, 28; Figs. 3A, 3B.

Electrodes 26, 42 and electrode runners 28, 48 are printed onto the cuff and tube "using a novel printing methodology that uses a positive displacement dispensing system." *Id*. ¶ 39. The methodology includes printing a polymeric underlayer on the cuff and tube, printing the conductive material on the underlayer, and printing a polymeric overlayer on top of the

conductive material, except for over a portion of the electrodes. *Id*. ¶¶ 15, 40, 44, 48, 49. Lowery states: "Generally, the width of the line formed by the conductive material will be less than that of the polymeric underlayer, such that no conductive material directly contacts either the distal portion of the tube 16 or the inflatable cuff 22." *Id*. ¶ 48.

c. Cook

Cook is a U.S. patent, which issued on January 2, 1990, and is titled "Biopotential Sensing Device and Method for Making." Ex. 1004, 1. Cook discloses a biopotential sensing device, which in one embodiment is catheter 10. *Id.* at col. 3, ll. 55–58. Figure 1 is reproduced below.

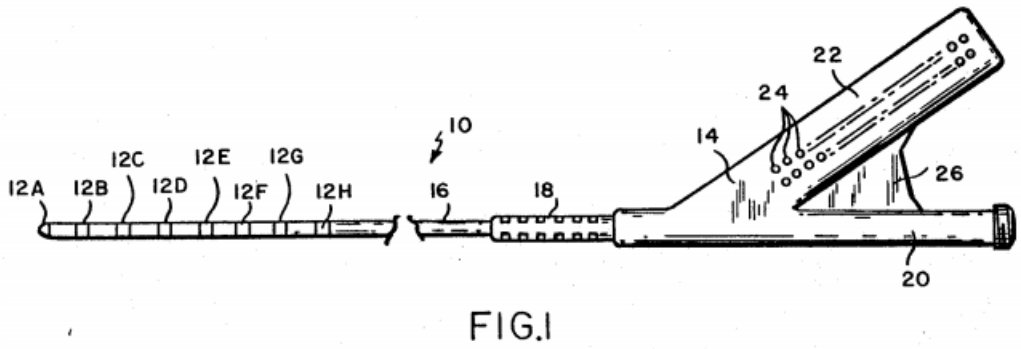

FIG.1

Figure 1 depicts a preferred catheter embodiment of Cook.

Catheter 10 includes flexible member 16 having tubing and circuitry at a distal end and fitting 14 having connector pins 24 at a proximal end. *Id*. at col. 3, 1. 55–col. 4, l. 3. Flexible member 16 is formed by tube 28 and substrate film 30 helically wrapped around tube 28. *Id*. at col. 4, ll. 4–15. A circuit pattern is printed on substrate film 30, utilizing known techniques, such as laminating a thin film copper foil onto the plastic film. *Id*. at col. 4, ll. 13–24.

Figure 3 depicts the printed circuit and is reproduced below.

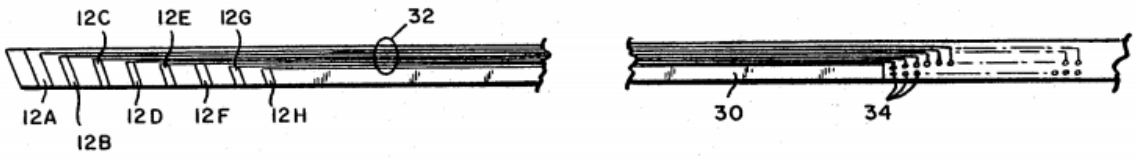

FIG. 3

Figure 3 depicts a top view of a circuit printed on a substrate.

The circuit includes printed electrode pads 12A–12H, printed circuit wires 32 connected to each electrode pad, and terminal pad 34 connected to each wire. *Id*. at col. 4, ll. 25–29.

d. Hutchings

Hutchings is an article titled "Direct Writing Technology — Advances and Development" and published on October 28, 2008. Ex. 1005, 601. Hutchings discloses that direct writing is "a group of processes which are used to precisely deposit functional and/or structural materials on to a substrate in digitally defined locations." *Id*. The substrate is an integral part of the final product and may be curvilinear, round, or flexible. *Id*. Hutchings discloses that metallic particles suspended in a suitable fugitive liquid can be printed by inkjet processes, and are used for electrical applications. *Id*. at 613.

ii. Claims 1–3, 5, 12, and 13

Independent claim 1 recites a "device for use in monitoring electrical signals during laryngeal electromyography." In particular, claim 1 requires that the device has a second electrode positioned to contact tissue, nerves, and muscle in the trachea or the tongue when the tube is positioned in the trachea.

Petitioner argues that independent claim 1 is unpatentable as being obvious over Goldstone, Cook, and Hutchings (Pet. 11–24) and is

unpatentable as being obvious over Lowery, Goldstone, and Hutchings (*id*. at 36–49). For both grounds, Petitioner relies upon Goldstone to teach the claim requirement that a second electrode positioned to contact tissue, nerves and muscle in the trachea when the tube is positioned in the trachea. *Id*. at 17–18, 44. Petitioner argues that if "tissue, nerves and muscle in the trachea" is construed to include the vocal cords, Goldstone teaches this requirement because Goldstone discloses a second electrode contacting the vocal cords in the same way as the first electrode contacts the vocal cords. *Id*.

As discussed in our claim construction section above, we do not construe "tissue, nerves and muscle of the trachea" as encompassing the vocal cords, and, thus, Petitioner's argument fails from the outset. Petitioner does not contend that Goldstone discloses a second electrode contacting a portion of the trachea or tongue, but only that the second electrode contacts the vocal cord. *See* Pet. 17–18, 44. Indeed, Goldstone discloses that its electrodes are positioned on the tube so that the uninsulated portions contact a set of laryngeal muscle, particularly a vocal cord of that set. Ex. 1003, col. 3, ll. 40–44; col. 5, l. 65–col. 6, l. 9; Fig. 6. Goldstone additionally discloses that "[t]he uninsulated portion must not, however, be so long that it contacts parts of the patient's anatomy other than the laryngeal muscles." *Id*. at col. 2, ll. 46–49. Petitioner fails to demonstrate that Goldstone teaches the claim requirement that a second electrode is positioned to contact "tissue, nerves and muscle in the trachea" or the tongue and does not rely upon Cook, Lowery, or Hutchings to cure this deficiency. *See* Pet. 17–18, 44.

Claim 5 depends from claim 4 and recites a similar limitation. Claim 12 depends from claim 10 and recites a similar limitation. Claims 2 and 3 depend from claim 1, and claim 13 depends from claim 12.

We determine that Petitioner has failed to demonstrated that there is a reasonable likelihood that claims 1–3, 5, 12, and 13 are unpatentable under 35 U.S.C. § 103(a) over Goldstone, Cook, and Hutchings or are unpatentable under 35 U.S.C. § 103(a) over Lowery, Goldstone, and Hutchings.

iii. Claim 4

Independent claim 4 recites a method of forming an electrode bearing endotracheal tube, having a retaining balloon on a distal end and electrodes, traces, and connection points on an exterior surface. In particular, claim 4 requires that "electrodes, traces, and connection points formed by applying a conductive ink or paint to the exterior surface of the endotracheal tube" and requires that an insulating barrier is formed over the traces.

a. Unpatentability over Goldstone, Cook, and Hutchings

Petitioner contends that claim 4 is unpatentable over Goldstone, Cook, and Hutchings. Pet. 25–26. According to Petitioner, Goldstone discloses an embodiment of endotracheal tube 10 that has retention balloon 13, surface electrodes 43, electrically conductive traces 42, and connection points "where external wires meet the traces." *See* Pet. 12–14; Ex. 1003, Fig. 1. Petitioner argues that Goldstone discloses that the traces are insulated. Pet. 20–21 (citing Ex. 1003, col. 5, ll. 22–25).

Goldstone discloses that electrodes 43 and traces 42 are formed from wires (16A–16D). Ex. 1003, col. 5, ll. 14–18. Goldstone, however, states that "[t]he term 'wires' includes any type of electrically conducting lead suitable for use as an electrode, *including metal paint, metallic tape or metal*

strips." *Id*. at col. 5, ll. 18–21 (emphasis added). Petitioner argues that this teaches an embodiment where the electrodes, traces and connection points are applied to the surface of the tube with metal paint. *See* Pet. 12–13.

Petitioner additionally relies upon Cook to teach connection points that are formed by metallic paint and that are connected to painted traces. Pet. 13–14 (citing Ex. 1004, Fig. 3; col. 4, ll. 25–32). Cook discloses a circuit pattern that includes electro pads (12A–12H) connected to terminal pads 34 by circuit wire 32. Ex. 1004, Fig. 3, col. 4, ll. 25–32. Petitioner argues that "[i]t would have been obvious to use Cook's connection points on Goldstone's tube when using printed/painted electrodes and traces, especially since the sensing circuits in Goldstone and Cook include overlapping features and perform the same function . . . and thus, are interchangeable." Pet. 15. Petitioner further argues that printing or painting the electrodes, traces, and connection points of Goldstone on the tube, as suggested by Cook, would result in a method of making a tube that is less expensive, that is optimal for each application, and that allows for the use of more electrodes. Pet. 21 (citing Ex. 1004, col. 6, ll. 17–27, 52–56, 59–65).

Given the above and taking into account Patent Owner's arguments, discussed below, we determine that Petitioner has demonstrated that there is a reasonable likelihood that claim 4 is unpatentable under 35 U.S.C. § 103(a) over Goldstone, Cook, and Hutchings.

Patent Owner first argues that a person of ordinary skill in the art would not have been motivated to combine Goldstone, Cook, and Hutchings, because Hutchings is incompatible with Goldstone and Cook and because Hutchings teaches away. Prelim. Resp. 43–46. According to Patent Owner, Hutchings teaches that there are problems using conductive ink, including difficulty in creating conductive stable deposits of ink, problems with the

ink's adhesion to a surface, and problems with edge acuity, and therefore, teaches away from using direct writing to print the electrodes, traces, and connection points directly onto the tube, without a substrate. *Id*. at 43 (citing Ex. 1005, 617). We are not persuaded by this argument because it is not commensurate with the scope of claim 4. Unlike independent claims 10 and 14, claim 4 does not require that the metallic paint, used to form the electrodes, traces, and connection points, be applied *directly* to the tube or applied *without a substrate*. Claim 4 more broadly requires that the electrodes, traces, and connection points are formed "by applying a conductive ink or paint to the exterior surface of the endotracheal tube." Claim 4 is silent as to how the ink or paint is applied and does not preclude applying the ink or paint to the surface of the tube via a substrate.

Patent Owner next argues that the combination of Goldstone, Cook, and Hutchings fails to teach direct application of conductive ink to the tube for the electrodes, traces, and connection points (Prelim. Resp. 47; *see id.* at 10–12, 10–16) and a connection point connected to or integral with each of the conductive traces, applied directly to the tube (*id*. at 48; *see id*. at 11, 15–16). We are not persuaded by these arguments because they are not commensurate with the scope of claim 4. As discussed above, claim 4 does not require *direct* application of the conductive ink or paint to the tube to form the electrodes, traces, and connection points, or require application of the electrodes without the use of a substrate. Claim 4 also does not require that the electrodes be positioned to contact tissues, nerves, and muscle in the trachea or tongue.

Patent Owner also argues that Goldstone and Cook fail to teach integrated conductive ink pads for connection to external monitoring equipment. *Id.* at 11, 15–16. We are not persuaded by this argument

because claim 4 does not require pads for connection, but "connection points at a proximal end of the first and second traces." Ex. 1001, col. 7, ll. 51–53. In this regard, Goldstone states "[a]ny means capable of forming electrical contact such as ports, alligator clips or *insulated wires with bared ends could be used with the present invention* instead of the depicted plugs." Ex. 1003, col. 5, ll. 60–63 (emphasis added). On this record, we agree with Petitioner that when the wires are formed of metallic paint, the connection points (i.e., the bare ends of the traces) meet this limitation. *See* Pet. 13.

Patent Owner finally argues that Goldstone and Cook fail to teach insulating a trace that is applied directly to the surface of the tube, because Goldstone and Cook teach insulating by embedding wires in the tube or by using a substrate. Prelim. Resp. 47 (citing Ex. 1003, Fig. 2, col. 3, ll. 18–20; col. 5, ll. 14–28). We are not persuaded by this argument because Goldstone's and Cook's teachings of insulating the traces are not limited only to those particular embodiments. Goldstone discloses that the wires could alternatively be metallic paint (Ex. 1004, col. 5, ll. 18–21), and traces formed of metallic paint would also need to be insulated to avoid contact with a patient's anatomy (*see id*. at col. 3, ll. 40–58). Cook discloses that it is known to insulate the traces to avoid unwanted contact with the body of the patients. Ex. 1004, col. 4, l. 67–col. 5, l. 7; *see id.* at col. 1, ll. 41–42. Cook states that "if additional protective coating is desired, a dielectric coating . . . can be provided over the helically-wrapped substrate to further insulate and protect the substrate and wiring." *Id*. at col. 5, ll. 8–12.

b. Unpatentability over Lowery, Goldstone, and Hutchings

Petitioner contends that claim 4 is unpatentable over Lowery, Goldstone, and Hutchings. Pet. 51–53. According to Petitioner, Lowery discloses an embodiment of endotracheal tube 12 that has retention balloon

22, surface electrodes 44, electrically conductive traces 48, and connection points 34 formed of conductive ink. *See id.* at 36; Ex. 1002, Fig. 1. In particular, Petitioner argues that Lowery discloses an endotracheal tube having a sensing circuit that includes electrodes, traces, and connection points that are formed using conductive ink. Pet. 36 (citing Ex. 1002, Figs. 1–3A), 45.

Petitioner states that it "recognizes that Lowery is directed to cardiac monitoring as opposed to laryngeal EMG monitoring" and relies upon Goldstone to teach electrodes positioned on the tube for laryngeal EMG monitoring. Pet. 38–39. Petitioner argues that it would have been obvious to one having ordinary skill in the art to incorporate Goldstone's electrodes on the tube of Lowery because this would allow for monitoring of more types of signals during surgery and reduce the risk of improper tube placement. *Id.* at 39.

Given the above and taking into account Patent Owner's arguments, discussed below, we determine that Petitioner has demonstrated that there is a reasonable likelihood that claim 4 is unpatentable under 35 U.S.C. § 103(a) over Lowery, Goldstone, and Hutchings.

Patent Owner first argues that a person of ordinary skill in the art would not have been motivated to combine Lowery, Goldstone, and Hutchings, because Hutchings is incompatible with Lowery and because Hutchings teaches away. Prelim. Resp. 49–50. According to Patent Owner, Hutchings teaches that there are problems using conductive ink, including difficulty in creating conductive stable deposits of ink, problems with the ink's adhesion to a surface, and problems with edge acuity, and, therefore, teaches away from using direct writing to print the electrodes, traces, and connection points directly onto the tube, without a substrate. *Id*. at 49 (citing

Ex. 1005, 617). We again are not persuaded by this argument because it is not commensurate with the scope of claim 4. Unlike independent claims 10 and 14, claim 4 does not require the metallic paint, used to form the electrodes, traces, and connection points, be applied *directly* to the tube or applied *without a substrate*. Claim 4 more broadly requires that the electrodes, traces, and connection points are formed "by applying a conductive ink or paint to the exterior surface of the endotracheal tube." Claim 4 is silent as to how the ink or paint is applied and does not preclude applying the ink or paint to the surface of the tube via a substrate.

Patent Owner also argues that the teachings of Lowery are incompatible with Goldstone and, thus, teaches away because Lowery is directed to non-repeatably formed substrates and Goldstone's tubes are repeatably-formed substrates. Prelim. Resp. 50. Patent Owner states: "NuVasive has not shown that it would be possible to apply the electrodes in the manner taught in Lowery to an ET tube taught in Goldstone." *Id*. We are not persuaded by this argument because it is not directed to the combination proposed by the Petitioner. As discussed above, Petitioner proposes adding the electrodes as placed in Goldstone onto the tube of Lowery. *See* Pet. 38–39. Although Lowery discloses electrode patches 24 placed on inflatable cuff 22, electrode patch 44 is placed on the tube. Ex. 1002, Figs. 1–2. Further, differences among prior art references alone do not demand or even necessarily support an argument that references "teach away" from each other. "The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed . . . ." *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

Patent Owner next argues that Lowery does not teach direct application of conductive ink to the tube for the electrodes, traces, and connection points. Prelim. Resp. 52. We again are not persuaded by this argument because it is not commensurate with the scope of claim 4. Unlike independent claims 10 and 14, claim 4 does not require that the metallic paint used to form the electrodes, traces, and connection points be applied *directly* to the tube or applied *without a substrate*. Claim 4 more broadly requires that the electrodes, traces, and connection points are formed "by applying a conductive ink or paint to the exterior surface of the endotracheal tube." Claim 4 is silent as to how the ink or paint is applied and does not preclude applying the ink or paint to the surface of the tube via a substrate.

Patent Owner finally argues that Lowery does not teach a connection point connected to or integral with each of the conduct traces and applied directly to the tube surface. We again are not persuaded by this argument. Claim 4 requires "connection points at a proximal end of the first and second traces." Ex. 1001, col. 7, ll. 51–53. Lowery discloses that in certain embodiments the ends of external wires 30 are connected to traced conductive circuit material 70 on flexible support material 72. The electrode runners 28 are printed on the tube, and flexible support material 72 is "applied over the termini of the electrode runners," such that external wires 30 are operably connected to the electrode runner. Ex. 1002 ¶ 28. Further, Goldstone states "[a]ny means capable of forming electrical contact such as ports, alligator clips or *insulated wires with bared ends could be used with the present invention* instead of the depicted plugs." Ex. 1003, col. 5, ll. 60–63 (emphasis added). On this record, we agree with Petitioner that the Lowery and Goldstone meet this limitation. *See* Pet. 13.

iv. Dependent Claims 6–9

Claims 6–9 depend from claim 4 and further define the composition of the conductive ink or paint. *See* Ex. 1001, col. 8, ll. 1–11. For both grounds, Petitioner relies upon Hutchings to teach the specific composition of the conductive ink or paint. Pet. 28, 53–54. Upon this record, we determine that Petitioner has demonstrated that there is a reasonable likelihood that claims 6–9 are unpatentable over Goldstone, Cook, and Hutchings and unpatentable over Lowery, Goldstone, and Hutchings. Patent Owner makes no additional arguments in the Preliminary Response directed to the limitations of claims 6–9.

v. Independent Claims 10 and 14

Independent claim 10 recites a method of monitoring electrical signals during laryngeal electromyography, which requires forming a tube having: 1) electrically conductive electrodes applied "directly to the surface of the tube, without inclusion of a carrier film between the tube surface and the electrodes"; 2) electrically conductive traces "applied directly to the tube surface"; and 3) connection points "connected to or integral with the conductive traces applied directly to the tube surface."
Ex. 1001, col. 8, ll. 12–35. Independent claim 14 recites a device for monitoring electrical signals during laryngeal electromyography and requires similar limitations.

a. Unpatentability over Goldstone, Cook, and Hutchings

Petitioner contends that claims 10 and 14 are unpatentable over Goldstone, Cook, and Hutchings. Pet. 11–24, 29–30, 32–33. Similar to Petitioner's assertions for claim 4 discussed above, Petitioner here argues that Goldstone and Cook teach the claimed tube, having electrically conductive electrodes, traces, and connection points form of metallic paint

or ink. *See id.* Petitioner also relies upon Hutchings to teach directly applying the electrodes, traces, and connection points to the tube, without inclusion of a carrier film between the tube surface and the electrodes. Pet. 22–24. Petitioner argues that "one of ordinary skill in the art . . . would have understood that the difference between printing a circuit on a flat substrate and printing the circuit on Goldstone's endotracheal tube was inconsequential given techniques for printing conductive features on tubes, as described in Hutchings." Pet. 22 (citing Decl. Goldstone ¶ 59; Decl. Lowery ¶ 85; Decl. Hutchings ¶ 25). Petitioner further argues that using the direct writing techniques described in Hutchings to apply the electrodes, traces, and connection points directly to the surface of the tube would have various benefits, such as cost reduction for prototyping and production. Pet. 23 (citing Ex. 1005, 617).

Given the above and taking into account Patent Owner's arguments, discussed below, we determine that Petitioner has demonstrated that there is a reasonable likelihood that claims 10 and 14 are unpatentable under 35 U.S.C. § 103(a) over Goldstone, Cook, and Hutchings.

Patent Owner argues that a person of ordinary skill in the art would not have been motivated to combine Goldstone, Cook, and Hutchings because Hutchings is incompatible with Goldstone and Cook and because Hutchings teaches away. Prelim. Resp. 43–46. According to Patent Owner, Hutchings teaches that there are problems using conductive ink, including difficulty in creating conductive stable deposits of ink, problems with the ink's adhesion to a surface, and problems with edge acuity, and therefore, teaches away from using direct writing to print the electrodes, traces, and connection points directly onto the tube, without a substrate. *Id*. at 43 (citing Ex. 1005, 617). We are not persuaded by this argument because, although

Hutchings discloses that there are some challenges with direct writing technology (Ex. 1005, 617), Hutchings also discloses benefits of direct writing technology (*id*.). *See Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) ("a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine."); *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000) ("The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another.").

Patent Owner also argues that Cook and Hutchings are incompatible because Cook teaches the use of a substrate to apply the printed circuit to the substrate and Hutchings teaches directly writing on the finished product, and thus Cook and Hutchings teaches away from the proposed combination. Prelim. Resp. 45–46. The mere fact that Cook and Hutchings have differences alone does not demand or even necessarily support an argument that references "teach away" from each other.

Also as with claim 4, Patent Owner argues that Goldstone and Cook fail to teach insulating the conductive traces and connection points connected to or integral with the conductive traces. We find these arguments unpersuasive because, on this record, we determine that Goldstone and Cook teach these limitations, as discussed above with regard to claim 4.

b. Unpatentability over Lowery, Goldstone, and Hutchings

Petitioner contends that claims 10 and 14 are unpatentable over Lowery, Goldstone, and Hutchings. Pet. 36–49, 54–55, 56–57. Similar to

Petitioner's assertions for claim 4 discussed above, Petitioner here argues that Lowery and Goldstone teach the tube of claims 10 and 14, which has electrically conductive electrodes, traces, and connection points formed of metallic paint or ink. *See id.* Petitioner also relies upon Hutchings to teach directly applying the electrodes, traces, and connection points to the tube, without inclusion of a carrier film between the tube surface and the electrodes. *Id.* at 48–49. Petitioner argues that "[i]t would have been obvious for one of ordinary skill in the art to use the techniques described by Hutchings to form conductive features like Lowery's . . . directly onto curved surfaces like Lowery's endotracheal tube." *Id*. at 48 (citing Decl. Lowery ¶ 82, Decl. Hutchings ¶ 23). Petitioner further argues that using the direct writing techniques described in Hutchings to apply the electrodes, traces, and connection points directly to the surface of the tube would have various benefits, such as cost reduction for prototyping and production. Pet. 49 (citing Ex. 1005, 617).

Given the above and taking into account Patent Owner's arguments, discussed below, we determine that Petitioner has demonstrated that there is a reasonable likelihood that claims 10 and 14 are unpatentable under 35 U.S.C. § 103(a) over Lowery, Goldstone, and Hutchings.

Patent Owner first argues that a person of ordinary skill in the art would not have been motivated to combine Lowery, Goldstone, and Hutchings, because Hutchings is incompatible with Lowery and because Hutchings teaches away. Prelim. Resp. 49–50. According to Patent Owner, Hutchings teaches that there are problems using conductive ink, including difficulty in creating conductive stable deposits of ink, problems with the ink's adhesion to a surface, and problems with edge acuity, and therefore, teaches away from using direct writing to print the electrodes, traces, and

connection points directly onto the tube, without a substrate. *Id*. at 49 (citing Ex. 1005, 617). We again are not persuaded by this argument because, although Hutchings discloses that there are some challenges with direct writing technology (Ex. 1005, 617), Hutchings also discloses benefits of direct writing technology (*id.*). Patent Owner also argues that Lowery and Hutchings are incompatible because Lowery teaches the use of an underlayer to apply the printed circuit to the tube and Hutchings teaches directly writing on the finished product, and thus Cook and Hutchings teaches away from the proposed combination. Prelim. Resp. 50. The mere fact that Lowery and Hutchings have differences alone does not demand or even necessarily support an argument that references "teach away" from each other.

As with claim 4, Patent Owner also argues that Lowery is incompatible with Goldstone and thus teaches way, and that Lowery does not teach a connection point connected to or integral with each of the conduct traces and applied directly to the tube surface. *Id*. at 50–54. We find these arguments unpersuasive for the same reasons as discussed above with regards to claim 4.

vi. Dependent Claims 11 and 15–19

Claim 11 depends from claim 10 and additionally requires that the period of monitoring is in excess of 24 hours. Claims 15 and 16 depend from claim 14 and additionally require that the electrodes and traces comprise a dried conductive ink or paint, which is free of a liquid carrier. Claims 17–19 depend from claim 14 and additionally define the placement of the electrodes.

Petitioner argues that the combination of Goldstone, Cook, and Hutchings, and that of Lowery, Goldstone, and Hutchings, teach these

limitations. Pet. 31, 33–36, 55, 57–59. Upon this record, we determine that Petitioner has demonstrated that there is a reasonable likelihood that claims 11 and 15–19 are unpatentable over Goldstone, Cook, and Hutchings and are unpatentable over Lowery, Goldstone, and Hutchings. Patent Owner makes no additional arguments in the Preliminary Response directed to the limitations of claims 11 and 15–19.

vii. Patent Owner's Additional Argument Regarding Alleged Objective Indicia of Non-Obviousness

Factual inquiries for an obviousness determination include secondary considerations based on evaluation and crediting of objective evidence of nonobviousness. *Graham*, 383 U.S. at 17–18. To be relevant, evidence of nonobviousness must be commensurate in scope with the claimed invention. *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011). Further, to be accorded substantial weight, there must be a nexus between the merits of the claimed invention and the evidence of secondary considerations. *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). "[N]exus" is a legally and factually sufficient connection between the objective evidence and the claimed invention, such that the objective evidence should be considered in determining nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988).

At this stage of the proceeding, we are not persuaded by Patent Owner's secondary consideration arguments (Prelim. Resp. 54–59), because Patent Owner fails to establish a nexus between any evidence and the merits of the claimed invention. Further, Patent Owner provides insufficient evidence to support its argument, and many of Patent Owner's assertions are mere attorney argument. *See In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) (Attorney arguments and conclusory statements that are unsupported

by factual evidence are entitled to little probative value.). Broad contentions regarding secondary considerations do not demonstrate nonobviousness.

III. CONCLUSION

On this record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on the grounds of claims 4, 6–11, and 14–19 being unpatentable under 35 U.S.C. § 103 over Goldstone, Cook, and Hutchings, and claims 4, 6–11, and 14–19 being unpatentable under 35 U.S.C. § 103 over Goldstone, Lowery, and Hutchings.

We determine that Petitioner has not demonstrated a reasonable likelihood of prevailing on the grounds of claims 1–3, 5, 12, and 13 being unpatentable under 35 U.S.C. § 103 over Goldstone, Cook, and Hutchings, and claims 1–3, 5, 12, and 13 being unpatentable under 35 U.S.C. § 103 over Goldstone, Lowery, and Hutchings.

The Board has not yet made a final determination as to the patentability the challenged claims.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the ’894 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; and

FURTHER ORDERED that the trial is limited to the grounds of claims 4, 6–11, and 14–19 being unpatentable under 35 U.S.C. § 103 over Goldstone, Cook, and Hutchings, and claims 4, 6–11, and 14–19 being unpatentable under 35 U.S.C. § 103 over Goldstone, Lowery, and Hutchings.

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