IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Petitioner:	NuVasive, Inc.
Patent Owner:	Neurovision Medical Products, Inc.
Patent No.:	8,634,894
Issue Date:	January 21, 2014
Application No.:	13/909,966
Filing Date:	June 4, 2013
In re Patent of:	Rea et al.
Title:	ELECTRODE FOR PROLONGED MONITORING OF LARYNGEAL ELECTROMYOGRAPHY
Attorney Dkt. No.:	NUVA-IPR-00016403

Mail Stop Patent Board
Patent Trial and Appeal Board
United States Patent & Trademark Office
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PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,634,894 PURSUANT TO 35 U.S.C. §§311-319 AND 37 CFR §42

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NuVasive, Inc. (“Petitioner”) petitions for *Inter Partes* Review (“IPR”) and challenges the patentability of claims 1-19 of U.S. Patent 8,634,894 (the “’894 patent”; Ex. 1001). Petitioner requests that the Patent Trial and Appeal Board (“Board”) of the U.S. Patent and Trademark Office (“Office”) grant this Petition since there is a reasonable likelihood that at least one of claims 1-19 is unpatentable.

I. The ’894 Patent Claims Technology That Has Been in Existence Since the Late 1980s

The ’894 patent describes and claims an endotracheal tube with a well-known circuit for sensing electromyographic (“EMG”) signals from the recurrent laryngeal nerve (“RLN”) during surgery. The well-known circuit described in the claims includes electrodes for sensing the signals, and traces for delivering those signals to external wires of monitoring equipment. The ’894 patent acknowledges that endotracheal tubes with electrodes for EMG monitoring were commonplace in the art before the earliest effective filing date:

> Endotracheal tubes may have electrodes on the surface thereof for performing laryngeal electromyography and monitoring the recurrent laryngeal nerve during medical procedures. <u>These electrodes on the endotracheal tube, referred to as laryngeal surface electrodes, are currently used</u> in various surgical procedures to provide monitoring of the electromyographic

> signals from the muscles of the vocal cords, or larynx. *'894 patent (Ex. 1001)* col. 1, ln. 16-23 (emphasis added).

This is not surprising. In the late 1980's, Dr. Andrew Goldstone and Dr. Raymond Schettino pioneered endotracheal tubes (the "Goldstone Tube") with electrodes for EMG monitoring of the RLN during their residencies at Johns Hopkins Medical School. *Declaration of Dr. Andrew Goldstone* ("*Dec. Goldstone*"; *Ex. 1011*) at ¶5; *Declaration of Dr. Raymond Schettino* ("*Dec. Schettino, Ex. 1013*) at ¶5.

The Goldstone Tube was a revolutionary development in the area of head and neck surgery. Over the decades since Dr. Goldstone and Dr. Schettino pioneered endotracheal tubes with electrodes for monitoring the RLN, surgeons have widely adopted such tubes to prevent damage to the RLN during surgeries of the neck and throat. *Dec. Goldstone (Ex. 1011)* ¶9; *Dec. Schettino (Ex. 1013)* ¶11. Many neck and throat surgeons consider EMG monitoring of the RLN with tubes like the Goldstone Tube to be indispensable in minimizing risk of nerve damage during surgeries on the throat and neck. Indeed, doctors have purchased hundreds-of-thousands of Goldstone Tubes since its introduction in the early 1990s. *Dec. Goldstone (Ex. 1011)* ¶9. Dr. Goldstone and Dr. Schettino's invention changed the face of modern throat and neck surgery and was disruptive technology.

The Goldstone Tube led to U.S. Pat. 5,024,228, issued in June 1991 ("Goldstone"; Ex. 1003). *Dec. Goldstone (Ex. 1011)* ¶8; *Dec. Schettino (Ex. 1013)*

¶5. Patent Owner of the '894 patent, Neurovision Medical Products, Inc. ("NMP"), encountered Goldstone during the prosecution of claims in the '894 patent relating to printed electrodes. NMP mischaracterized Goldstone in order to distinguish its claims by arguing that Goldstone "does not show or suggest electrodes printed on the surface of the endotracheal tube." *Response to Office Action dated 10/25/13 ("10/25/13 ROA"; Ex. 1014)* p. 8, ln. 1-2. Nothing could be further from the truth. Goldstone does indeed describe exposed electrodes wires on the surface of the endotracheal tube that are formed using "*any type of electrically conducting lead* suitable for use as an electrode, including *metal paint*" that can be printed on the endotracheal tube. *Goldstone (Ex. 1003)* col. 3 ln. 14-24 and col. 5 ln. 18-21 (emphasis added); *Dec. Goldstone (Ex. 1011)* ¶8; *Dec. Schettino (Ex. 1013)* ¶¶ 5, 8. NMP's inaccurate characterization of Goldstone during prosecution is at least one reason to grant this Petition.

II. Mandatory Notices

A. Real Party-In-Interest

NuVasive, Inc., located at 7475 Lusk Boulevard, San Diego, CA 92121, is the real party-in-interest for this Petition.

B. Related Matters

Petitioner is not aware of civil actions, IPRs, or pending prosecution concerning the '894 patent, but identifies the following judicial proceedings that may be affected by a decision in this proceeding: *Neurovision Medical Products, Inc. v. NuVasive, Inc.*, San Diego Superior Court Case No. 37-2014-00009821-CU-BT-CTL. NMP alleges the ’894 patent, in part, comprises its alleged trade secrets.

C. Lead And Back-Up Counsel

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D. Service Information

Service on Petitioner may be made by mail or hand delivery to lead counsel at the address provided in Section II.C of this Petition. Petitioner also consents to and requests electronic service by email at jkyle@klhipbiz.com (referencing Attorney Docket No. NUVA-IPR-00016403).

III. Payment of Fees

Payment of the fees set in 37 CFR §42.15(a) for this Petition is being made via credit card submitted herewith.

IV. Requirements for *Inter Partes* Review

A. Grounds for Standing

Petitioner certifies that the ’894 patent is eligible for IPR and that Petitioner is not barred or estopped from requesting IPR. Neither Petitioner, nor any party in privity with Petitioner, has filed a civil action challenging the validity of any claim of the '894 patent. The '894 patent has not been the subject of a prior *inter partes* review by Petitioner or a privy of Petitioner. There is no civil action against Petitioner or a privy of Petitioner alleging infringement of the '894 patent.

B. Challenge, Relief Requested, and Prior Art

Petitioner challenges claims 1-19 in this Petition on the grounds set forth in the table below. The prior art references include: Lowery et al., U.S. Pub. 2009-0227885, Sep. 10, 2009 ("Lowery"; Ex. 1002); Goldstone et al., U.S. Pat. 5,024,228, Jun. 18, 1991 ("Goldstone"; Ex. 1003); Cook et al., U.S. Pat. 4,890,623 Jun. 2, 1990 ("Cook"; Ex. 1004); and Hutchings et al., "Direct writing technology – Advances and developments", CIRP Annals – Manufacturing Technology, Vol. 57, Issue 2, pp. 601-620, published at the CIRP annual meeting on Aug. 25, 2008 and re-published Oct. 28, 2008 ("Hutchings"; Ex. 1005)[1]. Additional explanation is

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[1] Hutchings describes many technologies for printing conductive ink or paint on tubes. Many other publications describe technologies for printing conductive ink or paint on non-planar surfaces like tubes, including Mei et al., *Continuous ink-jet printing electronic components using novel conductive inks*, Fifteenth Solid Freeform Fabrication (SFF) Symposium, August 2-4, 2004 (Ex. 1006). *Dec. Hutchings (Ex. 1010)* ¶17 (describing printing of conductive traces on a cylinder).

set forth in the declarations of Dr. Andrew Goldstone ("Dec. Goldstone"; Ex. 1011), Dr. Raymond Schettino ("Dec. Schettino, Ex. 1013), Guy Lowery ("Dec. Lowery"; Ex. 1018), and Prof. Ian Hutchings ("Dec. Hutchings"; Ex. 1010). Petitioner requests cancellation of claims 1-19 of the '894 patent under these bases:

CLAIMS	BASIS FOR UNPATENTABILITY[2]
1-3, 4-9, 10-13, 14-19	Obvious (§103): Goldstone; Cook; and Hutchings
1-3, 4-9, 10-13, 14-19	Obvious (§103): Lowery; Goldstone; and Hutchings

Goldstone and Cook are prior art under at least 35 U.S.C. §102(b) (pre-AIA) since they were published more than one year prior to the '894 patent's earliest effective filing date of September 21, 2009. Lowery and Hutchings are prior art under at least 35 U.S.C. §102(a) (pre-AIA) because they were published before the earliest effective filing date. Hutchings does not appear to have been considered by the Office during prosecution of the '894 patent. Although the Office considered Goldstone, Cook and Lowery during prosecution of the '894 patent, the Office did

[2] Petitioner submits that the two grounds—i.e., (1) claims 1-19 are obvious under §103 over Goldstone in view of Cook and in further view of Hutchings; and (2) claims 1-19 are obvious under §103 over Lowery in view of Goldstone and in further view of Hutchings—are not duplicative or redundant by virtue of each ground considering different combinations of prior art, declarants, and motivations.

not consider each reference in the manner set forth in this petition, or in combination with other references that the Office has not yet considered, as detailed below. *Moreover, as discussed above, NMP's mischaracterization of Goldstone during prosecution warrants reconsideration of Goldstone.*

V. Relevant Information Concerning the '894 patent

A. Effective Filing Dates for Claims 1-19 in the '894 patent

The '894 patent issued from U.S. Appl. 13/909,966 (filed June 4, 2013), and is designated as a Division of U.S. Pat. 8,467,844 (filed September 21, 2010) (the "'844 patent"; Ex. 1016), which claims priority to U.S. Appl. 61/244,402 (provisional filed September 21, 2009) (Ex. 1015). Thus, three effective filing dates are possible: June 4, 2013 (not considered); September 21, 2010 (not considered); and September 21, 2009 (the "earliest effective filing date"). Petitioner applies the earliest effective filing date without waiving its right to challenge whether the 61/244,402 provisional application supports each claim.

B. Prosecution History of the '894 patent

During prosecution of the '894 patent, NMP misled the Office by incorrectly arguing that "Goldstone does not show or suggest electrodes printed on the surface of the endotracheal tube." *10/25/13 ROA (Ex. 1014)* p. 8, ln. 1-2. In fact, Goldstone describes surface electrodes (second wire portions) of an endotracheal tube using "any type of electrically conducting lead suitable for use as an electrode, including metal paint." *Goldstone (Ex. 1003)* col. 3 ln. 14-24 and col. 5 ln. 18-21. During prosecution, NMP stated that metal paint and ink were synonymous. *10/25/13 ROA (Ex. 1014)* p. 11, ln. 10-12 (stating that claims 1, 4, 11, and 15 all require printed electrodes "using a conductive ink or paint"). At a minimum, NMP's inaccurate arguments warrant reconsideration of Goldstone since electrodes formed from conductive paint are claimed.

C. Claim Construction

In IPR, the Board gives a claim its "broadest reasonable construction in light of the specification of the patent in which it appears." 37 CFR §42.100(b).[3] Petitioner submits that the Board should give all claim terms their plain meaning. Nevertheless, Petitioner provides four specific constructions to the extent the Board considers these claim constructions to be different from the plain meaning.

1. Tissues, nerves and muscle in the trachea (claims 1, 5, 12)

The '894 patent is unclear regarding what NMP considers to be "tissues, nerves and muscle in the trachea". *Dec. Schettino (Ex. 1013)* ¶21. For example, the '894 patent describes one possible option as a "vocal cord located on the front surface of the trachea," (*'894 patent (Ex. 1001)* col. 4, ln. 19-23) but the vocal

[3] Claim interpretation standards in litigation and Office proceedings differ; thus, claim interpretation in this IPR is not binding on petitioner in litigation.

cords are located in the larynx, not in the trachea, which is below the layrnx. *Dec. Schettino (Ex. 1013)* ¶¶21-22. In a response to an Office Action, NMP describes a "tracheal wall proximal of the vocal cords, such as closer to the tongue" (i.e. above the vocal cords). *10/25/13 ROA (Ex. 1014)* p. 7, ¶3. But again, the trachea is located *below* the larynx (which includes the vocal cords). *Dec. Schettino (Ex. 1013)* ¶22. From these excerpts of the '894 patent and the prosecution history, it seems that NMP believes the larynx, and the vocal cords contained in the larynx, are part of the trachea. *Dec. Schettino (Ex. 1013)* ¶23. NMP is wrong as a matter of human anatomy. The trachea is below the larynx and the vocal cords. *Id.* But if we approach the anatomy the way NMP seems to have considered it (i.e. that the larynx and the vocal cords are part of the trachea), then tissue, nerves and muscle in the "trachea" may be satisfied by tissue, nerves and muscle in the larynx. *Id*. According to the '894 patent, the vocal cords include "muscles and nerves" from NMP's point of view. '*894 patent (Ex. 1001)* col. 2, ln.27-28. *Dec. Schettino (Ex. 1013)* ¶24. Of course, the vocal cords also include tissue. *Id*. It follows that, if we approach anatomy the way NMP seems to have approached anatomy (without admitting or conceding that NMP's view of human anatomy is correct), then vocal cords are tissues, nerves and muscle in the trachea. *Id*.

2. *Electrodes that are substantially flush with the outer surface of an endotracheal tube" (claims 3, 17)*

The '894 patent does not provide a definition of "substantially flush"; however, electrodes and traces are disclosed as having a thickness of 25 microns "so that the diameter of the endotracheal tube is substantially unchanged …" in the vicinity of the electrodes or traces. *'894 patent (Ex. 1001)* col. 5, ln. 57-59. Therefore, Petitioner submits that "substantially flush" includes at least any thickness up to 25 microns. *Dec. Goldstone (Ex. 1011)* ¶17; *Dec. Lowery (Ex. 1018)* ¶29; *Dec. Hutchings (Ex. 1010)* ¶32.

3. *Dry conductive paint or ink (claim 2) and dried conductive paint or ink free of a liquid carrier (claim 16)*

The '894 patent describes conductive paint or ink consisting of a liquid solution that is dried (col. 2, ln. 40-46), evaporated (col. 4, ln. 62-65) or removed (col. 5, ln. 12-15) to form an electrically conductive layer on the tube. Based on this disclosure, Petitioner submits that "dry" or "dried" conductive paint or ink includes paint or ink that may be wet when applied to the tube, but that is eventually dried to leave the conductive features of the paint or ink on the tube. *Dec. Goldstone (Ex. 1011)* ¶18; *Dec. Lowery (Ex. 1018)* ¶30; *Dec. Hutchings (Ex. 1010)* ¶27.

4. *Carrier film between tube surface and electrodes (claims 1, 10, 14)*

Petitioner submits that a carrier film is a substrate between the tube and the conductive material that forms the electrodes, traces, and connection points.

D. One of Ordinary Skill in the Art

Petitioner submits that one of ordinary skill in the art would have been someone with: (i) a degree in engineering, science or medicine; and (ii) 3 years of experience in product development or use of endotracheal tubes with electrodes. One of ordinary skill in the art in the field of printing conductive ink/paint on a tube would have been someone with working knowledge that conductive ink/paint was available for printing conductive features on curved surfaces. *Dec. Goldstone (Ex. 1011)* ¶13; *Dec. Lowery (Ex. 1018)* ¶24; *Dec. Hutchings (Ex. 1010)* ¶11.

VI. Claims 1-3 are rendered obvious by Goldstone in view of Cook and Hutchings under 35 U.S.C. §103

A. Summary of Unpatentability

Claim 1 describes a well-known sensing circuit with electrodes for sensing signals. The well-known circuit also includes "traces" for delivering the signals from the electrodes to a connection point that in turn provides the signals to external wires connected to monitoring equipment. This well-known circuit is printed or painted on an endotracheal tube that also includes a retention balloon.

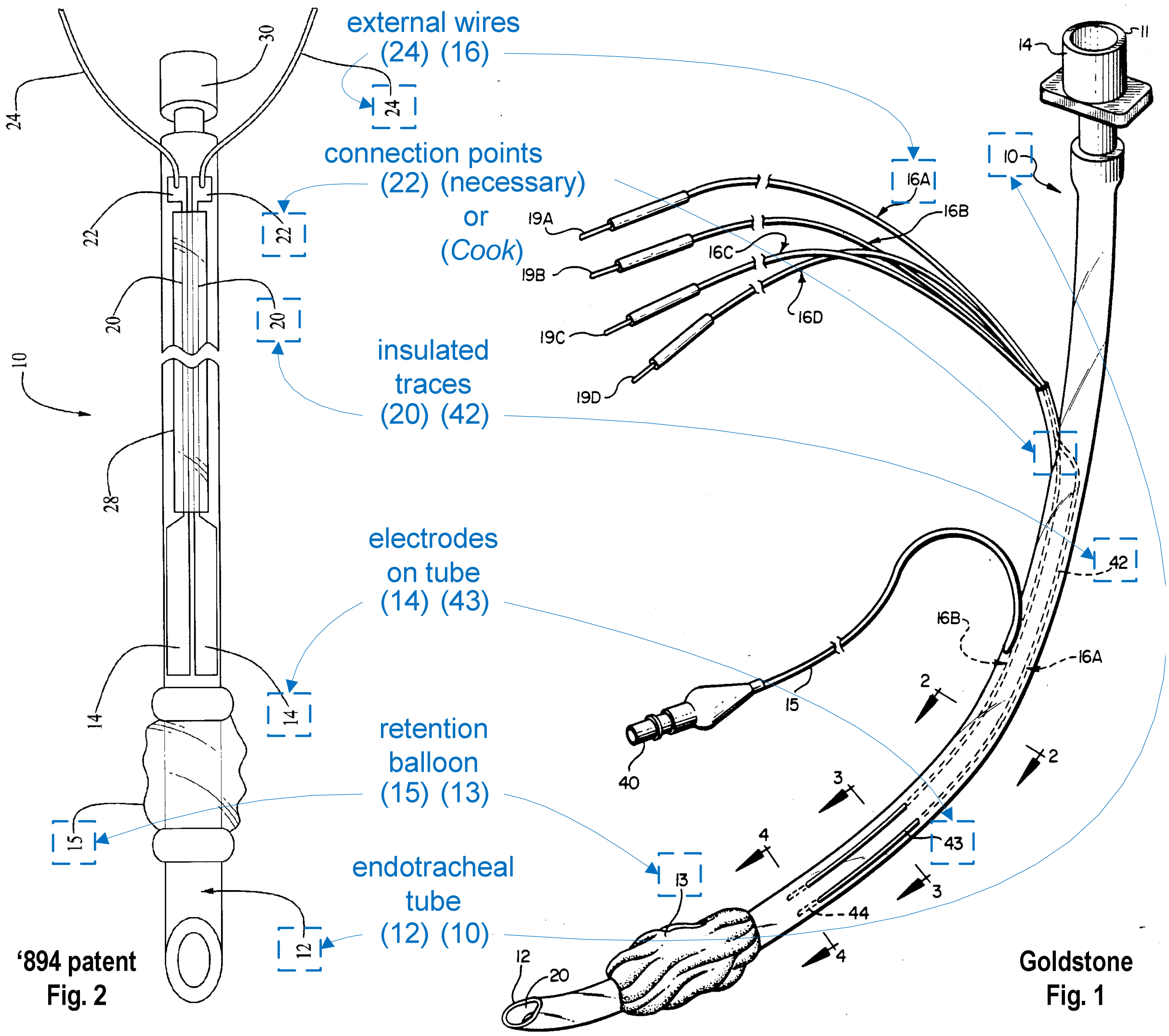
Like claim 1, Goldstone describes an endotracheal tube (10) with a retention balloon (13) and a sensing circuit that includes surface electrodes (43) for monitoring signals, and also includes traces (42). *Dec. Goldstone (Ex. 1011) ¶¶*

21, 25-30, 32, 34-36*;* *Dec. Lowery (Ex. 1018) ¶¶* 16, 35, 37, 39, 42, 51, 55, 58, and 60.

Goldstone also describes an embodiment, like claim 1, where the electrodes (43) and the traces (42) are painted. *Goldstone (Ex. 1003)* col. 5, ln. 29-31 ("A second wire portion 43 is located between distal end 12 and first wire portion 42, on outer surface 23 of tube 10."), and col. 5, ln. 18-21 ("The term 'wires' includes any type of electrically conducting lead suitable for use as an electrode, including *metal paint* ….") (emphasis added). *Dec. Goldstone (Ex. 1011)* ¶¶37, 40; *Dec. Schettino (Ex. 1013) ¶*5; *Dec. Lowery (Ex. 1018)* ¶47.

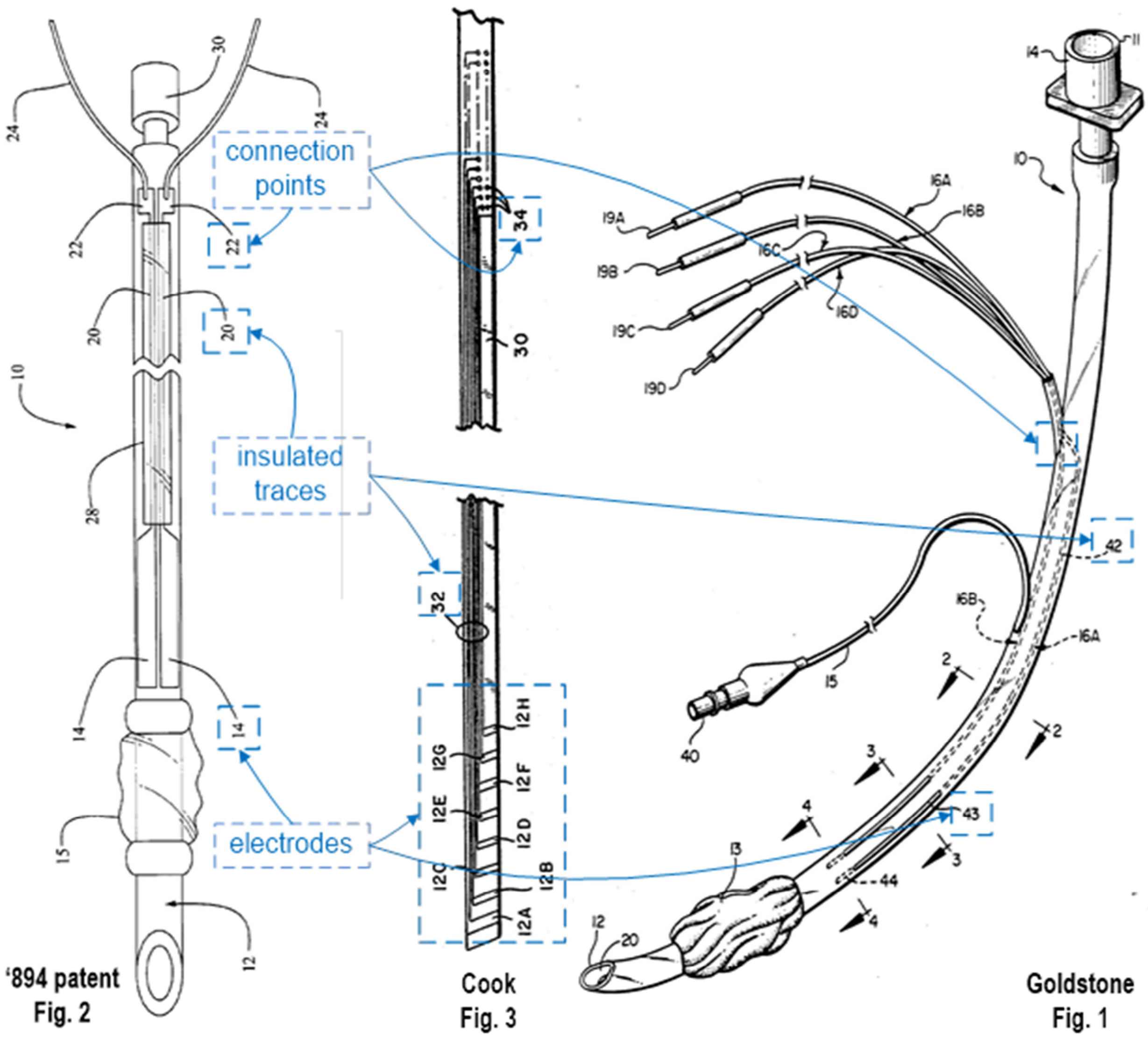
Despite the clear disclosure of painted electrodes in Goldstone, NMP incorrectly argued during prosecution that "Goldstone does not show or suggest electrodes printed on the surface of the endotracheal tube." *10/25/13 ROA (Ex. 1014)* p. 8, ln. 1-2. Goldstone, however, plainly discloses metal paint to form not only the electrodes, but also the traces. *Dec. Goldstone (Ex. 1011)* ¶¶37, 40; *Dec. Schettino (Ex. 1013) ¶*5; *Dec. Lowery (Ex. 1018)* ¶47.

For reference, the endotracheal tube, retention balloon, electrodes, traces and external wires of claim 1 and Goldstone are shown below in a comparison of the '894 patent's Fig. 2 and Goldstone's Fig. 1.



As shown above in Goldstone's Fig. 1, Goldstone also depicts points of connection where external wires meet the traces (42). Thus, connection points are arguably inherent, or otherwise would have been obvious, since connection points would be necessary for the Goldstone embodiment that uses metal paint for the traces. *Dec. Goldstone (Ex. 1011)* ¶34. Even if the Board disagrees that Goldstone depicts connection points, such connection points of sensing circuits were well-known, as illustrated by Cook's *printed* circuit, which includes the electrodes, traces *and* connection points of claim 1. *Cook (Ex. 1004)* Fig. 3, col. 4 ln. 25-32 ("The printed circuit pattern … consists of eight electrode pads [electrodes], 12A-12H, each of which is connected by a printed circuit wire 32 [trace] to a corresponding terminal pad 34 [connection points]."); *Dec. Goldstone (Ex. 1011) ¶56*; *Dec. Lowery (Ex. 1018)* ¶¶ 40, 43, 45, 48.

For reference, the overlapping disclosures in Goldstone and Cook are shown below next to an illustrative representation of claim 1's sensing circuit.



'894 patent Fig. 2

Cook Fig. 3

Goldstone Fig. 1

It 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—i.e., they sense signals and transmit those signals—and thus, are interchangeable.[4] *Dec. Goldstone (Ex. 1011) ¶*57; *Dec. Lowery (Ex. 1018) ¶*85.

Petitioner notes that the prominent embodiment of Cook's circuit is printed on a flat substrate that wraps around a tube. *Cook (Ex. 1004)* col. 2, ln. 51-58, 64-66; *Dec. Goldstone (Ex. 1011) ¶*59. One of ordinary skill in the art, however, would have understood that the difference between printing a circuit on a flat substrate and printing that circuit directly on a tube was inconsequential given well-known techniques for printing conductive features on tubes, as Hutchings describes.[5] *Dec. Goldstone (Ex. 1011) ¶59; Dec. Lowery (Ex. 1018)* ¶¶84-85; *Dec. Hutchings (Ex. 1010)* ¶25.

B. Claim 1: A device for use in monitoring electrical signals during laryngeal electromyography

Goldstone describes an endotracheal tube device for laryngeal electromyography. *Goldstone (Ex. 1003)* col. 1, ln. 5-8 ("The present invention relates generally to electrodes for detecting electromyographic (EMG) signals of

[4] Petitioner describes further motivation for combining Goldstone and Cook below.

[5] Petitioner describes Hutching and motivation for using Hutchings below.

the laryngeal muscles, and more particularly to electrodes which are mounted on an endotracheal tube."), col. 3, ln. 3-6 ("There is provided … an endotracheal tube which performs the functions of … monitoring the EMG signals of the laryngeal muscles."), and Fig. 1 (showing the endotracheal tube 10 with electrode wire portions 43); *Dec. Goldstone (Ex. 1011) ¶25; Dec. Lowery (Ex. 1018)* ¶66.

1. *An endotracheal tube having a retention balloon* at *a distal end*

Goldstone includes an endotracheal tube with a retention balloon (cuff). *Goldstone (Ex. 1003)* col. 3, ln. 7-10, and Fig. 1; *Dec. Goldstone (Ex. 1011) ¶26; Dec. Lowery (Ex. 1018)* ¶37. Goldstone's cuff is located at a distal end of the tube, as shown in Fig. 1 and described at col. 4, ln. 64 – col. 5, ln. 6 ("Referring initially to FIGS. 1-4, indicated generally at 10, is an electrode endotracheal tube … having a proximal end 11 and a distal end 12. … A cuff 13 is located near distal end 12.").

2. *Electrically conductive electrodes proximal of the balloon, applied directly to the surface of the tube without a carrier film between the surface and the electrodes, and electrically isolated from each other*

Goldstone discloses electrodes (second wire portions) that are located on the surface of the endotracheal tube without a carrier film and proximal of the retention balloon. *Goldstone (Ex. 1003)* Fig. 1, Fig. 3 (showing electrically isolated electrode wires 16A-D on the surface of the tube), and col. 5, ln. 29-32 ("A second wire portion 43 is located between distal end 12 and first wire portion 42, on outer surface 23 of tube 10."); *Dec. Goldstone (Ex. 1011) ¶27; Dec. Lowery (Ex. 1018)* ¶¶ 39, 60.

Like Goldstone, Cook describes a sensing circuit that includes electrodes (along with traces and connection points claimed below). *Cook (Ex. 1004)* Fig. 3, col. 4 ln. 25-32 ("The printed circuit pattern … consists of eight electrode pads [electrodes], 12A-12H, each of which is connected by a printed circuit wire 32 [trace] to a corresponding terminal pad 34 [connection points]."); *Dec. Goldstone (Ex. 1011) ¶56*; *Dec. Lowery (Ex. 1018)* ¶¶ 40, 43, 45, 48, 52, 61.[6]

3. One of the electrodes is positioned to contact the vocal cords

Goldstone's endotracheal tube includes at least one electrode that is positioned to contact the vocal cords when the tube is in place for electromyography. *Goldstone (Ex. 1003)* Figs. 5-6, col. 3, ln. 40-43 and col. 5, ln. 64 - col. 6, ln. 7 (second wire portions 43 contact laryngeal muscles 35 and 36, which include the vocal cords). *Dec. Goldstone (Ex. 1011) ¶28; Dec. Lowery (Ex. 1018)* ¶62. In this configuration, the retention balloon is distal of the vocal cords.

4. One of the electrodes is positioned to contact tissues, nerves and muscle in the trachea or the tongue

Claim 1 also specifies a second electrode that may be positioned to contact tissue, nerves and muscle in the trachea. As stated in Section V.C.1, if anatomy is

[6] The motivation for combining Goldstone and Cook is presented in Section VI.9.

approached the way NMP seems to have approached anatomy by including the vocal cords and larynx in the trachea, then a second electrode in Goldstone contacts tissues, nerves and muscle by contacting a vocal cord in a similar way that the first electrode contacts a vocal cord. *Dec. Schettino (Ex. 1013)* ¶25; *Goldstone (Ex. 1003)* col. 3, ln. 40-43, col. 5, ln. 29-32, col. 5, ln. 64 - col. 6, ln. 7, Fig. 1, Fig. 3 and Figs. 5-6 (second wire portions 43 of electrode wires 16A-D are electrodes that contact the vocal cords and other tissues, nerves and muscle in the larynx; the four second wire portions collectively contact the vocal cords in front and rear portions of the larynx). *Dec. Goldstone (Ex. 1011) ¶*29.

5. *Electrically conductive traces running along the length of the tube, connected to or integral with the electrodes, electrically isolated from each other, and applied to the surface of the tube*

Goldstone discloses electrically conductive traces (first wire portions 42) that run along the length of the endotracheal tube from the electrodes (second wire portions 43). *Goldstone (Ex. 1003)* Fig. 1, col. 3, ln. 14-18, and col. 5, ln. 14-32 (each electrode wire includes a first portion 42 located between proximal and distal ends of the tube); *Dec. Goldstone (Ex. 1011) ¶*30*; Dec. Lowery (Ex. 1018)* ¶42. Goldstone's Figs. 1-2 show electrically isolated traces (i.e., electrode wires 16A-D). *Dec. Goldstone (Ex. 1011) ¶*30*; Dec. Lowery (Ex. 1018)* ¶60.

Goldstone broadly discloses traces that need only extend along the length of the tube between ends of the tube (*Goldstone (Ex. 1003)* col. 3, ln. 14-20), which provides for various embodiments, including traces on the tube, traces embedded in the walls of the tube, and traces inside the lumen of the tube. *Dec. Goldstone (Ex. 1011) ¶¶*31-32; s*ee also Goldstone (Ex. 1003)* col. 8, ln. 7-12 and col. 8, ln. 31-34 (independent claim 1 includes a first wire portion broadly located between ends of a tube, and dependent claim 3 narrowly claims a particular embodiment of the first wire portion). Dr. Goldstone and Dr. Schettino even marketed a tube with surface-mounted traces. *Dec. Goldstone (Ex. 1011) ¶*31.

Like Goldstone, Cook describes a printed sensing circuit that also includes traces (along with the electrodes and connection points). *Cook (Ex. 1004)* Fig. 3, col. 4 ln. 25-32 ("The printed circuit pattern … consists of eight electrode pads [electrodes], 12A-12H, each of which is connected by a printed circuit wire 32 [trace] to a corresponding terminal pad 34 [connection points]."); *Dec. Goldstone (Ex. 1011) ¶*56; *Dec. Lowery (Ex. 1018)* ¶¶40, 43, 45, 48, 52, 61.

6. A connection point connected to or integral with each of the conductive traces, applied directly to the tube surface on the endotracheal tube

As described in the preceding Summary section, Goldstone's Fig. 1 depicts points of connection where external wires meet the traces (first wire portions 42). In the Goldstone embodiment that uses metal paint to form the electrodes and the traces, connection points at the end of the painted traces for connecting external wires to the painted traces are necessarily present, and if not, would have been obvious. *Dec. Goldstone (Ex. 1011) ¶*34.

As further described in the preceding Summary section, Cook describes a printed sensing circuit that also includes connection points (along with the electrodes and the traces claimed above). *Cook (Ex. 1004)* Fig. 3, col. 4 ln. 25-32 ("The printed circuit pattern … consists of eight electrode pads [electrodes], 12A-12H, each of which is connected by a printed circuit wire 32 [trace] to a corresponding terminal pad 34 [connection points]."); *Dec. Goldstone (Ex. 1011) ¶*56; *Dec. Lowery (Ex. 1018)* ¶¶40, 43, 45, 48, 52, 61.

7. *Electrical leads connected to the connection points, and adapted to connect to monitoring equipment*

Goldstone includes electrical leads (external wires) that are connected to the traces, and that connect to monitoring equipment. *Goldstone (Ex. 1003)* Fig. 1 and col. 5, ln. 58-63 (an EMG processing machine connects to electrical connecting plugs 19A-D of wires 16A-D that extend from insulated portions of those wires). *Dec. Goldstone (Ex. 1011) ¶*35*; Dec. Lowery (Ex. 1018)* ¶58.

8. *The electrically conductive traces covered by an insulating material along their length from a point adjacent the electrode to which it is attached to a point adjacent the electrical leads*

Goldstone indicates that the electrically conductive traces (first wire portion) are insulated. *Goldstone (Ex. 1003)* col. 5, ln. 22-25 ("Each electrode wire has a first portion 42, located between proximal end 11 and distal end 12, and insulated against electrical contact."), and col. 3, ln. 16-18; *Dec. Goldstone (Ex. 1011) ¶*36*; Dec. Lowery (Ex. 1018)* ¶55. Thus, Goldstone's broad disclosure of insulated traces extends to embodiments where the traces are applied on the surface of the endotracheal tube or any other configuration of the traces (e.g., embedded traces).

9. Motivation for combining Goldstone and Cook

One of ordinary skill in the art would have viewed the sensing circuits in Goldstone and Cook as interchangeable since they perform the same functions of sensing and transmitting signals, and include common features. *Dec. Lowery (Ex. 1018)* ¶85; *Dec. Goldstone (Ex. 1011)* ¶57. One of ordinary skill in the art would have recognized that including Cook's circuit with electrodes, traces and connection points on the surface of Goldstone's tube (i) would have provided an approach for forming a sensing circuit on the surface of Goldstone's endotracheal tube that was "many times less expensive" than other approaches (*Cook (Ex. 1004)* col. 6, ln. 59-65), (ii) would have allowed "the size, shape and orientation of each electrode to be individually controlled to provide a sensing device [i.e., an electrode bearing endotracheal tube] which is optimal for each application" (*Cook (Ex. 1004)* col. 6 ln. 52-56), (iii) would have resulted in a number of electrodes that "can be increased substantially without any corresponding increase in the size of the device" (i.e., the endotracheal tube) (*Cook (Ex. 1004)* col. 6 ln. 17-27), and (iv) would have provided painted connection points for connecting external wires with Goldstone's painted traces, each of which would have yielded predictable results of an endotracheal tube with electrodes for monitoring a signal, including signals during laryngeal electromyography. *Dec. Goldstone (Ex. 1011) ¶58; Dec. Lowery (Ex. 1018)* ¶¶ 85, 86. Furthermore, it would have been obvious to one of ordinary skill in the art to include the printable connection points of Cook on Goldstone's endotracheal tube using Goldstone's conductive paint in order to connect painted traces to external wires. *Dec. Goldstone (Ex. 1011) ¶*58.

10. Motivation for combining Goldstone, Cook and Hutchings

Petitioner notes that the prominent embodiment of Cook's circuit is printed on a flat substrate that wraps around a tube. *Dec. Goldstone (Ex. 1011) ¶*59. One of ordinary skill in the art, however, 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. *Dec. Goldstone (Ex. 1011) ¶*59*; Dec. Lowery (Ex. 1018)* ¶85; *Dec. Hutchings (Ex. 1010)* ¶25.

For example, Hutchings describes "direct writing" techniques that "deposit … materials on to a substrate" that is "flat, curvilinear, round, flexible, irregular or inflatable." *Hutchings (Ex. 1005)* p. 601, col. 2, sec. 1, p. 613, col. 2, sec. 7.2 (liquid metals and metallic particles printed by inkjet process), p. 614, col. 2, sec. 7.4 (laser-based direct writing), p. 611, col. 1, sec. 5.1 (flow-based direct writing), and p. 601, col. 2, sec. 1 and p. 615, col. 1, sec. 8 (printing on curved substrates);

Dec. Goldstone (Ex. 1011) ¶60; *Dec. Lowery (Ex. 1018)* ¶¶ 49, 53; *Dec. Hutchings (Ex. 1010)* ¶¶ 14-19.

As Hutchings describes, the deposited materials include conductive inks or paints, which would have included the metal paint from Goldstone. *Hutchings (Ex. 1005)* p. 613, col. 2, sec. 7.2 ("Possible routes to metallic deposits include the direct deposition of liquid metals, printing of metallic particles …."), p. 613, col. 2, sec. 7.2 ("Metallic particles suspended in a suitable fugitive liquid can be printed by inkjet processes, and are used for both structural and electrical applications."), and p. 613, Table 2 (list of metal materials); *Dec. Goldstone (Ex. 1011)* ¶61; *Dec. Lowery (Ex. 1018)* ¶¶ 49, 53; *Dec. Hutchings (Ex. 1010)* ¶16.

It would have been obvious to one of ordinary skill in the art to use the techniques in Hutchings to deposit Cook's printed circuit on Goldstone's endotracheal tube. *Dec. Goldstone (Ex. 1011)* ¶62; *Dec. Lowery (Ex. 1018)* ¶84; *Dec. Hutchings (Ex. 1010)* ¶¶ 24-25. Doing so would achieve various benefits Hutchings describes, including "cost reduction for prototyping and production" of medical devices like endotracheal tubes, "process chain simplification through the reduction of process steps" like Cook's step of printing on a substrate that is then wrapped around a tube, "greater design freedom due to its geometrical versatility" in terms of printing on curved surfaces like tubes, and a lower "environmental footprint" by minimizing material wastage. *Hutchings (Ex. 1005)* p. 617, col. 2, sec. 10; *Dec. Goldstone (Ex. 1011) ¶62; Dec. Lowery (Ex. 1018)* ¶84; *Dec. Hutchings (Ex. 1010)* ¶¶ 24-25. The above motivations also apply to claims 2 and 3 below.

C. Claim 2: Use of different conductive materials

Claim 2 specifies electrodes, traces and connection points comprising a dry conductive paint or ink. During prosecution, NMP stated that Goldstone does "not show or suggest electrodes printed on the surface of the endotracheal tube" (*10/25/13 ROA (Ex. 1014)* p. 8, ln. 1-2). NMP was wrong. Goldstone actually describes conductive metal paint that is used for surface electrodes (i.e., Goldstone's second wire portion 43). *Goldstone (Ex. 1003)* col. 5, ln. 18-21 ("The term 'wires' includes any type of electrically conducting lead suitable for use as an electrode, including metal paint …"); *Dec. Goldstone (Ex. 1011) ¶*37. This disclosure also extends to Goldstone's traces (first wire portions). As discussed in Section V.C.3, dry conductive paint or ink includes paint or ink that is wet when applied, but later dried to leave behind conductive material. Goldstone's metal paint is a dry conductive ink or paint. Hutchings also describes printable/paintable materials that include dry conductive inks or paints. *Hutchings (Ex. 1005)* p. 613, col. 2, sec. 7.2 ("Possible routes to metallic deposits include the direct deposition of liquid metals, printing of metallic particles …."), p. 613, col. 2, sec. 7.2 ("Metallic particles suspended in a suitable fugitive liquid can be printed by inkjet processes"), and p. 613, Table 2 (list of metal materials); *Dec. Goldstone (Ex. 1011) ¶*63*; Dec. Lowery (Ex. 1018)* ¶¶ 49, 53, 70; *Dec. Hutchings (Ex. 1010)* ¶16.

D. Claim 3: Substantially flush electrodes

Claim 3 specifies surfaces of the electrodes that are substantially flush with the tube's surface. As discussed in Section V.C.2, "substantially flush" includes thicknesses up to 25 microns. Metal paint in Goldstone can be substantially flush. Hutchings also describes "substantially flush" heights of printed/painted electrodes, including 1.3 to 25 microns (μm): "The line … with a height from 1.3 to 250 μm." *Hutchings (Ex. 1005)* p. 611, col. 2, sec. 5.2; *Dec. Goldstone (Ex. 1011) ¶*64*; Dec. Lowery (Ex. 1018)* ¶76; *Dec. Hutchings (Ex. 1010)* ¶32.

VII. Claims 4-9 are rendered obvious by Goldstone in view of Cook and Hutchings under 35 U.S.C. §103

A. Claim 4: Formation of endotracheal tube for laryngeal electromyography

Claim 4 is arguably broader than claim 1.[7] Claim 4 includes the following limitations that effectively appear in claim 1: an endotracheal tube that has a retention balloon at a distal end thereof; electrodes applied on the surface of the endotracheal tube and located proximal of the retention balloon; electrically

[7] Notably, claim 4 does *not* specify electrodes positioned to contact the vocal cords or tissue, nerves and muscle in the trachea or the tongue. *Dec. Goldstone (Ex. 1011) ¶*38.

conductive traces applied to the surface of the endotracheal tube that are attached to the electrodes; connection points at a proximal end of the traces; and insulating material covering the traces. *Dec. Goldstone (Ex. 1011) ¶¶* 38, 65. The analysis in Section VI for the above limitations in relation to claim 1, and the motivations for combining Goldstone, Cook and Hutchings, are incorporated by reference here.

In addition to the above claim limitations, Claim 4 also specifies a method of forming the endotracheal tube. Goldstone describes a method of forming an endotracheal tube with electrodes and traces using metal paint. *Goldstone (Ex. 1003)* col. 5, ln. 29-31 ("A second wire portion 43 is located between distal end 12 and first wire portion 42, on outer surface 23 of tube 10."); col. 5, ln. 18-21 ("The term 'wires' includes any type of electrically conducting lead suitable for use as an electrode, including metal paint …."); *Dec. Goldstone (Ex. 1011) ¶*39.

Claim 4 also specifies that the electrodes, traces and connection points are formed using conductive ink or paint. *Dec. Goldstone (Ex. 1011) ¶*40. Contrary to NMP's misleading arguments during the prosecution of the '894 patent that Goldstone does "not show or suggest electrodes printed on the surface of the endotracheal tube" (*10/25/13 ROA (Ex. 1014)* p. 8, ln. 1-2), Goldstone actually describes using conductive metal paint for electrodes (i.e., Goldstone's second wire portion 43) on the surface of the tube. *Goldstone (Ex. 1003)* Fig. 1 and col. 5, ln. 18-21 ("The term 'wires' includes any type of electrically conducting lead suitable for use as an electrode, including metal paint ….”); *Dec. Goldstone (Ex. 1011)* ¶40. This disclosure also extends to Goldstone’s traces (first wire portions 42). *Dec. Goldstone (Ex. 1011)* ¶40.

Any limitations of claim 4 that do not appear in claim 1 do not affect the motivation to combine Goldstone, Cook and Hutchings stated above for claim 1. Thus, Petitioner incorporates by reference those motivations here. Those motivations also apply to claims 5-9 below.

B. Claim 5: Placement of electrodes

As stated in Section V.C.1, if anatomy is approached the way NMP seems to have approached anatomy by including the vocal cords and the larynx in the trachea, then the electrode designated by 16D in Fig. 6 is positioned to contact nerves and muscle in the rear of the trachea by being positioned to contact part of a vocal cord in the rear half of the larynx (as compared to the electrode designated by 16C, which is in the front half of the larynx). *Dec. Schettino (Ex. 1013)* ¶25; *Goldstone (Ex. 1003)* col. 3, ln. 40-43, col. 5, ln. 29-32, col. 5, ln. 64 - col. 6, ln. 7, Fig. 1, Fig. 3 (showing four electrodes 16A-D) and Figs. 5-6 (showing electrodes 16B and 16C in the front half the larynx and 16D in the rear half of the larynx). *Dec. Goldstone (Ex. 1011)* ¶¶29, 41, 66.

C. Claims 6-9: Use of different conductive materials

Claim 6 includes ink or paint with conductive particles in a liquid carrier, which Hutchings describes. *Hutchings (Ex. 1005)* p. 613, col. 2, sec. 7.2 ("Metallic particles suspended in a suitable fugitive liquid can be printed by inkjet processes"); *Dec. Goldstone (Ex. 1011) ¶*67*; Dec. Lowery (Ex. 1018)* ¶71; *Dec. Hutchings (Ex. 1010)* ¶¶16, 28.

Claims 7 and 8 specify that the electrically conductive particles comprise finely divided particles or flakes of elemental silver (Ag), silver salt (silver nitrate), gold (Au), copper (Cu), *or* platinum (Pt) (among other alternatives), which Hutchings describes. *Hutchings (Ex. 1005)* p. 613, Table 2 and p. 614, col. 1; *Dec. Goldstone (Ex. 1011) ¶*68*; Dec. Lowery (Ex. 1018)* ¶72; *Dec. Hutchings (Ex. 1010)* ¶¶16, 29.

Claim 9 specifies conductive particles comprising at least 60% of the ink, which Hutchings describes. *Hutchings.*at p. 614, col. 2, sec. 7.3 ("… deposit a silver ink which contained 57–62 wt.% of Ag [silver] nanoparticles …."); *Dec. Goldstone (Ex. 1011) ¶*69; *Dec. Lowery (Ex. 1018)* ¶73; *Dec. Hutchings (Ex. 1010)* ¶30.

VIII. Claims 10-13 are rendered obvious by Goldstone in view of Cook and Hutchings under 35 U.S.C. §103

A. Claim 10: A method for monitoring electrical signals during laryngeal electromyography

Claim 10 includes the following limitations that effectively appear in claim 1 and/or 4: an endotracheal tube that has a retention balloon at a distal end thereof; electrodes located proximal of the balloon, and applied on the surface of the endotracheal tube without the inclusion of a carrier film; electrically conductive traces connected to or integral with the electrodes, applied to the tube surface and extending along the length of the endotracheal tube from the electrodes to a proximal portion of the tube; connection points connected to or integral with the traces, and applied to the tube surface; electrical leads connected to the connection points; insulating material covering the traces; the electrodes, traces and connection points comprise a conductive paint or ink; and an electrode that contacts the vocal cords. *Dec. Goldstone (Ex. 1011) ¶¶* 42, 70. The analysis in Sections VI-VII above for claims 1 and 4, and the motivations for combining Goldstone, Cook and Hutchings, are incorporated by reference here.

Claim 10 also recites monitoring electrical signals with the electrode that contacts the vocal cords, which is described in Goldstone's col. 1, ln. 5-8 ("The present invention relates generally to electrodes for detecting electromyographic (EMG) signals of the laryngeal muscles") and col. 3, ln. 59 ("The electrodes are capable of detecting EMG signals"). *Dec. Goldstone (Ex. 1011) ¶43; Dec. Lowery (Ex. 1018)* ¶66.

Claim 10's preamble (which is not limiting) recites that electrical signals are monitored during laryngeal electromyography for a period of time in excess of 8 hours without injury to the trachea. Goldstone's endotracheal tube can monitor signals for any period of time, including over 8 hours without injury. *Goldstone (Ex. 1003)* col. 1, ln. 5-8 ("The present invention relates generally to electrodes for detecting electromyographic (EMG) signals of the laryngeal muscles….") and col. 3, ln. 59 ("The electrodes are capable of detecting EMG signals of two distinct types."); *Dec. Goldstone (Ex. 1011) ¶44; Dec. Lowery (Ex. 1018)* ¶67. Even NMP admits that surface-level painted electrodes (e.g., like those in the Goldstone embodiments with metal paint for the surface electrodes) permit long term use of the endotracheal tube for monitoring RLN signals over more than 24 hours without detrimental reduction in the quality of the signal. *'894 patent (Ex. 1001)* col. 6, ln. 30-58 (stating that an endotracheal tube with imprinted electrode surfaces "allows safe, long term intubation and clinical monitoring of human laryngeal electromyographic signals without detrimental reduction in the quality of the electrical signal or injury to the trachea"; and further stating that painted electrodes make long term intubations in excess of 24 hours possible).

Claim 10 also recites that the monitored signals do not show a detrimental reduction in the quality thereof, which is a characteristic of signals monitored by painted electrodes (e.g., Goldstone's painted metal electrodes) on the surface of an endotracheal tube, as admitted by NMP. *Dec. Goldstone (Ex. 1011) ¶*45*; Dec. Lowery (Ex. 1018)* ¶68; *'894 patent (Ex. 1001)* col. 6, ln. 30-58 (stating that an endotracheal tube with imprinted electrode surfaces "allows … clinical monitoring of human laryngeal electromyographic signals without detrimental reduction in the quality of the electrical signal").

Any limitations of claim 10 that do not appear in claims 1 and 4 do not affect the motivation to combine Goldstone, Cook and Hutchings stated above for claims 1 and 4. Thus, Petitioner incorporates by reference those motivations here. Those motivations also apply to claims 11-13 below.

B. Claim 11 and 13: Period of monitoring

Claims 11 and 13 specify a monitoring period in excess of 24 hours. Goldstone's endotracheal tube with painted electrodes can monitor signals for any period of time including over 24 hours without injury. *See Section VIII.A; Dec. Goldstone (Ex. 1011) ¶¶* 46, 71*; Dec. Lowery (Ex. 1018)* ¶80.

C. Claim 12: Placement of electrodes

As stated in Section V.C.1, if anatomy is approached the way NMP seems to have approached anatomy by including the vocal cords and the larynx in the trachea, then the electrode designated by 16D in Fig. 6 is positioned to contact tissue, nerves and muscle in the rear of the trachea by being positioned to contact part of a vocal cord in the rear half of the larynx (as compared to the electrode designated by 16C, which is in the front half of the larynx). *Dec. Schettino (Ex. 1013)* ¶25; *Goldstone (Ex. 1003)* col. 3, ln. 40-43, col. 5, ln. 29-32, col. 5, ln. 64 - col. 6, ln. 7, Fig. 1, Fig. 3 (showing four electrodes 16A-D) and Figs. 5-6 (showing electrodes 16B and 16C in the front half the larynx and 16D in the rear half of the larynx). *Dec. Goldstone (Ex. 1011) ¶¶*29, 47, 72.

IX. Claims 14-19 are rendered obvious by Goldstone in view of Cook and Hutchings under 35 U.S.C. §103

A. *Claim 14: A device for use in monitoring electrical signals during laryngeal electromyography*

Claim 14 includes the following limitations that appear in claim 1, 4 and/or 10: an endotracheal tube that has a retention balloon at a distal end thereof; electrodes located proximal of the balloon, electrically isolated from each other, and applied on the surface of the endotracheal tube without the inclusion of a carrier film; an electrode positioned to contact the vocal cords; electrically conductive traces connected to or integral with the electrodes, applied to the tube surface, electrically isolated from each other, and extending along the length of the endotracheal tube from the electrodes to a proximal portion of the tube; optional connection points connected to or integral with the traces, and applied to the tube surface; electrical leads configured to connect to monitoring equipment, and optionally connected to the connection points; and insulating material covering the traces. *Dec. Goldstone (Ex. 1011) ¶¶* 48, 73. The analysis above in Sections VI-VIII for these limitations in relation to claims 1, 4 and 10, and the motivations for combining Goldstone, Cook and Hutchings, are incorporated by reference here.

Claim 14 also indicates that the electrical leads are optionally connected to the traces, which is illustrated in Fig. 1 of Goldstone where the wires 16A-D exit the tube from the traces (i.e., the end of wire portion 42). *Dec. Goldstone (Ex. 1011) ¶*49.

Any limitations of claim 14 that do not appear in claims 1, 4 and 10 do not affect the motivation to combine Goldstone, Cook and Hutchings stated above for claim 14. Thus, Petitioner incorporates by reference those motivations here. Those motivations also apply to claims 15-19 below.

B. Claims 15-16: Conductive material

Claim 15 specifies that the electrically conductive electrodes and traces comprise a conductive paint or ink. As established above in Sections VI.C and VII.A. in the analysis of claims 2 and 4, which is incorporated here by reference, and contrary to NMP's misleading characterization of Goldstone during the prosecution of the '894 patent, Goldstone actually describes using conductive metal paint for electrodes on the surface of the tube. *Dec. Goldstone (Ex. 1011)*

¶50. Hutchings also describes materials that include conductive inks or paints. *Hutchings (Ex. 1005)* p. 613, col. 2, sec. 7.2 ("Possible routes to metallic deposits include the direct deposition of liquid metals, printing of metallic particles …."), p. 613, col. 2, sec. 7.2 ("Metallic particles suspended in a suitable fugitive liquid can be printed by inkjet processes"), and p. 613, Table 2 (list of metal materials); *Dec. Goldstone (Ex. 1011) ¶74; Dec. Lowery (Ex. 1018)* ¶¶ 49, 53, 74; *Dec. Hutchings (Ex. 1010)* ¶16.

Claim 16 specifies that the conductive paint or ink is dried and free of a liquid carrier. As discussed in Section V.C.3, dried conductive paint or ink includes paint or ink that is wet when applied, but later dried to leave behind conductive material. Metal paint described in Goldstone is a dried paint. *Dec. Goldstone (Ex. 1011) ¶*51. Hutchings also describes dried conductive ink. *Hutchings (Ex. 1005)* p. 603, col. 1, sec. 3.1 ("Inkjet-based direct writing involves the formation and deposition of a sequence of droplets of liquid material, often called an ink or fluid. After deposition this material usually becomes solid, by the evaporation of a solvent …."), p. 607, col. 1, sec. 4.2.2 (describes applying temperature that decomposes a liquid to cause deposition of a metallic layer on the substrate); *Dec. Goldstone (Ex. 1011) ¶75; Dec. Lowery (Ex. 1018)* ¶75; *Dec. Hutchings (Ex. 1010)* ¶31.

C. Claim 17: Substantially flush electrodes

Claim 17 specifies surfaces of electrodes that are substantially flush with the surface of the tube. As discussed in Section V.C.2, "substantially flush" includes thicknesses up to 25 microns. Metal paint in Goldstone can be substantially flush. Hutchings also describes "substantially flush" heights of printed/painted electrodes, including 1.3 to 25 microns (µm): "The line … with a height from 1.3 to 250 µm." *Hutchings (Ex. 1005)* p. 611, col. 2, sec. 5.2; *Dec. Goldstone (Ex. 1011) ¶*76*; Dec. Lowery (Ex. 1018)* ¶76; *Dec. Hutchings (Ex. 1010)* ¶32.

D. Claims 18-19: Position of electrodes

Claim 18 specifies a first electrode and a second electrode that are located a predetermined distance proximal of the balloon, which is depicted in Goldstone's Fig. 1 and col. 5, ln. 41-46 (showing second wire portions 43 that begin at predetermined distances that are proximal to the cuff 13). *Dec. Goldstone (Ex. 1011) ¶¶* 52, 77*; Dec. Lowery (Ex. 1018)* ¶77. Claim 18 also specifies that the first and second electrodes are electrically isolated from each other, and that the first electrode is positioned to contact the vocal cords. *Dec. Goldstone (Ex. 1011) ¶¶* 52, 77. Since these limitations appear in claim 14, the analysis above for claim 14 in relation to these limitations is incorporated by reference here. *Id*.

Claim 19 specifies a first electrode on a posterior surface of the endotracheal tube and a second electrode anterior thereto, which is illustrated in Goldstone's

Figs. 1-3 (showing electrode wires 16A-D that are on posterior and anterior surfaces of the endotracheal tube depending on how the tube is inserted into the trachea). *Dec. Goldstone (Ex. 1011) ¶¶* 53, 77*; Dec. Lowery (Ex. 1018)* ¶78.

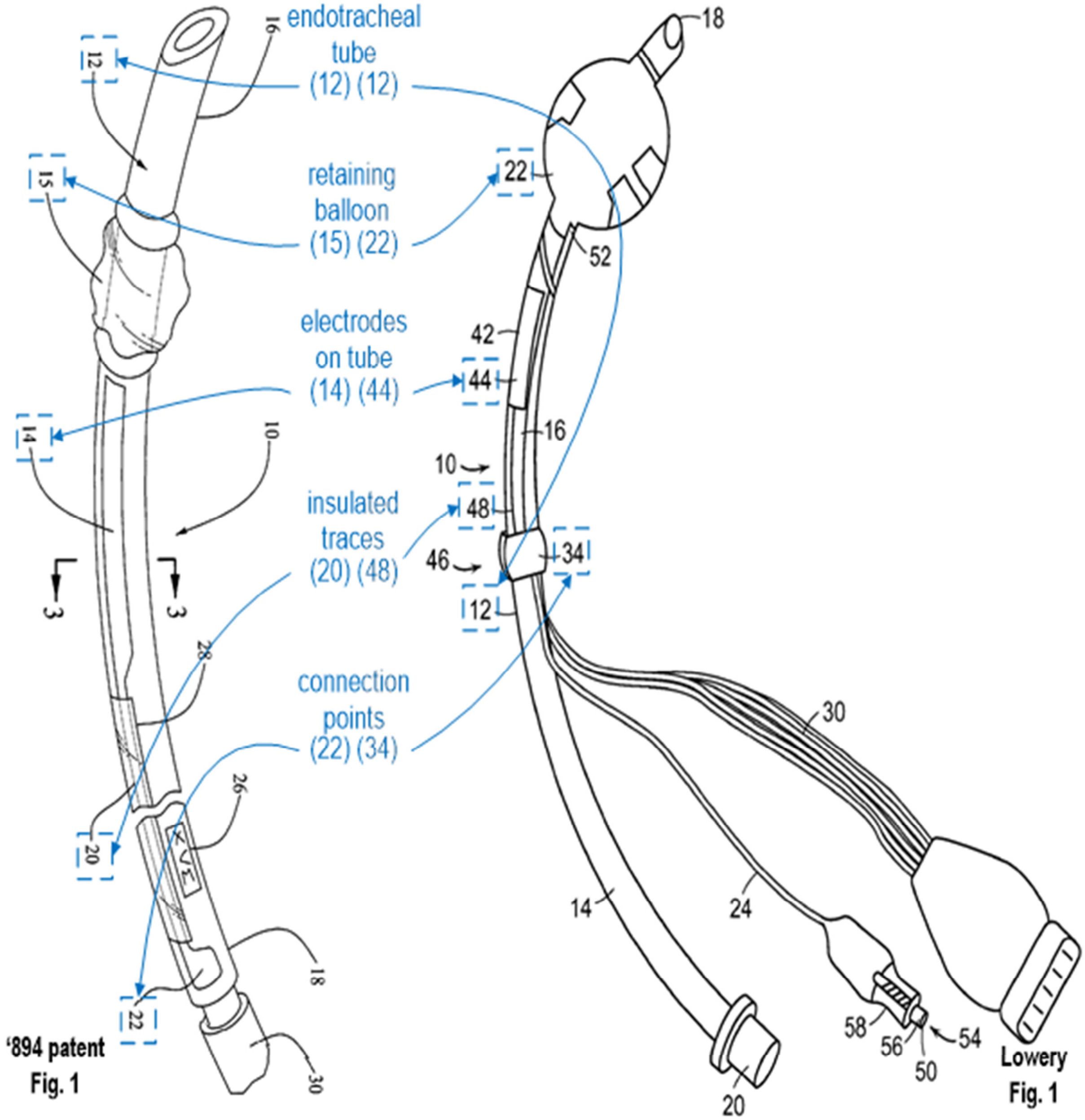
X. Claims 1-3 are rendered obvious by Lowery in view of Goldstone and Hutchings under 35 U.S.C. §103

A. Summary of Unpatentability

Claim 1 describes a well-known sensing circuit with electrodes for sensing signals. The well-known circuit also includes "traces" for delivering the signals from the electrodes to a connection point that in turn provides the signals to external wires connected to monitoring equipment. This well-known circuit is printed or painted on an endotracheal tube that also includes a retention balloon.

Like claim 1, Lowery describes an endotracheal tube (12) with a retention balloon (22) and the well-known sensing circuit that includes electrodes (44), traces (48) and connection points (34) formed using conductive ink. *Lowery (Ex. 1002)* Figs. 1-3A and ¶¶ [0002], [0008], [0010], [0026]-[0028], [0034], [0048]; *Dec. Lowery (Ex. 1018)* ¶¶ 34, 36, 38, 41, 44, 46, 50, 54, 57, 59.

The images below depict the striking similarity between claim 1 (illustrated by Fig. 1 of the '894 patent) and Lowery's disclosure (depicted by Fig. 1 of Lowery).



Even assuming one narrow interpretation of Lowery (further explained in sub-section B below) where the electrodes, traces and connection points are applied to a surface of a substrate attached to the tube, the difference between forming those features on the tube versus on a substrate that is attached to the tube were insignificant given direct writing techniques for applying conductive ink on tube-shaped surfaces, as Hutchings describes. *Hutchings*, at p. 613, col. 2, sec. 7.2 (metallic particles printed by inkjet process for electrical applications), p. 614, col. 2, sec. 7.4 (laser-based direct writing for depositing metals), p. 611, col. 1, sec. 5.1 (flow-based direct writing for depositing ink on a substrate), and p. 601, col. 2, sec. 1 and p. 615, col. 1, sec. 8 (printing on round substrates); *Dec. Lowery (Ex. 1018)* ¶¶ 18, 49, 53; *Dec. Hutchings (Ex. 1010)* ¶¶ 14-19, 23.

As discussed in further detail later, it would have been obvious to one of ordinary skill in the art before the earliest effective filing date to use the techniques in Hutchings to deposit Lowery's conductive ink directly on Lowery's endotracheal tube. *Dec. Lowery (Ex. 1018)* ¶82; *Dec. Hutchings (Ex. 1010)* ¶23. Doing so would achieve various benefits, including "cost reduction for prototyping and production" of medical devices like endotracheal tubes, "process chain simplification through the reduction of process steps" like Lowery's step of printing on a substrate attached to a tube, "greater design freedom due to its geometrical versatility" in terms of printing on surfaces like tubes, and a lower "environmental footprint" by minimizing wastage. *Hutchings (Ex. 1005)* p. 617, col. 2, sec. 10; *Dec. Lowery (Ex. 1018)* ¶82; *Dec. Hutchings (Ex. 1010)* ¶23.

Petitioner recognizes that Lowery is directed to cardiac monitoring as opposed to laryngeal EMG monitoring. However, Goldstone discloses electrodes for laryngeal EMG monitoring and also discloses many features in claim 1 of the

’894 patent. *Goldstone (Ex. 1003)* col. 1, ln. 5-8 and col. 3, ln. 3-6; *Dec. Lowery (Ex. 1018)* ¶¶ 35, 37, 39, 42, 47, 51, 55, 58, 60, 62, 66; *see also Sections VI through IX* (which identify the features in Goldstone). As discussed in further detail below, it would have been obvious to one of ordinary skill in the art before the earliest effective filing date of the ’894 patent to incorporate the electrodes of Goldstone’s endotracheal tube onto Lowery’s endotracheal tube in order to enable Lowery’s tube to monitor more types of signals during more types of surgery, including monitoring signals for laryngeal EMG. *Dec. Lowery (Ex. 1018)* ¶83; *Dec. Goldstone (Ex. 1011) ¶78*. Doing so would realize advantages described in Goldstone, including reducing the risk of nerve damage during surgery, and reducing the risk of doctors improperly placing Lowery’s endotracheal tube, which is critical to avoid serious complications from improper ventilation resulting from improper tube placement, like insufficient oxygen to the brain and even death. *Goldstone (Ex. 1003)* col. 4, ln. 12-22; *Dec. Lowery (Ex. 1018)* ¶83; *Dec. Goldstone (Ex. 1011) ¶78*.; *Dec. Schettino (Ex. 1013)* ¶¶6-7. Use of the painted electrodes from Goldstone on Lowery’s tube would have yielded predictable results, including a tube with electrodes for monitoring different signals, including signals during laryngeal EMG. The resulting tube would have provided more functionality and a broader market for the Lowery tube. *Dec. Goldstone (Ex. 1011) ¶78*.

For the following reasons, claims 1-3 are rendered obvious by Lowery in view of Goldstone and Hutchings.

B. Claim 1: *A device for monitoring electrical signals during laryngeal electromyography*

Lowery illustrates an endotracheal tube with electrodes printed on the tube. *Lowery (Ex. 1002)* ¶[0010] ("The tube of the apparatus may be an endotracheal tube."), ¶[0002] ("The electrodes are printed on the tube."), ¶[0008] ("… the sense electrodes and the current electrode are disposed on the inflatable cuff and the distal portion of the tube."), ¶[0010] ("Also, the current electrode is disposed on the distal portion of the tube. … Optionally, the ground electrode is also placed on the tube."), and ¶[0034] ("The apparatus 10 also includes a current electrode 42. The current electrode 42 has an electrode patch 44 …. Preferably, the current electrode 42 is located on the outer radius of the curve formed by the tube."); *Dec. Lowery (Ex. 1018)* ¶34.

Lowery does not explicitly show an endotracheal tube for monitoring EMG signals during laryngeal electromyography.[8] Goldstone, however, describes an endotracheal tube with electrodes for monitoring such EMG signals. *Dec. Lowery*

[8] Monitoring of electrical signals during laryngeal EMG is stated in the preamble of claim 1 and is not limiting.

(Ex. 1018) ¶66; *see also Sections VI through IX,* which are incorporated here by reference for the teachings of Goldstone.

It would have been obvious to one of ordinary skill in the art, before the earliest effective filing date of the '894 patent, to incorporate Goldstone's electrodes for monitoring EMG signals onto Lowery's electrode-bearing endotracheal tube to enable Lowery's tube to monitor more types of signals during more types of surgery, including EMG signals during laryngeal electromyography. *Dec. Lowery (Ex. 1018)* ¶83; *Dec. Goldstone (Ex. 1011) ¶*78. Goldstone's disclosure would have motivated one of ordinary skill in the art to incorporate Goldstone's electrodes onto Lowery's endotracheal tube because doing so would have resulted in an endotracheal tube that could "alert a surgeon when potentially damaging contact with a laryngeal nerve is imminent" or "alert doctors when the endotracheal tube is either too proximal or too distal in the trachea to allow proper ventilation," which is critical to avoid serious complications like insufficient oxygen to the brain and death. *Goldstone (Ex. 1003)* col. 4, ln. 12-22; *Dec. Lowery (Ex. 1018)* ¶83; *Dec. Goldstone (Ex. 1011) ¶*78; *Dec. Schettino (Ex. 1013)* ¶¶6-7. As further illustrated below, the endotracheal tubes in Lowery and Goldstone both include many claimed features, which makes the combination of Lowery in view of Goldstone even more obvious to one of ordinary skill in the art.

1. An endotracheal tube having a retention balloon at *a distal end*

Lowery discloses an endotracheal tube with a distal end. *Lowery (Ex. 1002)* ¶[0026] ("... FIG. 1 contains tube 12 having … distal portion 16."). Lowery also illustrates a retaining balloon (cuff) that is located at the distal end of the tube. *Lowery (Ex. 1002)* ¶[0026] ("Connected to the distal portion 16 is an inflatable cuff 22 …."); *Dec. Lowery (Ex. 1018)* ¶36. Like Lowery, Goldstone also includes an endotracheal tube with a retaining balloon (cuff) located at a distal end of the endotracheal tube. *Dec. Lowery (Ex. 1018)* ¶37; *See also Sections VI through IX,* which are incorporated here by reference for the teachings of Goldstone.

2. Electrically conductive electrodes proximal of the balloon, applied directly to the surface of the tube without a carrier film between the surface and the electrodes, and electrically isolated from each other

Fig. 1 of Lowery shows an electrode (patch 44) that is located proximal of the balloon (cuff 22). Lowery's Figs. 1-2 show electrically isolated electrode patches (i.e., the claimed electrodes). Electrode patches in Lowery are located on the surface of the tube proximal of the retaining balloon. *Lowery (Ex. 1002)* ¶[0010] ("The tube of the apparatus may be an endotracheal tube."), ¶[0002] ("The electrodes are printed on the tube …."), ¶[0008] ("… the sense electrodes and the current electrode are disposed on … the distal portion of the tube …."), ¶[0010] ("Also, the current electrode is disposed on the distal portion of the tube. … Optionally, the ground electrode is also placed on the tube."), and ¶[0034] ("The current electrode 42 has an electrode patch 44 [i.e., the claimed electrode] …. Preferably, the current electrode 42 is located on the outer radius of the curve formed by the tube."); *Dec. Lowery (Ex. 1018)* ¶38.

Like Lowery, Goldstone discloses electrically isolated first and second electrodes (second wire portions) that are located on the surface of the endotracheal tube proximal of the retaining balloon (cuff). *Dec. Lowery (Ex. 1018)* ¶¶39, 60; *See also Sections VI through IX,* which are incorporated here by reference for the teachings of Goldstone.

As previously stated, one of ordinary skill in the art would have been motivated to incorporate the first and second electrodes (second wire portions) of Goldstone's endotracheal tube onto Lowery's endotracheal tube to realize advantages described by Goldstone, including reducing the risk of doctors improperly placing Lowery's tube (which could cause improper ventilation leading to brain damage or death), and reducing the risk of nerve damage during certain types of surgery. *Dec. Lowery (Ex. 1018)* ¶83; *Dec. Goldstone (Ex. 1011) ¶78*; *Dec. Schettino (Ex. 1013) ¶¶6-7.*

3. One of the electrodes is positioned to contact the vocal cords

Goldstone's endotracheal tube includes at least one electrode that is positioned to contact the vocal cords when the tube is placed in a trachea for electromyography. *Dec. Lowery (Ex. 1018)* ¶62; *See also Sections VI through IX,* which are incorporated here by reference for the teachings of Goldstone. In this configuration, the retention balloon is distal of the vocal cords.

4. *One of the electrodes is positioned to contact tissues, nerves and muscle in the trachea or the tongue*

Claim 1 also specifies a second electrode that may be positioned to contact tissue, nerves and muscle in the trachea. As stated in Section V.C.1, if we approach anatomy the way NMP seems to have approached anatomy by including the vocal cords in the larynx as part of the trachea, then a second electrode in Goldstone contacts tissues, nerves and muscle by contacting a vocal cord in a similar way that the first electrode contacts a vocal cord. *See Sections VI through IX,* which are incorporated here by reference for the teachings of Goldstone.

5. *Electrically conductive traces running along the length of the tube, connected to or integral with the electrodes, electrically isolated from each other, and applied to the surface of the tube*

Lowery discloses traces (electrode runners) on the tube that are attached to the electrodes (electrode patches). *Lowery (Ex. 1002)* ¶[0034] ("The current electrode 42 also includes an electrode runner 48 extending distally from the flex circuit 30 of the apparatus to the electrode patch 44 of the current electrode 42."); *Dec. Lowery (Ex. 1018)* ¶41. Lowery's Figs. 1-2 demonstrate that the traces are electrically isolated.

Like Lowery, Goldstone discloses electrically conductive traces (insulated first wire portions) attached to the electrodes (second wire portions), where the traces are electrically isolated. *Dec. Lowery (Ex. 1018)* ¶¶42, 60; *See also Sections VI through IX,* which are incorporated here by reference for the teachings of Goldstone.

6. *A connection point connected to or integral with each of the conductive traces, applied directly to the tube surface on the endotracheal tube*

Lowery discloses connection points (conductive compound/circuit) on the tube where the proximal ends of traces (electrode runners) meet external wires. *Lowery (Ex. 1002)* Figs. 1-3B and ¶¶ [0027]-[0028] (describing a connection between electrode runners and external wires using a conductive compound, and also describes a conductive circuit material that forms an electrical connection between the electrode runners and external wires); *Dec. Lowery (Ex. 1018)* ¶44. Fig. 1 of Lowery illustrates electrode runner 48 terminating into the conductive compound/circuit designated as "34". *Dec. Lowery (Ex. 1018)* ¶44.

7. *Electrical leads connected to the connection points, and adapted to connect to monitoring equipment*

Electrical leads are shown by Lowery's Figs. 1-3 and ¶¶ [0002], [0028] (external wires 30 extend from a connection point designated by 34, 70 and 72 on the tube 12 to what is an obvious interface for connecting the wires 30 to monitoring equipment), and are also described by Goldstone. *Dec. Lowery (Ex. 1018)* ¶¶ 57, 58; *See also Sections VI through IX,* which are incorporated here by reference for the teachings of Goldstone.

8. The electrically conductive traces covered by an insulating material along their length from a point adjacent the electrode to which it is attached to a point adjacent the electrical leads.

Lowery indicates that an electrically conductive trace (electrode runner) is insulated with an overlayer. *Lowery (Ex. 1002)* ¶[0034] ("Furthermore, the current electrode runner 48 is covered by a polymeric overlayer applied to the conductive material."); *Dec. Lowery (Ex. 1018)* ¶54. Lowery's Fig. 1 illustrates a length of the insulated, electrically conductive trace (electrode runners) that extends from the electrode (electrode patch) to the connection point (conductive compound/circuit designated as 34). Like Lowery, Goldstone also specifies traces (insulated first wire portions) that are insulated. *Dec. Lowery (Ex. 1018)* ¶55; *See also Sections VI through IX,* which are incorporated here by reference for the teachings of Goldstone.

9. Electrodes, traces and connection points directly on the surface of the endotracheal tube

Lowery describes electrode patches (i.e., the claimed electrode) and electrode runners (i.e., the claimed traces) that may be formed on the tube without any requirement of an underlayer. *Lowery (Ex. 1002)* ¶[0034] (an "electrode" includes an "electrode patch" and an "electrode runner"), ¶[0002] ("electrodes" [i.e., the patches and runners] are "printed on the tube"), and ¶[0034] (the electrode comprising an electrode patch and electrode runner is "located on the outer radius of the curve formed by the tube" such that the "electrode patch of the current electrode 44 [sic] *may* be separated from the tube by the polymeric underlayer" but need not be separated from the tube with the underlayer) (emphasis added), and ¶¶ [0008]-[0010] (the electrodes are disposed "on" the distal portion of the tube; *Dec. Lowery (Ex. 1018)* ¶¶ 38,50. Although Lowery discloses one embodiment in which the electrode runner 48 is "…separated from the tube by a polymeric underlayer that is applied to the tube prior to application of the conductive material" (*Lowery (Ex. 1002)* ¶[0034]), Lowery also discloses other electrode runners 28 that are formed directly on the surface of the tube. *Lowery (Ex. 1002)* ¶[0028] ("the electrode runners 28 are printed *on the tube* 12.") (emphasis added). This disclosure would lead those of ordinary skill to conclude that electrode runner 48 may be formed directly on the tube without an underlayer. *Dec. Lowery (Ex. 1018)* ¶50.

Lowery further demonstrates that the connection points (conductive compound/circuit) are formed on the tube 12. *Dec. Lowery (Ex. 1018)* ¶50. For example, Lowery's FIG. 3A illustrates a flexible support material 72 between the conductive circuit material 70 and the tube 12, but does not limit that flexible support material 72 to non-conductive material, as one of ordinary skill in the art would recognize. Thus, the flexible support material 72 could be made of conductive material that is applied to the tube 12.

Even if the Board determines that Lowery does not clearly disclose forming conductive material for electrodes (electrode patches), traces (electrode runners) and connection points (conductive compound/circuit) directly on Lowery's endotracheal tube instead of on an underlayer, the direct writing technology described by Hutchings would have made it obvious to one of ordinary skill in the art to form the conductive material of the electrodes, traces and connection points directly on Lowery's endotracheal tube. *Dec. Lowery (Ex. 1018)* ¶82; *Dec. Hutchings (Ex. 1010)* ¶23.

Hutchings describes various "direct writing" techniques that "precisely deposit functional and/or structural materials [like Lowery's conductive materials] on to a substrate" where the "topology of the substrate could be flat, curvilinear, round [like a tube], flexible, irregular or inflatable." *Hutchings (Ex. 1005)* p. 601, col. 2, sec. 1; *see also Hutchings (Ex. 1005)* p. 615, col. 1, sec. 8; *Dec. Lowery (Ex. 1018)* ¶¶ 49, 53; *Dec. Hutchings (Ex. 1010)* ¶¶ 14-19.

It 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 electrodes (electrode patches), traces (electrode runners), and connection points (conductive compound/circuit) directly onto curved surfaces like Lowery's endotracheal tube. *Dec. Lowery (Ex. 1018)* ¶82; *Dec. Hutchings (Ex. 1010)* ¶23. Doing so would improve the manufacturing process and functionality of Lowery's endotracheal tube. *Dec. Hutchings (Ex. 1010)* ¶23. One of ordinary skill in the art would have been motivated to combine Hutchings with Lowery in order to achieve various benefits identified by Hutchings in relation to producing medical devices like endotracheal tubes, including lower costs, fewer steps, and less impact on the environment (e.g., by not having to include any underlayer in Lowery). *Hutchings (Ex. 1005)* p. 617, col. 2, sec. 10; *Dec. Lowery (Ex. 1018)* ¶82; *Dec. Hutchings (Ex. 1010)* ¶23.

The motivations for combining Lowery, Goldstone and Hutchings from above also apply to claims 2-3 below.

C. Claim 2: Use of different conductive materials

Claim 2 specifies electrodes, traces and connection points comprising a dry conductive paint or ink.

As described above, Lowery describes electrodes (electrode patches), traces (electrode runners), and connection points that are formed using conductive material. *Lowery (Ex. 1002)* ¶[0034] (an "electrode" includes an "electrode patch" and an "electrode runner"), ¶[0002] ("The electrodes [i.e., the patches and runners] are printed on the tube …."), ¶[0009] ("In certain embodiments … the electrode [i.e., the patches and runners] contains electrically conductive silver particles suspended in a resin and a volatile solvent that forms a polymeric matrix material once cured (such as Creative Materials—CMI 101-59) …."), ¶[0028] (the connection point uses a conductive "compound" or "circuit material" with conductive polymeric material), and Claim 6 ("… the electrode comprises an electrically conductive ink …"); *Dec. Lowery (Ex. 1018)* ¶46.

Lowery indicates that possible conductive materials include conductive ink. *Lowery (Ex. 1002)* ¶[0048] ("As used herein, materials useful as a conductive material include electrically conductive inks … or any other electrically conductive particles such as silver or gold particles that are suspended in a resin and a solvent."); *Dec. Lowery (Ex. 1018)* ¶46.

Like Lowery, Goldstone states that conductive paint may be used for Goldstone's electrodes (second wire portion) and traces (insulated first wire portion). *Dec. Lowery (Ex. 1018)* ¶47; *See also Sections VI through IX,* which are incorporated here by reference for the teachings of Goldstone.

The functional or structural materials of Hutchings include conductive inks or paints. *Hutchings (Ex. 1005)* p. 613, col. 2, sec. 7.2 ("Possible routes to metallic deposits include the direct deposition of liquid metals, printing of metallic particles …."), p. 613, col. 2, sec. 7.2 ("Metallic particles suspended in a suitable fugitive liquid can be printed by inkjet processes, and are used for both structural and electrical applications."), and p. 613, Table 2 (list of metal materials); *Dec. Lowery (Ex. 1018)* ¶¶ 49, 53; *Dec. Hutchings (Ex. 1010)* ¶16.

As discussed in Section V.C.3, dry conductive paint or ink includes paint or ink that is wet when applied, but later dried to leave behind conductive material. Lowery's conductive materials like ink, Goldstone's metal paint, and Hutchings inks are all dry conductive paints or ink.

D. Claim 3: Substantially flush electrodes

Claim 3 specifies that the surfaces of the electrodes are substantially flush with the surface of the tube. As discussed in section V.C.2, "substantially flush" is a thickness up to 25 microns. The ink and paint in Lowery and Goldstone can be any thickness including no more than 25 microns, and Hutchings describes various "substantially flush" heights of electrodes, including 1.3 to 25 microns (µm). *Hutchings.* p. 611, col. 2, sec. 5.2 ("The line … with a height from 1.3 to 250 µm."); *Dec. Lowery (Ex. 1018)* ¶76; *Dec. Hutchings (Ex. 1010)* ¶32.

XI. Claims 4-9 are rendered obvious by Lowery in view of Goldstone and Hutchings under 35 U.S.C. §103

A. Claim 4: Formation of endotracheal tube for laryngeal electromyography

Claim 4 is arguably broader than claim 1 since it includes *fewer* claim limitations than claim 1.[9] Claim 4 includes the following limitations that effectively appear in claim 1: an endotracheal tube that has a retention balloon at a

[9] Notably, claim 4 does *not* specify electrodes positioned to contact the vocal cords or tissue, nerves and muscle in the trachea or the tongue.

distal end thereof; electrodes applied on the surface of the endotracheal tube and located proximal of the retention balloon; electrically conductive traces applied to the surface of the endotracheal tube that are attached to the electrodes; connection points at a proximal end of the traces; and insulating material covering the traces. The analysis in Section X for the above limitations in relation to claim 1, and the motivations for combining Lowery, Goldstone and Hutchings, are incorporated by reference here.

Claim 4 also specifies a method of forming the endotracheal tube. Lowery discloses a method of forming the electrode-bearing endotracheal tube using "conductive material … applied by a positive displacement dispensing system" like a MicroPen® system. *Lowery (Ex. 1002)* ¶¶ [0012]-[0013]; *Dec. Lowery (Ex. 1018)* ¶64. Goldstone also describes a method of forming an endotracheal tube with electrodes and traces using metal paint. *See Sections VI through IX,* which are incorporated here by reference for the teachings of Goldstone.

Claim 4 further specifies that the electrodes, traces and connection points are formed using conductive ink or paint. Formation of these features using ink or paint is discussed in Section X.C above in relation to claim 2, which is incorporated by reference here for claim 4.

Any limitations of claim 4 that do not appear in claim 1 do not affect the motivation to combine Lowery, Goldstone and Hutchings stated above for claim 1.

Thus, Petitioner incorporates by reference those motivations here. Those motivations also apply to claims 5-9 below.

B. Claim 5: Placement of electrodes

Claim 5 specifies a first electrode positioned to contact the vocal cords, and a second electrode positioned to contact nerves and muscle in the rear of the trachea, which are shown in Goldstone. *See Section VII.B* for claim 5*,* which is incorporated here by reference.

C. Claims 6-9: Use of different conductive materials

Claim 6 specifies that conductive ink or paint comprises electrically conductive particles in a liquid carrier, which Hutchings describes. *Hutchings (Ex. 1005)* p. 613, col. 2, sec. 7.2 ("Metallic particles suspended in a suitable fugitive liquid can be printed by inkjet processes"); *Dec. Lowery (Ex. 1018)* ¶71; *Dec. Hutchings (Ex. 1010)* ¶¶ 16, 28; *Dec. Goldstone (Ex. 1011) ¶*67.

Claims 7 and 8 specify that the electrically conductive particles comprise finely divided particles or flakes of elemental silver (Ag), silver salt (silver nitrate), gold (Au), copper (Cu), *or* platinum (Pt) (among other alternatives), which Hutchings describes. *Hutchings (Ex. 1005)* p. 613, Table 2 and p. 614, col. 1; *Dec. Lowery (Ex. 1018)* ¶72; *Dec. Hutchings (Ex. 1010)* ¶¶ 16, 29; *Dec. Goldstone (Ex. 1011) ¶*68.

Claim 9 specifies that conductive particles comprise at least 60% of the ink, which Hutchings describes. *Hutchings (Ex. 1005)* p. 614, col. 2, sec. 7.3 ("As an example, … deposit a silver ink which contained 57–62 wt.% of Ag [silver] nanoparticles."); *Dec. Lowery (Ex. 1018)* ¶73; *Dec. Hutchings (Ex. 1010)* ¶30; *Dec. Goldstone (Ex. 1011) ¶*69.

XII. Claims 10-13 are rendered obvious by Lowery in view of Goldstone and Hutchings under 35 U.S.C. §103

A. Claim 10: A method for monitoring electrical signals during laryngeal electromyography

Claim 10 includes the following limitations that effectively appear in claim 1 and/or 4: an endotracheal tube that has a retention balloon at a distal end thereof; electrodes located proximal of the balloon, and applied on the surface of the endotracheal tube without the inclusion of a carrier film; electrically conductive traces connected to or integral with the electrodes, applied to the tube surface and extending along the length of the endotracheal tube from the electrodes to a proximal portion of the tube; connection points connected to or integral with the traces, and applied to the tube surface; electrical leads connected to the connection points; insulating material covering the traces; the electrodes, traces and connection points comprise a conductive paint or ink; and an electrode that contacts the vocal cords. The analysis in Sections X-XI for the above limitations in relation to claims 1 and 4, and the motivations for combining Lowery, Goldstone and Hutchings, are incorporated by reference here.

Claim 10 also recites monitoring electrical signals with at least one electrode, recites that electrical signals are monitored during laryngeal electromyography for a period of time in excess of 8 hours without injury to the trachea (in the preamble, which is not limiting), and recites that the monitored electrical signals do not show a detrimental reduction in the quality thereof during the period of monitoring, which are described by Goldstone. *See Section VIII,* which is incorporated here by reference for the teachings of Goldstone.

Any limitations of claim 10 that do not appear in claims 1 and 4 do not affect the motivation to combine Lowery, Goldstone and Hutchings stated above for claims 1 and 4. Thus, Petitioner incorporates by reference those motivations here. Those motivations also apply to claims 11-13 below.

B. Claim 11 and 13: Period of monitoring

Claims 11 and 13 specify a monitoring period in excess of 24 hours. Goldstone's endotracheal tube can monitor signals for a period in excess of 24 hours. *See Section VIII*, which is incorporated here by reference for the teachings of Goldstone.

C. Claim 12: Placement of electrodes

Claim 12 specifies a first electrode positioned to contact the vocal cords, and a second electrode positioned to contact tissue, nerves and muscle in the rear of the trachea, which are shown in Goldstone. *See Section VIII.C* for claim 12, which is incorporated here by reference.

XIII. Claims 14-19 are rendered obvious by Lowery in view of Goldstone and Hutchings under 35 U.S.C. §103

A. Claim 14: A device for monitoring electrical signals during laryngeal electromyography

Claim 14 includes the following limitations that appear in claim 1, 4 and/or 10: an endotracheal tube that has a retention balloon at a distal end thereof; electrodes located proximal of the balloon, electrically isolated from each other, and applied on the surface of the endotracheal tube without the inclusion of a carrier film; an electrode positioned to contact the vocal cords; electrically conductive traces connected to or integral with the electrodes, applied to the tube surface, electrically isolated from each other, and extending along the length of the endotracheal tube from the electrodes to a proximal portion of the tube; optional connection points connected to or integral with the traces, and applied to the tube surface; electrical leads configured to connect to monitoring equipment, and optionally connected to the connection points; and insulating material covering the traces. The analysis above in Sections X-XII for these limitations in relation to claims 1, 4 and 10, and the motivations for combining Lowery, Goldstone and Hutchings, are incorporated by reference here.

Claim 14 also indicates that the electrical leads are optionally connected to the traces, which is illustrated in Fig. 1 of Lowery (trace 48 meets wires 30 at point of connection 34) and Fig. 1 of Goldstone (wires 16A-D exit the tube from the traces 42). *See also Section IX,* which are incorporated here by reference for the teachings of Goldstone.

The above limitations of claim 14 that do not appear in claims 1, 4 and 10 do not affect the motivation to combine Lowery, Goldstone and Hutchings stated above for claims 1, 4 and 10. Thus, Petitioner incorporates by reference those motivations here. Those motivations also apply to claims 15-19 below.

B. Claims 15-16: Conductive material

Claim 15 specifies that the electrically conductive electrodes and traces comprise a conductive paint or ink. Use of conductive ink or paint for electrodes and traces is discussed in Sections X and XI above in relation to claims 2 and 4, which are incorporated by reference here for claim 15. *See also Dec. Lowery (Ex. 1018)* ¶74. Claim 16 specifies that the conductive paint or ink is dried and free of a liquid carrier. As discussed in Section V.C.3, dried conductive paint or ink includes paint or ink that is wet when applied, but later dried to leave behind conductive material. The paints and inks in Lowery, Goldstone and Hutchings are dried conductive paints or inks discussed in Sections X and XI above in relation to claims 2 and 4, which are incorporated by reference here for claim 16. *See also Dec. Lowery (Ex. 1018)* ¶75.

C. Claim 17: Substantially flush electrodes

Claim 17 specifies that the surfaces of the electrodes are substantially flush with the surface of the tube. This is discussed in relation to claim 3 above in Section X.D, which is incorporated by reference here for claim 17.

D. Claims 18-19: Position of electrodes

Claim 18 specifies a first electrode and a second electrode that are located a predetermined distance proximal of the balloon, which is shown in Fig. 1 of Lowery and Fig. 1 of Goldstone. *Dec. Lowery (Ex. 1018)* ¶77; *See also Section IX,* which is incorporated here by reference for the teachings of Goldstone. Claim 18 also specifies that the first and second electrodes are electrically isolated from each other, and that the first electrode is positioned to contact the vocal cords. Since these limitations appear in claims 1 and 14, the arguments in Sections X and XIII.A made for claims 1 and 14 in relation this limitation are incorporated here. *Dec. Lowery (Ex. 1018)* ¶77.

Claim 19 specifies that a first electrode is on a posterior surface of the endotracheal tube and a second electrode is anterior thereto, which is described in

Goldstone. *Dec. Lowery (Ex. 1018)* ¶78; *See also Section IX,* which is incorporated here by reference for the teachings of Goldstone.

XIV. Conclusion

As demonstrated above, the different combinations of prior art references identified in this petition disclose each limitation of claims 1-19. Thus, there is a reasonable likelihood that the petitioner would prevail with respect to at least one of claims 1-19, and Petitioner therefore requests that the Board institute a trial and that it cancel claims 1-19 of the ’894 patent as unpatentable for each reason stated in this Petition.

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