IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CORPAK MEDSYSTEMS, INC. and HALYARD HEALTH, INC,
Petitioners

v.

KIRN MEDICAL DESIGN, L.L.C. and APPLIED MEDICAL TECHNOLOGY, INC.,
Patent Owner.[1]

U.S. Patent No. 6,631,715 to Kirn

Inter Partes Review No.: IPR2017-01990

Petition for *Inter Partes* Review of U.S. Patent No. 6,631,715 Under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42

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Patent Trial and Appeal Board
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[1] Petitioners note that Applied Medical Technology, Inc. is the exclusive licensee of the '715 patent. Additional details are provided *infra* fn. 2.

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I. INTRODUCTION

Corpak Medsystems, Inc. and Halyard Health, Inc. (collectively "Petitioners") petition for *Inter Partes* Review ("IPR") seeking cancellation of Claim 18 ("challenged claim") of U.S. Patent No. 6,631,715 to Kirn ("the '715 patent") (EX1001), which, according to the current records of the USPTO, is assigned to Applied Medical Technology, Inc. ("AMT" or "Exclusive Licensee").[2]

II. OVERVIEW

A. The '715 patent

The '715 patent issued on October 14, 2003 from U.S. Appl. No. 09/939,399 ("the '399 application"), which was filed on August 24, 2001. EX1001, *see*

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[2] Petitioners note that AMT is the exclusive licensee of the '715 patent and in prior IPR proceedings Kirn Medical Design, L.L.C. ("Kirn" or "Patent Owner") confirmed AMT's authority to conduct *Inter Partes* Review. EX1012 at 4, *Corpak Medsystems, Inc. et al., v. Kirn Medical Design, L.L.C.*, IPR2017-00646 (Exclusive Licensee Applied Medical Technology, Inc.'s Mandatory Notices Pursuant to 37 C.F.R. § 42.8(a)(2), Paper 5) (February 7, 2017).

EX1004 at ¶ 33.[3] The '715 patent has thirty-two claims. *See* EX1004 at ¶ 34. This petition for *Inter Partes* Review, however, is directed only to a single claim, Claim 18, the text of which is reproduced below:

> 18. A method of placing and securing at least one tube through a nose into a patient comprising:
>
> inserting the at least one tube into a first or second nare of the nose;
>
> inserting an end portion of a flexible member having a magnet attached thereto into a first nare of the nose;
>
> inserting a magnetic probe into a second nare of the nose for attracting said magnet and said end portion of said flexible member;
>
> removing said probe from the second nare of the nose thereby retrieving said end portion of said flexible member through the second nare of the nose; and
>
> snapping the at least one tube into a channel formed in a receiver.

EX1001 at Claim 18; *see also* EX1004 at ¶ 36.

Claim 18 is generally directed to a method of placing a first tube with a magnetic element into one of the nasal passages of the patient (referred to in the claim as a "nare"), retrieving the first tube through the second nasal passage by

[3] The '399 application claims priority to U.S. Provisional Application No. 60/230,525, which was filed on September 1, 2000. *Id.*

placing a second tube with a corresponding magnetic element into the second nasal passage to magnetically mate with the magnetic element on the first tube, and then guiding the first tube out through the second nasal passage. EX1004 at ¶ 35. In addition, Claim 18 recites "snapping the at least one tube into a channel formed in a receiver," which as the Board has explained means, "that snapping occurs with respect to a tube and a channel, based on the express language…" EX1013, *Corpak Medsystems, Inc. et al., v. Kirn Medical Design, L.L.C.*, IPR2017-00646, Paper 9 at 8 (Decision).[4]

The medical device to which the method of Claim 18 is directed is generally known as a "nasal bridle system."[5] *Id.* Applications of such medical devices include uses as feeding tubes, nasogastric tubes, and nasotracheal tubes. EX1001

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[4] Petitioners previously filed a petition requesting institution of an IPR of Claim 18 of the '715 patent. EX1014. The Board's prior decision is discussed in more detail, *infra,* at Section VI.C.

[5] Petitioners note that Claim 18 purportedly covers any "method of placing and securing at least one tube through a nose into a patient . . . ," and therefore covers any device that performs the recited method, and is not limited to any particular device.

at 1:15-18; EX1002 at 1:5-18 (U.S. Patent No. 5,185,005 to Ballantyne, referred to hereinafter as "Ballantyne"); EX1003, Jeffrey A. Meer, *A New Nasal Bridle for Securing Nasoentereal Feeding Tubes*, 13 J. Parenteral & Enteral Nutrition, 331, 331-33 (1989); *see also* EX1004 at ¶ 27.

Claim 18, however, is rendered obvious by the prior art. EX1004 at ¶ 126. Indeed, even the patentee admitted in the '715 specification that Ballantyne discloses most of the elements of Claim 18:

> One such method disclosed in U.S. Pat. No. 5,185,005 to Ballantyne requires a bridle which is pulled into a nare of a patient's nose, around the posterior nasal septum, and out the other nare by a cord attached to the bridle and an insertion tool. Specifically, first and second installation tools are inserted into the nares of the patient's nose. Magnets associated with each tool couple together behind the posterior nasal septum.

EX1001 at 1:15-32; *see also* EX1004 at ¶ 60. *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1570 (Fed. Cir. 1988) (holding that an applicant's admissions regarding prior art are binding); *In re Fout*, 675 F.2d 297, 300, (C.C.P.A. 1982) ("Valid prior art may be created by the admissions of the parties.").

Indeed, in its preliminary response to the earlier petition for *Inter Partes* Review (IPR2017-00646), AMT did not dispute that Ballantyne taught all but one element of Claim 18; AMT contested only that Ballantyne did not teach "snapping the at least one tube into a channel formed in a receiver." EX1015 *Corpak Medsystems*, IPR2017-00646, Paper 7 at 1 (Preliminary Response). The Board agreed with AMT based on the art submitted and AMT's proposed construction of this term and declined to institute IPR2017-00646. EX1013 at 14, 21.

The current petition is not redundant of the prior IPR petition, and although this petition cites Ballantyne as a reference, it presents different combinations of references, grounds and arguments to demonstrate that a claim that recites "snapping the at least one tube into a channel formed in a receiver" would have been obvious. *Valeo N.A. Inc. et al. v. Magna Electronics, Inc.*, IPR2014-01206, Paper 13, at 11 (P.T.A.B. Decision Granting Institution, Dec. 23, 2014) ("We are not persuaded that the art and arguments presented in this Petition are the same or substantially the same prior art or arguments previously presented to the Office. For example, none of the grounds of unpatentability in this Petition rely upon exactly the same combination of prior art as the grounds of unpatentability asserted against the same claims in the 227 IPR."); *see also Nestle USA, Inc., v. Steuben Foods, Inc*., IPR2014-01235, Paper 12 at 7 (P.T.A.B., Decision Granting Institution, Dec. 22, 2014) (declining to deny petition under § 325(d) where

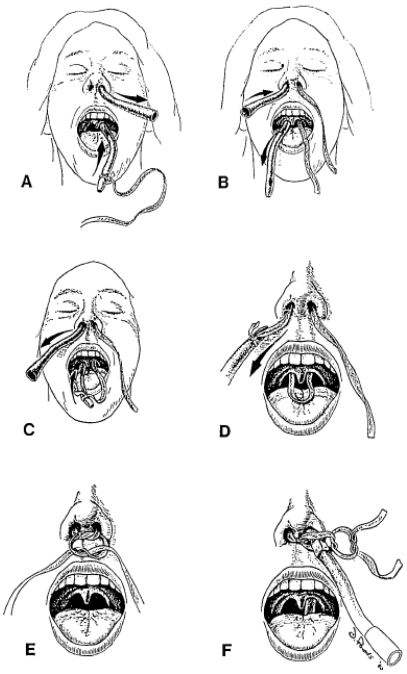
petition relied on "combination of references previously not considered and [was] supported by a declaration previously not considered"); *Facebook, Inc. v. TLI Commc'ns, LLC*, IPR2015-00778 Paper 17, at 19 (P.T.A.B., Decision Granting Institution, Aug. 28, 2015) ("We have compared the prior art and arguments presented by Petitioner in IPR2014-00566, and by Google Inc. in IPR2015-00283, with the prior art and arguments presented by Petitioner in this proceeding, and do not determine that the prior art and arguments presented in either IPR2014-00566 or IPR2015-00283 are the same or substantially the same as the prior art and arguments presented by Petitioner in this proceeding. The fact that there is overlap in some respect does not mean the prior art as a whole or the arguments as a whole are the same or substantially the same."); *Oxford Nanopore Tech. Ltd. v. Univ. of Washington*, IPR2015-00057, Paper 28, at 21 (P.T.A.B., Decision Granting Institution, April 27, 2015) ("Moreover, as to the challenge to claim 10 based on the '782 patent and Butler, Petitioner has not presented substantially the same arguments as presented in the '512 Petition, as shown by our determination to institute a trial in relation to this ground and claim here, in contrast with our prior decision not to institute a trial based on the '512 Petition."). Accordingly, Petitioners request that its petition be granted and that Claim 18 of the '715 patent be cancelled.

B. Background of Nasal Bridles

Nasal bridles are nothing new, and, in fact, have been used in the medical care field since at least 1980 to prevent accidental dislodgement of a nasogastric tube. Jeffrey A. Meer, *A New Nasal Bridle for Securing Nasoentereal Feeding Tubes*, 13 J. Parenteral & Enteral Nutrition, 331, 331 (1989) (EX1003); *see also* EX1004 at ¶¶ 26-29. Nasogastric tubes are commonly used to deliver medication and/or nutrition to hospitalized patients. *Id*. As Meer explained, dislodgement of nasogastric tubes was common, occurring in as much as one half of patients. *Id.* Dislodgement resulted in many problems such as delayed feeding, increased risk of aspiration, expenditure of health care professionals' time, and increased hospital stay time. *Id.* Indeed, the earliest designs of nasal bridles were difficult to install, and thus health care professionals opted for alternative, albeit lesser, means for securing feeding tubes. *Id.*

As originally described, a nasal bridle was "a length of material looped around the patient's nasal septum and then secured to the feeding tube." W. Frederick McGuirt, *Securing of intermediate duration feeding tubes*, 90 Laryngoscope, 2046-2048 (1980) (EX1005); *see also* EX1004 at ¶¶ 26-29. One of the earliest methods of installing the nasal bridle involved inserting a flexible tube into the nare (used interchangeably with "nostril" herein) of a patient, extracting the tube from the patient's mouth, tying umbilical tape to the catheter, and then

removing the catheter from the nostril in order to pull the tape through the nostril. *Id.* The catheter is then passed through the other nare and umbilical tape introduced into the patient's nasal cavity in the same, aforementioned manner. *Id.* The below figures provide an illustration of the installation of this type of nasal bridle. *Id.*



Additional references disclose the installation of a nasal bridle by introducing the bridle into the patient's nares, extracting the bridle from the patient's mouth, and forming the bridle into a loop ultimately positioned behind the patient's nasal septum. EX1006, Albert Barrocas, *The bridle: increasing the use of nasoenteric feedings*. 2 Nutritional Support Servs., 8, 8-10 (1982); EX1003 at

331-33; EX1010, Albert Levenson, *Feeding Tube Anchor*, 5 Nutritional Support Servs. 8, 40, 42 (1985); *see also* EX1004 at ¶¶ 26-29.

III. STANDING (37 C.F.R. § 41.104(A)); PROCEDURAL STATEMENTS

Petitioners certify that: (1) the '715 patent is available for IPR; and (2) the Petitioners are not barred or estopped from requesting IPR of any claim of the '715 patent on the grounds identified herein. This Petition is filed in accordance with 37 C.F.R. § 42.106(a). Concurrently filed herewith are a Power of Attorney for each Petitioner and an Exhibit List pursuant to § 42.10(b) and § 42.63(e), respectively. The required fee is paid through an online credit card, and the office is authorized to charge any fee deficiencies and credit any overpayments to Deposit Acct. No. 160605 (Customer ID No. 00826).

IV. MANDATORY NOTICES (37 C.F.R. § 42.8(A)(1))

A. Each Real Party-in-Interest (37 C.F.R. § 42.8(b)(1))

The real parties in interest are Halyard Health, Inc., Medsystems Holdings, Inc., Corpak Medsystems, Inc., and Halyard Sales, LLC.

B. Notice of Related Matters (37 C.F.R. § 42.8(b)(2))

1. Judicial Matters

The '715 patent is currently the subject of the litigation styled *Applied Medical Technology, Inc. v. Corpak Medsystems, Inc.*, 1:16-cv-02190 (N.D. Ohio).

2. Administrative Matters

The Public Patent Application Information Retrieval ("Public PAIR") system indicates that the '715 patent issued from the '399 application, which claims priority to Provisional U.S. Application No. 60/230,535, which was filed on September 1, 2000. Public PAIR also indicates that U.S. Patent No. 6,837,237, which issued January 4, 2005, also claims priority to the aforementioned '399 application. The '715 was previously challenged on other grounds in *Corpak Medsystems,* and the Board denied institution. EX1013.

C. Designation of Lead and Back-Up Counsel (37 C.F.R. § 42.8(b)(3))

Lead counsel is Richard M. McDermott (Reg. No. 40,720) and back-up counsel are Jitendra Malik Ph.D. (Reg. No. 55,823) and Alissa M. Pacchioli (Reg. No. 74,252). Please direct all correspondence to lead counsel at the following address: 101 S. Tryon St, Ste 4000, Charlotte, NC 28280; telephone 704-444-1000. Pursuant to 37 C.F.R. § 42.10(b), Powers of Attorney are being submitted with this Petition. Petitioners consent to email service at: rick.mcdermott@alston.com, jitty.malik@alston.com, and alissa.pacchioli@alston.com. 37 C.F.R. § 42.8(b)(4).

V. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR (37 C.F.R. § 42.22(a))

Petitioners request institution of an IPR and cancellation of Claim 18. Petitioners' full statement of the reasons for the relief requested is set forth in detail below.

VI. THE '715 PATENT AND CLAIM CONSTRUCTION

A. The '715 Patent

The specification of the '715 patent is allegedly directed to "systems for placing and securing a nasal tube; and more particularly to such a system which utilizes magnets in the placement of a bridle used in combination with a receiver to secure the nasal tube." EX1001 at 1:8-12; *see also* EX1004 at ¶ 34. In other words, the '715 patent's specification purports to describe an apparatus and corresponding method for use in "placing and securing at least one nasal tube in a patient." EX1001 at 2:21-32; *see also* EX1004 at ¶ 34.

The apparatus described in the specification of the '715 patent is straightforward: It consists of a "flexible member" with a magnet secured at one end, another instrument consisting of a "magnetic probe," and a "receiver." *Id.*; *see also* EX1004 at ¶ 35. Similarly, the method disclosed in the '715 patent is as straightforward as the disclosed apparatus. *Id.* The method described in the specification requires insertion of the magnetic end of the flexible member into one

nostril and insertion of the magnetic probe into the second nostril so that the magnets mate. EX1001 at 6:30-46; *see also* EX1004 at ¶ 35. Once the magnets have mated, the magnetic probe is withdrawn from the second nostril and the flexible member is pulled "into the first nare and out through the second nare" and thus "looped around the nasal septum." EX1001 at 6:61-66; *see also* EX1004 at ¶ 35. The magnetic probe and the flexible member are then separated and the end portions of the flexible member and nasal tube are secured in a receiver. EX1001 at 7:1-14; *see also* EX1004 at ¶ 35.

Claim 18 recites elements directed to the aforementioned method, which mirrors the disclosure of Ballantyne and adds "snapping the at least one tube into a channel formed in a receiver." EX1001 at Claim 18; *see also* EX1004 at ¶ 36.[6] As explained in further detail below, in the previous petition for IPR, the Board explained that "snapping the at least one tube into a channel formed in a receiver,"

[6] The preamble to Claim 18 includes the transition term "comprising." EX1001 at Claim 18; *see also* EX1004 at ¶ 37. This means that "other elements may be added and still form a construct within the scope of the claim." *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997) (internal quotations and citations omitted).

means "that snapping occurs with respect to a tube and a channel, based on the express language…" EX1013 at 8.

B. The Priority Date of the '715 Patent

The '715 patent issued from the '399 application, which was filed on August 24, 2001. EX1001. The face of the '715 patent claims priority to U.S. Prov. Appl. No. 60/230,535, which was filed on September 1, 2000. *Id.* AMT, however, has stated in the related patent litigation involving Petitioner Corpak Medsystems, Inc. that Claim 18 of the '715 patent is entitled to priority only to August 24, 2001, the filing date of the '399 application. EX1009, Patent Owner's Initial Infringement Contentions at 2; *see also* EX1004 at ¶ 33. In any event, as described below, whether the correct priority date is September 1, 2000 or August 24, 2001, all of the references relied upon by Petitioners qualify as prior art under 35 U.S.C. §102(b) (pre-AIA). EX1004 at ¶ 33.

C. Board's Prior Decision

Petitioners previously filed a petition requesting institution of an IPR of Claim 18 of the '715 patent. EX1014. The Board denied institution of the IPR. EX1013. The Board's decision focused on Claim 18's recitation of "snapping the at least one tube into a channel formed in a receiver." The Board found that Ballantyne did not disclose snapping a tube into a channel. EX1013 at 16. For the same reasons, the Board held that the prior petition did not establish a reasonable

likelihood that Claim 18 is obvious in light of Ballantyne, Ballantyne and the ’448 patent, or Ballantyne and the ’199 and ’538 patents. EX1013 at 18-21.

D. Claim Construction

In an *inter partes* review, the Board generally interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b). In the view of the Petitioners and their expert, Dr. Layton, the limitations of Claim 18 should be given their broadest reasonable interpretation in light of the specification of the ’715 patent. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2144-46 (2016); *see also* EX1004 at ¶ 23. In other words, the claim terms should be given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention, in the context of the entire patent disclosure. *In re Translogic Tech., Inc*., 504 F.3d 1249, 1257 (Fed. Cir. 2007); EX1004 at ¶ 23. As discussed *supra*, the previously filed petition for IPR was denied and the Board explained that “snapping the at least one tube into a channel formed in a receiver,” as recited by claim 18 means “that snapping occurs with respect to a

tube and a channel, based on the express language…" EX1013 at 8. Petitioners apply the same construction herein.

VII. PERSON OF ORDINARY SKILL IN THE ART ("POSA") AND STATE OF THE ART

A POSA is a hypothetical person who is presumed to be aware of all pertinent art, thinks along conventional wisdom in the art, and is a person of ordinary creativity. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 420 (2007); *see also* EX1004 at ¶ 30-32. A POSA of the '715 patent would have had education and/or experience in the biological sciences, engineering, medical device manufacturing, and/or design along with knowledge of the scientific literature in the field. EX1004 at ¶¶ 30-32. Although education and experience levels may vary, a POSA would have had at least a bachelor's degree in biology, bioengineering, biomedical engineering, zoology or equivalent. *Id.*

A POSA also would have had work experience in the field of medical devices including several years of experience designing fluid administration and/or fluid collection devices and the attachment mechanisms for the devices including experience with devices used in nasogastric/nasoenteric intubation and corresponding attachment systems. EX1004 at ¶¶ 30-32. A person holding only a bachelor's degree would be required to have had five years of relevant work experience to qualify as a POSA, but a person with a more advanced degree, such

as a Master of Science, could qualify as a POSA with fewer years of experience. *Id.*

Petitioners note that in the prior IPR proceeding, exclusive licensee AMT did not dispute, *and in fact adopted*, Petitioners' definition of a person of ordinary skill in the art. EX1015, (Preliminary Response) at 5 (P.T.A.B. April 28, 2017). The Board also adopted this definition. EX1013 at 9.

VIII. IDENTIFICATION OF THE CHALLENGE (37 C.F.R. § 42.104(B))

Institution of IPR of Claim 18 of the '715 patent is respectfully requested on the grounds of unpatentability listed below. Per 37 C.F.R. § 42.6(d), copies of the references are filed herewith. In support of the proposed grounds for unpatentability, this Petition includes the declaration of a technical expert, Dr. Terry Layton (EX1004), explaining what the art would have conveyed to a POSA as of the priority date. Dr. Layton has offered a declaration from the perspective of a POSA as of the priority date.

Reference(s)	Basis	Claim Challenged
U.S. Patent No. 5,185,005 (EX1002) in view of U.S. Patent No. 5,752,511 (EX1007)	§ 103	18
U.S. Patent No. 5,185,005 (EX1002) in view of U.S. Patent No. 5,097,827 (EX1008)	§ 103	18
U.S. Patent No. 5,185,005 (EX1002) in view of U.S. Patent No. 5,752,511 (EX1007) and WO 99/20334 (EX1011)	§ 103	18

Other prior art references, in addition to the primary references listed above, provide further background in the art, further motivation to combine the teachings of the primary references, and/or further support for why a POSA would have a reasonable expectation of success in combining the teachings of the primary references to arrive at the method described in Claim 18. *See* EX1004 at ¶¶ 26-29.

IX. INVALIDITY ANALYSIS

The controlling inquiry for obviousness was established by the Supreme Court in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966). The *Graham* factors require an examination of: (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) consideration of secondary considerations of non-obviousness.[7] *See* EX1004 at ¶¶ 15-18. The obviousness analysis "need not seek out precise teachings to the specific subject matter of the challenged claim, for a court can take account of inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418; *see Translogic*, 504 F.3d at 1259.

[7] Objective indicia are discussed in Section IX.F. *Infra*.

A. The Level of Ordinary Skill in the Pertinent Art

The POSA is defined above. *Supra* Section VII. The POSA, the center of the obviousness inquiry, possesses the creativity and ability to make inferences as would be expected of a person with the requisite background and knowledge. *KSR*, 550 U.S. at 418.

B. The Scope and Content of the Prior Art

Graham's "scope and content of the prior art" requirement not only focuses on the disclosure of the prior art, but also serves to provide an understanding of the state of the art that the POSA would find themselves in as of the priority date. *See Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d 1338, 1340 (Fed. Cir. 2010).

1. State of the Art

a) Ballantyne

Ballantyne, entitled "Method and Apparatus for Securing a Nasogastric Tube," was filed on June 4, 1991 and issued on February 9, 1993.[8] *Id.* at ¶ 43.

[8] Ballantyne was disclosed to the PTO during prosecution of the '715 patent but it was not cited in an Office Action or referred to during prosecution. EX1001 (showing Ballantyne in the "References Cited" on the face of the patent, but not showing any asterisk notation indicating that the examiner relied upon the

reference). *Husky Injection Molding Systems, Ltd. v. Plastic Engineering & Technical Services, Inc*., No. IPR2016-00432, slip op. 6-7 (P.T.A.B. June 24, 2016) (Paper 10) ("Patent Owner has not demonstrated that this particular combination of references, as formulated by the Petitioner, was ever considered by the Examiner"). Moreover, the fact a reference was disclosed to the Examiner is not a bar to institution of an IPR. *See Praxair Distribution, Inc. v. Ino Therapeautics, LLC*, IPR2015-00893 (Institution Decision, Paper 14) at pp. 7-8 (Sept. 22, 2015); *Praxair Distribution, Inc. v. Ino Therapeautics, LLC*, IPR2015-00889 (Institution Decision, Paper 14) at pp. 9-10 (Sept. 22, 2015); *Microsoft Corp. v. Parallel Networks Licensing, LLC*, IPR2015-00483 (Institution Decision, Paper 10) at p. 15 (July 15, 2015); *Microsoft Corp. v. Parallel Networks Licensing, LLC*, IPR2015-00486 (Institution Decision, Paper 10) at p. 15 (July 15, 2015); *Int'l Business Machines Corp. v. Intellectual Ventures I LLC*, IPR2015-00302 (Institution Decision, Paper 8) at pp. 14-15 (June 2, 2015); *Cisco Sys., Inc., et al. v. Crossroads Sys., Inc.*, IPR2014-01544 (Institution Decision, Paper 9) at pp. 13-14 (April 3, 2015).

Accordingly, Ballantyne qualifies as a prior art reference to the ’715 patent under 35 U.S.C. § 102(b) (pre-AIA). *See* EX1004 at ¶ 43.

The Board and the skilled artisan need go no further than the Abstract of Ballantyne to see the similarities between Ballantyne and Claim 18 of the ’715 patent:

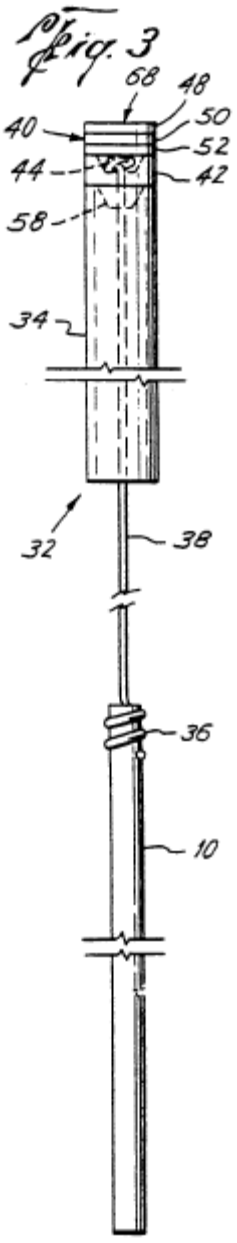
> A nasogastric tube anchor, and a method of its use employing a bridle which passes through the patient's nostrils and nasopharynx, the ends of the bridle being fastened to a nasogastric tube exterior to the patient's nose to anchor said tube against undesired movement relative to the patient's nostril. Installation tools and methods are provided for positioning said bridle within the patient's nose such that one end of the bridle extends from each nostril.

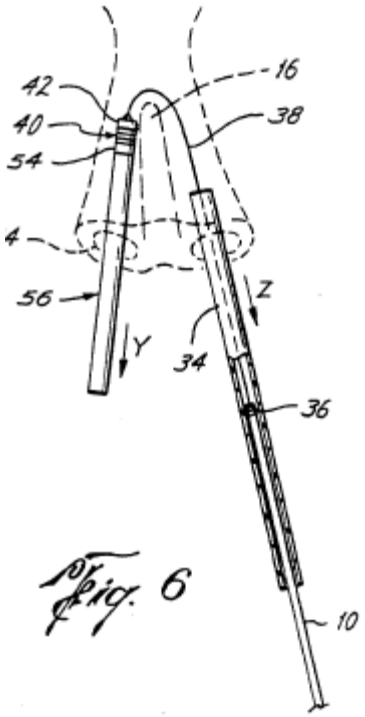
EX1002 at Abstract; *see also* EX1004 at ¶ 44.

Much like Claim 18 of the ’715 patent, Ballantyne teaches a method for anchoring a nasogastric tube by inserting a nasal bridle into one nostril, through the nasopharynx and beyond the nasal septum, and drawing the tube out of the other nostril. EX1002, Abstract and 2:20-32; *see also* EX1004 at ¶¶ 44-45. Figure 2 of Ballantyne, reproduced below, further illustrates the teachings of Ballantyne:

EX1002 at Fig. 2; EX1004 at ¶ 45.

Ballantyne describes the method of placing its bridle devices in the nasal passages by primarily referring to Figures 3 and 6 (reproduced below):





EX1002 at Figs. 3, 6; EX1004 at ¶¶ 46-47.

In reference to these figures, "[f]irst installation tool 34 comprises an adequately rigid tube sized to be slidable over bridle member 10, yet narrow enough to be easily insertable into a nostril such that the distal end 68 of first installation assembly 32 resides within the nasopharynx beyond the posterior nasal septum." EX1002 at 5:63-6:1; EX1004 at ¶ 47. Ballantyne further teaches that:

> Referring to FIGS. 3 and 4, in a preferred embodiment, bridle 10 is installed in a patient's nose by a method comprising *inserting the distal end 68 of first installation assembly 32 into a first nostril* of the patient until magnetic member 40 is positioned beyond the posterior nasal septum. *The distal end 66 of second installation assembly 56 is then inserted into a second nostril* of the patient until magnet 54 is beyond the posterior nasal septum, in close proximity to magnetic member 40. When this configuration is achieved, pulling cord 38 extending from the proximal end of first installation tool 34 is released, allowing magnetic member 40 to be pulled by magnetic force toward and to couple with magnet 54. *At this point the two magnets, 40 and 54, are coupled together by magnetic force.*

EX1002 at 7:14-32 (emphasis added); *see also* EX1004 at ¶¶ 48. Thus, Ballantyne teaches the use of magnetic elements that are "coupled together." *Id.*

To complete placement of its bridle devices, Ballantyne explains that:

> Referring to FIG. 6, first installation tool 34 is withdrawn in direction Z from the nostril, while pulling cord 38 and bridle 10 are allowed to slide through tool 34 as it is withdrawn. Tool 34 is slidably removed over cord 38 and bridle 10 until it is entirely separated from cord 38 and bridle 10. Second installation tool 56 is then withdrawn from the second nostril in direction Y, pulling with it magnetic member 40 with the leading end of pulling cord 38 attached thereto. As second installation tool 56 and the leading end of pulling cord 38 are withdrawn from the second nostril, the trailing end of pulling cord 38 and the leading end of bridle 10 enter the first nostril. When second installation tool 56 is entirely removed from the second nostril, pulling cord 38 can be grasped and bridle 10 pulled into its proper position by exertion of tension on pulling cord 38, pulling the leading end of bridle 10 into the first nostril, around the posterior nasal septum, and down through the second nostril until it passes out of the nasal opening.

EX1002 at 7:32-51; *see also* EX1004 at ¶ 49.

Ballantyne also describes an "alternative[]" system for placement of the bridle device, which involves leaving the installation tool 34 in place after the magnets have been coupled:

> Alternatively, first installation tool 34 can be left in place in the nostril, or partially withdrawn, after the magnets have coupled, while second installation tool 56 and pulling cord 38 are pulled from the second nostril to draw bridle 10 into first installation tool 34, around the posterior nasal septum, and further into its operative position with the leading end of bridle 10 external to the second nostril. First installation tool 34 is then removed from the nostril, while the portion of bridle 10 remaining inside said tool slides relative to said tool and retains its position in the nose. In this way first installation tool 34 may operate to shield nasal tissues from abrasion and irritation while bridle 10 is pulled into position.

EX1002 at 7:52-64; *see also* EX1004 at ¶ 50.

b) Simmons

U.S. Patent No. 5,752,511 ("Simmons"), entitled "Universal Medical Tube Retainer and Nasal Wall Tissue Dilator," was filed on November 22, 1996 and

issued on May 19, 1998.[9] *See* EX1007; EX1004 at ¶ 53. Accordingly, Simmons qualifies as a prior art reference to the '715 patent under 35 U.S.C. § 102(b) (pre-AIA). *See* EX1004 at ¶ 53.

Simmons teaches medical devices designed to retain medical tubing. EX1007 at 1:13-15. Simmons teaches the problems with then existing strategies for placing and holding such tubing:

> In addition, without any means to hold the tubing stable it is easy for normal patient movement to disturb or dislodge such tubing. Nasogastric and feeding tubes are commonly held in place by the subjective placement of adhesive medical tape strips to one side of the patient's face. As such, effectiveness of application is left to the skill of the medical attendant, and can interfere with patient comfort and contradict the presence of oxygen cannula.

EX1007 at 1:29:36; EX1004 at ¶ 54.

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[9] Simmons was not disclosed to the PTO during prosecution of the '715 patent or cited in an Office Action or referred to during prosecution. Simmons was not cited in Petitioners' earlier petition for *Inter Partes* Review (IPR2017-00646).

In fact, Simmons expressly discusses Ballantyne and the design deficiencies of Ballantyne, including its anchoring clip:

> U.S. Pat. No. 5,185,005 to Ballantyne, 2/9/93 … appears to effectively prevent other treatments requiring nasally inserted tubing or oxygen by occupying the nasal passages with hardware for the apparatus *and placing an anchoring clip across the breadth of the nasal passages when in use*.

EX1007 at 2:11-20 (emphasis added); EX1004 at ¶ 55.

Simmons solves these deficiencies through use of a retainer depicted by Figure 7B:

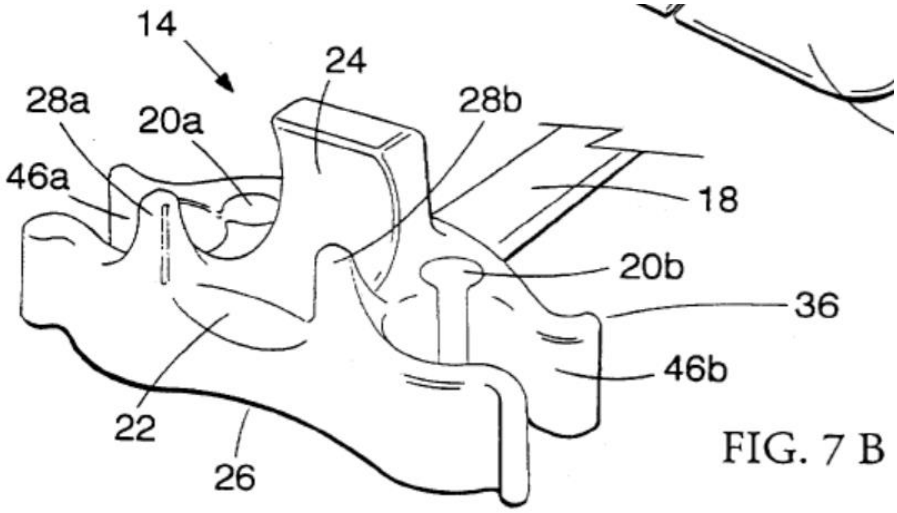


FIG. 7 B

EX1004 at ¶ 56.

This retainer clip assembly 14 is designed to "retain[] any typical combination of medical tubing…" EX1007 at 4:21-22; EX1004 at ¶ 57. Retainer

clips 46a and 46b are referred to as nasogastric/oxygen tube retainer clips, depending upon the type of nasal tubing (*i.e.*, nasogastric, oxygen cannula, or feeding) retained in each clip. *Id.*; EX1007 at 4:1, 4:21-23. The '715 patent assembly "includes an opening along an axial direction thereof which is smaller along at least portions of its length than an outer diameter of the nasal tube T_1 for securing the tube in the channel." EX1001 at 5:24-28; EX1004 at ¶ 57. Similarly, the assembly taught by Simmons states that the interior openings of the two clips (46a and 46b) are approximately 5 mm in diameter but may expand up to 6 mm and depend upon the type of tubing utilized and captured. EX1007 at 4:63-5:2; EX1004 at ¶ 57. Simmons teaches that standard 16 or 18 french size nasogastric tubing can be used without compression. EX1007 at 4:67-5:1. Dr Layton explains that the diameters of the french size tubing are equivalent to 5.3 mm or 6 mm, respectively. EX1004 at ¶ 57. Based on these teachings and Figure 7B, the openings of the nasogastric/oxygen tube retainer clips are also smaller in diameter than the tube itself. EX1004 at ¶ 57.

Figure 6 specifically depicts an embodiment of the medical device with a nasogastric tube 35 attached, captured, or retained:

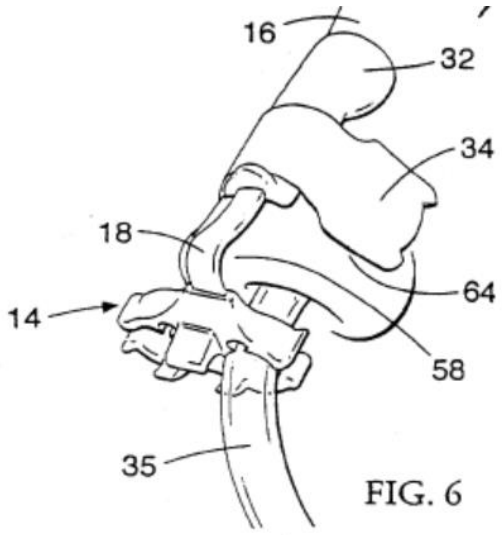


FIG. 6

Simmons' assembly employs an adjustable arm 18 which is bent to fit a patient's specific nasal anatomy and to position the retainer clip assembly 14 under the nose. The medical tube 35 is then placed and secured in the retainer clips 46a and/or 46b. EX1007 at 5:36-52; Claim 1; EX1004 at ¶¶ 58-59.

Simmons' assembly also can retain and secure medical tube 40 within feeding tube fixture 20a or 20b. *See* Figure 7B above. Feeding tube fixtures 20a and 20b are "3 mm in diameter, with attendant openings to allow tube entry of approximately 1.5 mm." EX1007 at 5:27-30; EX1004 at ¶ 59.

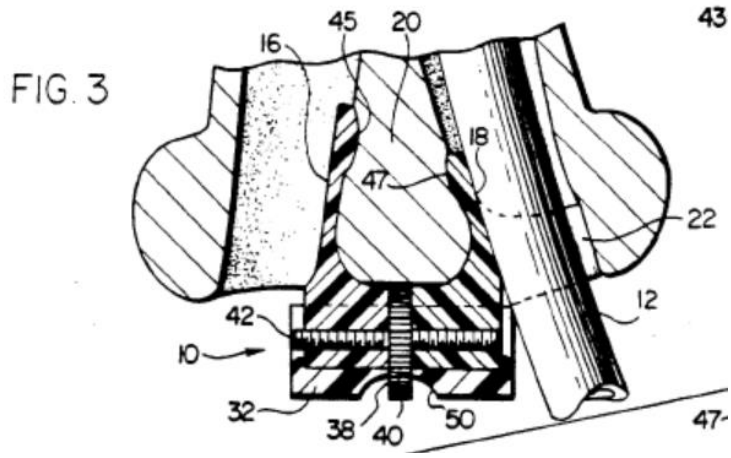
c) Izumi

U.S. Patent No. 5,097,827 ("Izumi"), entitled "Holder for Medical Tubing" was filed on March 22, 1991 and issued on March 24, 1992.[10] *See* EX1008; EX1004 at ¶ 84. Accordingly, Izumi qualifies as a prior art reference to the '715 patent under 35 U.S.C. § 102(b) (pre-AIA). *See* EX1004 at ¶ 84.

Izumi teaches "a medical tube holder for attachment to a patient's nose septum for holding medical tubing," including nasogastric tubing. EX1008 at

[10] Izumi was disclosed to the PTO during prosecution of the '715 patent but was not cited in an Office Action or referred to during prosecution. EX1001 (showing Izumi in the "References Cited" on the face of the patent, but not showing any asterisk notation indicating that the examiner relied upon the reference). *Husky Injection Molding Systems*, No. IPR2016-00432, slip op. 6-7 (P.T.A.B. June 24, 2016) (Paper 10). *See also supra* fn. 8 (discussing that the fact a reference was disclosed to the Examiner is not a bar to institute an IPR). Izumi was not cited in Petitioners' earlier petition for *Inter Partes* Review (IPR2017-00646).

1:58-61, Abstract; EX1004 at ¶ 85. The holder includes a tub holding portion 22 and tube 12 which is shown in the figure reproduced below:



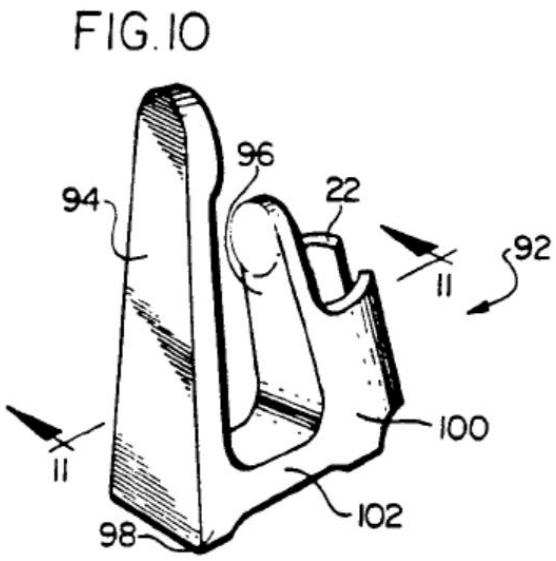
EX1008 at Figure 3; EX1004 at ¶ 85.

Izumi explains the medical tube holder of Figure 3:

> One of the arms such as illustrated arm 18 includes a tube holding portion 22 formed with 45 a split cylindrical section. Tube holding portion 22 is adapted in dimensions so as to enable tubing 12 to be inserted into the split cylinder *section while still maintaining the tubing in position*.

EX1008 at 3:44-49 (emphasis added); EX1004 at ¶ 86.

Figure 10 illustrates holding portion 22 and gives a perspective view of the split cylinder section (not labeled):



EX1004 at ¶ 87.

Izumi's assembly operates through two opposing clamp arms which attach to the patient's septum, as seen in Figure 3 (above). One of the arms 18 contains the holding portion 22 for medical tubing 12. EX1004 at ¶¶ 88. The distance between the clamp arms can be adjusted using a thumbscrew to fit both adult and child patients. EX1008 at 2:20-27; EX1004 at ¶ 88.

d) Bierman

PCT International Application Publication No. WO 99/20334 ("Bierman"), entitled "Anchoring System for a Medical Article," was filed on October 16, 1998

and published on April 29, 1999.[11] EX1011; EX1004 at ¶ 105. Accordingly, Bierman qualifies as a prior art reference to the '715 patent under 35 U.S.C. § 102(b) (pre-AIA). *See* EX1004 at ¶ 105.

Bierman teaches anchoring systems for medical articles. EX1011 at 1:4-5; EX1004 at ¶ 106. Bierman solves problems with the existing anchoring systems by use of "a simply-structured anchoring system that secures a catheter to a patient, without occluding or otherwise restricting fluid flow through the catheter." EX1011 at 2:9-10; EX1004 at ¶ 106. Bierman discusses this system:

> The grooves 30, 36 formed in the base 22 and the cover 24 define a channel 60 when the retainer 20 is closed. The channel 60 is capable of receiving a portion or length of the catheter 8 and is generally configured to house, grip and secure the affected catheter portion.

EX1011 at 8:18-20; EX1004 at ¶ 106.

Figure 4 depicts such a system:

[11] Bierman was not disclosed to the PTO during prosecution of the '715 patent or cited in an Office Action or referred to during prosecution. Bierman was not cited in Petitioners' earlier petition for *Inter Partes* Review (IPR2017-00646).

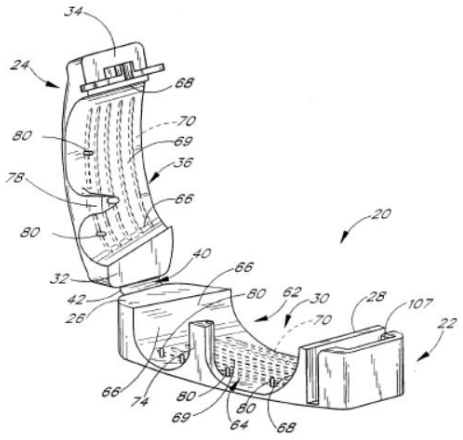


FIG. 4

EX1004 at ¶ 107.

Bierman further describes the interior of the system:

> Alternatively, the projection 81 can be used with the receptacle 79 to capture a section of the catheter. When the cover 24 is closed, the projection 81 could force a portion of the catheter body 8 into the receptacle 79 to capture a structural portion of the catheter 8 between these components without occluding an inner lumen of the catheter. This engagement of the retainer 20 with the catheter body 8 would inhibit axial catheter movement relative to the retainer 20.

EX1011 at 12:4-8; EX1004 at ¶ 107.

Figure 6 depicts one such example with interior projections 81 as described:

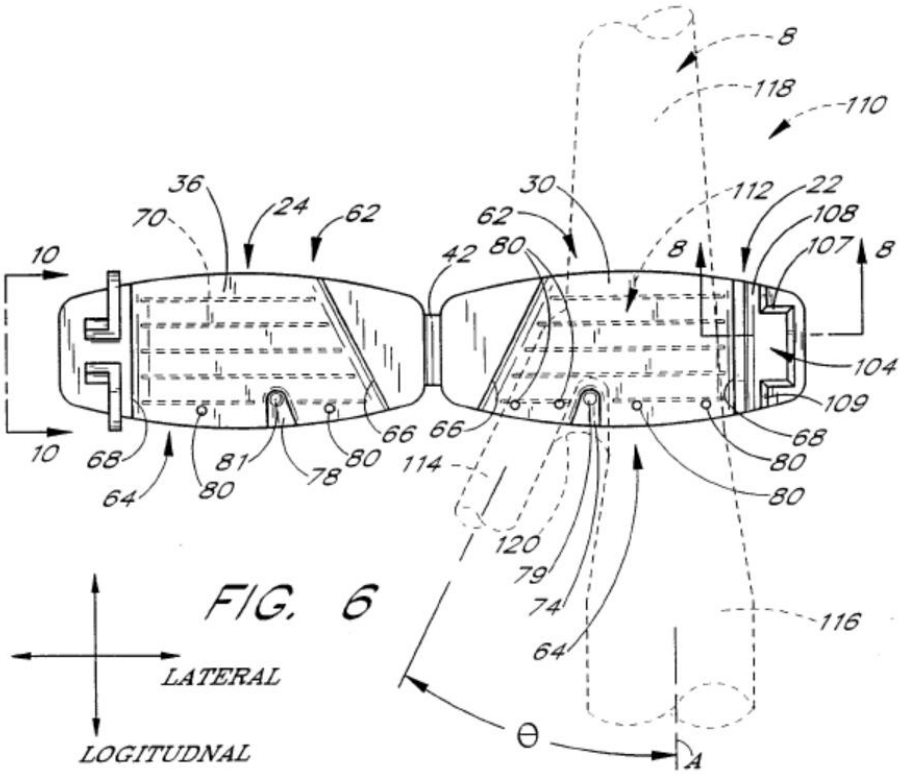


FIG. 6

EX1004 at ¶ 108.

Bierman teaches that such assemblies may also be used for other medical procedures including nasogastric tubes. EX1011 at 4:9-11 ("[T]he retainer disclosed herein can also be configured to receive and secure central venous catheters, peripherally inserted central catheters, hemodialysis catheters, surgical drainage tubes, feeding tubes, chest tubes, nasogastric tubes, scopes, as well as electrical wires or cables connected to external or implanted electronic devices or sensors."); EX1004 at ¶ 109.

C. Ground 1: Claim 18 Would Have Been Obvious Over Ballantyne in View of Simmons

1. The Level of Ordinary Skill in the Pertinent Art

The POSA is defined above. *Supra* Section VII.

2. The Scope and Content of the Prior Art

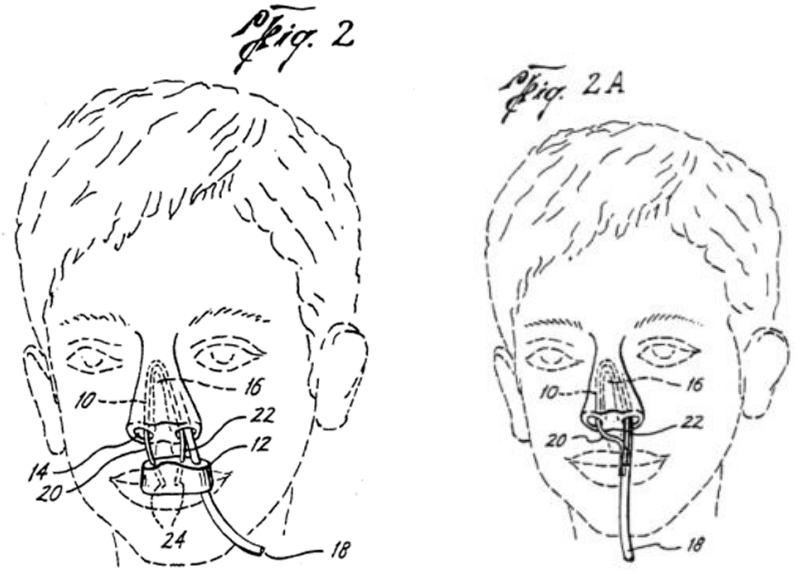
The scope and content of the prior art has been described above. *See supra* Section IX.B.

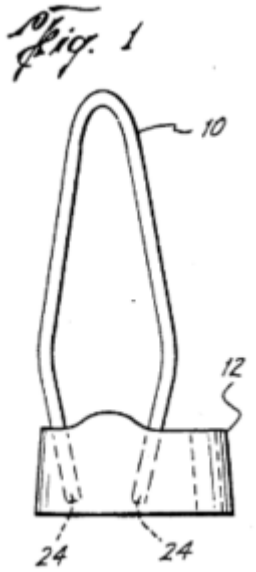
3. Differences Between the Claims and the Prior Art

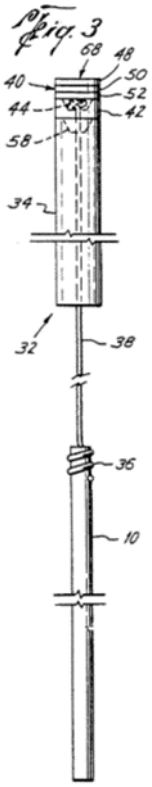
As Dr. Layton explains, Ballantyne teaches utilizing magnets to improve the method of installation of nasal bridles in order to ensure a more efficient placement of the bridle. EX1004 at ¶¶ 43-51. Ballantyne provides two examples of using magnets to install a nasal bridle in a patient. *Id.*

In support of their obviousness argument, Petitioners rely on the chart (below), which includes citations from the disclosure of Ballantyne (with corresponding citations to Dr. Layton's declaration). Following the chart, Petitioners provide additional analyses supporting obviousness in view of Ballantyne in light of Simmons.

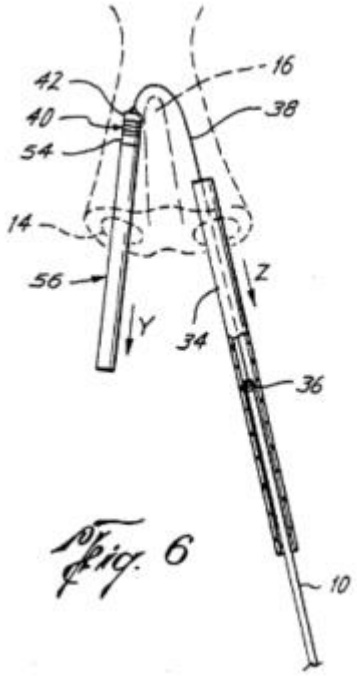
Claim 18	Prior Art Disclosure
A method of placing and securing at least	"[T]he claimed invention comprises a method for anchoring a tube extending into a patient's nostril comprising inserting a bridle within a patient's nose by the

Claim 18	Prior Art Disclosure
one tube through a nose into a patient comprising:	methods discussed above or otherwise. . . ." EX1002 at 4:10-19, 1:6-19, Abstract; *see also id.* at Claims 7-15; *see also* EX1004 at ¶¶ 60, 62.  *See, e.g.* EX1002, Figs. 2, 2A.
inserting the at least one tube into a first or second nare of the nose;	"[T]he claimed invention comprises a method for anchoring a tube extending into a patient's nostril comprising inserting a bridle within a patient's nose by the methods discussed above or otherwise, and further . . ., inserting the tube to be anchored into the patient's nostril . . .." EX1002 at 4:10-19, 5:4-15, 5:25-28; *see also id.* at Claim 9; *see also* EX1004 at ¶¶ 60, 63.

Claim 18	Prior Art Disclosure
	 *See, e.g.* EX1002 at Figs. 1, 2, & 2A.
inserting an end portion of a flexible member having a magnet attached thereto into a first nare of the nose;	"The leading end of pulling cord 38 is attached to magnetic member 40 and the trailing end of pulling cord is attached to bridle 10. The trailing end of bridle 10 is inserted into the distal end of and through first installation tool 34. . . . bridle 10 is installed in a patient's nose by a method comprising inserting the distal end 68 of first installation assembly 32 into a first nostril of the patient until magnetic member 40 is positioned beyond the posterior nasal septum." EX1002 at 6:34-7:32; *see id.* at 3:44-4:2; *see also id.* at Claims 2-3; *see also* EX1004 at ¶¶ 60, 64.

Claim 18	Prior Art Disclosure
	 EX1002 at Fig. 3. "[I]n another embodiment, the pulling cord is omitted and the leading end of the bridle is directly attached to the first magnet. The bridle is then inserted through the first installation tool until the first magnet is held in place against the distal end of said installation tool prior to insertion of the tool into the nostril." EX1002 at 5:21-26; *see also* EX1004 at ¶¶ 60, 64. "Alternatively, the first installation assembly can be assembled without a pulling cord. In such an embodiment, the leading end of bridle member 10 itself is directly attached to magnetic member 40, for example, by

Claim 18	Prior Art Disclosure
	providing a fastening plate 42 which is drilled and countersunk such that the leading end of bridle 10 can be inserted through the drilled hole and knotted, such that knot 60 fits within the countersunk cavity but does not pull through the drilled hole. This embodiment is constructed and operated in the same manner as is the embodiment described above, except that no pulling cord is present between magnetic member 40 and the leading end of bridle 10." EX1002 at 6:49-61; *see also id.* at 5:21-26; *see also* EX1004 at ¶¶ 60, 64.
inserting a magnetic probe into a second nare of the nose for attracting said magnet and said end portion of said flexible member;	"[A] second installation assembly 56 comprises adequately rigid member 62 with one or more permanent magnets 54, 64 preferably permanently affixed to the distal end thereof. . . . Second installation assembly 56 is sized to permit it to be easily inserted into a patient's nostril sufficiently to position magnet 54 beyond the posterior nasal septum." EX1002 at 6:49-7:3; *see id.* at 7:14-64; *see also id.* at Claim 2; *see also* EX1004 at ¶¶ 60, 65.
removing said probe from the second nare of the nose thereby retrieving said end portion of said flexible member through the second nare of the nose; and	"Referring to FIG. 6, first installation tool 34 is withdrawn in direction Z from the nostril, while pulling cord 38 and bridle 10 are allowed to slide through tool 34 as it is withdrawn. . . . Second installation tool 56 is then withdrawn from the second nostril in direction Y, pulling with it magnetic member 40 with the leading end of pulling cord 38 attached thereto. As second installation tool 56 and the leading end of pulling cord 38 are withdrawn from the second nostril, the trailing end of pulling cord 38 and the leading end of bridle 10 enter the first nostril. When second installation tool 56 is entirely removed from the second nostril, pulling cord 38 can be grasped and bridle 10 pulled into its proper position . . . around the posterior nasal

Claim 18	Prior Art Disclosure
	septum, and down through the second nostril until it passes out of the nasal opening." EX1002 at 7:14-51; *see id.* at 3:44-4:2; *see also* Claims 9, 11, 13, and 15; *see also* EX1004 at ¶¶ 60, 66.  Fig. 6 EX1002 at Fig. 6.
snapping the at least one tube into a channel formed in a receiver.	*See below.*

As Dr. Layton explains, Ballantyne discloses a method for placing and securing a tube through the nose of a patient. EX1004 at ¶¶ 44-45; EX1002 at 4:10-19; *see id.* at 1:6-19; *see also id.* at Claims 7-15. A POSA would further

understand that Ballantyne discloses inserting a tube into the patient's nostril as Ballantyne discloses the step of "inserting the tube to be anchored into the patient's nostril . . . ." EX1002 at 4:10-19; *see also* EX1004 at ¶¶ 60, 62-63.

Similarly, a POSA would understand that Ballantyne teaches inserting the magnetic end of a flexible member into a patient's nose. EX1004 at ¶¶ 60, 64-65. Indeed, Ballantyne discloses multiple embodiments that meet this claim limitation. EX1002 at 6:34-48 (disclosing an embodiment that utilizes a pulling cord), 6:49-61 (disclosing an embodiment that does not utilize a pulling cord); *see also* EX1004 at ¶¶ 48-50. Ballantyne discloses a method of installing a nasal bridle using a "pulling cord." EX1002 at 6:34-48, 7:14-32; *see also* EX1004 at ¶¶ 48-49, 64. One end of the pulling cord is attached to a nasal bridle, and the other end has a magnetic member attached to it. EX1002 at 6:34-48; *see also* EX1004 at ¶¶ 48-49, 64. The nasal bridle is then inserted into the "first installation tool," and the nasal bridle is installed by inserting the first installation tool into the patient's nostril "until magnetic member 40 is positioned beyond the posterior nasal septum." EX1002 at 6:34-7:19; *see id.* at 3:44-4:2; *see also id.* at Claim 2-3; *see also* EX1004 at ¶¶ 48-49, 64.

Moreover, a POSA, reading Ballantyne, would understand that the use of a "pulling cord" is simply an additional part of the apparatus and, at most, results in

an additional step being taken in the installation of the nasal bridle. EX1004 at ¶¶ 48-49, 64. Accordingly, a POSA would have a reasonable expectation of success in operating this particular embodiment as disclosed by Ballantyne in installing a nasal bridle between the nose of a patient to secure a tube. *Id.*

To the extent AMT argues that a "pulling cord" is not recited by Claim 18 (notwithstanding the fact that the claim is a "comprising" claim), a POSA would understand from the disclosure of Ballantyne that the "pulling cord" could simply be eliminated in favor of attaching the magnet to the bridle, itself:

> **Alternatively, the first installation assembly can be assembled without a pulling cord**. In such an embodiment, the leading end of bridle member 10 itself is directly attached to magnetic member 40, for example, by providing a fastening plate 42 which is drilled and countersunk such that the leading end of bridle 10 can be inserted through the drilled hole and knotted, such that knot 60 fits within the countersunk cavity but does not pull through the drilled hole. This embodiment is constructed and operated in the same manner as is the embodiment described above, except that no pulling cord is present between magnetic member 40 and the leading end of bridle 10.

EX1002 at 6:49-61 (emphasis added); *see also* EX1004 at ¶¶ 48-49, 64.

Ballantyne additionally discloses the insertion of a magnetic probe, in the form of "a second installation assembly 56" into the patient's nostril. EX1002 at 6:49-7:3; *see id.* at 7:14-64; *see also id.* at Claim 2; *see also* EX1004 at ¶¶ 48-49, 65. The "second installation assembly" has a magnet affixed to one end, and the magnetic end is inserted into the patient's nostril "sufficiently to position magnet 54 beyond the posterior nasal septum." *Id.*

A POSA having read the aforementioned disclosure would have understood that the magnet attached to the end of the flexible member located inside the patient's facial structure would be attracted, through magnetic forces, to the magnet affixed or otherwise attached to the probe that is inserted through the patient's nose. EX1004 at ¶¶ 48-49, 64. Further, a POSA would have a reasonable expectation of success in carrying out these steps. *Id.*

Ballantyne goes on to disclose removing the probe from the patient's nose in order to properly place the nasal bridle. EX1002 at 7:14-51; *see id.* at 3:44-4:2; *see also id.* at Claims 9, 11, 13, and 15, Fig. 6; *see also* EX1004 at ¶¶ 60, 65. Ballantyne discloses that withdrawal of the "second installation tool 56" pulls "magnetic member 40 with the leading end of pulling cord 38 attached thereto." EX1002 at 7:33-51; *see also* EX1004 at ¶ 66. Ballantyne further discloses "grasping" the pulling cord in order to pull the bridle "into its proper position."

EX1002 at 7:33-51; *see also* EX1004 at ¶ 66. Therefore, Ballantyne teaches using the disclosed magnetic probe to complete the placement of the nasal bridle in the nose. *Id.*

As to Claim 18's recitation of "snapping . . . the tube into a channel," such a recitation would have been obvious in view of Simmons. Simmons relates primarily to medical devices designed to retain medical tubing. EX1007 at 1:13-15; EX1004 at ¶ 67. As noted above, Simmons expressly discusses Ballantyne and the deficiencies of the design disclosed therein:

> U.S. Pat. No. 5,185,005 to Ballantyne, 2/9/93 … appears to effectively prevent other treatments requiring nasally inserted tubing or oxygen by occupying the nasal passages with hardware for the apparatus and *placing an anchoring clip across the breadth of the nasal passages when in use*.

EX1007 at 2:11-20 (emphasis added); EX1004 at ¶67.

Simmons teaches a solution to these deficiencies through use of a retainer compatible with existing technology. EX1007 at 2:57-60; EX1004 at ¶ 68. For example, Simmons teaches such a retainer depicted by Figure 7B:

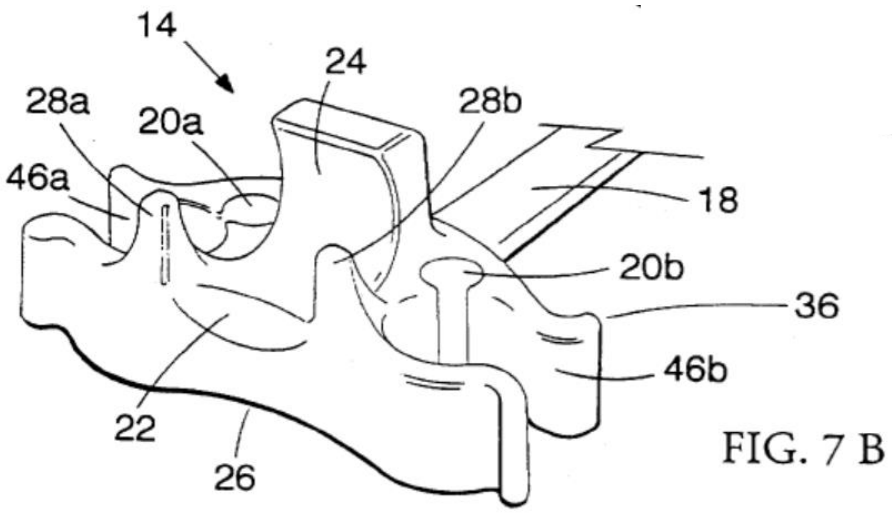


FIG. 7 B

As Figure 7B shows, 46a and 46b are nasogastric/oxygen tube retainer clips where interior openings are approximately 5 mm in diameter but may expand up to 6 mm and depend upon the type of nasogastric tubing utilized. EX1004 at ¶ 69. Simmons teaches that the materials used to form such a retainer clip assembly should be "semi-rigid, injection molded thermoplastic" to provide "structural integrity to provide support for tubing, flexibility to provide gripping tension upon the nasogastric tubing 35…" EX1007 at 4:41-46; EX1004 at ¶ 69. Simmons further explains that nasogastric/oxygen clip corners 36 "assist clipping of oversize tubing." EX1007 at 5:11-13; EX1004 at ¶ 69.

The diameter of the interior openings of the retainer clips taught by Simmons mirrors the explanation of snapping put forth by Exclusive Licensee in their previous Preliminary Reply and adopted by the Board in the Final Decision. Exclusive Licensee alleged:

> Patentee's use of "snapping" in claim 18 and the '715 specification is consistent with this ordinary and customary meaning. As noted above, the '715 specification explains that *the channel includes an opening along an axial direction thereof that is smaller along at least portions of its length than an outer diameter of the nasal tube for securing the tube in the channel, or in other words, that the size of the axial opening allows the nasal tube to be snapped into place*.

EX1015 at 17-18 (emphasis added); EX1004 at ¶ 72.

As Dr. Layton explains, Simmons teaches such a channel with an axial opening that allows the tube to be snapped into place, because the channel formed by the retainer clip in Figure 7B has an opening which is smaller than the diameter of a nasogastric or oxygen tube. EX1007 at Figure 7B; Claim 13; EX1004 at ¶¶ 69-70. Moreover, Simmons teaches the opening in the channel is smaller along at least portions of its length than an outer diameter of the nasal tube. EX1004 at ¶69; EX1007 at 5:11-13 (further explaining that nasogastric/oxygen clip corners 36 "assist clipping of oversize tubing."); FIG. 6 (reproduced below):

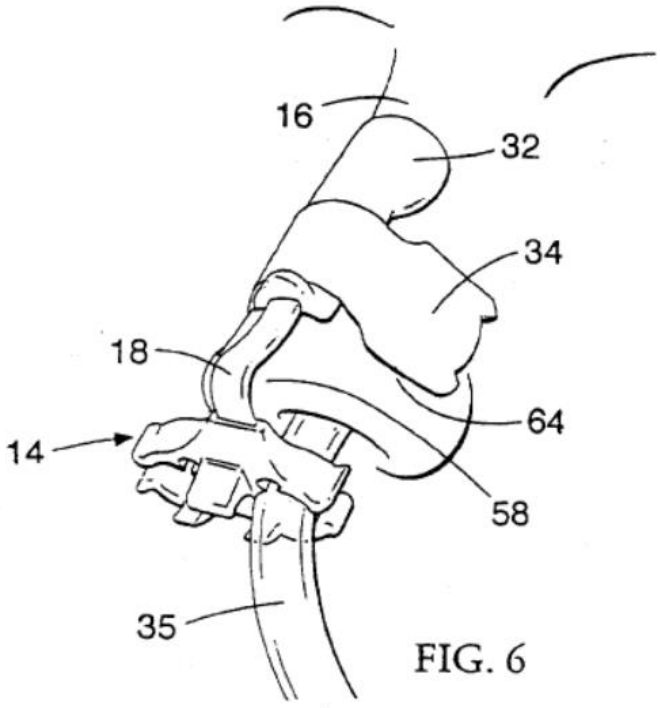


FIG. 6

As Dr. Layton explains, Simmons teaches snapping (or fitting) the at least one tube (*i.e.*, nasogastric tubing 35) into a channel (*i.e.*, the interior openings of 46a and 46b) formed in a receiver because the opening of the retainer clip is smaller than the diameter of the clip, and as shown in Figure 6, the tube diameter is larger than the opening of the retainer clip. EX1004 at ¶ 70. Furthermore, Figure 6 shows that the tube fits securely within the clip. *Id.* Therefore, the tube would fit or snap into the channel. Therefore, Simmons teaches snapping the at least one tube (*i.e.*, nasogastric tubing 35) into a channel (*i.e.*, the interior openings of 46a and 46b) formed in a receiver. *Id.* Therefore, Simmons discloses the snapping element of Claim 18 for use with nasogastric tubing. EX1004 at ¶ 70.

Additionally, as Dr. Layton explains, Simmons teaches a second channel in the retainer clip for retaining and stabilizing a feeding tube. EX1004 at ¶ 70. Figure 7B depicts feeding tube fixtures 20a and 20b which are set within nasogastric/oxygen tube retainer clips 46a and 46b. EX1004 at ¶70. Figure 4, reproduced below, depicts a feeding tube 40 held within one such feeding tube fixture:

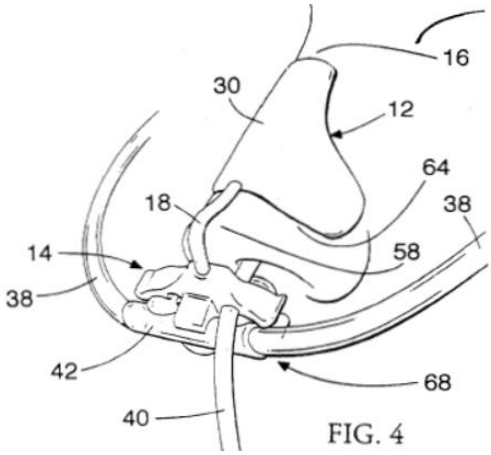


FIG. 4

The diameter of the interior openings of the feeding tube fixtures taught by Simmons mirrors the explanation of snapping put forth by Exclusive Licensee, as discussed above. As Dr. Layton explains, Simmons teaches that feeding tube fixtures 20a and 20b are "3 mm in diameter, with attendant openings to allow tube entry of approximately 1.5 mm." EX1004 at ¶ 71; EX1007 at 5:27-30. Therefore, Simmons teaches a channel with an axial opening that is smaller along at least a portion of its length than the outer diameter of the tubing. *Id*. As Dr. Layton explains, Simmons teaches snapping (or fitting) the at least one tube (*i.e.*, feeding

tube 40) into a channel (*i.e.*, the interior openings of 20a and/or 20b) formed in a receiver because the opening of the feeding tube fixture is smaller than the diameter of the fixture, and as shown in Figure 4, the tube diameter is larger than the opening of the retainer clip. EX1004 at ¶ 71. Furthermore, Figure 4 shows that the tube fits securely within the clip. *Id*. Therefore, Simmons discloses the snapping element of Claim 18 for use with at least one tube, such as a nasogastric or feeding tube. *Id*.

Exclusive Licensee additionally previously contended that "snapping" could be defined based on the "joining of two parts based on a brief deformation of one or both parts being joined." EX1015 at 13-14. Even if the "snapping" recited by Claim 18 was construed as such, a POSA still would have found it obvious to "snap[ ] . . . the tube into a channel" based on the disclosure of Simmons. EX1004 at ¶ 72. As Dr. Layton explains, by its very nature, if the diameter of the tube is greater than the diameter of the channel, then the tube is placed, forced fitted into or snapped into the channel. *Id.*

Exclusive Licensee stated:

> Snapping a tube into a channel formed in a receiver would be understood to include a *deformation of the tube and/or receiver*, at an opening into the channel, which is brief,

> lasting just *during the operation of joining the tube and the receiver at the channel*, not for an extended period.

EX1015 at 17 (emphasis added).

Simmons teaches that the materials used are "semi-rigid" to provide flexibility. EX1007 at 4:41-46; EX1004 at ¶ 73. As explained by Dr. Layton, based on these materials and the knowledge that the tubing is sized larger than the clip corners, introduction of the tube into the channel of Simmons would necessarily result in the brief deformation of the tube and/or clip corners, achieving the "snapping" as construed by Exclusive Licensee. EX1004 at ¶¶ 72-73.

Moreover, a POSA, reading Ballantyne and Simmons, would understand that both patents disclose medical devices designed to retain nasogastric tubing which are inserted into a patient's nasal cavity. EX1004 at ¶ 74. Thus, a POSA would be motivated to combine the teachings of these two references because both patents disclose a similar manner of securing a nasogastric/nasoenteric tube through the nose of the patient. *Id.*; *see In re Icon Health and Fitness, Inc.*, 496 F.3d 1374, 1379-80 (Fed. Cir. 2007) (holding that a reference is analogous art if it is "reasonably pertinent to the problem addressed"). A POSA would also note that Simmons specifically references the devices of Ballantyne, teaches deficiencies related to Ballantyne, and designed a solution to these deficiencies compatible with then existing assembly designs. EX1007 at 2:57-60; EX1004 at ¶ 74. A POSA

would be motivated to combine the references as a result of this performance improvement as well. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1368, (Fed. Cir. 2006) ("[A]n implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the 'improvement' is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient."). EX1004 at ¶¶ 74-76; *see also* EX1002 at 5:35-40. Because a POSA would understand that the system of Ballantyne fails to prevent friction and irritation caused by tubing, the POSA would have found it obvious and would have been motivated to incorporate a system to prevent such dislodging of the tubing as disclosed by Simmons or other catheter retaining devices, which takes advantage of the tension within the channel surrounding the tubing. EX1007 at 1:29-36, 4:43-48; EX1004 at ¶ 74.

As Dr. Layton explains, Simmons teaches the fitting (snapping) of a tube into a receiver in a manner intentionally compatible with the design of Ballantyne. Accordingly, a POSA would have had a reasonable expectation of success with combining these two references. EX1004 at ¶ 75.

A POSA would have understood that Ballantyne in view of Simmons, would have taught installing a nasal bridle by passing it through the patient's nose and would have a reasonable expectation of success in creating such a method of installation. EX1004 at ¶ 76. A POSA would further find it obvious to implement the method disclosed by Ballantyne, which utilizes magnetic coupling. *Id.* The POSA would be motivated to add the additional step of securing the tube and/or the ends of the flexible member in a receiver as disclosed by Ballantyne. EX1004 at ¶ 76. To the extent Ballantyne does not disclose "snapping. . . the tube into a channel," Simmons would have taught this element. EX1004 at ¶ 76.

To the extent any modifications of the features of Ballantyne and Simmons would have been necessary, notwithstanding the fact that Simmons disclosed a retaining clip that was compatible with Ballantyne, such modifications would have been well within the skill of the POSA as both Ballantyne and Simmons disclose nasal bridles that are mechanically similar, serve a similar purpose, and are installed in a similar manner. EX1004 at ¶ 77. As the Federal Circuit has explained, "[t]he test for obviousness is not whether the features of one reference may be bodily incorporated into the structure of the other reference, but rather 'what the combined teachings of the references would have suggested to those of ordinary skill in the art.'" *In re Keller*, 642 F.2d 413, 425 (Fed. Cir. 1981); *Ethicon Endo-Surgery, Inc. v. Covigien AG*, IPR2015-01274 (Final Written

Decision, Paper 25) at p. 18 (Nov. 30, 2016); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420, (2007) ("Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle").[12]

D. Ground 2: Claim 18 Would Have Been Obvious Over Ballantyne in View of Izumi

1. The Level of Ordinary Skill in the Pertinent Art

The POSA is defined above. *Supra* Section IX.A.

[12] Moreover, to the extent Simmons teaches additional elements, *i.e.*, an adjustable arm (18) which is bent to fit a patient's specific nasal anatomy, the preamble to Claim 18 includes the transition term "comprising." EX1001 at Claim 18; *see also* EX1004 at ¶ 37. This means that "other elements may be added and still form a construct within the scope of the claim." *Genentech, Inc.*, 112 F.3d at 501 (internal quotations and citations omitted). Any such additional elements are not inconsistent with the teaching and devices of Ballantyne.

2. The Scope and Content of the Prior Art

The scope of the prior art has been discussed above. *See supra* Section IX.B.

3. Differences Between the Claims and the Prior Art

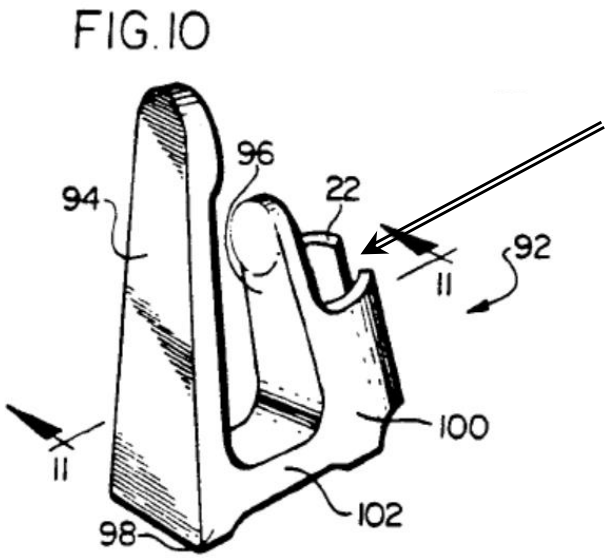
Claim 18 would have been obvious to a POSA over Ballantyne in view of Izumi. EX1004 at ¶¶ 79-98. In support of their obviousness argument, Petitioner relies on the chart above at Section IX.C.3, which provides the relevant disclosures of Ballantyne (with corresponding citations to Dr. Layton's declaration). *See supra* Section IX.C.3. Petitioners provide additional analyses supporting obviousness in view of Ballantyne in light of Izumi.

The disclosure of Izumi, like that of Ballantyne, teaches a medical tube holder designed to retain nasogastric tubing which are fit to a patient's nasal cavity. EX1008 at 1:58-61; EX1004 at ¶¶ 85, 96. Thus, a POSA would be motivated to combine the teachings of these two references because both patents disclose a similar manner of securing a nasogastric/nasoenteric tube to arrest excessive movements. EX1004 at ¶ 96.

Izumi discloses "snapping . . . the tube into a channel," as cited in Claim 18. EX1004 at ¶ 91. As explained *supra*, the Board explained that "snapping the at least one tube into a channel formed in a receiver," as recited by Claim 18 means

"that snapping occurs with respect to a tube and a channel, based on the express language…" EX1013 at 8. Petitioners apply the same construction herein.

Izumi teaches that a "[t]ube holding portion 22 is adapted in dimensions so as to enable tubing 12 to be inserted into the split cylinder section while still maintaining the tubing in position." EX1008 at 3:46-49; EX1004 at ¶ 90. Figure 10 illustrates holding portion 22 and the split cylinder section (indicated by Dr. Layton with an arrow for clarity):



As Dr. Layton explains, Izumi's assembly operates through two opposing clamp arms which attach to the patient's septum. One of the arms contains the holding portion for medical tubing. EX1004 at ¶ 91. As Dr. Layton explains, Izumi teaches inserting (*i.e.*, snapping) the at least one tube (*i.e.*, tubing) into a channel (*i.e.*, the holding portion 22) formed in a receiver. EX1004 at ¶ 91.

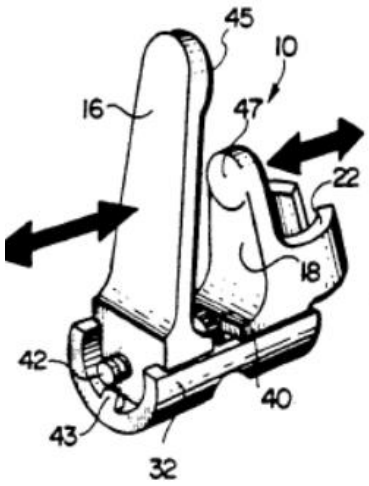
The diameter of the interior openings of the holding portion and split cylinder section taught by Izumi mirrors the explanation of snapping put forth by Exclusive Licensee in their previous Preliminary Reply. EX1004 at ¶¶ 92-94. Exclusive Licensee alleged:

> Patentee's use of "snapping" in claim 18 and the '715 specification is consistent with this ordinary and customary meaning. As noted above, the '715 specification explains that *the channel includes an opening along an axial direction thereof that is smaller along at least portions of its length than an outer diameter of the nasal tube for securing the tube in the channel, or in other words, that the size of the axial opening allows the nasal tube to be snapped into place*.

EX1015 at 17-18 (emphasis added).

As Dr. Layton explains, Izumi teaches such a channel with an axial opening that allows the tube to be snapped into place because the opening taught by Izumi (*i.e.*, 22) is "adapted in dimensions so as to enable tubing 12 to be inserted into the split cylinder section while still maintaining the tubing in position." EX1008 at 3:46-49; EX1004 at ¶¶ 92-93; EX1008 at FIG. 2 (reproduced below):

FIG. 2



As Dr. Layton explains, holding portion 22 has a cylinder with a channel defined as the internal diameter of the cylinder. Holding portion 22 also has a split cylinder section shown in Fig 2 but not labeled. EX1004 at ¶ 93. Therefore, as Dr. Layton explains, Izumi teaches "snapping" the tube through this opening into the channel (or holding portion) because the opening of the tube holding portion, *i.e.*, the split cylinder section, is smaller than the internal diameter of the tube holding portion, as shown in Figures 2 and 3 (reproduced *supra*). The tube outer diameter is larger than the opening of the retainer clip. Thus, the tubing 12 must be inserted, or snapped, into the channel through the split cylinder section. A POSA would understand from Figures 2 and 3 that there is a cylinder with a slit and the slit dimension is less than the internal diameter of the cylinder. EX1004 at ¶ 93.

Therefore, Izumi discloses the snapping element of Claim 18 for use with nasogastric tubing. *Id*.

Moreover, a POSA, reading Ballantyne and Izumi, would be motivated to combine the teachings of these two references because both patents disclose a similar manner of securing a nasogastric tube through the nose of the patient. EX1004 at ¶ 95. A POSA would be motivated to combine the references as a result of these similarities. EX1004 at ¶ 95. Moreover, as Dr. Layton explains, because a POSA would understand that the system of Ballantyne fails to prevent friction and irritation caused by movement of the tubing, the POSA would have found it obvious and been motivated to incorporate a system to prevent such dislodging of the tubing as disclosed by Izumi, which takes advantage of the particular dimensions of the split cylinder section to maintain the tubing in position. EX1008 at 3:44-49; EX1004 at ¶ 95.

Accordingly, a POSA would have had a reasonable expectation of success with combining these two references. EX1004 at ¶¶ 95-96.

A POSA would have understood that Ballantyne in view of Izumi would have taught installing a nasal bridle by passing it through the patient's nose and would have a reasonable expectation of success in creating such a method of installation. EX1004 at ¶¶ 95-96. A POSA would further find it obvious to

implement the method disclosed by Ballantyne, which utilizes magnetic coupling and securing the tube and/or the ends of the flexible member in a receiver. *Id.* To the extent Ballantyne does not disclose "snapping. . . the tube into a channel," Izumi would have taught this element. EX1004 at ¶¶ 93-95.

To the extent any modifications of the features of Ballantyne and Izumi would have been necessary, such modifications would have been well within the skill of the POSA as both Ballantyne and Izumi disclose nasal assemblies that are mechanically similar, serve a similar purpose, and are installed in a similar manner. EX1004 at ¶ 97. *In re Keller*, 642 F.2d at 425.

E. Ground 3: Claim 18 Would Have Been Obvious Over Ballantyne in View of Simmons and Bierman

1. The Level of Ordinary Skill in the Pertinent Art

The POSA is defined above. *Supra* Section VII.

2. The Scope and Content of the Prior Art

As stated above, the test for obviousness under 35 U.S.C. § 103 was laid out in *Graham v. John Deere, Inc.* The scope of the prior art has also been discussed above. *See supra* Section IX.B.

3. Differences Between the Claims and the Prior Art

Claim 18 would have been obvious to a POSA over Ballantyne in view of Simmons and Bierman. EX1004 at ¶¶ 99-122. In support of their obviousness

argument, Petitioner relies on the chart above, which provides the relevant disclosures of Ballantyne (with corresponding citations to Dr. Layton's declaration). *See supra* Section C.3. The relevant disclosures of Ballantyne in view of Simmons are also discussed *supra*. Petitioners provide additional analyses supporting obviousness in view of Ballantyne in light of Simmons and Bierman.

A POSA, reading Ballantyne, Simmons and Bierman, would understand that each disclose a method of securing a medical article comprising delivery tubes to a patient and preventing both movement of the tubes as well as movement of the system against the patient. EX1004 at ¶¶ 115, 117, 120. Bierman teaches that the anchoring system can be used to secure a variety of medical articles including nasogastric tubes. EX1011 at 4:5-14; EX1004 at ¶ 109. Thus, a POSA would be motivated to combine the teachings of these three references because the patents disclose a similar manner of securing a nasogastric/nasoenteric tube to arrest excessive movements. EX1004 at ¶ 115, 117, 120. A POSA would also note other similarities shared between the references, including disclosure of a receiver or retainer with opened and closed positions for receiving and securing medical tubing. EX1004 at ¶ 120; *see also* EX1011 at Figure 4; EX1002 at 3:56-58.

A POSA would have understood that Ballantyne in view of Bierman, would have taught securing a medical assembly and nasogastric tubes by pressing (*i.e.*,

snapping) said tubes into a channel formed in the assembly to restrict unwanted movement and would have a reasonable expectation of success in creating such a method of installation. EX1004 at ¶¶ 117, 121. A POSA would understand that snapping the tube into a receiver channel would decrease the risk that the patient would dislodge the harness or otherwise disturb the tubes. *Id.* To the extent Ballantyne and/or Bierman does not disclose "snapping" the tube into a channel, Simmons would have taught this element. EX1004 at ¶ 116.

Bierman taught:

> The grooves 30, 36 formed in the base 22 and the cover 24 define a channel 60 when the retainer 20 is closed. The channel 60 is capable of receiving a portion or length of the catheter 8 and is generally configured to house, *grip and secure the affected catheter portion*.

EX1011 at 8:18-20 (emphasis added); EX1004 at ¶ 111.

See for example, Figures 5a and 13:

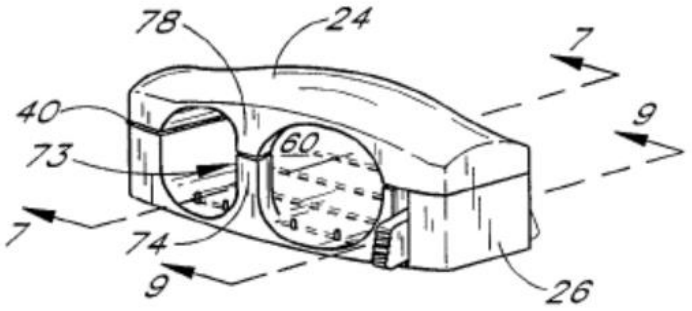


FIG. 5a

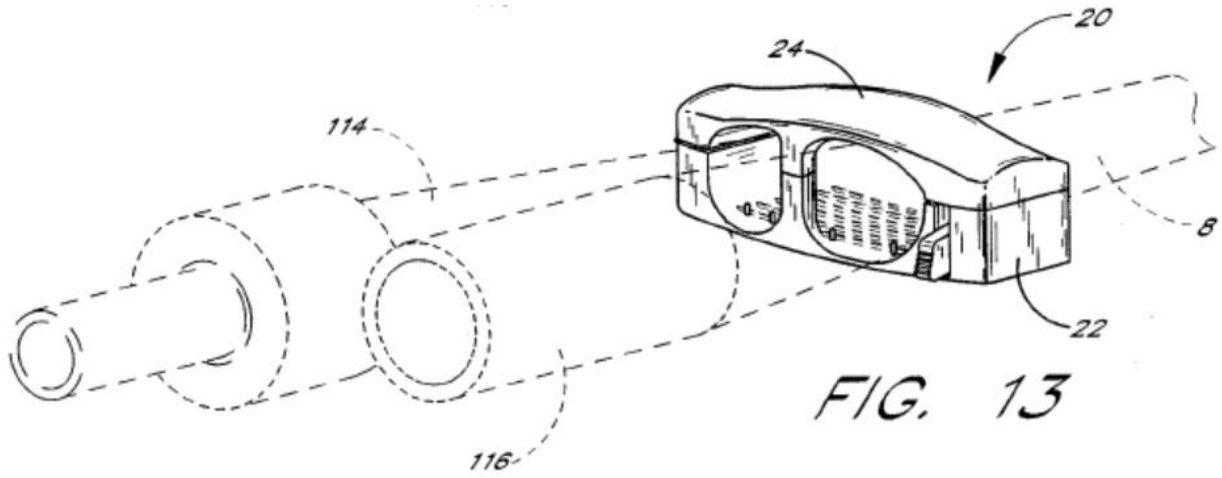


FIG. 13

As Dr. Layton explains, Figure 5a illustrates the channel 60 which is created upon closing lid 24 and Figure 13 illustrates the placement of tubing (*i.e.*, catheter 8) within the channel. EX1004 at ¶ 112.

Bierman further described the action of restricting such tubing (*e.g.*, a catheter 8) within the retainer:

> Alternatively, the projection 81 can be used with the receptacle 79 to capture a section of the catheter. When the cover 24 is closed, the projection 81 could force a portion

> of the catheter body 8 into the receptacle 79 to capture a structural portion of the catheter 8 between these components without occluding an inner lumen of the catheter. *This engagement of the retainer 20 with the catheter body 8 would inhibit axial catheter movement relative to the retainer 20*.

EX1011 at 12:4-8; EX1004 at ¶ 113 and Figure 5b:

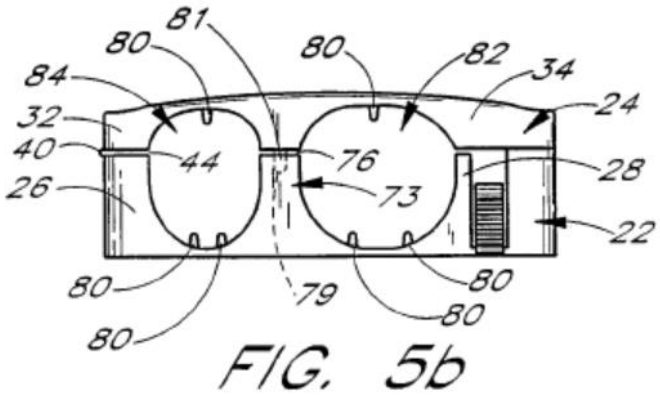


FIG. 5b

As Dr. Layton explains, the barbs (80) of the illustration also work to retain and prevent movement of the catheter body in the longitudinal direction. EX1004 at ¶ 114; EX1011 at 12:9-11.

To the extent any modifications of the features of Ballantyne and Bierman would have been necessary, such modifications would have been well within the skill of the POSA as both Ballantyne and Bierman disclose a method of securing a medical article comprising delivery tubes to a patient and are installed in a similar manner. EX1004 at ¶ 115. Because a POSA would understand that the system of

Ballantyne fails to prevent tissue irritation caused by tubing movement, the POSA would have found it obvious and been motivated to incorporate a system to prevent such dislodging of the tubing as disclosed by Bierman, which takes advantage of the assembly shape, barbs, and channels created by closing the assembly to control catheter movement relative to the retainer. EX1004 at ¶ 115. To the extent that Bierman does not disclose "snapping" of the tube in the channel, a POSA would have known from the teachings of Simmons that designing the channel to allow for snapping is another method to insert a tube into a holder that offers stability or minimizes movement. EX1004 at ¶ 116

As discussed *supra*, a POSA would have been motivated to combine the teachings of Ballantyne with Simmons because they occupy the same art space and Simmons explicitly addresses the deficiencies of Ballantyne. EX1004 at ¶ 117. A POSA would be motivated to combine Simmons with Bierman as well because both relate to improving the stability (*i.e.*, preventing movement) of medical tubing for nasal assemblies. *Id*.

As Dr. Layton explains, Simmons' nasogastric/oxygen tub retainer clips act to retain the tubing in place with expandable openings to admit oversized tubing. EX1004 at ¶ 119. The diameter of the interior openings of the retainer clips taught by Simmons mirrors the explanation of snapping put forth by Exclusive Licensee

in their previous Preliminary Reply and adopted by the Board in the Final Decision. *Id*. As Dr. Layton explains, Simmons teaches such a channel with an axial opening that allows the tube to be snapped into place, because the channel formed by the retainer clip in Figure 7B (reproduced above) has an opening along an axial direction which is smaller than the tubing diameter. EX1004 at ¶ 119; EX1007 at Figure 7B; Claim 13. Moreover, Simmons teaches the opening in the channel is smaller along at least portions of its length than an outer diameter of the nasal tube. EX1004 at ¶ 119; EX1007 at 5:11-13 (further explaining that nasogastric/oxygen clip corners 36 "assist clipping of oversize tubing."); FIG. 6. Therefore, as Dr. Layton explains, Simmons teaches snapping the at least one tube (*i.e.*, nasogastric tubing 35) into a channel (*i.e.*, the interior openings of 46a and 46b) formed in a receiver. EX1004 at ¶ 119. Therefore, Simmons discloses the snapping (or clipping) element of Claim 18 for use retaining nasogastric tubing. EX1004 at ¶ 119.

Moreover, a POSA reading Simmons and Bierman would understand that both patents disclose medical devices designed to retain nasogastric tubing which are fit to a patient's nasal cavity. EX1004 at ¶ 120. Accordingly a POSA would have been motivated to modify the channels taught by Bierman to have a slightly smaller opening like those of Simmons, for example, at the channels illustrated in the Figure 4 below. *Id.*

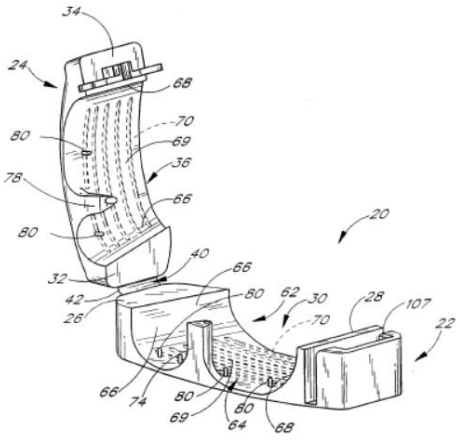


FIG. 4

Bierman teaches "[v]ariations on the channel's shape of course are also possible, as noted above….Either the first 66 or second 68 side, or both sides, may vary in distance relative to the axis A of the received catheter length so as to inhibit longitudinal movement of the retained section of the catheter 8." EX1011 at 9:20-25; EX1004 at ¶ 121. Therefore, as Dr. Layton explains, a POSA would have had a reasonable expectation of success by incorporating a channel within a tubing/catheter retainer that allows the tube to be placed into the retainer either by snapping through the opening that is smaller than the channel diameter (as taught by Simmons) or by snapping the retainer top into the retainer bottom (as taught by Bierman). EX1004 at ¶ 121; *DyStar*, 464 F.3d at 1368. Because a POSA would understand that the system of Ballantyne fails to prevent friction and irritation caused by tubing, the POSA would have found it obvious and been motivated to incorporate a system to prevent such dislodging of the tubing as disclosed by

Bierman and Simmons, which take advantage of the particular dimensions of the channel to maintain the tubing in position. EX1004 at ¶ 121; EX1007 at 2:57-68.

To the extent any modifications of the features of Ballantyne, Simmons or Bierman would have been necessary, notwithstanding the fact that Simmons disclosed a retaining clip that was compatible with Ballantyne, such modifications would have been well within the skill of the POSA as each disclose medical devices designed to retain tubing. EX1004 at ¶ 122. *In re Keller*, 642 F.2d at 425.

F. Secondary Considerations of Non-Obviousness

As to obviousness (*i.e.*, Grounds 1-3), although objective indicia of non-obviousness must be taken into account in the obviousness calculus, they do not necessarily control the obviousness conclusion. *Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988); *see also* EX1004 at ¶ 118. A strong case of obviousness, such as the instant one, cannot be overcome by objective evidence of non-obviousness. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2008); *Hoffmann-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1334 (Fed. Cir. 2014).

To the extent Patent Owner does in fact assert any objective indicia in this proceeding, detailed consideration of Patent Owner's evidence should not be undertaken until Petitioners have had an opportunity to respond to Patent Owner's

position. *Amneal Pharmaceuticals, LLC v. Supernus Pharmaceuticals, Inc.*, IPR2013-00368 (Institution Decision, Paper 8) at pp. 12-13 (Dec. 17, 2013); *see also* EX1004 at ¶¶ 123-125 (Petitioner's expert explaining that he is not aware of the existence of any evidence of any secondary considerations).

X. CONCLUSION

Petitioners have demonstrated by a preponderance of the evidence that Claim 18 of the '715 patent is unpatentable as obvious over the prior art cited herein and respectfully requests that the Board so find. *See* EX1004 at ¶ 126.

XI. CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24, the undersigned attorney for the Petitioner, Petitioners declare that the argument section of this Petition (Sections I-X) has a total of 12,643 words, according to the word count tool in Microsoft Word™.

Date: August 29, 2017

By: /Richard M. McDermott/

Richard M. McDermott (Reg. No. 40,720)

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Alissa M. Pacchioli (Reg. No. 74,252)

CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(1) and 42.6(e)(4)(iii), and by agreement of the parties, the undersigned certifies that on August 29, 2017, a complete and entire copy of this Petition for *Inter Partes* Review and all supporting exhibits were provided via electronic means to counsel for Applied Medical Technology, Inc. as follows:

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Pursuant to 37 CFR §§ 42.6(e)(1) and 42.6(e)(4)(iii), the undersigned certifies that on August 29, 2017, a complete and entire copy of this Petition for *Inter Partes* Review and all supporting exhibits were deposited for delivery via UPS Next Day Air to Kirn Medical Design, L.L.C. at the correspondence address of record for the ’715 patent as follows:

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