UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDBOX MEDICAL, LLC.

Petitioner,

v.

NEOTECH PRODUCTS, INC.

Patent Owner.

Case No.: IPR2019-00246

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,958,050

Table of Contents

Certificate of Service

I hereby certify that on this 9th day of November, 2018, a copy of this Petition for *Inter Partes* Review and associated Exhibits 1001- 1024 were served by United Parcel Service overnight delivery on the following correspondence address of record for the subject patent:

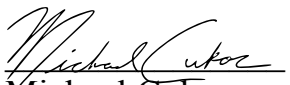
Mr. William W. Haefliger
Suite 512
201 S. Lake Ave.
Pasadena CA 91101

I further certify that on this 9th day of November, 2018, I caused to be sent a copy of this Petition for *Inter Partes* Review and associated Exhibits 1001- 1024 by United Parcel Service overnight delivery on the following counsel for the patent owner:

Michael A. Dinardo, Esq.
Kelly & Kelley, LLP
6320 Canoga Ave, Suite 1650
Woodland, CA 91367

Dated: November 9, 2018

Respectfully submitted,



Michael Cukor

List of Evidence and Exhibits Relied Upon in the Petition

Exhibit #	Name
1001	U.S. Patent 6,958,050 (‘050 Patent)
1002	File History of U.S. Patent 6,958,050
1003	U.S. Patent 3,595,234 (‘234 Patent or Jackson)
1004	U.S. Patent 4,813,926 (‘926 Patent or Kerwin)
1005	U.S. Patent 3,319,628 (‘628 Patent or Halligan)
1006	U.S. Patent 4,699,138 (‘138 Patent or Behrstock)
1007	U.S. Patent 5,114,415 (‘415 Patent or Shedlock)
1008	U.S. Patent 3,945,385 (‘385 Patent or Sackner)
1009	U.S. Patent 3,965,901 (‘901 Patent or Penny)
1010	U.S. Patent 5,496,268 (‘268 Patent or Perla)
1011	Declaration of Leslie H. Sherman
1012	Declaration of Read McCarty
1013	Letter from John Kelly Dated October 5, 2015
1014	Neotech Products Inc.’s Complaint for Patent Infringement
1015	American Association of Respiratory Care Clinical Practice Guideline Endotracheal Suctioning of Mechanically Ventilated Adults and Children with Artificial Airways (Resp Care 1993;38:500-504)
1016	American Association of Respiratory Care Clinical Practice Guideline

	Nasotracheal Suctioning (Resp Care 1992;37:898-901)
1017	ASTM International (ASTM) F1981-99, Suction Catheters for use in the Respiratory Tract
1018	International Standards Organization (ISO) 8836:1997(E) 2nd Edition, Suction Catheters for use in the Respiratory Tract
1019	Omitted
1020	American Association of Nurse Anesthetists (AANA) and American Latex Allergy Association – AANA Latex Protocol - approved by AANA Board of Directors on July 31, 1998.
1021	NIOSH ALERT: Preventing Allergic Reactions to Natural Rubber Latex in the Workplace. DHHS (NIOSH) Publication No. 97-135
1022	US Patent 63,709 (‘709 Patent or Dibble)
1023	US Patent 213,356 (‘356 Patent or Snow)
1024	US Patent 2,715,899 (‘899 Patent or MacClean)

1. INTRODUCTION

Petitioner requests *inter partes* review for claims 1-10 of U.S. Patent 6,958,050 ('050 Patent) (Exhibit 1001) under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq*. The '050 Patent is directed to a medical suctioning or aspiration device with a soft flexible tip and a side inlet to manually adjust suction. Exhibit 1001 at Abstract. The '050 Patent issues from Application 10/173,257 filed on June 18, 2002. The '050 Patent names Pradip V. Choski, Thomas R. Thornbury, and Craig McCrary, all of Chatsworth, CA, as the inventors, and Neotech Products, Inc. ("Neotech") as the assignee. Exhibit 1001.

The '050 Patent has one independent claim and 9 dependent claims. All of the '050 Patent claims recite aspects of an aspirator for medical suctioning. Exhibit 1001 at claims 1-10. The claims recite a two-piece plastic suctioning device with a soft, flexible tip made up of three sections, and a side inlet for manually controlling suction. The purported advance over prior art suctioning devices is "increased overall utility, as well as ease and effectiveness of use and operation." Exhibit 1001 at 1:10-12. All of the embodiments simply arrange known mechanical elements to achieve predictable results. Exhibit 1011 at ¶ 11.

In 1971 U.S. Patent No. 3,595,234 (Jackson or '234 Patent) (Exhibit 1003) disclosed all the salient features of the claimed inventions. The '234 Patent taught a two-piece medical suctioning device with three sections, and a side inlet for

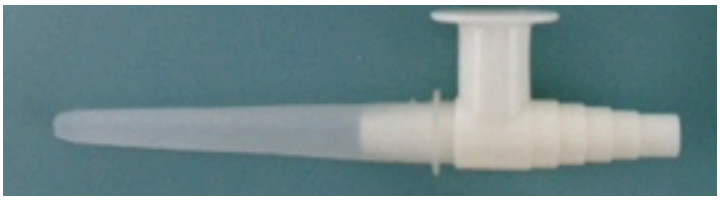
manually controlling suction. Exhibit 1003 at Figs 1-4. The suctioning device in Jackson (Exhibit 1003) includes a side inlet that can be manually covered and uncovered to control suction. Exhibit 1003 at Figs. 1-3. The device also includes a catheter portion with three sections. *Id.* at Fig. 1.

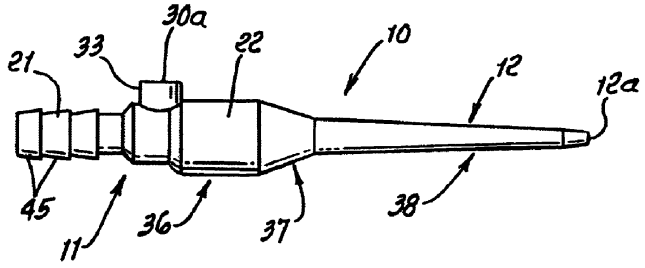
The '050 Patent recites 10 claims to a simple aspirator. Jackson (Exhibit 1003) renders all of them obvious either in view of prior art references teaching the minor design details recited in the claims, or in view of the common knowledge of the person of ordinary skill in the art ("POSA"). Claims directed to minor mechanical features, such as transparent or latex-free plastic, would have been obvious to the POSA at the time of the invention because such mechanical details were within the common knowledge of the POSA. The prior art also specifically disclosed the claimed mechanical details and the reasons for implementing them. Exhibit 1011 at ¶ 11.

Petitioner Sandbox Medical, LLC. ("Sandbox"), a Massachusetts Limited Liability Company, has been in business since 2009, and employs a husband and wife team to design, market and sell medical products directed to the premature infant and newborn infant market. It sells, among other things, a nasal aspirator for premature infants called the Boogie Baby. Exhibit 1012 ¶4. The Patent Owner, Neotech, asserted that Sandbox's Boogie Baby product infringed the '050 Patent and demanded that Sandbox cease all sales of the accused roducts in the United

States. Exhibit 1012 ¶6. Mr. Read McCarty, co-founder and Partner of Sandbox, advised Neotech that Sandbox does not believe the Boogie Baby product infringes the '050 Patent because (among other reasons) the Boogie Baby's catheter implements a single section of plastic and is not comprised of three separate (Primary, Secondary and Tertiary) sections with different taper angles as the claims require. Exhibit 1012 ¶7.

An image of the accused Boogie Baby product and Figure 1 from the '050 Patent shows the differences between the accused product and the claimed embodiment.





Nevertheless, Neotech continued to assert the '050 Patent against Sandbox's products, and filed a patent infringement action against Sandbox.

2. FILING REQUIREMENTS

2.1 REAL PARTY-IN-INTEREST

Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner certifies that the real party-in-interest of this petition is Sandbox Medical, LLC. Sandbox Medical, LLC is a Massachusetts Limited Liability Company, and the address of its principal place of business is 750 Corporate Park, Pembroke, MA 02359. Petitioner further certifies that no other party exercised control or could exercise control over Sandbox's participation in this proceeding, the filing of this Petition, or the conduct of any ensuing trial. Exhibit 1012 ¶9.

2.2 RELATED MATTERS

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner states that on May 5, 2017, Neotech filed a patent infringement action asserting the '050 Patent against Sandbox in the Central District of California, 2:17-cv-03410-CAS-SS. *Id*. Neotech voluntarily dismissed the action on September 29, 2017, and refiled in the District of Delaware. Exhibit 1012 ¶8. Neotech then filed a Motion to Transfer its own case to Massachusetts and Petitioner filed a Motion to Dismiss. *Id*. On October 10, 2018, the Court ordered the case transferred to the District of Massachusetts but left pending Petitioner's Motion to Dismiss. *Id*. Petitioner has challenged service in that case and awaits a ruling from the Court. This Petition is filed prior to the anniversary of the date Neotech's alleged service. *Id*. Petitioner is not aware of

any other action involving the '050 Patent. *Id*.

2.3 LEAD AND BACK-UP COUNSEL

Pursuant to 37 C.F.R. § 42.8(b)(3), Petitioner designates lead counsel as Vincent E. McGeary (Reg. No. 42,862), and back-up counsel as Michael Cukor (*pro hace vice* motion to be filed).

2.4 SERVICE INFORMATION

Pursuant to 37 C.F.R. § 42.8(b)(4), papers concerning this matter should be served, and Petitioner hereby consents to email service of papers, on the following:

Address: Vincent E. McGeary
7 Dumont Place
Morristown NJ 07960
E-Mail: vmcgeary@mcgearycukor.com
cc: mcukor@mcgearycukor.com
Telephone: 973-339-7985
Fax: 973-200-4837

2.5 PAYMENT OF FEES

The undersigned has paid by approved method $30,500.00 for the fee set forth in 37 C.F.R. § 42.15(a) for this Petition for *Inter Partes* Review. Petitioner seeks review of 10 claims. The fee calculation is $15,500 for the first 20 claims in the petition + $15,000 for up to 15 claims post institution = $30,500.00

2.6 GROUNDS FOR STANDING

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the '050 Patent is

available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review challenging the claims of the '050 Patent. The '050 Patent has not been subject to a previous estoppel-based proceeding and Petitioner has not been served with any complaint alleging infringement of the '050 Patent that would preclude filing this IPR. *See,* 35 U.S.C. §315. Exhibit 1012 ¶9.

Patent Owner voluntarily dismissed its Complaint in the Central District of California; therefore, any service of the voluntarily dismissed action does not preclude this Petition. Petitioner has challenged service of the pending action, which Patent Owner contends occurred on November 14, 2017. *Id*. Even if the Court were to determine that Patent Owner properly served the action, such service would not preclude this request because this request is made less than one year from the time of the purported service of the Complaint alleging infringement. Also, neither Petitioner, its privy nor a real-party-in-interest has commenced a civil action challenging the claims of the '050 Patent. *Id*.

2.7 PRECISE STATEMENT OF RELIEF REQUESTED

Pursuant to 37 C.F.R. § 42.104(b), Petitioner requests that the Patent Trial and Appeal Board (the Board) institute an *inter partes* review of claims 1-10 of the '050 Patent and declare and cancel the challenged claims as unpatentable on the following grounds:

Ground 1: Claims 1-6 and 8 - 10 are unpatentable under 35 U.S.C.

§ 103(a)[1] over the '234 Patent (Jackson) (Exhibit 1003) in view of the '926 Patent (Kerwin) (Exhibit 1004) or the '138 Patent (Behrstock) (Exhibit 1006) in further view of the '901 Patent (Penny) (Exhibit 1009) or the '628 Patent (Halligan) (Exhibit 1005).

Ground 2: Claim 7 is unpatentable under 35 U.S.C. § 103(a) for the reasons of Ground 1 in further view of the '415 Patent (Shedlock) (Exhibit 1007).

Ground 3: Claim 10 is unpatentable under 35 U.S.C. § 103(a) for the reasons of Ground 1 in further view of the '268 Patent (Perla) (Exhibit 1010).

Ground 4: Claims 1-10 are unpatentable under 35 U.S.C. § 103(a) over the '234 Patent (Jackson) in view the Common Knowledge of the POSA.

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[1] All claims have an effective filing date prior to March 16, 2013. References to 35 U.S.C. §§ 102-103 are references to pre-AIA 35 U.S.C. *See,* 35 U.S.C. § 100.

3. TECHNOLOGY OVERVIEW

3.1 NASAL ASPIRATORS AND SUCTION CATHETERS

Aspirators have been used in medicine and dentistry for at least 150 years. From their introduction and continuing to at least the time of the '050 Patent, aspirators have included the same basic elements: a connection to a vacuum source or an integral vacuum source such as a squeeze bulb syringe, a handle, a catheter and a tip. Sometimes these elements are referred to by different names. In many instances elements have been combined, resulting in fewer physical parts. Some aspirators purported design improvements such as the inclusion of suction control and/or specialized tip shapes. Some of the earliest designs included flexible tubing, as shown in US Patent 63,709 (1867) to Dibble and US Patent 213,356 (1879) to Snow. Exhibits 1022 and 1023. As plastics and better molding techniques evolved, aspirators and aspirator parts transitioned from predominantly metal to predominantly plastic as shown in US Patent 3,319,628 (1967) to Halligan (Exhibit 1005) and US Patent 3,937,220 (1976) to Coyne. Exhibit 1011 ¶ 25.

Side inlets to control suction

Before the advent of high-performance pumps, suction was often created manually. The squeeze bulb syringe illustrates a basic manual suction device that is still used today. Foot- and hand-powered pumps improved suction power over a squeeze bulb.

Today, virtually all applications use suction derived from electric pumps. These pumps are capable of producing high vacuum and air-flow levels. If not controlled properly, excessive vacuum can harm the patient by inducing tissue damage, anxiety, variation of intracranial pressure, pneumothorax, hypoxia and even cardiac hazard. Exhibit 1011 at ¶ 26. At the time of the '050 Patent, it was desirable to control the level of suction close to where the suction was applied whenever possible. *Id*.

Side inlets were known to control suction in nasal aspirators and suction catheters since long before the '050 Patent. For example, the US Patent 2,715,899 (1952) to MacClean (Exhibit 1024) showed a curette with a port in its handle designed to control suction, while Halligan (Exhibit 1005) introduced a generic regulator to control the fluid flow of a suction catheter. Exhibit 1011 at ¶ 26.

Material Choices

Transparent or translucent materials also have been used in nasal aspirators and suction catheters since long before the '050 Patent. Transparent or translucent materials are preferred over opaque materials where medical care personnel need to identify what is being suctioned or need to immediately cease suctioning when unexpected conditions occur. The '050 Patent suggests transparent or translucent materials for the same reason these materials were used in the prior art. "The device is preferably translucent or transparent for easy visualization as during use."

‘050 Patent, (Exhibit 1001 at 3:41-42). This was known to the skilled artisan from well before the date of the ’050 Patent. *See e.g.* Halligan (Exhibit 1005 at 2:53-55) (“It is convenient to use a tubing which is translucent or transparent as opposed to an opaque tubing, although an opaque tubing may be used.”).

Latex – natural rubber – is commonplace in our daily lives, is virtually impossible to avoid and is a health problem for people who are allergic to it. Exhibit 1011 at ¶ 29. Healthcare workers commonly suffer from the allergy because of their constant exposure to it. *Id*. While healthcare professionals today use gloves without latex, such as nitrile, a patient’s contact with latex can cause allergic reactions ranging from contact dermatitis - itching, swelling and redness of the skin - to hives, asthma or, in sever cases, full-blown anaphylactic shock. For someone who is predisposed to the allergy, prolonged exposure to latex increases the chance that symptoms will grow continually over time. For this reason it has been the standard operating procedure in many hospitals since before the ‘050 Patent to expose patients to latex as infrequently as possible. *Id*.

The intended function of a particular aspirator dictates its shape.

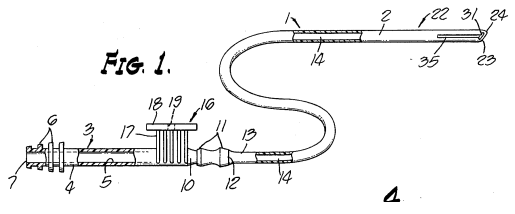
Prior art aspirators came in various sizes and shapes. As would be expected, the intended use and the particularities of the patient have bearing on the size and shape of prior art aspirators. The prior art discloses design considerations such as that the control piece or handle should be comfortable to hold and easily managed

by the caregiver. The patient-contacting tube or tip, also called a catheter, is often application-specific: short or long depending on how far the catheter must be inserted into the patient. For example, it was known at the time of the '050 Patent that a combination tube and tip should be short if only suctioning upper nasal or oral passages. Catheters were proportionately longer when performing nasogastric or tracheal suction on patients of different sizes, from infants through adults.

Well before the '050 Patent, the industrial designer of ordinary skill in the art knew that the use of an injection-molded, hard plastic handpiece with a generic interface for use with any number of catheters made for a logical value proposition for commercialization-from both a cost and functionality standpoint. Exhibit 1011 at 30.

Prior Art Examples

The '050 Patent made no breakthroughs in the art of medical aspirators. Many examples existed at the time of the invention. Penny (Exhibit 1009) Figure 1 shows a prior art aspirator of similar design to the '050 Patent disclosure.



Halligan (Exhibit 1005) Figure 1 shows an aspirator with similar features and Fig. 1 prominently displays suction control.

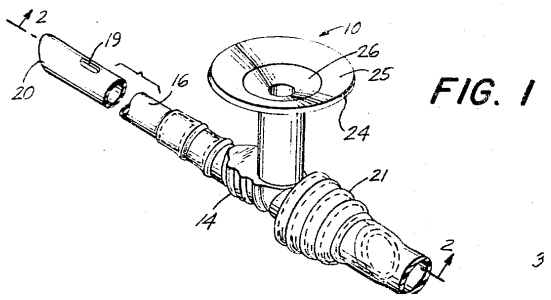
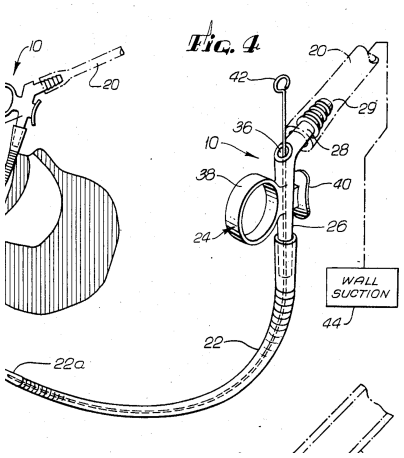


FIG. 1

Behrstock (Exhibit 1006) at Figure 4 demonstrates yet another similar aspirator.



These aspirators as well as others existed at the time of the invention. As the Petition shows, the Patent Owner simply rearranged known elements in a predictable fashion and presented them prior to the Supreme Court's guidance in *KSR International Co. v Teleflex Inc.,* 550 U.S. 398 (2007). In view of the

obviousness guidelines as clarified in *KSR*, the Board should grant this Petition and proceed to a trial.

3.2 THE '050 PATENT

The '050 Patent describes a two-piece suction catheter with a thumb vent, three different angled sections, and a flexible tip. In the original claim 1 of the application, the applicant recited an aspirator with suction control but without the particulars of the catheter:

1. A multi-purpose medical suctioning device, comprising

a) a first tubular body portion,

b) a second tubular portion operatively connected to said first tubular body portion,

c) said second tubular portion having a flexible tip portion which is relatively soft and pliable and has an entrance of reduced area, said second tubular portion being easily maneuverable as by bending,

d) there being a side inlet associated with at least one of said first and second portions, to be manually blocked and unblocked to control suctioning of fluid from said tip portion entrance and through said second and first tubular portions.

Exhibit 1002 Pg. 000145

One of the drawings embodies these claim elements:

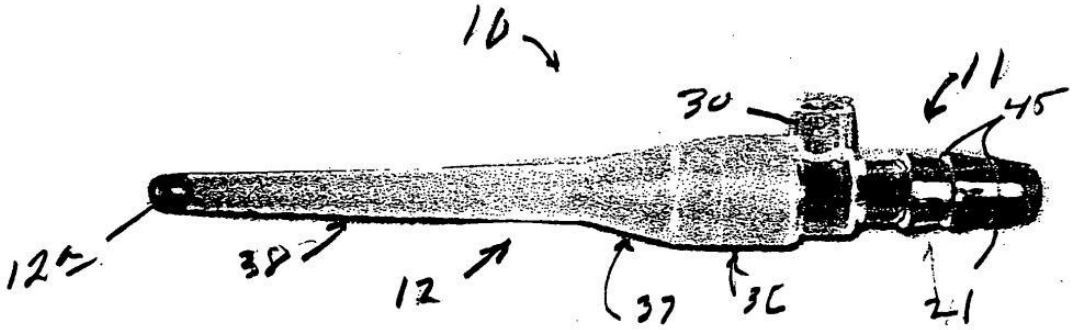


Fig 1

Exhibit 1002 Pg. 000132.

On June 1, 2004, the PTO rejected all of the proposed claims of the '257 Application in a First Office Action. Claim 1 was rejected pursuant to, *inter alia*, 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a). Exhibit 1002 Pg. 00050. The examiner found that all of the elements of proposed claim 1 were found in Halligan (US Patent 3,319,628).

Halligan discloses a suction catheter comprising a) a first tubular body portion (14), b) a second tubular portion (16) operatively connected to said first tubular body portion, c) the second tubular portion having a flexible tip portion which is relatively soft and pliable, see Column 2, lines 1-2 and 34-35, and has an entrance of reduced area, see Figure 2 and Column 2, lines 38- 41, distal tip (20) is smaller relative to the proximal end of tube (16)

which flares outwardly to accommodate the first tubular body portion therein, the second tubular portion being easily maneuverable as by bending, d) there being a side inlet (22) associated with the first portion, to be manually blocked and unblocked to control suctioning of fluid from the tip portion entrance and through the second and first tubular portions.

Exhibit 1002 Pg. 00054.

The examiner also found that all limitations of proposed claim 1 were found in Behrstock (Exhibit 1006) (US Patent 4,699,138 A).

Behrstock discloses a suction device comprising a) a first tubular body portion (26,28), b) a second tubular portion (22) operatively connected to the first tubular body portion, c) the second tubular portion having a flexible tip portion which is relatively soft and pliable, see Column 5, lines 16-33, and has an entrance of reduced area, see Figures 1 and 4, distal tip (22a) is smaller relative to the proximal end of tube (22), the second tubular portion being easily maneuverable as by bending, d) there being a side inlet (36) associated with the first portion, to be manually blocked and unblocked to control suctioning of fluid from the tip portion entrance and through the second and first tubular portions.

Exhibit 1002 Pg. 00053.

In § 103 rejections, the Examiner found that original claim 1 was

unpatentable over US Patent 4,813,926 (Kerwin) (Exhibit 1004) in view of US Patent 4,729,765 (Eckels et al.) or Halligan (Exhibit 1005).

Kerwin discloses a suction device comprising a) a first tubular body portion (14), b) a second tubular portion (16/18) operatively connected to said first tubular body portion, c) said second tubular portion having a flexible tip portion (18) which is relatively soft and pliable and has an entrance (56) of reduced area, see Figure 2, said second tubular portion being easily maneuverable as by bending, see Column 6, lines 17-20 and 22-32; wherein the second tubular portion has primary (A, see labeled figure below), secondary (B, see labeled figure below) and tertiary (C, see labeled figure below) lengthwise extending sections, the primary section fitting telescopically to the first tubular body portion, the tertiary section being flexible and tapering toward the tip at a relatively lesser taper angle, and the secondary section extending between the primary and tertiary sections, at a relatively greater taper angle; and wherein the secondary and tertiary sections have respective lengths L2 and L3 wherein L3 is elongated and L3»L2, flexibility of the tertiary section thereby being enabled along its major elongated length, to facilitate suctioning usage of the tertiary section as the tertiary section is easily bent in response to engagement with tissue of a patient.

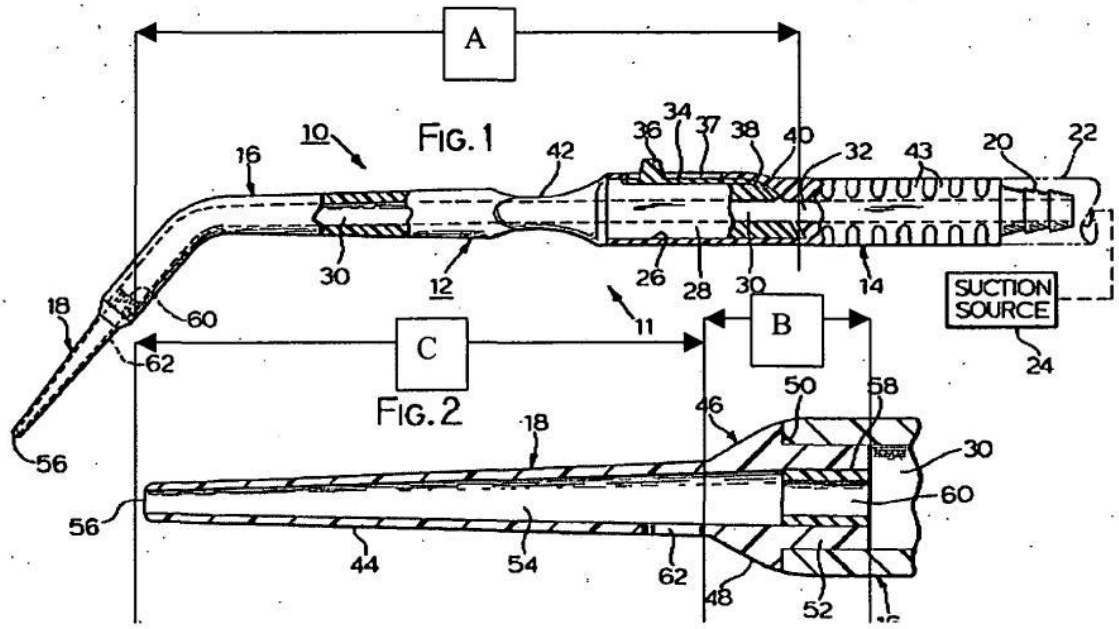


Exhibit 1002 Pg. 00055-56.

To overcome these rejections, Patentee amended claim 1 to add new limitations e, f, g, and h. As shown below, these limitations were drawn to particulars such as the shape and pliability of the catheter and to usability such as "being maneuverable with one hand":

> e) and wherein said first tubular body portion consists of relatively hard plastic material, and said second tubular portion consists of relatively soft plastic material, the tip being maneuverable as by one hand of the user, while the user's other hand controls said side inlet,
>
> f) said second tubular portion having primary secondary and tertiary lengthwise extending sections, said primary section fitting telescopically to

said first tubular body portion, and with friction, said tertiary section being flexible and tapering toward said tip at a relatively lesser taper angle, and said secondary section extending between said primary and tertiary sections, at a relatively greater taper angle, said primary section fitting over said first tubular body portion to define a device maximum diameter proximate the entrance of said side inlet and between said inlet and said flexible tip portion, for finger control of the device including finger control of said inlet and control of said primary section to control tip portion bending,

g) said secondary and tertiary sections having respective lengths L2 and L3, where L3, is elongated and L3»L2, flexibility of said tertiary section thereby being enabled along its major elongated length, to facilitate suctioning usage of the tertiary section as the tertiary section is easily bent in response to engagement with tissue of a patient,

h) and wherein said device is characterized by one of the following:

i) said body portions are transparent

ii) said body portions are translucent

iii) at least one of said body portions is transparent

iv) at least one of said body portions is translucent.

Exhibit 1002 Pg. 00041-42.

As far as structure, this extended verbiage relates mostly to reciting that the catheter included three tapered sections where one section is elongated relative to another section and where the tip section is flexible and transparent or translucent. Although Patentee used many words, the claim basically recites a device shown in Fig. 1 of the patent, which, as shown below, was well known in the prior art.

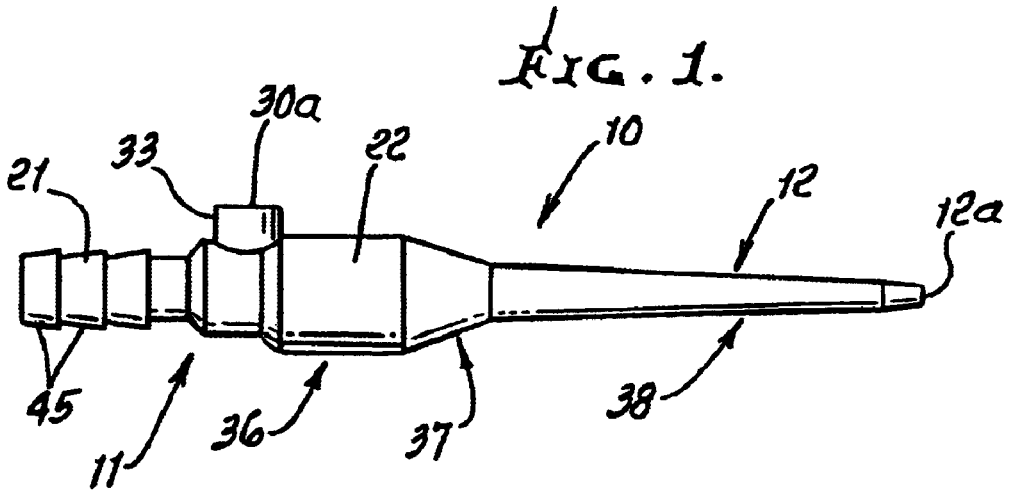


Exhibit 1002 Pg. 00010.

Despite the amendment, the Patent Office notified Patentee that its reply to the office action was not fully responsive since it did not address the cited art. Exhibit 1002 Pg. 000-37. Patentee filed another Amendment and addressed the cited prior art. While Patentee's arguments with regard to Kerwin (Exhibit 1004) were not accurate, Patentee articulated what it believed Kerwin (Exhibit 1004)

failed to show with regard to claim 1 as amended.[2]

> Kerwin's vent 62 is near his tip 56, and not near his body maximum diameter at region 14 ; he lacks a "second tubular portion having primary secondary, and tertiary sections" as per f) of claim 1, and he lacks transparency features of h) of claim 1.

Exhibit 1002 Pg. 00030-31.

The Patentee offered no reasons why these picayune features amounted to invention, or why a skilled artisan wouldn't readily implement such design choices. Nevertheless, on May 26, 2005, the Examiner allowed the amended claims without further comment. Exhibit 1002 Pg. 0016.

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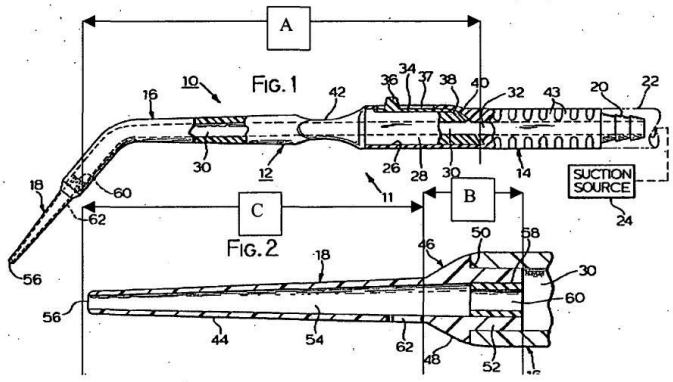
[2] Patentee's alleged distinction regarding Kerwin's (Exhibit 1004) vent is incorrect. Kerwin discloses a finger-controlled vent at 36, which is proximal to 14, the portion of Kerwin Patentee identifies as the device maximum diameter. Kerwin (Exhibit 1004 at 2:46-60).



The figure above from Kerwin (Exhibit 1004), as modified by the Examiner during prosecution, shows the finger-controlled vent at 36. Exhibit 1002 Pg. 0056.

4. PROPOSED CLAIM CONSTRUCTIONS

As of the filing of this Petition, the "broadest reasonable interpretation" claim construction standard applies to an *inter partes* review. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC,* 778 F.3d 1271, 1281 (Fed. Cir. 2015). Petitioner acknowledges that the Patent Office will apply the standard announced in *Phillips v AWH Corp*., 415 F.3d 1303 (Fed. Cir. 2005) (en banc) to petitions filed on or after November 13, 2018. In this case, for terms with an ordinary meaning, Petitioner submits that the ordinary meaning to the POSA constitutes the broadest reasonable interpretation as well as the correct construction under *Phillips*. Similarly, Petitioner relies on the claim language itself read in view of the interpretation for its proposed constructions; therefore, its proposed constructions for the broadest reasonable interpretation comport with *Phillips.*

Petitioner proposes the following claim constructions:

"Device Maximum Diameter" – Claim 1

Claim 1 uses the term "device maximum diameter." The '050 Patent refers to its primary section as the device maximum diameter. The primary section constitutes the largest diameter of all circular portions of the device. In general, the word diameter refers to any straight line between two points on the circumference of a circle that also passes through the center of the circle. Since Patent Owner chose the word diameter he intended to restrict this limitation to the length of a line

that passes through the center of a circular portion of the device. This is further confirmed by Patentee's identification of the area 36 as the device maximum diameter. The width of the area below area 30a is greater than the diameter of 36 but is not considered the device maximum diameter because Patentee was referencing the largest width of a *circular* portion of the device. Accordingly, "device maximum diameter" should be construed as the largest straight line between two points on the circumference of a circular portion of the device that passes through the center of the circle. Exhibit 1011 at ¶ 45.

"Relatively Lesser Taper Angle" and "Relatively Greater Taper Angle" – Claim 1.

The comparative terms "relatively lesser taper angle" and "relatively greater taper angle" are both used in claim 1 without explanation as to what comparison is intended and Petitioner reserves the right to contend the claims are indefinite in any other proceeding.[3] Exhibit 1011 at ¶ 46. *See, e.g.*, *Ex parte Miyazaki*, 89 USPQ2d 1207 (Bd. Pat. App. & Inter. 2008) (precedential) and *Ex parte Brummer*, 12 USPQ2d 1653 (Bd. Pat. App. & Inter. 1989). However, for purposes of this Petition and any ensuing *inter partes* review, Petitioner proposes a construction of

[3] The same is true for Claim 1(c) "*relatively* soft and pliable"; 1(e) "*relatively* hard plastic" and "*relatively* soft plastic"; 3 "*relatively* enlarged end"; and 4 "*relatively* large end."

this language in view of Fig. 1. Petitioner proposes that "relatively lesser taper angle" refers to the angle of the tertiary section which is lesser than the angle of the secondary section, and "relatively greater taper angle" refers to the angle of the secondary section which is greater than the angle of the tertiary section.

"Telescopically"

The patent uses the term "telescopically" consistent with how the term would be used by a POSA, which is "consisting of parts that slide one within another." Exhibit 1011 at ¶47. This understanding is supported by the Patentee's description of how the two main pieces of the device connect. "Endwise assembly of the two parts 11 and 12 is mechanical, for or by frictional retention." Exhibit 1003 '050 Patent, (Exhibit 1001 at 3:61-62). Petitioner proposes that "telescopically" requires no separate construction or, if construed, that "telescopically" means sliding one part within another.

Lastly, the claims also recite intended uses of the device. Since recitations of intention are simply suggestions of theoretical utility rather than defining what the device is, or how the device works, these limitations do not impart a patentable distinction. "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). The '050 Patent's "recitation with respect to the manner in which [the] claimed apparatus is intended to be employed does not differentiate the claimed

apparatus from a prior art apparatus" if the prior art teaches all the structural limitations of the claim. *Ex parte Masham,* 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). MPEP § 2114.

Claim 1 of the '050 Patent contains numerous examples. Claim 1(c) states "said second tubular portion being easily maneuverable as by bending"; (d) a side inlet "to be manually blocked and unblocked to control suctioning of fluid from said tip portion entrance and through said second and first tubular portions"; (e) "the tip being maneuverable as by one hand of the user, while the user's other hand controls said side inlet"; (f) "for finger control of the device including finger control of said inlet and control of said primary section to control tip portion bending"; (g) "flexibility of said tertiary section thereby being enabled along its major elongated length, to facilitate suctioning usage of the tertiary section as the tertiary section is easily bent in response to engagement with tissue of a patient."

Petitioner proposes that such language be construed as not imparting a limitation to the claim for purposes of a patentability analysis. However, out of an abundance of caution, the analysis below, where practicable, treats such language as limitations with respect to the prior art, but none of the intended use language is capable of imparting patentable distinctions to the '050 Patent's claims. Petitioner's caution is not an admission or concession that the claim language ought to be considered in a patentability determination.

5. INVALIDITY

5.1 PERSON OF ORDINARY SKILL IN THE ART

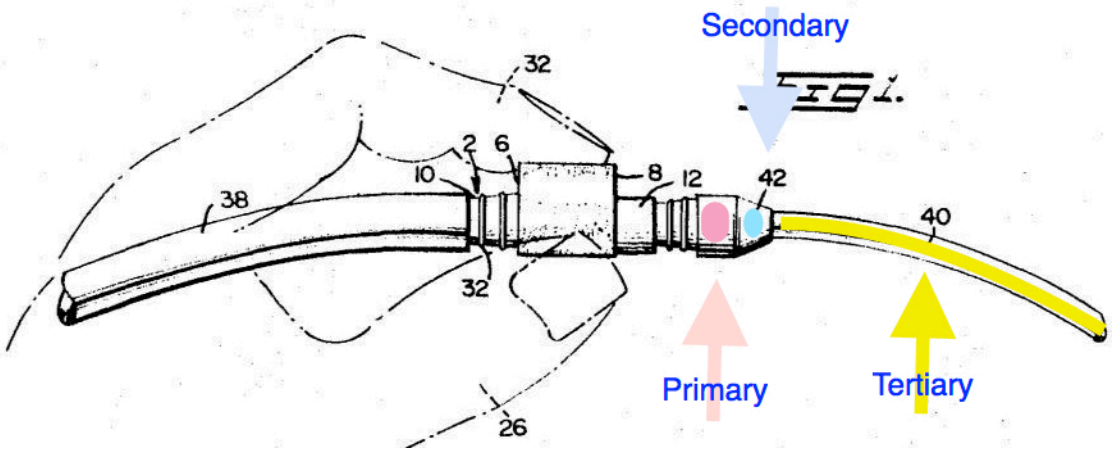
For purposes of this Petition only, Petitioner proposes that a person of ordinary skill in the art in the field of the '050 Patent would have been a mechanical technician having the equivalent of 4 years of undergraduate education in mechanical technology, or two years of education and two years of practical experience in industrial design. This level of skill could be achieved through formal education, a combination of education and experience, or even purely through experience. Exhibit 1011 ¶20.

5.2 GROUND 1

Claims 1-6 and 8-10 recite a long list of elements for a basic suction catheter: a flexible tip with an entrance of reduced area, a side inlet manufactured of plastic, two portions that fit together with friction, one of the portions having three separate sections with different lengths and taper angles, and transparent or translucent parts. The combination of these known elements in a predictable manner was not inventive.

The vast majority of the claimed elements can be found explicitly in the '234 Patent. Exhibit 1011 at ¶ 49. The '234 Patent is prior art under 35 U.S.C. § 102(b), Claims 1-6 and 8-10 are obvious under 35 U.S.C. § 103 in view of the '234 Patent,

in further view of either Kerwin or Behrstock and in further view of Halligan or Penny. Exhibit 1011 at ¶ 49-50. As shown below, the '234 Patent discloses a two-piece medical suction device made of plastic, where the first piece has a side inlet for controlling suction, and the second piece is a catheter with three sections.

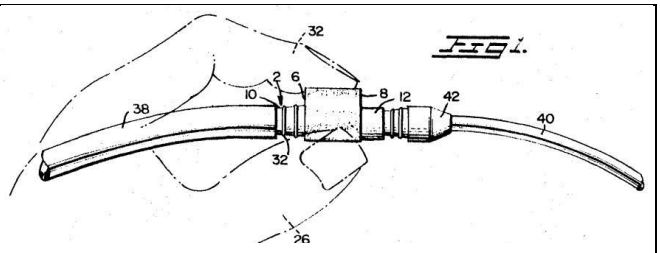


While the '234 Patent does not specifically state that the plastic is transparent or translucent and flexible, those limitations recite mere design choices that would have been obvious to one of ordinary skill in the art and were already disclosed in other prior art, such as in Behrstock (Exhibit 1006). Likewise, while the '234 Patent discloses tapering the primary and secondary catheter sections, both Kerwin and Behrstock teach reducing the diameter from the primary to the tip with taper angles. (Exhibits 1004 and 1006). The '234 Patent also explicitly shows inserting the primary section to the tubular body and both Halligan and Penny demonstrate inserting the tubular body into the primary section. Exhibit 1002 Pg.

00054 and Exhibit 1009.

The table below shows where each element of claims 1-6 and 8-10, as construed, can be found in the '234 Patent as modified by the secondary references. The table also provides the rationale for making the proposed modification. The table may include further references to prior art relevant to this or other Grounds.

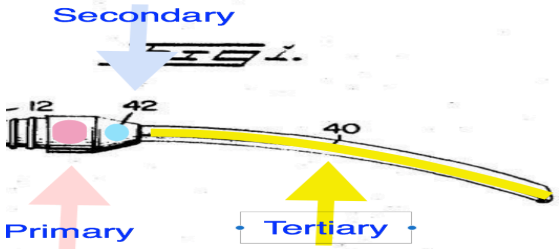
Claim 1 – US 6,958,050	Prior Art: 3,595,234 - Jackson (Exhibit 1003) – 1971 (Exhibit 1003)
A multi-purpose medical suctioning device, comprising a) a one piece first tubular body portion,	"A principal object of the present invention is the provision of a new form of vacuum controller for medicosurgical suction tubes." (Exhibit 1003 at 1:64-66); "As additional preferred features, the vacuum controller is molded as an integral or single unit of plastic material, although it can be fabricated from metal parts as a single unit or separate parts suitably screwed or otherwise fastened together." (Exhibit 1003 at 2:52-55). The overall similarity between the '050 Patent and Jackson (Exhibit 1003) are also seen in Figure 1.

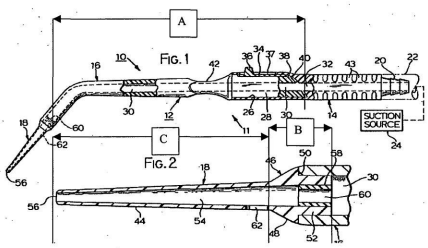
	 See also Exhibit 1011 at 29.
b) a one piece second tubular portion operatively connected to said first tubular body portion,	"The controller 2 may be made as a separate unit without being permanently attached to either a connector tube or to a suction catheter." (Exhibit 1003 at 4:64-66). "In a preferred embodiment, the suction catheter 40 will be provided on its proximal end section with a male connector 42 which is tapered to fit into the female connector end 12 of the vacuum controller." (Exhibit 1003 at 3:57-61). This limitation is also met by Penny (Exhibit 1009 at Fig. 1, element 13), Halligan (Exhibit 1005 at Fig. 1, element 16), Behrstock (Exhibit 1006) Fig. 4, element 22), and Kerwin (Exhibit 1004 Fig. 1, element 18). See also Exhibit 1011 at 30-31.
c) said second tubular	Halligan (Exhibit 1005 at 2:1-2 and 34-

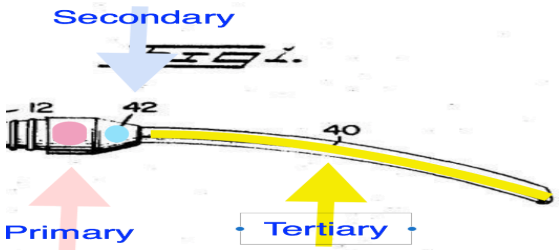
portion having a flexible tip portion which is relatively soft and pliable and has an entrance of reduced area, said second tubular portion being easily maneuverable as by bending,	35), Behrstock (Exhibit 1006 at 5:16-33), and Kerwin (Exhibit 1004 at 6:17-20 and 22-32) disclose a tubular portion with a flexible tip. Fig. 1 of Jackson shows a bend in the tubular portion. Jackson further suggests substituting various tubes for medical applications: "Medicosurgical suction tubes are constructed in a variety of shapes and sizes for a number of different applications in medical and surgical procedures. Such medicosurgical suction tubes can take the form of suction catheters which are used for the aspiration of mucus from the nose, mouth. pharynx, trachea or bronchi of patients. Alternatively, such suction tubes may be used for connection to sump drain tubes or other pieces of equipment or structures where application of a vacuum as a part of a clinical or surgical operation is required. The new vacuum controllers of this present invention are contemplated for use in connection with any form of medicosurgical suction tube whether it be a suction catheter, suction connector tube or the like." (Exhibit 1003 at 1: 6-19). Jackson (Exhibit 1003 at Fig. 1) shows the distal end 40 of the suction catheter having a reduced opening as compared to the proximal end 42.

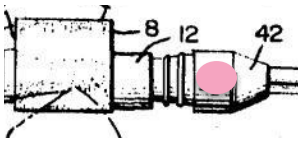
	It also would have been obvious to a POSA to use any number of flex tubes as suction catheter 40 as flexible catheters were well known in the prior art. Jackson provides the motivation in the prior art to substitute different catheter types. (Exhibit 1011 at 31-32).
d) there being a side inlet associated with at least one of said first and second portions, to be manually blocked and unblocked to control suctioning of fluid from said tip portion entrance and through said second and first tubular portions,	"Vacuum control means for medicosurgical suction tubes, e.g., suction catheters or the like, in which control of the suction can be obtained by manipulation of a thumb or finger of the person administering treatment to a patient but in which the thumb or finger effecting the control does not come into direct contact with the aperture through which control of the suction is regulated." (Exhibit 1003 at 1:66-73 and Figs. 1-3) See also Exhibit 1011 at 32.
e) and wherein said first tubular body portion consists of relatively hard plastic material,	"As additional preferred features, the vacuum controller is molded as an integral or single unit of plastic material..." (Exhibit 1003 at 2:52-54). This limitation is also specifically disclosed in Kerwin (Exhibit 1004 at 6:18-26) and Halligan (Exhibit 1005 at 1:57-59). It would have been obvious to a POSA to

	use a relatively hard plastic to manufacture the handle as hard plastic handles and their advantages were well known in the prior art. (Exhibit 1011 at 32-33).
and said second tubular portion consists of relatively soft plastic material, the tip being maneuverable as by one hand of the user, while the user's other hand controls said side inlet,	See 1c and 1d. "Medicosurgical suction tubes are constructed in a variety of shapes and sizes for a number of different applications in medical and surgical procedures. Such medicosurgical suction tubes can take the form of suction catheters which are used for the aspiration of mucus from the nose, mouth. pharynx, trachea or bronchi of patients. Alternatively, such suction tubes may be used for connection to sump drain tubes or other pieces of equipment or structures where application of a vacuum as a part of a clinical or surgical operation is required. The new vacuum controllers of this present invention are contemplated for use in connection with any form of medicosurgical suction tube whether it be a suction catheter, suction connector tube or the like." Exhibit 1003 at 1:6-19, and Fig. 1. This limitation is also specifically

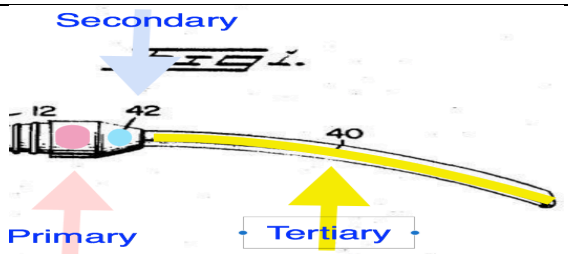
	disclosed in Halligan (Exhibit 1005 at 2:1-2 and 34-35), Behrstock (Exhibit 1006 at 5:16-33) and Kerwin (Exhibit 1004 at 6:17-20 and 22-32). It also would have been obvious to a POSA to use any number of flexible catheters in place of suction catheter 40, including flexible catheters as flexible catheters were well known in the prior art Exhibit 1011 at 33-34. As stated by Penny (Exhibit 1009) in 1976, "[t]raditionally, suction catheters have consisted of a flexible plastic tube having a beveled end, an end opening, and an opening spaced substantially back from the beveled end and passing through the top wall section, that is, the wall section which extends to form the tip of the beveled end."
f) said second tubular portion having primary secondary and tertiary lengthwise extending sections,	Annotated Figure 1 of Exhibit 1003 below shows the second tubular body portion having three sections.  This limitation is also disclosed in Kerwin

	(Exhibit 1004), as pointed out by the Examiner during prosecution, where the second tubular portion has primary (A, see labeled figure below), secondary (B, see labeled figure below) and tertiary (C, see labeled figure below) lengthwise extending sections.  Exhibit 1002 Pg. 00056. This limitation is also disclosed in Penny (Exhibit 1009 at Fig.1 at elements 11, 12 and 13). See also Exhibit 1011 at 34.
said primary section fitting telescopically to said first tubular body portion, and with friction,	"In a preferred embodiment, the suction catheter 40 will be provided on its proximal end section with a male connector 42 which is tapered to fit into the female connector end 12 of the vacuum controller." (Exhibit 1003 at 3:57-61). This limitation is also disclosed at Kerwin (Exhibit 1004 at 2:39-46), Behrstock (Exhibit 1006 at Fig. 4, elements 22 and 26), Penny (Exhibit 1009 at Fig. 1, elements 10 and 11), and Halligan (Exhibit 1005 at 2:23-37). See also Exhibit 1011 at 34-35. Telescopic fits with

	friction were well known and Jackson itself provides a reason for using a telescopic fit.
said tertiary section being flexible and tapering toward said tip at a relatively lesser taper angle,	This limitation is specifically disclosed in Kerwin (Exhibit 1004 at Fig. 2 element 18), Behrstock (Exhibit 1006 at Fig. 4 element 22a), and Penny (Exhibit 1009 at Fig. 1 element 23). Exhibit 1011 at 35. Moreover, the prior art teaches that nasal aspirators are often designed to accommodate multiple tips and/or multiple catheter portions. Tapered tips were well known in the prior art. Exhibit 1011 at 35-36. It would have been obvious to a POSA to use a tertiary section with a tapered tip. Exhibit 1011 at 35-36.
and said secondary section extending between said primary and tertiary sections, at a relatively greater taper angle,	 Annotated Figure 1 shows that the tertiary section has no taper so the secondary section taper angle is greater. (Exhibit 1003 at Fig. 1.). This limitation is also specifically

	disclosed in Kerwin (Exhibit 1004 at Fig. 2, element 48); Penny (Exhibit 1009 at Fig. 1, element 12). It is mechanically advantageous for a suction catheter to contain a long tapered tip for effective suction control. There are a number of different ways to transition from the narrow bore at the distal end of the catheter to the wide bore at the proximal end. A POSA would know that one way to make that transition would be to create a stepped secondary section. (Exhibit 1011 at 36-37). It would also have been obvious to a POSA to use a secondary section with any number of different taper angles including a greater taper angle as many different tapered tip suction catheters were known in the prior art. (Exhibit 1011 at 36-37).
said primary section fitting over said first tubular body portion to define a device maximum diameter proximate the entrance of said side inlet and between said inlet and said flexible tip portion, for finger	Jackson shows that the primary section terminates with a ribbed portion that fits into section 12 of the first tubular body portion; a female connection. 

control of the device including finger control of said inlet and control of said primary section to control tip portion bending,	The primary section (identified above in pink) of Jackson (Exhibit 1003) is the device maximum diameter when measuring the largest diameter of all circular portions of the device. The device maximum diameter is also proximate the entrance of the side inlet and between the inlet and the flexible tip portion. The Jackson (Exhibit 1003) device uses a female connection but the choice between a male and female connection was a design choice. (Exhibit 1011 at 37-39). A POSA would know that connecting the primary and secondary section could be done with a number of different connections, including a twisting connection and several variations of the friction fit connection claimed by Patentee. A POSA would also know that a friction fit connection could be accomplished with either a male or a female connection. (Exhibit 1011 at 37-39). This limitation is also disclosed in Halligan (Exhibit 1005 Fig. 1, between elements 14 and 21, and 2:45-49) and Penny (Exhibit 1009 at 2:58-62).

	It would have been obvious to a POSA to use a male or female connection to connect the second tubular body portion of Jackson (Exhibit 1003) to the first tubular body portion as this was merely a design choice and male and female connections were well known in the prior art. See Exhibit 1011 at 37-39. Further, when distinguishing over the prior art cited during prosecution, Patentee asserted that this limitation was not met by either Behrstock (Exhibit 1006) or Kerwin (Exhibit 1004) but did not assert that the limitation was not shown in Halligan (Exhibit 1005). Exhibit 1002 at 29-32.
g) said secondary and tertiary sections having respective lengths L_2, and L_3 where L_3 is elongated and $L_3 >> L_2$, flexibility of said tertiary section thereby being enabled along its major elongated length, to facilitate suctioning usage of the tertiary section as the tertiary section is	 Annotated Figure 1 shows that the tertiary section is much longer than the secondary section. See also Exhibit 1003 at 1:6-19 showing that a variety of different tips can be used. This limitation is also specifically

easily bent in response to engagement with tissue of a patient,	disclosed in Halligan (Exhibit 1005 at 2:1-2 and 34-35), Behrstock (Exhibit 1006 at 5:16-33) and Kerwin (Exhibit 1004 at 6:17-20 and 22-32). It would have been obvious to a POSA to use any number of flexible catheters in place of suction catheter 40, including flexible catheters as flexible catheters were well known in the prior art. See Exhibit 1011 at 39.
h) and wherein said device is characterized by one of the following: i) said body portions are transparent ii) said body portions are translucent iii) at least one of said body portions is transparent iv) at least one of said body portions is translucent.	"The E-T tube 22 is a commonly used, stock item in the art, and is made of a plastic having a predetermined curve which is configured so as to encourage insertion into the trachea 12. Such tubing is made of a variety of clear plastic materials as is also commonly known in the art." Behrstock (Exhibit 1006 at 4:22-27). See also Exhibit 1006 at 1:6-19 showing that a variety of different materials can be used. "It is convenient to use a tubing which is translucent or transparent as opposed to an opaque tubing, although an opaque tubing may be used." Halligan (Exhibit 1005 at 2:52-55).

	It would have been obvious to a POSA to use any number of clear or translucent materials for both primary and secondary sections, including specifically transparent and/or translucent materials as transparent and/or translucent materials were well known in the prior art and used routinely in suction devices. Exhibit 1011 at 39-41.

Claim 2

2. The device of claim 1 including a suctioning source operatively connected to said first tubular body portion.	"In view of the foregoing description, the method of use of the new vacuum controllers will be readily apparent to those acquainted with the use of suction catheters and equivalent medicosurgical suction tubes. As shown in FIG 1, the connector tube 38 is positioned over male connector end 10 and attached at the other end to a source of vacuum (not shown) and the male connector 42 of the suction catheter 40 is inserted into the female connector 12 of the vacuum controller." Exhibit 1003 at 3:61-69. All of the other referenced

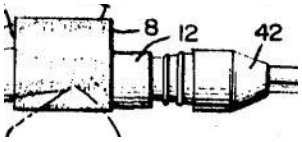
	prior art also connects to a suctioning source. See Exhibit 1011 at 41.

Claim 3

3. The device of claim 1 wherein said side inlet is carried by said relatively hard plastic first tubular body portion in offset relation to a relatively enlarged end of said second tubular portion.	"The body portion 4 may have any desired number of sides but a triangular cross section comprising three side faces 20, 22 and 24 is preferred since this enables the controller to be most easily accommodated to the fingers of the hand 26 of the operator using the suction tube structure incorporating the vacuum controller. The side face 24 of the body portion 4 is concave in shape and an elliptical opening 28 extends through the face 24 into the longitudinal bore 14." Exhibit 1003 at 3:28-36. As seen in Figure 1, element 34 is the side inlet and it is in an offset relation to the relatively enlarged end of 42, the end of the second tubular portion. This limitation is also disclosed in Penny (Exhibit 1009 at 2:65 –3:4), Kerwin (Exhibit 1004 at 2:46-60),

	Halligan (Exhibit 1005 at 2:11-15), and Behrstock (Exhibit 1006 at 3:31-34). See also Exhibit 1011 at 41-42.

Claim 4

4. The device of claim 1 wherein said first tubular body portion extends telescopically into said relatively large end of said second tubular portion.	This limitation is shown in Penny (Exhibit 1009 at Fig. 1 and 2:58-62). The figure below from the '234 Patent shows that the primary section terminates with a ribbed portion that fits into section 12 of the first tubular body portion; a female connection. While the patentee described a male connection, a POSA would know that the choice between a female or male connection as in Penny was a mere design choice that did not effect the device's operation.  It would have been obvious to a POSA to use a male or female connection to connect the second tubular body portion to the first tubular body portion as this was merely a design choice and male and female connections

	were well known in the prior art. Exhibit 1011 at 42-43. See also Section 1(f) above.

Claim 5

5. The device of claim 4 wherein said second tubular portion has elongated flexible extent tapering toward said tip.	This limitation is specifically disclosed in Kerwin (Exhibit 1004 at Figs. 1-4 element 18), Behrstock (Exhibit 1006 at Fig. 4, element 22a), and Penny (Exhibit 1009 at Fig. 10, elements 58 and 59). As discussed above, there are mechanical benefits for a suction catheter with an elongated flexible tip known in the prior art. The POSA would be motivated to use flex tubes for the predictable purpose of pliability, which is desirable for the applications taught. Exhibit 1011 at 32 and 43. It would also have been obvious to a POSA to use a tertiary section with a different tapered angle as tapered tip suction catheters were well known in the prior art. Exhibit 1011 at 43.

Claim 6

6. The device of claim 1 wherein said primary and secondary sections are translucent.	"The E-T tube 22 is a commonly used, stock item in the art, and is made of a plastic having a predetermined curve which is configured so as to encourage insertion into the trachea 12. Such tubing is made of a variety of clear plastic materials as is also commonly known in the art." Behrstock (Exhibit 1006 at 4:22-27). See also (Exhibit 1003 at 1:6-19) showing that a variety of different materials can be used. "It is convenient to use a tubing which is translucent or transparent as opposed to an opaque tubing, although an opaque tubing may be used." Halligan (Exhibit 1005 at 2:52-55).

	"The one-piece aspirating device, which is a primary feature of the present invention, is formed from the same piece of flexible, transparent, non-irritating plastic material, such as polyethylene." Perla (Exhibit 1010 at Abstract). It would have been obvious to a POSA to use any number of clear or translucent materials for both primary and secondary sections as suggested by Halligan, including specifically transparent and/or translucent materials as transparent and/or translucent materials were well known in the prior art and used routinely in suction devices. Exhibit 1011 at 43-45.

Claim 8

8. The device of claim 1 wherein	'234 Patent at Fig. 1 (Exhibit

said tip portion entrance is the only entrance at said tip portion.	1003 at Fig. 1). This limitation is also disclosed in Kerwin (Exhibit 1004) and Penny (Exhibit 1009). This limitation was also obvious to the POSA as Patentee pointed out a tip with a single entrance point "allows sealing of the device against the nostril, for proper suctioning." Exhibit 1001 at 3:45-46. The POSA was well aware of this need and the ability to use different types of tips in aspirator devices since long before the '050 Patent. Exhibit 1011 at 46-47.

Claim 9

9. The device of claim 1 wherein said tip portion entrance has a cross sectional flow area which is the least cross sectional flow area of said second tubular portion.	This limitation is specifically disclosed in Kerwin (Exhibit 1004 at '926 Fig. 2 and 3:20-23 "The tip is circular in cross-section with the

	diameter of passage 54 at the orifice 56 being smaller than that at any other point along the passage 54." This limitation is also disclosed in Behrstock (Exhibit 1006 at Fig. 4) and Penny (Exhibit 1009 at Fig. 10). Tips with the narrowest opening at the tip of a suction catheter have long been used in the aspirator art for a variety of reason including creating increased suction at the tip and for creating a small diameter tip for insertion into small orifices of a patient. This was recognized by Patentee in the '050 Patent. "The inside cross-section is typically smallest at the tip. Therefore, material that is sucked into the device encounters less resistance to flow once it enters the tip, due to highest

	flow velocity at lesser cross sectional area. Thus there will be no hang ups of, or blockages by, secretions, within the product." '050 Patent, (Exhibit 1001 at 3:52-57). It would have been obvious to a POSA to use any number of tips with varied openings, including tips with the narrowest opening at the tip, and such tips were well known in the prior art. Exhibit 1011 at 47.

Claim 10

10. The device of claim 1 wherein said body portions consist of molded plastic material that excludes vinyl and latex.	See claim 1. Halligan teaches using nylon. (Exhibit 1005 at 2:29-32). The POSA would have a reason to exclude latex and vinyl because such substances were known irritants. As also previously explained, at the time of the invention it was

	known in the medical field to exclude vinyl and latex from material that may come in contact with patients. Exhibit 1011 at 48-49.

5.3 GROUND 2

Claim 7 includes a flange at the end of the catheter. Since long before the '050 Patent, flanges have been routinely used as safety features at the end of suction devices to permit only minimal insertion of the catheter and prevent injury to the patient. During prosecution of the '050 Patent the examiner repeatedly cited prior art teaching the flange element of claim 7. The Patentee never challenged the examiner's conclusion.

> Shedlock [Exhibit 1007] [US 5,114,415] discloses a suction apparatus comprising a nozzle (22) with integral flange (100) made of flexible rubber-like material. It would have been obvious to one having ordinary skill in the art to have modified Kerwin (Exhibit 1004) in view of Eckels et al. or Halligan's suction device with the flexible nozzle flange taught by Shedlock so as to enable use of the device in the oropharynx or nasopharynx and thus permit only minimal insertion of the nozzle to prevent injury to the patient.
>
> …

> U.S. Patent 3,945,385 to Sackner discloses a suction catheter in which an elongate flexible plastic tube having an open distal tip is provided with axially extending flanges at its distal end with apertures extending through the wall of the catheter between the flanges.

Exhibit 1002, Pg. 57-59.

The table below shows how the prior art teaches the elements of claim 7 and states the reason for applying the teachings of Shedlock.

7. The device of claim 1 including a soft pliable flange on said tertiary section near said tip.	For the recitations of claim 1, see claim 1 of Ground 1. The '415 patent to Shedlock (Exhibit 1007 at Figs. 6-8, Element 100 and 1:54 - 2:7). '385 patent (Exhibit 1008 at 1:34-48). It would have been obvious to a POSA to include a soft pliable flange on the tertiary section near the tip as flanges were well known in the prior art and used routinely in suction devices. Exhibit 1011 at 46.

5.4 GROUND 3

Claim 10 adds the design choice of manufacturing the device without latex or vinyl. As the examiner noted during prosecution, it was an obvious design choice to use materials without latex or vinyl.

Perla (Exhibit 1010) discloses an aspirating apparatus comprising a) a first tubular body portion (31), b) a second tubular body portion (26) made from flexible, transparent polyethylene.

It would have been obvious to one having ordinary skill in the art to have modified Kerwin (Exhibit 1004) in view of Eckels et al. or Halligan's suction device with the flexible, transparent polyethylene material taught by Perla (Exhibit 1010) so as to minimize irritation of tissue which may come into contact with the device, as well as to enable visualization of the material being removed from the patient.

Exhibit 1002 at 00058.

The table below applies the prior art to claim 10 and states the rationale for modifying Jackson in further view of Perla.

10. The device of claim 1 wherein said body portions consist of molded plastic material that excludes vinyl and latex.	See claim 1 of Ground 1. Perla (Exhibit 1010) teaches transparent, polyethylene material. It would have been obvious to a POSA to use any number of plastic materials including plastic materials that exclude vinyl and latex as catheters made of plastic material that excludes vinyl and latex were well known in the

	prior art. Exhibit 1011 at 48-49.

5.5 GROUND 4.

Jackson in view of the common knowledge of the ordinarily skilled artisan at the time of the invention also renders claims 1-10 obvious. As discussed in the Background of Aspirators, the knowledge of the skilled artisan included the implementation and design features the Patent Owner recited in claims 1-10. Inlet controlled aspirators were known. The POSA had common knowledge of the pliable materials, the benefits of translucency, using taper angles to reduce the diameter of the flow passage, and all the other particulars of the claimed inventions. Moreover, the skilled artisan understood the benefits of implementing these features and the reasons for doing so.

Ground 4 asserts that Jackson modified by the Common Knowledge of the skilled artisan renders all the claims unpatentable. In many cases, this Ground demonstrates the common knowledge of the POSA with prior art references. Nevertheless, Ground 4 is non-cumulative as the prior art references serve to further support the testimony of Mr. Sherman, who explains the common knowledge of the POSA in his declaration. Patent Owner in this case undertook a

prosecution strategy in which the claims recite many well-known features in an effort to force the examiner to rely on multiple references to maintain a rejection with the stringent "teaching, suggestion, or motivation" standard commonly used prior to the decision in *KSR International Co. v Teleflex Inc.,* 550 U.S. 398 (2007).

In *KSR*, the United States Supreme Court explained that claims implementing known features in a predictable way are not patentable:

> If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Sakraida* and *Anderson's-Black Rock* are illustrative — a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

550 U.S. at 417. In this Ground, Petitioner demonstrates that the claims are unpatentable because the modifications to Jackson constitute the predictable implementation of features known to the skilled artisan.

As to all the claims and with reference to Ground 1, Jackson teaches a nasal aspirator with a one-piece tubular body portion (claim element 1a); a one-piece second tubular portion operatively connected to said first tubular body portion

(1b); the second tubular portion having a tip portion (1c); a side inlet for controlling suction (1d); the first tubular body consisting of hard plastic (1e); the second tubular section having primary, secondary and tertiary sections (1f); the primary section fitting telescopically and with friction to the primary section; the primary section defining a device maximum diameter proximate the entrance of the side inlet (1f); the tertiary is longer than the secondary section (1g); and the use of translucent materials for the aspirator. Jackson also teaches a suction device connected to the first tubular body (claim 2) and situating the inlet in an offset relation to an enlarged end of the second tubular body (claim 3).

Once the skilled artisan at the time of the invention knows of Jackson, the claimed inventions arise from the implementation of well-known features in a predictable manner. Halligan, Kerwin, Penny and Behrstock are all examples of aspirator devices and so constitute related art. A skilled artisan had in common knowledge the features of a flexible and pliable catheter tip (1c, 1d, 1e, 1f, claim 5) and the reasons for using such a tip as demonstrated in Halligan, Behrstock and Kerwin. A POSA knew to use hard plastic for the first tubular portion (1e) as shown in Kerwin and Halligan. The claimed feature of tapering the tip section at a lesser taper angle and the secondary section at a greater taper angle was a common sense design choice specifically suggested in Kerwin and Penny (1f). While Jackson shows fitting the primary section into the first tubular body, it was

common knowledge in the aspirator art to fit the first tubular body section into the primary section (1f, claim 4), as at least Halligan and Penny showed. Patent Owner also recited the well-known design feature of making at least one of the body portions translucent (1h) or making them both translucent (claim 6). This again constitutes a common design choice suggested in Behrstock and Halligan (1h, claim 6). Exhibit 1011 at ¶ 28-31.

Flanges and their uses were well known in the related arts, and Shedlock demonstrates this feature (claim 7). In claim 8, Patent Owner recites the obvious feature of "wherein said tip portion is the only entrance at said tip portion." No reference is required to demonstrate that such a feature resided in the common knowledge of the POSA; nevertheless, Kerwin and Penny are exemplary. Similarly, Patent Owner recites that the tip portion entrance has the least cross-sectional flow of the second tubular portion—a trivial design feature at the time of the invention (9). Kerwin, Behrstock and Penny are all examples that this element was within the POSA's common knowledge of design. Finally, in claim 10 Patent Owner wants exclusive rights over implementing this medical apparatus without vinyl or latex although both were known irritants and the POSA knew to use other materials to avoid triggering a reaction (claim 10). Perla separately discloses this knowledge. Exhibit 1011 at 29-50.

Therefore, as a separate ground of unpatentability, the Board should institute a trial and find that claims 1-10 are unpatentable in view of Jackson as modified by the common knowledge of the POSA at the time of the invention.

6. CONCLUSION

Petitioner requests *inter partes* review of claims 1-10 of the '050 Patent for the foregoing reasons.

Respectfully submitted November 9, 2018

By: 
Vincent McGeary (Lead Counsel)
Reg. No. 42,862

Proposed Statement of Material Facts

Petitioner believes that the following statements are true and material to the resolution of this matter. Petitioner also believes that the issues in this matter will be sharpened quickly by having the Patent Owner admit or deny each Fact in its Preliminary Response.

1. The '234 Patent, Exhibit 1003 is a prior art reference against the challenged claims.
2. The '926 Patent, Exhibit 1004 is a prior art reference against the challenged claims.
3. The '628 Patent, Exhibit 1005 is a prior art reference against the challenged claims.
4. The '138 Patent, Exhibit 1006 is a prior art reference against the challenged claims.
5. The '415 Patent, Exhibit 1007 is a prior art reference against the challenged claims.
6. The '385 Patent, Exhibit 1008 is a prior art reference against the challenged claims.
7. The '901 Patent, Exhibit 1009 is a prior art reference against the challenged claims.

8. The ‘268 Patent, Exhibit 1010 is a prior art reference against the challenged claims.

9. Exhibit 1013 is a true copy of a letter from John Kelly to Mr. Read McCarty dated October 5, 2015.

10. Exhibit 1015 is a prior art publication against the challenged claims.

11. Exhibit 1016 is a prior art publication against the challenged claims.

12. Exhibit 1017 is a prior art publication against the challenged claims.

13. Exhibit 1018 is a prior art publication against the challenged claims.

14. Exhibit 1020 is a prior art publication against the challenged claims.

15. Exhibit 1021 is a prior art publication against the challenged claims.

16. Petitioner is not barred or estopped from requesting *inter partes* review challenging the claims of the ‘050 Patent.

17. Transparent or translucent materials are often preferred over opaque as medical care personnel need to identify what is being suctioned and to immediately cease suctioning when unexpected conditions occur.

18. Side inlets were used regularly for control of suction in nasal aspirators and suction catheters before the filing of the ‘050 Patent.

19. Flanges were regularly used for safety reasons in nasal aspirators and suction catheters before the filing of the ‘050 Patent.

20. Latex free medical equipment was often chosen by hospitals for patient and staff allergy reasons before the filing of the ‘050 Patent.

21. Nasal aspirators designed for use with multiple different catheters were used by hospitals before the filing of the ‘050 Patent.

22. On June 1, 2004, the PTO rejected all of the proposed claims of the ‘257 Application in a First Office Action where the examiner found that all of the elements of proposed claim 1 were found in Halligan (Exhibit 1005) (US Patent 3,319,628) and in Behrstock (Exhibit 1006) (US Patent 4,699,138 A).

23. The Examiner also found that proposed claim 1 was unpatentable over US Patent 4,813,926 (Kerwin) in view of US Patent 4,729,765 (Eckels et al.) or Halligan (Exhibit 1005).

24. To overcome the Examiner’s rejections, Patentee amended claim 1 to add new limitations e, f, g, and h.

25. When Patentee used the term diameter, he meant the length of any straight line between two points on the circumference of a circle that passes through the center of the circle.

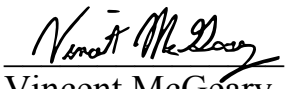
26. The choice between a male friction fit connection and a female friction fit connection between primary and secondary pieces of a nasal aspirator is a design choice that would be obvious to a POSA.

27. It is mechanically advantageous for a suction catheter to contain a long tapered tip for effective suction control.

CERTIFICATE OF WORD COUNT

I hereby certify that the foregoing Petition of Inter Partes Review constitutes less than 14,000 words. I relied upon a word count tool of a word processing program to make this certification. To calculate the total applicable word count, I subtracted the word counts of the cover sheet, Table of Contents, Table of Exhibits, Mandatory Notices, Certificate of Word Count and Certificate of Service from the total word count of this document.

Respectfully submitted,



Vincent McGeary

Dated: November 9, 2018

Certificate of Service

I hereby certify that on this 9th day of November, 2018, a copy of this Petition for *Inter Partes* Review and associated Exhibits 1001- 1024 were served by United Parcel Service overnight delivery on the following correspondence address of record for the subject patent:

Mr. William W. Haefliger
Suite 512
201 S. Lake Ave.
Pasadena CA 91101

I further certify that on this 9th day of November, 2018, I caused to be sent a copy of this Petition for *Inter Partes* Review and associated Exhibits 1001- 1024 by United Parcel Service overnight delivery on the following counsel for the patent owner:

Michael A. Dinardo, Esq.
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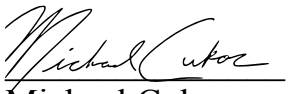
Woodland, CA 91367

Dated: November 9, 2018

Respectfully submitted,



Michael Cukor