UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APEX MEDICAL CORP.

Petitioner

V.

RESMED LIMITED

Patent Owner

U.S. Patent No. 7,159,587 Issued: January 9, 2007 Inventors: Drew et al.

Title: RESPIRATORY MASK HAVING GAS WASHOUT VENT AND GAS WASHOUT VENT ASSEMBLY FOR RESPIRATORY MASK

Case Number: IPR2013-00511

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,159,587 UNDER TO 35 U.S.C. §§ 311 *ET SEQ*. AND 37 C.F.R. § 42.100 *ET SEQ*.

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LIST OF EXHIBITS

Petition Exhibit 1001	U.S. Patent No. 7,159,587 to Drew <i>et al.</i> issued on January 9, 2007 ("the '587 Patent")
Petition Exhibit 1002	International Publication No. WO 98/34665 ("Kwok")
Petition Exhibit 1003	Complaint filed April 8, 2013 in the case of <i>Resmed Inc.</i> , <i>v APEX Medical Corporation</i> , No. 8:13-cv-00498 (C.D. Cal)
Petition Exhibit 1004	Declaration of Joseph Dyro ("Dyro Decl.")
Petition Exhibit 1005	U.S. Patent No. 4,601,465 ("Roy")
Petition Exhibit 1006	U.S. Patent No. 6,083,141 ("Hougen")
Petition Exhibit 1007	Complaint filed March 28, 2013 titled <i>Certain Sleep-Disordered Breathing Treatment Systems And Components Thereof</i> , Inv. No. 337-TA-879

PETITION FOR INTER PARTES REVIEW UNDER 35 U.S.C. §§ 311 ET SEQ. AND 37 C.F.R. § 42.100 ET SEQ.

The Real Party in Interest, Apex Medical Corp. (hereinafter "Petitioner") hereby respectfully requests *inter partes* review pursuant to 35 U.S.C. §§ 311 *et seq.* and 37 C.F.R. §§ 42.100 *et seq.*, of claim 15 of U.S. Patent No. 7,159,587 ("the '587 patent") filed November 1, 2004 and issued January 9, 2007 to Drew et al. *See* Exhibit 1001.

As will be explained in detail below, claim 15 of the '587 patent is unpatentable under 35 U.S.C. § 103 in view of the prior art references cited herein. Accordingly, Petitioner respectfully requests that claim 15 of the '587 patent be canceled based on the ground of unpatentability explained in detail herein. Petitioner meets the statutory threshold standard for instituting an *inter partes* review because this Petition demonstrates "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a).

An *Inter Partes* Review fee as set forth in 37 C.F.R. § 42.15(a) accompanies this Petition.

A copy of this Petition and all supporting evidence has been served on the Owner, ResMed Limited (hereinafter "PO") at the correspondence address of record for the patent-at-issue as required by 37 C.F.R. § 42.105(a).

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

Petitioner satisfies each requirement for *Inter Partes* Review of the '587 patent pursuant to 37 C.F.R. § 42.8(a)(1).

A. Real Party In Interest Under 37 C.F.R. § 42.8(b)(1)

The Real Party In Interest is Apex Medical Corp.

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

1. District Court Proceedings

The '587 patent is presently the subject of the following litigations:

Resmed Inc., v APEX Medical Corporation, No. 8:13-cv-00498
 (C.D. Cal). Petition Exhibit 1003.

2. ITC Proceedings

 Complaint filed March 28, 2013 titled Certain Sleep-Disordered Breathing Treatment Systems And Components Thereof, Inv. No. 337-TA-879. Petition Exhibit 1007.

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

Petitioner is represented by the following counsel:

Lead Counsel: Henry Petri, Reg. No. 33,063

Back-up Counsel: James Murphy, Reg. No. 55,474

Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney has been filed with this Petition.

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Service information for lead and back-up counsel is as follows:

NOVAK DRUCE CONNOLLY BOVE + QUIGG LLP 1000 Louisiana Street, 53rd Floor Houston, Texas 77002

Petitioner also consents to service by e-mail to the following address: ApexIPR@novakdruce.com.

II. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a)

Petitioner certifies that the patent for which review is sought is available for *inter partes* review and that the Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in the Petition. 37 C.F.R. 42.104(a).

III. IDENTIFICATION OF CLAIMS FOR WHICH REVIEW IS REQUESTED 37 C.F.R. § 42.104(b)(1)

Petitioner requests inter partes review of claim 15 of the '587 Patent.

IV. THE SPECIFIC STATUTORY GROUNDS ON WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b)(2)

Petitioner requests that claim 15 of the '587 patent be cancelled based on the following statutory grounds of unpatentability:

Ground A: Claim 15 is rendered obvious by Kwok under 35 U.S.C. §103; and

Ground B: Claim 15 is rendered obvious by Roy in view of Hougen under 35 U.S.C. §103.

V. HOW THE CHALLENGED CLAIMS ARE TO BE CONSTRUED UNDER 37 C.F.R. § 42.104(b)(3)

Petitioner requests that claim terms of the '587 Patent be given their broadest reasonable interpretation, as understood by a person of ordinary skill in the art ("POSITA") and consistent with the disclosure. *See* 37 C.F.R. § 42.100(b); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, (Fed. Cir. 2005). This means that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989). The Federal Circuit has held that the Office applies a broader standard than a Court does when interpreting claim scope and that the Office is not bound by any prior district court claim construction. *In re Trans Texas Holding Corp.*, 498 F.3d 1290, 1301 (Fed. Cir. 2007).

VI. OVERVIEW OF THE '587 PATENT

A. Overview of the '587 Patent

The '587 patent is generally directed towards a respiratory mask that can be used for Continuous Positive Airway Pressure ("CPAP") treatment. '587 patent at Abstract. In the respiratory mask, there can be gas washout vents that have a membrane across the vents. '587 patent at Abstract. The vents and the membranes are constrained to certain sizes, thicknesses, and the number of apertures contained therein. '587 patent at 4:34-61.

B. Reasons for Allowance

There is no explicit reason for allowance in the file history. A terminal disclaimer was filed to overcome a double patenting rejection over claim 20 of the application that became U.S. Patent No. 6,823,865 ("the '865 patent"). Claim 20 of the application issued as claim 17 of the '865 patent. In the '865 patent's prosecution history, the PO argued and the Office accepted that the prior art of record failed to teach "a gas washout vent including an air permeable member with a plurality of holes each having a length and a diameter in total open area due to the presence of the holes that are selected to help eliminate or reduce noise while maintaining sufficient CO₂ washout during patient breathing, wherein the thickness of the member is less than 3 mm and the diameter of the holes extending through the member is less than about 0.2 mm." PO Response of 2-26-2004 in the '865 patent. Accordingly, the corresponding features of claim 15 of the '587 patent are presumed to be the allowable features of the claims. Specifically, "a gas washout vent portion having a plurality of holes extending therethrough, each said hole having a diameter selected to allow gas to quietly exit from the breathing cavity, wherein: the vent portion has a thickness of less than about 3 mm." Notably, in the prosecution history, the claim referenced "less than 3 mm" whereas claim 15 of the '587 patent recites "less than about 3 mm."

VII. HOW THE CONSTRUED CLAIMS ARE UNPATENTABLE UNDER 37 C.F.R. § 42.104(b)(4)

In view of the subject matter of the '587 patent, a POSITA as of the year 2000 was typically a person who had a bachelor's degree in mechanical engineering or biomedical engineering and three years of experience in the field of medical devices or respiratory therapy, or an advanced degree, including a medical doctor, and one to two years of experience in the field. Dyro Decl. at ¶17. Moreover, skill is presumed on the part of those practicing in the art. *See In re Sovish*, 769 F.2d 738, 743 (Fed. Cir. 1985). Hence, this level of knowledge and skill is utilized throughout this Petition.

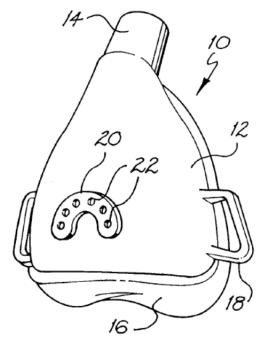
A. Kwok Renders Obvious Claim 15 of the '587 Patent

Kwok was filed February 6, 1998, claims priority to an Australian application filed February 10, 1997, and was published on August 13, 1998. Therefore, Kwok constitutes prior art under 35 U.S.C. § 102. *See* Petition Exhibit 1002. Kwok discloses a mask with a gas washout vent that includes a membrane. Kwok at Abstract.

<u>Claim 15</u>

15. A respiratory mask comprising:

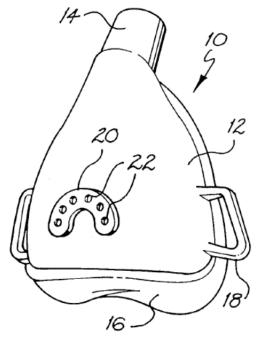
Kwok discloses that the "present invention relates to a mask and a vent assembly therefor." Kwok at 1:4. Accordingly, Kwok is teaching a respiratory mask.



Kwok, FIG. 3

a patient interface;

Kwok discloses that "[t]he mask shell 12 also includes a flexible sealing membrane 16 which is used to provide a gas tight seal between the face of the wearer and the interior of the shell 12." Kwok at 5:9-14.



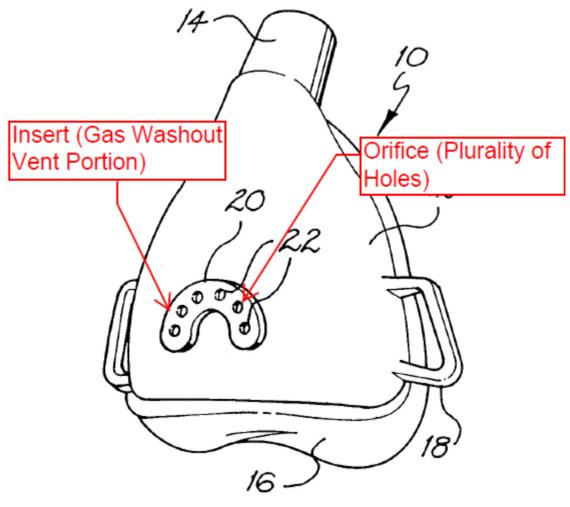
Kwok, FIG. 3

a breathable gas inlet to provide pressurized gas to a breathing cavity formed at least in part by the patient interface when the mask is in use; and

Kwok teaches that "[t]he mask includes a rigid plastics shell 12 having an inlet tube 14 for connection to supply conduit to communicate breathable gas from a flow generator (not shown) to the nasal passages of the mask wearer." Kwok at 5:9-14. Accordingly, since the frame 12 has a patient interface, *e.g.*, flexible sealing membrane, and it also has a supply conduit, *i.e.*, breathable gas inlet, that provides breathable gas from a flow generator, the features of this claim are taught by Kwok.

a gas washout vent portion having a plurality of holes extending therethrough,

Kwok teaches that "[t]he mask includes a Silastic TM insert 20 through which is provided an orifice 22 for gas washout." Kwok at 5:15-16. Further, the "insert 20 includes more than one orifice 22." Kwok at 5:27-29. Accordingly, Kwok teaches that the insert, *i.e.*, gas washout vent portion, can include more than one orifice, *i.e.*, a plurality of holes therethrough.



Kwok, FIG. 3 (Annotated)

each said hole having a diameter selected to allow gas to quietly exit from the breathing cavity, wherein:

Kwok teaches that "[t]he mask 10 produces less noise than an identical mask having a similar sized and shaped orifice(s) formed directly in the mask shell 12 instead of formed in the flexible insert 20. It is thought than the noise reduction occurs due to the flexible insert 20 damping vibrations caused by the air passage through the orifice(s) 22...." Kwok at 6:14-18.

the vent portion has a thickness of less than about 3 mm, and the vent portion is made of a hydrophobic material.

Interpreting "less than about 3 mm"

This claim recites a vent portion that has a thickness of "less than about 3 mm." This should be interpreted as the PO attempting to claim fractions of a millimeter above 3 mm, since the claim explicitly covers all fractions under 3 mm via the clause "less than." Reading "less than about 3 mm" as expanding claim scope under 3 mm would be redundant since the fractions of a millimeter under 3 is covered by the "less than" portion recited in the claim language. The only reason the claim includes "about" when referencing 3 mm is to expand the claim coverage above 3 mm. PO has provided no technological significance or any discernible reason why the thickness of 3 mm is important, thus precision is not strictly required.

Further, the Federal Circuit has held that when claim limitations include dimensions that are mere "window dressing" and do not cause any differences in

operation of the device, then the dimensions are not given any patentable weight. See Gardener v. Tec Systems Inc., 725 F.2d 1338 (C.A. Fed 1984). In Gardener the Federal Circuit quotes approvingly from the District Court Judge who states:

To this Court, they were incantations that may have superficially made the application sound like something unique and inventive but had no real function. So far as this poor observer could conclude, adherence to these dimensional mandates did not produce any discernible result or any synegistic [sic] effect. Nor did departure therefrom cause a failure of the web support. Surely, the patent law does not attach uniqueness to dimensional claims that have no significance in the operation of the claimed invention.

See Garderner at 1346. This case is very similar, as the "less than about 3 mm" limitation does not have any actual significance to the operation of the device and there is no "discernible result" from the recited dimensions. Moreover, the specification does not describe any technical reason ascribing an importance to the thickness of the gas washout vent portion. Without any guidance from the specification as to the importance of this thickness, and in light of Dr. Dyro's declaration stating that "less than about 3 mm" is of no actual significance without more context, there is no evidence that the phrase should be afforded any patentable weight.

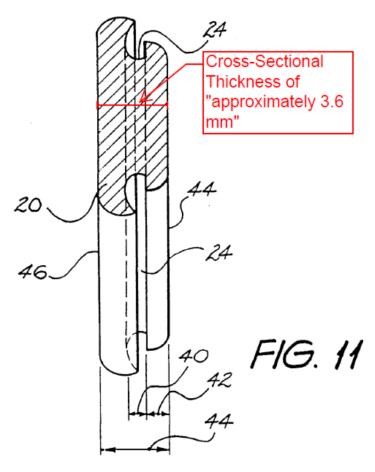
Accordingly, the proper claim interpretation based on the language of the claim and the lack of significance in the precision recited in the claim includes, "less than about 3 mm" being read to cover fractions of a millimeter above 3 mm, and the "less than about 3 mm" limitation being afforded no patentable weight, as it operates in exactly the same manner, *i.e.*, the gas exits quietly form the mask, despite the slight variation in thickness.

Application of Kwok to Claim 15

As can be seen in FIG. 11, below, Kwok teaches that the flexible insert has an "approximate" thickness of 3.6 mm. Kwok at 6:3-6. It would be obvious to a person of ordinary skill in the art that the thickness of 3.6 mm is merely a design choice that can be altered to fit a particular application. Further, since there is no technological significance provided for the thickness, and the thickness taught by Kwok is "approximate," it would be obvious to a person of ordinary skill in the art to design the thickness of the flexible insert to be "less than about 3 mm" especially in light of the fractions of millimeters above 3 mm recited by the claim.

To expand on this point, based on the claim interpretation and the teachings of Kwok, "less than about 3 mm" recited in the claim is equivalent to "approximately" 3.6 mm as recited by the prior art. PO is attempting to claim fractions of a millimeter above 3 mm, and Kwok also states the thickness is "approximately" 3.6 mm. Thus, a POSITA would understand that the thickness can

vary within allowable parameters. *See* Dyro Decl. Accordingly, when a person of ordinary skill in the art analyzes Kwok, it is obvious that "approximately 3.6 mm" teaches "less than about 3 mm" when both phrases are interpreted with the appropriate precision attached to each phrase.



Kwok, FIG. 11 (Annotated)

Additionally, the PO admits that the thickness of "3-4 mm" was well known in the art, and specifically that Kwok has a "cross-sectional thickness of 3-4 mm." '587 patent at 2:49 and 63-67. This is important because in the '587's parent application, the reason for allowance hinged in part on the insert having a thickness

"less than 3 mm." PO Response of 2-26-2004 in the '865 patent. By broadening the claims to include thicknesses above 3 mm, the claims are now admittedly known in the art. Since PO admitted that it was known to make the insert of Kwok a thickness of "3-4 mm," it would have been obvious to a person of ordinary skill in the art to design a flexible insert for Kwok that is "less than about 3 mm" thick.

Finally, Kwok teaches that the insert is designed to overcome the problems associated with "moisture from the patient's respiratory system." Kwok at 2:26-3:2 and 3:10-12. It would be obvious to a person of ordinary skill in the art that to overcome the problems associated with moisture as relates to the inserts, a hydrophobic material would be used. Dyro Decl. at ¶¶ 21 and 33.

Accordingly, Kwok teaches the features of this claim by teaching a hydrophobic membrane with a thickness of approximately 3.6 mm. Further, PO has admitted that the thickness of "less than about 3 mm" was known in the art and specifically, that Kwok was known to have an insert with a thickness of "less than about 3 mm. Finally, based on *Gardener*, the claim interpretation, and the specification of the '587 patent, the features of this claim are not patentably distinct from Kwok, because the phrase "less than about 3 mm" deserves no patentable weight.

B. Roy in view of Hougen Renders Obvious Claim 15 of the '587 Patent

Roy was filed March 22, 1984 and issued on July 22, 1986. Therefore, Roy constitutes prior art under 35 U.S.C. § 102. *See* Petition Exhibit 1005. Roy generally teaches a breathing device for aiding the stimulation of a respiratory system. Roy at Abstract.

Hougen was filed November 26, 2007 and is a CIP of an application filed February 10, 1995. Hougen was issued on July 4, 2000. Therefore, Hougen is prior art under 35 U.S.C. § 102. *See* Petition Exhibit 1006. Hougen is generally directed towards a respiratory exercise breathing apparatus. Hougen at Abstract.

Reasons to Combine

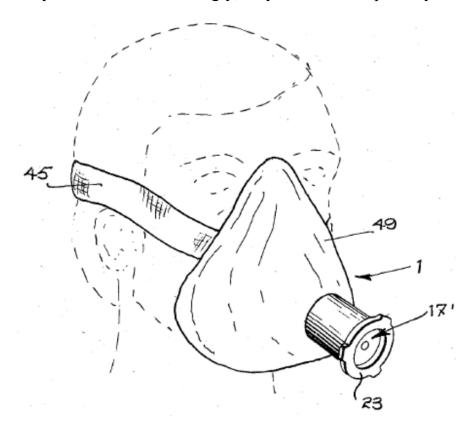
It would be obvious to a person of ordinary skill in the art to add a forced oxygen connector to the intake passage 5. Dyro Decl. at ¶ 29. Adding oxygen to the intake passage is advantageous for patients suffering respiratory ailments related to oxygen transmission to the body. Dyro Decl. at ¶ 29. Further, increased pressure assists in preventing the collapse of the alveoli. Dyro Decl. at ¶ 29. Based on this knowledge, a person of ordinary skill in the art would understand that adding the pressurized oxygen from Hougen to Roy would increase the effectiveness of the treatment. Dyro Decl. at ¶ 29. This combination is within the skill of the art and the end result of this combination would be entirely predictable. Dyro Decl. at ¶ 29. Specifically, the Roy device would have an oxygen connector

on the exterior surface of the intake passage 5. This would allow a patient to make full use of the device taught by Roy. Dyro Decl. at ¶ 29.

Claim 15

15. A respiratory mask comprising:

Roy teaches a "mask 49 which covers not only the mouth but also the nose of the user." Roy at 6:14-17. Accordingly, Roy teaches a respiratory mask.

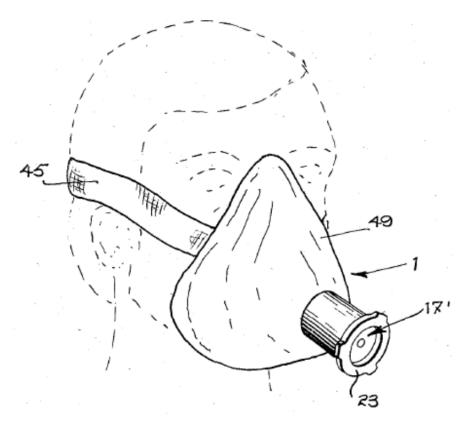


Roy, FIG. 7

a patient interface;

Roy teaches a "mask 49 which covers not only the mouth but also the nose of the user [and] may be fixed to the user's face by means of a strap 45, in any conventional manner." Roy at 6:14-17. Accordingly, it would have been obvious to

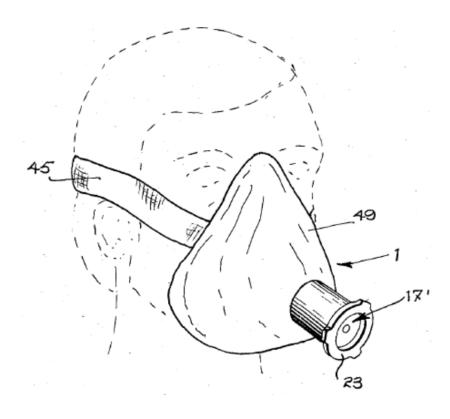
a person of ordinary skill in the art that the mask, which is fixed to the user's face, has a patient interface.



Roy, FIG. 7

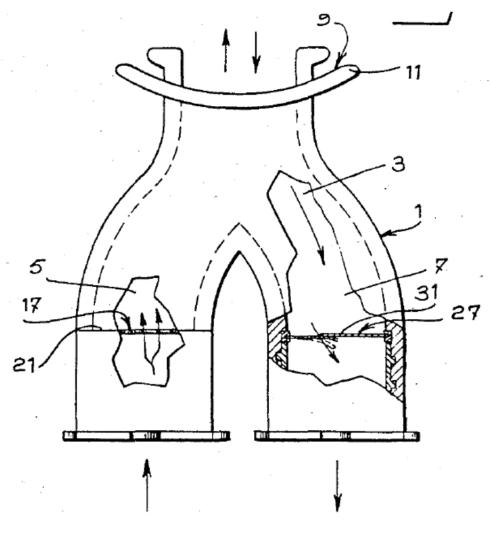
a breathable gas inlet to provide pressurized gas to a breathing cavity formed at least in part by the patient interface when the mask is in use; and

Roy teaches a breathing cavity formed at least in part by the patient interface when the mask is used for inhalation and exhalation. *See* FIG. 7.



Roy, FIG. 7

Further, Roy teaches that the mask embodiment of FIG. 7 can operate either with the single air duct as shown, or can operate with two parallel passages as shown below in FIG. 3. Roy at 6:24-27. The two parallel passages 5 and 7 are the intake and exhaust passages respectively.

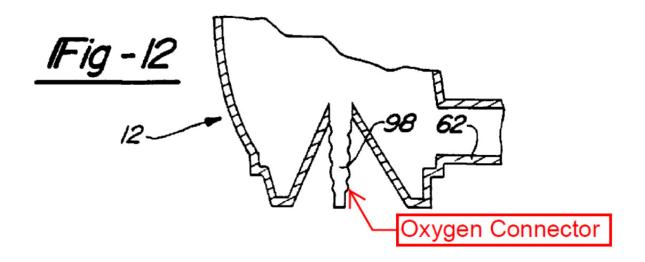


Roy, FIG. 3

Based on the mask with two parallel passages, intake passage 5 and exhaust passage 7, it would be obvious to a person of ordinary skill in the art to add forced air, *e.g.*, oxygen, to the intake passage 5.

Hougen teaches that oxygen can be added to a respiratory exercise apparatus, like the one taught by Roy. Specifically, as shown below in FIG. 12, Hougen teaches that an "oxygen connector 98" which allows for pressurized oxygen to be added to a respiratory exercise apparatus. Hougen at 10:14. Further,

the "oxygen connector" can be "externally mounted" on the device. Hougen at 10:14-16.



Hougen, FIG. 12 (annotated)

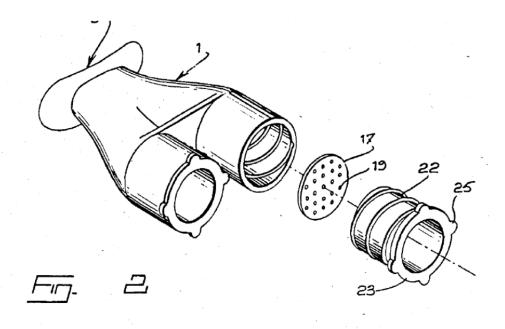
Accordingly, it would have been obvious to a person of ordinary skill in the art to add an externally mounted "oxygen connector" as taught by Hougen to the intake passage, 5, of Roy to provide additional oxygen to a patient. Hougen teaches, "Some people are able to take only shallow breaths because they are suffering from lung ailments such as asthma, emphysema, chronic bronchitis, chronic obstructive pulmonary disease, or other ailments which reduce the oxygen/CO₂ exchange. Frequently, patients recovering from abdominal surgery experience pain during deep breathing and may therefore restrict their own breathing to shallow breaths. In both of the above situations, recovery is slowed because the patients suffer from reduced exchange of oxygen and carbon dioxide

in the tissue." Hougen at 1:35-44. There are multiple solutions to the above described problems, two of which are described by Roy and Hougen. Specifically, a respiratory exercise regime will aid patients with these ailments, as well as provide additional oxygen to these patients to aid in recovery. This combination is taught by Roy in view of Hougen.

a gas washout vent portion having a plurality of holes extending therethrough,

The '587 patent provides at least one definition of a gas washout vent, stating that a gas washout vent comprises "an opening with a thin air permeable membrane extending across the opening." '587 patent at 3:60-62. Roy teaches this feature.

Roy teaches an intake "passage 5" in FIG. 3, has an "obstruction" or "disc 17 made of rigid material such as rigid rubber, rigid plastic or any other non-oxydizable material." Roy at 4:29-34. The disc 17 can be seen below in FIG. 2. Roy also teaches that the disc can be located in exhaust passage 7. Roy at 5:21-24. This disc in exhaust passage 7 is a gas washout vent portion. Further, the disc has "a predetermined number of holes 19 to make it permeable to air." Roy at 4:29-34. Finally, the "periphery of the disc" is threaded, and the threaded periphery is screwed into a threaded end of the passage 7. Roy at 4:35-41.



Roy, FIG. 2

Accordingly, a thin air permeable membrane, *e.g.*, disc with a predetermined number of holes, extends across the opening of exhaust passage 7.

each said hole having a diameter selected to allow gas to quietly exit from the breathing cavity, wherein:

Initially, the '587 patent provides no indication of the level of noise allowable within the limitation of a "gas quietly exit[ing] from the breathing cavity." A person of ordinary skill in the art would be motivated to reduce the noise caused by the exhaust gas, because a patient is more likely to use a device that is convenient and unobtrusive.

Roy teaches that the gas washout vent portion, *e.g.*, obstruction or disc, "may consist of a membrane permeable to air." Roy at 2:41-42. This obstruction or

disc may have "a plurality of small perforations wide enough to allow air to pass therethough. The person using the device may have several membranes each capable of putting up a different resistance to air due to a variation in the number of holes, or the diameter thereof." Roy at 2:51-54. Roy teaches that there are multiple membranes with multiple numbers of holes and each membrane having holes of different diameters. Therefore, it would be obvious to a person of ordinary skill in the art to design membranes that have advantageous qualities, including membranes that allow for low decibel output.

the vent portion has a thickness of less than about 3 mm, and the vent portion is made of a hydrophobic material.

Interpreting "less than about 3 mm"

This claim recites a vent portion that has a thickness of "less than about 3 mm." This should be interpreted as the PO attempting to claim fractions of a millimeter above 3 mm, since the claim explicitly covers all fractions under 3 mm via the clause "less than." Reading "less than about 3 mm" as expanding claim scope under 3 mm would be redundant since the fractions of a millimeter under 3 is covered by the "less than" portion recited in the claim language. The only reason the claim includes "about" when referencing 3 mm is to expand the claim coverage above 3 mm. PO has provided no technological significance or any discernible

reason why the thickness of 3 mm is important, thus precision is not strictly required.

Further, the Federal Circuit has held that when claim limitations include dimensions that are mere "window dressing" and do not cause any differences in operation of the device, then the dimensions are not given any patentable weight. *See Gardener v. Tec Systems Inc.*, 725 F.2d 1338 (C.A. Fed 1984). In *Gardener* the Federal Circuit quotes approvingly from the District Court Judge who states:

To this Court, they were incantations that may have superficially made the application sound like something unique and inventive but had no real function. So far as this poor observer could conclude, adherence to these dimensional mandates did not produce any discernible result or any synegistic [sic] effect. Nor did departure therefrom cause a failure of the web support. Surely, the patent law does not attach uniqueness to dimensional claims that have no significance in the operation of the claimed invention.

See Garderner at 1346. This case is very similar, as the "less than about 3 mm" limitation does not have any actual significance to the operation of the device and there is no "discernible result" from the recited dimensions. Moreover, the specification does not describe any technical reason ascribing an importance to the thickness of the gas washout vent portion. Without any guidance from the

specification as to the importance of this thickness, and in light of Dr. Dyro's declaration stating that "less than about 3 mm" is of no actual significance without more context, there is no evidence that the phrase should be afforded any patentable weight.

Accordingly, the proper claim interpretation based on the language of the claim and the lack of significance in the precision recited in the claim includes, "less than about 3 mm" being read to cover fractions of a millimeter above 3 mm, and the "less than about 3 mm" limitation being afforded no patentable weight, as it operates in exactly the same manner, *i.e.*, the gas exits quietly form the mask, despite the slight variation in thickness.

Application of Roy in view of Hougen to Claim 15

Roy teaches that the "obstruction" or "disc 17" is "made of rigid material such as rigid rubber, rigid plastic or any other non-oxydizable material." Roy at 4:29-34. Roy also teaches that the disc can be located in exhaust passage 7. Roy at 5:21-24. This disc in exhaust passage 7 is a gas washout vent portion. A person of ordinary skill in the art understands that rubbers, plastics, and non-oxydizable materials as used in breathing devices are typically hydrophobic. *See* Dyro Decl. Since the obstruction or disc is used in the humid environment of a patient's breath, it would be obvious to a person of ordinary skill in the art to choose a

variant of rubber, plastic, or non-oxydizable material that does not absorb water. See Dyro Decl.

Further, when designing a disc out of rigid material, a person of ordinary skill in the art understands that "when using rigid material, the thickness of that material is of little importance above the minimum thickness required to withstand the forces associated with breathing." Dyro Decl. at ¶32. For most rigid plastics "a 1mm thickness would be sufficient" for a typical breathing application. Dr. Dyro at ¶32. Finally, it is within the knowledge of a person of ordinary skill in the art to optimize the thickness of the disc based on the materials chosen. Dyro Decl. at ¶32. Specifically, a person of ordinary skill in the art would make the "disc as thin as possible while maintaining mechanical characteristics to optimize the economics, ease of production, and to minimize the weight associated with the device...."

Based on the teachings of Roy in view of Hougen and in view of the knowledge of a person of ordinary skill in the art, it would be obvious to design the disc of Roy to be "less than about 3mm." Further, based on *Gardener*, the claim interpretation, and the specification of the '587 patent, the features of this claim are not patentably distinct from Roy in view of Hougen, because the phrase "less than about 3 mm" deserves no patentable weight.

VIII. CONCLUSION

In view of the foregoing, claim 15 of the '587 Patent is not patentable over the prior art documents cited herein. The prior art documents teach the subject matter of the '587 Patent in a manner establishing a reasonable likelihood that the Petitioner will prevail with respect to at least one of the claims challenged in this Petition as required by 35 U.S.C. § 314(a).

Accordingly, Petitioner respectfully requests that Trial be instituted and claim 15 of the '587 Patent be canceled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of this **PETITION FOR** *INTER PARTES* **REVIEW OF U.S. PATENT NO. 7,159,587 UNDER TO 35 U.S.C.** §§ 311 *ET SEQ.* AND 37 C.F.R. § 42.100 *ET SEQ.* together with all exhibits, has been served via priority mail on August 16, 2013 upon the following:

Nixon & Vanderhye, PC 901 North Glebe Road, 11th Floor Arlington, VA 22203

> /Stephanie Dominguez/ Stephanie Dominguez