No. 23-_____

In the Supreme Court of the United States

FLEUR T. TEHRANI,

Petitioner,

v.

HAMILTON TECHNOLOGIES LLC,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the Court of Appeals for the Federal Circuit erred by declaring a non-expert as a POSITA despite all the evidence presented to the contrary.

2. Whether the Court of Appeals for the Federal Circuit erred by relying on unsupported statements against the Petitioner in the face of reliable published evidence to the contrary.

3. Whether the Court of Appeals for the Federal Circuit erred by affirming the decision by the Patent Trial and Appeal Board invalidating the challenged claims of US Patent 7,802,571 while none of the requirements of those claims were met by any combinations of the alleged prior art.

4. Whether the Court of Appeals for the Federal Circuit erred by using a) a paper presenting untrue results and b) a fatal device against the challenged claims of US Patent 7,802,571.

5. Whether the Court of Appeals for the Federal Circuit ("Federal Circuit") erred by affirming the decision by the Patent Trial and Appeal Board invalidating the challenged claims of U.S. Patent 7,802,571 while none of the requirements of obviousness under 35 U.S.C. § 103(a) were met by either of the alleged grounds, and against the Decisions of the Supreme Court of the United States and the Precedents of the Federal Circuit.

PARTIES TO THE PROCEEDINGS

Petitioner

- Petitioner is Fleur T. Tehrani, PhD, an individual.

Respondent

- Respondent is Hamilton Technologies LLC

RULE 29.6
CORPORATE DISCLOSURE STATEMENT

The Petitioner is an individual. No interest of the Petitioner in this case is assigned to any corporation or any publicly held company.

LIST OF PROCEEDINGS

U.S. Court of Appeals for the Federal Circuit
No. 2022-1732
Fleur Tehrani v. Hamilton Technologies LLC
Final Opinion: June 28, 2023
Rehearing Denial: August 23, 2023

U.S. Patent and Trademark Office, Patent Trial and Appeal Board
No. IPR2020-01199
Hamilton Technologies LLC v. Fleur Tehrani
Final Judgment: December 28, 2021

TABLE OF CONTENTS

Page

QUESTIONS PRESENTED i

PARTIES TO THE PROCEEDINGS ii

RULE 29.6 CORPORATE DISCLOSURE STATEMENT ii

LIST OF PROCEEDINGS iii

TABLE OF AUTHORITIES ix

PETITION FOR A WRIT OF CERTIORARI 1

OPINIONS BELOW 1

JURISDICTION 1

STATUTORY PROVISIONS INVOLVED 2

STATEMENT OF THE CASE 2

A. Introduction 2

B. The Patented Invention and the Patent 3

C. The Main References Used Against the Patent Claims Are Heterogeneous, Uncombinable, and Present Methods That Are Against the Method of the Patent Claims. 7

D. Summary Description of the Main References Used Against the Patent Claims 9

E. Federal Circuit Did Not Address Most of the Errors by the Board. 13

F. By Casting Doubt on the Meaning of a Key Claim Term "a Next Breath," the Opinion Supports the Use of Intermittent Charts and Tables That the Patent Is Designed to Replace and Are Against the Patent Claims. 16

TABLE OF CONTENTS – Continued

Page

G. The Reference Combinations Proposed by the Respondent and Affirmed by the Federal Circuit Are Not Possible and Are Against Scientific Principles. 20

H. The Manual Adjustments Depicted in a Survey Chart in Carmichael Have No Relation to the Continuous Closed-Loop Algorithm of the Patent for a Next Breath. .. 21

I. The Federal Circuit Used a Paper Presenting Untrue Results and a Device Using a Fatal Method Against the Patent Claims. 24

J. The Federal Circuit Makes a Serious Mistake by Stating That PID Control of PEEP Is Used in the Patent. 25

K. Neither Ground Meets Any of the Requirements of Obviousness. 26

L. None of the References, Either Individually, or in the Alleged Combinations, Can Meet Any of the Requirements of the Patent Claims. 29

M. The Judgment of the Federal Circuit Conflicts with the Decisions of the Supreme Court, Is Against 35 U.S.C. § 103(a), and the Precedents of the Federal Circuit. 30

TABLE OF CONTENTS – Continued

Page

REASONS FOR GRANTING THE PETITION..... 30

I. THIS PETITION SHOULD BE GRANTED TO PREVENT STRIPPING PATENTEES' RIGHTS AGAINST WELL-ESTABLISHED PATENT LAWS. . 30

II. THE FEDERAL CIRCUIT HAS RULED AGAINST ITS OWN PRECEDENTS IN THIS CASE. 32

III. THE RULING OF THE FEDERAL CIRCUIT IN THIS CASE CONFLICTS WITH THE DECISIONS OF THE SUPREME COURT AND DISRUPTS THE SETTLED EXPECTATIONS OF THE INVENTING PUBLIC..... 32

CONCLUSION..... 34

TABLE OF CONTENTS – Continued

Page

APPENDIX TABLE OF CONTENTS

OPINIONS AND ORDERS

Opinion, United States Court of Appeals for the Federal Circuit (June 28, 2023) 1a

Judgment, Final Written Decision U.S. Patent and Trademark Office (December 28, 2021) 11a

REHEARING ORDER

Order Denying Petition for Rehearing, United States Court of Appeals for the Federal Circuit (August 23, 2023) 89a

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Anderson et al., *Clinical Trial of a Non-linear Closed-loop Controller for Oxygenation During ARDS*, Critical Care Medicine, Vol 22, A188, Jan. 1994..... 151a

TABLE OF CONTENTS – Continued

Page

PATENT VOLUME TABLE OF CONTENTS

United States Patent No. 7802571 (Tehrani)
(September 28, 2010)..... Patent.1

United States Patent No. 5388575 (Taube)
(February 14, 1995) Patent.27

TABLE OF AUTHORITIES

Page

CASES

Abtox, Inc. v. Exitron Corp.,
122 F.3d 1019, 43 USPQ2d 1545
(Fed. Cir. 1997) 18

*Bell Communications Research, Inc.
v. Vitalink Communications Corp.*,
55 F.3d 615, 34 USPQ2d 1816
(Fed. Cir. 1995) 18

*Consol. Edison Co. v. Nat'l Labor Relations
Bd.*, 305 U.S. 197 (1938) 24, 28

Diamond v. Chakrabarty,
447 U.S. 303, 100 S.Ct. 2204,
65 L.Ed.2d 144 (1980) 30, 31

*Festo Corp. v. Shoketsu Kinzoku
Kogyokabushiki Co.*, 535 U.S. 722 (2002) 33

Gen. Elec. Co. v. Raytheon Techs. Corp.,
983 F.3d 1334 (Fed. Cir. 2020) 23, 28

Graham v. John Deere Co.,
383 U.S. 1, 86 S.Ct. 684,
15 L.Ed.2d 545 (1966) 26

Home Diagnostics, Inc. v. LifeScan, Inc.,
381 F.3d 1352 (Fed. Cir. 2004) 18

In re Gordon,
733 F.2d 900 (Fed. Cir. 1984) 21, 27

In re Kubin,
561 F.3d 1351 (Fed. Cir. 2009) 26

In re Ratti,
270 F.2d 810 (CCPA 1959) 21, 27

TABLE OF AUTHORITIES – Continued

Page

In re Vaeck,
947 F.2d 488 (Fed. Cir. 1991) 27, 32

KSR Int'l Co. v. Teleflex, Inc.,
550 U.S. 398 (2007) 27, 33

Markman v. Westview Instruments Inc.,
517 U.S. 370 (1996) 30

Merck & Cie v. Gnosis S.P.A.,
808 F.3d. 829 (Fed. Cir. 2015) 26

Para–Ordnance Mfg., Inc. v. SGS Imps. Int'l, Inc., 73 F.3d 1085 (Fed. Cir. 1995) 23, 28

Phillips v. AWH Corp.,
415 F.3d 1303 (Fed. Cir. 2005) 16

Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243 (Fed. Cir.1998)..... 18

Santarus, Inc. v. ParPharm., Inc.,
694 F.3d 1344 (Fed. Cir. 2012) 23, 28

Vitronics Corp. v. Conceptronic, Inc.,
90 F.3d 1576 (Fed. Cir. 1996) 18

Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997)..... 33

CONSTITUTIONAL PROVISIONS

U.S. Const., art. I § 8, cl. 8..... 32

STATUTES

28 U.S.C. § 1254(1) 1

35 U.S.C. § 103(a) ..... i, 2, 30

35 U.S.C. § 282(b) 16

TABLE OF AUTHORITIES – Continued

Page

JUDICIAL RULES

Fed. R. Evid. 702(c) 9

Fed. R. Evid. 702(d) 9

REGULATIONS

37 C.F.R. § 42.65(a) 9

37 C.F.R. § 42.100(b) 16

OTHER AUTHORITIES

A. Rossi, *Intrinsic Positive End-Expiratory Pressure (PEEPi)*, 21 INTENSIVE CARE MED. 522 (1995) 7

Acute Respiratory Distress Syndrome Network, *Ventilation with Lower Tidal Volumes as Compared with Traditional Tidal Volumes for Acute Lung Injury and the Acute Lung Respiratory Distress Syndrome*, 342 NEW ENGLAND J. MED. 1301 (2020) 7

Jeffrey Anderson et al., *Clinical Trial of a Non-Linear Closed-Loop Controller for Oxygenation During ARDS*, CRITICAL CARE MEDICINE, Vol 22, A188, Jan. 1994 11

Jeffrey R. Anderson et al., *A Closed-Loop Controller for Mechanical Ventilation of Patients with ARDS*, 38 BIOMEDICAL SCIS. INSTRUMENTATION SYMPOSIUM 289 (2002) ..... 7-12, 14, 15, ... 20-25, 27-29, 31

TABLE OF AUTHORITIES – Continued

Page

John C. Taube,
U.S. Patent No. 5,388,575 ..... 7-9, 12-15, 20, 24, 25, 28, 29, 31

Laurence C. Carmichael et al.,
Diagnosis and Therapy of Acute Respiratory Distress Syndrome in Adults: An International Survey, 11 J. CRITICAL CARE 9 (March 1996) 7-10, 14-15, 19-23, 27-29

Thomas Jefferson,
WRITINGS OF THOMAS JEFFERSON (Washington ed. 1871) 31

U.S. Patent and Trademark Office,
MPEP 2173.05(e) 7, 16

PETITION FOR A WRIT OF CERTIORARI

Fleur T. Tehrani, PhD, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The decision of the U.S. Court of Appeals for the Federal Circuit (App.1a-10a) was entered on June 28, 2023, and is not reported. The final decision of the Patent Trial and Appeal Board (App.11a-88a) was entered on December 28, 2021, and is reported.

JURISDICTION

The decision of the Court of Appeals for the Federal Circuit issued on June 28, 2023. (App.1a). A timely filed petition for rehearing was denied on August 23, 2023. (App.89a). The jurisdiction of the Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

35 U.S.C. § 103(a)

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

STATEMENT OF THE CASE

A. Introduction

The Patent at issue is US7,802,571 (the '571 patent or the Patent). In an *inter partes* review (IPR) procedure (IPR2020-01199) the Patent Trial and Appeal Board ("Board") decided that claims 1-6, 9-12, 29-33, and 41 of the Patent were invalid as obvious on December 28, 2021. An appeal was made to the Court of Appeals for the Federal Circuit ("Federal Circuit") and the Federal Circuit issued its judgment ("Judgment") along with an opinion ("the Opinion") on June 28, 2023, affirming the Board's decision. The Petitioner filed a petition for a panel rehearing and/or

rehearing *en banc* on July 24, 2023. The Federal Circuit denied that petition on August 23, 2023.

The Opinion and the Judgment issued by the Appeals Court in this case are contrary to the law as none of the requirements for obviousness is met by the alleged prior art. The Opinion and the Judgment are against the precedents of the Appeals Court and the rulings of the Supreme Court. The decision of the Appeals Court disrupts the settled expectations of the inventing public since the requirements of the law have been completely overlooked. Accordingly, this case deserves to be heard by this Court to show that patent rights in the US are respected and are upheld.

B. The Patented Invention and the Patent

The Patent (Patent.1-Patent.26) describes the 1st fully automatic mechanical ventilation system in which the main outputs of a ventilator for control of oxygenation, which are the fraction of inspired oxygen (FIO2) and the positive-end-expiratory pressure (PEEP), are determined and controlled automatically for a next breath of the patient. The Patent further describes the 1st fully automatic system in which all the main outputs of a ventilator for control of oxygenation and ventilation (*i.e.*, FIO2, PEEP, respiration frequency, tidal volume, and the ratio of inspiration to expiration time, I:E) are determined and controlled automatically in a dynamic system, in relation to each other, for a next breath of the patient. The Patent incorporates the Petitioner's earlier US4,986,268 patent (the '268 patent) by reference that describes automatic control of two of the main outputs of a ventilator (*i.e.*, tidal volume and respiration frequency).

At the priority date of the Patent, there were manual look-up tables and protocol-driven systems (based on intermittent look-up tables) that were not for breath-by-breath oxygenation of ICU patients and were not fast enough to be effective for those patients. The Patent offered a significant improvement over prior art. It describes a fully automatic and robust control system for oxygenation and ventilation for mechanically ventilated patients for a next breath by which the grave consequences of lack of oxygen on the brain and poor ventilation can be prevented. Figure 1 of the Patent reproduced below shows a block diagram of the invention.

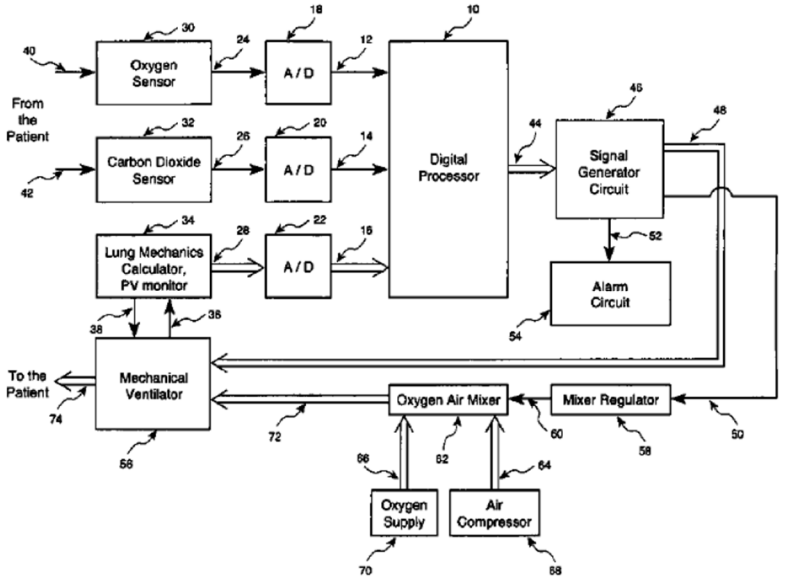

FIGURE 1 OF THE PATENT

The automatic control of the ventilator in the Patent is done through feedback control systems, continuously and within seconds (for a next breath of

the patient) (*see e.g.*, col. 10, lines 30-34 and Figure 3i at 318 of the Patent). (Patent.22, Patent.16).

The Patent has two independent claims. Claim 1 is an independent means plus function claim (the Patent: 12:49-13-3) (Patent.23-Patent.24) directed to an apparatus. Claim 1 reads as follows:

> 1. An apparatus for automatically controlling a ventilator comprising:
>
> first means for processing data indicative of at least a measured oxygen level of a patient, and for providing output data indicative of;
>
> required concentration of oxygen in inspiratory gas of the patient (*FIO2*) and positive end-expiratory pressure (PEEP) for a next breath of the patient;
>
> wherein *FIO2* is determined to reduce the difference between the measured oxygen level of the patient and a desired value;
>
> wherein PEEP is determined to keep a ratio of PEEP/*FIO2* within a prescribed range and, while keeping the ratio within the prescribed range, to keep the measured oxygen level of the patient above a predefined value; and
>
> second means, operatively coupled to the first means, for providing control signals, based on the output data provided by the first means, to the ventilator;

> wherein the control signals provided to the ventilator automatically control PEEP, and *FIO2,* for a next breath of the patient.

Claim 29 is an independent claim directed to a method for automatically controlling a ventilator (the Patent 15:15-31) (Patent.25) with similar steps as to claim 1.

One of the counterparts of the Patent, the UK patent GB2423721 was revoked by the UK patent office at the order of the UK Intellectual Property Enterprise Court through an invalidity claim by the Respondent (IP-2019-000196). The UK patent office stated in its final decision on February 7, 2023, as follows:

> "Central to the judgment of Hacon HHJ was the meaning to be ascribed to the phrase "a next breadth of a patient." Hacon HHJ noted that: "52. The point in issue was whether "*a* next breath" should be construed to mean "*the* next breath", implying that the control signals adjust FiO2 and PEEP for every breath of the patient. Alternatively "a next breath" just means a breath some time in the future." He went on to conclude, having regard to the ordinary meaning of the use of the indefinite article in "a next breath", that it meant the latter – "a breadth some time in the future." This subsequently led to the patent being found invalid." (emphasis added)

Therefore, GB2423721 with 79 claims was revoked based on using "a" v. "the" in the claim term "a next

breath" despite the fact that the claim language is in accordance with MPEP 2173.05(e).

C. The Main References Used Against the Patent Claims Are Heterogeneous, Uncombinable, and Present Methods That Are Against the Method of the Patent Claims.

The Board decided and the Federal Circuit affirmed that claims 1-6, 9-12, 29-33, and 41 of the Patent were invalid as obvious based on two Grounds: (1) a combination of Carmichael, Anderson, the '268 patent, and Rossi[1], and (2) a combination of Taube, Carmichael, ARDSNET, Clemmer, and Rossi[2].

The main references used against the Patent independent claims were Carmichael and Anderson in one Ground, and Carmichael and Taube in the other Ground. The additional references in the two Grounds were not utilized to meet any of the requirements of claims 1 and 29 of the Patent and were used to attack the validity of the challenged dependent claims.

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[1] Laurence C. Carmichael et al., *Diagnosis and Therapy of Acute Respiratory Distress Syndrome in Adults: An International Survey*, 11 J. CRITICAL CARE 9 (March 1996) ("Carmichael"); Jeffrey R. Anderson & Thomas D. East., *A Closed-Loop Controller for Mechanical Ventilation of Patients with ARDS*, 38 BIOMEDICAL SCIS. INSTRUMENTATION SYMPOSIUM 289 (2002) ("Anderson"); U.S. Patent No. 4,986,268 (the '268 patent); A. Rossi, *Intrinsic Positive End-Expiratory Pressure (PEEPi)*, 21 INTENSIVE CARE MED. 522 (1995) ("Rossi").

[2] U.S. Patent No. 5,388,575 ("Taube"); The Acute Respiratory Distress Syndrome Network, *Ventilation with Lower Tidal Volumes as Compared with Traditional Tidal Volumes for Acute Lung Injury and the Acute Lung Respiratory Distress Syndrome*, 342 NEW ENGLAND J. MED. 1301 (2020) ("ARDSNET"); U.S. Patent No. 6,148,814 ("Clemmer").

Carmichael is a survey report on how physicians adjusted PEEP and FIO2 manually and several hours apart. Anderson is a non-reviewed conference presentation claiming to have combined continuous closed loop control with a manual table. Taube is a US patent presenting an unstable positive feedback system for control of PEEP and FIO2 and Taube, that presents a fatal device, was raised during the prosecution of the Patent and was fully responded to before the Patent was allowed. It should be obvious to any person of ordinary skill in the art of the Patent that these references a) are not combinable as they present mutually exclusive methods, and 2) that the proposed impossible combinations cannot render the claims of the Patent directed to a negative feedback continuous system as obvious. The decision of the Board and the Judgment are the result of reliance on the testimonies of the Respondent's expert, Dr. Richard Imbruce.

The Board provided the acceptable qualifications of a POSITA in this case as: 1–A medically trained physician or clinician 2–An electrical engineer with an MS degree 3–An electrical engineer with a BS degree. (App.25a-26a). Dr. Imbruce is a biologist, has no engineering degree or experience, and has no publication or patent on mechanical ventilation. Dr. Imbruce, who was disqualified in another case, provided testimonies on this case as a "clinician" claiming he was a respiratory therapist (RT). However, Dr. Imbruce's RT certificate expired more than forty years ago, and he has not practiced as a clinician since that time. Therefore, he clearly is not a "clinician." The Board did not confirm that Dr. Imbruce was a POSITA on this case, but its decision on the case was entirely based on Dr. Imbruce's testimonies.

The panel at the Federal Circuit overlooked all the problems associated with Dr. Imbruce's qualifications as a POSITA and declared him a POSITA. The Opinion states that Dr. Imbruce's qualifications include: 1) "developing clinical protocols for new modalities in artificial ventilation" 2) has worked in "artificial ventilation since 1981" and 3) he is a "clinician specializing in treating respiratory failure." (App.6a). These are erroneous. There is no documented evidence other than Dr. Imbruce's deposition testimony verifying that he ever developed any modality for artificial ventilation. Further, he has not been a "clinician" for more than forty years.

According to 37 C.F.R. § 42.65(a), "Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight." The errors in the Opinion are not only the result of relying on expert testimonies against Fed. R. Evid. 702(c),(d) but are also due to relying on unsubstantiated testimonies versus Petitioner's testimonies who has an extensive record of publications in the field of the Patent and Petitioner's testimonies were supported by credible publications presented in the case (App.91a-111a).

D. Summary Description of the Main References Used Against the Patent Claims

The references against independent claims 1 and 29 were Carmichael and Anderson in one Ground, and Carmichael and Taube in the other Ground.

Carmichael (App.112a-135a) reports the results of a postal survey mailed to physicians. In Carmichael, adjustments of FIO2 and PEEP by the physicians who responded to the survey were done intermittently and

by trial-and-error. Figure 7 of Carmichael (App.124a) reproduced below shows the survey results of manual adjustments of FIO2 and PEEP performed several hours apart. According to this chart, Physicians changed PEEP up to a maximum value at any discrete level of FIO2 before increasing FIO2 to the next higher level. There is no mention of any ratio of PEEP/FIO2 anywhere in Carmichael let alone any prescribed range of such ratio.

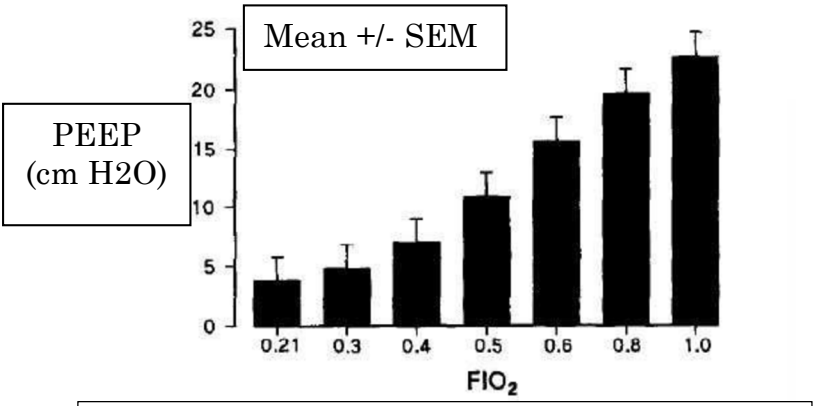

Fig. 7. The maximum PEEP used at various FiO2s.

FIGURE 7 OF CARMICHAEL (App.124a)

Anderson is a non-reviewed conference presentation that claims to have combined an intermittent look-up table reproduced below with proportional-integral-derivative (PID) control of PEEP and FIO2. (App.136a-150a).

Figure 3. *Look Up* Tables determine the therapy parameters to be changed based on current PEEP, FiO2 and PaO2 category.

FIGURE 3 OF ANDERSON SHOWING THE LOOK-UP TABLE USED IN ANDERSON (App.142a)

Anderson presents clinical results (Tables 1 and 2 and Figure 7 of Anderson) that are identical to clinical results produced by the same authors eight years prior[3] which described a look-up table only and did not describe using any PID control. Figure 7 of Anderson reproduced below shows that despite large variations in the patient's oxygen level, PEEP was not changed for more than ten hours followed by a few stepwise changes in PEEP about 30 minutes apart. In

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[3] Anderson et al., *Clinical Trial of a Non-Linear Closed-Loop Controller for Oxygenation During ARDS*, CRITICAL CARE MEDICINE, Vol 22, A188, Jan. 1994 ("Anderson94") (App.151a-153a)

addition to many other reasons explained by the Petitioner, Figure 7 of Anderson clearly shows that: 1) no PID control of PEEP was used in Anderson or else the value of PEEP would have been changing during the ten hours and 2) that PEEP was adjusted manually. Therefore, the clinical results presented in Anderson are not true. The Appellant's counsel explained this at the hearing (Oral Arg at Federal Circuit.:11:42-12:49).

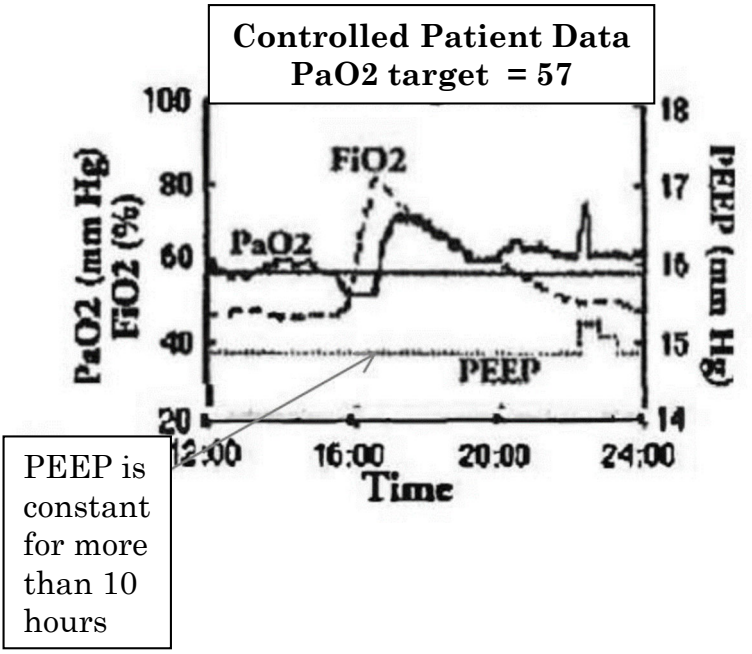


FIGURE 7 OF ANDERSON SHOWING CLINICAL RESULTS (App.147a)

Taube (Patent.27- Patent.33) is a US patent that was raised by the examiner during the prosecution of the '571 patent application and was fully responded to before the Patent was allowed. In Taube, PEEP and FIO2 are controlled by PID and the following equations

are given for calculation of modifications of PEEP and FIO2 (Patent.30):

FIO2 (FIO2 =PaO2xKL)
PEEP (PEEP=PaO2xKP)

These direct relationships show that in the system of Taube, if the patient's oxygen level, PaO2, increases (*i.e.*, improvement in oxygenation), the treatment levels of FIO2 and PEEP increase unbounded and vice versa. This is against clinical practice. Taube is an example of a positive feedback system which is inherently unstable and no set desired value for oxygen can be defined in Taube. Taube is a fatal device (App.62a, footnotes).

E. Federal Circuit Did Not Address Most of the Errors by the Board.

The Petitioner described twelve major errors in the Board's decision to the Federal Circuit. Those errors are presented below as they were listed to the Federal Circuit:

1. The Board erred by determining that a traditional mode of ventilation known as Assist-Control is for automatic determination of PEEP and FIO2 against several refereed articles stating otherwise. (page 28 of FWD)
2. The Board erred in determining the meaning of a key claim term "for a next breath of the patient."
3. The Board erred by completely ignoring all the PO's arguments and defense in regard to dependent claims 2-6, 9-12, 30-33 and 41 of the Patent.

4. The Board erred by deciding that a survey chart reporting manual adjustments of PEEP and FIO2 several hours apart (Figure 7 of Carmichael) is for automatic determination and adjustment of the said parameters for a patient's next breath (page 28 of FWD)

5. The Board erred by deciding that a method based on an intermittent look-up table (Anderson) provides a continuous control system for a patient's next breath. (pages 30-31 of FWD)

6. The Board erred by deciding that a look-up table in Anderson can be combined with a manual survey chart (Figure 7 of Carmichael) and the combination as proposed in Ground 3, would result in the continuous negative feedback control system of the Patent for a next breath. (pages 27-31 of FWD)

7. The Board erred by considering against the Patent, an unstable positive feedback system (Taube) that had been fully considered by the examiners during prosecution of the Patent and had been rejected by the examiners.

8. The Board erred by deciding that an unstable positive feedback system (Taube) could be combined with a manual survey chart (Figure 7 of Carmichael). (Pages 44-45 of FWD)

9. The Board erred by deciding that the alleged combination of the positive feedback system of Taube with the manual survey chart in Carmichael (Figure 7 of Carmichael), would result in the negative feedback control system

of the Patent for a next breath. (Pages 44-45 of FWD)

10. The Board failed to recognize that PID control of PEEP is not covered by the Patent claims and is against the method of the Patent. (pages 36 and 47 of FWD)

11. The Board failed to recognize that the alleged combinations in Grounds 3 and 4, both require PID control of PEEP and cannot render the Patent claims obvious because PID control of PEEP is not covered by the Patent claims and is against the method of the Patent. (*id*)

12. The Board erred by using against the Patent claims, Anderson which does not present true data, and Taube that presents an admittedly "fatal" unstable positive feedback method against clinical practice (page 46 of FWD in the footnotes).

Each item listed above is serious that by itself would warrant the reversal of the Board's decision. The Opinion did not address Taube, that presents a "fatal" positive feedback system, or how Taube can be combined with a survey chart in Carmichael to render obvious the independent claims of the '571 patent (which are directed to a continuous negative feedback system for oxygenation). The Opinion did not address why the Board could ignore all the arguments of the Appellant in relation to many challenged dependent claims. The Opinion did not address a very important error that PID control of PEEP, that is required in both Grounds, is against the method of the Patent and is not covered by its claims. The Opinion addressed

items 2, 4, 5, and 6 only. In addressing those items, the Federal Circuit made serious errors, as described below.

F. By Casting Doubt on the Meaning of a Key Claim Term "a Next Breath," the Opinion Supports the Use of Intermittent Charts and Tables That the Patent Is Designed to Replace and Are Against the Patent Claims.

It is well known that only a few minutes of brain oxygen deprivation results in brain damage, coma, and can lead to death. Many ICU patients cannot breathe on their own and depend on ventilators for their oxygenation and ventilation requirements. At the priority date of the Patent, only look-up tables and protocol-driven systems, based on look-up tables for adjustment of oxygenation parameters, PEEP, and FIO2, existed that could be used every 15 minutes to several hours. There was no effective fully automatic ventilation plus oxygenation system for breath-by-breath determination of the control parameters. The Patent filled that important gap in the art.

Claim terms are construed "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b). *Phillips v. AWH Corp.,* 415 F.3d 1303 (Fed. Cir. 2005).

The claim term "a next breath" is used to refer to the next breath or the next breathing cycle in accordance with MPEP 2173.05(e). The word "next" means

"immediately following in time." The term "for a next breath of the patient" means for "a patient's breath immediately following in time" or simply "the next breathing cycle of the patient." This is clear from 1) the plain language of the claims that require determination of the required output data and providing the output data to the ventilator "for a next breath of the patient" and 2) the specification of the Patent in numerous places. For example, i) Figure 2c at 144 (Patent.7) that states: "Send the control data to the output ports and hold the routine for the duration of the next breathing cycle" and the corresponding description at column 7, lines 12-14 (Patent.21); ii) Figure 3i at 318 (Patent.16), that states "Hold the routine for a fixed interval (*e.g.*, 0.75 seconds)" and the corresponding description in column 11, lines 34-36, (Patent.23) column 9, lines 55-58 (Patent.22), describing the sampling interval of the PID system as 0.75 seconds (which must be shorter than the period of one breath for PID control to be stable); and iv) column 10, lines 33-34 (Patent.22) where it states "The controller is designed to correct hypoxemia within seconds and to avoid hyperoxemia." (Emphasis added)

Two other important claim terms are "determining/ determined" and "calculated." These terms need to be construed broadly to encompass the different schemes described in the Patent. The term "determined" should be construed as "decided upon" and "calculated" should be construed as "determined or ascertained by mathematical methods". The constructions of these claim terms were provided by using dictionary definitions and by relying on the Patent specification.

"[T]he claims define the scope of the right to exclude; the claim construction inquiry, therefore,

begins and ends in all cases with the actual words of the claim," *Renishaw PLC v. Marposs Societa' per Azioni,* 158 F.3d 1243, 1248 (Fed. Cir.1998). "[T]he language of the claim defines the scope of the protected invention," *Bell Communications Research, Inc. v. Vitalink Communications Corp*., 55 F.3d 615, 619-20, 34 USPQ2d 1816, 1819 (Fed. Cir. 1995). "[T]he language of the claim frames and ultimately resolves all issues of claim interpretation." *Abtox, Inc. v. Exitron Corp.,* 122 F.3d 1019, 1023, 43 USPQ2d 1545, 1548 Fed. Cir. 1997). The words of a claim "are generally given their ordinary and customary meaning," *Vitronics Corp. v. Conceptronic, Inc.* 90 F.3d 1576, 1582 (Fed. Cir. 1996). A court construing a patent claim needs to ascertain "the meaning of the claim terms to one of ordinary skill in the art at the time of invention."; *Home Diagnostics, Inc. v. LifeScan, Inc.,* 381 F.3d 1352, 1358 (Fed. Cir. 2004).

The Respondent claimed that the term "a next breath" should be construed as "any next breath." The Respondent's construction meant the time of a next breath would be extended to infinity, the entire patent specification would be meaningless, and the Patent could be invalidated based on nothing but manual charts and tables. The Board did not construe the key claim term "a next breath," but cast doubt on the meaning of this term (App.50a-51a). The Board erroneously claimed that regardless of the meaning of this claim term, the references in two alleged Grounds would meet the claims' requirements. The Board stated that *"*for a next breath of the patient" mean different things for different parts of the same limitation*."* (*id*). The Board made this statement by erroneously defining "determining" as "changing"

(rather than Petitioner's definition of "deciding upon") and by relying on the Patent specification advising not to "change" PEEP for a certain period of time (*e.g.*, 240 seconds) for patient's safety. This was in contrast to the recitation in all the Patent claims requiring "determining" PEEP and FIO2 for a next breath, which is always done at a fraction of a second, and not necessarily "changing" them.

In affirming the Board's decision, the Federal Circuit stated in the Opinion (App.7a) that: "Dr. Tehrani's proposed construction would contradict her argument that the specification requires *adjusting* PEEP after a 240-second delay, see '571 patent 11:56-60." (emphasis added). However, there is no limitation in the claims that requires a fixed period between successive changes in PEEP. Instead, the claims of the Patent require "determining" (which means "deciding upon") of PEEP and FIO2 for a next breath and not necessarily "adjusting" or "changing" the parameters for a next breath as stated above. This is an important key issue since both Grounds require combinations with a manual survey chart (Figure 7 of Carmichael, App.124a), and combining a chart which requires manual intermittent adjustments with any other system cannot produce any system functioning "for a next breath" as required by the Patent claims. Neither system in two Grounds functions "for a next breath" as was explained by the Petitioner's counsel at the hearing (Oral Arg at Federal Circuit:29:01-29:28).

G. The Reference Combinations Proposed by the Respondent and Affirmed by the Federal Circuit Are Not Possible and Are Against Scientific Principles.

In one Ground, the main combination is a manual survey chart in Carmichael (Fig, 7 of Carmichael, App.124a) with Anderson which claims to be a closed-loop system. Any POSITA would understand that such combination is impossible. In the other Ground, the main combination is the manual survey chart in Carmichael with Taube which is a closed-loop system. Again, the proposed combination is impossible and against scientific principles.

Based on Dr. Imbruce's testimonies, the Opinion concludes (App.8a) that PID control of PEEP and FIO2 can be combined with a look-up table as claimed in Anderson. The opinion further states: "Anderson's look-up tables serve the same function as the '571 patent's loop indicators." (App.9a). These errors are the result of the reliance of the panel at the Federal Circuit on the unsupported testimonies of Dr. Imbruce in the face of credible published evidence presented by the Petitioner and the Petitioner's experience. The Petitioner presented a refereed review article (App. 91a-111a) that described: 1) the fundamental differences between continuous closed-loop automatic ventilation systems versus intermittent protocol-driven systems using look-up tables; 2) the fact that continuous systems function based on negative continuous feedback while systems based on look-up tables function based on trial-and-error; and 3) that the two systems cannot be combined. PID is a continuous closed-loop system that cannot be interrupted by using

a value from a manual table at every breath. Combinations that change the "basic principles under which the [prior art] was designed to operate," *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959), or that render the prior art "inoperable for its intended purpose," *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984), may fail to support a conclusion of obviousness."

Furthermore, loop indicators are frequently used in continuous algorithms to distinguish between loops that are within other loops. The loop indicators in the Patent algorithm (Fig. 3a-3i of the Patent, Patent.8-Patent.16) that are used in every fraction of a second have nothing to do with the intermittent manual look-up table used in Anderson.

H. The Manual Adjustments Depicted in a Survey Chart in Carmichael Have No Relation to the Continuous Closed-Loop Algorithm of the Patent for a Next Breath.

As can be read from Claim 1 recited above, one of the main requirements of the Patent claims is determination of PEEP in relation to FIO2 for a next breath. The claims require determination of PEEP to keep the ratio of PEEP/FIO2 within a prescribed range, and while keeping the said ratio in the prescribed range, to adjust PEEP based on the patient's measured oxygen level.

The Respondent used a survey chart in Carmichael (Figure 7 of Carmichael, App.124a) claiming that the said claim requirement could be met by using the manual survey chart in Carmichael.

The Opinion on pages 8 and 9 (App.8a-9a) states "it would have been obvious to employ Anderson's

automated system to implement Carmichael's treatment protocol for adjustment of PEEP and FIO2 in ARDS" and "Carmichael teaches a treatment protocol of increasing FIO2 and incrementally changing PEEP and using the relationship between FIO2 and PEEP to achieve the desired oxygen saturation level within a prescribed range" and continues to state that "The slope in Figure 7 indicates the limits of the relationship between FIO2 and PEEP. See Oral Arg. at 14:30-16:19." These statements are based on incorrect understanding of the references and the requirements of the Patent claims.

a. Anderson's PID control cannot be combined with the manual chart of Carmichael (App. 91a-111a).

b. The Patent claims a continuous closed-loop oxygenation system requiring PEEP to be determined for a next breath to keep the ratio of PEEP/FIO2 within a prescribed range. In every breath, FIO2 can go higher or lower and PEEP is determined to be adjusted to go higher or lower. In the Patent, FIO2 which is subject to continuous control, is not kept at a fixed level with PEEP going higher and higher up to a maximum level as depicted in Figure 7 of Carmichael. There is no maximum PEEP used in the Patent. There is no relation between the manual method of Carmichael and the continuous algorithm method of the Patent claims. The chart in Figure 7 of Carmichael does not have a slope. If one assumes that by talking about "the slope in Fig. 7" what was meant by the Respondent was the slope of a line drawn

through the maximum PEEP points in Fig. 7 of Carmichael, that line would only indicate the maximum PEEP values at various discrete levels of FIO2 and would not represent keeping a ratio within any prescribed range. There is no mention or use of any ratio of PEEP/FIO2 anywhere in Carmichael, let alone keeping the ratio in any prescribed range. Therefore, there can be no relation between the method of the Patent claims and what is depicted or may be learned from Fig. 7 of Carmichael.

c. Taking the argument further, if a method had been found in the prior art by which PEEP was adjusted in relation to a changing value of FIO2 to keep the ratio of PEEP/FIO2 within a prescribed range as is claimed in the Patent, that method could not be combined with PID control of PEEP in Anderson because the two methods are mutually exclusive and teach away from one another. "Whether a prior art reference teaches away from the claimed invention is a question of fact." *Para–Ordnance Mfg., Inc. v. SGS Imps. Int'l, Inc.,* 73 F.3d 1085, 1088 (Fed. Cir. 1995) and in "*Santarus, Inc. v. ParPharm., Inc.,* 694 F.3d 1344, 1354 (Fed. Cir. 2012), which is also reviewed for substantial evidence. *Gen. Elec. Co. v. Raytheon Techs. Corp.*, 983 F.3d 1334, 1344 (Fed. Cir. 2020). Substantial evidence is "such evidence as a reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co. v.*

Nat'l Labor Relations Bd., 305 U.S. 197, 229 (1938).

I. The Federal Circuit Used a Paper Presenting Untrue Results and a Device Using a Fatal Method Against the Patent Claims.

For numerous reasons, Anderson, which is a non-reviewed conference presentation, does not present true data. The authors of the paper are two non-clinicians who claim to have done significant device clinical tests in a US hospital without presenting the required FDA permission, and Anderson presents wrong formulas for its claimed discretized PID system. In addition, 1) Anderson claims to have used PID control in combination with a manual look-up table, which is impossible, 2) the clinical results of Anderson were identically presented in another paper by the same authors 8 years prior to Anderson without any PID control and by using a look-up table only, and 3) Figure 7 of Anderson shows that despite large variations in the patient's measured oxygen level, PEEP remained constant for more than ten hours and afterwards there were a few stepwise changes in PEEP about 30 minutes apart. These results show clearly that no PID control was used in Anderson. Therefore, the paper does not present true data. The Petitioner's counsel described to the Federal Circuit panel at the hearing that the results of Anderson presented in its Fig. 7 showed that PEEP was adjusted by hand many hours apart and there could not have been any PID control of PEEP in Anderson (Oral Arg. at the Federal Circuit:11:42-12:49).

Furthermore, as stated in the preceding sections, in Taube that was not addressed by the Opinion but was used against the Patent Claims by the Federal

Circuit, the linear equations for PEEP and FIO2 modifications clearly show that Taube is an unstable positive feedback system whose output is unbounded. Therefore, Taube presents a fatal device against clinical practice.

Nonetheless, the Federal Circuit used Anderson, a non-reviewed paper presenting untrue results, and Taube, a "fatal" device, against the Patent claims without even addressing the serious problems associated with these documents in the Opinion.

J. The Federal Circuit Makes a Serious Mistake by Stating That PID Control of PEEP Is Used in the Patent.

The Opinion states that PEEP is adjusted by PID control in the Patent. It states on page 2 (App.2a):

> The software algorithm includes a proportional, integral, derivative ("PID") control program which "is designed to automatically adjust" the fraction of inspired oxygen in a patient's inspiratory gas ("FIO2") and the patient's Positive End-Expiratory Pressure ("PEEP") "based on at least the measured oxygen levels of the patient.

Id. at 2:54-57.

However, this is not what the Patent recites. Col. 2:54-57 (Patent.18) of the Patent states as follows:

> The software algorithm is divided into two control programs. One control program which can either be used by itself or along with the other program, is designed to automatically adjust FIO2 and PEEP (or CPAP), based on

at least the measured oxygen levels of the patient.

The Opinion's description is incorrect, and this is a serious error of the Opinion. PID control of PEEP is not used in the Patent. PID control of PEEP is against the Patent description and claims as was described by the Petitioner numerous times before the Federal Circuit. PID control of PEEP is very hazardous, can be fatal, is against the method of the Patent claims and is not covered by those claims. One cannot control PEEP by PID and at the same time keep the ratio of PEEP to another time varying parameter FIO2 within a prescribed range as required by the Patent claims. The combinations in the two Grounds both require PID control of PEEP which is against the method of the Patent claims. Therefore, those combinations cannot render any of the Patent claims obvious.

K. Neither Ground Meets Any of the Requirements of Obviousness.

"Obviousness is a question of law based on underlying findings of fact." *In re Kubin,* 561 F.3d 1351, 1355 (Fed. Cir. 2009). The factual findings include: "(1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness, if any." *See Graham v. John Deere Co.,* 383 U.S. 1, 17–18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966), and also *Merck & Cie v. Gnosis S.P.A.,* 808 F.3d. 829, 833 (Fed. Cir. 2015).

Well-established patent law holds that an obviousness rejection cannot be sustained unless the cited reference(s): (a) provide a suggestion or motivation to

combine reference teachings in the manner claimed; (b) provide a reasonable expectation of success; and (c) teach all of the claim limitations, except for those limitations already within the knowledge or common sense of a person of ordinary skill in the art. *In re Vaeck,* 947 F.2d 488, 493 (Fed. Cir. 1991); *KSR Int'l Co. v. Teleflex, Inc.,* 550 U.S. 398 (2007).

In one Ground, the main references are a manual survey chart (Fig. 7 of Carmichael, App.124a) combined with Anderson (App.136a-150a). Even if Anderson is considered as true and the impossible combination of PID and a look-up table is accepted:

a) the manual chart of Carmichael cannot be combined with the look-up table of Anderson or PID because this would change the basic principles of how Anderson or PID were designed to operate and these impossible combinations have no chance of success. Combinations that change the "basic principles under which the [prior art] was designed to operate," *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959), or that render the prior art "inoperable for its intended purpose," *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984), may fail to support a conclusion of obviousness."

b) the method of the Patent claims recite that determinations are made for a next breath. "For a next breath" determinations require a continuous negative feedback loop and not a manual chart or a look-up table that can only be used intermittently.

c) PID control of PEEP allegedly used in Anderson is against the method of the Patent claims and they are mutually exclusive as described above. "Whether a prior art reference teaches away from the claimed invention is a question of fact." *Para–Ordnance Mfg., Inc. v. SGS Imps. Int'l, Inc.,* 73 F.3d 1085, 1088 (Fed. Cir. 1995) and in "*Santarus, Inc. v. ParPharm., Inc.,* 694 F.3d 1344, 1354 (Fed. Cir. 2012), which is also reviewed for substantial evidence. *Gen. Elec. Co. v. Raytheon Techs. Corp.,* 983 F.3d 1334, 1354 (Fed. Cir. 2020). Substantial evidence is "such evidence as a reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co. v. Nat'l Labor Relations Bd.,* 305 U.S. 197, 229 (1938).

Therefore, neither any of the references nor their alleged impossible combination meets any of the requirements of the Patent claims. Hence, this Ground does not meet any of the requirements for obviousness stated above.

In the other Ground that was not addressed by the Opinion, the main references consist of the manual chart in Carmichael and a device (Taube, Patent.27-Patent.33) that works based on positive feedback and represents a fatal device. In this Ground,

a) a manual chart that can only be used intermittently cannot be combined with a continuous system "for a next breath" as they are mutually exclusive, and thus, this combination has no chance of success;

b) the method of the Patent claims "for a next breath" cannot be disclosed by an intermittent manual chart because they are mutually exclusive,

c) PID control of PEEP used in Taube is against the method of the Patent claims because they are mutually exclusive as explained above,

d) the use of positive feedback in Taube which is inherently unstable and cannot use any desired oxygen level is against the use of negative feedback in the Patent and they are mutually exclusive.

Therefore, based on well-established patent law and the precedents as listed above, neither the references individually nor their alleged impossible combination meets any of the requirements of the Patent claims. Hence, this Ground does not meet any of the requirements of obviousness.

L. None of the References, Either Individually, or in the Alleged Combinations, Can Meet Any of the Requirements of the Patent Claims.

The Opinion concludes that although the individual prior art references do not meet the limitations of the Patent claims, their alleged combinations in two Grounds meet all the limitations of the claims at issue (App.10a). Focusing on the key independent claims 1 and 29, the main references against those claims are a manual survey chart (Fig. 7 of Carmichael), Anderson which is a conference paper presenting untrue data, and a fatal unstable device (Taube). The other additional references do not meet the limitations of the independent claims of the Patent. The

references in two grounds do not meet any of the requirements of the Patent claims either individually or in combination as described above.

M. The Judgment of the Federal Circuit Conflicts with the Decisions of the Supreme Court, Is Against 35 U.S.C. § 103(a), and the Precedents of the Federal Circuit.

As explained in the foregoing sections, the two Grounds against the challenged claims of the Patent do not meet any of the requirements of obviousness under U.S.C § 103(a), and are contrary to the Precedents of The Federal Circuit, and decisions of the Supreme Court. Many serious errors have led to the Judgment and those errors need to be rectified by this Court.

REASONS FOR GRANTING THE PETITION

I. THIS PETITION SHOULD BE GRANTED TO PREVENT STRIPPING PATENTEES' RIGHTS AGAINST WELL-ESTABLISHED PATENT LAWS.

As this Court has held, the patent system is authorized by the United States Constitution and plays an important role in encouraging innovation. *Markman v. Westview Instruments Inc.,* 517 U.S. 370, 373 (1996); *Diamond v. Chakrabarty,* 447 U.S. 303, 307, 100 S.Ct. 2204, 2206-07, 65 L.Ed.2d 144 (1980). The United States has been at the forefront of innovation and has achieved its technological advances due to numerous valuable inventions. In fact, the importance of patents in promoting innovations was realized and emphasized by the Founding Fathers of this country. The

Patent Act "embodie[s] Jefferson's philosophy that 'ingenuity should receive a liberal encouragement.'" *Chakrabarty*, 447 U.S. at 308-09 (quoting 5 WRITINGS OF THOMAS JEFFERSON 75-76 (Washington ed. 1871).

As was explained in the foregoing sections of this Petition, by totally relying on the unsupported testimonies of a non-expert in the field of the Patent and ignoring testimonies supported by credible published evidence by the Petitioner, the Board and the Federal Circuit have made numerous serious mistakes in this case. Those serious mistakes include using a conference presentation that clearly presents untrue results (Anderson) and a device presenting a fatal method (Taube) against the patent claims and approving of many impossible combinations against scientific principles. The Board and the Federal Circuit have completely misinterpreted the requirements of the claims at issue, have used manual charts and tables that teach away from the method of the claims, have completely ignored that the claims of the Patent do not cover PID control of PEEP that is required in both Grounds, have ignored that neither of the Grounds proposed by the Respondent present any system "for a next breath" as required by the Patent claims, and indeed none of the requirements of obviousness are met by either of the proposed Grounds.

By the Board's decision that is affirmed by the Federal Circuit, the Petitioner would be stripped of her patent rights against the U.S. patent laws. This case presents a clear opportunity to this Court to show that patent rights must be upheld and respected in the United States. Furthermore, the patentee in this case is an individual academic inventor. It is an undeniable

fact that many major inventions that resulted in placing the US at the forefront of technology have been developed by individual inventors. Individual and academic inventors continue to develop new innovative technologies and rely on the patent protection that they are assured to receive under the law. It is important that the Court grants this petition to show that individual and academic patent rights are not to be taken lightly and are not fading away in this country.

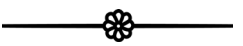
II. THE FEDERAL CIRCUIT HAS RULED AGAINST ITS OWN PRECEDENTS IN THIS CASE.

The Federal Circuit has ruled against numerous precedents of its own on claim construction, on combining heterogenous uncombinable references teaching away from the method of the claims at issue, by using references presenting untrue results, and by using flawed unsupported testimonies versus credible published evidence and testimonies. Samples of such precedents were provided in the foregoing sections. These are serious errors that need to be rectified by this Court.

III. THE RULING OF THE FEDERAL CIRCUIT IN THIS CASE CONFLICTS WITH THE DECISIONS OF THE SUPREME COURT AND DISRUPTS THE SETTLED EXPECTATIONS OF THE INVENTING PUBLIC.

The patent system is to foster innovation under the constitutional mandate "to promote the progress of . . . .useful arts." U.S. Const., art. I § 8, cl. 8. To foster innovation and protect patent rights, the requirements of obviousness are well-established by patent law and are emphasized to be upheld by this Court. *In re Vaeck,* 947 F.2d 488, 493 (Fed. Cir. 1991);

KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (2007). As discussed in detail above, none of those requirements are met by the decision of the Federal Circuit in this case. This Court has repeatedly advised that "courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo Corp. v. Shoketsu Kinzoku Kogyokabushiki Co.*, 535 U.S. 722, 724 (2002); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997). The decision of the Federal Circuit in this case clearly conflicts with the previous decisions of the Supreme Court and disrupts the settled expectations of the inventing public. Under the present circumstances that technological advancements are becoming highly competitive internationally, if the inventors lose their faith in the enforceability of patent rights in the US, it is not likely that many inventors will continue to strive to develop cutting edge technologies in this country. That will have a chilling effect on the ability of the patent system to foster innovation under the constitutional mandate.



CONCLUSION

For all the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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November 16, 2023