Appeal No. 2022-1732

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

FLEUR TEHRANI
Appellant

v.

HAMILTON TECHNOLOGIES LLC
Appellee

Appeal from the United States Patent and Trademark Office
Before The Patent Trial and Appeal Board
Case IPR2020-01199
US Patent No. 7,802,571

APPELLANT'S PETITION FOR PANEL REHEARING OR REHEARING EN BANC

Mark Kendrick
Kendrick Intellectual Property Law
4127 Woodcliff Road
Sherman Oaks, California 91403
Telephone: (818) 941-8604
Email: mkendrick852001@gmail.com

Attorney for the Petitioner
Fleur Tehrani, Ph.D., P.E.

CERTIFICATE OF INTEREST

Counsel for Appellant Fleur Tehrani (the Patent Owner "PO") certifies the following:

1. The full name of all entities represented by the undersigned counsel in this matter is Fleur Taher Tehrani.
2. There are no other real parties in interest represented by the undersigned.
3. There are no parent corporations or publicly held companies that own 10 percent or more of the stock of the party represented by the undersigned.
4. The names of all law firms, partners, and associates that (a) appeared for the party now represented by me in the originating court or agency or (b) are expected to appear in this Court for the entity (not including those who have already entered an appearance in this case) are: None
5. The cases that will directly affect or be directly affected by this Court's decision in the pending appeal (not including the original case number for this case) are: None
6. Information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees):

   None/ Not Applicable

Dated: July 24, 2023

/Mark Robert Kendrick/
Mark R. Kendrick,
Reg. No. 48,468
Kendrick Intellectual Property Law
4127 Woodcliff Road
Sherman Oaks, CA 91403
Telephone: 818 941-8604
Email: mkendrick852001@gmail.com

Attorney for Appellant Dr. Fleur Tehrani

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases

Page

TABLE OF AUTHORITIES

(continued)

Page

Statutes

Rules

Other Authorities

STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision is contrary to the following decisions of the Supreme Court of the United States or the precedents of this court: *Para–Ordnance Mfg., Inc. v. SGS Imps. Int'l, Inc.,* 73 F.3d 1085,1088 (Fed.Cir.1995), *Santarus, Inc. v. ParPharm., Inc.,* 694 F.3d 1344, 1354 (Fed. Cir. 2012), *Consol. Edison Co. v. Nat'l Labor Relations Bd.,* 305 U.S. 197, 229 (1938), *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959), *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984), *In re Vaeck,* 947 F.2d 488 (Fed. Cir. 1991); *KSR Int'l Co. v. Teleflex, Inc.,* 550 U.S. 398 (2007).

/Mark Robert Kendrick/
Mark Robert Kendrick
Attorney of Record for Appellant

INTRODUCTION AND STATEMENT OF THE CASE

The Patent at issue, US7,802,571 (the '571 patent or the Patent) describes the 1st fully automatic mechanical ventilation system in which all 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), and 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 controlled in a dynamic system, in relation to each other, for a next breath of the patient. Appellant's Brief (AB) pages 5-7. The Patent incorporates the Appellant'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 effective for breath-by-breath oxygenation of ICU 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*, Id.* Figure 1 of the Patent reproduced below shows a block diagram of the invention.

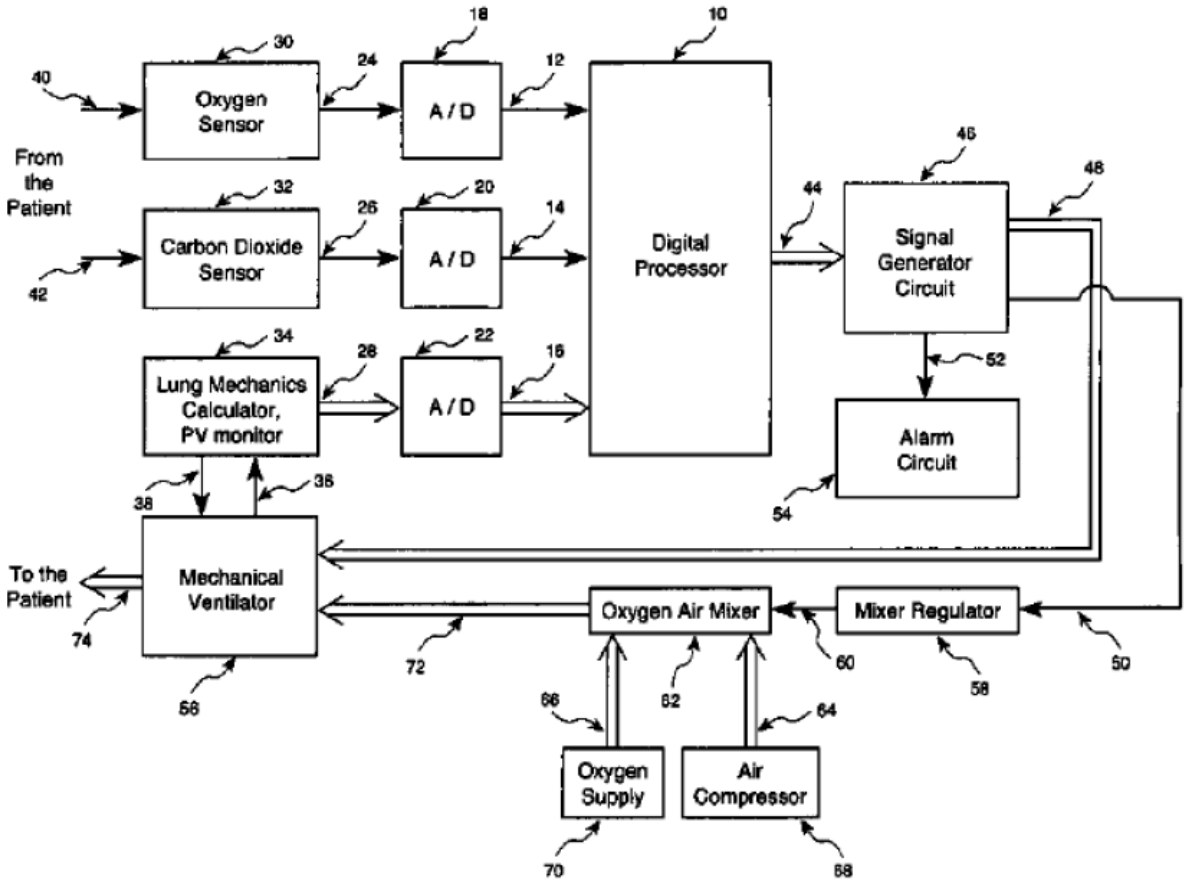

Figure 1 of the Patent.

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). Appx85, Appx2016.

The Patent has two independent claims. Claim 1 is an independent means plus function claim (the Patent:12:49-13-3) and Claim 29 is an independent method claim. *Id.*:15:15-31.

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 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 Appellant appealed the Board's decision to this Court. A hearing was held on this appeal on June 7, 2023, and the Court issued its judgment ("Judgment") along with an opinion ("the Opinion") on June 28, 2023, affirming the Board's decision. The Opinion issued by the Court only addressed a few errors in the Board's decision as were outlined in the Appellant's Brief (AB) and dismissed the majority of the stated errors as "unpersuasive."

REASONS FOR GRANTING REHEARING

A. The Opinion Is Based on Unsupported Statements of the Appellee's Expert in the Face of Evidence Presented by the Appellant.

[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"); 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").

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. (Appx13). The Appellee's expert, 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 (Appx2449-2462) 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." (AB:34). The Board did not confirm that Dr. Imbruce was a POSITA on this case but its decision on the case is entirely based on Dr. Imbruce's testimonies.

The panel overlooked all the problems associated with Dr. Imbruce's qualifications as a POSITA and declared him as 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."* (the Opinion:6). These are erroneous. There is no evidence other than what Dr. Imbruce stated during his deposition to show that he ever developed any modality for artificial ventilation. Further, he has not been a "clinician" for more than forty years.

The Opinion is based on the testimonies of Dr. Imbruce. 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 testimonies given by the Appellant with an extensive record of publications in the field of the Patent (Appx1778-1790) and credible published evidence.

B. The References Used Against the Patent Independent Claims Are Carmichael And Anderson in Ground 3 and Carmichael and Taube Ground 4.

The references used against the independent claims 1 and 29 were Carmichael and Anderson in Ground 3, and Carmichael and Taube in Ground 4. The other references including the '268 patent that is incorporated by reference in the '571 patent were used only to attack the validity of the dependent claims.

Carmichael (Appx419-428) 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 (Appx422) reproduced below shows the survey results of adjustments of FIO2 and PEEP manually and 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 (AB:40-41).

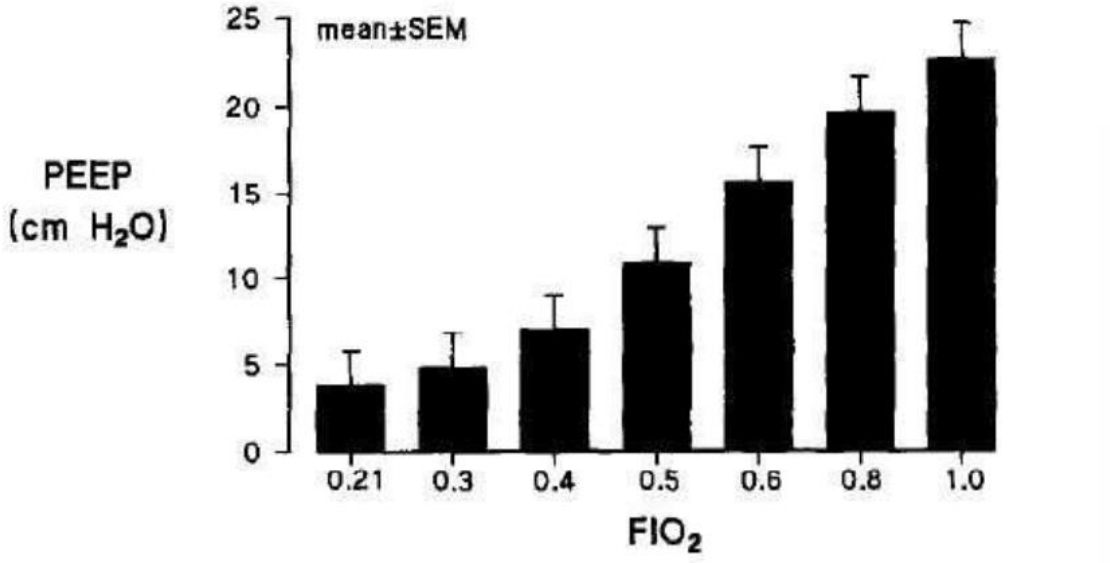

Fig 7. The maximum PEEP used at various FIO_2s.

Figure 7 of Carmichael

Anderson is a non-reviewed conference presentation that claims to have combined an intermittent look-up table with PID control of PEEP and FIO2. (Appx1114-1121, AB:15-17). 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] by using a look-up table only and without any PID control. Figure 7 of Anderson reproduced below shows that PEEP was not changed for more

[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 (Appx1843)

than ten hours followed by a few stepwise changes in PEEP about 30 minutes apart. In addition to many other reasons explained by the Appellant (AB:17-22), 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 ten hours, 2) that PEEP was adjusted manually, and 3) the clinical results presented in Anderson are not true. The Appellant's counsel explained this at the hearing (Oral Arg.:11:42-12:49).

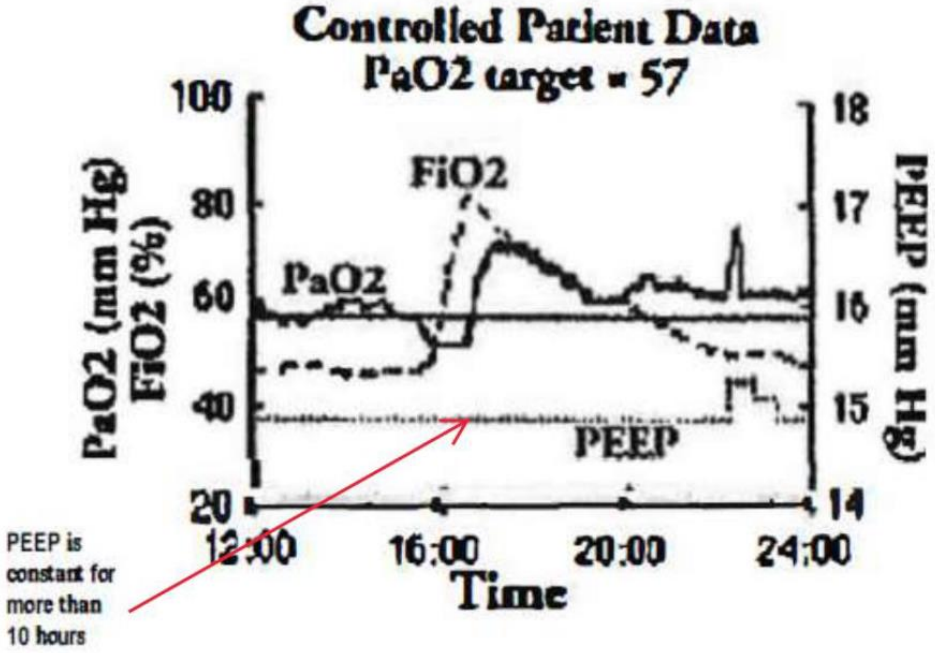

Figure 7 of Anderson showing clinical results.

Taube (Appx429-435) 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:

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 increase 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 (AB:23-27). Even the Board recognized Taube as arguably a *fatal* device (Appx 46, footnotes)

C. There Are Many Errors on the Issues That Were Addressed by the Panel.

The Petitioner had described twelve major errors in the Board's decision (AB:30 -32). Those errors are listed below:

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, Appx28)*
2. *The Board erred in determining the meaning of a key claim term "for a next breath of the patient."(Appx35-36)*
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. (Appx10)*

4. *The Board erred by deciding that a survey chart reporting manual adjustments of PEEP and FIO2 several hours apart (Figure 7 of Carmichael, Appx422) is for automatic determination and adjustment of the said parameters for a patient's next breath (page 28 of FWD, Appx28)*
5. *The Board erred by deciding that a method based on an intermittent look-up table (Anderson) (Appx1116) provides a continuous control system for a patient's next breath. (pages 30-31 of FWD, Appx30-31)*
6. *The Board erred by deciding that a look-up table in Anderson (Appx1116) can be combined with a manual survey chart (Figure 7 of Carmichael, Appx422) 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, Appx27-31)*
7. *The Board erred by considering against the Patent, an unstable positive feedback system (Taube) (Appx429-435) 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) (Appx429-435) could be combined with a manual survey chart (Figure 7 of Carmichael, Appx422). (Pages 44-45 of FWD, Appx44-45)*

9. *The Board erred by deciding that the alleged combination of the positive feedback system of Taube (Appx429-435) with the manual survey chart in Carmichael (Figure 7 of Carmichael, Appx422), would result in the negative feedback control system of the Patent for a next breath. (Pages 44-45 of FWD, Appx44-45)*
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, Appx36, Appx47)*
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 (Appx1114-1121) which does not present true data, and Taube (Appx429-435) that presents an admittedly "fatal" unstable positive feedback method against clinical practice (page 46 of FWD in the footnotes, Appx46)."*

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. The errors in those addresses are listed below:

I. The claim term "a next breath" means a patient's breath immediately following in time, "the next breath" or "the next breathing cycle" (AB:9-10). The term "a next breath" to refer to "the next breath" is the correct language in accordance with MPEP 2173.05(e). The Opinion on page 7, states "*Dr. Tehrani's proposed construction would contradict her argument that the specification requires <u>adjusting</u> PEEP after a 240-second delay, see '571 patent 11:56-60.*." (emphasis added). There is no limitation in the claims that requires a fixed period between successive changes in PEEP. Further, 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. This is an important issue since both Grounds require combinations with a manual survey chart (Figure 7 of Carmichael), and combining a manual intermittent chart with any other system cannot produce any system functioning "for a next breath." Neither

system in two Grounds functions "for a next breath" as was explained by the Appellant's counsel at the hearing (Oral Arg.:29:01-29:28).

II. Based on Dr. Imbruce's testimonies, the Opinion on page 8 concludes 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*." These errors are the result of the panel's reliance on the unsupported testimonies of Dr. Imbruce in the face of credible published evidence presented by the Appellant and the Appellant's experience. The Appellant presented a refereed review article (Appx1810-1816) that described the fundamental differences between continuous closed-loop automatic ventilation systems versus intermittent protocol-driven systems using look-up tables; 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 that the two systems cannot be combined (AB:35-40). 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) that are used in every fraction of a second have nothing to do with the intermittent manual look-up table used in Anderson.

III. The Opinion on pages 8 and 9 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.

1) Anderson's PID control cannot be combined with the manual chart of Carmichael (Appx1810-1816).

2) 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 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 Appellee 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 any prescribed range of such ratio. Indeed, 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.

3) 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. (AB:40-41, 44-50). "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) & in "*Santarus, Inc. v. ParPharm., Inc.,* 694 F.3d 1344, 1354 (Fed. Cir. 2012), which is also reviewed for substantial evidence. *GE v. Raytheon Techs. Corp.,* 983 F.3d 1334, 1354 (Fed. Cir. 2020). And 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).

D. The Opinion Does Not Address the Fact That Anderson Presents Untrue Data.

The Appellant brought to the attention of the Court that Anderson does not report true data (AB:15-22, 52). The Appellant's counsel described to the 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.:11:42-12:49). The Opinion completely overlooked this important fact and used Anderson against the Patent claims.

E .The Opinion Has Used an Incorrect Description of the Patent

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

"*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, instead of the above statement, col. 2:54-57 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, against the Patent description and claims, and against what has been described numerous times before this Court. **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 (Appellant's Reply Brief:11). **The combinations in 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.**

F. The Board's Decision Is against 35 U.S.C § 103(a), Decisions of the Supreme Court of the United States, And the Precedents of This Court

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. 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 any 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.

G. Neither Ground 3 Nor Ground 4 Meets Any of the Requirements of Obviousness.

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 (Fed. Cir. 1991); *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).

In Ground 3, the Appellee's main references are a manual survey chart (Fig. 7 of Carmichael) combined with Anderson. 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 and these impossible combinations have no chance of success, b) the method of the Patent claims is against using a manual chart or a look-up table because they are mutually exclusive since "for a next breath" determinations require a continuous negative feedback loop and not a manual chart or a look-up table, 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. Therefore, neither any of the references nor their alleged impossible combination meets any of the requirements of the Patent claims. Ground 3 does not meet any of the requirements for obviousness stated above. (AB:51-52).

In Ground 4 that was not addressed by the Opinion, the main references consist of the manual chart in Carmichael and a device (Taube) that works based on positive feedback and even the Board recognized as arguably "fatal" (Appx46). In this

Ground, a) a manual chart cannot be combined with a continuous system, they are mutually exclusive, and an impossible combination has no chance of success; b) the method of the Patent claims is against using a 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, d) the use of positive feedback in Taube is against the use of negative feedback in the Patent and they are mutually exclusive. Therefore, neither the references individually nor their alleged impossible combination meets any of the requirements of the Patent claims. (AB:52-56). Ground 4 does not meet any of the requirements of obviousness.

CONCLUSION

The Opinion issued in this case is contrary to the law, the rulings of the Supreme Court and the precedents of this Court. The panel has misinterpreted the requirements of the Patent claims and the references. The Appellant is respectfully requesting for a panel rehearing and/or rehearing en banc.

Respectfully submitted,

/Mark Robert Kendrick/

Mark Robert Kendrick
Attorney of Record for Appellant,
Dr. Fleur Tehrani