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Paper 6
Entered: January 6, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HAMILTON TECHNOLOGIES LLC,
Petitioner,

v.

FLEUR TEHRANI,
Patent Owner.

IPR2020-01199
Patent 7,802,571

Before LINDA E. HORNER, KEVIN W. CHERRY, and JAMIE T. WISZ, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

A. Background and Summary

Hamilton Technologies LLC ("Petitioner") filed a Petition (Paper 2, "Pet.") seeking *inter partes* review of claims 1–6, 9–12, 29–33, and 41 of U.S. Patent No. 7,802,571 B2 (Ex. 1001, "the '571 patent"). Fleur Tehrani ("Patent Owner") filed a Preliminary Response. Paper 5 ("Prelim. Resp.").

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the information presented in the petition and the preliminary response shows "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." A decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

Upon consideration of the Petition and the Preliminary Response, and for the reasons explained below, we determine that Petitioner has shown a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. Thus, we grant the Petition and institute an *inter partes* review of claims 1–6, 9–12, 29–33, and 41 of the '571 patent.

B. Real Parties in Interest

Hamilton Technologies LLC identifies itself and its affiliated subsidiaries, including Hamilton Holding Medical Corporation, Hamilton Company, Hamilton Medical AG, Hamilton Medial Inc., and Hamilton Bonaduz AG, as the real parties in interest. Pet. 1. Dr. Fleur T. Tehrani, Ph.D., P.E., identifies herself as the real party in interest. Paper 4, 1.

C. Related Matters

Petitioner identifies that GB 2 423 721 B, which claims priority to the '571 patent, is the subject of an ongoing UK civil action: *Fleur Tehrani v. Hamilton Bonaduz AG et al.*, High Court of Justice, Business and Property Courts of England and Wales, Intellectual Property List (ChD), Intellectual Property Enterprise Court, Claim IP-2019-000196, Issue date 29 November 2019. Pet. 1. Patent Owner also lists the ongoing UK litigation, and states that there are no related judicial or administrative matters in the U.S. Paper 4, 1.

D. The '571 Patent

The '571 patent, titled " Method and Apparatus For Controlling a Ventilator," issued September 28, 2010, from U.S. Application No. 10/935,446, filed September 7, 2004, and claims the benefit of priority to U.S. Provisional Application No. 60/481,693, filed November 21, 2003. Ex. 1001, codes (54), (45), (21), (22), (65). The '571 patent relates to "a method and apparatus for controlling a ventilator based on the measured levels of oxygen of the patient on the ventilator, as well as other physical conditions of the patient." *See id.* at 1:21–23. Specifically, the '571 patent describes a method and apparatus to control Positive End-Expiratory Pressure ("PEEP") and the concentration of oxygen in a patient's inspiratory gas, or the fraction of inspired gas ("F_{IO2}") to improve the oxygenation of patients during ventilator therapy. *Id.* at 2:25–27, 3:51–58.

We reproduce Figure 1 from the '571 patent below.

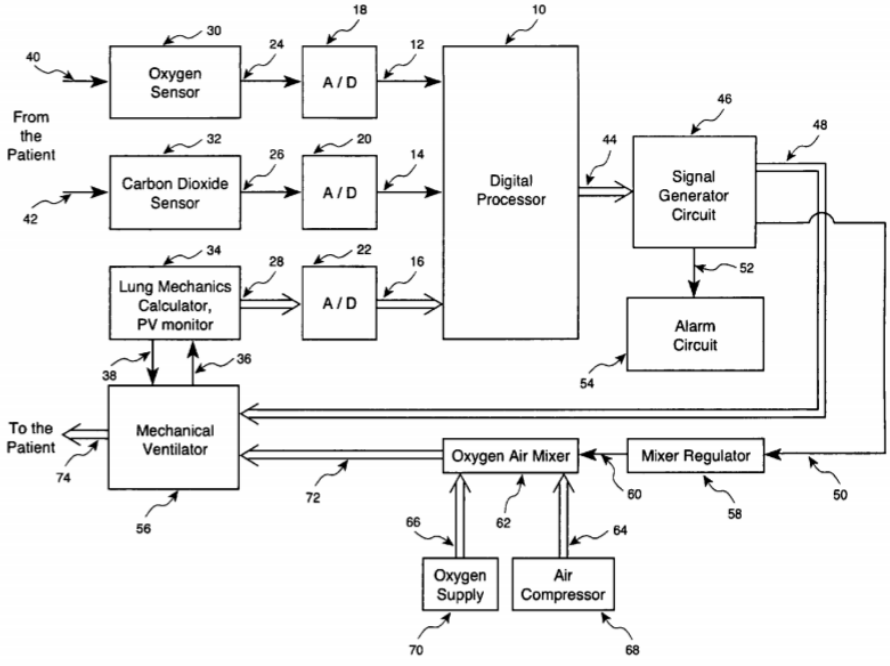

Figure 1

Figure 1 depicts a block diagram of a mechanical ventilator and the control apparatus of the claimed invention. Ex. 1001, 3:26–28. Digital processor 10 includes a programmable controller coupled to receive outputs 12, 14, and 16 of A/D converters 18, 20, and 22. *Id.* at 3:67–4:2. The A/D converters receive inputs 24, 26, and 28 from oxygen sensor 30, carbon dioxide sensor 32, and lung mechanics calculator and PV monitor 34. *Id.* at 4:5–9. Inputs 40 and 42 for sensors 30 and 32 come from the patient, and input 36 for monitor 34 comes from mechanical ventilator 56. *Id.* at 4:16–18, 22–24. Outputs 44 from digital processor 10 are applied to signal generator circuit 46. Signal generator circuit 46 sends alarm instruction signals 52 to alarm circuit 54, control signals 48 to mechanical ventilator 56, and control signals 50 to mixer regulator circuit 58.[1] *Id.* at 4:26–36. Control signals 48 include signals to control PEEP, breathing frequency, tidal volume, and adjustment of the I:E ratio of the patient. *Id.* at 4:32–34. Control signals 50 include signals to control mixer 62 to adjust F_{IO2}. *Id.* at 4:34–36.

The '571 patent describes that digital processor 10 has a software algorithm that automatically controls PEEP and F_{IO2} according to the method shown in the flow chart of Figures 3*a*–3*i*. *Id.* at 7:34–41. The desired set point for arterial partial pressure of oxygen is defined and the initial values of F_{IO2} and PEEP are set. *Id.* at 7:47–53, Fig. 3*a*, steps 200, 202, 204. Then, a time parameter (e.g., TP) for PEEP adjustment is defined and initially set to zero and another parameter, AP, for PEEP adjustment is defined to

[1] A schematic diagram of signal generator circuit 46 and alarm circuit 54 for use in the invention is shown in Figure 4 of the '571 patent. Ex. 1001, 3:38–40, 12:4–22.

control whether PEEP is controlled manually or automatically. *Id.* at 8:4–14, Fig. 3*a*, steps 206, 208. In the next step, threshold values for arterial hemoglobin oxygen saturation (S_{pO2}) are defined for the specific patient. *Id.* at 8:15–17, Fig. 3*a*, step 210. A loop indicator is defined and a first loop is started. *Id.* at 8:23–25, Fig. 3*a*, step 212. The patient's S_{pO2} data is read from one of the input ports, and the arterial partial pressure of oxygen is calculated from the S_{pO2} data. *Id.* at 8:26–41, Fig. 3*a*, steps 214, 216. The calculated partial pressure of oxygen, P_{aO2}, is compared with a minimum acceptable value to detect artifacts in the measurement of S_{pO2}. *Id.* at 8:42–45, Fig. 3*b*, step 218. If the calculated P_{aO2} is found to be less than the minimum acceptable value, then an artifact is assumed, an alarm is generated, the S_{pO2} data is discarded and the previous value of P_{aO2} in memory is resumed. *Id.* at 8:45–49, Fig. 3*b*, steps 220, 222. If the calculated P_{aO2} is found to be greater than or equal to the minimum acceptable value, its value is accepted. *Id.* at 8:50–52.

In the next steps, F_{IO2} is automatically controlled. Ex. 1001, 8:53–10:15, Figs. 3*c*-3*e*. The '571 patent describes this process of automatic control of F_{IO2} as using two different mechanisms: (1) a rapid stepwise control scheme[2] which responds instantly to fast declines in S_{pO2}, and (2) a more finely controlled PID algorithm[3] that provides fine control of F_{IO2} in the absence of sharp hazardous declines in S_{pO2}. *Id.* at 10:16–23. The stepwise controller has three loops, each with its defined minimum and maximum S_{pO2} threshold levels. *Id.* at 10:23–26. The controller switches

[2] The rapid stepwise control scheme is shown in Figures 3*c*–3*e* and described in the '571 patent in column 8, line 53 through column 9, line 33.
[3] The PID control algorithm is shown in Figure 3*f* and described in the '571 patent in column 9, line 33 through column 10, line 15.

from PID control to the rapid stepwise algorithm only if rapid declines in S_{pO2} are detected. *Id.* at 10:28–30. Once in the stepwise mode, the controller continuously checks S_{pO2}, and if it rises, the controller reduces F_{IO2} to minimize the exposure of the patient to high and toxic levels of F_{IO2}. *Id.* at 10:30–33.

After the required F_{IO2} is determined, the procedure of adjusting PEEP begins with calculating the ratio of PEEP/F_{IO2}. Ex. 1001, 10:43–45, Fig. 3*g*, step 282. If the control parameter AP was set for automatic control of PEEP, then an automatic PEEP adjustment control loop is started. *Id.* at 10:61–64, Fig. 3*g*, step 284, Fig. 3*h*, step 294.

In performing the automatic PEEP adjustments, the PEEP/F_{IO2} value is kept within a clinically acceptable range. Ex. 1001, 11:48–49. If the PEEP/F_{IO2} value is too low, PEEP is increased by a fixed increment (e.g., 2 cm H_2O). *Id.* at 11:50–51, 10:64–11:18, Fig. 3*h*, steps 296, 298, 300, 302, Fig. 3*i*, steps 304, 306. If the PEEP/F_{IO2} value is within the acceptable range and S_{pO2} is low, then PEEP is increased by a fixed increment (e.g., 2 cm H_2O) to improve patient's oxygenation. *Id.* at 11:51–54, 11:37–47, Fig. 3*i*, step 320. On the other hand, if the PEEP/F_{IO2} value increases beyond a maximum defined value, the program reduces PEEP in fixed amounts (e.g., 2 cm H_2O). *Id.* at 11:54–56, 11:19–34, Fig. 3*i*, steps 308, 310, 312, 314, 316. In any case, the interval between two successive PEEP adjustments is at least equal to a fixed period (e.g., 240 seconds), to allow for the changes in PEEP to have an observable and measurable impact on the patient's oxygenation. *Id.* at 11:56–60.

E. Illustrative Claims

The Petition challenges claims 1–6, 9–12, 29–33, and 41. Of these, claims 1 and 29 are independent. Claim 1, which is illustrative of the subject matter at issue, is directed to an apparatus and is reproduced below.

> 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 (F_{IO2}) and positive end-expiratory pressure (PEEP) for a next breath of the patient;
>
> wherein F_{IO2} 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/F_{IO2} 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 F_{IO2}, for a next breath of the patient.

Ex. 1001, 12:48–13:3. Independent claim 29 is directed to a method for automatically controlling a ventilator comprising steps similar to the functions recited in claim 1. *Id.* at 15:15–31.

F. Evidence

The following references form the basis of the grounds presented in the Petition:

References	Date	Exhibit No.
Carmichael, L.C. et al., "Diagnosis and Therapy of Acute Respiratory Distress Syndrome in Adults: An International Survey," J. of Critical Care, Vol. 1, No. 1 (March 1996), pp. 9–18 ("Carmichael")	March, 1996	1004
US 5,388,575 ("Taube")	Feb. 14, 1995	1005
US 4,986,268 ("Tehrani '268")	Jan. 22, 1991	1006
Brower, R.G., M.D. et al., "Ventilation with Lower Tidal Volumes as Compared with Traditional Tidal Volumes for Acute Lung Injury and the Acute Respiratory Distress Syndrome," The New England J. of Med., Vol. 342, No. 18 (May 4, 2000), pp. 1301–08 ("ARDSNET").	May 4, 2000	1007
US 6,148,814 ("Clemmer")	Nov. 21, 2000	1008
Waisel, D.B. et al., "PEFIOS: An Expert Closed-Loop Oxygenation Algorithm," MEDINFO '95 Proceedings of the Eighth World Congress of Medical Informatics, pp. 1132–36 ("Waisel")	1995	1011
Anderson, J.R. et al., "A Closed-Loop Controller for Mechanical Ventilation of Patients with ARDS," Technical Papers, Proceedings of the 39th Annual Rocky Mountain Bioengineering Symposium & 39th Int'l ISA Biomedical Sciences Instrumentation Symposium, Vol. 38, Presented at Copper Mountain, Colorado, April 12–14, 2002, pp. 289–94 ("Anderson")	April 12–14, 2002	1013
Rossi, A. et al., "Intrinsic positive end-expiratory pressure ($PEEP_i$)," Intensive Card Med (1995) 21:522–535 ("Rossi")	1995	1015

For each of the above-listed publications, Petitioner provides evidence to show "the authenticity of the documents" and "when and how each of these documents was disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could have located the documents." Declaration of Sylvia D. Hall-Ellis, Ph.D. (Ex. 1017), ¶ 12 (describing scope of the declaration), ¶¶ 51–68, 77–84, 94–110 (discussing above-listed references). At this stage of the proceeding, Patent Owner has not challenged the prior art status of any of the cited references. Prelim. Resp., *passim*.

Petitioner also relies on the Declaration of Richard Imbruce ("Imbruce Dec.") as evidence of the state of the art, the knowledge of one having ordinary skill in the art, and the anticipation and obviousness of the challenged claims based on the grounds presented in the Petition. Ex. 1002. Patent Owner relies on the Declaration of Fleur T. Tehrani ("Tehrani Dec.") in rebuttal. Ex. 2002.[4]

[4] The Tehrani Declaration includes two appendices that provide claim charts comparing the challenged claims to the disclosures in the prior art references relied on in the Petition. Ex. 2002, App. 1, App. 2. The Preliminary Response attempts to incorporate by reference the arguments from these appendices. Prelim. Resp. 16, 23, 70. The AIA trial rules impose word limits for preliminary responses and prohibit incorporating arguments by reference from one document into another. 37 C.F.R. §§ 42.24(b)(1), 42.6(a)(3). As explained in our Consolidated Trial Practice Guide (CTPG), "parties that incorporate expert testimony by reference in their petitions, motions, or replies without providing explanation of such testimony risk having the testimony not considered by the Board." CTPG, 35–36 (citing *Cisco Systems, Inc. v. C-Cation Techs., LLC*, IPR2014-00454, Paper 12 (PTAB Aug. 29, 2014) (informative)).

G. Prior Art and Asserted Grounds

Petitioner asserts that the challenged claims are unpatentable on the following grounds:

Claims Challenged	35 U.S.C. §	References/Basis
1, 2, 5, 6, 11, 29, 31–33, 41	102(b)	Carmichael
1, 2, 5, 6, 11, 29, 31–33, 41	103(a)	Carmichael (as evidenced by ARDSNET and Waisel)[5]
1–6, 9–12, 29–33, 41	103(a)	Carmichael, Anderson, Tehrani '268, Rossi
1–6, 9–12, 29–33, 41	103(a)	Taube, Carmichael, ARDSNET, Clemmer, Rossi

II. PROCEDURAL CONSIDERATIONS

A. Requirement for Back-Up Counsel

In the Patent Owner Submission of Mandatory Notice Information Pursuant to 37 C.F.R. § 42.8(a), Patent Owner designated Mark R. Kendrick as lead counsel. Paper 4, 1. Patent Owner requested waiver of the requirement to designate back-up counsel:

> The Patent Owner is an individual inventor of limited resources and has been unable to retain back-up counsel. The Patent Owner respectfully requests that the Board exercise its authority under 37 C.F.R. § 42.5(b) to waive or suspend the requirement under 37 C.F.R. § 42.10 that the Patent Owner designate at least one back-up counsel.

Id. Petitioner has not responded to or opposed this request.

[5] Petitioner provides this obviousness ground as an alternative to the anticipation ground based on Carmichael. *See, e.g.*, Pet. 35–38. We list it as a separate ground because it is based on a different statutory provision than the anticipation ground.

The Consolidated Trial Practice Guide explains that the Board's Rules require parties to designate at least one back-up counsel because "instances may arise where lead counsel may be unavailable." CTPG at 10 (citing 37 C.F.R. § 42.10(a)). That said, we understand that the Patent Owner here is an individual inventor with limited financial resources, and has chosen to hire a solo practitioner for representation in this proceeding. Under these circumstances, it would be too onerous of a requirement to hire separate counsel to serve as back-up counsel in this matter. Thus, we find good cause exists to waive the requirement under 37 C.F.R. § 42.10, and we suspend the requirement for Patent Owner to designate back-up counsel.

We caution Patent Owner that designating only lead counsel carries a risk. This proceeding has certain deadlines imposed by statute that require the Board to move at a fast pace and require good cause to be shown for extensions. Should Patent Owner's lead counsel become unavailable in this proceeding due to conflict, incapacity, unavailability, or other unforeseen circumstances, Patent Owner may be strategically disadvantaged in having to hire replacement counsel at the last minute. The Board cannot guarantee that it will be able to grant Patent Owner extra time to locate replacement counsel and allow any replacement counsel to become familiar with the case in advance of upcoming scheduling deadlines.

B. Discretion Under 35 U.S.C. § 325(d)

Patent Owner contends that we should exercise our discretion under 35 U.S.C. § 325(d) to deny the Petition, applying our precedential decisions in *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (precedential) ("*Advanced Bionics*") and *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) (precedential as to § III.C.5,

first paragraph) ("*Becton, Dickinson*"). Prelim. Resp. 8–9. Specifically, Patent Owner argues that five of the Petition's eight main references were "referenced in the Patent and reviewed by the examiners in the United States and several other countries." Prelim. Resp. 21 (citing Taube, Clemmer, Waisel, Tehrani '268, and Rossi). Patent Owner also argues that Anderson "is similar [to] and presents the exact same results as" an earlier Anderson article ("Anderson 94")[6] "referenced in the '571 Patent and reviewed by the examiners." *Id.* Patent Owner argues that "it is not necessary for the Patent Office to reconsider those references because they were already cited and/or considered by the Patent Office and reconsidering them would be a waste of the PTAB's resources." *Id.*

Petitioner argues that the Office's failure to consider material, non-cumulative prior art relied on in the Petition constitutes material error. Pet. 75 (discussing "newly cited prior art to Carmichael, ARDSNET, and Anderson"). Petitioner also argues that the Petitioner points to material misrepresentations about Taube made during prosecution and overlooked disclosure in Taube, and that these mischaracterizations and overlooked citations, coupled with new, non-cumulative prior art in the Petition, "highlight material errors of prosecution that warrant institution." *Id.* at 76.

For the reasons provided below, we do not exercise our discretion to deny institution under § 325(d).

1. Applicable Framework

Section 325(d) provides that, in determining whether to institute an *inter partes* review, "the Director may take into account whether, and reject

[6] Anderson, J.R. et al., "Clinical trial of a non-linear closed-loop controller for oxygenation during ARDS," Critical Care Medicine, Vol. 22, 188 (Jan. 1994). Ex. 2008.

the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. § 325(d) (2018). The Board uses a two-part framework in determining whether to exercise its discretion under § 325(d), specifically:

> (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and
>
> (2) if either condition of [the] first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics at 8.

In applying the two-part framework, we consider several non-exclusive factors from *Becton, Dickinson*, which provide "useful insight into how to apply the framework" (*Advanced Bionics* at 9): (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art; (e) whether Petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments. *Becton, Dickinson* at 17–18. If, after review of factors (a), (b), and (d), we determine that the same or substantially the same art or arguments previously were presented to the Office, we then review factors (c), (e), and (f), which relate to whether the petitioner demonstrates that the

Office erred in a manner material to the patentability of the challenged claims. *Advanced Bionics* at 10.

2. Analysis under 35 U.S.C. § 325(d)

We start our analysis with a review of the prosecution history of the '571 patent.

a) Prosecution History of the '571 patent

The application that matured into the '571 patent was filed September 7, 2004, with 79 original claims. Ex. 1009, 525–586. Shortly after the application filing, the applicant filed an Information Disclosure Statement ("IDS") having six pages of citations, including Taube, Tehrani '268, Rossi, and Waisel. *Id.* at 359–367. The applicant later filed a Preliminary Amendment and a second IDS that included seven additional references. *Id.* at 336–358. The Preliminary Amendment did not add or delete any claims, but it amended original claims 1, 29, and 46. *Id.* A few months later, the applicant filed a third IDS, which included Clemmer. *Id.* at 330–332. Two years later, the applicant filed a fourth IDS that included three references. *Id.* at 320–322. The applicant then filed a fifth IDS that included three additional references. *Id.* at 315–319.

In January, 2009, the examiner issued an office action requiring the applicant to restrict the application to either of two recited inventions. Ex. 1009, 292–298. After a telephone interview with the examiner to clarify the restriction, the applicant elected to prosecute the invention of claims 1–13 and 29–45, directed to methods and devices for controlling a respirator using oxygen as input. *Id.* at 287–289.

In February, 2009, the examiner issued a first office action on the merits. Ex. 1009, 245–258. Accompanying this first office action, the examiner provided signed copies of all five IDSs filed by the applicant. *Id.*

at 259–286. The examiner also attached a Notice of References cited (PTO-892) that listed three additional references, including Taube. *Id.* at 256. The examiner examined elected claims 1–13 and 29–45 and rejected claims 1, 2, 5, 6, 9–11, 13, 29, 31, 34–38, and 41–43 under 35 U.S.C. § 103(a) as unpatentable over Taube and Acorn[7] and claims 3, 4, 12, and 30 under 35 U.S.C. § 103(a) as unpatentable over Taube, Acorn, and Raemer.[8] *Id.* at 248–253.

The examiner found, in relevant part, that Taube discloses an apparatus for controlling ventilation that processes data indicative of at least a measured oxygen level of a patient and provides output data indicative of required concentration of oxygen in inspiratory gas and PEEP, wherein the inspiratory gas is determined to reduce the difference between the measured oxygen level of the patient and a desired value. Ex. 1009, 249, 252–53 (citing Taube, col. 4, col. 5 lines 1–25 and 45–51, and col. 6, lines 1–10). The examiner also found that Taube discloses that PEEP is determined to keep a ratio of PEEP/inspiratory gas within a prescribed range. *Id.* (citing Taube, cols. 4 and 5). The examiner found that Taube did not disclose the required concentration of oxygen in inspiratory gas and PEEP "for a next breath of the patient." *Id.* The examiner found that Acorn filled the gap in Taube. *Id.*

In response, the applicant argued that Taube does not disclose determining F_{IO2} to reduce the difference between the measured oxygen level of the patient and a desired value. Ex. 1009, 233–234. The applicant argued that Taube's control system is designed to obtain "the highest

[7] U.S. 5,705,735, issued Jan. 6, 1998.
[8] U.S. 5,365,922, issued Nov. 22, 1994.

obtainable oxygen level, *i.e.*, complete saturation of the bloodstream with O_2." *Id.* at 233 (citing Taube, Fig. 3). The applicant also argued that Taube's system is "fundamentally flawed" and "contrary to sound medical practice" because the flowchart of Figure 3 shows that as the patient's oxygen level increases, the patient is given more oxygen, and as the patient's oxygen level decreases, the patient is given less oxygen. *Id.* at 234. The applicant also argued that there is no teaching in Taube or Acorn for controlling the PEEP/F_{IO2} ratio within a prescribed range. *Id.* at 235–236 (arguing Acorn teaches a device for measuring respiratory gases to assess nutritional requirements of a patient and does not teach a ventilator control system).

The examiner then issued a second, final office action maintaining the rejections. Ex. 1009, 193–203. The examiner disagreed with the applicant's arguments about Taube. The examiner found that "[c]olumn 4 of [Taube] does disclose output data indicative of F_{IO2} to reduce the difference between the measured oxygen level of the patient and a desired value" and "[c]olumns 4 and 5 of [Taube] does teach controlling the PEEP to F_{IO2} ratio within a prescribed range." *Id.* at 194. The examiner also pointed to passages in Acorn to supply the missing subject matter of "determining either the patient's F_{IO2} or PEEP for a next breath of the patient." *Id.* at 195.

The applicant then appealed the final office action and presented the same arguments regarding Taube and Acorn as presented in its prior response to the examiner. Ex. 1009, 129–173.

In response, the examiner reopened prosecution, withdrew the previous rejections, and entered new rejections of claims 1–13, 29–38, 41,

and 42 under 35 U.S.C. § 102(e) as anticipated by DeVries.[9] Ex. 1009, 107–117.

The applicant then appealed a second time and argued that DeVries teachings modifying an industrial blower to operate as a compressor for a medical ventilator by applying well-known control schemes and does not teach the automatic control algorithms claimed. Ex. 1009, 69 (arguing that DeVries does not teach "determining and controlling F_{IO2} and PEEP").

In response, the examiner reopened prosecution a second time, withdrew the anticipation rejection, and entered new rejections of claims 1–13, 29–31, 36–38, and 41 under 35 U.S.C. § 102(e) as anticipated by Banner.[10] Ex. 1009, 38–47. The applicant and examiner then conducted an interview to discuss Banner, and it was agreed that Banner does not teach the required F_{IO2} and PEEP for a next breath of the patient in combination with determining PEEP to keep the PEEP/F_{IO2} ratio within a prescribed range in order to keep the patient's oxygen level above a predefined value. *Id.* at 21–23. The examiner also entered an examiner's amendment to cancel withdrawn claims 46–79, rejoined previously withdrawn claims 14–28, and allowed claims 1–45. *Id.* at 24.

b) Part One of the Advanced Bionics *Framework*

In the first part of the *Advanced Bionics* framework, we examine whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office. Patent Owner argues that the examiner raised Taube in rejections during prosecution and the applicant

[9] US 2005/0051168 A1, published Mar. 10, 2005.
[10] US 2004/0003813 A1, published Jan. 8, 2004.

fully responded to these rejections. Prelim. Resp. 21. Patent Owner also argues that Clemmer, Waisel, Tehrani '268[11], and Rossi were referenced in the '571 patent and reviewed by the examiner during prosecution. *Id.* Patent Owner also argues that Anderson is similar to Anderson 94, which was referenced in the '571 patent and reviewed by the examiner during prosecution. *Id.* Patent Owner argues that Carmichael and ARDSNET, although not previously considered, do not describe any system related to the '571 patent. *Id.* at 22.

Petitioner does not dispute that Taube, Clemmer, Waisel, Tehrani '268, and Rossi were previously presented to the Office. Pet. 75–77. Instead, Petitioner's arguments focus on material error of the original prosecution and failure to consider material, non-cumulative prior art, discussed below. *Id.*

Grounds 1 and 2 are based on anticipation by and obviousness in view of Carmichael. Pet. 29–45. Carmichael was not previously presented to the Office during prosecution of the '571 patent. Patent Owner does not assert that Carmichael is substantially similar to prior art previously presented to the Office. Further as discussed below, Carmichael discloses a relationship between PEEP and F_{IO2} delivered to a patient during mechanical ventilation that is not substantially similar to the prior art previously presented to the Office. *See* Section III.D.1 below. Although Ground 2 relies on Waisel for evidence that an "assist control mode" operating with "F_{IO2}" and "PEEP" control signals is understood as a processor-based ventilator having an F_{IO2}, PEEP signal generator (Pet. 35), this teaching is relied on simply to confirm

[11] Tehrani '268 is incorporated by reference in the '571 patent. Ex. 1001, 1:10–12.

the understanding of a person skilled in the art as to the scope of the disclosure of "assist-control mode" in Carmichael. Thus, it does not change our view that Grounds 1 and 2 do not rely on the same or substantially the same art previously presented to the Office.

Ground 3 relies on Carmichael, Anderson, Tehrani '268, and Rossi. Pet. 46–60. As discussed above, Carmichael was not previously presented to the Office. It is undisputed that Tehrani '268 and Rossi were previously presented to the Office. Pet. 75–77; Prelim. Resp. 21. This ground, however, does not rely on Tehrani '268 and Rossi in a significant manner. For instance, these references are not relied on in the challenge to independent claims 1 and 29 or dependent claims 2, 30, and 41 of Ground 3. Pet. 48–57, 59 (relying on Tehrani '268 only for disclosure of artifacts and alarms recited in challenged dependent claims 3–6, 10–12, and 31–33); *id.* at 54–57 (relying on Rossi only for disclosure of $PEEP_i$ recited in challenged dependent claims 9 and 10). Patent Owner argues that Anderson is similar to Anderson 94 referenced in the '571 patent and reviewed by the examiner during prosecution. Prelim. Resp. 22. We disagree.

Anderson discloses more than the earlier Anderson 94 because Anderson discloses using Proportional-Integral-Derivative (PID) controllers for a continuously controlled closed-loop feedback controller for PEEP and F_{IO2} settings in a ventilator to maintain a patient's PaO_2 level at a target value with minimal therapy. Ex. 1013, 289 (Abst.), 290 (Introduction), 291 (Fig. 2). Although the earlier Anderson 94 discloses a closed-loop control system to continuously control F_{IO2} and PEEP on a mechanical ventilator using input from a PaO_2 sensor, the earlier Anderson 94 is silent as to how it determines the PEEP and F_{IO2} output. Ex. 2008. Ground 3 relies

substantially and primarily on the combined teachings of Carmichael and Anderson, both of which were not previously presented to the Office.

Ground 4 relies on Taube, Carmichael, ARDSNET, Clemmer, and Rossi. Pet. 60–74. It is undisputed that Taube, Clemmer, and Rossi were previously presented to the Office. Pet. 73–75; Prelim. Resp. 21. Although Carmichael and ARDSNET were not previously presented to the Office, Petitioner's substantial reliance on the disclosure of Taube in the challenge in this fourth ground leads us to conclude that Ground 4 is based on the same or substantially the same prior art as previously presented to the Office. Because this ground is based on substantially the same art as previously presented to the Office, we assess part two of the *Advanced Bionics* framework below.

c) Part Two of the Advanced Bionics *Framework*

We focus our inquiry under Part Two on Ground 4, as this is the only ground presented in the Petition that relies on substantially the same prior art previously presented to the Office.

Petitioner argues that "[t]he newly cited prior art to Carmichael, ARDSNET, and Anderson address key elements regarding determining of PEEP, after determining FIO2, to keep a calculated PEEP/FIO2 ratio within a prescribed range, while keeping measured oxygen above a predefined value." *Id.* at 75–76. Petitioner asserts that "[t]hese claim elements improperly led to allowance." *Id.* at 76.

As to Taube, Petitioner argues that the Petition places Taube "in a new light by highlighting material mischaracterizations made during prosecution that were relied upon by the Examiner regarding controlling a ventilator to a desired value of oxygen, and by citing to sections of Taube

not previously cited to the Examiner." *Id.* at 76–77 (citing Ex. 1005 (Taube), Abst., 1:31–41, 5:12–38).

As to Clemmer, Rossi, Waisel, and Tehrani '268, Petitioner argues that the examiner did not fully appreciate these references. *Id*. at 77.

Taube was evaluated during examination and the examiner rejected the claims based primarily on Taube in the first and second office actions. Ex. 1009, 192–203, 245–255; *see also* section II.B.2.a above. As recounted above, the applicant made several arguments to distinguish Taube from the claimed subject matter, including that Taube does not teach determining F_{IO2} to reduce the difference between the measured oxygen level of the patient and a desired value, and that Taube does not teach determining PEEP so that the PEEP/F_{IO2} ratio remains within a prescribed range. Ex. 1009, 143–151. The examiner withdrew the rejections based on Taube in light of these arguments, and entered a new ground of rejection based on different prior art. *Id.* at 107–117.

Petitioner now relies on Carmichael, as evidenced by ARDSNET, to teach that it was known in the art to set PEEP based on F_{IO2} to maintain the PEEP/F_{IO2} ratio within a prescribed range. Pet. 64–65. Because Carmichael and ARDSNET were not before the examiner, the examiner could not have considered the combination of Taube with the teachings of these references during prosecution. This additional evidence presented in the Petition warrants reconsideration of Taube in combination with these additional teachings. Thus, we find that the examiner materially erred in allowing the claims over Taube because the examiner did not have the benefit of the teachings of Carmichael and ARDSNET.

d) Conclusion

Because three of the four asserted grounds rely solely or substantially on prior art not previously presented to the Office, and because the fourth ground presents the previously presented prior art in combination with additional teachings not previously presented to the Office that warrant reconsideration, we decline to exercise discretion under 35 U.S.C. § 325(d) to deny institution.

III. UNPATENTABILITY ANALYSIS

A. Legal Standards

Petitioner's first asserted ground of unpatentability is based on anticipation under 35 U.S.C. § 102(b). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). To establish anticipation, "all of the elements and limitations of the claim must be shown in a single prior reference, arranged as in the claim." *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001).

Petitioner's remaining asserted grounds of unpatentability are based on obviousness under 35 U.S.C. § 103.

> Section 103(a) forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary

skill in the art; and (4) when available, objective evidence, such as commercial success, long felt but unsolved needs, and failure of others.[12] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

"[O]bviousness must be determined in light of *all the facts*, and . . . a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine" teachings from multiple references. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (emphasis added); *see also PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014) ("The presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact.").

B. Level of Ordinary Skill in the Art

The level of skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Petitioner contends that a person having ordinary skill in the art of the '571 patent would be:

> (i) a medically trained physician or clinician specializing in treating respiratory failure issues with at least five years of practical clinical ventilator experience treating such conditions; or (ii) a Master's degree in Electrical Engineering or a related field and about five years of practical experience with developing ventilators for clinical patient treatment; or (iii) a Bachelor's degree in Electrical Engineering or a related field and about 10 years of practical experience with developing ventilators for clinical patient treatment.

[12] The Patent Owner does not direct us to any objective evidence of non-obviousness in the current record.

Pet. 20–21 (referencing Ex. 1002 ¶¶ 71–72). Petitioner proposes that "[a] higher level of education or specific skill might compensate less experience, and vice versa." *Id.*

Patent Owner does not present an opposing view of the level of skill of the hypothetical person having ordinary skill in the art of the '571 patent. Instead, Patent Owner argues that Petitioner's expert does not have "specialized knowledge applicable to aspects of the claimed subject matter." Prelim. Resp. 19 (emphasis omitted). Specifically, Patent Owner argues that Petitioner's expert "has no training and background knowledge in the field of automatic control as applied to mechanical ventilation[,] which is the technological backbone of the ['571] [p]atent." *Id.* at 18–19.

For the purposes of this Decision, we apply Petitioner's definition of the level of ordinary skill in the art. We determine that this definition is consistent with the prior art of record and the skill reflected in the Specification of the '571 patent, based on our review of the limited record.

As to Patent Owner's arguments about the qualifications of Petitioner's expert, no requirement exists for a perfect match between the expert's experience and the relevant field. *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010). Nonetheless, our preliminary review of Mr. Imbruce's credentials shows that he ostensibly falls under Petitioner's definition of a person having ordinary skill in the art. For instance, Mr. Imbruce has a doctorate degree in biology and is a "registered respiratory therapist", has worked as an officer and a member of various societies and organizations pertaining to respiratory devices and treatment for 25 years, and has worked as a clinical scientist. *See* Ex. 1002 ¶¶ 10, 14–16; Ex. 1003 (curriculum vitae). These qualifications are sufficient for

purposes of institution. Patent Owner will have the opportunity during trial to question Petitioner's expert in a deposition as to his qualifications.

C. Claim Construction

In *inter partes* reviews, we interpret a claim "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)." 37 C.F.R. § 42.100(b). Under this standard, we construe 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." *Id.*

Petitioner offers express constructions for nine claim terms. Pet. 22–27. Patent Owner offers express constructions for five claim terms. Prelim. Resp. 12–15. Included in each parties' claim construction briefing are proposed constructions for the means-plus-function claim terms "first means" and "second means" recited in claim 1. Pet. 22–23; Prelim. Resp. 12–13.

We determine that, for purposes of this institution decision, we need to expressly construe only the terms "first means" and "second means." *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

These claim terms are written in means-plus-function claim language. *See* 35 U.S.C. § 112, sixth paragraph ("An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure,

material, or acts described in the specification and equivalents thereof."). Construction of means-plus-function terms "must identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function." 37 C.F.R. § 42.104(b)(3). Construing a means-plus-function claim term is a two-step process that includes (1) identifying the claimed function and (2) "then determine what structure, if any, disclosed in the specification corresponds to the claimed function." *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1351 (Fed. Cir. 2015).

1. First means

The function associated with the "first means" in claim 1 includes "processing data indicative of at least a measured oxygen level of a patient" and "providing output indicative of . . . required concentration of oxygen in inspiratory gas of the patient (F_{IO2}) and positive end-expiratory pressure (PEEP) for a next breath of the patient." Ex. 1001, 12:51–56. Claim 1 further recites that "F_{IO2} is determined to reduce the difference between the measured oxygen level of the patient and a desired value" and "PEEP is determined to keep a ratio of PEEP/F_{IO2} within a prescribed range and, while keeping the ratio within a prescribed range, to keep the measured oxygen level of the patient above a predefined value." *Id.* at 12:57–64.

The structure disclosed in the '571 patent corresponding to this claimed function is digital processor 10, which includes a programmable controller that receives inputs and performs the algorithm described in Figures 3*a* through 3*i* to provide the F_{IO2} and PEEP outputs recited in claim 1. Ex. 1001, 2:49–57, 3:67–4:28, 7:34–12:3, Figs. 1, 3*a*–3*i*. *See* Section I.D. above (discussing disclosure of the '571 patent).

Petitioner's proposed construction also proposes that the structure corresponding to the claimed function includes a processor configured to execute the algorithm shown in Figures 2*a*–2*c* of the '571 patent. Pet. 22. We disagree with this portion of Petitioner's proposed construction. The '571 patent describes that the control program of Figures 2*a*–2*c* is designed to control the frequency and ventilation for a next breath of the patient by adjusting the I:E ratio based on the patient's respiratory mechanics data. Ex. 1001, 2:63–3:4, 3:29–34, 4:44–7:33. The function of adjusting the I:E ratio is not recited in claim 1 and the algorithm of Figures 2*a*–2*c* does not determine F_{IO2} or PEEP as recited in claim 1. Thus, the structure (i.e., the algorithm) of Figures 2*a*–2*c* does not correspond to the functions of the "first means" recited in claim 1.

Thus, the "first means" recited in claim 1 is the structure identified above, and equivalents thereof, for performing the claimed function.

2. Second means

The function associated with the "second means" in claim 1 includes "providing control signals, based on the output data provided by the first means, to the ventilator." Ex. 1001, 12:65–67. Claim 1 further recites that "the control signals provided to the ventilator automatically control PEEP, and F_{IO2}, for a next breath of a patient." *Id.* at 13:1–3.

The structure disclosed in the '571 patent corresponding to this claimed function is signal generator circuit 46 which receives outputs 44 from digital processor 10 and provides control signals 48 to ventilator 56. Ex. 1001, 4:26–34, 12:4–21, Figs. 1, 4. *See* Section I.D. above (discussing disclosure of the '571 patent).

Thus, the "second means" recited in claim 1 is the structure identified above, and equivalents thereof, for performing the claimed function.

D. Ground 1: Claims 1, 2, 5, 6, 11, 29, 31–33, and 41 as Anticipated by Carmichael

Petitioner contends that Carmichael anticipates independent claims 1 and 29, and claims 2, 5, 6, 11, 31–33, and 41, which depend from claim 1 or claim 29. In the subsections below, we discuss the scope and content of Carmichael and the asserted anticipation of independent claims 1 and 29.

1. Carmichael

Carmichael is a publication reporting the results from a questionnaire sent to 3,164 physician members of the American Thoracic Society Critical Care Assembly asking the members' opinions regarding factors important in diagnosis and treatment of adult respiratory distress syndrome (ARDS). Ex. 1004, 9 (first col.). The data from the 31% of responding physicians was collected and reported. *Id.* The survey included questions about modes of mechanical ventilation used for treatment and how physicians apply PEEP at various levels of arterial oxygenation. *Id.* at 10 (first col.), 17–18 (questionnaire questions). The survey results showed that the initial treatment of patients with ARDS was most commonly accomplished using volume-cycled ventilation in the assist/control mode. *Id.* at 9 (first & second cols.), 11 (first col.) (disclosing, with reference to Figure 2, that assist/control was the favored ventilator mode). The survey results also showed that "[o]n average, oxygen toxicity was thought to begin at an F[i]O_2 between 0.5 and 0.6," and that "modest levels of [PEEP] were used in incremental fashion as F[i]O_2 requirements increased." *Id.* at 1 (second col.), 11 (second col.) (referencing Figure 4 showing level of F_{IO2} at which oxygen toxicity begins), 12 (second col.) (referencing Figure 7 showing the maximum PEEP used at various levels of F_{IO2} before increasing to the next higher level of F_{IO2}). Carmichael also discloses that conventional teaching

in the 1970s was that "a PaO_2 > 60 mmHg was desirable and should be achieved through the use of increased FiO_2s and incremental application of PEEP." *Id.* at 13 (bottom of second col.) – 14 (top of first col.). Carmichael discloses that in the early 1990s it was recognized that peak inspiratory pressures could induce lung injury and this understanding engendered interest in limiting peak inspiratory pressure. *Id.* at 14 (first col.). Carmichael reports that "[t]o many, the 'best PEEP' is the least PEEP at which hemoglobin-oxygen saturation is considered adequate on nontoxic concentrations of inspired oxygen." *Id.* at 14 (second col.).

2. Analysis of Claim 1

Petitioner asserts that Carmichael discloses an apparatus for automatically controlling a ventilator that includes the claimed "first means" for processing data indicative of at least a measured oxygen level of a patient, and for providing data indicative of F_{IO2} and PEEP for a next breath of the patient. Pet. 29–34. Specifically, Petitioner asserts that Carmichael's disclosed assist control mode uses the measured arterial oxygen level to provide data indicative of F_{IO2} and PEEP for a patient's next breath. *Id.* at 31 (referencing Ex. 1004, 11–12, Fig. 7). Petitioner asserts that Carmichael teaches a desirable PaO_2 level achieved through the use of increased F_{IO2} and incremental applications of PEEP, teaching a level of PEEP that would not be exceeded before increasing to the next higher F_{IO2}. *Id.* (referencing Ex. 1004, 12, 13–14).

Patent Owner argues that Carmichael discloses survey results "based on intermittent, manual, trial and error adjustment of F_{IO2} and PEEP." Prelim. Resp. 28–29. Patent Owner argues that "in Carmichael, the F_{IO2} value is kept constant with PEEP being manually and incrementally increased to a maximum level before the next change in F_{IO2}" but in the '571

patent, "F_{IO2} is continuously determined based on the patient's measured oxygen level." *Id.* at 29. In other words, Patent Owner argues that in Carmichael's trial-and-error system, "[n]o difference between a measured and desired oxygen level of a patient is defined and reduced as required by the claims of the patent." *Id.*

We agree with Patent Owner that Carmichael appears, on this preliminary record, to lack adequate disclosure to anticipate the apparatus of claim 1. Specifically, because Carmichael focuses on the result of physician surveys, and not on the description of a ventilation system per se, Carmichael lacks details as to the specific manner in which the assist control mode was being used to control PEEP and F_{IO2} levels. Specifically, we cannot discern from the preliminary record that Carmichael's discussion of an assist control mode for mechanical ventilation necessarily entails adjustments to F_{IO2} and PEEP "for a next breath of the patient" as recited in claim 1. As explained by Patent Owner, it is possible that the parameters of PEEP and F_{IO2} could have been set manually by the physician and/or could have been updated only periodically during treatment. *See, e.g.,* Prelim. Resp. 25–26. Thus, on this preliminary record, Petitioner has not shown a reasonable likelihood of prevailing on the assertion that Carmichael anticipates claim 1, or claims 2, 5, 6, and 11 that depend from claim 1.

3. Analysis of Claim 29

Independent method claim 29 recites the step of determining required F_{IO2} and PEEP for a patient and providing data signals indicative of the required F_{IO2} and PEEP "for a next breath of the patient." Ex. 1001, 15:19–30. Petitioner relies on the same findings as to the disclosure of Carmichael as discussed above in the analysis of claim 1. Pet. 41–43. As discussed above, on this preliminary record, Petitioner has not shown a reasonable

likelihood of prevailing on the assertion that Carmichael anticipates claim 29, or claims 31–33 and 41 that depend from claim 29.

E. Ground 2: Claims 1, 2, 5, 6, 11, 29, 31–33, and 41 as Unpatentable over Carmichael, as evidenced by ARDSNET and Waisel

Petitioner contends that Carmichael, as evidenced by ARDSNET and Waisel, renders obvious the subject matter of independent claims 1 and 29, and claims 2, 5, 6, 11, 31–33, and 41, which depend from claim 1 or claim 29. In the subsections below, we discuss the scope and content of the prior art and any differences between the claimed subject matter and the prior art, on a limitation-by-limitation basis.

1. Carmichael

A general discussion of Carmichael's disclosure is provided above in Section III.D.1.

2. ARDSNET

ARDSNET is an article published in The New England Journal of Medicine reporting on the results of a trial to determine whether ventilation with lower tidal volumes would improve the clinical outcomes in patients with acute lung injury and ARDS. Ex. 1007, 1301 (Background). The article provides a table summarizing the ventilator procedures used during the trial. *Id.* at 1303 (Table 1). The table shows that the trial treated two groups of patients, a first group receiving traditional tidal volumes and a second group receiving lower tidal volumes. *Id.* Both groups were treated with a "volume assist-control" ventilator and using an oxygenation goal of PaO_2 of 55–80 mm Hg or SpO_2 of 88–95%. *Id.* The Table lists a range of "allowable combinations of [F_{IO2}] and PEEP" that includes F_{IO2} of 0.3 to 1.0 and PEEP of 5 to 24 cm of water. *Id.* ARDSNET describes that various data were recorded "in four hours before ventilator settings were changed on

day 0" and that data "were recorded between 6 and 10 a.m. on days 1, 2, 3, 4, 7, 14, 21, and 28." *Id.* at 1304.

3. Waisel

Waisel is an article published in association with the Proceedings of the Eighth World Congress on Medical Informatics reporting on "preliminary experience with a closed-loop, computer-controlled, expert algorithm [("PEFIOS")] that allows automated changes in [PEEP] and [F_{IO2}] based on arterial oxygen saturation." Ex. 1011, 1132 (Introduction) (describing that "[c]losed-loop control can be defined as a system in which neither data input nor action output requires human intervention."). Waisel describes that the PEFIOS algorithm is driven with input from a pulse oximeter that measures the oxygen saturation of hemoglobin (SaO_2) during pulsatile blood flow. *Id.* at 1132 (Materials and Methods). The PEFIOS algorithm has four tiers, each corresponding to a different SaO_2 range and the range's relationship to the goal saturation. *Id.* Waisel explains the four tiers as follows:

> A measured SaO_2 greater than the goal saturation decreases therapy, and a SaO_2 less than the goal increases therapy. Two levels of decreasing therapy (rapidly decreasing and slowly decreasing) and two levels of increasing therapy (slowly increasing and rapidly increasing) flank the goal saturation. The levels of rapid change are at a greater numerical distance from the goal saturation than the levels of slower change. Associated with each level is a table of FiO_2 and PEEP adjustments based on the current FiO_2, PEEP, and distance of the level from the goal saturation.

Id. Waisel illustrates the table used for Level 2: Therapy slowly decreasing, which is reproduced below.

FiO_2	PEEP	≥5 ≤8	>8 ≤12	>12 ≤15	>15 ≤20	>20 ≤25
=1	PEEP	2	1	1	1	1
	FiO_2	0	0	0	0	0
<1	PEEP	2	1	1	1	0
≥0.8	FiO_2	0	0	1	1	1
<0.8	PEEP	1	1	1	0	0
≥0.6	FiO_2	0	0	1	1	1
<0.6	PEEP	1	0	0	0	0
≥0.4	FiO_2	0	1	2	2	2
<0.4	PEEP	0	0	0	0	0
≥0.21	FiO_2	1	2	3	3	3

Figure 1. Level 2: Therapy Slowly Decreasing

Number from PEFIOS Table

FiO_2	Action
-4	decrease FiO_2 by 0.1 every 15 minutes
-2	decrease FiO_2 by 0.1 every 30 minutes
-1	decrease FiO_2 by 0.05 every 15 minutes
1	increase FiO_2 by 0.1 every 15 minutes
2	increase FiO_2 by 0.2 every 15 minutes
3	increase FiO_2 by 0.3 every 15 minutes

PEEP	Action
-3	decrease PEEP by 3 cmH_2O every 2 hours
-2	decrease PEEP by 2 cmH_2O every 2 hours
-1	decrease PEEP by 1 cmH_2O every 2 hours
1	increase PEEP by 2 cmH_2O every 30 minutes
2	increase PEEP by 4 cmH_2O every 30 minutes
3	increase PEEP by 6 cmH_2O every 30 minutes

Id. This table illustrates, for example, at Level 2, for a current $F_{IO2} \geq 0.6$ and < 0.8 and for a current PEEP > 12 and ≤ 15, the PEFIOS algorithm will signal the ventilator to increase the F_{IO2} by 0.1 every 15 minutes and increase the PEEP by 2 cmH_2O every 30 minutes. *Id.*

Waisel describes that the ventilator workstation is "a fully programmable, mechanical ventilator based on the Amadeus, a microprocessor controlled ventilator." *Id.* at 1134 (Equipment). Waisel describes that the ventilator workstation can operate in "automated mode, in which a host computer has control over the Amadeus." *Id.*

4. Analysis of Claim 1

Petitioner asserts that Carmichael discloses "volume controlled ventilation" by mechanical ventilators and monitoring devices to achieve "best PEEP" using "assist control mode," which is "the automatic control of a ventilator." Pet. 29–30 (referencing Ex. 1004, 9 (2:1–2), 10 (1:28–38), 13, Fig. 2; Ex. 1002 ¶¶ 119–123). Petitioner argues that "[t]o the extent Carmichael's ARDS 'assist control mode' is challenged as not specifically illustrating structural components for providing disclosed FIO2 and PEEP control signals, contemporaneous documents confirm that Carmichael's

disclosed therapy of a mechanical ventilator 'assist control mode' is a recognized processor-based ventilator control mode." Pet. 35 (referencing ARDSNET (Ex. 1007) and Waisel (Ex. 1011)).

As to ARDSNET, Petitioner argues that "ARDSNET Table 1 and related text demonstrate Carmichael's prescribed control range of PEEP/FIO2." Pet. 35.

Patent Owner argues that "ARDSNET does not describe a ventilator or any automatic control system for any ventilation parameter" because ARDSNET describes "manual, trial and error adjustments of PEEP and F_{IO2} of ARDS patients every 'four hours.'" Prelim. Resp. 33.

We agree with Patent Owner that on this preliminary record, Petitioner has failed to show that ARDSNET describes automatic control of PEEP and F_{IO2} for a next breath of the patient. Table 1 of ARDSNET discusses "allowable combinations of FiO_2 and PEEP" which, similar to Carmichael, discloses that these parameters are interrelated, and it also provides an "Oxygenation goal" of PaO_2, but it does not provide adequate detail of how the "Volume assist-control" ventilator mode worked during these studies and if the PEEP and F_{IO2} parameters were adjusted manually or managed through a feedback loop. Ex. 1007, 1303. Thus, Petitioner has not shown, on this preliminary record, that ARDSNET cures the deficiencies in Carmichael discussed above.

With regard to Waisel, Petitioner argues that Waisel's PEFIOS controller demonstrates that "a ventilator 'assist control mode' at the time of Carmichael included first/second means for processor-based control of FIO2 and PEEP with closed-loop control of oxygen." Pet. 37. Specifically, Petitioner argues that in Waisel, when measured oxygen saturation is greater than a desired goal saturation, the assist control mode decreases therapy, and

when measured oxygen saturation is less than a desired goal saturation, the assist control mode increases therapy. *Id.* (referencing Ex. 1011, § 2).

Patent Owner argues that Waisel describes a PEFIOS system that uses a look up table to find combinations of PEEP and F_{IO2} for making adjustments to these parameters in intervals of 15 minutes to 2 hours. Prelim. Resp. 37–38. Patent Owner argues that because these adjustments are done intermittently and not continuously, Waisel does not adjust PEEP and F_{IO2} "for a next breath" of the patient as claimed. *Id.*

As described above in detail in Section III.E.3, Waisel describes "a closed-loop, computer-controlled, expert algorithm that allows automated changes in [PEEP] and [F_{IO2}] based on arterial oxygen saturation (PEFIOS)." Ex. 1011, 1132 ("Introduction"). The system compares a measured oxygen saturation level to a goal saturation and tailors its response based on how far off the measured level is from the goal. *Id.* (Materials and Methods). The PEFIOS algorithm has four tiers, each corresponding to a different SaO_2 range and the range's relationship to the goal saturation. *Id.* Adjustments to PEEP and F_{IO2} are made intermittently based on current F_{IO2}, PEEP, and difference between measured level of oxygen saturation and goal using look-up table of adjustments. *Id.* (Figure 1). Petitioner has not shown a reasonable likelihood of prevailing on this preliminary record to show that Waisel's disclosure of an intermittent adjustment of F_{IO2} and PEEP provides the required F_{IO2} and PEEP "for a next breath of the patient," as recited in claim 1. Thus, on this preliminary record, Petitioner has not shown a reasonable likelihood of prevailing on the assertion that Carmichael, as evidenced by ARDSNET and Waisel, renders obvious the subject matter of claim 1, or claims 2, 5, 6, and 11 that depend from claim 1.

5. Analysis of Claim 29

Independent method claim 29 recites the step of determining required F_{IO2} and PEEP for a patient and providing data signals indicative of the required F_{IO2} and PEEP "for a next breath of the patient." Ex. 1001, 15:19–30. Petitioner relies on the same findings as to the disclosures of Carmichael, ARDSNET, and Waisel as discussed above in the analysis of claim 1. Pet. 41–43. As discussed above, on this preliminary record, Petitioner has not shown a reasonable likelihood of prevailing on the assertion that Carmichael, as evidenced by ARDSNET and Waisel, renders obvious the subject matter of claim 29, or claims 31–33 and 41 that depend from claim 29.

F. Ground 3: Claims 1–6, 9–12, 29–33, and 41 as Unpatentable over Carmichael, Anderson, Tehrani '268, and Rossi

Petitioner contends that the combination of Carmichael and Anderson renders obvious the subject matter of independent claims 1 and 29 and claims 2, 30, and 41, which depend from claim 1 or claim 29. Petitioner contends that the combination of Carmichael, Anderson, and Tehrani '268 renders obvious the subject matter of dependent claims 4–6, 11, 12, and 31–33, and that the combination of Carmichael, Anderson, and Rossi renders obvious the subject matter of dependent claims 9 and 10. In the subsections below, we discuss the scope and content of the prior art and any differences between the claimed subject matter and the prior art.

1. Carmichael

A general discussion of Carmichael's disclosure is provided above in Section III.D.1.

2. Anderson

Anderson is a technical paper of The Instrumentation, Systems, and Automation Society (ISA), presented at the Proceedings of the 39th Annual Rocky Mountain Bioengineering Symposium and 39th Annual International ISA Biomedical Sciences Instrumentation Symposium. Ex. 1013. Anderson is a report describing a "closed-loop control system based on well-established protocols to systematically maintain appropriate levels of [PEEP] and [FiO_2] in patients with [ARDS]." *Id.* at 289.

Anderson describes that the system consists of an in-dwelling arterial oxygenation (PaO_2) sensor coupled to a computer that continuously controls FiO_2 and PEEP settings on a Hamilton Amadeus ventilator. Ex. 1013, 289; *see also id.* at 290, Fig. 1. Anderson acknowledges that "when high concentrations of inspired oxygen or high airway pressures become necessary in a very ill patient, the ventilator itself may further damage the patient's lungs." *Id.* at 290. Anderson states that "[t]he implemented protocols provide continuous closed-loop control of oxygenation and a balance between patient need and minimal therapy." *Id.* at 289. Specifically, "[t]he controller is based on a traditional proportional-integral-derivative (PID) approach. . . to control, or maintain, the patient's PaO2 level at a target value." *Id.* The controller also uses "non-linear and adaptive characteristics that allow the system to respond more aggressively to 'threatening' levels of PaO2." *Id.*

Anderson illustrates the basic elements of the closed-loop controller, reproduced below:

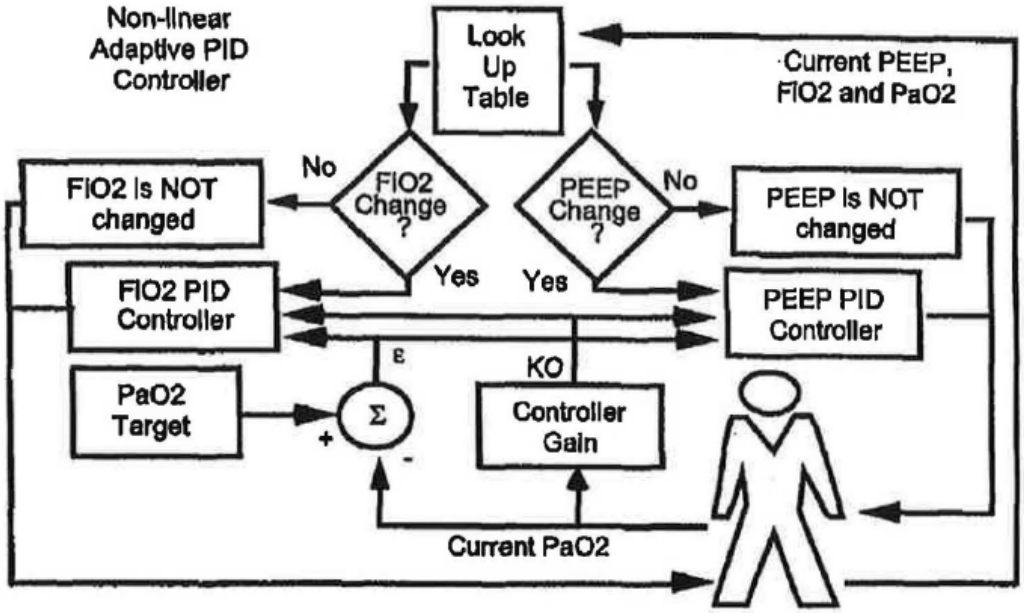

Figure 2. Components of the non-linear adaptive PID controller.

Ex. 1013, 291. Figure 2 of Anderson depicts "the look up tables or the decision mechanism, the FiO2 and PEEP PID controllers that calculate the amount of therapy adjustment, and the adaptive overall gain term." *Id.*

Anderson describes that the look up tables "contain the logic used to dictate changes in therapy based on the patient's current level of PaO2 and the current PEEP and FiO2 settings." Ex. 1013, 291. Anderson shows five logic tables corresponding to different levels of patient blood oxygenation (i.e., supersatisfactory, satisfactory, acceptable, marginal, and threatening) having physician-defined thresholds for each level. *Id.* at 291 (Fig. 3). Anderson also discloses equations that "describe the discrete recursive form of the PID controller used to calculate the appropriate change in oxygenation therapy." *Id.* at 291 (equation #1 and equation #2). This PID controller uses gain to provide "more aggressive response to hypoxemia and a more conservative response to PaO2 above the desired goal." *Id.* at 292, Fig. 2 (showing graph of adaptive gain).

3. Tehrani '268

Tehrani '268 is a U.S. patent titled "Method and Apparatus for Controlling an Artificial Respirator." Ex. 1006, code [54]. The patent relates to a method and apparatus for controlling a respirator based on the measured levels of carbon dioxide and oxygen of a patient on the respirator, as well as other physical conditions of the patient. *Id.* at 1:14–18. The patent describes a programmable microcomputer that uses the measured levels of carbon dioxide and oxygen of the patient to provide digital output data representing the amount and optimum frequency of ventilation required for the next breath. *Id.* at 2:2–7. Figure 1 of Tehrani '268 is reproduced below.

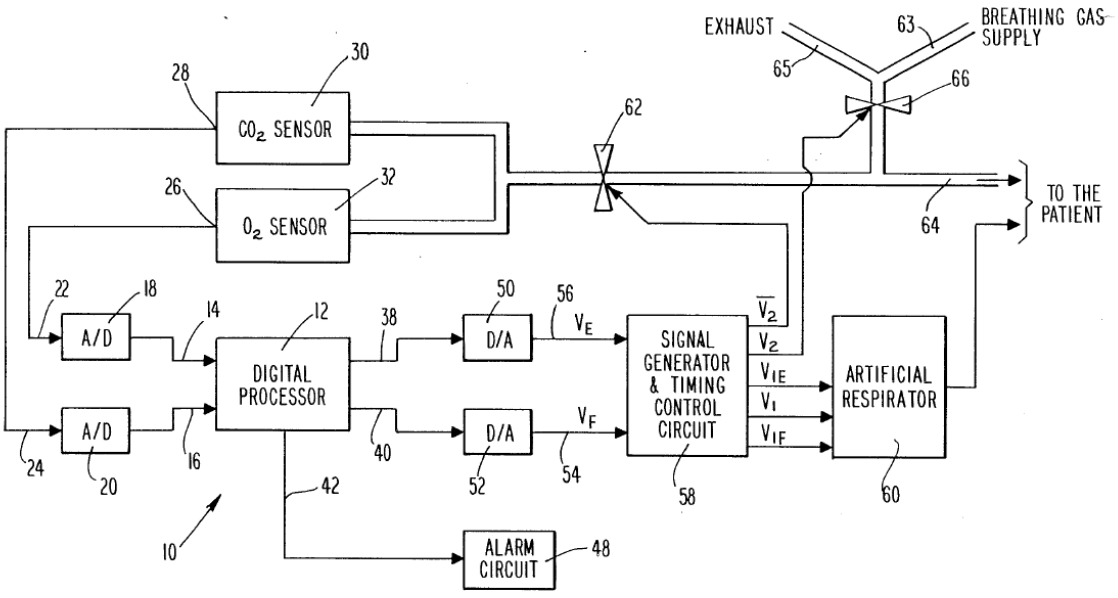

Fig. 1

Figure 1 is a block diagram of an artificial respirator and control apparatus. Ex. 1006, 2:35–37. The apparatus disclosed in Tehrani '268 includes A/D converters 18, 20 "coupled to the outputs 26 and 28 of an oxygen sensor 32 and a carbon dioxide sensor 30, respectively." *Id.* at 2:64–

67. Tehrani '268 also discloses D/A converters 50 and 52 for control signals generated by the ventilator computer to be sent to analog components. *Id.* at 2:23–24. Tehrani '268 teaches that ventilators use measured values "supplied via the A/D converters" so that "they can also be monitored continuously." *Id.* at 3:8–11.

Tehrani '268 also describes that the apparatus calculates the pressures of oxygen and carbon dioxide in the patient's arterial blood, and compares these values to upper and lower alarm limits to generate an alarm if either pressure is outside of the specified range. Ex. 1006, 8:5–34.

4. Rossi

Rossi is a review article published in Intensive Care Medicine. Ex. 1015. Rossi describes that alveolar pressure can remain positive throughout expiration without PEEP set by the ventilator whenever the time available to breathe out is shorter than the time required to decompress the lungs to the elastic equilibrium volume of the total respiratory system. *Id.* at 522 (first col.). Rossi describes that this phenomenon has been termed "intrinsic PEEP owing to its similarity and contrast with PEEP set by the ventilator." *Id.* (first and second columns). Rossi describes that in assisted modes of mechanical ventilation, intrinsic PEEP (or $PEEP_i$) should be measured routinely. *Id.* at 530 (first col.).

5. Analysis of Claim 1

Petitioner relies on Carmichael to disclose automated ventilators operating in assist control mode to provide prescribed ARDS treatment protocols. Pet. 46. Petitioner acknowledges that Carmichael does not disclose the ventilator architectures in detail. *Id.* Petitioner relies on Anderson to show a closed-loop control system using an oxygenation sensor and a computer to continuously control F_{IO2} and PEEP settings on a

Hamilton Amadeus ventilator based on a traditional PID approach to control, or maintain, the patient's oxygen level at a target value. *Id.* at 46–47 (citing Ex. 1013, 289 (Abstract), 290, Fig. 1; Ex. 1002 ¶¶ 264–275). Petitioner asserts that a person of ordinary skill in the art would have been expected to implement Carmichael's disclosed PEEP/F_{IO2} treatment protocol on an automated ventilator, as disclosed by Anderson, to "systematically maintain appropriate levels of [PEEP] and [F_{IO2}]." *Id.* at 47 (quoting Ex. 1013, 289). Petitioner asserts that operation of Anderson's ventilator according to Carmichael's treatment protocol of "determining PEEP, after determining [F_{IO2}], to keep a calculated ratio of PEEP/[F_{IO2}] within a prescribed range would have been predictable and routine ventilator operation." *Id.* at 47–48 (referencing Ex. 1002 ¶¶ 273–275). On review of the preliminary record and for the reasons discussed below, Petitioner has demonstrated a reasonable likelihood of prevailing on this ground. Pet. 46 (referencing assertions as to the scope and content of Carmichael as set forth in anticipatory Ground 1).

Petitioner has shown a reasonable likelihood that Carmichael discloses it was known in the art at the time of the invention to use volume-cycled ventilation in the assist/control mode to implement treatment protocols for treatment of ARDS patients through automatic control of a ventilator. Pet. 29–30; Ex. 1004, 9 (first & second cols.), 11 (first col.); Ex. 1002 ¶¶ 119–123. Petitioner has shown a reasonable likelihood that Carmichael discloses a treatment protocol of increased F_{IO2} and incremental application of PEEP at the F_{IO2} level to achieve a desired oxygen saturation level. Pet. 30–31; Ex. 1004, 11 (second col.) (referencing Figure 4 showing level of F_{IO2} at which oxygen toxicity begins), 12 (second col.) (referencing Figure 7 showing the maximum PEEP used at various levels of F_{IO2} before

increasing to the next higher level of F_{IO2}), 13 (bottom of second col.) – 14 (top of first col.) (conventional teaching was that "a PaO2 > 60 mmHg was desirable and should be achieved through the use of increased FiO2s and incremental application of PEEP"); Ex. 1002 ¶¶ 124–127. Petitioner has shown that Carmichael discloses "[t]o many, the 'best PEEP' is the least PEEP at which hemoglobin-oxygen saturation is considered adequate on nontoxic concentrations of inspired oxygen." *Id.* at 14 (second col.). Thus, Petitioner has shown a reasonable likelihood that Carmichael discloses a relationship between F_{IO2} and PEEP used to achieve a desired oxygen saturation. Petitioner also has shown a reasonable likelihood that Carmichael's treatment protocol determines F_{IO2} to reduce the difference between the measured oxygen level of the patient and a desired value. Pet. 32; Ex. 1004, 13–14 (describing selection of F_{IO2} to achieve a desired oxygen saturation (PaO_2 > 60 mmHG)); Ex. 1002 ¶ 136.

Petitioner has also shown that Anderson discloses a closed-loop automated ventilator and control system for continuous control of PEEP and F_{IO2} based on oxygen saturation. Pet. 46–47. Petitioner has shown a reasonable likelihood that the treatment protocol disclosed in Carmichael, as implemented on the closed-loop continuous control system of Anderson, would include the claimed first means (or equivalents thereof) for determining PEEP and F_{IO2} in the manner claimed and the claimed second means (or equivalents thereof) for providing signals to control the ventilator by automatically controlling PEEP and F_{IO2} for a next breath of the patient. Pet. 46–48.

As to Carmichael, Patent Owner argues that the main outputs of the ventilator are set manually by an operator by trial and error and are not automatically controlled. Prelim. Resp. 23–25. We need not decide this

matter for purposes of institution because we find Petitioner's reasoning adequate, on this preliminary record, for implementing Carmichael's treatment protocol using the automated system of Anderson, which combined teaching would have resulted in the claimed apparatus for automatically controlling a ventilator.

Patent Owner argues that "[w]hen utilizing manual trial and error adjustment, F_{IO2} is not determined to reduce the difference between the measured oxygen level of a patient and a desired value." Prelim. Resp. 26 ("There is no mechanism in place to reduce such difference systematically"). As discussed above, Petitioner has shown that Carmichael discloses adjusting F_{IO2} to reach a desired oxygen level. We find sufficient evidence and reasoning, for purposes of institution, that one having ordinary skill in the art, implementing such a protocol to adjust F_{IO2} to reach a desired oxygen level, as taught in Carmichael, in the automated system of Anderson, would have been led adjust F_{IO2} to minimize the difference between the measured and desired oxygen levels.

Patent Owner also argues that Carmichael fails to disclose that PEEP is determined to keep a ratio of PEEP/F_{IO2} within a prescribed range. Prelim. Resp. 26. As discussed above, Petitioner has shown that Carmichael disclosed it was known in the art to select PEEP based on the level of F_{IO2} and to avoid exceeding a maximum PEEP for a certain F_{IO2} by moving to next higher level of F_{IO2} when the PEEP reached the maximum level. Ex. 1004, 12, Fig. 7. Figure 7 of Carmichael shows that the maximum level of acceptable PEEP increased as the F_{IO2} level increased. *Id.* Petitioner describes adequately, for purposes of institution, how this disclosed protocol selects PEEP to maintain a ratio of PEEP/F_{IO2} within a certain range. Pet. 32–33.

As to Anderson, Patent Owner also argues that Anderson's disclosure of a look up table to control PEEP and F_{IO2} suggests discrete pairs for intermittent adjustments of the two variables, while Anderson's "PID controllers are designed to control the output continuously and based on error signals." Prelim. Resp. 42. Patent Owner argues that these two are contradictory means of adjusting PEEP and F_{IO2}. *Id.* Patent Owner does not cite to any evidence in its Preliminary Response to support this argument that Anderson is internally inconsistent. Further, Anderson discloses that the look up tables shown in Figure 3 contain the logic used to dictate if changes in therapy are needed "based on the patient's current level of PaO2 and the current PEEP and FiO2 settings." Ex. 1013, 291. Thus, these logic tables are used to determine whether a change in PEEP and/or a change in F_{IO2} is necessary. *Id.*, Fig. 3 (showing indicators of "B" when both PEEP and F_{IO2} are to be changed, an "F" if only F_{IO2} is to be changed, a "P" if only PEEP is to be changed, and "N" if neither is to be changed). Anderson does not disclose using these look up tables to determine the amount of the change to either or both of these parameters. Rather, Anderson uses equations to calculate the appropriate changes. *Id.* at 291 (eq. #1, eq. #2), Fig. 2 (describing using the F_{IO2} and PEEP PID controllers to determine the amount of change needed).

Patent Owner further argues that the equations disclosed in Anderson for PID control "are erroneous" and "the paper has no description of the coefficients used in the separate PID controllers." Prelim. Resp. 43. Again, Patent Owner does not cite to any evidence in its Preliminary Response to

support these assertions, nor does Patent Owner provide in its Preliminary Response any explanation for the basis of these assertions.[13]

Patent Owner seeks to have us infer that Anderson's system did not use any PID control, despite Anderson's explicit disclosure of PID controllers, because the clinical results reported in Anderson are identical to results in Anderson's 1994 paper (Ex. 2008) published eight years earlier. Prelim. Resp. 43. Patent Owner asserts that this earlier system "is 'protocol' based (meaning it used a look-up table)." *Id.* Patent Owner argues that because Anderson's results are the same, it appears that the authors used only a look-up table. *Id.*; Ex. 2002 ¶¶ 105-121. We decline to ignore Anderson's explicit teaching of use of PID controllers to determine the amount of change needed for continuous adjustment of PEEP and F_{IO2}. We also decline to infer from this preliminary record, that the mention in the 1994 Anderson paper to the use of "protocols" to design its closed-loop system necessarily means that Anderson's earlier system was based solely on look up tables. Ex. 2008 ("A system was designed based on these protocols which provides continuous closed-loop control of oxygenation"). This 1994 article is silent as to the particular logic used in its software to provide the control of PEEP and F_{IO2}. *Id.*

Finally, Patent Owner argues that Anderson's use of a PID controller would result in constant changing to PEEP that would be hazardous to a patient, which is why no commercial ventilator has used a PID controller to control PEEP. Prelim. Resp. 44. Again, Patent Owner does not cite to any evidence in its Preliminary Response to support this assertion. On this

[13] Although not cited in the Preliminary Response, Patent Owner provides similar assertions in her declaration without any further explanation or reasoning to explain the basis for these assertions. Ex. 2002 ¶ 108.

preliminary record, we credit Anderson's disclosure that its clinical results showed that the system disclosed in Anderson was safe for control of PEEP and F_{IO2} in the patients on which is was tested. Ex. 1013, 293.

As to the combination, Patent Owner argues that "Anderson's alleged system would be rendered inoperable if combined with Carmichael's manual setting of parameters." Prelim. Resp. 75–76. This argument misstates Petitioner's proposed combination. Petitioner does not propose to modify Anderson's automated ventilator control system to use manual controls. Rather, Petitioner proposes that it would have been obvious to employ Anderson's automated system to implement Carmichael's treatment protocol for adjustment of PEEP and F_{IO2} in ARDS patients. Pet. 47–48.

Patent Owner also asserts that the Petitioner never specifically addresses how Anderson determines F_{IO2} and PEEP "for a next breath of the patient." Prelim. Resp. 76–77. Petitioner describes, with reference to Figure 1 of Anderson, that Anderson's "computer constantly reads important information from both the PaO2 monitor and Ventilator via RS232 serial ports" and uses this information "to calculate new values of PEEP and FiO2 that are subsequently transmitted to the ventilator for proper adjustments in patient therapy." Pet. 47 (citing Ex. 1002 ¶¶ 271–272; Ex. 1013, 290). Petitioner's declarant explains in the cited paragraphs that the closed-loop adaptive controller of Anderson's Figure 2 "continuously controls FiO2 and PEEP." Ex. 1002 ¶ 272 (citing Ex. 1013, 291). We understand Petitioner, in its contentions that the computer "constantly reads" information from the patient and "continuously controls FiO2 and PEEP" to address the requirement that the system determines F_{IO2} and PEEP "for a next breath of the patient."

For these reasons, Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion of unpatentability of claim 1 based on the combined teachings of Carmichael and Anderson.

6. Analysis of Claim 29

Petitioner relies on the same findings and combination of Carmichael and Anderson to challenge method claim 29 as presented for its challenge to claim 1. Pet. 57–58. Patent Owner does not present separate arguments for claim 29. *See* Prelim. Resp. 30–33, 45–46, 74–77 (presenting the same arguments for claims 1 and 29). Thus, for the same reasons discussed above in our analysis of claim 1, Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion of unpatentability of claim 29 based on the combined teachings of Carmichael and Anderson.

7. Analysis of Claims 2–6, 9–12, 30–33, and 41

Claims 2–6, 9–12, 30–33, and 41 all depend directly or indirectly from claim 1 or claim 29. We have reviewed Petitioner's cited evidence and explanation regarding why the combination of Carmichael and Anderson, either by itself, or further combined with Tehrani '268 and Rossi, renders obvious the subject matter of these dependent claims and find the evidence and reasoning sufficient at this stage. Although Patent Owner discusses Tehrani '268 in its Preliminary Response, Patent Owner does not address or contest Petitioner's reliance on Tehrani '268 for its disclosure of an A/D converter or a D/A converter (claim 5, 10, 31). Prelim. Resp. 57–59 (arguing only that Tehrani '268 does not disclose certain subject matter of claims 1 and 29 and does not disclose the features of unchallenged claim 14). Patent Owner argues that Petitioner's reliance on Tehrani '268 for teaching an alarm unit (claims 3, 4, 11, 12) is misplaced. Prelim. Resp. 69–70. We disagree. Petitioner has shown adequately for purposes of

institution that the combined teachings of Carmichael, Anderson, and Tehrani '268 would have rendered the subject matter of these claims obvious. Pet. 48–50; Ex. 1002 ¶¶ 277–295 (demonstrating that it was well known in the art of automated control for a ventilator computer to detect an artifact and generate an alarm output).

Further, although Patent Owner discusses Rossi in its Preliminary Response, Patent Owner does not contest Petitioner's reliance on Rossi for its disclosure of measurement of $PEEP_i$ (claims 9, 10, 30). Prelim. Resp. 56–57 (arguing that Rossi individually does not describe any system to control a ventilator or to control PEEP, and not presenting arguments against Rossi in combination with the teachings of Carmichael and Anderson).

At this stage, Patent Owner raises no other arguments regarding these claims other than those considered above with respect to claim 1. On this record, we determine that Petitioner has shown a reasonable likelihood of success that Carmichael, Anderson, Tehrani '268, and Rossi renders obvious claims 2–6, 9–12, 30–33, and 41.

G. Ground 4: Claims 1–6, 9–12, 29–33, and 41 as Unpatentable over Taube, Carmichael, as evidenced by ARDSNET, Clemmer, and Rossi

Petitioner contends that the combination of Taube, Carmichael, as evidenced by ARDSNET, Clemmer, and Rossi renders obvious independent claims 1 and 29, and claims 2–6, 9–12, 30–33, and 41, which depend from claim 1 or claim 29. In the subsections below, we discuss the scope and content of the prior art and any differences between the claimed subject matter and the prior art, on a limitation-by-limitation basis.

1. Taube

Taube is a U.S. patent titled, "Adaptive Controller for Automatic Ventilators." Ex. 1005. Taube describes automatic controls for positive pressure ventilation systems. *Id.* at 1:6–8. Specifically, Taube's system is intended to make more automatic the control of inspiratory ventilation time (Tinsp), PEEP, and F_{IO2}. *Id.* at 1:25–30. Taube discloses using a pulse oximeter to determine hemoglobin saturation and of the patient's blood to calculate the partial pressure of arterial oxygen (PaO_2), which is used to regulate Tinsp, PEEP, and F_{IO2}. *Id.* at 1:31–37. Taube describes, "[t]he control mechanism is derived from the known relationship between the preset level of Tinsp, PEEP, minimum required FiO_2 delivered to the patient, and predetermined lung function dynamics in order to maintain a desirable PaO_2." *Id.* at 1:37–41.

Taube describes prior art devices for controlling the oxygen content of blood by controlling breathing parameters, and using an optical oximeter and a temporary oxygen deficient mixture to prevent super saturation. *Id.* at 1:62–2:66. Taube describes using sensed hemoglobin saturation to concurrently and adaptively control F_{IO2}, Tinsp, and PEEP from a ventilator to address "the patient's changing need for increasing and decreasing of blood oxygenation." *Id.* at 2:67–3:7. Taube's system automatically provides "the highest oxygen saturation in the blood" while maintaining the highest possible Tinsp, the lowest possible PEEP, and the lowest possible F_{IO2} delivered to the patient. *Id.* at 3:15–29.

Figure 1 of Taube is shown below.

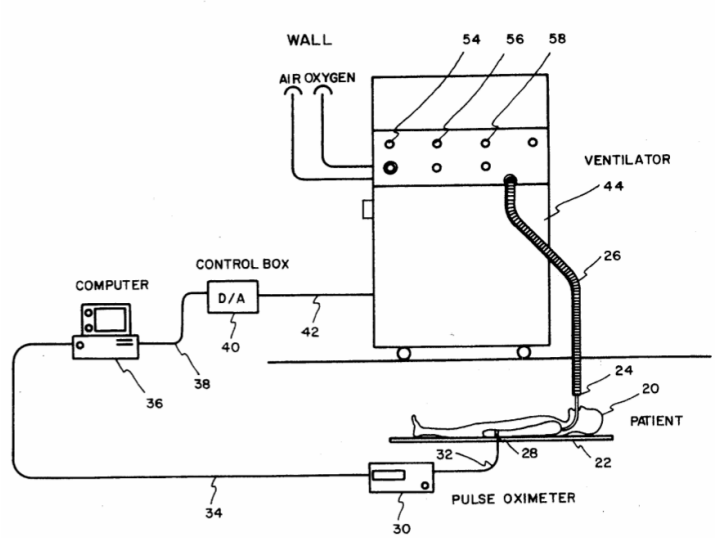

FIG. 1

Figure 1 of Taube is a diagrammatic view of the automatic ventilator control system. Ex. 1005, 3:64–65. Figure 1 shows optical sensor 28 placed on the finger of patient 20. *Id.* at 4:17. Pulse oximeter 30 is connected to sensor 28 and computer 36. *Id.* at 4:18–24. The outputs from computer 36 pass through D/A converter 40 to ventilator 44. *Id.* at 4:24–26.

Taube discloses the control program with reference to Figure 3, which is reproduced below.

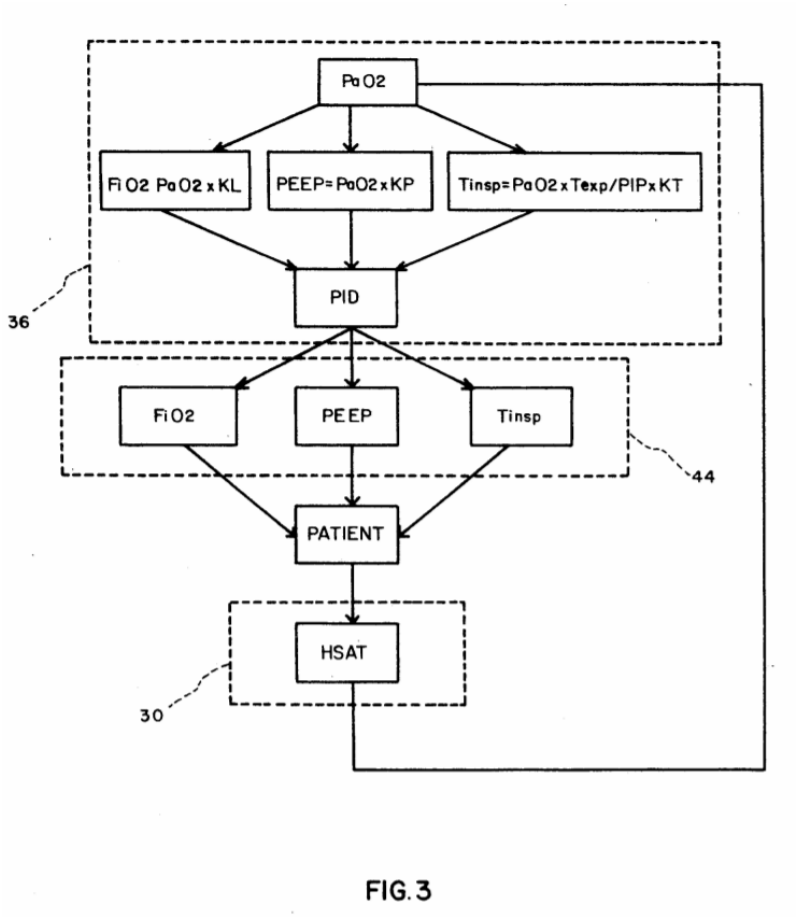

FIG. 3

Figure 3 is a flow diagram showing the operation of Taube's system. Ex. 1005, 3:67–68. Taube describes that computer 36 receives a hemoglobin saturation signal from pulse oximeter 30 and calculates a partial pressure of arterial oxygen (PaO_2) value for patient 20. *Id.* at 5:16–18. According to Taube, "The computer then determines modification values of Tinsp, PEEP, and FiO_2 from the calculated PaO_2." *Id.* at 5:19–21. After the modification values are determined, the "computer then determines the proportional, differential, and integral gain coefficients to develop control signals to the ventilator" and "sends control signals to the ventilator for the modification of Tinsp, PEEP, and FiO_2 values." *Id.* at 5:22–27. Taube then describes that "[t]he patient then breath[e]s in through a breathing tube the positive air pressure at the modified Tinsp, PEEP, and FiO_2 values." *Id.* at

5:28–30. Taube explains that "[t]he values of Tinsp, PEEP, and FiO_2 are chosen by the computer to maintain a desired level of the patient's blood oxygen level." *Id.* at 5:30–33.

2. Carmichael

A general discussion of Carmichael's disclosure is provided above in Section III.D.1.

3. ARDSNET

A general discussion of ARDSNET's disclosure is provided above in Section III.E.2.

4. Clemmer

Clemmer is a U.S. patent titled, "Method and System for Patient Monitoring and Respiratory Assistance Control Through Mechanical Ventilation by the Use of Deterministic Protocols." Ex. 1008, code [54]. Clemmer describes its objective as generating executable instructions for patient care which takes into account a large number of parameters of patient conditions and ventilation. *Id.* at code [57] (Abstract). "Patient data are processed according to a set of protocols which contain rules for patient care decisions arranged in a logical sequence to generate detailed, executable instructions for patient care." *Id.* The data can be acquired and the patient care instructions can be carried out automatically, and instructions are updated when new data is acquired. *Id.* Specifically, Clemmer describes monitoring and controlling a patient's oxygenation while being treated through mechanical ventilation by controlling the patient's oxygen partial pressure by adjusting PEEP and FiO_2. *Id.* at 5:65–6:1. Clemmer describes various protocols for generating patient care instructions. *Id.* at Figs. 2–18B.

5. Rossi

A general discussion of Rossi's disclosure is provided above in Section III.F.4.

6. Analysis of Claim 1

Petitioner relies on Taube to disclose automated control of a ventilator to adjust PEEP and F_{IO2}. Pet. 61. Petitioner maps Taube's ventilation system to the first means and second means of claim 1. *Id.* at 61–63 (citing Ex. 1005, 1:25–30, 1:37–41, 4:30–50, 5:8–6:15, Fig. 1; Ex. 1002 ¶¶ 409–412). Petitioner acknowledges that Taube does not explicitly discuss a desired value for a hemoglobin saturation setpoint. *Id.* at 64.

Petitioner asserts that Carmichael discloses a desired setpoint of "oxygen saturations of 86% to 90%" and discloses monitoring a patient's measured oxygen saturation level and increasing F_{IO2} and incremental application of PEEP to bring the patient's oxygen saturation closer to the setpoint. Pet. 64 (citing Ex. 1004, 13–14; Ex. 1002 ¶¶ 413–418). Petitioner asserts that a person of ordinary skill in the art would have been motivated to modify Taube's ventilator system control to keep the PEEP/F_{IO2} ratio within a prescribed range, as disclosed by Carmichael, "to ensure that mechanical ventilation would improve important clinical outcomes in patients by keeping the patient's hemoglobin saturation closer to the desired 'oxygen saturations of 86% to 90%' while avoiding an application of PEEP that could be higher than a permissible maximum value." *Id.* at 64–65 (citing Ex. 1004, 12–14; Ex. 1002 ¶¶ 419–430).

Petitioner relies on Clemmer as "evidence of the skill level in the art for programming an automated ventilator with any of a variety of treatment protocols" and to show that modifying Taube's system to use Carmichael's treatment protocols would have involved "known programming techniques

and constituted a predictable, expected result." Pet. 66. On review of the preliminary record, Petitioner has demonstrated a reasonable likelihood of prevailing on this ground.

Pointing to Figure 3 of Taube, Patent Owner argues that Taube differs from claim 1 because in Taube, if PaO_2 increases (i.e., an improvement in oxygenation), then the levels of F_{IO2}, PEEP, and Tinsp are increased. Prelim. Resp. 49; *see also id.* at 70–71. Patent Owner argues that Taube's control algorithm is against clinical practice, in which levels of PEEP and F_{IO2} are increased if the oxygen level decreases. *Id.* Patent Owner's characterization of Taube's Figure 3 appears overly simplistic. When Figure 3 is considered in combination with the accompanying description, Taube teaches that the computer chooses the values of the parameters (F_{IO2}, PEEP, Tinsp) "to maintain a desired level of the patient's blood oxygen level." Taube, 5:30–33. Taube also recognizes, discussing the prior art, the problem of oversaturation. Thus, we do not understand Taube to disclose in Figure 3 a system that continues to increase PEEP and F_{IO2} levels as the patient's oxygen levels increase.

Patent Owner acknowledges that Taube's Figure 3 shows adjustment of PEEP, F_{IO2} and Tinsp by PID control, but argues that "Taube does not provide any specifications of such control." Prelim. Resp. 49. Patent Owner also argues that in Taube, F_{IO2} is not determined to reduce the difference between measured oxygen level and desired level and PEEP is not controlled to keep ratio of PEEP/F_{IO2} within a prescribed range. *Id.* at 50. Petitioner relies on Carmichael[14], however, for the specifications of the PEEP and F_{IO2}

[14] We addressed above, in our analysis of the other grounds, the scope and content of Carmichael.

control, and relies on Clemmer to show that it would have been a matter of routine programming to implement Carmichael's control of PEEP and F_{IO2} in Taube's automated ventilator control system.

As to Clemmer, Patent Owner argues that Clemmer's "protocols" provide for manual adjustment of treatment parameters by physicians, and the adjustments are made several hours apart. Prelim. Resp. 53 (citing Ex. 1008, 26:39–42). Patent Owner also argues that Clemmer does not use a PID control system or closed-loop feedback control. *Id.*

We disagree with Patent Owners assertion that Clemmer's protocols require manual adjustment. For instance, Clemmer discusses, with reference to Figure 4, an alternative with continuous monitoring and adjustment. Ex. 1008, 18:53–63. Further, whether Clemmer discloses PID control or closed-loop feedback control is not relevant to the asserted ground, which relies on Taube for disclosing these features. Pet. 61–63.

As to the combination, Patent Owner argues that "combining any of Carmichael, ARDSNET or Clemmer's manual adjustments of parameters would render Taube's system inoperable." Prelim. Resp. 76; *see also id.* at 71–72. This argument misstates Petitioner's proposed combination. Petitioner does not propose to modify Taube's automated ventilator control system to use manual adjustments. Rather, Petitioner proposes that it would have been obvious to employ Taube's automated system to implement Carmichael's treatment protocol for adjustment of PEEP and F_{IO2} in ARDS patients, using routine programming, as evidenced by Clemmer. Pet. 65–66.

For these reasons, Petitioner has demonstrated, on this preliminary record, a reasonable likelihood of prevailing on its assertion of unpatentability of claim 1 based on the combined teachings of Taube, Carmichael, and Clemmer.

7. Analysis of Claim 29

Petitioner relies on the same findings and combination of Taube, Carmichael, and Clemmer to challenge method claim 29 as presented for its challenge to claim 1. Pet. 70–72. Patent Owner does not present separate arguments for claim 29. *See* Prelim. Resp. 30–33, 51–54 (presenting the same arguments for claims 1 and 29). Thus, for the same reasons discussed above in our analysis of claim 1, Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion of unpatentability of claim 29 based on the combined teachings of Taube, Carmichael, and Clemmer.

8. Analysis of Claims 2–6, 9–12, 30–33 and 41

Claims 2–6, 9–12, 30–33, and 41 all depend directly or indirectly from claim 1 or claim 29. We have reviewed Petitioner's cited evidence and explanation regarding why the combination of Taube, Carmichael, Clemmer, and Rossi, renders obvious the subject matter of these dependent claims and find the evidence and reasoning sufficient at this stage. Although Patent Owner discusses Rossi in its Preliminary Response, Patent Owner does not contest Petitioner's reliance on Rossi for its disclosure of measurement of $PEEP_i$ (claims 9, 10, 30). Prelim. Resp. 56–57 (arguing that Rossi individually does not describe any system to control a ventilator or to control PEEP, and not presenting arguments against Rossi in combination with the teachings of Taube, Carmichael, and Clemmer).

At this stage, Patent Owner raises no other arguments regarding these claims other than those considered above with respect to claim 1. On this record, we determine that Petitioner has shown a reasonable likelihood of success that Taube, Carmichael, Clemmer, and Rossi renders obvious claims 2–6, 9–12, 30–33, and 41.

IV. CONCLUSION

After considering all the evidence and arguments presently before us, we determine Petitioner has established a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. Accordingly, we institute an *inter partes* review on all challenged claims and grounds.

Our determination at this stage of the proceeding is based on the evidentiary record currently before us. This decision to institute trial is not a final decision as to patentability of any claim for which *inter partes* review has been instituted. Our final decision will be based on the full record developed during trial.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 1–6, 9–12, 29–33, and 41 of U.S. Patent No. 7,802,571 B2 on all grounds set forth in the Petition; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is given of the institution of a trial, which commences on the entry date of this Decision.

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