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Paper 57
Entered: December 28, 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 B2

Before JOSIAH C. COCKS, KEVIN W. CHERRY, and JAMIE T. WISZ, *Administrative Patent Judges.*

CHERRY, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)
Denying-In-Part, Granting-In-Part, and Dismissing-In-Part Petitioner's Motion to Exclude
Denying-In-Part and Dismissing-In-Part Patent Owner's Motion to Exclude
37 C.F.R. § 42.64(c)

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"). Petitioner supported the Petition with the Declaration of Richard Imbruce. Ex. 1002. Fleur Tehrani ("Patent Owner") filed a Preliminary Response. Paper 5 ("Prelim. Resp.").

On January 6, 2021, based on the record before us at the time, we instituted an *inter partes* review of all challenged claims on all grounds alleged. Paper 6 ("Institution Decision" or "Inst. Dec.").

Patent Owner filed a Request for Rehearing of our Institution Decision. Paper 9. We denied Patent Owner's Request for Rehearing on March 5, 2021. Paper 17 ("Reh'g Dec.").

Patent Owner filed a Response in opposition to the Petition (Paper 19, "PO Resp."). Petitioner filed a Reply in support of the Petition (Paper 25, "Reply"). Patent Owner also filed a Sur-Reply in response to Petitioner's Reply. Paper 28 ("Sur-Reply").

Petitioner filed a motion to exclude evidence. Paper 35 ("Pet. Mot."). Patent Owner filed an opposition. Paper 37 ("PO Opp."). Petitioner filed a Reply. Paper 40 ("Pet. Mot. Reply"). Patent Owner also filed a motion to exclude evidence. Paper 33 ("PO Mot."). Petitioner filed an opposition. Paper 37 ("Pet. Opp."). Patent Owner filed a reply. Paper 41 ("PO Mot. Reply").

Both parties requested an Oral Hearing. *See* Paper 32. A transcript of the Oral Hearing is entered in the record. Paper 53 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. The evidentiary standard is a preponderance of the evidence. *See* 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d) (2020). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

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, (54), (45), (21), (22), (60). 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 1:20–23. 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}" or "FIO2") to improve the oxygenation of patients during ventilator therapy. *Id.* at 2:25–27, 3:52–59.

We reproduce Figure 1 from the '571 patent below.

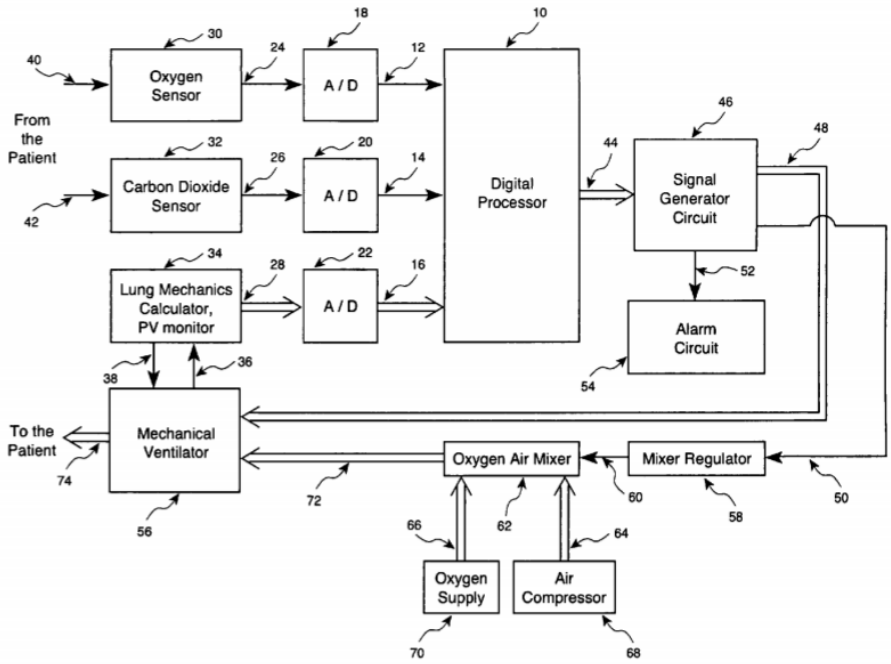

Figure 1

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 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

[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.

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 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.

[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.

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, 12:49–13:3. 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. 11, 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 Care Med (1995) 21:522–536 ("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). Patent Owner has not challenged the prior art status of any of the cited references.[4] PO Resp., *passim*.

Petitioner also relies on the Declaration of Richard Imbruce (Ex. 1002) 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. Patent Owner supported its Preliminary Response with the Declaration of Fleur T. Tehrani (Ex. 2002) in rebuttal. Patent Owner supported its Patent Owner Response with the Second Declaration of Dr. Fleur Tehrani, dated March 31, 2021 (Ex. 2010).[5] Petitioner supported the Reply with a second Declaration of Richard Imbruce (Ex. 1029). Petitioner also submitted with its Reply the

[4] Patent Owner does make certain challenges to the admissibility of the references that we address in discussing Patent Owner's Motion to Exclude. *See infra* IV.

[5] The Tehrani Declaration and Second Tehrani Declaration both include 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; Ex. 2010, App. 1, App. 2. The Patent Owner Response attempts to incorporate by reference the arguments from these appendices. *E.g.*, PO Resp. 56, 65, 72. 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). We informed Patent Owner that we would not consider such incorporation by reference in our Institution Decision *and* our Rehearing Decision. *See* Inst. Dec. 9 n.4; Reh'g Dec. 3–5. Patent Owner has repeated this error. As explained in our Consolidated Trial Practice Guide (CTPG) (Nov. 2019), https://www.uspto.gov/TrialPracticeGuideConsolidated, "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)). We do not consider these appendices in reaching this Decision.

Declaration of Dr. Jeffrey R. Anderson, P.E. (Ex. 1028). Patent Owner filed two declarations with its Sur-Reply: the Third Declaration of Dr. Fleur Tehrani (Ex. 2022) and the Declaration of Dr. James H. Roum (Ex. 2026).

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)[6]
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. 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

[6] 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.

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.[7] *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.").

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

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.

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.* at 21.

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. *See* PO Resp. *passim*.

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 record.

C. Weight to Give Dr. Imbruce's Testimony

Patent Owner argues that we should disregard the testimony of Petitioner's Declarant. *See* PO Resp. 75–77; Sur-Reply 14–15. Patent Owner asserts that we should disregard Dr. Imbruce's testimony because he

did "not identify[] that certain references had technically erroneous disclosures," he "was not forthcoming in his deposition," he "did not identify in his CV that he had been an expert witness in prior matters." *Id.* Patent Owner located a case where his testimony had been excluded. *Id.* Patent Owner also argues that his testimony is unreliable because he testified that the claim term "for a next breath" was arbitrary and meaningless. *Id.*

We do not agree with Patent Owner that Dr. Imbruce's testimony should be disregarded. With respect to Patent Owner's contentions about "technically erroneous disclosures" and the construction of "for a next breath," those are really about Patent Owner's disagreements about those matters, not whether Dr. Imbruce was attempting to mislead the Board. Disagreement between the experts is not a basis for disregarding testimony. We have also reviewed the entirety of Dr. Imbruce's deposition, and, in particular, the various parts identified by Patent Owner. PO Resp. 76–77. And, contrary to Patent Owner's assertions, we found Dr. Imbruce gave detailed answers in response to Patent Owner's questions. We found Dr. Imbruce's testimony to be adequate. *See, e.g.*, Ex. 2016, 107:11–115:8 (discussion of Anderson references, explaining the similarities of the references, but declining to vouch for data he has not seen or collected); 115:9–116:6 (FDA permission, offering to confirm what reference said about FDA approval, but attorney moving on to other questions). Thus, we do not find Dr. Imbruce's behavior during cross examination as a reason to give no weight to the entirety of his testimony.

As for Patent Owner's complaint about the disclosure of his prior testimony, Patent Owner does not point us to any requirement that such testimony be disclosed. Moreover, Patent Owner was free to inquire of Dr. Imbruce on the topic, and did. *See* Ex. 2016, 13:14–17:19.

Patent Owner focuses on the exclusion of Dr. Imbruce's testimony in *Smith v. Terumo Cardiovascular Sys. Corp.* (Ex. 2017), but we do not find it informative about the weight we should give Dr. Imbruce's testimony in this case. The *Terumo* case dealt with failure analysis of a different device, and the court in *Terumo* excluded Dr. Imbruce's testimony because he was not an expert in failure analysis of such devices and applied a methodology that the party had abandoned, not whether he was knowledgeable about automated ventilators, the subject matter of this case. *See* Ex. 2017, 12–13. Indeed, the court explained

> Dr. Imbruce may have the knowledge to describe the general physiology of oxygenation. Dr. Imbruce may have the knowledge regarding the various medical devices he invented. But Dr. Imbruce does not have the knowledge to do a failure analysis and make the very specific determination that a Terumo System 1 heart-lung bypass machine failed due to software issues that had never been identified by the manufacturer or—from the available information—any other user of the System. . . .

Id. at 11.

Patent Owner also asserts that Dr. Imbruce's background does not match with the technology. Sur-Reply 15. As we explain below in response to Patent Owner's motion to exclude, there need not be a perfect match between the expert's qualifications and the patent at issue. *See SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010). It is not necessary for Dr. Imbruce to demonstrate that he spent the bulk of his career personally designing mechanical ventilators. Indeed, to testify as an expert under Federal Rule of Evidence 702, a person need not be one of ordinary skill, but may be "qualified in the pertinent art." *See B/E Aerospace, Inc. v. MAG Aerospace Indus. LLC*, IPR2014-01513, Paper 104 at 13–14 (PTAB March 18, 2016) (Final Written Decision) (declining to exclude the

testimony of expert witness that lacked hands-on experience with the claimed subject matter). We agree with Petitioner that Dr. Imbruce's lengthy experience, including: a) developing ventilator devices and work on a portable oxygen generator to provide emergency care to patients undergoing respiratory distress (Ex. 1003, Rapid Oxygen Company work; Ex. 2016, 10:23–12:22); (b) "developing clinical protocols for new modalities in artificial ventilation" in the relevant 2003–2009 time period of the patent at issue in this IPR; (c) "laboratory and clinical research funded by DOD developing oxygen delivery therapies to treat hemorrhagic shock in wounded soldiers" in the 2009–2016 time period (Ex. 1003); and (d) ongoing design and use of ventilators, provides him sufficient experience and knowledge of the claimed subject matter for his opinion to remain of record. Ex. 1003; Ex. 2016, 10:23–12:22.

Instead of disregarding Dr. Imbruce's testimony in its entirety, we evaluate each of his assertions on their own, in light of the explanation offered, his answers on the specific topics under cross examination, and the other evidence of record.

D. 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. PO

Resp. 11–13. Included in each party's initial 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.

In our Institution Decision, we determined that only the claim terms "first means" and "second means" required construction. Inst. Dec. 25–27. Neither party disputes those constructions and we maintain and adopt them for the purposes of this Decision.

We determine that, for purposes of this decision, no other terms require express construction. *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))).

E. 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 9 (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." PO Resp. 29. Patent Owner argues that "in Carmichael, the F_{IO2} value is kept constant with PEEP being manually and incrementally increased to some 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 29–30 (emphasis omitted). 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.*

In our Institution Decision, we determined Petitioner had not shown a reasonable likelihood that Carmichael anticipates the challenged claims because it lacked adequate disclosure of the apparatus claimed. Inst. Dec. 29–30. In particular, we preliminarily found that "Carmichael lacks details as to the specific manner in which the assist control mode was being used to control PEEP and F_{IO2} levels" and whether Carmichael's disclosure "necessarily entails adjustments to F_{IO2} and PEEP." Inst. Dec. 30.

Petitioner argues that we should reconsider our initial finding because a qualified POSITA with hands-on clinical experience would have recognized Carmichael as necessarily disclosing determined adjustments of PEEP and F_{IO2} in providing control/data signals to "automatically control PEEP and F_{IO2} for a next breath of the patient." Pet. Reply 6. However, Petitioner states it "will focus on Ground 2 evidence of record," which supports a finding that Carmichael anticipates. *Id.*

We agree with Patent Owner that Carmichael lacks 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 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.,* PO Resp. 25–26. Thus, Petitioner has not shown by a preponderance of evidence 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. For the same

reasons discussed above, Petitioner has not shown by preponderance of the evidence that Carmichael anticipates 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.[8] Petitioner contends that the combination of Carmichael, Anderson, and Tehrani '268 renders obvious the subject matter of dependent claims 3–6, 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.E.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

[8] Petitioner relies on only Carmichael and Anderson for claims 1, 2, 29–33, and 41. Tehrani '268 is added for claims 3–6, 11, and 12. Rossi is added for claims 9 and 10.

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, in Figure 2 of Anderson, which is reproduced below:

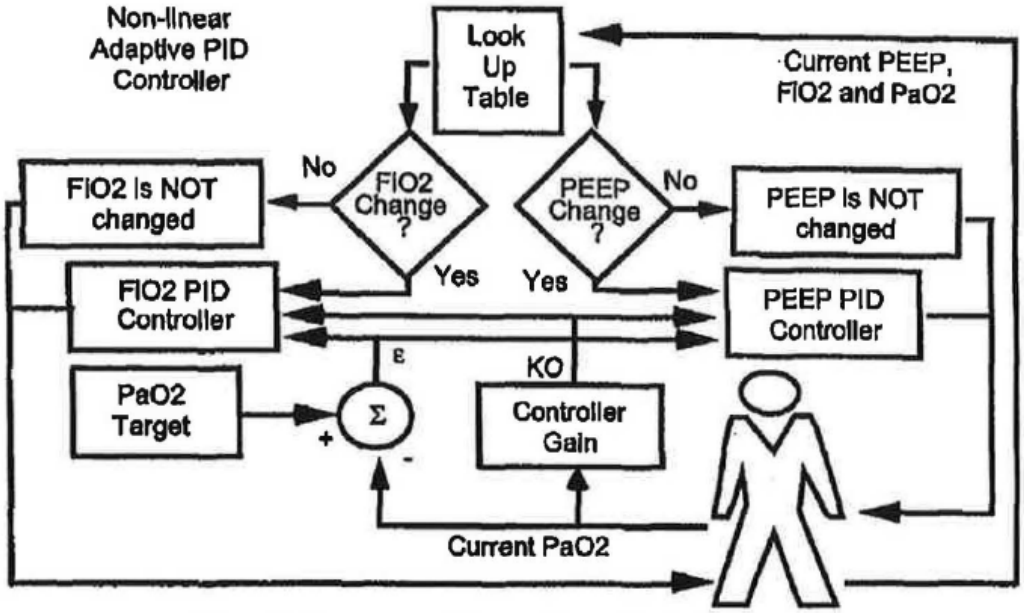

Figure 2. Components of the non-linear adaptive PID controller.

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, [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.

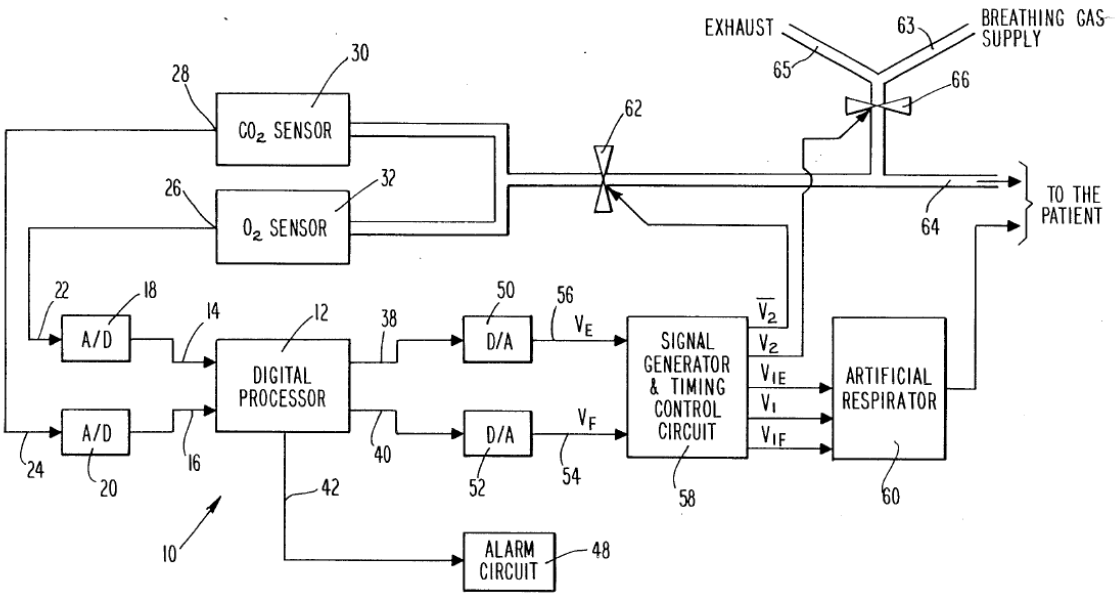

Fig. 1

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. *Id.* at 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).

Petitioner has shown by a preponderance of the evidence 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 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]oo [sic] 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 that Carmichael discloses a relationship between F_{IO2} and PEEP used to achieve a desired oxygen saturation. Petitioner also has shown 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 that the treatment protocol disclosed in Carmichael, as implemented, with a reasonable expectation of success, 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; Pet. Reply 18–19 (citing Ex. 1002 ¶¶ 147, 274, 275, 290).

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. PO Resp. 23–27 (citing Ex. 2007, 2012). Exhibit 2007, cited by Patent Owner, is a 1992 paper presented during a conference on the "Essentials of Mechanical Ventilators." Ex. 2007, 1026. This paper describes that "Assist/control ventilation (A/C) is a mode of ventilator operation in which mandatory breaths are delivered at a set [frequency], pressure or volume, and inspiratory flow. Between machine-initiated

breaths, the patient can trigger the ventilator and receive a mandatory breath at the volume or pressure set on the ventilator." *Id.* at 1032. Exhibit 2012, which is cited by Patent Owner, is an article from "RT Magazine," dated February 7, 2007. Ex. 2012, 1. Exhibit 2012, to the extent it has any weight as it is from long after the filing of the challenged patent, provides a similar understanding. Ex. 2012, 2 ("ACMV still delivers a set tidal volume at a set respiratory rate, but also responds to a patient's inspiration."). We disagree with Patent Owner's premise that an apparatus "for automatically controlling a ventilator" must provide automatic control of some of the outputs "for a next breath of the patient." PO Resp. 26, 58–59. The preamble of the challenged independent claims, which is where Carmichael is cited by itself for disclosing automatic control of a ventilator, does not recite "for a next breath of the patient." Ex. 1001, 12:48–49, 15:15–16. Petitioner relies on the combination of the references where the claim does recite "for a next breath of a patient. *See* Pet. 46–48. Indeed, the Specification of the '571 patent describes a clinician manually setting the initial values and allows for manual control of PEEP in the preferred embodiment of the invention. *Id.* at 7:67–8:2, 8:10–14, 10:16–65, 11:48–49, 12:23–28. Thus, Patent Owner's argument that "[a]n automatic ventilator cannot have manually set outputs that are adjusted intermittently by an operator" is inconsistent with the description in the challenged patent. *See* PO Resp. 58. Our finding that Carmichael discloses automatic control of a ventilator is based on our understanding that Carmichael discloses a ventilator that allows an operator to select a desired PEEP and FIO2, and the ventilator controls the output to deliver machine initiated breaths at these desired values. Ex. 1002 ¶¶ 122, 123. This understanding is supported by Petitioner's evidence and is

consistent with the description of "assist/control ventilation" provided in Patent Owner's Exhibit 2007.

Further, this ground is based on the modification of Carmichael's assist control ventilator with Anderson's automated ventilator architecture to provide automated control for a next breath of the patient. Pet. 46–48. The record contains extensive evidence that highly sophisticated microprocessor-controlled ventilator systems capable of very high gas outputs, complex monitoring were known in the art at the time of the invention. *See* Ex. 1011 (Waisel), 1132 (§ 2), 1134 (§ 2.3); Ex. 1013 (Anderson); Ex. 1006 (Tehrani '268). Thus, Patent Owner's separate attack on Carmichael is simply not persuasive when the Petition relies on the combination of references.

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. PO Resp. 27–30. 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 reaches 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, and we find persuasive, how this disclosed protocol selects PEEP to maintain a ratio of PEEP/F_{IO2} within a certain range. Pet. 32–33.

Patent Owner argues that "[b]y 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 as required in the Patent." PO Resp. 27 ("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. *See* Ex. 1002 ¶¶ 129–135. Patent

Owner's arguments about trial-and-error are beside the point. Importantly, even if clinicians in Carmichael reached their preferred treatment by trial-and-error, Carmichael reports this preferred treatment, which a person of ordinary skill would have been motivated to implement in the automated system of Anderson with a reasonable expectation of success. *See* Ex. 1002 ¶¶ 267–275. We find sufficient evidence and reasoning 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 to adjust F_{IO2} to minimize the difference between the measured and desired oxygen levels.

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 "Proportional-Integral-Derivative (PID) controllers are designed to control the output continuously and based on error signals." PO Resp. 35, 62. Patent Owner argues that these two techniques are contradictory means of adjusting PEEP and F_{IO2}. *Id.* at 36. We disagree that Anderson is internally inconsistent. 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.* at 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); Ex. 1028 ¶¶ 16–18; Ex. 1029 ¶¶ 6, 7, 11. Anderson discloses that the look up tables contain "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. Different "tables correspond to different levels of patient blood oxygenation." *Id.* PID equations then control FIO2 and PEEP settings. Ex. 1013, 291–292, eqs.1–2, Fig. 4. 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); Pet. Reply 16 (showing annotated version of Figure 7 of Anderson showing FiO2 being adjusted while PEEP is maintained and then both being adjusted later).

We further note the similarity of Anderson's use of Lookup Tables to the Loop Indicators (LIs) of the '571 Patent, which operate in conjunction with PID control. Pet. Reply 16. As Petitioner explains, a selected look up table (LUT) of Anderson defines logic to apply PID control of PEEP and FIO2. *Id.* A selected loop indicator of the '571 Patent does the same. Ex. 1001, 8:23–25; Figs. 3a–3h: steps 212, 224–226, 252.

Patent Owner further argues that the equations disclosed in Anderson for PID control "are erroneous." PO Resp. 37. Patent Owner points to Anderson's disclosure that the equations are for the "discrete recursive form of the PID controller." *Id.* (citing Ex. 1013, 291). Patent Owner then argues that "[t]he parameters of a discretized PID are functions of the sampling interval and are not constant," citing "equation 8-52 on page 312 of Exhibit 2013." *Id.* We have reviewed Exhibit 2013, and fail to see on its face, and Patent Owner does not provide adequate explanation, exactly how it

supports Patent Owner's assertions.[9] Patent Owner further argues that "discretized PID is not applicable to the subject of Anderson." *Id.* Again, Patent Owner does not cite to any evidence in its Patent Owner Response to support these arguments, nor does Patent Owner provide in its Patent Owner Response any explanation for the basis of these assertions.[10] In contrast, Dr. Anderson confirms in his testimony that the equations are accurate. Ex. 1028 ¶ 15. We find this testimony consistent with the disclosure of Anderson and give it significant weight.

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 the 1994 Anderson paper (Ex. 2008) published eight years earlier. PO Resp. 37–40, 60–62. Patent Owner asserts that this earlier article describes that the system "is 'protocol' based as stated in the paper (meaning it used a look up table) and it does not use any PID controller." *Id.* at 40. Patent Owner argues that because Anderson's results are the same as the 1994 paper (Ex. 2008), it appears the authors used only a look up table for both articles. *Id.*; Ex. 2010 ¶¶ 84–87. Patent Owner bases this contention on an interpretation of the sentence "A system was designed based on these protocols which provides continuous closed-loop control of oxygenation." Ex. 2008, A188; Ex. 2010 ¶¶ 83–87, 141–150.

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[9] Dr. Tehrani makes identical allegations in her declaration. Ex. 2010 ¶ 83. However, no additional explanation is provided in that paragraph. *Id.*

[10] Although not cited in the Patent Owner Response, Patent Owner provides similar assertions in her declaration without any further explanation or reasoning to explain the basis for these assertions. Ex. 2010 ¶ 83. We decline to give weight to this unsupported testimony.

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 that the mention in the 1994 Anderson paper to the use of "protocols" to design its closed-loop system necessarily means that the earlier system in the 1994 Anderson paper 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"). The 1994 Anderson paper is silent as to the particular logic used in its software to provide the control of PEEP and F_{IO2}. *Id.* The natural reading of Anderson's discussion of "protocols" is that a treatment protocol was developed by clinicians and the system was designed "based on" that "protocol," and nothing more. Ex. 2008, A188. This conclusion is further supported by the testimony of Dr. Anderson. *See* Ex. 1028 ¶¶ 3–5. Dr. Anderson acknowledges that the data included in the two papers is the same, and explains that the "protocols" discussed are the treatment protocols developed by some of the co-authors, not the architecture of the system. Ex. 1028 ¶¶ 7, 8. This testimony and our reading is consistent with the two papers when they are read together. The 1994 Andersen paper (Exhibit 2008) is a brief synopsis of the work in progress, less than a half a page long. It provides minimal details regarding the architecture of the system. *See generally* Ex. 2008. The Anderson reference (Exhibit 1013) is a lengthy detailed description of the work. *See generally* Ex. 1013. We note that Exhibit 1013 contains a similar description of the design criteria to Exhibit 2008: "We have designed a system based on well-established protocols for management of mechanical ventilation that provides continuous loop control of oxygenation and a balance between patient need and minimal therapy." Ex. 1013, 290. Thus, Exhibit 1013 is consistent with Exhibit 2008.

Patent Owner's reading of these two papers—where Exhibit 2008's use of the word "protocol" must mean that the system used look up tables and, therefore, Exhibit 1013 is a falsified article—is unreasonable, takes the word "protocol" as it is used in Exhibit 2008 entirely out of context, ignores the more natural reading of the two papers together, and goes against Dr. Anderson's unimpeached and well-explained testimony. Patent Owner's accusations are serious ones, but are based on nothing more than conjecture and suspicions. We find Patent Owner's contentions unsupported and against the great weight of the evidence. Thus, we disagree with Patent Owner that Anderson should be disregarded.

Patent Owner contends that experiments, such as Anderson's, require FDA approval, but Anderson does not "provide the essential and required information about an FDA permission to conduct its claimed closed-loop clinical experiments." PO Resp. 40–41. Patent Owner's argument is not persuasive. Patent Owner points to no evidence that any article about a study must discuss FDA permission specifically. *See id.* And there is no requirement that a party submit an FDA number to the Board to show something is prior art. *See* 35 U.S.C. § 102. Anderson explicitly discloses clinical compliance of trials conducted in Salt Lake City, Utah, where "Informed consent was obtained from 2 ARDS patients in the Shock/Trauma ICU at LDS Hospital for a clinical trial." Ex. 1013, 292. Dr. Anderson's testimony confirms that the proper approvals were obtained for the trial. Ex. 1028 ¶¶ 5–14, 19–22. Patent Owner cites FDA documents apparently from 2006—long after the trial discussed in Anderson took place. Exs. 2014, 2015. However, even if we consider these documents from long after the trial, at most, all these FDA documents suggest is that FDA permission must be obtained for such clinical trials. *Id.* Patent Owner fails

to point out any requirement that any paper describing such clinical trials must explicitly discuss FDA approval of the study they are describing. *See* PO Resp. 40–41; Sur-Reply 30–31. Thus, Patent Owner's conclusion that no clinical trial actually took place because the article does not contain evidence of FDA permission is completely speculative, wholly without evidentiary support, and against the entire weight of the evidence in the record.

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. PO Resp. 41. Patent Owner does not cite to any evidence in its Patent Owner Response to support this assertion.[11] Patent Owner does

[11] We note that Patent Owner's argument that continuous changing of PEEP is "against the method of the patent" is directly in tension with Patent Owner's proposed construction of "for a next breath of the patient." PO Resp. 11–12, 42. For claim construction, Patent Owner argues that "[t]he term "for a next breath of the patient" simply means "for a patient's breath **immediately** following in time" or simply "the next breathing cycle of the patient" as evident from the claims and the entire patent specification." *Id.* at 12. However, with respect to Anderson and Taube, Patent Owner argues that adjusting F_{IO2} is required, but adjusting PEEP breath-by-breath is forbidden. Indeed, Patent Owner asserts that the Specification discloses only adjusting PEEP after a 240 second delay. *See* PO Resp. 41 ("In the Patent, PEEP is determined (i.e., decided upon) every fraction of a second (e.g., every 0.75 seconds as shown in Figure 3h) and for a next breath of the patient, but it is not 'changed' until a fixed period (e.g., 240 seconds) has passed since the last 'change' in PEEP."). The challenged claims make no distinction between F_{IO2} and PEEP, but instead recite automatically controlling both of them "for a next breath of a patient." *See, e.g.*, Ex. 1001, 13:1–3 ("wherein the control signals provided to the ventilator *automatically control PEEP, and F_{IO2}, for a next breath of the patient*" (emphasis added)). Without meaningful explanation, Patent Owner would have "for a next breath of the patient" mean different things for different parts of the *same*

cite to its declarant's testimony on this point, but the declaration cites no other evidence to support the factual contentions underlying this opinion. Ex. 2010 ¶ 92. Thus, we give this testimony little weight. Anderson discloses 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 it was tested. Ex. 1013, 293. Dr. Anderson provides similar testimony as to the safety and efficacy of the system. Ex. 1028 ¶¶ 7–14. Thus, we find that the preponderance of the evidence in this record does not support Patent Owner's contentions.

Moreover, even if Patent Owner were correct regarding this contention about adjusting PEEP, "just because better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes." *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012) (citing *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)). Patent Owner fails to explain how PID control would be outside the scope of the language of the claims. Instead, Patent Owner agreed that PID control was within the meaning of "determining" and "calculating." *See* PO Resp. 13; Ex. 1027, 116:25–117:3.

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. PO Resp. 73–75. This argument misstates Petitioner's proposed combination. Petitioner does not propose to modify

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limitation. We do not need to resolve this tension between the proposed claim construction and these admissions regarding the disclosure of the challenged patent, because we determine that regardless of whether we adopt Patent Owner's or Petitioner's claim construction, Grounds 3 and 4 meet this limitation.

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. "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference," *In re Keller*, 642 F.2d at 425; *see also In re Mouttet*, 686 F.3d at 1332 (citing *In re Keller*, 642 F.2d at 425), but rather whether "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention," *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). Anderson itself describes that existing treatment protocols were used to design the system. Ex. 1013, 290. This goal is reflected in other references in this art in the record as well. *See, e.g.*, Ex. 1011, 1133 (noting the goal of "mimic[ing] how expert clinicians care for patients").

Patent Owner also asserts that the Petitioner never specifically addresses how Anderson determines F_{IO2} and PEEP "for a next breath of the patient." PO Resp. 62. 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, Dr. Imbruce, 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).

Carmichael's protocol targets a desired PaO2 level "through the use of increased FiO2s [sic] and incremental application of PEEP" while keeping PEEP to a value within a range of zero to 25 cmH2O for a given FIO2 value. Ex. 1004, 13–14; Ex. 1002 ¶ 147. 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" in view of Carmichael's teachings.

For these reasons, Petitioner has demonstrated by a preponderance of the evidence that claim 1 would have been obvious 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* PO Resp. 10, 11, 27, 29, 35–43, 56–65, 72–75 (presenting the same arguments for claims 1 and 29). We have reviewed Petitioner's evidence and arguments for claim 29, and find them sufficient. *See* Pet. 57–58. Thus, for the same reasons discussed above in our analysis of claim 1, Petitioner has shown by a preponderance of the evidence that claim 29 would have been obvious 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 to show by a preponderance of the evidence that these claims are unpatentable. Although Patent Owner discusses Tehrani '268 in its Patent Owner 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). PO Resp. 54–55 (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. PO Resp. 55. We disagree. Petitioner has shown persuasively 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 Patent Owner Response, Patent Owner does not contest Petitioner's reliance on Rossi for its disclosure of measurement of $PEEP_i$ (claims 9, 10, 30). PO Resp. 53–54 (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).

Patent Owner raises no other arguments regarding these claims other than those considered above with respect to claim 1. We determine that Petitioner has shown by a preponderance of the evidence that the combined teachings of Carmichael, Anderson, Tehrani '268, and Rossi render 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.

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.

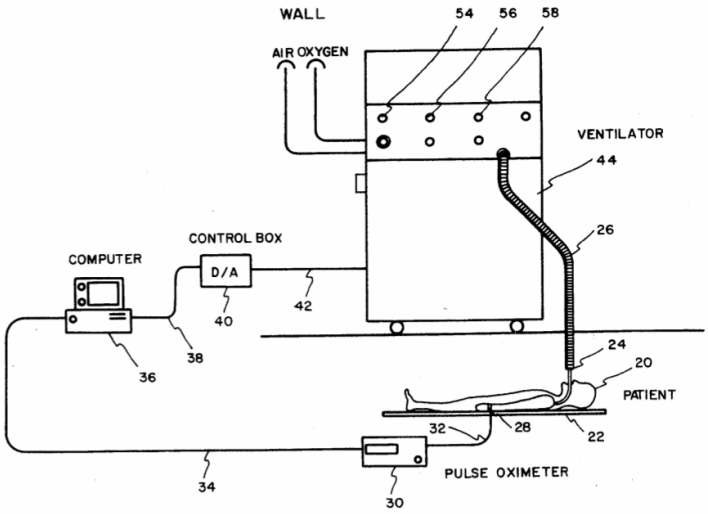

FIG. 1

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.

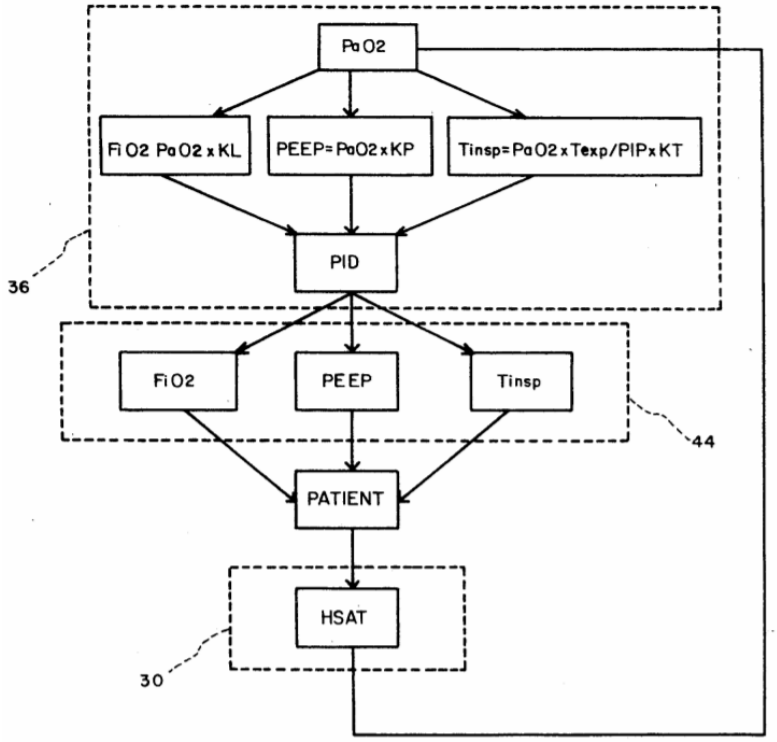

FIG. 3

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 II.E.1.

3. 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 the 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 1303.

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, [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 [57]. "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 II.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 entire record, Petitioner has shown by a preponderance of the evidence that claim 1 would have been obvious over the combination of Taube, Carmichael, as evidenced by ARDSNET, Clemmer, and Rossi.

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. PO Resp. 49; *see also id.* at 50–51; Sur-Reply 28–29. 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." Ex. 1005, 5:30–33. Taube also recognizes, discussing the prior art, the problem of oversaturation. Ex. 1005, 2:14–20. We agree

with Dr. Imbruce, and give substantial weight to his testimony, that Patent Owner's reading of Taube is unreasonable and contrary to Taube's own disclosure. *See* Ex. 1029 ¶¶ 13–19. 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.[12]

Patent Owner acknowledges that Taube's Figure 3 shows adjustment of PEEP, F_{IO2} and T_{insp} by PID control, but argues that "[a]s described with regard to Anderson, the output of a PID controller changes continuously with time and cannot be used to safely adjust PEEP whose effect on patient's oxygenation is not instantaneous." PO Resp. 49. Patent Owner contends that "[u]sing PID controllers to adjust PEEP automatically can be quite hazardous to patients, has not been done in any commercial ventilators, and is not used in any of the embodiments of the Patent," and "[f]or this reason alone, the PTAB should not rely on Taube's disclosure." *Id.* Patent Owner does not provide adequate evidentiary support for this argument.[13]

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[12] Even assuming that Patent Owner was correct, i.e., that Taube disclosed a device that would administer a therapy that a person of ordinary skill would immediately recognize was fatal to the patient, such disclosure would not disqualify Taube as prior art. To begin with, nothing in the claims requires a particular level of efficacy or a treatment result. Moreover, under an obviousness analysis, a reference need not work to qualify as prior art; "it qualifies as prior art, regardless, for whatever is disclosed therein." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003). "Even if a reference discloses an inoperative device, it is prior art for all that it teaches." *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989).

[13] The only evidence in the record that seems to support this argument is in Dr. Tehrani's Declaration. *See* Ex. 2010 ¶ 92. However, Dr. Tehrani provides no citations to support the factual contentions underlying this argument, and the record contains two prior art references—Taube and

Moreover, even if Patent Owner were correct, "just because better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes." *In re Mouttet*, 686 F.3d at 1334 (citing *In re Gurley*, 27 F.3d at 553). Patent Owner fails to explain how PID control would be outside the scope of the language of the claims. Instead, Patent Owner agreed that PID control was within the meaning of "determining" and "calculating." *See* PO Resp. 13; Ex. 1027, 116:25–117:3.

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. PO Resp. 51–52. Petitioner relies on Carmichael,[14] however, for the specifications of the PEEP and F_{IO2} 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. *See* Pet. 66.

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. PO Resp. 52 (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.* at 53, 67.

We disagree with Patent Owner's assertion that Clemmer's protocols require manual adjustment. For instance, Clemmer discusses, with reference to Figure 4, an alternative with continuous monitoring and adjustment.

Anderson—that do describe PID control of PEEP. Thus, we give this testimony little weight.

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

Ex. 1008, 18:53–63. Moreover, Clemmer teaches that "patient instructions can be carried out automatically" and the control programming instructions of the "inventive system therefore accomplished closed loop control of ventilation." Ex. 1008, Abstract, 5:2–3, 9:3–4. 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 "Carmichael is all about manual adjustments of PEEP and FIO2 several hours apart," and "Taube claims continuous PID control of PEEP and FIO2." PO Resp. 69. Patent Owner contends that "combining any of Carmichael, ARDSNET or Clemmer's manual adjustments of parameters would render Taube's PID automatic control of PEEP and FIO2 system inoperable and thus Taube would not operate on the same principles." *Id.* at 74. 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.

Patent Owner contends that "[n]ot only it is impossible to combine these systems, but a desired oxygen level is not definable in Taube, because "Taube maximizes the patient's oxygen level if that level increases." *Id.* at 69. However, as we explained above, *supra* pp. 45–47, this argument is based on Patent Owner's unreasonable interpretation of Taube. *See* Ex. 1029 ¶¶ 13–19. Moreover, Petitioner proposes to modify Taube's treatment regime to implement the treatment regime of Carmichael. Patent

Owner never addresses that combination.[15] We have reviewed Petitioner's evidence and find it persuasive that such a combination would have been obvious to a person of ordinary skill at the time of the invention. *See* Pet. 60–66; Ex. 1002 ¶¶ 419–438.

For these reasons, Petitioner has demonstrated, by a preponderance of the evidence, the unpatentability of claim 1, under 35 U.S.C. § 103(a), based on the combined teachings of Taube, Carmichael, as evidenced by ARDSNET, Clemmer, and Rossi.

7. Analysis of Claim 29

Petitioner relies on the same findings and combination of Taube, Carmichael, as evidenced by ARDSNET, Clemmer, Rossi 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* PO Resp. 30–33, 51–54 (presenting the same arguments for claims 1 and 29). We have reviewed Petitioner's evidence and arguments for claim 29, and find them sufficient. *See* Pet. 70–72. Thus, for the same reasons discussed above in our analysis of claim 1, Petitioner has shown by a preponderance of the evidence that claim 29 would have been obvious based on the combined teachings of Taube, Carmichael, and Clemmer.

[15] Patent Owner also argues that we failed to take into account the Examiner's consideration of Taube during prosecution. *See* PO Resp. 47, 67. However, we discussed at length the Examiner's consideration of Taube in our Institution Decision, and we found that the Examiner materially erred in the consideration of Taube. Inst. Dec. 11–22 (explaining the material errors in the Examiner's consideration of Taube). Therefore, we do not find the Examiner's prior consideration of Taube to be entitled to any weight in determining whether the challenged claims are patentable over the combination of Taube, Carmichael, ARDSNET, Clemmer, and Rossi.

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, as evidenced by ARDSNET, Clemmer, and Rossi, renders obvious the subject matter of these dependent claims and find the evidence and reasoning sufficient to show by a preponderance of the evidence that these claims are also unpatentable as obvious. Although Patent Owner discusses Rossi in its Patent Owner Response, Patent Owner does not contest Petitioner's reliance on Rossi for its disclosure of measurement of $PEEP_i$ (claims 9, 10, 30). PO Resp. 53–54 (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).

Patent Owner raises no other arguments regarding these claims other than those considered above with respect to claim 1. We determine that Petitioner has shown by a preponderance of the evidence that Taube, Carmichael, Clemmer, and Rossi renders obvious claims 2–6, 9–12, 30–33, and 41.

H. Remaining Grounds

Having determined that Petitioner establishes by a preponderance of the evidence that the subject matter of claims 1–6, 9–12, 29–33, 41 would have been obvious over the combination of Carmichael, Anderson, Tehrani '268, and Rossi and the combination of Taube, Carmichael, as evidenced by ARDSNET, Clemmer, and Rossi, we do not address Petitioner's additional ground of obviousness based on Carmichael (as evidenced by ARDSNET and Waisel) challenging claims 1, 2, 5, 6, 11, 29, 31–33, 41 (Ground 2). *See*

SAS Inst. Inc. v. Iancu, 138 S. Ct. 1348, 1359 (2018) (holding a petitioner "is entitled to a final written decision addressing all of the claims it has challenged"); *Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App'x 984, 990 (Fed. Cir. 2020) (nonprecedential) ("We agree that the Board need not address [alternative grounds] that are not necessary to the resolution of the proceeding.").

III. PETITIONER'S MOTION TO EXCLUDE

Petitioner seeks to exclude Exhibits 2009, 2012, 2013, 2014, 2015, 2018, 2022, 2024, 2025, 2026, and 2027. We grant-in-part, deny-in-part, and dismiss-as-moot-in-part Petitioner's Motion to Exclude.

A. Untimely Exhibits (Exhibits 2022, 2024–2026)

Under 37 C.F.R. § 42.23(b), a "sur-reply may only respond to arguments raised in the corresponding reply and may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witness." 37 C.F.R. § 42.23(b). The Consolidated Trial Practice Guide states that a "sur-reply may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witness." CTPG, at 73.

Patent Owner filed two declarations with its Sur-Reply: the Third Declaration of Dr. Fleur Tehrani (Ex. 2022) and the Declaration of Dr. James H. Roum (Ex. 2026). Patent Owner contends that these exhibits were necessary because Petitioner's Reply contained new arguments and was, in effect, "a brand-new Petition based on new declarations and evidence." PO Opp. 3. In particular, Patent Owner contends that Petitioner's construction of "for a next breath" was new and required new evidence to respond. *Id.*

at 4. As for Exhibit 2026, Patent Owner argues that Dr. Roum's declaration is necessary to "prevent Petitioner from misleading the Board." *Id.* at 5. In particular, Patent Owner asserts that Dr. Roum's declaration is necessary to respond to Dr. Anderson's and Dr. Imbruce's testimony "regarding the alleged clinical trials in Anderson having been conducted in accordance with a hospital Internal Review Board (IRB) regulations and the FDA rules." *Id.* at 5–6.

We agree with Petitioner that Exhibits 2022 and 2026 are untimely and should be excluded. Rule 42.23(b) and the Consolidated Trial Practice Guide are clear that such declarations cannot be filed with a sur-reply. There is no automatic "responding to new arguments" exception to that prohibition. As the Consolidated Trial Practice Guide explains, the proper course if new arguments were presented in the Reply would be to seek authorization to file a motion to strike. CTPG, 80–81. Patent Owner did not do that. Regardless, our rules do not permit a party to file exhibits without authorization. 37 C.F.R. § 42.7(a) (forbidding filings not authorized); § 42.23(b) (forbidding new evidence other than deposition transcripts with a sur-reply). Our rules only authorize limited exhibits that may be filed with a sur-reply. *See* 37 C.F.R. § 42.23(b). Patent Owner did not seek authorization to file these additional exhibits.

Moreover, we disagree with Patent Owner that the interests of justice support allowing these declarations. First, Patent Owner's contention that Petitioner's challenge to Dr. Tehrani's credentials requires a response is not persuasive. Petitioners routinely challenge the credentials of experts. Dr. Tehrani has testified at length about her credentials in her first two declarations and has provided a curriculum vitae and other materials that will allow us to assess them. Dr. Tehrani was also allowed to testify to her

credentials in her deposition and her counsel could have asked her additional questions on re-direct. We see no need for additional testimony from either Dr. Tehrani or Dr. Roum on that matter. Second, as for the disputes regarding the Anderson reference, we explained above why Patent Owner's arguments about FDA authorization and the intricacies of clinical trials were not persuasive. Patent Owner's new testimony simply repeats the same assertions and does not add anything new that would change that conclusion. Therefore, that testimony is also unnecessary. Finally, with respect to the alleged new claim construction, we disagree with Patent Owner that the claim construction is new or that additional expert testimony on the claim construction that was already thoroughly discussed in Patent Owner's prior declarations will add any further illumination to this subject. Moreover, we have found that the claim constructions make no difference to the result on Grounds 3 and 4, which also render this testimony unnecessary. Accordingly, because they were filed in violation of our rules and the interests of justice do not support excusing that violation, we grant Petitioner's Motion to Exclude Exhibits 2022 and 2026.

In addition to the declarations discussed above, Patent Owner also filed Exhibits 2024 and 2025 with its Sur-Reply. Exhibit 2024 is an article entitled "What You Need to Know About Brain Oxygen Deprivation," which was published in 2021. Ex. 2024. Patent Owner cited Exhibit 2024 to address how the term "oxygen deprivation" would have been understood at the time of the invention of the '571 patent. Sur-Reply 15. Patent Owner argues that this article is necessary to address the "next breath" dispute. PO Opp. 13–14. Exhibit 2025 is a definition of "trial and error" from the Merriam-Webster Online Dictionary. Patent Owner argues that this exhibit is necessary to respond to alleged new arguments in the Reply. *Id.* at 14.

We agree with Petitioner that these exhibits are also untimely and should be excluded. We are also not persuaded that the interests of justice require us to allow these exhibits. With respect to Exhibit 2024, we fail to see why an article on oxygen deprivation, at a very general level, is necessary for this proceeding given that there seems to be no dispute about the need to prevent oxygen deprivation. As for Exhibit 2025, we do not believe that a dictionary definition of the common expression "trial and error," a term not found in the claims of the '571 patent, is necessary for this proceeding. Accordingly, because they are untimely and the interests of justice would not be served by allowing them to be admitted, we grant Petitioner's Motion to Exclude Exhibits 2024 and 2025.

B. Exhibits 2009, 2018, and 2027

Exhibit 2009 is The Opinion of the United Kingdom Intellectual Property on Infringement of the GB2423721 Patent, Opinion#09/18, issued on June 6, 2018. Ex. 2009, 1. Exhibit 2018 is several pages from the textbook *Mechanical Ventilation* by Neil R. MacIntyre and Richard D. Branson. Exhibit 2027 purports to be an email between an employee of the UK Intellectual Property Office and Dr. Tehrani. Ex. 2027, 1. Petitioner argues that these exhibits should be excluded. Pet. Mot. 3–5, 9–10, 12; Pet. Opp. 10–11. We did not rely on Exhibits 2009, 2018, and 2027 in reaching our decision in this case because Patent Owner does not cite them in making any arguments regarding patentability or, as to Exhibit 2018, which as with Exhibit 2007 and 2012 discusses assist/control mode ventilation, they are cumulative of other exhibits discussed. Therefore, we dismiss Petitioner's Motion to Exclude Exhibits 2009, 2018, and 2027 as *moot*.

C. Exhibits 2012–2015

Exhibit 2012 is purportedly a website entitled "Ventilation Modes and Monitoring." Ex. 2012. Exhibit 2013 appears to be portions of a chapter of a book entitled "Digital Control System Analysis & Design," by Charles L. Phillips et al. Ex. 2013, 1. Exhibit 2014 is an information sheet from the U.S. FDA's website. Ex. 2014, 1. Exhibit 2015 is an Investigational Device Exemption (IDE) form printed from the U.S. FDA's website. Petitioner argues that these exhibits are irrelevant and should be excluded under Fed. R. Evid. 401–403. Pet. Mot. 4–5. Petitioner also contends that Exhibits 2012, 2014, and 2015 should be excluded under Fed. R. Evid. 901–902.

Here, Patent Owner does rely on these exhibits to support its arguments. We find this sufficient to clear the very low bar of relevance. *See United States v. Whittington*, 455 F.3d 736, 739 (6th Cir. 2006) ("[T]he district court correctly noted that the relevance threshold is very low under Rule 401.") (internal quotation marks omitted). As for Fed. R. Evid. 403, assuming that it applies in these non-jury proceedings, *Schultz v. Butcher*, 24 F.3d 626, 632 (4th Cir. 1994) (finding court should not exclude evidence under Rule 403 in non-jury trial on grounds of unfair prejudice), we find that Petitioner's arguments deal not with prejudice, but rather, the weight we should give the evidence.

As for authentication, documents are authenticated by evidence "sufficient to support a finding that the item is what the proponent claims it is." Fed. R. Evid. 901(a). Authenticity is, therefore, not an especially high hurdle for a party to overcome. *See United States v. Patterson*, 277 F.3d 709, 713 (4th Cir. 2002); *see also United States v. Ceballos*, 789 F.3d 607, 617–18 (5th Cir. 2015) (noting "low" burden for authentication); *United States v. Isiwele*, 635 F.3d 196, 200 (5th Cir. 2011) (noting flaws in

authentication go to weight not admissibility). Patent Owner's counsel has offered a declaration attesting to the accuracy of these documents. *See* Ex. 2019 ¶¶ 3–5. We find this testimony sufficient to clear the low bar for authentication. Accordingly, we deny Petitioner's Motion to Exclude Exhibits 2012–2015.

D. Summary

Accordingly, for the reasons above, we grant Petitioner's Motion to Exclude Exhibits 2022, 2024–2026, dismiss-as-moot Petitioner's Motion to Exclude Exhibits 2009, 2018, and 2027, and deny Petitioner's Motion to Exclude Exhibits 2012–2015.

IV. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner moves to exclude Exhibits 1002, 1005, 1011, 1013, 1023, 1024, 1025, 1026, 1028, and 1029. We consider each of these exhibits in turn. For the following reasons, we deny-in-part and dismiss-as-moot-in-part Patent Owner's Motion to Exclude.

A. Exhibit 1002

Exhibit 1002 is the First Declaration of Dr. Richard Imbruce. Patent Owner argues that Dr. Imbruce's experience is distant from the '571 patent and not up to date. PO Mot. 3–4. Patent Owner contends that "Exhibit 1002 presents numerous incorrect, and totally unsubstantiated allegations about the prior art and the Patent." *Id.* at 4. Patent Owner asserts that "Dr. Imbruce, has offered expert testimony on matters outside his knowledge in the past. The Patent Owner brought to the attention of the Board that Dr. Imbruce had to be disqualified in another case (Ex. 2017) (POR, 75-77), because he had offered incorrect testimony not within his expertise as

admitted by the Petitioner (PRPOR at 23)." *Id.* at 5. Patent Owner also argues that Dr. Imbruce failed to bring "to the attention of the Board that two of the Petitioner's alleged prior art, Ex. 1011 and Ex. 1013, both non-reviewed papers, do not present true data as explained by the Patent Owner." *Id.* Patent Owner submits that "Ex. 1002 is a large collection of flawed and unsubstantiated allegations that has caused an unjustified institution in this case." *Id.* at 6. Patent Owner "requests the exclusion of this evidence because it is totally misleading and prejudicial (FRE 401-403), is not based on sufficient facts or data and the expert has not reliably applied the principles and methods to the facts of the case (FRE 702) and is not based on evidence (FRE 901)." *Id.*

Petitioner opposes, pointing to the relevant experience in Dr. Imbruce's curriculum vitae and that the experiences he testified about in his deposition. Pet. Opp. 1 (citing Ex. 1003; Ex. 2016, 10:23–12:22).

Patent Owner's arguments go to the weight we should give Dr. Imbruce's testimony, not its admissibility. *See Microfinancial, Inc. v. Premier Holidays Int'l.*, 385 F.3d 72, 81 (1st Cir. 2004) ("When the factual underpinning of an expert's opinion is weak, it is a matter affecting the weight and credibility of the testimony—a question to be resolved by the [factfinder]."). The prior case where Dr. Imbruce's testimony was excluded (Ex. 2017) involved a very narrow and specialized area (failure analysis of a particular specialized medical device—a heart-lung machine). Patent Owner's arguments do not persuade us that we should exclude Dr. Imbruce's testimony. There need not be a perfect match between the expert's qualifications and the patent at issue. *See SEB S.A.*, 594 F.3d at 1373. It is not necessary for Dr. Imbruce to demonstrate that he spent the bulk of his career personally designing mechanical ventilators. Indeed, to

testify as an expert under Fed. Rule Evid. 702, a person need not be one of ordinary skill, but may be "qualified in the pertinent art." *See B/E Aerospace, Inc. v. MAG Aerospace Indus. LLC*, Paper 104 at 13–14 (Final Written Decision) (declining to exclude the testimony of expert witness that lacked hands-on experience with the claimed subject matter). We agree with Petitioner that Dr. Imbruce's lengthy experience, including a) developing ventilator devices and work on a portable oxygen generator to provide emergency care to patients undergoing respiratory distress (Ex. 1003, Rapid Oxygen Company work; Ex. 2016, 10:23–12:22); (b) "developing clinical protocols for new modalities in artificial ventilation" in the relevant 2003–2009 time period of the patent at issue in this IPR; (c) "laboratory and clinical research funded by DOD developing oxygen delivery therapies to treat hemorrhagic shock in wounded soldiers" in the 2009–2016 time period (Ex. 1003); and (d) ongoing design and use of ventilators, provides him sufficient experience and knowledge of the claimed subject matter for his opinion to remain of record. Ex. 1003; Ex. 2016, 10:23–12:22.

Moreover, "[t]he policy considerations for excluding expert testimony, such as those implemented by the gatekeeping framework established by the Supreme Court in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), are less compelling in bench proceedings such as inter partes reviews than in jury trials." *Nestle Healthcare Nutrition, Inc. v. Steuben Foods, Inc.*, IPR2015-00249, Paper 76 at 23 (PTAB June 2, 2016). To be sure, we take into account the qualifications of an expert witness—and any shortcomings revealed through cross-examination—when evaluating the weight to be given that witness's testimony. But the wholesale exclusion of a witness's declarations is rarely called for in a proceeding before the Board.

We have considered Dr. Imbruce's qualifications in determining the weight to be given his testimony.

Patent Owner's other objections are without merit. Fed. R. Evid. 901 has no application here—there is no doubt that Dr. Imbruce's declaration is authentic. Nor can there any doubt that it is relevant under Fed. R. Evid. 401. *See Whittington*, 455 F.3d at 739 ("[T]he district court correctly noted that the relevance threshold is very low under Rule 401.") (internal quotation marks omitted). As for Fed. R. Evid. 403, assuming that it applies in these non-jury proceedings, *Schultz*, 24 F.3d at 632 (finding court should not exclude evidence under Rule 403 in non-jury trial on grounds of unfair prejudice), we find that Patent Owner's arguments deal not with prejudice, but rather, the weight we should give the testimony. Accordingly, we deny Patent Owner's Motion to Exclude Exhibit 1002.

B. Exhibit 1005

Patent Owner argues that we should exclude the Taube patent under Federal Rules of Evidence 401–403. PO Mot. 6. In particular, Patent Owner argues that it was "raised by the Examiner" and "was fully responded to before the Patent was allowed" and "cannot be combined with any manual chart or table" and is "detrimental" and "[a] Patent describing a detrimental method should not be used at any trial because it is misleading, irrelevant to the facts and prejudicial." *Id.*

We agree with Petitioner that Patent Owner's arguments fail to provide any basis for excluding evidence under Federal Rules of Evidence 401–403. *See* Pet. Opp. 2, 4–6. Federal Rule of Evidence 401 provides that evidence is relevant if it "has any tendency to make a fact more or less probable than it would be without the evidence" and "the fact is of

consequence in determining the action." Fed. R. Evid. 401; Fed. R. Evid. 402 ("Relevant evidence is admissible"). Courts have characterized the relevance threshold as being "very low." *United States v. White*, 692 F.3d 235, 246 (2d Cir. 2012) (quoting *United States v. Al-Moayad*, 545 F.3d 139, 176 (2d Cir. 2008)). The fact that Taube was considered by the Examiner does not negate its relevance or admissibility. Similarly, the argument about whether Taube can be combined goes to the merits of the combination, not the admissibility of the evidence, because although the combination might not be obvious, the evidence would still be relevant. Finally, Patent Owner's arguments that Taube is not relevant because of the the alleged detrimental nature of Taube—i.e., that Taube allegedly discloses a device that will increase and decrease oxygen levels in a way that is harmful (*see supra* pp. 45–46) are also unpersuasive. *See* PO Mot. 6; PO Reply 2. Under an obviousness analysis, a reference need not work to qualify as prior art; "it qualifies as prior art, regardless, for whatever is disclosed therein." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003). "Even if a reference discloses an inoperative device, it is prior art for all that it teaches." *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989). Thus, even if Patent Owner's arguments regarding the operation of Taube were correct, which as we explain above they are not, *see supra* pp. 45–46, it would not be basis for excluding Exhibit 1005. Instead, we find that Exhibit 1005 easily clears the very low threshold of relevance.

Patent Owner's argument that Federal Rule of Evidence 403 compels exclusion is equally unavailing. PO Mot. 6; PO Reply 2. Rule 403 has limited applicability, if any, to bench trials like this proceeding. *See, e.g., Schultz*, 24 F.3d at 632 (holding that "in the context of a bench trial,

evidence should not be excluded under 403" because the court can "hear relevant evidence, weigh its probative value and reject any improper inferences"). In the end, Patent Owner's arguments simply go to the weight the evidence should be given and not its admissibility. Accordingly, we deny Patent Owner's Motion to Exclude Exhibit 1005.

C. Exhibit 1011

Patent Owner argues that Exhibit 1011, Waisel, should be excluded because it "does not present true data" and it is "misleading, presents unreliable data, is irrelevant to the facts and prejudicial." PO Mot. 7; PO Reply 2–3. Again, even if Patent Owner's assertions are correct, under an obviousness analysis, a reference need not work to qualify as prior art; "it qualifies as prior art, regardless, for whatever is disclosed therein." *Amgen*, 314 F.3d at 1357. Moreover, Patent Owner's assertions that Waisel does not present true data are based on speculation and are not persuasive. In addition, as we explained above, Patent Owner's contentions that Waisel cannot be considered because it does not disclose an FDA Investigational Device Exception is not persuasive. *See supra* pp. 34–35 (explaining with respect to Anderson why similar contentions were not persuasive). Patent Owner also argues Waisel should be excluded under Federal Rule of Evidence 702 (PO Mot. 7), but that rule relates to expert testimony, which this prior art reference is not. Finally, we find that Petitioner has provided more than sufficient evidence to authenticate Waisel (*see* Ex. 1017 ¶¶ 77–84, 120), so Patent Owner's authentication objection (PO Mot. 7) is not persuasive. Accordingly, for similar reasons as we articulated for Exhibit 1005, we deny Patent Owner's Motion to Exclude Exhibit 1011.

D. Exhibit 1013

Patent Owner argues that Exhibit 1013, the Anderson reference, should be excluded "because it presents misleading and unreliable data, is irrelevant to the facts and prejudicial ((FRE 401-403), is not based on reliable facts and data (FRE 702), and is not based on evidence (FRE 901)." PO Mot. 8. For the reasons stated above for Exhibits 1005 and 1011, these arguments with respect to Federal Rules of Evidence 401–403 and 702 are not persuasive. As for Patent Owner's objection under Federal Rule of Evidence 901, Petitioner has provided more than sufficient evidence that Exhibit 1013 is what it purports to be, i.e., a copy of the Anderson reference. *See, e.g.*, Ex.1017 ¶¶ 94–101, 120; Ex. 1028 ¶¶ 3–5. Accordingly, we deny Patent Owner's Motion to Exclude Exhibit 1013.

E. Exhibits 1023–1025

Patent Owner seeks to exclude Exhibits 1023–1025, which are three exhibits relating to the Terumo Advanced Perfusion System. *See* Exs. 1023–1025. Patent Owner's declarant was questioned on these exhibits at her deposition, but neither party cites or discusses these exhibits. We did not rely on these exhibits in reaching our decision, so we dismiss Patent Owner's Motion to Exclude Exhibits 1023–1025 as *moot*.

F. Exhibit 1026

Exhibit 1026 s a United Kingdom Intellectual Property Office UK IPO Opinion dated March 19, 2021, regarding invalidity of a UK Patent No. GB 2423721, a parallel UK patent to the US Patent at issue in this proceeding. Patent Owner argues that we should exclude Exhibit 1026 because it is "a non-binding, non-final opinion from another jurisdiction that

is presently under review and thus is completely irrelevant to the facts and prejudicial (FRE 401–403) is not based on evidence (FRE 901), and was relied upon for the first time in Petitioner's Reply." PO Mot. 2. We did not rely on Exhibit 1026 in reaching our decision in this case. Therefore, we dismiss Patent Owner's Motion to Exclude Exhibit 1026 as *moot*.

G. Exhibit 1028

Patent Owner argues that Exhibit 1028, the Declaration of Dr. Jeffrey R. Anderson, P.E., should be excluded because "it is irrelevant to the facts and prejudicial (FRE 401 – 403), is inadmissible hearsay (FRE 801), is not based on sufficient facts or data (FRE 702), is not based on substantiated evidence (FRE 901), and was relied upon for the first time in Petitioner's Reply." PO Mot. 13–14. None of these arguments is persuasive. First, Federal Rule of Evidence 702 does not apply because Dr. Anderson is not offered as an expert witness, but instead as a fact witness based on his first-hand knowledge. *See* Pet. Opp. 8. Second, Patent Owner provides no explanation of how Dr. Anderson's testimony is hearsay (under Federal Rule of Evidence 801) or how it is not authentic under Federal Rule of Evidence 901. *See id.*; PO Mot. Reply 5. Federal Rule of Evidence 801(c) defines "hearsay" as "a statement that: (1) the declarant does not make while testifying at the current trial or hearing; and (2) a party offers in evidence to prove the truth of the matter asserted in the statement." Here, Dr. Anderson's declaration is *testimony offered in the current trial*, and is, therefore, by definition *not* hearsay. Thus, Patent Owner's blanket hearsay objection against the entire declaration is without merit. As for Federal Rule Evidence 901, that rule deals with authentication. *See* Fed. R. Evid. 901. There is no dispute that Dr. Anderson's declaration is what it purports to

be—i.e., the declaration of Dr. Jeffrey Anderson. A Rule 901 objection has no place here. To the extent that Patent Owner means Federal Rule of Evidence 602, which requires that a witness have personal knowledge in order to testify as a fact witness, Dr. Anderson, as one of the named authors of the paper in question has shown that he has the requisite personal knowledge to testify. *See* Ex. 1028 ¶¶ 3–22 (explaining his personal knowledge of the events on which he testifies).

Finally, Patent Owner's arguments regarding relevance (Fed. R. Evid. 401), prejudice (Fed. R. Evid. 403), and the alleged lateness of the exhibit are not persuasive. Patent Owner argued extensively in the Patent Owner Response with supporting testimony in her First and Second Declarations and in the Patent Owner Response that Dr. Anderson's paper was false and the reported trial never occurred. *See* PO Resp. 37–41, 60–63. Petitioner was entitled to respond in its Reply to the arguments that Patent Owner made. *See* 37 C.F.R. § 42.23(b) ("A reply may only respond to arguments raised in the corresponding opposition, patent owner preliminary response, patent owner response, or decision on institution."). Our rules allow that response to be supported by new evidence. *See id.* (only limiting the evidence that may be filed with a sur-reply). We find that Dr. Anderson's testimony is not new, but is directly responsive to Patent Owner's own arguments and accusations of misrepresentation attributed to Dr. Anderson and his co-authors. Thus, we agree with Petitioner that Dr. Anderson's testimony is relevant and timely. As for Patent Owner's prejudice argument, Patent Owner does not offer a credible explanation as to any prejudice that arises from Dr. Anderson's testimony that seeks to refute the argument made by Patent Owner that Dr. Anderson misrepresented data in his 1994 paper. Accordingly, we deny Patent Owner's Motion to Exclude Exhibit 1028.

H. Exhibit 1029

Patent Owner seeks to exclude Exhibit 1029, the Second Declaration of Dr. Richard Imbruce. PO Mot. Exclude 14. Patent Owner argues that "Dr. Imbruce makes numerous unsubstantiated and incorrect allegations in this declaration and therefore, Ex. 1029 is irrelevant and prejudicial (FRE 401-403)." *Id.* Patent Owner further contends that Dr. Imbruce's second declaration should be excluded because it relies on other exhibits Patent Owner has sought to exclude. *Id.* Patent Owner also argues that "Dr. Imbruce even signs his name as RRT (i.e., Registered Respiratory Therapist) despite that he has not practiced respiratory therapy or renewed his RT certificate for 40 years." *Id.*

Patent Owner additionally seeks to exclude Exhibit 1029 because Patent Owner contends that "Petitioner is requesting a new claim construction for 'a next breath of the patient,' and is providing new arguments on Waisel." *Id.* Patent Owner requests that Exhibit 1029 be excluded in its entirety, or alternatively, that the portions of Exhibit 1029 referring to the new claim construction be excluded, which appear to be paragraphs 22–28 of Exhibit 1029. *Id.*

Petitioner responds that Dr. Imbruce's testimony does not offer a new claim construction, but seeks to respond to Patent Owner's arguments and the Institution Decision's preliminary findings regarding Waisel. Pet. Opp. 9–10. Thus, Petitioner contends that the testimony is proper.

We agree with Petitioner that Patent Owner's request to exclude Exhibit 1029 should be denied. To begin with, an expert may rely on otherwise inadmissible evidence in forming his or her opinion. Thus, even if Dr. Imbruce relied on some exhibits that are inadmissible, it would not

necessarily warrant excluding his testimony. *See* Fed. R. Evid. 703. Moreover, as we found above, Patent Owner's objections to the exhibits relied on by Dr. Imbruce are without merit, so we find unavailing the argument that Dr. Imbruce relied on excluded evidence. Furthermore, Patent Owner's arguments concerning Dr. Imbruce's title and experience go to the weight we should give Dr. Imbruce's testimony, not its admissibility. *See Microfinancial, Inc.*, 385 F.3d at 81 ("When the factual underpinning of an expert's opinion is weak, it is a matter affecting the weight and credibility of the testimony—a question to be resolved by the [factfinder]."). Patent Owner was free to cross examine Dr. Imbruce on these points, which it has. Finally, as for the allegedly new arguments, we begin by noting that a motion to exclude is not the proper vehicle to seek to strike new arguments. *See* CTPG, at 79 ("Nor should a motion to exclude address arguments or evidence that a party believes exceeds the proper scope of reply or sur-reply."). In any event, the allegedly new arguments in paragraphs 20–28 are not a basis for excluding the entirety of Exhibit 1029. As for paragraphs 20–28, we have reviewed them and agree with Petitioner that they are not new arguments, but instead, respond directly to the Decision to Institute and the arguments Patent Owner has made in this proceeding. Accordingly, we deny Patent Owner's Motion to Exclude Exhibit 1029.

V. CONCLUSION[16]

After considering all the evidence and arguments presently before us, we determine Petitioner has established by a preponderance of the evidence that the challenged claims are unpatentable.

In summary,

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1, 2, 5, 6, 11, 29, 31–33, 41	102	Carmichael		1, 2, 5, 6, 11, 29, 31–33, 41
1, 2, 5, 6, 11, 29, 31–33, 41	103(a)	Carmichael (as evidenced by ARDSNET and Waisel)[17]		
1–6, 9–12, 29–33, 41	103(a)	Carmichael, Anderson, Tehrani '268, Rossi	1–6, 9–12, 29–33, 41	

[16] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

[17] This ground was not reached. *See supra* § II.H.

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–6, 9–12, 29–33, 41	103(a)	Taube, Carmichael, ARDSNET, Clemmer, Rossi	1–6, 9–12, 29–33, 41	
Overall Outcome			1–6, 9–12, 29–33, 41	

We grant-in-part, deny-in-part, and dismiss-as-moot-in-part Petitioner's Motion to Exclude. We deny-in-part and dismiss-as-moot-in-part Patent Owner's Motion to Exclude.

VI. ORDER

For the reasons given, it is:

ORDERED, that Petitioner *has shown* based on a preponderance of evidence, that claims 1–6, 9–12, 29–33, and 41 of U.S. Patent 7,613,649 B2 are unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude is *granted-in-part, denied-in-part,* and *dismissed-as-moot-in-part*;

FURTHER ORDERED that Patent Owner's Motion to Exclude is *denied-in-part* and *dismissed-in-part*; and

FURTHER ORDERED because this is a final written decision, the parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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