No. 23-575

In The

Supreme Court of the United States

Fleur Tehrani,
Petitioner,

v.

Hamilton Technologies LLC,
Respondent.

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

RESPONDENT'S BRIEF IN OPPOSITION

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INTRODUCTION

Petitioner Fleur Tehrani presented five questions for review, none of which rise to the level of warranting review by the Supreme Court of the United States as being publicly important, legally important or involving a conflict between the lower circuit courts. *See* S.Ct. Rule 10. Petitioner has not identified a legal error, but rather is seeking to reargue established facts that have been fully evaluated in holding challenged patent claims of Petitioner's US Patent unpatentable.

In the United States Patent and Trademark Office, the Patent Trial and Appeal Board (PTAB) (hereinafter "the Board"), as the fact finder, thoroughly cited to substantial evidence in support of its findings in holding the challenged patent claims at issue to be unpatentable. All findings were affirmed at the Court of Appeals for the Federal Circuit ("Federal Circuit") in its original decision and subsequent denial of Petitioner's Request for Rehearing. Petitioner now turns to raising unfounded accusations against both the Board and the Federal Circuit over alleged improper factual determinations. However, the Board and the Federal Circuit cited substantial evidence in support of all factual findings and applied established legal principles to those factual findings.[1]

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[1] The holdings of both the Board and the Federal Circuit align with factual findings of the United Kingdom Intellectual Property Enterprise Court, which found the entirety of a related UK patent (GB 2423721) to be invalid. The Court also ordered that "[t]he Claimant [Fleur Tehrani/Petitioner] shall pay to the Defendants [Hamilton] on or before 28 days after the hearing

For these and the following reasons, this Court should deny Fleur Tehrani's Petition.

I. STANDARD OF REVIEW

Traditionally, lower courts' decisions implicating questions of law are reviewable *de novo* and discretionary matters are reviewed for abuse of discretion. *Highmark Inc. v. Allcare Health Management System, Inc.*, 572 U.S. 559, 563 (2014). The Board's factual findings should be given deference unless such findings are unsupported by substantial evidence. *Dickerson v. Zurko*, 527 U.S. 150, 164-65 (1999).

The present case involves earlier decided factual findings and discretionary issues in support of a holding that the challenged clams within Petitioner's patent are unpatentable. No questions of law are presented. Petitioner does not challenge a legal error in the Board's determination that challenged claims of Petitioner's US Patent are unpatentable. Rather, Petitioner re-argues the factual content and applicability of the prior art documentary evidence relative to the obviousness of the patent claims at issue. These arguments are directed exclusively to factual issues. *See Arctic Cat, Inc. v. Bombardier Recreational Products, Inc.*876 F.3d 1350, 1358 (Fed. Cir. 2017) ("The Graham factors—(1) the scope and content of the prior art; (2) the differences between the claims and the prior art;

£50,000 of their costs of this action." Petitioner has not paid the required sum. An enforcement action is currently being undertaken in the California State Court system so Hamilton receives the payment Petitioner was ordered to pay.

(3) the level of ordinary skill in the art; and (4) objective considerations of nonobviousness—are ***questions of fact*** reviewed for substantial evidence."). The Federal Circuit determined that the Board did not abuse its discretion in weighing testimony supporting a holding that challenged patent claims recited in the US Patent at issue are unpatentable as being obvious based on substantial evidence.

II. STATEMENT OF THE CASE

Fleur Tehrani ("Tehrani" or "Petitioner") holds U.S. Patent No. 7,802,571 (the "'571 Patent"), which discloses "a method and apparatus for controlling a ventilator", including mechanical ventilators and CPAP machines. Hamilton Technologies LLC ("Hamilton" or "Respondent") filed a petition for inter partes review of the '571 Patent with the Board on July 10, 2020. The Board granted institution on January 6, 2021, concluding that Hamilton had established a reasonable likelihood that it would prevail with respect to at least one of the challenged claims being invalid in view of the prior art.

The Board's Final Written Decision of December 28, 2021, determined Hamilton had shown by a preponderance of evidence that claims 1-6, 9-12, 29-33 and 41 of the '571 Patent were unpatentable and obvious in light of the prior art.

Petitioner subsequently requested the Director of the United States Patent and Trademark Office to review of the Board's decision. This request was denied. Petitioner then appealed the Board's decision

to the Federal Circuit on April 26, 2022. The Federal Circuit affirmed the Final Written Decision of the Board on June 28, 2023, finding the claims of the '571 Patent unpatentable. The Federal Circuit also held that the Board did not err in its obviousness determinations and that they were based on substantial evidence. Upon receiving the final judgement of the Federal Circuit, Petitioner filed a motion for rehearing *en banc*. This motion was denied. Unsuccessful challenges at both the Board and Federal Circuit led Petitioner to file a Petition for Writ of Certiorari to this Court on November 28, 2023.

III. PETITIONER'S QUESTIONS FOR REVIEW REARGUE FACTUAL ISSUES DISPOSED OF BY THE BOARD AND AFFIRMED BY THE FEDERAL CIRCUIT

Petitioner presents five questions for this Court to review. These questions all derive from factual issues which were squarely addressed by the Board as the fact finder and affirmed by the Federal Circuit on appeal. During oral argument before the Federal Circuit, Petitioner raised 12 factual issues fully vetted AND resolved by the Board. When pressed by the Federal Circuit, Petitioner was unable to identify any legal errors made by the Board. Instead, Petitioner referred to the factual findings as legal errors, which they are not. *See* App.157a at 3:8-22.

> Judge Stark: What do you think is your strongest issue?

> Mr. Kendrick: The strongest issue is that the prior art documents that were cited against us, the court error in determining that they presented true information, as well as that they could be combined with the other reference, the se -- second reference.
>
> Judge Stark: On -- on the true information, I --I saw that there was an attack on the accuracy of certain -- of the prior art reference. Is that what you're referring to?
>
> Mr. Kendrick: Yes. Accuracy
>
> Judge Stark: And isn't that inherently a fact question and –and wasn't there substantial evidence for the Board to find that the references actually were reporting true information?

Because the Federal Circuit found the factual findings made by the Board to be properly based on substantial evidence, the Federal Circuit affirmed the Board's Final Written Decision. Notwithstanding this affirmance, Petitioner reasserts the same factual arguments in the current Petition.

Petitioner provides no correlation between the Questions Presented and the arguments made in her Statement of the Case. By way of this opposition, Respondent attempts to correlate each of the arguments to the relevant question. To the extent an argument does not appear relevant to a particular

Question Presented, it is addressed elsewhere with the question to which it appears most relevant to thereby address all of Petitioner's arguments.

a. Petitioner's First Question Presented Does Not Serve as a Basis for Granting its Petition.

Petitioner asks this Court to address whether the Federal Circuit erred "by declaring a non-expert as a Person of Ordinary Skill In The Art ("POSITA") despite all the evidence presented to the contrary." This question invokes the abuse of discretion standard and whether the Board, as fact finder, abused its discretion in weighing the testimony of Hamilton's expert, Dr. Richard Imbruce for evaluating the scope and content of prior art documentary evidence presented to the Board and in weighing the testimony of Dr. Anderson with regard to the Anderson prior art document that Dr. Anderson authored.

Petitioner appears to present their supporting arguments in "Section C" of their Petition. There, Petitioner disputes whether Respondent's expert was a POSITA. Petitioner acknowledges that the disjunctive options defining qualifications for a POSITA were agreed upon by the parties but then Petitioner disparages Respondent's expert, Dr. Imbruce, by focusing on the last time he renewed his clinician's license and seeking dismissal of his experience in the ventilator industry during the relevant time period of the '571 Patent's early development.

The Board as the fact finder stated that "[w]e found Dr. Imbruce's testimony to be adequate" (App.27a) and that Dr. Imbruce had "sufficient experience and knowledge of the claimed subject matter for his opinion to remain of record." (App.29a). This factual determination, clearly made by the Board, was based on Dr. Imbruce's qualifications. Therefore, the determination was underpinned by substantial evidence.

On appeal to the Federal Circuit, Petitioner made the same factual arguments as are presented in this Petition. For example, at oral argument, Petitioner's counsel emphasized that Dr. Imbruce's clinical experience occurred more than 40 years ago. App.165a at 11:10-11. The Federal Circuit's retort stated that the Board's definition of a person of ordinary skill in the art imposes no restriction as to when the skilled artisan's clinical experience must have occurred. *Id.* at 11:14. In their Decision, the Federal Circuit stated that "[i]ssues relating to the extent and timing of Dr. Imbruce's clinical experience may affect the weight that the Board should choose to give his opinions, but those do not render his opinions unreliable." App.6a, FN 3. What is more, The Federal Circuit emphasized that:

> Dr. Imbruce is a person of ordinary skill in the art, as he is a "clinician specializing in treating respiratory failure issues with at least five years of practical clinical ventilator experience treating such conditions," which is one of the disjunctive options provided in the agreed-upon definition of an ordinary artisan, which

> the Board adopted. J.A. 13. Even assuming there was error in the Board failing to expressly find that Dr. Imbruce was a person of ordinary skill in the art, such error was harmless, because, as we have explained, Dr. Imbruce plainly has the qualifications to make him such a person.

App.6a.

The Federal Circuit concluded that "[t]here is no basis for us to find the Board abused its discretion in the weight it placed on this witness' testimony." App.7a. Ultimately the Federal Circuit held that "[t]he Board did not abuse its discretion" and that "[t]he Board found Dr. Imbruce's testimony "adequate."

b. Petitioner's Second Question Presented Does Not Serve as a Basis for Granting its Petition.

The second question that Petitioner presents on appeal asks whether the Federal Circuit "erred by relying on unsupported statements against the Petitioner in the face of reliable published evidence to the contrary." This question invokes the substantial evidence standard and whether the Board's findings with regard to prior art documentary evidence were properly grounded in substantial evidence.

Petitioner appears to allege a basis for this question in Sections D and F of the Petition. Petitioner's arguments are based on misstatements of

facts as they relate to the prior art documents at issue and a fundamental misunderstanding of claim terminology. The prior art documents that Petitioner specifically attempts to mischaracterize as lying, untrue and/or against clinical experience are prior art documents authored by Dr. Carmichael, Dr. Anderson and John Taube.

Petition Section D and the factual misstatements therein contradict what the Board found to be substantial evidence supporting its findings. In Section D, Petitioner first characterizes a prior art report authored by Dr. Carmichael (App.112a-135a) as based on "trial and error" in an attempt to disparage the disclosure's relevance. The Carmichael report is, however, a compilation of survey results of a questionnaire sent to critical care physicians where "an anonymous single mailing of the questionnaire to all 3,264 members of the American Thoracic Society Assembly of Critical Care Medicine was conducted in late 1992." App.115a. Nowhere in the Carmichael report is the phrase "trial and error" mentioned. Rather, it is one of the earliest summaries of the clinical factors influencing diagnosis and treatment of patients with acute respiratory distress syndrome by critical care physicians.

Petitioner also misstates factual aspects of Carmichael by alleging that "[t]here is no mention of any ratio of PEEP/FIO2 anywhere in Carmichael let alone any prescribed range of such ratio." Pet. 10. FIO2 is also notated "FIO_2" and "FiO_2". Ratios are clearly evident and shown in Carmichael's Figure 7 using references to PEEP and FIO_2:

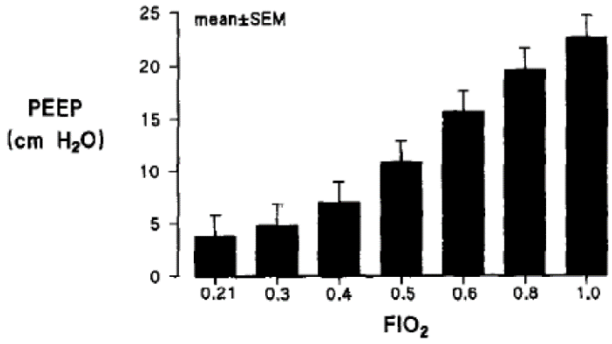

Fig 7. The maximum PEEP used at various FIO_2s.

The y-axis of Figure 7 is the positive end-expiratory pressure ("PEEP") measured in cm H_2O and the x-axis is the fraction of inspired oxygen ("FIO_2"). The slope of the correlation between the x and y axes is a ratio. Because each of the bars on the x-axis contains a range, there is a range of ratios. The narrative of Carmichael makes this explicitly clear by referring to "mean" values in stating "[a]t an FIO2 of 0.5, the mean maximum PEEP applied was 11 cm H2O, 16 $\pm$ 6 cmH2O at 0.6, 20 $\pm$ 6 cmH2O at 0.8, and 23 $\pm$ 7 cmH2O at 1.0 (Fig 7)." App.123a.

The Board found that "Figure 7 of Carmichael shows that the maximum level of acceptable PEEP increases as the FIO2 level increased" (App.9a) and that Carmichael discloses that "modest levels of [PEEP] were used in incremental fashion as F[i]O2 requirements increased. Carmichael also discloses that conventional teaching in the 1970s was that '[an oxygen saturation level] PaO2 > 60 mmHG was desirable and should be achievable through the use of increased FiO2s and incremental application of

PEEP'". App.31a-32a. Substantial evidence was therefore cited to support the Board's findings.

The Federal Circuit found the Board had substantial evidence to conclude that Carmichael's Figure 7 teaches the protocol of adjusting FIO2 and PEEP to obtain an oxygen saturation level PaO2 within a prescribed range. App.9a.

Regarding the prior art document authored by Dr. Anderson, Petitioner again attempts to disparage its disclosure by alleging it to be a non-peer-reviewed presentation. However, Petitioner fails to cite any support for the proposition that a prior art document must be "peer-reviewed"; what matters is the content of the disclosure. Petitioner also attempts to advance a theory that because there is inexact similarity between the graphics in two of Dr. Anderson's articles that were published at different points in time, statements made by Dr. Anderson in the Anderson document relied upon by Hamilton must be untrue. These arguments have no bearing on the findings of the Board, and the affirmance by the Federal Circuit, that the Anderson document is prior art disclosing limitations of the '571 Patent claims at issue.

For example, the Board found that "Anderson is a report describing a 'closed-loop control system based on well-established protocols to systemically maintain appropriate levels of [PEEP] and [FiO2] in patients with [ARDS].'" App.35a. The Board also found "Anderson states '[t]he implemented protocols provide continuous closed-loop control of oxygenation" and that Anderson's "controller is based on a traditional proportional-integral-derivative (PID)

approach . . . to control, or maintain, the patient's PaO2 level at a target value." App.36a. The Board found this paper included accurate information based on the text of the document and a sworn declaration of Dr. Anderson. App.46a. Substantial evidence supports these findings, which includes the literal text of the prior art and testimony from its author. In contrast, Petitioner asks the Court, without evidence, to find that Dr. Anderson presented false data in his paper.

The Federal Circuit found that substantial evidence supports the Board's finding that Anderson's look-up tables contain the logic used to dictate if changes in therapy are needed "based on the patient's current level of PaO2 and current PEEP and [FIO2] settings." App.9a. Anderson uses "[FIO2] and PEEP PID controllers that calculate the amount of therapy adjustment. Anderson's look-up table serves the same function as the '571 Patent's loop indicators, defining the logic that determines if and when PID controllers change FIO2 and PEEP." *Id.* Notably, the Board and the Federal Circuit found the sworn testimony of Dr. Anderson as to the contents of his document reliable. *See* App.82a-83a. ("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.").

Regarding the prior art document authored by Mr. Taube, Petitioner misstates that the equations disclosed in this publication are "against clinical practice" and that the publication is "an example of a

positive feedback system which is inherently unstable" and that "Taube is a fatal device."

The Board previously addressed Petitioner's arguments by stating "Patent Owner's reading of Taube is unreasonable and contrary to Taube's own disclosure." App.62a. For example, the Board found that "[w]hen [Taube's] Figure 3 is considered in combination with the accompanying description, Taube teaches that the computer chooses the values of the parameters (FIO2, PEEP, Tinsp) 'to maintain a desired level of the patient's blood oxygen level'" and further that "Taube also recognizes, discussing the prior art, the problem of oversaturation." App.63a. The Board states that "[w]e agree with [Hamilton's expert] 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." *Id.* Petitioner's fact-based arguments do not merit Supreme Court review, particularly where Petitioner's arguments lack any reasonable factual underpinning. Taube is prior art and discloses the limitations of the claims at issue. This is a factual issue that was addressed by the Board.

With regard to Petitioner's arguments as to how the '571 Patent's claim term "a next breath" should be construed, the Federal Circuit addressed this issue by acknowledging that the Board's decision was based on substantial evidence. The Board stated:

> Dr. Tehrani also contends that the Board should have construed the claim term "for a next breath of the patient" as controlling PEEP and FIO2 for "a patient's breath

> immediately following in time" or "the next breathing cycle of the patient." J.A. 35-36 n.11; Appellant's Br. at 41-43. Hamilton instead proposed the plain and ordinary meaning as not limited to the immediate next breath or breathing cycle. J.A. 2509-11. "[W]e review the Board's ultimate claim constructions de novo." *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1297 (Fed. Cir. 2015), overruled on other grounds by *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017). Here, however, the Board did not actually construe this claim term. Instead, after noting that Dr. Tehrani's proposed construction would contradict her argument that the specification requires adjusting PEEP after a 240-second delay, see '571 patent 11:56-60, the Board determined that the claim limitation was taught in the prior art combinations "regardless of whether we adopt Patent Owner's or [Hamilton's] claim construction." J.A. 35-36 n.11. The Board had substantial evidence for this finding.

App.7a.

Petitioner's claim construction was specifically addressed and applied in the finding that the '571 Patent claims were obvious and unpatentable.

c. Petitioner's Third Question Presented Does Not Serve as a Basis for Granting its Petition.

Petitioner's third question presented to the Court asks whether the Federal Circuit erred in affirming the Board's decision to invalidate the challenged claims "while none of the requirements of those claims were met by any combinations of the alleged prior art." This question invokes the substantial evidence standard and whether the Board's findings with regard to the combination of the prior art documents were properly grounded in substantial evidence. Petitioner advances this argument in sections C, E, G, H, J, K, L and M of her Petition.

For example, Petitioner argues that the Federal Circuit did not address most of the alleged errors of the Board. However, as discussed *infra*, Judge Stark specifically asked Petitioner "[w]hat do you think is your strongest issue?" If Petitioner's strongest argument was unsuccessful in convincing the Federal Circuit, why would any other? The truth is that the Federal Circuit addressed every issue set before it. To the extent Petitioner keeps changing the goal line when they get an adverse decision does not mean the Federal Circuit did not address an issue.

Petitioner's arguments that the combinations of prior art teachings are not possible and against scientific principles fail to recognize that it is the disclosure of the limitation in the prior art when viewed as a whole that renders the claims obvious. The Board's decision on this was factual in nature and

based on substantial evidence which the Federal Circuit affirmed.

Petitioner argues that the combination of teachings from the Carmichael and Anderson documents does not determine "PEEP in relation to FIO2 for a next breath" as required by the '571 Patent claims. Pet. 21-22. The Board found that Petitioner's argument misstates [Hamilton's] proposed combination ("Anderson's automated system to implement Carmichael's treatment protocol for adjustment of PEEP and FIO2 in ARDS patients"). App.52a. With reference to Dr. Imbruce's testimony, the Board found that the Anderson closed-loop adaptive controller "continuously controls FiO2 and PEEP" and Carmichael achieves a desired PaO2 level "though the use of increased FiO2s [sic] and incremental application of PEEP while keeping PEEP to a value within a range of zero to 20 cmH20 for a given FIO2 value." App.53a. Therefore, the Board cited substantial evidence to conclude that the combination of teachings from the Carmichael and Anderson documents met the requirements of the challenged claims to render them obvious. All of the limitations are present in the cited publications, which each qualify as prior art to the '571 Patent. The Board's decision was based on substantial evidence and properly found all the limitations of the claims to be disclosed or suggested by the combination of cited art when viewed as a body of prior art work.

Petitioner also asserts that the Federal Circuit made a serious mistake by stating PID control of PEEP is used in the '571 Patent. This portion of the Federal Circuit decision is a general summary of the

'571 Patent's disclosure and is not the basis of the Federal Circuit's findings as it concerns the Federal Circuit's affirmance of the Board's ruling. This is not a basis for granting the current Petition.

d. Petitioner's Fourth Question Presented Does Not Serve as a Basis for Granting its Petition.

Petitioner's fourth question on appeal asks whether the Federal Circuit erred by "using a) a paper presenting untrue results and b) a fatal device against the challenged claims of US Patent 7,802,571." Petitioner appears to argue this point in sections D, E and I of her Petition. This question invokes the substantial evidence standard and whether the Board's findings with regard to the applicability of the prior art documents were properly grounded in substantial evidence.

Petitioner's arguments are all based on unsubstantiated, alleged flaws in the prior art documents relied upon to establish unpatentability of the '571 Patent. More specifically, Petitioner alleges that the Anderson document does not present true data because "1) no PID control of PEEP was used in Anderson or else the value of PEEP would have been changing during the 10 hours and 2) that PEEP was adjusted manually [as evidenced by Figure 7 of Anderson]." (Pet. 12, 24). Anderson expressly discloses PID control to produce changing values of "PEEP" illustrated in Anderson's Figure 7:

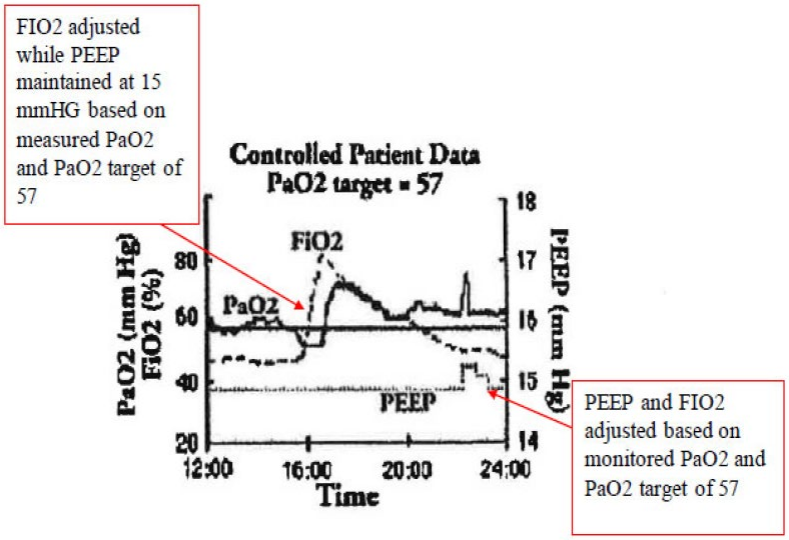

Figure 7. Typical patient data showing the controller's maintenance of PEEP and FiO2.

Petitioner similarly argues that Taube presents a "fatal device" because the direct relationships between the treatment levels of PEEP and FIO2 and PaO2 create an unbounded output which is against clinical practice. Petitioner argues that "Taube is an example of a positive feedback system which is inherently unstable and no set desired value for oxygen can be defined in Taube." (Pet. 13, 25).

Petitioner's conclusory assertions fail to substantiate how the Board erred in relying on both Anderson and Taube. The Board found that the Petitioner's argument that Anderson presented false data were serious accusations "but are based on nothing more than conjecture and suspicions" and that the "great weight of the evidence" was against

Tehrani's argument. App.48a. The Board found that Dr. Anderson provided "unimpeached and well-explained testimony" (App.48a) supporting the accuracy of the text of the Anderson reference and that Dr. Anderson's disclosed ventilator controller was safe to use and was effective (App.51a). With regard to the Taube document, the Board noted that Petitioner failed to provide "adequate evidentiary support" for her claims that automatically adjusting PEEP with PID controllers is hazardous to patients and thus the Taube reference should not be relied on. App.63a. In fact, the Taube reference's explicit disclosure contradicted Petitioner's unfounded assertion that Taube disclosed a fatal device. App.62a. Petitioner's attempt to discredit the prior art based on conclusory, unsupported argument (e.g., Petitioner's assertion that the Anderson document included false information in the face of Dr. Anderson's sworn testimony as to its accuracy) is a factual issue that was resolved by the Board.

e. Petitioner's Fifth Question Presented Does Not Serve as a Basis for Granting its Petition.

Petitioner's fifth question presented to the Court alleges that the Federal Circuit erred by affirming the Board's decision to find the challenged claims of the '571 Patent invalid under 35 U.S.C §103(a) and this was "against the Decision of the Supreme Court of the United States and Precedents [sic] of the Federal Circuit." Petitioner appears to make this argument in sections K and M of the Petition and in portions of sections C, G, H, J, L, and M of the Petition.

This question invokes the substantial evidence standard and whether the Board's findings with regard to the applicability of the prior art documents in invalidating the challenged claims were properly grounded in substantial evidence.

Petitioner argues that an obviousness objection based on the combination of teachings from the Carmichael and Anderson documents cannot be sustained because not only is it impossible and inoperable, but also the combination of the art teaches away from the claimed invention. Pet. 27-28. Similarly, Petitioner argues that the combination of teachings of Carmichael and Taube "has no chance of success" and therefore does not meet the requirements of obviousness. *Id.* at 28-29. These conclusory arguments raised by Petitioner were recognized as lacking factual support before the Board, and Petitioner presents no new information to warrant reconsideration. The Federal Circuit found Petitioner's assertions "unpersuasive" based on substantial evidence of record. App.10a.

Before this Supreme Court, Petitioner raises only factual issues that have been fully vetted by both the Board and the Federal Circuit and fails to identify any legal error. Petitioner alleges that "the main reference used against the patent claims are heterogeneous, uncombinable and present methods that are against the method of the patent claims." (Pet. 7). However, the Board determined and the Federal Circuit affirmed that the '571 Patent claims 1-6, 9-12, 29-33 and 41 were obvious in light of a combination teachings from (i) Carmichael, Anderson, Petitioner's own patent, U.S. Patent No.

4,986,268 (the "'268 patent"), and Rossi and a combination of teachings from (ii) Taube, Carmichael, ARDSNET, Clemmer and Rossi. The Board found, and the Federal Circuit affirmed, that such combinations were appropriate based on substantial evidence that included expert testimony, testimony from the author Dr. Anderson, and the factual content of the documentary references. Here, Petitioner demonstrates a fundamental misapplication of the law of obviousness by relying upon unsubstantiated challenges to underlying factual issues without evidentiary support. *See e.g.* App.48a-49a, finding "Patent Owner's reading of these two papers [of Dr. Anderson, Exhibits 2008, 2013]—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.").

Obviousness is a question of law with underlying ***factual issues*** relating to the scope and content of the prior art, differences between the prior art and the claims at issue, the level of ordinary skill in the pertinent art, and any objective indicia of non-obviousness. *Randall Mfg. v. Rea*, 733 F.3d 1355,

1362 (Fed. Cir. 2013) (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406, 127 S. Ct. 1727, 167 L. Ed. 2d 705 (2007)).

Petitioner attacks the veracity of individual references but fails to distinctly point out any error the Board made in relying on them to define the scope and content of the prior art. Petitioner argues that the combination of teachings with regard to the manual survey chart of Carmichael and the look-up PID table of Anderson is impossible, such that these references do not meet the requirements of obviousness. (Pet brief 27-28). Petitioner advances a similar argument with regard to the combination of teachings of the manual survey chart of Carmichael and the device of Taube. *See* App.157a-168a at 3:9-4:15. (Federal Circuit Panel questioning whether the Board's determination of the accuracy and combination for the prior art documents is a factual issue). Additionally, Petitioner argues that the combinations of Carmichael and Anderson and Carmichael and Taube do not meet the requirements of obviousness because the combinations have no chance of success. (Pet. 27-28).

However, unsubstantiated conclusory accusations regarding factual issues involving combinations of prior art teachings and merely "[i]dentifying flaws in individual references does not defeat Hamilton's showing that both combinations relied on by the Board disclose, collectively, all the limitations of the challenged claims." App. 10a. *See Par Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014) (quoting *Alza Corp. v. Mylan Lab'ys, Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006))

("The presence or absence of a motivation to combine references in an obviousness determination is a ***question of fact***. The presence or absence of a reasonable expectation of success is also a ***question of fact***."). Here, Petitioner's arguments for contesting a reasonable expectation of success are based only on argument that is conclusory and contrary to the disclosure of the prior art (*see, e.g.,* App.62a-63a) and fail to address combinations relied upon by Hamilton. App.64a-65a. For example, the Board addressed Petitioner's contention (i.e., as Patent Owner) regarding the combining of teachings of the Taube and Carmichael documents. Petitioner, as Patent Owner, had asserted "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.' 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, [Hamilton] proposes to modify Taube's treatment regime to implement the treatment regime of Carmichael." App.65a. Petitioner never addressed this combination of prior art relied upon by Hamilton. App.65a-66a.

It is clear that Petitioner only seeks to relitigate questions of fact, all of which were properly evaluated by the Board and fully vetted by the Federal Circuit on appeal.

IV. PETITIONER FAILS TO IDENTIFY A COMPELLING REASON TO GRANT THIS PETITION.

A Petition for Writ of Certiorari is only granted for "compelling reasons." Those reasons include circuit conflicts and important unsettled questions of federal law. S. Ct. Rule 10. The US Supreme Court rarely grants a Petition for Writ of Certiorari when "the asserted error consists of erroneous factual findings." *Id.*

The case at bar does not present "compelling reasons." Petitioner's arguments do not implicate circuit conflicts or unsettled questions of federal law. The obviousness standard has been settled for over fifteen years in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007). Petitioner does not raise issues of law and fails to describe how any finding or holding is in conflict with the precedent of this Court or the Federal Circuit.

Petitioner's sole basis for appeal is a disagreement with how factual evidence was evaluated, weighed, and deemed to satisfy the substantial evidence standard in support of factual findings and legal conclusions rendered. The Petition relies exclusively on alleged factual errors, which the Supreme Court has stated are not sufficient to grant certiorari. In this case the judicial system functioned as intended. The Board as the fact finder addressed the exact factual issues that the Petitioner seeks to relitigate here, and those findings were held by the Federal Circuit to be grounded in substantial evidence.

V. CONCLUSION

For the foregoing reasons, the Petition for Writ of Certiorari should be denied.

Respectfully submitted,

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APPENDIX TABLE OF CONTENTS

APPENDIX A

[PLANET DEPOS COVER SHEET]

Transcript of Hearing

Date: June 7, 2023

Case: Tehrani -v- Hamilton Technologies

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HEARING IN THE MATTER OF
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P R O C E E D I N G S

JUDGE REYNA: This case is 22-1732, Tehrani versus Hamilton Technologies. Counselor Kendrick, you've asked for seven minutes for rebuttal; is that correct?

MR. KENDRICK: That's correct.

JUDGE REYNA: All right. We're ready when you are, sir.

MR. KENDRICK: Good morning, Your Honor, may it please the Court. My name, is Mark Robert Kendrick and I am representing Dr. Fleur Tehrani in this case 22-1732.

At issue in this appeal are claims 1 through 6, 9 through 12, 29 through 33, and 41 of U.S. Patents 7,802,571. Claims 1 and 29 are independent claims and the other claims at issue are dependent claims.

The patent covers the first fully automatic oxygenation and ventilation system. The oxygenation parameters, fraction of inspired oxygen, FIO2, and the end expiratory pressure, PEEP, are determined automatically every fraction of a second. For example, every 0.75 seconds as shown in Figure 3i of the patent, step 318 and appendix 85 --

JUDGE STARK: Mr. Kendrick –

MR. KENDRICK:-- or a [inaudible] --

JUDGE STARK: -- I -- I -- I think we're familiar with the technology from the briefing and the record. You raise 10 or l2 issues by my count, it's a lot of issues.

What do you think is your strongest issue?

MR. KENDRICK: The strongest issue is that the prior art documents that were cited against us, the Court errored in determining that they presented true information, as well as that they could be combined with the other reference, the se— -- second reference.

JUDGE STARK: On -- on the true information, I -- I saw there was an attack on the accuracy of certain -- of the prior art references.

Is that what you're referring to?

MR. KENDRICK: Yes. Accuracy.

JUDGE STARK: And isn't that inherently a fact question and -- and wasn't there substantial evidence for the Board to find that the references actually were reporting true information?

MR. KENDRICK: No, we don't believe there was substantial evidence for the Board to find that. Because if you look at the testimonies of Dr. Tehrani versus their testimonies, we don't believe there was substantial evidence.

JUDGE STARK: But I mean that just sounds inherently like something that is for the Board to

make fact findings on and they believed, you know, something different than you wanted them to believe.

Isn't that what the Board's there for?

MR. KENDRICK: The Board is there for that but we don't believe that they considered our arguments thoroughly enough because -- and didn't understand, potentially, the technology at issue as much as they should have been.

JUDGE REYNA: This is -- this perhaps a good point for me to make the following comment, which I wanted to address before we started argument.

In -- in your brief, you -- you used terms like baseless schemes that are made up by the Board. A double standard and fallacy implemented by the Board to -- to keep the petitioner's exhibits, etcetera.

And -- and this kind of -- this -- this tone that you have runs throughout your brief and I just want you to know, I find it to be disrespectful, discourteous and -- and not beneficial. It doesn't -- doesn't help your case at all to attack with labels the other side, especially the Board and -- and the decision.

Now, the decision may be wrong, it may be without a -- a basis or something of that nature, but the personal attacks is something that there's just simply no room for. Not only in this courtroom but in this profession.

MR. KENDRICK: Understood.

JUDGE REYNA: Thank you.

MR. KENDRICK: I understand, Your Honor, and I -- I take that under advisement.

JUDGE STOLL: Do you want to talk about specifics? For example, you said that your -- you think one of your strongest issues is that you don't think that the Board -- you think the Board -- there wasn't substantial evidence to support the Board's finding that the prior art taught what it purported to teach?

Do you want to say specifically why? Are you prepared to identify specific testimony today? Because that's -- you know, if you're talking about lack of substantial evidence, you -- you need to have specific cites and direct us to specific argument -- specific evidence.

MR. KENDRICK: Yeah. I -- I think because --

JUDGE STOLL: And it's not going to be enough just to cite to the evidence that supports you. You need to explain why the evidence that's contrary to your position should be disregarded.

MR. KENDRICK: Understood. And I will --

JUDGE STOLL: Okay.

MR. KENDRICK: -- attempt to do that as much as possible.

What -- when we look at the evidence that we

feel was not considered by the Board, first we can start with Carmichael. And Carmichael is a survey that is prepared, it was a number of physicians.

They took a -- they mailed in the survey and they talked about the different PEEP and FIO2 that they could use for automated ventilators. And most of those physicians -- I'm sorry -- most of those physicians or doctors utilized -- excuse me --

JUDGE STOLL: We are to [inaudible] -- we're familiar with the prior art, so we -- we have it all in front of us so if you want to get in just specifically what -- what Carmichael lacks.

MR. KENDRICK: Okay. So, what Carmichael lacks is, Carmichael doesn't talk about that you can determine a FIO2 or F— -- or PEEP for a [inaudible]. It doesn't talk about that in any way, shape or form. It's talking about an assist control ventilator.

Assist control ventilator on those what you do is you set the PEEP and you set the FIO2 initially and then you let it run and then basically you'll go on back and based upon the results later from 15 minutes to two hours in time, you will then change those settings to see if you can improve the oxygena— -- oxygenation parameters for the ventilator.

JUDGE STOLL: It's a manual setting of those two parameters?

MR. KENDRICK: Yes. Yes, that's one of the assist control. It also, when you look at Carmichael,

the one thing it talks about is it doesn't talk about keeping a ratio of PEEP to FIO2 within a specific range.

The argument that is made and if I -- if you look at Figure 7 of Carmichael, the argument is made that, oh, if you look at the highest PEEP versus the F- -- FIO2, that is where you can determine what the ratio is.

But if you look at that, you basically are looking at a -- Figure 7 is a chart that shows -- I want to make sure I say it correctly. It shows multiple values that can be utilized for each of the values of FIO2, multiple PEEP values.

And it even talks about the fact that the -- the typical best PEEP, which I believe is what the appellee mentioned before was, for example, for 0.5 was ll plus or minus 5 centimeters of H20 for PEEP, right. So, it's not really talking about a specific specified range. It's talking about a number of range.

For example, for 0.5 you could have multiple ratios: ll over 0.5, 9 over 0.5, 7 over 0.5 or 6 over 0.5. So, that's why we -- we don't believe that Carmichael teaches that part of the invention.

In addition, we don't believe, and this is overall with all of our arguments, we don't believe that you can take protocols, like it's what -- that's what they're referring to here where they're talking about different pairs of PEEP and FIO2 that you can do that and you can put that into an automated system, an automated

ventilator, because they just don't operate that way.

And specifically, that would bring me over to Anderson. Anderson is -- and really the key there -- there's Figure 2 in Anderson and then there's also Figure 7 in Anderson.

Figure 2 talks about the actual system construction of Anderson and I need -- I want to -- we believe Figure 2 of Anderson is wrong because of the fact that you can't have a PID control that's also utilizing the look—up table as part of the system because PID control is a negative feedback system and a negative feedback system provides -- requires complete control, meaning complete -- excuse me -- negative control.

And what you're not doing there, you can't, for every breath of the patient go up to the look—up table -- and the look—up table is shown in like Figure 3 -- and determine whether or not the term on or off PEEP, or FIO2. Okay. And then also --

JUDGE STARK: Can I ask you --

MR. KENDRICK: -- you can't --

JUDGE STARK: -- about Dr. Imbruce, that was their expert that you challenged; correct?

MR. KENDRICK: Yes. Yeah.

JUDGE STARK: Do you -- you argue, I think, that he was not a person of skill in the art but you did

not provide a definition of person of skill in the art, you agreed to their definition; is that right?

MR. KENDRICK: We agreed to their definition but their definition was -- I'm sorry.

JUDGE STARK: And -- and so which part of their definition does Dr. Imbruce not meet?

MR. KENDRICK: Any of them because he's not -- I believe there was an engineer, two different engineers of skill in the art or an engineer with a Master's Degree or clinician. We don't believe --

JUDGE STOLL: It's your per— --

MR. KENDRICK: -- that --

JUDGE STOLL: -- you -- you don't think he's a clinician?

MR. KENDRICK: No.

JUDGE STARK: But he -- but he was a clinician, some time ago, but he was a clinician; correct?

MR. KENDRICK: He -- he was a clinician 40 years ago but things have changed --

JUDGE STARK: Does the --

MR. KENDRICK: -- in the last 40 years.

JUDGE STARK: -- does the definition of person in the skill, say, they have to be a clinician more recently than 40 years ago?

MR. KENDRICK: Well, I think they have to understand the -- you know, we don't believe he had the knowledge regar— -- regarding automated ventilators --

JUDGE STARK: But do you --

MR. KENDRICK: -- you -- you need --

JUDGE STARK: -- but what makes him not within the definition of person of skill in the art, is it that lack of an engineering degree or is it that he's –

MR. KENDRICK: Well --

JUDGE STARK: -- not a clinician --

MR. KENDRICK: -- well --

JUDGE STARK: -- or both?

MR. KENDRICK: -- it's lack of an engineering degree but also we don't believe he's a clinician because he hasn't been a clinician in 40 years. He didn't renew his respiratory therapist certificate, and he doesn't really have the experience on these ventilators that you need to have in order to make his declaration.

JUDGE STOLL: Did the Board find that there

was -- that -- did the Board find that he was a person of ordinary skill in the art?

MR. KENDRICK: The -- the Board did, I -- I believe so. Yes. That he was a clinician.

JUDGE REYNA: In your view –

JUDGE STOLL: I'm sorry –

JUDGE REYNA: -- is that a factual finding? In your view.

MR. KENDRICK: I'm not the most experienced in this Court, I'll -- I'll tell you that. It's a factual I -- I believe they made a factual determination but I believe it was an error that they . The other –

JUDGE STOLL: I couldn't hear you. They made a finding of what? Could you repeat that?

MR. KENDRICK: Oh, and I said it was just an error. They -- that the factual determination they made was an error, that it was incorrect.

In addition, and again, I'm -- sh— -- should I keep going? I've gone over -- have I gone over my time or –

JUDGE STOLL: You're in your right time.

JUDGE REYNA: Yeah, you're still -- you still have a little bit of rebuttal time. You're into your time. You -- you want to finish now or –

MR. KENDRICK: I'll talk a little bit about --

JUDGE REYNA: -- go back?

MR. KENDRICK: -- Anderson and then I'll finish.

JUDGE REYNA: Okay. Great.

MR. KENDRICK: Figure 7 of Anderson is also really dispositive. Figure 7 shows that PEEP was not changed for 12 hours. Okay? It also shows that FIO2, if you look at FIO2 it starts out at 45, goes to 80, comes back down to -- I say 45 but it's between 45 and 50.

And that shows, again, that the ratio wasn't maintained, there was no ratio maintained because PEEP was going up and down what -- I'm sorry, FIO2 was going up and down like that and PEEP was staying the same.

You also, if you look at PEEP, if you're in -- if there was PID control of PEEP like it has been alleged in Anderson, then it would never stay the same for that long of st— -- it -- it wouldn't stay the same for minutes at a time, right, because that's just the way it is, but it would not stay for 12 hours which is what it said.

And even when it is changed, it's changed in a way where's it's stepped up and that clearly, to us, shows that it's a manual adjustment because it's not something that was ramped up, it was something that was stepped up.

JUDGE REYNA: Okay. Well, we thank you.

Now, Counselor Keane.

MR. KEANE: May it please the Court, Patrick Keane and co—counsel Matthew Fedowitz on behalf of the appellee Hamilton.

I have three quick points I'd like to make and then I will offer some comments in response to those of my friend on behalf of the appellant.

The three points I would like to begin with are, that there is substantial evidence for all of the Board's factual findings detailed throughout the final written decision which is at l to 69 of the appendix.

There was no error of law to the extent an error of law is -- is implicated, it's based on -- on factual underpinnings which are supported by substantial evidence.

And finally, the Board acted fully appropriately in the implementation and management of all of its rules. With those three points, the final written decision should be affirmed.

And now I'd like to offer a few comments on -- on some of the points that my friend addressed there. I - - they -- they are all factual issues as Your Honors seem to appreciate.

The Carmichael reference, which was referred to was the base reference used in a -- a ground that

was initially an anticipation ground that involved what were, in fact, automated ventilators. The ventilators have a

JUDGE STOLL: Can you --

MR. KEANE: -- computer --

JUDGE STOLL: -- can you explain why Figure 7 shows ratios? I think I understand why it is but could you explain?

MR. KEANE: Yes. Certainly, Your Honor.

Figure 7 is showing the -- the -- the limits on the oxygen, the FIO2 and the pressure, the positive end expiratory pressure. And the ratios are the slope, basically, of that curve.

And what the patent claim is directed to, is managing an automated ventilator so that for patient safety you don't exceed certain limits of PEEP and FIO2, that's what the PEEP ratio --

JUDGE STOLL: Is the idea that when you look at Figure 7 and you see there's a certain PEEP for a certain FIO2, like ranges, if you will, that that's what the ratios are, that that inherently shows, you know, for certain PEEP you'd have a certain FIO2, which itself is a ratio? Is that --

MR. KEANE: Well, Your --

JUDGE STOLL: -- how I understand --

MR. KEANE: Honor --

JUDGE STOLL: -- that?

MR. KEANE: -- the -- the --

JUDGE STOLL: Or I --

MR. KEANE: claim talks about --

JUDGE STOLL: -- am misunderstanding?

MR. KEANE: I'm sorry.

JUDGE STOLL: I'm just talking about the prior art --

MR. KEANE: Yes.

JUDGE STOLL: -- not the claim, but Carmichael, what --

MR. KEANE: Yeah.

JUDGE STOLL: -- Carmichael teaches.

MR. KEANE: Well, it does -- what Carmichael shows is a boundary, a limit on what the PEEP can be, as you're indicating, and a boundary on what the FIO2 can be. So, for patient safety, they can -- neither of those ranges can be exceeded so for a certain FIO2, PEEP can only be so high.

For another -- FIO2 PEEP can only be so high.

So PEEP is restricted to something like .6 millimeters of hemoglobin, I think was the -- was the number; I don't have it right in front of me but PEEP is limited. And, so -- and PEEP's the pressure. You can't allow that pressure to exceed certain limits where you could damage a patient's lungs.

So what the chart is showing is that we're going to allow therapy to continue until PEEP is at a certain limit and if we're not achieving a desired level of therapy, we're going to adjust the amount of oxygen and then incrementally move the pressure to push that oxygen into the patient.

But nevertheless we're going to observe limits and the limits are relative to PEEP and the FIO2 limits are demonstrated by the slope of that curve.

JUDGE STOLL: Thank you.

JUDGE STARK: The appellant says there's no reference to automatic in Carmichael. Is that true and is that a problem for your obviousness contention?

MR. KEANE: It's not a problem. What is mentioned in -- I think what my friend's definition of automatic is, is something like a fully automatic and what -- what Carmichael was -- was de— -- was using were automated ventilators that had computers in them to perform this assist control whereas I think Your Honor's noted you could set a -- an adjustment.

You could set an FIO2 or a PEEP and then the automated ventilator would with a computer perform

to that set level.

So, there was automation and there was automation -- Carmichael was -- was -- was being used at the time to develop what would be appropriate limits for PEEP and FIO2. And, so, it was using existing ventilators.

And some of those existing ventilators were in the prior art that we relied upon such as, you know, our earlier grounds, the Wasel patent was an existing fully automated ventilator that most likely was used by Carmichael, by the phy— -- by the clinicians in Carmichael to run those tests, but it just didn't say it and the Board said, we want to see the actual structural characteristics of a ventilator in -- in a reference.

And that's what why we brought in our grounds three and four that, with substantial evidence the Board said, yes, we see the application of an automated ventilator around -- you know, using these clinically derived limits for PEEP and FIO2 and simply programming the automated ventilators of an Anderson or in ground three it worked [inaudible] and ground four to provide patient therapy around the limits of PEEP and FIO2 that are announced in Carmichael.

My friend did mention Anderson presented untrue data and that you couldn't use a look—up table with -- with PID control. PID being proportional integral derivative control.

Of course, the -- that was fully vetted before the Board and the Board found substantial evidence to support its finding that, in fact, PID could be used with a look-up table in an exactly similar fashion as to what the patent disclosed using loop indicators to set different types of therapy.

So, it's not a question of going back and forth to a look—up table every breath. At every breath the computer can look at what the parameters are, the settings for the PEEP and the FIO2 and it can see if they're within the limits of what the look-up table says they should be.

But the actual continuous control is through the PID controller to the -- to the ventilator. So, the Board found that you -- that -- that look-up tables could be used with PID control.

The third point I would address is -- and -- and Judge Stark mentioned the -- the qualifications of Dr. Imbruce as a POSITA and the Board did find that -- that Dr. Imbruce had been a practicing clinician at the time -- at the relevant time that this patent was developed.

JUDGE STOLL: Do you think that the Board -- we -- we have some case law like Kirasera [ph] for example or Sundance that says that for somebody to testify on an issue that is viewed from the perspective of a person of ordinary skill in the art, like say obviousness, that they have to actually be a person of ordinary skill in the art. Do you think the Board followed that case law?

MR. KEANE: I mean, absolutely. I would say that the Board vetted Dr. Imbruce' credentials as a clinician who had experience in developing, designing, producing. I believe he was involved in the development of a major ventilator for a -- a well-known international company.

So, he had experience in the design of ventilators and in the application of therapy to those, such as PEEP and FIO2 limits. So, it's certainly his clin— -- clinical experience in the relevant time period when he was familiar with the ventilators, the automated ventilators that existed at the time, such as Anderson's and how qualified as -- him as a POSITA.

Does that –

JUDGE STOLL: It does. I -- I -- I -- there are some -- the Board never says, per— -- he is a person of ordinary skill in the art. So, should I be concerned about that?

MR . KEANE: I --

JUDGE STOLL: It -- it -- I mean, you can look at where it never uses that exact phraseology. The question would be whether they in fact said he was a person of ordinary skill in the art by going through the definition of a person of ordinary skill in the art.

MR. KEANE: I thought -- I -- I believe that and I -- we can check our -- our -- the final written decision, but I was confident that the Board did say we consider him to be a person of skill in the art and we don't

accept my friend's assertions at the time during the process of the IPR that -- that Dr. Imbruce did not so qualify.

And -- and I would add also that because of the accusations that were made on the Anderson paper, we -- we went out and questioned Dr. Anderson and actually brought him in as a witness to substantiate things that Dr. Imbruce was saying about the application of therapy, a treatment FIO2 and PEEP ratios to automated ventilators and Dr. Anderson supported Dr. Imbruce and Dr. Imbruce supported Dr. Anderson, so we had counter—bailinq declarations to support the -- what Dr. Ruse [ph] was saying was in fact true and accurate. And --

JUDGE REYNA: Was -- was the issue of a person in the skill in the art was that actually in dispute [inaudible]?

MR. KEANE: I think what was a dispute was whether -- was the accuracy of statements made by Dr. Imbruce to which one way we addressed that was to have Dr. Anderson testify --

JUDGE REYNA: [inaudible] --

MR. KEANE: -- and s— -- and -- and his -- and -- and the support of those two declarations in tandem I think the Board found compelling, but there was no reason, really, to question Dr. Imbruce's qualifications because he squarely met the first prong of the POSITA as it was defined and agreed upon by the parties, which was someone who had at least five years of

experience in clinical therapy with ventilators.

And he not only had that, he had something like l0 years and he had been involved in the design and he had patents, so he was familiar with the patent process and so forth. So, he was more than qualified, I would say.

JUDGE STARK: But whether -- whether he was a person of skill in the art I think was put in dispute and like Judge Stoll, I'm not seeing where the Board made an express finding that he was one of skill in the art, notwithstanding both counsel telling us that there was such a finding.

I haven't found it yet. If that's how we see the record, is that a harmless error or what do we do? That is if we say there was a dispute over whether Dr. Imbruce was a person of skill in the art and the Board didn't make an express finding on it, what -- what do we do?

MR. KEANE: Well, I -- I think that the -- the Board found on its own that the -- the references taught the invention as claimed and I think that they felt very compelling evidence was -- [whispering in background, inaudible]

MR. KEANE: -- what the -- what the -- the Board found very compelling was Dr. Anderson's testimony about his -- his ventilator.

And I would add that Dr. Anderson's testimony did go to the application of the limits that were

described in the Carmichael reference to the ventilator that Anderson was actually running in a full— -- fully automated continuous ventilator therapy mode.

For example, the look-up tables that were in -- I'm sorry, not -- yeah, I think it was the look-up -- there was -- there is a figure in Anderson -- and I don't have it right in front of me -- but where he does show that you could choose different treatment therapies and he -- and he talked about boundaries that aligned with those of -- of Carmichael.

So, if -- yeah, I -- I would say to that extent, it is harmless but I -- but I do also think that the Board repeatedly recognized the weight that it would attribute to Dr. Imbruce's testimony and that appears in their final written decision at Appendix 13 where they talked about the weight to give Dr. Imbruce's testimony and concluded that we do not agree that -- with patent owner that Dr. Imbruce's testimony should be dis— -- disregarded.

And, so, if not nearly expressed, that's a very implicit statement that we consider his testimony, the veracity of his testimony to be high and reliable in terms of comments he made with regard to the grounds that were used for supporting a -- a finding that -- that -- that the challenge [inaudible] were not patentable.

So the last point I would like to address is the response, again, to Dr. Anderson's Figure 7. And there was a comment in there about how it must be manual but, again, the Board evaluated Dr. Anderson's

disclosures in light of Dr. Anderson's testimony and found it to be accurate and -- and reliable and therefore the interpretations that the Board relied upon in its findings and the substantial evidence that it attributed in the form of Dr. Anderson's declaration were compelling for its conclusion that both grounds -- well, ground three involving Dr. -- Dr. Anderson's paper rendered the claims unpatentable.

And with that I -- I have nothing more to say. If you have any questions -- other questions, I'd be happy to answer.

JUDGE REYNA: We -- we thank you, Attorney Keane for your --

MR. KEANE: Thank you, Your Honors.

JUDGE REYNA: Mr. Kendrick, I'm going to restore you to three minutes of time since you covered -- I do caution you to -- to limit your comments to the -- the points raised by the other side.

MR. KENDRICK: Absolutely. In regards to the accuracy of Dr. Imbruce's testimony and the weight that was poured to it, I mean one of the things that we also looked at was what -- he didn't disclose certain things in his CV that, you know, I've seen before in a CV like whether or not he had been an expert before, which he had.

And then during deposition he talked about that he worked on Siemens' ventilators -- automated ventilators and that wasn't in his CV also. So, that was

one of the other things why we believe that Dr. Tehrani is -- that her testimony should be given more weight than what --

JUDGE STOLL: Hard for us in an appellant court to decide how much weight to give to different witnesses' testimony, right --

MR. KENDRICK: Mm-hmm.

JUDGE STOLL: -- that's really something for the trial court, the lower court to decide --

MR. KENDRICK: Mm-hmm.

JUDGE STOLL: -- why would we be deciding that?

MR. KENDRICK: Just -- because I -- I just think they made an error when they made that determination, they didn't look at all the facts.

With regard to Dr. Anderson, yes, he is a doctor. He's a doctor in regards to engineering. He's not necessarily a clinician who worked on the Anderson case.

We believe that also there's certain things that, you know -- one of the things is when you have a device that's being utilized on patients and it's automatic, you do have to get FDA approval and he -- well, he said he thought they had FDA approval, there was no affirmative or definitive statement that it was on -- excuse me -- that there was FDA approval with

regards to that.

We also just don't believe he has the background in terms of automated ventilators that needs -- he would need to be -- have in order to provide such a statement.

JUDGE STOLL: One of the things that you see in that uncontested definition of what a person of ordinary skill in the art is there's a sentence at the end that says, "A higher level of education or a specific skill might compensate for less experience and vice versa."

How does that play into it? Doesn't that give a little bit of wiggle room at least with respect to whether he was a clinician with at least five years of practical clinical ventilator experience, for example?

MR. KENDRICK: Is -- is this for Dr. Anderson or Dr. Imbruce?

JUDGE STOLL: For the expert on which you are challenging whether he was a person of ordinary skill in the art [inaudible] --

MR. KENDRICK: Aww, for Dr. Imbruce —

JUDGE STOLL: Dr. Imbruce.

MR. KENDRICK: Yeah, I -- I just don't believe his education applies over to the technology that we're looking at, the automated ventilators for a next breath of a patient. So, that's why it's my opinion that his

testimony shouldn't be heard.

The last thing I did want to make, there was not a discussion of any ventilators in Carmichael, so to make a statement like that these other ventilators that exist at the time that they were utilized in Carmichael, that's just -- we don't believe an accurate statement and really overall there's ju— -- the prior art doesn't show that PEEP and FIO2 are controlled for a next breath, automatically controlled for next breath.

So, based upon that, we would ask the Court to reverse the Board's decision, we're respectfully requesting the Court to reverse the Board's decision.

JUDGE REYNA: Okay. Thank you.

MR. KENDRICK: Thank you.

JUDGE REYNA: We -- we thank the parties for their arguments. This case will be taken under advisement.

CERTIFICATE OF TRANSCRIBER

I, Chris Naaden, a transcriber, hereby declare under penalty of perjury that to the best of my ability from the audio recordings and supporting information; and that I am neither counsel for, related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome, the above 31 pages contain a full, true and correct transcription of the tape-recording that I received regarding the event listed on the caption on page 1.

I further declare that I have no interest in the event of the action.

/s/_____

December 18, 2023
Chris Naaden

(519131, Tehrani v. Hamilton Technologies, 6-7-23)