NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

FLEUR TEHRANI,
Appellant

v.

HAMILTON TECHNOLOGIES LLC,
Appellee

2022-1732

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2020-01199.

Decided: June 28, 2023

MARK ROBERT KENDRICK, Kendrick Intellectual Property Law, Sherman Oaks, CA, argued for appellant.

PATRICK C. KEANE, Buchanan Ingersoll & Rooney PC, Alexandria, VA, argued for appellee. Also represented by MATTHEW L. FEDOWITZ, Washington, DC; RALPH GEORGE FISCHER, Pittsburgh, PA.

Before REYNA, STOLL, and STARK, *Circuit Judges*.

STARK, *Circuit Judge*.

Dr. Fleur Tehrani invented and owns U.S. Patent No. 7,802,571 (the "'571 patent"). Hamilton Technologies LLC ("Hamilton"), a licensee of another of Dr. Tehrani's patents, petitioned for *inter partes* review ("IPR") of the '571 patent. The Patent and Trial Appeal Board ("Board") instituted an IPR and ultimately concluded that claims 1-6, 9-12, 29-33, and 41 of the '571 patent were invalid as obvious. *Hamilton Techs. LLC v. Tehrani*, IPR2020-01199, 2021 WL 6339598 (P.T.A.B. 2021), J.A. 1-69. Dr. Tehrani sought Director review, which was denied. She then timely appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A). We affirm.

I

The '571 patent, entitled "Method and Apparatus for Controlling a Ventilator," 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." '571 patent 1:20-23. The method and apparatus includes a "first means" comprising "a programmable microprocessor" controlled by "a software algorithm" that operates on input data, such as respiratory mechanics, pressure-volume data, and the patient's measured carbon dioxide levels, to provide "digital output data to control the ventilator and the gas mixer of the ventilator." *Id.* at 2:43-54. The software algorithm includes a proportional, integral, derivative ("PID") control program which "is designed to automatically adjust" the fraction of inspired oxygen in a patient's inspiratory gas ("F_{IO2}") and the patient's Positive End-Expiratory Pressure ("PEEP") "based on at least the measured oxygen levels of the patient." *Id.* at 2:54-57. "The processing means detects hazardous conditions based on the input data and/or artifacts, replaces and/or corrects the measurement artifacts, and instructs generation of appropriate warning signals."

Id. at 2:60-63. The subsequent output data is then transmitted through the second means "to a Signal Generator which is equipped with converters and/or other electronic components to generate the control and appropriate warning signals," which are then supplied to the ventilator or a mixer regulator unit to adjust the concentration of oxygen. *Id.* at 3:5-17.

Figures 3a-i of the '571 patent show a flowchart describing the software algorithm's process. The first loop begins after establishing initial values of F_{IO2} and PEEP, desired set points for arterial partial pressure of oxygen, threshold values for arterial hemoglobin oxygen saturation ("S_{pO2}"), and a loop indicator. *Id.* at 7:47-8:25. The patient's S_{pO2} data is input and used to calculate the arterial partial pressure of oxygen, which is then compared to a minimum acceptable value. *Id.* at 8:26-44. If the value is greater than or equal to the minimum acceptable value, the value is accepted; otherwise, an alarm is generated. *Id.* at 8:45-52. The subsequent steps control F_{IO2}, either with a rapid stepwise control scheme for fast declines in S_{pO2} or a finely controlled PID algorithm. *Id.* at 10:16-23. After F_{IO2} is determined, the protocol then calculates the ratio of PEEP/F_{IO2}. *Id.* at 10:43-45. If the ratio is not within a clinically acceptable range, the PEEP is increased or decreased by a fixed increment over a fixed period, followed by observation and measure of any change in PEEP on the patient's oxygenation. *Id.* at 11:48-60.

Of the challenged claims, claims 1 and 29 are independent. Claim 1, which is directed to an apparatus, is illustrative and 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.

Id. at 12:49-13:3. Claim 29 is directed to a method for automatically controlling a ventilator with steps like those recited in claim 1. *Id.* at 15:15-31.

II

The Board concluded that the claims were invalid as obvious on two grounds: (1) a combination of Carmichael, Anderson, Dr. Tehrani's U.S. Patent No. 4,986,268 (the

"'268 patent"), and Rossi,[1] and (2) a combination of Taube, Carmichael, ARDSNET, Clemmer, and Rossi.[2]

Dr. Tehrani raises a dozen issues on appeal. None has merit and only a few warrant discussion.

Dr. Tehrani argues that the Board should not have credited Hamilton's expert, Dr. Richard Imbruce, because he is "a) not a respiratory therapist, b) none of his listed patents [are] on mechanical ventilation, and c) he was disqualified in another case for offering expert testimony on a subject he was not familiar with." Appellant's Br. at 34. Dr. Tehrani also claims that Dr. Imbruce is not a person having ordinary skill in the art. *Id.* at 35. We review the Board's determinations as to what weight to accord expert testimony for abuse of discretion. *See Shoes by Firebug LLC v. Stride Rite Children's Grp., LLC*, 962 F.3d 1362, 1372 (Fed. Cir. 2020).

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[1] Laurence C. Carmichael et al., *Diagnosis and Therapy of Acute Respiratory Distress Syndrome in Adults: An International Survey*, 11 J. Critical Care 9 (March 1996) ("Carmichael"); Jeffrey R. Anderson & Thomas D. East., *A Closed-Loop Controller for Mechanical Ventilation of Patients with ARDS*, 38 Biomedical Scis. Instrumentation Symposium 289 (2002) ("Anderson"); A. Rossi, *Intrinsic Positive End-Expiratory Pressure ($PEEP_i$)*, 21 Intensive Care Med. 522 (1995) ("Rossi").

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

The Board did not abuse its discretion. As the Board explained, Dr. Imbruce has decades of experience with ventilator devices and portable oxygen generators, including developing clinical protocols for new modalities in artificial ventilation and oxygen delivery therapies for hemorrhagic shock in wounded soldiers. Dr. Imbruce is an inventor on two patents related to a portable oxygen generator for emergency use, has worked in industry related to oxygen delivery and artificial ventilation since 1981, and has at least eleven years of clinical experience in pulmonary function and respiratory therapy. The Board found Dr. Imbruce's testimony "adequate," J.A. 14, and it was free to do so.

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.[3]

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[3] At oral argument, Dr. Tehrani's counsel emphasized that Dr. Imbruce's clinical experience occurred more than 40 years ago. Oral Arg. at 9:44-10:29. 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. Issues 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 issues do not render his opinions unreliable.

Dr. Tehrani also contends that the Board should have construed the claim term "for a next breath of the patient" as controlling PEEP and F_{IO2} 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 Petitioner's claim construction." J.A. 35-36 n.11. The Board had substantial evidence for this finding. *See, e.g.*, J.A. 1114-15, 1118 (Anderson stating "[t]he computer constantly reads important [input] information" to "continuously control[] FiO2 and PEEP" and disclosing graph showing changes in F_{IO2} and PEEP over time); J.A. 446 ('268 patent teaching "controlling a respirator" based on input data and "provid[ing] digital output data representing the amount and optimum frequency of ventilation required for the next breath"). In combination, the prior art teaches that F_{IO2} and PEEP can be controlled for an immediate next breath or a later breath, satisfying both parties' competing constructions.

There is no basis for us to find the Board abused its discretion in the weight it placed on this witness' testimony.

Most of Dr. Tehrani's remaining arguments challenge the Board's factual findings, which we review for substantial evidence. "Obviousness under 35 U.S.C. § 103 is a mixed question of law and fact. We review the Board's ultimate obviousness determination de novo and underlying fact-findings for substantial evidence." *Hologic, Inc. v. Smith & Nephew, Inc.*, 884 F.3d 1357, 1361 (Fed. Cir. 2018). Two examples are sufficient to illustrate the lack of merit in Dr. Tehrani's contentions on appeal.

Dr. Tehrani argues that Anderson's use of look up tables contradicts the '571 patent's PID control and, further, that Carmichael does not teach the use of an automatic ventilator and a ratio of PEEP/F_{IO2}. Oral Arg. at 5:06-7:18, 7:48-8:57. Substantial evidence supports the Board's finding 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 [(Acute Respiratory Distress Syndrome)] patients." J.A. 37. As Dr. Imbruce explained, the combination of Anderson and Carmichael, along with the '268 patent and Rossi, teaches every challenged limitation of the '571 patent. In particular, Anderson teaches a "closed-loop control system," using an oxygenation sensor and computer to use a "traditional proportional-integral-derivative (PID) approach" to "continuously control[] F_{IO2} and PEEP settings on a Hamilton Amadeus ventilator." J.A. 1114. Substantial evidence, including Dr. Imbruce's second declaration, also 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 [F_{IO2}] settings.'" J.A. 30 (quoting J.A. 1116 (Anderson)). Anderson uses "[F_{IO2}] and PEEP PID controllers that calculate the amount of therapy adjustment." J.A. 1116. Anderson's look-up tables serve the same function as the '571 patent's loop indicators, defining the logic that

determines if and when PID controllers change F_{IO2} and PEEP. J.A. 31, 2715; '571 patent 8:23-25.

The Board also had substantial evidence to conclude that Carmichael teaches a treatment protocol of increasing F_{IO2} and incrementally changing PEEP and using the relationship between F_{IO2} and PEEP to achieve the desired oxygen saturation level within a prescribed range, as depicted below in Carmichael's Figure 7. J.A. 26-27, 29, 422 (illustrating maximum acceptable PEEP used at each F_{IO2} level); *see also* J.A. 215-17 ("Carmichael discloses a desired oxygen level of a patient 'should be achieved through the use of increased [F_{IO2}] and incremental application of PEEP.") (quoting J.A. 423-24). The slope in Figure 7 indicates the limits of the relationship between F_{IO2} and PEEP. *See* Oral Arg. at 14:30-16:19; *see also* J.A. 29 ("Figure 7 of Carmichael shows that the maximum level of acceptable PEEP increased as the F_{IO2} level increased.").

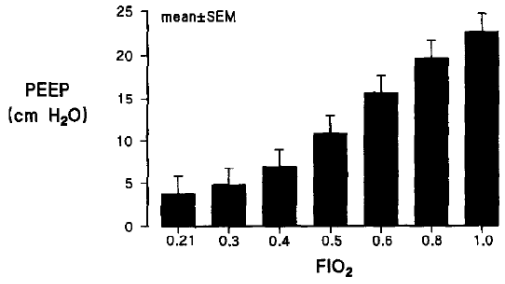

Fig 7. The maximum PEEP used at various FIO_2s.

J.A. 422 (Carmichael Fig. 7).

Many of Dr. Tehrani's arguments are directed to pointing out limitations that are not present in individual prior art references, but what matters is what the combination of references collectively contain, not what they individually contain or lack. *See Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1380 (Fed. Cir. 2023) (explaining courts "'look to interrelated teachings of multiple patents'")

(quoting *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)). Identifying 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.

III

We have considered Dr. Tehrani's remaining arguments and find them unpersuasive. For the foregoing reasons, we affirm.

AFFIRMED