United States Court of Appeals for the Federal Circuit

02-1177, -1178, -1227

FLEUR T. TEHRANI, Ph.D., P.E.,

Plaintiff-Appellee,

v.

HAMILTON MEDICAL, INC. and HAMILTON MEDICAL, A.G.,

Defendants-Appellants.

Kenneth R. O'Rourke, O'Melvney & Myers LLP, of Los Angeles, California, argued for plaintiff-appellee. With him on the brief were Mark C. Scarsi, Todd Fitzsimmons, and John Tehranian, O'Melvney & Myers LLP, of Newport Beach, California.

Pamela Banner Krupka, Banner & Witcoff, LTD, of Washington, DC, argued for defendants-appellants. With her on the brief were Bradley C. Wright, and Thomas L. Stoll.

Appealed from: United States District Court for the Central District of California

Judge Gary L. Taylor

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DECIDED: June 13, 2003

Before MAYER, Chief Judge, NEWMAN, and BRYSON, Circuit Judges.

BRYSON, Circuit Judge.

Hamilton Medical, Inc., and Hamilton Medical, A.G., (collectively, "Hamilton") appeal from a final judgment entered by the United States District Court for the Central District of California in a patent case. The appeal focuses on the district court's grant of summary judgment of infringement to Dr. Fleur T. Tehrani, the owner of U.S. Patent No. 4,986,268 ("the '268 patent"). We vacate and remand.

I

The '268 patent relates to an apparatus and method for automatically controlling a respirator used for mechanical ventilation of a patient who needs assistance in breathing. The claimed apparatus controls the number of breaths delivered to the patient per minute (breath frequency) and the volume of gas delivered with each breath (tidal volume or ventilation). The apparatus calculates the proper breath frequency and tidal volume based on data representing at least five factors: air viscosity in the lungs, lung elastance, barometric pressure, oxygen level of the patient, and carbon dioxide level of the patient.

The two independent claims of the '268 patent provide as follows:

1. In a respirator for varying tidal volume and frequency of breaths of a patient, an apparatus for automatically controlling the respirator comprising:

first means for processing data representing at least air viscosity factor in lungs of the patient, barometric pressure, lung elastance factor of the patient and measured levels of carbon dioxide and oxygen levels of the patient, and for providing, based upon said data, digital output data indicative of required ventilation and optimum frequency for a next breath of the patient;

second means operatively coupled to the first means for converting the digital output data to analog data; and,

third means operatively coupled to the second means and to the respirator for converting the analog data to timing and control signals and supplying the timing and control signals to the respirator, the timing and control signals automatically and variably controlling the tidal volume and frequency of inhaled gas provided to the patient by the respirator based upon actual ventilation and breathing frequency requirements of the patient as determined by the first means.

16. In a respirator for varying tidal volume and frequency of breaths of a patient, a method of automatically controlling the respirator comprising the steps of:

(a) measuring levels of carbon dioxide and oxygen of the patient and providing a first pair of data signals indicative of the same;

(b) providing data indicative of at least the patients' lung elastance factor, air viscosity factor in the lungs and barometric pressure;

(c) determining from said first pair of data signals and from the data provided in step (b) the required ventilation and breathing frequency for a next breath of the patient and providing a second pair of data signals indicative of the same; and,

(d) providing, based upon said second pair of data signals, final data signals for automatically and variably controlling the ventilation and breathing frequency of the respirator based upon actual ventilation and breathing frequency requirements of the patient as determined in step (c).

'268 patent, col. 11, ll. 18-41; col. 12, ll. 45-64.

The written description of the '268 patent describes the preferred embodiment in some detail. Oxygen and carbon dioxide sensors detect the levels of those gases in the patient and send data signals to an analog-to-digital converter. From the converter the data is sent to a digital processor, also known as the controller, which includes a microcomputer that uses an algorithm to determine the values for tidal volume and breath frequency based on the carbon dioxide and oxygen data signals and the data for lung elastance, barometric pressure, and air viscosity. Specifically, the data values for carbon dioxide and oxygen in the patient are used in conjunction with the value for barometric pressure to calculate the partial pressures of carbon dioxide and oxygen. Those partial pressures are then used to calculate the dead space volume, which in turn is used to calculate the target values for tidal volume and breath frequency. The controller produces digital signals for those target values, which are converted to analog signals and then sent to a signal generator and timing control circuit. That circuit then transmits appropriate signals to control the opening and closing of valves in the respirator.

Dr. Tehrani charged Hamilton with infringing claims 1 and 16 of the '268 patent through the manufacture and sale of its Galileo ventilators. The Galileo ventilator allegedly infringes when operating in Adaptive Support Ventilation ("ASV") mode, a setting in which the device evaluates the patient's breathing effort. If there is no detected breathing effort, the device provides full mechanical ventilation, but if there is some patient effort, the device supplements that effort to achieve the target ventilation. The Galileo operator's manual explains that "[t]he target breathing pattern (tidal volume and rate) is calculated using Otis' equation, based on the assumption that the optimal breath pattern results in the least work of breathing, and hence also in the least amount of ventilator-applied inspiratory pressure when the patient is passive." Otis's equation is an algorithm for calculating the tidal volume and frequency of breaths needed to provide proper gas exchange in humans.

The operator of a Galileo ventilator in ASV mode uses keys and knobs to input the patient's ideal body weight (based on height), the desired positive end expiratory pressure ("PEEP"), and the desired concentration level of inspired oxygen. The PEEP setting on the Galileo ventilator causes the device to apply a selected positive pressure to the patient's lungs in order to stabilize the alveoli in the lungs during exhalation and to keep them open during the entire ventilation cycle. The oxygen concentration setting affects only the oxygen concentration in the inspired gas; it does not affect the volume of the gas delivered or the frequency of breaths.

The operator of the Galileo ventilator can also select a setting for percent minute volume ("%MinVol"), which allows the device either to provide full ventilatory support or, at lesser values, to encourage spontaneous breathing by the patient. When the %MinVol control is set at 100 percent, the ventilator delivers 100 milliliters of air per minute per kilogram of weight to an adult patient.

The Galileo device contains no sensor to measure the oxygen or carbon dioxide levels in the patient's blood or expired gas. Rather, the operator of the device is expected to measure the patient's levels of oxygen and carbon dioxide manually. If the patient's blood gas levels are not within the desired ranges, the operator can affect those levels by adjusting one of the input settings described above—either PEEP, oxygen concentration, or %MinVol. The Galileo operator's manual suggests that if the patient's carbon dioxide level is high, the %MinVol setting can be increased; if the carbon dioxide level is low, the % MinVol setting can be decreased. If the patient's oxygen level is low, the manual suggests increasing the PEEP setting or the oxygen concentration level.

In the Galileo device, the expired gas from the patient travels through a flow sensor, which contains a membrane allowing bi-directional flow through an orifice. The sensor measures the flow, volume, and pressure of the gases passing through the patient's airway. According to the Galileo operator's manual, those values are used to calculate the expiratory time constant ("RCexp"). The expiratory time constant indicates the patient's ability to exhale. It is described as the product of compliance and resistance. Compliance refers to the distensibility of the lungs, i.e., the change in volume resulting from a given change in pressure. Resistance is the opposition to flow caused by the forces of friction. According to the Galileo operator's manual, those features of lung mechanics affect the proper tidal volume and breath frequency for a particular patient.

Once the operator has entered the patient's ideal body weight and selected the percent minute volume of gas, the Galileo ventilator in ASV mode uses those inputs, in addition to the data from the flow sensor, to calculate the target tidal volume and breath frequency. The ventilator then implements those target values by adjusting the inspiratory gas pressure and breathing rate. Both the calculation of the target values and the adjustments necessary to reach those values are performed by a microprocessor, which controls a servo valve that delivers the required volumes of air to the patient.

In its order granting Dr. Tehrani's summary judgment motion, the district court analyzed whether the Galileo device satisfied the limitation in claim 1 of a "means for processing data representing . . . measured levels of carbon dioxide and oxygen levels of the patient" and concluded that the Galileo ventilator "appears to provide" that means. Based on the Galileo operator's manual, the court concluded that the %MinVol setting provided a means for processing data representing measured levels of carbon dioxide of the patient and that the patient's ideal body weight provided an initial representation of the patient's carbon dioxide level. The court stated that "[a]lthough the %MinVol dial may not represent the actual carbon dioxide level, carbon dioxide must be measured by some means for proper operation of the Galileo Ventilator, and the dial is adjusted accordingly." The court relied on the operator-controlled oxygen concentration and PEEP settings in the Galileo device to satisfy the limitation regarding the processing of data representing the oxygen level of the patient. The court stated that, during operation of the device, "a patient's blood oxygen level is measured, and the measured value is used to adjust the oxygen concentration which is then processed by the device." The court added that the Galileo operator's manual instructs operators to measure the patient's oxygen level and adjust the PEEP and/or oxygen setting if the oxygen level is too low or too high. The court then concluded, "In sum, the Operator's Manual can be read to show both the Galileo Ventilator's inhalation and exhalation monitoring of a patient's gas levels, which, if true, would read on the first clause of Claim 1 of the '268 Patent."

With respect to the "means for processing data representing . . . barometric pressure" limitation of claim 1, the district court found that the Galileo ventilator clearly satisfied that limitation. The court noted that a portion of the Galileo operator's manual states that the servo valve of the device must be adjusted for altitude and provides a table to calibrate the valve based on altitude. The court also stated that the Galileo ventilator uses an oxygen sensor, which measures the ratio of the patient's inspired partial pressure of oxygen to the barometric pressure. Based on that information, the court concluded that "[i]n order for the device to be calibrated, there must be some input or adjustment of barometric or atmospheric pressure in the Galileo Ventilator." The court also rejected Hamilton's contention that the calibration of the servo valve is not data processed by the microprocessor and is not part of the algorithm that controls tidal volume and breath frequency. The court ruled that the "adjustment of the servo valve is itself an input of information which is processed by the device."

With respect to claim 16, the court stated that "[t]he same arguments for the claim limitation as discussed above hold true." The court added that "the %MinVol, oxygen level and PEEP/CPAP dials . . . are representative of the adjustment of the carbon dioxide and oxygen levels of the patient." Based on those conclusions, the court granted summary judgment of infringement as to claim 16 as well.

A jury trial was held on damages. At the conclusion of trial, the jury determined that Hamilton Medical, Inc.'s infringement was willful, but it was unable to resolve whether Hamilton Medical, A.G., also acted willfully. The district court then issued a permanent injunction against Hamilton and awarded damages of approximately $1,480,000, plus approximately $1,000,000 in attorney fees and costs.

II

Hamilton argues that the district court erred in its claim construction in several respects and that the order of summary judgment must be reversed for that reason.

A

Hamilton first argues that the claims require the use of each of the five specified data values to calculate tidal volume and breath frequency. Although the district court did not explicitly adopt that claim construction, we agree that the claims must be construed to require that the device first process the five data values and then use those data values to calculate tidal volume and breath frequency. Claim 1 requires a "means for processing data representing at least air viscosity factor in lungs of the patient, barometric pressure, lung elastance factor of the patient and measured levels of carbon dioxide and oxygen levels of the patient, and for providing, based upon said data, digital output data indicative of required ventilation and optimum frequency for a next breath of the patient." Claim 16, in turn, includes steps for providing a pair of data signals indicative of carbon dioxide and oxygen levels and data indicative of at least the lung elastance factor, air viscosity factor, and barometric pressure and then "determining from said first pair of data signals and from the data provided" the ventilation and breath frequency. The claim language makes it clear that all five data values must be used to determine the ventilation and breath frequency output, a point that is confirmed by the specification and the prosecution history. As Dr. Tehrani advised the examiner during prosecution, "The novelty of the present invention lies in its use of all of the data recited in claims 1 and 16 in determining the ventilation and breathing frequency for a patient." Therefore, for purposes of infringement analysis, all of the data must be processed by the device and used to formulate the output.

B

Hamilton next argues that the court failed to set forth its construction of the terms "representing," "indicative of," and "of the patient." Claim 1 requires means for processing data "representing . . . measured levels of carbon dioxide and oxygen levels of the patient." Claim 16 requires the step of "measuring levels of carbon dioxide and oxygen of the patient and providing a first pair of data signals indicative of the same." Dr. Tehrani responds that the court defined the first two terms according to their ordinary meanings and that the meaning of the third term "of the patient" was not in dispute and therefore did not require construction.

Both sides rely on dictionary definitions of the term "representing." Hamilton argues that "representing" should be construed to mean "equivalent to," and that Dr. Tehrani used the term "representing" because it would be improper to use the term "equivalent" to refer to digital data signals that correspond to a physical measurement. Dr. Tehrani proposes broader terms such as "to stand for" or "symbolizing" as the proper definition of the term "representing." The district court acknowledged the dispute over the term, but failed to state explicitly which party's proposed definition it adopted. We find it implicit in the district court's opinion, however, that it chose the broader definition of "to stand for" or "symbolizing" because its analysis is not consistent with the narrower definition of "equivalent to."

We look to the ordinary meaning of the term "representing" because the record does not suggest that the applicant assigned a special meaning to the term. When a term has multiple dictionary definitions, we must consult the intrinsic record "to identify which of the different possible dictionary meanings of the claim terms in issue is the most consistent with the use of the words by the inventor." Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1203 (Fed. Cir. 2002). We agree with Dr. Tehrani that the ordinary meaning of "representing" is broad enough to include "symbolizing" or "to stand for," and that the '268 patent did not assign the term a narrower meaning. On the other hand, the statement that one item "represents" another cannot be interpreted so broadly as to include any case in which the two items are related in some way. Rather, the first item must be directly related to and stand for, or be a reasonable proxy for, the latter item.

Dr. Tehrani argues that the term "indicative of" is broader than the term "representing" and means "suggestive." Hamilton points out, however, that the patent uses the terms "indicative of" and "representing" interchangeably and argues that they must be construed to mean the same thing. Thus, while claim 1 refers to digital output data "indicative of required ventilation and optimum frequency for a next breath of a patient," the summary of the invention refers to input data "representing the amount and optimum frequency of ventilation required for the next breath," '268 patent, col. 2, ll. 5-7, and the detailed description of the preferred embodiment refers to the signals "representing the total ventilation and the frequency of breathing," id., col. 3, ll. 63-64. Moreover, while claim 16 refers to data "indicative of" the levels of carbon dioxide and oxygen, the lung elastance factor, the air viscosity factor, and the barometric pressure, other portions of the patent refer to the same data as "representing" those factors. Id., col. 1, l. 68, to col. 2, l. 2; col. 7, ll. 58-60. We agree with Hamilton that the intrinsic evidence indicates that the patentee meant for those two terms to be interchangeable and to carry the same meaning within the claims.

Although the district court did not expressly construe the phrase "of the patient," the parties agree that, consistent with its ordinary meaning, the phrase means "derived or coming from the patient; originating at or from the patient." We concur with that construction.

C

Hamilton contends that the court improperly construed the "means for processing" limitation in claim 1. The "means for processing" limitation is written in means-plus-function form, as permitted by 35 U.S.C. § 112, paragraph 6. Such a limitation recites a function to be performed and is construed "to cover the corresponding structure, materials, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112, ¶ 6; Odetics, Inc. v. Storage Tech. Corp., 185 F.3d 1259, 1266-67 (Fed. Cir. 1999). Hamilton asserts that the court did not identify the structure that corresponds to the "processing" function, as required for a claim written in means-plus-function form, and did not explain how the structure of the accused device performing that function was identical or equivalent to that recited in the '268 patent. Dr. Tehrani contends that both parties and the court agreed that the limitation refers to a processor running an algorithm as described in the specification of the '268 patent.

We agree with the parties that the structure corresponding to the processing function is the disclosed microprocessor that is programmed to perform the disclosed algorithm. The specification teaches that the "first means, which preferably comprises a programmable microcomputer, is controlled by a software algorithm to operate upon the input data and provide digital output data representing the amount and optimum frequency of ventilation required for the next breath." '268 patent, col. 2, ll. 2-7. See WMS Gaming Inc. v. Int'l Game Tech., 184 F.3d 1339, 1348-49 (Fed. Cir. 1999) ("In a means-plus-function claim in which the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm.").

The district court, however, has not determined the precise algorithm that is part of the recited structure. Nor have we been able to make that determination based on the record on appeal. We therefore cannot determine whether the algorithm employed by the Galileo device is identical or equivalent to the algorithm recited in the '268 patent. For that reason, we must remand this case for the district court to determine what algorithm forms part of the structure of the "means for processing" limitation of claim 1. In particular, the court should consider whether the algorithm consists solely of the resultant equations for tidal volume and breath frequency, '268 patent, col. 10, ll. 27-29, l. 44, or includes the underlying calculations described in columns 8, 9, and 10 of the '268 patent used to determine values for variables found in those resultant equations for tidal volume and breath frequency.

D

Hamilton next argues that the district court should have construed claim 16 to require that the accused device automatically measure the patient's levels of carbon dioxide and oxygen, in effect excluding a system in which an operator measures the gas levels and inputs those values into the device. The district court concluded that "the patented method need not 'automatically measure' the concentration of carbon dioxide and oxygen in the exhaust of a patient, as Defendant contends." In support of its argument, Hamilton points to the specification, the preamble language, and the prosecution history.

Although we regard the question as close, we agree with Dr. Tehrani that the method of claim 16 does not require that the respirator itself measure the carbon dioxide and oxygen levels of the patient. While the specification describes an apparatus and method for automatically measuring the concentration of carbon dioxide and oxygen in the exhaust of a patient, that disclosure is not a sufficient basis on which to read the limitation of automatic measurement into the claim. See N. Telecom Ltd. v. Samsung Elecs. Co., 215 F.3d 1281, 1290 (Fed. Cir. 2000); Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed. Cir. 1998) ("While . . . claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims."). The claim requires simply "measuring levels of carbon dioxide and oxygen of the patient," and it neither includes the word "automatically" in describing that function, nor specifies that the respirator must do the measuring.

Nor does the preamble language "[i]n a respirator" require that the measurement step be performed by the respirator itself. We interpret the preamble language as requiring that the various steps of the method be performed in the context of a "respirator for varying tidal volume and frequency of breaths of a patient," but not requiring that the data inputs to the respirator all be obtained automatically. The claim language indicates that what is automatic is the control function, not the input of data. Thus, the claim recites "a method of automatically controlling the respirator."

Hamilton points out that Dr. Tehrani amended claim 16 to replace "A method of controlling a respirator" in the preamble with "In a respirator for varying tidal volume and frequency of breaths of a patient, a method of automatically controlling the respirator." Hamilton argues that Dr. Tehrani amended the claim in that manner to distinguish her invention from the prior art. The applicant explained that the amendment to claim 16 was made because the prior art reference on which the examiner had relied was not a respirator, but a gas mixer, and that it did not provide for automatic control of the respirator in the claimed manner. That prosecution history is simply not sufficiently specific to persuade us that the language of the claim must be read restrictively, to limit the claim to a method in which the respirator automatically measures the patient's oxygen and carbon dioxide levels rather than having that data provided from a different source. In any event, this issue may be of limited practical importance to the ultimate disposition of this case, as Hamilton does not argue that claim 1 is limited in this fashion, and indeed the language of claim 1 clearly is not limited to a device that automatically measures the patient's oxygen and carbon dioxide levels.

III

Hamilton next contends that even apart from the asserted errors in claim construction, the district court erred in granting summary judgment of infringement. In particular, Hamilton argues that there is at least a disputed question of fact as to whether, in the Galileo ventilator, (1) the PEEP or oxygen concentration setting represents the oxygen level of the patient; (2) the oxygen level of the patient is used to control tidal volume and breath frequency; (3) the %MinVol setting represents the carbon dioxide level of the patient; (4) the barometric pressure is used to control tidal volume and breath frequency; and (5) the algorithm for calculating the outputs is the same as or equivalent to the algorithm recited in the '268 patent. We agree with Hamilton that on the present state of the record it was improper for the district court to enter summary judgment of infringement.

A

The district court relied on the PEEP setting of the Galileo device to satisfy the "processing data representing . . . oxygen levels" limitation of claim 1 and the corresponding limitation of claim 16. In so doing, the court referred to the Galileo operator's manual, which suggests that the operator adjust the PEEP setting or the oxygen concentration setting if the patient's oxygen level is either too high or too low. The referenced statement in the manual, however, does not establish that the PEEP level in any way represents the patient's oxygen level. The patient's oxygen level will likely increase with an increase in the PEEP level because an increase in PEEP will encourage gas exchange during the exhalation phase. While that passage establishes that there is some association between the PEEP level and the level of oxygen in the patient, i.e., that the PEEP level may affect the patient's oxygen level, it falls far short of establishing that the PEEP level "represents" the patient's oxygen level.

Dr. Tehrani also has not established as a matter of law that the PEEP setting is used by the microprocessor to perform the function of providing the tidal volume and breath frequency output. The district court did not explain how a change in the PEEP value would affect the tidal volume and breath frequency outputs, although that point was specifically contested by Hamilton.

In the district court, Dr. Tehrani argued that "the inspired pressure delivered by the Galileo Ventilator depends on PEEP," citing a table of safety limits in a Hamilton document. Dr. Tehrani, however, has not explained how that pressure limit is used in any claimed form of the algorithm for calculating and controlling tidal volume or breath frequency.

On appeal, Dr. Tehrani points to an equation in which the dynamic compliance of a patient is calculated in part from the PEEP value. Dr. Tehrani directs us to a passage in the Galileo operator's manual that explains that the optimal breath pattern is adjusted based on dynamic compliance: "Once calculated, the optimal breath pattern is revised with each breath according to the measurements of RCexp and dynamic compliance. Otis' equation is applied and a new target breathing pattern is calculated." That statement, however, does not explain how dynamic compliance is used by any form of the algorithm. We note that the manual also states that "ASV uses the original equation by Otis (Otis 1950) and calculates the optimal rate based on operator entries of %MinVol and Body Wt as well as on the measurement of RCexp," and that neither dynamic compliance nor PEEP is included in this list. Dr. Tehrani's brief discusses Otis's equation as separate from the dynamic compliance equation and fails to relate the two or explain how or whether dynamic compliance fits into Otis's equation.[1]

The same paragraph in the Galileo operator's manual that begins with the statement cited by Dr. Tehrani ends by stating that "[t]he changes in RCexp and dynamic compliance affect the safety limits accordingly and with each breath." Hamilton contends that dynamic compliance is used solely in the calculation of safety limits in the accused device and not in the breathing algorithm. Even Dr. Tehrani's counsel stated at oral argument that the dynamic compliance calculation is the safety limit calculation. Hamilton argues that if a safety limit of the Galileo device is reached, such as minimum frequency or maximum tidal volume, the calculated values for tidal volume and frequency under Otis's equation are discarded and replaced with the calculated safety limits. Dr. Tehrani responds that the safety limits do not override the Otis equation calculations, but we have found nothing in the record to support that assertion. To the contrary, the manual indicates an override. On summary judgment, a court draws inferences in the non-movant's favor. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). Therefore, given the present state of the record, we must infer that dynamic compliance is used only to determine safety limits and that the safety limits override the calculated optimal ventilation and breath frequency. The safety limit calculations cannot be considered as a matter of law to be structure that is equivalent to the algorithm because the safety limit calculations, as described in the operator's manual, do not use the five required data input values. Accordingly, we conclude that Hamilton has raised a genuine issue of material fact as to whether PEEP (as the alleged data representing oxygen levels) is used in conjunction with the four other data values by the structure of a microprocessor performing the algorithm, or an equivalent thereof, to calculate the output of tidal volume and breath frequency.[2]

The district court pointed to the oxygen concentration setting and the sensor for measuring the concentration of oxygen delivered to the patient as satisfying the limitation of processing data representing oxygen levels of the patient. Dr. Tehrani, however, no longer appears to contend that either the oxygen concentration setting or the reading of the oxygen concentration sensor satisfies that limitation, and we conclude that the district court erred in relying on those features for that purpose. The evidence indicates that the percentage concentration of oxygen in the gas delivered to the patient is not part of the calculation of tidal volume and breath frequency. Instead, it is merely a means for modifying the concentration of oxygen within the calculated tidal volume to compensate for a low oxygen level in the patient. The function of the oxygen sensor, moreover, is simply to check to determine if the requested oxygen concentration in the gas to be delivered to the patient has been achieved.

B

The district court concluded that the Galileo ventilator processes data representing measured levels of carbon dioxide of the patient through the %MinVol setting. The court again pointed to a chart in the Galileo operator's manual that suggests increasing the %MinVol when a high partial pressure of carbon dioxide is detected in the patient's blood gas. That suggestion fails to establish that %MinVol represents the carbon dioxide level of the patient. Indeed, the district court acknowledged that the %MinVol setting "may not represent the actual carbon dioxide level in the patient," but the court concluded that "carbon dioxide must be measured by some means for proper operation of the Galileo Ventilator, and the dial is adjusted accordingly."

Hamilton's expert, Dr. Brunner, explained that the %MinVol setting does not represent the carbon dioxide levels of the patient, but rather the "amount of ventilation the physician believes is appropriate for the patient on a per minute basis." The Galileo operator's manual confirms that the %MinVol is the degree of ventilation support that the respirator should provide. If an operator specifies a %MinVol setting of 50 percent, the Galileo will provide 50 percent of the 100 milliliters per minute multiplied by the patient's ideal body weight (based on height). Dr. Tehrani's evidence establishes only that the %MinVol setting may be increased when the patient has high carbon dioxide levels. As in the case of the PEEP setting, that evidence establishes that there is a relationship between the %MinVol setting and the patient's carbon dioxide level, but it does not establish that the %MinVol setting represents the patient's carbon dioxide level. Indeed, the decision to reset the %MinVol may be completely unrelated to carbon dioxide levels. Dr. Tehrani agrees that when a patient is being weaned off the ventilator, "%MinVol is deliberately adjusted to a lower value than what the patient's measured level of carbon dioxide dictates, in order to force the patient to breathe spontaneously." Additionally, the Galileo operator's manual suggests starting any patient in ASV mode at a %MinVol setting of 100 percent and adding percentage points based on body temperature and altitude. While an appropriate response to high carbon dioxide levels may be to increase the minute ventilation, a response is distinct from a representation. Summary judgment for Dr. Tehrani was therefore not appropriate on this issue.

The district court stated that "the Operator's Manual also explains the use of another input, the patient's ideal body weight, as an initial representative of the patient's carbon dioxide level." However, the operator's manual text cited by the district court does not explain that ideal body weight is an initial estimate of a patient's carbon dioxide level. Also, the ideal body weight constant, approximated from the patient's height, does not clearly symbolize a measured level of carbon dioxide, as required by the claims.

C

There is also a genuine issue of material fact as to whether the Galileo ventilator satisfies the limitation of claim 1 (and the corresponding limitation of claim 16) requiring the respirator to process data representing barometric pressure and to generate tidal volume and breath frequency based on that data. The district court relied on the calibration of the servo valve of the Galileo ventilator to satisfy that limitation. The court stated that the "adjustment of the servo valve, is itself an input of information which is processed by the device," but failed to explain how the servo valve is involved in determining the output of tidal volume and breath frequency. The court noted that "Defendants also contend the calibration procedure is completely distinct from the operation of the algorithm that controls tidal volume and frequency of breath," but failed to explain why the defendants' contention was wrong.

Even accepting the district court's conclusion that the adjustment of the servo valve for altitude [3] is data representing barometric pressure, Hamilton has raised a question of fact as to whether that data is used by the microprocessor to determine tidal volume and breath frequency. Hamilton's witness Dr. Brunner stated that the calibration requires a correction for altitude, but that "Galileo does not use barometric pressure in the algorithm . . . that determines breathing frequency or tidal volume. Barometric pressure is neither entered into the device nor used by the device." He repeated that "no value representing barometric pressure is input or measured and no such value is considered by the algorithm that controls breathing frequency or tidal volume." Dr. Tehrani contends that the adjustment of the valve impacts the measurement of a factor used to calculate dynamic compliance. Dr. Tehrani, however, has not clearly established that the microprocessor uses dynamic compliance, along with the four other data inputs, to calculate the output.

Before the district court, Dr. Tehrani argued that the inspiratory pressure is adjusted to satisfy the target volume, that the servo valve delivers the tidal volume to the patient based upon the pressure drop across the valve, and that the pressure drop is based on the calibration of the valve. The Galileo operator's manual, however, states that "[o]nce ASV is started, Galileo calculates optimal breathing pattern and associated target values for tidal volume and rate. . . . ASV then adjusts the inspiratory pressure [ ] and machine rate [ ] to achieve the targets." This implies that the inspiratory pressure, relied on by Dr. Tehrani, is not used to calculate the tidal volume and breath frequency, but rather is used to achieve the proper values after they are calculated. It may be that the pressure drop across the valve provides input to the microprocessor to calculate the output, but that factual issue is not clear on the record before us.

Dr. Tehrani argues that, aside from the servo valve, all the pressure sensors must be calibrated with respect to barometric pressure and that the pressure sensors provide data that is used to calculate tidal volume and breath frequency. Dr. Tehrani cites pages of the Galileo service manual to support her contention that the pressure sensors are calibrated for barometric pressure. We have examined those pages, but we find no support for that proposition there. The service manual discusses adjusting the zero points of the sensors using a potentiometer, but it does not indicate that the adjustment relates to barometric pressure. The only reference to altitude in the manual is with respect to the servo valve. It may be that the adjustment of the servo valve for altitude impacts the calibration of the pressure sensors, but Dr. Tehrani does not say as much. Therefore, we leave it to the district court to resolve this argument and identify specifically the data representing barometric pressure that is processed by the structure of the microprocessor executing the algorithm.

We agree with Hamilton that the district court erred by relying on the oxygen sensor at all. As previously stated, the record indicates that the oxygen sensor only verifies the oxygen concentration that is being delivered to the patient and does not impact the tidal volume delivered or the frequency of breaths. The Galileo operator's manual and Dr. Brunner's declaration support that conclusion.

D

Hamilton contends that the district court failed to compare the algorithm used in the Galileo ventilator with the algorithm disclosed in the '268 patent. As previously noted, we believe that the district court did not adequately set out the structure, including the algorithm, associated with the first means of claim 1. Once the district court identifies the appropriate algorithm from the specification of the '268 patent, it should explicitly compare that algorithm with that used by the accused device to determine whether it is the same or equivalent.

In sum, we are unable to agree with the district court that Hamilton has failed to raise at least a disputed issue of material fact with respect to the issue of infringement under a proper claim construction, and we therefore vacate the summary judgment and remand for further proceedings. Although Hamilton urges us to bypass further district court proceedings and direct the entry of summary judgment in its favor, there are sufficient remaining questions raised by the record before us that we decline to take that unusual step at this juncture.

Each party shall bear its own costs for this appeal.

VACATED and REMANDED.

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[1] It is possible that dynamic compliance is used to formulate the expiratory time constant, but the relationship is neither argued to us by Dr. Tehrani nor explained in the Galileo operator's manual.

[2] Because claim 16 is not written in means-plus-function form, an accused device can infringe even if it does not use the recited structure or its equivalent from the corresponding means-plus-function limitation in claim 1. However, claim 16 still requires that the accused device determine the outputs of tidal volume and breath frequency using all five required data inputs. The algorithm is the only means that Dr. Tehrani suggests Hamilton's accused device uses to satisfy that requirement.

[3] The Galileo service manual teaches that the nominal pressure for an orifice related to the valve must be corrected for altitude and provides a table of correction values to adjust the nominal pressure.