United States District Court,
W.D. Pennsylvania.

RESPIRONICS, INC. and Ric Investments, Inc,
Plaintiff.
v.
INVACARE CORP,
Defendant.

Aug. 30, 2006.

Frederick H. Colen, Gene A. Tabachnick, Joshua S. Bish, Reed Smith, for Plaintiff.

Charles B. Lyon, Jennifer B. Wick, John T. Wiedemann, Calfee, Halter & Griswold, Cleveland, OH, Eric G. Soller, William Pietragallo, II, Pietragallo, BOSICK & GORDON, PITTSBURGH, PA, Ernest P. Mansour, Mansour, Gavin, Gerlack & Manos, Cleveland, OH, for Defendant.

MEMORANDUM and ORDER

GARY L. LANCASTER**, District Judge.**

This is an action in patent infringement. Plaintiffs, Respironics, Inc. and RIC Investments, Inc. ("Respironics") allege that defendant Invacare Corporation ("Invacare") has infringed several of its patents by making, using, selling, or offering to sell the Polaris EX CPAP with SoftX device. Defendant's SoftX device, and plaintiffs' C-Flex device are both used in the treatment of sleep apnea. Defendant contends that its SoftX product does not infringe plaintiffs' patents, and/or that the patents are invalid. The court is prepared to set forth its claim construction rulings pursuant to Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed.Cir.1995) (*en banc*), *aff'd,* 517 U.S. 370 (1996).

I. *FACTUAL BACKGROUND*

A. *Dispute between the Parties*

Plaintiffs specialize in the development, manufacture and marketing of sleep therapy devices for the treatment of obstructive sleep apnea ("OSA"). OSA is a condition that causes a patient's airway to collapse during sleep, interrupting the normal flow of breath and waking the patient throughout the night. There are various types of treatment devices for OSA, including CPAP, bilevel, and exhalation unloading. CPAP, or Continuous Positive Airway Pressure, therapy involves blowing a steady stream of air through a nasal mask into the patient's airway while he sleeps in order to keep the airway open. Bi-level positive airway pressure treatment therapy involves blowing a lower pressure of air into the patient's mask during exhalation in order to relieve the discomfort of having to breathe out against a steady stream of air. Finally, exhalation unloading therapy reduces the pressure each time the patient begins exhaling even more than with bi-level therapy, resulting in even greater comfort for the user.

Plaintiffs own numerous patents in this field of sleep therapy devices. Two sets of patents are at issue in this case: the Early Patents and the Later Patents. Put in simple terms, the Early Patents cover bi-level treatment devices and the Later Patents cover exhalation unloading treatment devices.

1. ***The Early Patents-the '802 and*** '193 Patents

Plaintiffs assert that defendant has infringed and continues to infringe claims 3 and 24 of United States Patent No. 5,148,802 ("the '802 Patent") and claims 9, 44, and 53 of United States Patent No. 5,433,193 ("the '193 Patent"). These patents cover bi-level treatments. They allow a computer to determine, by measuring and comparing flow rates, even in the presence of leakage, when a patient is exhaling so that the device can switch to a lower pressure magnitude during exhalation in order to increase patient comfort. *Respironics, Inc. v. AirSep Corp.,* No. 96-cv-2129, Opinion at 12-13 (W. D.Pa. Nov. 10, 1997).

1. ***The Later Patents-the '575 and*** '517 Patents

Plaintiffs assert that defendant has infringed and continues to infringe claims 21, 23, 43, and 44 of United States Patent No. 6,105,575 ("the '575 Patent"). Plaintiffs also assert that defendant infringed claims 29, 30, and 32 of United States Patent No. 6,609,517 ("the '517 Patent") at the MedTrade '03 trade show. These patents cover exhalation unloading treatments. They allow the exhalation pressure to be decreased at the beginning of exhalation, even below the decrease found in bi-level therapy. The patents teach two methods for causing this pressure decrease: (1) in conjunction with the depth of a patient's breathing *(i.e.,* proportional); or (2) independently of a patient's breathing *(i.e.,* predetermined).

B. ***Contested Claims with Disputed Terms or Phrases Highlighted***

1. ***The Early Patents-the '802 and*** '193 Patents

The claims of the Early Patents that plaintiffs allege defendant's device has infringed are reproduced in full immediately below, with the terms and/or phrases that are in dispute, and allegedly in need of construction by this court, indicated in bold and underlined text. Although these claims are lengthy, the disputed terms are repeated throughout the claims, and need only be construed once.

In short, the court must construe the following terms or phrases of The Early Patents: (1) "selected higher and lower pressure magnitudes"; (2) "flow rate"; (3) "continually detecting the instantaneous flow rate"; (4) "utilizing [and utilizing at least one of] said instantaneous flow rate and said reference indicia to select one of said higher and said lower pressure magnitudes for said flow of breathing gas to be applied in the airway of such a patient."

(a) ***The*** '802 Patent, ***Claim 3***

A method of medical treatment for a patient comprising the steps of:

providing a flow of breathing gas from a source for delivery to the airway of such a patient at ***selected higher and lower pressure magnitudes*** hat least as great as ambient atmospheric pressure;

continually detecting the instantaneous flow rate of said breathing gas flowing between said source and the airway of such a patient;

continually processing selected parameters including said instantaneous ***flow rate*** to provide a reference indicia corresponding to an average ***flow rate*** of breathing gas flowing between said source and said patient; and

utilizing said instantaneous flow rate and said reference indicia to select one of said higher and said lower pressure magnitudes for said flow of breathing gas to be applied in the airway of such a patient.

b) ***The '802 Patent, Claim 24***

A method of treating sleep apnea comprising the steps of:

providing a flow of breathing gas from a source for delivery to the airway of a patient at ***selected higher and lower pressure magnitudes*** at least as great as ambient atmospheric pressure;

continually detecting the instantaneous flow rate of said breathing gas flowing between said source and the airway of a patient;

continually processing selected parameters including said instantaneous ***flow rate*** to provide a reference indicia corresponding to an average ***flow rate*** of breathing gas flowing between said source and said patient; and

utilizing said instantaneous flow rate and said reference indicia to select one of said higher and said lower pressure magnitudes for said flow of breathing gas.

(c) ***The*** '193 Patent, ***Claim 9***

A method of medical treatment for a patient comprising the steps of:

providing a flow of breathing gas from a source for delivery to the airway of such a patient at selected higher and lower pressure magnitudes at least as great as ambient atmospheric pressure and permitting said flow of gas to pass from the patient;

monitoring said flow to detect an instantaneous flow rate of such breathing gas;

processing selected parameters including said instantaneous flow rate to provide a reference indicia corresponding to an average flow rate of such breathing gas; and

utilizing at least one of said instantaneous flow rate and said reference indicia to select one of said higher and said lower pressure magnitudes to be applied in the airway of such a patient.

(d) '193 Patent, ***Claim 44***

A method of treating sleep apnea syndrome comprising the steps of:

providing a flow of breathing gas from a source for delivery to the airway of a patient at selected higher and lower pressure magnitudes at least as great as ambient atmospheric pressure;

permitting said flow of breathing gas to pass from such a patient;

monitoring said flow of breathing gas to detect an instantaneous flow rate of said breathing gas;

processing selected parameters including said instantaneous flow rate to provide a reference indicia corresponding to an average flow rate of said breathing gas; and

utilizing at least one of said instantaneous flow rate and said reference indicia to select one of said higher and said lower pressure magnitudes for said supply flow of breathing gas.

(e) '193 Patent, ***Claim 53***

A method of treating sleep apnea syndrome comprising the steps of:

providing a flow of breathing gas from a source for delivery to the airway of a patient at selected higher and lower pressure magnitudes at least as great as ambient atmospheric pressure;

permitting said flow of breathing gas to pass from such a patient;

monitoring said flow of breathing gas to detect an instantaneous flow rate of said breathing gas;

processing selected parameters including said instantaneous flow rate to provide a reference indicia; and

utilizing at least one of said instantaneous flow rate and said reference indicia to select one of said higher and said lower pressure magnitudes for said supply flow of breathing gas.

2. ***The Later Patents-the '575 and*** '517 Patents

The claims of the Later Patents that plaintiffs allege defendant's device has infringed are reproduced in full immediately below, with the terms and/or phrases that are in dispute, and allegedly in need of construction by this court, indicated in bold and underlined text. Although these claims are lengthy, several of the disputed terms are repeated throughout the different claims, but need only be construed once. In addition, several of the disputed terms or phrases in these patents will have already been construed by the court in the context of the Early Patents.

In short, the court must construe the following phrases of the Later Patents: (1) "A proportional positive airway pressure apparatus"; (2) "predetermined pressure profile"; (3) "wherein a shape of said predetermined pressure profile is set independent of any monitored respiratory characteristics of such a patient"; (4) "fluid characteristic associated with a flow of gas"; (5) "controlling said supply of gas to such a patient during at least a portion of a breathing cycle based on said fluid characteristic signal and said first gain"; (6) "minimally sufficient pressure"; (7) "prevent airway collapse, wherein said minimally sufficient pressure is a summation of a pressure needed to prevent airway collapse and pressure needed to overcome respiratory effort"; (8) "further comprising a step of setting at least one of a magnitude and a duration of said pressure profile"; and (9) "controlling a pressure of the flow of breathing gas delivered to a patient based on a product of the expiratory gain and the fluid characteristic during at least a portion of an expiratory phase of such a patient's breathing cycle, so that a pressure of the flow of breathing gas delivered to the patient during at least a portion of the expiratory phase varies with fluctuations of the fluid characteristic."

(a) '575 Patent, ***Claim 21***

A proportional positive airway pressure apparatus for delivering pressurized breathing gas to an airway of a patient, said apparatus comprising:

a gas flow generator;

a patient interface adapted to couple said gas flow generator to an airway of a patient;

a sensor adapted to detect at least one physiological condition of such a patient, wherein said physiological condition is suitable for use to differentiate between an expiratory phase and an inspiratory phase of a breathing cycle of such a patient and to output a signal indicative thereof;

a pressure controller associated with at least one of said gas flow generator and said patient interface to control a pressure of said breathing gas provided by said gas flow generator;

control means for controlling said pressure controller so as to cause said breathing gas to be delivered to such a patient at a first pressure level during at least a portion of said inspiratory phase of said breathing cycle and in accordance with a ***predetermined pressure profile*** during said expiratory phase of said breathing cycle, ***wherein a shape of said predetermined pressure profile is set independent of any monitored respiratory characteristics of such a patient.***

(b) '575 Patent, ***Claim 23***

A method of providing pressured breathing gas to an airway of a patient, said method comprising the steps of:

supplying gas to an airway of such a patient from a source of gas via a patient interface;

determining a ***fluid characteristic associated with a flow of gas*** within said patient interface and outputting a fluid characteristic signal indicative thereof;

establishing a first gain to be applied to said fluid characteristic signal; and

controlling said supply of gas to such a patient during at least a portion of a breathing cycle based on said fluid characteristic signal and said first gain so as to deliver said gas to such a patient at a minimally sufficient pressure to perform at least once of the following functions at any given moment during at least a portion of a breathing cycle:

(1) reduce cardiac preload and afterload, wherein said minimally sufficient pressure needed to reduce cardiac preload and afterload in an absence of respiratory loading and a pressure needed to overcome an impact of respiratory loading on cardiac preload and afterload; and

(2) ***prevent airway collapse, wherein said minimally sufficient pressure is a summation of a pressure needed to prevent airway collapse and pressure needed to overcome respiratory effort.***

(c) '575 Patent, ***Claim 43***

A method of delivering pressurized breathing gas to an airway of a patient, said method comprising the steps of:

providing a gas flow generator and a patient interface adapted to couple said gas flow generator to an airway of a patient;

detecting at least one physiological condition of such a patient, wherein said physiological condition is suitable for use to differentiate between an expiratory phase and an inspiratory phase of a breathing cycle of such a patient and outputting signals indicative thereof; and

controlling said gas flow to such a patient at a first pressure level during at least a portion of said inspiratory phase and in accordance with a ***predetermined pressure profile*** during said expiratory phase of said breathing cycle, ***wherein a shape of said predetermined pressure profile is set independent of any monitored respiratory characteristics of such a patient.***

(d) '575 Patent, ***Claim 44***

The method of claim 43, ***further comprising a step of setting at least one of a magnitude and a duration of said pressure profile.***

(e) '517 Patent, ***Claim 29***

A method of delivering pressurized breathing gas to an airway of a patient, comprising:

generating a flow of breathing gas;

sensing ***a fluid characteristic associated with the flow of breathing gas*** and outputting a signal corresponding to the fluid characteristic;

selecting an expiratory gain; and

controlling a pressure of the flow of breathing gas delivered to a patient based on a product of the expiratory gain and the fluid characteristic during at least a portion of an expiratory phase of such a patient's breathing cycle, so that a pressure of the flow of breathing gas delivered to the patient during at least a portion of the expiratory phase varies with fluctuations of the fluid characteristic.

(f) '517 Patent, ***Claim 30***

The method claim 29, wherein generating the flow of breathing gas includes carrying the flow of breathing gas to an airway of a patient via conduit, and wherein controlling the pressure of the flow of breathing gas includes exhausting gas from the conduit.

(g) '517 Patent, ***Claim 32***

The method claim 29, wherein controlling a pressure of the flow of breathing gas delivered to a patient based includes controlling the pressure of the flow of breathing gas based on:

(1) an inspiratory positive airway pressure (IPAP) during an inspiratory phase of such a patient's breathing cycle, and

(2) ***based on the product of the expiratory gain and the fluid characteristic during at least a portion of an expiratory phase of such a patient's breathing cycle, so that a pressure of the flow of breathing gas delivered to such a patient during at least a portion of the expiratory phase varies with fluctuations of the fluid characteristic.***

II. *LEGAL BACKGROUND*

Claim construction is not a simple task.

Claim construction requires a degree of imagination from the court. First, the court must obtain sufficient currency with the technical terms employed to read the patent because the objective of claim construction is to ascertain the meaning that a person of ordinary skill in the art would give to the terms in dispute. Second, the court must travel in time, for the operative time for interpreting the claim terms is the date of the application for the patent.

Thomson Consumer Elecs., Inc. v. Innovatron, S.A., 43 F.Supp.2d 26, 29 (D.D.C.1999) (citations omitted). Patent claim construction is a matter of law for the court. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995), aff' d 517 U.S. 370 (1996). According to the Court of Appeals for the Federal Circuit, "[i]t is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.' " Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005)(en banc) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed.Cir.2004)). Therefore, we must begin our claim construction analysis with the words of the claim. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996).

The words of the claim are generally given their ordinary and customary meaning. Id. at 1582. The ordinary and customary meaning of a claim term "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1313. The person of ordinary skill in the art views the claim term in light of the entire intrinsic record. *Id*. Thus, the claims "must be read in view of the specification", which is the single best guide to determining the meaning of a claim term, and the prosecution history. Markman, 52 F.3d at 979; Phillips, 415 F.3d at 1315; Vitronics, 90 F.3d at 1582.

Claims should be interpreted consistently with the specification, of which that are a part, because the specification provides context for the proper construction of the claims and explains the nature of the patentee's invention. *See* Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed.Cir.1998). " 'The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.' " Phillips, 415 F.3d at 1316.

However, the Federal Circuit has cautioned against limiting the scope of a claim to a preferred embodiment or specific examples disclosed in the specification. *See ie.g.,* Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1303 (Fed.Cir.1997); Intervet America, Inc. v. Kee-Vet Laboratories, Inc., 887 F.2d 1050, 1053 (Fed.Cir.1989) ("[L]imitations appearing in the specification will not be read into claims, and ... interpreting what is meant by a word in a claim 'is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.' ") (citation omitted). While the specification may describe very

specific embodiments of the invention, we cannot confine the claims to those embodiments. Phillips, 415 F.3d at 1323.

In addition to the specification, "the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Id. at 1317. The public has a right to rely on statements made by the patent applicant or his attorney during prosecution that define the scope of the claims. *See* Ekchian, 104 F.3d at 1304.

Therefore, a court must include a review of the patent's specification and prosecution history in its claim construction analysis. Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed.Cir.1998); Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed.Cir.2005). In fact, it is error for a court to issue a claim construction that is divorced from the context of the written description and prosecution history. Nystrom v. Trex Comp., Inc., 424 F.3d 1136, 1144-45 (Fed.Cir.2005).

While resort to dictionaries and treatises may be helpful, they may not be consulted before the specification and prosecution history in order to define claim terms. Phillips, 415 F.3d at 1318-21; C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed.Cir.2004). Such extrinsic evidence is less reliable than intrinsic evidence and poses the risk that it will be used to "change the meaning of claims in derogation of the 'indisputable public records consisting of the claims, the specification and the prosecution history,' thereby undermining the public notice function of patents." Phillips, 415 F.3d at 1319 (quoting Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed.Cir.1995)).

Claim construction is an essential first step to conducting an infringement analysis; however it is not an infringement analysis. The fact that an accused device may contain a claim element that has been construed by the court does not mean the accused device infringes. The accused device must contain every element of a claim, or the substantial equivalent of each element, in order to infringe the patent. If just one claim element or its substantial equivalent is not present in the accused device, then that claim is not infringed. Carroll Touch, Inc. v. Electro Mech. Sys., Inc., 15 F.3d 1573, 1576 (Fed.Cir.1993); Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1562 (Fed.Cir.1990); Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed.Cir.1998) (en *banc)*. Therefore, even if the accused device contains the element of a claim that is being construed by the court, if it does not contain all other elements of the claim, it does not infringe.

III. *CLAIM CONSTRUCTION*

A. *The Early Patents*

Having identified the claim terms and phrases in need of construction, and summarized the applicable law, we will now engage in our claim construction analysis.

1. *At Selected Higher and Lower Pressure Magnitudes*

This phrase is found in Claims 3 and 24 of the '802 Patent and Claims 9, 44, and 53 of the '193 Patent.

Phrase: At selected higher and lower pressure magnitudes

Construction: at a higher pressure magnitude and a lower pressure magnitude that have been chosen prior to

operation of the computer circuitry that is used to determine whether the patient is inhaling or exhaling.

Reasoning: The dispute between the parties focuses on when, and how, the two pressures must be selected. Plaintiffs contend that they can be selected in any manner and at any time prior to their being applied. In fact, at the hearing, plaintiffs contended that the lower pressure could fluctuate breath by breath while the device is in operation. Defendant contends that the pressures must be selected manually prior to operation.

In construing the term "selected" it is of primary importance to understand the overall context of the patents themselves. These patents disclose bi-level treatment devices. The claims disclose a treatment method that senses the occurrence of the exhalation or inhalation phase of the breathing cycle, even in the presence of system leakage, based on the spontaneous breathing of the patient, so that the system knows when to apply a higher pressure magnitude *(i.e.,* during inhalation), or a lower pressure magnitude *(i.e.,* during exhalation).

With that said, in arriving at the proper construction of the term "selected", we must look at the entirety of the claims. By way of example, the word "select" appears in Claim 3 of the '802 Patent twice. It is the first occurrence of the term that we are being asked to construe. The first time, "select" is used it appears in the past tense as part of the first step of the claim *(i.e.,* "... for delivery to the airway of such a patient at ***selected*** *higher and lower pressure magnitudes* ..."). The second time, "select" appears it is used in the present tense as part of the final "utilizing" step of the claim *(i.e.,* "utilizing said instantaneous flow rate and said reference indicia ***to select*** one of said higher and said lower pressure magnitudes"). When the claim is read in its entirety, it is clear that the "selected" higher and lower pressure magnitudes of the first step are pre-selected, before the computer circuitry does its detecting, processing, and utilizing, so that once the circuitry has completed these tasks, it can pick which of the two pressures to apply. Apart from the structure of the claim itself, this is supported by the fact that in the final "utilizing" step, the higher and lower pressures are referred back to as "said", or previously mentioned/referenced, pressures *(i.e .,* "utilizing said instantaneous flow rate and said reference indicia to select one of ***said*** higher and said lower pressure magnitudes").

This reading of the claim language is consistent with the remaining intrinsic evidence. The specifications, figures, and prosecution history all presuppose that the two pressures are chosen before the device starts detecting, processing, and utilizing. *See ie.g.,* Prosecution History, '802 Patent, Amendment and Remarks (June 11, 1990) at 19-20; '802 Patent, Fig. 4; cl. 2, lns. 59-63; cl. 3, lns. 24-28; cl. 6, lns. 43-46, 55-59, 61-66; cl. 8, lns. 53-55; cl. 11-12, lns. 62-22; cl. 13, lns. 24-32, 40-42. There is no indication in the patents that the lower pressure magnitude can somehow be changed breath by breath, as was asserted at the hearing. While a person of ordinary skill in the art might be able to modify the invention so as to "select" the pressures via computer screen, rather than dial, there is nothing to suggest that the "selected" step is nearly as broad as plaintiffs contend.

2. *Flow Rate*

This phrase is found in Claims 3 and 24 of the '802 Patent and Claims 9, 44, and 53 of the '193 Patent.

Phrase: Flow rate

Construction: The volume of breathing gas moving per unit of time.

Reasoning: The dispute between the parties centers on whether flow rate must account for a volume of gas, or merely the movement of gas. Plaintiffs propose that the phrase flow rate means a signal indicative of the

movement of gas (e.g., direction) over time. Defendant contends that flow rate means a quantified volume of gas moving per unit of time. Resolution of this dispute is easily reached by reviewing the specification. The '802 patent gives various examples of flow rates. These consistently are expressed in terms of "cc's per second" [*i.e.*, volume per time]. '802 Patent, cl. 11-12, lns. 68-1, 22-31. No other examples, measurement tools, or definitions of flow rate are given in the patent. It is clear, when viewed objectively, that plaintiffs used the term "flow rate" in a particular way in their patents.

While an individual with ordinary skill in the art may be able to modify the teachings of the patent to allow flow rate to account for weight of gas, or some other quantified value, plaintiffs' contention that the term flow rate simply means gas movement is contradicted by the patent itself, and plaintiffs' other claim construction arguments. Both parties agree that the term flow means a signal indicative of movement of breathing gas. Therefore, flow rate must mean something more than gas movement.

Furthermore, the volume per time definition used in the specification is in accordance with the common definition of flow rate which is a "weight or volume of flowable material flowing per unit of time." *McGraw Hill Dictionary of Scientific and Technical Terms* (4th ed.). A construction that accounts for volume also makes sense in the overall context of the patents because flow rates are relevant to these patents, which measure leakage. Leakage is an amount of gas that is being lost due to movement of the nasal mask during sleep. By measuring the various rates, accounting for leakage, and comparing them, the circuitry is able to distinguish between inhalation mode and exhalation mode, and apply the appropriate corresponding pressure.

3. *continually detecting the instantaneous flow rate*

This phrase is found in Claims 3 and 24 of the '802 Patent and Claims 9, 44, and 53 of the '193 Patent.

Phrase: continually detecting the instantaneous flow rate

Construction: Without interruption, creating a signal corresponding to the flow rate at a particular point of time.

Reasoning: At its core, there is little dispute between the parties as to the meaning of this phrase. Both parties agree that the computer circuitry detects the instantaneous flow rate by creating a signal corresponding to the instantaneous flow rate. The real dispute between the parties is over the meaning of "flow rate", which we have already construed above.

4. *utilizing said instantaneous flow rate and said reference indicia ...*

This phrase is found in Claims 3 and 24 of the '802 Patent and Claims 9, 44, and 53 of the '193 Patent.

Phrase: Utilizing said instantaneous flow rate and said reference indicia to select one of said higher and said lower pressure magnitudes for said flow of breathing gas to be applied in the airway of such a patient

Construction: Comparing the instantaneous flow rate signal to the average flow rate signal to determine whether to provide the previously selected higher pressure magnitude (for inhalation) or the previously selected lower pressure magnitude (for exhalation) to the patient.

Reasoning: Again, the court can discern little difference between the two proposed constructions. Both

parties agree that a comparison is made between the two flow rate values or signals to determine whether the patient is inhaling or exhaling, resulting in a decision as to whether to apply the higher or the lower pressure. The real dispute between the parties is as to the meaning of "flow rate" and "selected higher and lower pressure magnitudes," which phrases the court has already construed.

5. ***Utilizing at least one of ...***

This phrase is found in Claims 9, 44, and 53 of the '193 Patent.

Phrase: Utilizing at least one of said instantaneous flow rate and said reference indicia to select one of said higher and said lower pressure magnitudes to be applied in the airway of such a patient.

Construction: Using the instantaneous flow rate or the average flow rate, or both, to determine whether to provide the previously selected higher pressure magnitude (for inhalation) or the previously selected lower pressure magnitude (for exhalation) to the patient.

Reasoning: This phrase adds the "at least one of" language to the previously construed claim language of the '802 patent. The parties do not dispute that the language means that either the instantaneous flow rate, or the reference indicia, or both, can be used to select between the higher and lower pressures. Again, the real dispute between the parties is as to the meaning of now previously defined terms such as "flow rate" and "selected higher and lower pressure magnitudes."

B. ***The Later Patents***

1. ***A Proportional Positive Airway Pressure Apparatus***

This phrase is found in the preamble of Claim 21 of the '575 Patent.

Phrase: A proportional positive airway pressure apparatus

Construction: The inclusion of the term "proportional" in the preamble of this claim is found to be in error and not to effect the claimed invention.

Reasoning: Plaintiffs contend that the term "proportional" appears in the preamble of Claim 21 by mistake. According to plaintiffs, the balance of Claim 21 discloses the predetermined pressure profile version of the invention, and not the proportional version. Defendant argues that because the '575 patent does claim an alternative proportional version of the invention, we cannot find that there is no reasonable debate that the word appears in this preamble by accident, and thus, cannot excise it. We disagree and find that upon consideration of the patent as a whole, it is clear that Claim 21 refers not to the proportional version of the invention, but to the predetermined version of it.

There is no question that the '575 patent includes a proportional version and a predetermined version of the invention. The proportional version is more complex and constantly monitors the patient in order to ensure that only the minimally sufficient pressure is applied at any time. The predetermined version monitors the patient only to determine when exhalation begins, and upon sensing it, applies a predetermined pressure profile. This latter version is described as more cost effective and able to be used in conjunction with existing CPAP devices. '575 Patent, cl. 20, lns. 16-20, 66-67; cl. 21, lns. 1-11. Claim 21 discloses this predetermined version of the invention, as evidenced by the fact that the pressure applied during exhalation

is predetermined and by the fact that the claim does not require or mention a minimally sufficient pressure.

2. ***Predetermined Pressure Profile***

This phrase is found in Claims 21 and 43 of the '575 Patent.

Phrase: Predetermined Pressure Profile

Construction: This phrase is not part of the means plus function language.

Reasoning: The dispute between the parties regarding construction of this phrase is the extent to which section 112, para. 6 applies. Defendant contends that no structure in the specification is linked to the "Predetermined Pressure Profile", making the claim fatally flawed. Plaintiff claims that "Predetermined Pressure Profile" is not part of the means plus function language, and is to be construed in accordance with standard claim construction standards.

Limitations contemplated by section 112, para. 6, often referred to as means-plus-function or step-plus-function limitations, recite a specified function to be performed rather than the structure, material, or acts for performing that function. Such limitations are "construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U .S.C. s. 112, para. 6 (1994); IMS Technology, Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1429-30 (Fed.Cir.2000). In claim 21, the recited function consists of controlling said pressure controller. The claim recites no structure supporting the means for performing that function. Therefore, in accordance with s. 112, para. 6, the means is construed to cover the disclosed structure, PPAP circuitry, and its equivalents. We reject defendant's argument that the "Predetermined Pressure Profile" is part of the means plus function language. Rather, we find that it is not part of the steps that perform the recited function of controlling, and is therefore not subject to construction under section 112, para. 6.

3. ***Wherein a Shape of Said Predetermined Pressure Profile ...***

This phrase is found in Claims 21 and 43 of the '575 Patent.

Phrase: Wherein a shape of said predetermined pressure profile is set independently of any monitored respiratory characteristics of such a patient

Construction: Wherein the magnitude and duration of the predetermined pressure profile are set without reference to or consideration of any monitored breathing characteristics of such a patient.

Reasoning: The dispute between the parties is whether the shape of the Predetermined Pressure Profile is synonymous with its magnitude and duration, or is a wholly different characteristic. After close review of the intrinsic record, we find that the shape of the profile is made up of its duration and magnitude.

The predetermined pressure profile is used in the less complex, and more cost effective version, of the invention. The predetermined pressure profile is applied to reduce the constant pressure of CPAP or the reduced EPAP pressure of bi-level therapy once the device detects the expiratory breathing phase. According to the teachings of the patent, the predetermined pressure profile has two parts: a magnitude, that represents the drop in pressure from the higher pressure value; and a duration that is ideally based on an average expiration period of the patient. These pre-set or pre-programmed magnitude and duration values

approximate the values that would be generated by the proportional version of the invention. '575 Patent, cl. 20, lns. 44-65. Read in context of the language of the patent, the predetermined pressure profile is programmed into the computer with a magnitude value and a duration value so that the device can reduce the pressure during expiration independently of the patient's breath (other than sensing when exhalation begins). '575 Patent, cl. 20, lns. 66-67 and cl. 21, lns. 1-8.

The term shape appears in the '575 Patent four times, apart from being included in Claims 21 and 43. The first three times it appears, it does not refer to the shape of the predetermined pressure profile. '575 Patent, cl. 16, lns. 21, 55; cl. 18, lns. 43-44. The last time the word appears, it does refer to the predetermined pressure profile. '575 Patent, cl. 20, ln. 25. In describing a preferred embodiment of the invention, the patent states that the defined pressure profile has a shape that generally corresponds to a patient's normal flow. Because, in the proportional version of the invention, the patient's normal flow is used to determine the magnitude and duration of the pressure, this reference to the term "shape" indicates that the shape of a profile is comprised of its magnitude and its duration. This reading is further supported by the overall context of the patent, wherein pressure profiles, sometimes called waveforms, are consistently comprised of magnitudes and durations. '575 Patent, cl. 20, lns. 54-58.

This construction is also supported by the prosecution history. The limitation that the shape be set independently of any patient monitored characteristic was added to these claims to differentiate them from prior art. The prior art generated an expiratory model waveform based on the inspiratory waveform, which was set by monitoring patient flow. Prosecution History, '575 Patent, Response to Office Action (Nov. 24, 1999) at 13. At the time, plaintiff distinguished the prior art by explaining that the shape of its predetermined profile is not based on any monitored respiratory characteristics. Id. In the context of these inventions, the pressure profiles are defined by how large a drop in pressure there will be, and for how long. In that context, the argument that the profile is independent of the respiration of the patient, indicates that these factors, *i.e.,* magnitude and duration, will be set without reference to the patient.

Our construction is also in accord with the dictionary definition of the applicable term. In discussing this issue in the office action response, plaintiffs used the terms waveform profile, waveform, model waveform, and shape of the expiratory waveform model interchangeably. The dictionary definition of a waveform is a graphic representation of the shape of a wave that indicates its characteristics (as frequency and amplitude), called also waveshape. *Merriam-Webster's Medical Dictionary* (2002).

We do not accept plaintiffs' argument that the "shape" of the profile is separate and apart from the characteristics that define the profile. According to plaintiffs, the pressure profile's shape is "a bathtub." There is no support in the patent for such a construction. The only time that the patent describes how the waveform or profile might look it speaks to the pressure dropping off quickly at the start of expiration and then rising slowly toward the baseline pressure, which actually describes more of an off-center U, or rounded checkmark, shape, rather than a "bathtub" shape. '575 Patent, cl. 20, lns. 61-65. Regardless, in so describing this form, the patent labels it the "contour", not the shape, of the profile. Id.

Based on the patent language and the prosecution history, and buttressed by the dictionary definition of the relevant term, the shape of the pressure profile is its magnitude and duration. And, according to the plain language of the patent, these values must be set independently of any respiratory characteristic of the patient.

Finally, there is no support for plaintiff's argument that the magnitude and duration are not set in Claim 21

because Claim 22 recites the act of setting the magnitude or duration. Claim 22 claims an apparatus "comprising the means for setting" these values. A claim for the means for doing an act does not mean that Claim 21 does not claim the act itself.

4. ***Fluid Characteristic Associated with the Flow of a Gas***

This phrase is found in Claim 23 of the '575 Patent. It is also found in Claims 29 and 32 of the '517 Patent.

Phrase: Fluid characteristic associated with the flow of a gas Construction: flow rate.

Reasoning: Both parties agree that this phrase refers to flow rate. The real dispute as to the meaning of the term "flow rate". However, in construing the claims of the Early Patents, we have already arrived at the appropriate meaning of that term, i.e., the volume of breathing gas moving per unit of time.

5. ***controlling said supply of gas to such a patient during at least a portion of a breathing cycle based on said fluid characteristic signal and said first gain***

(a) ***at least a portion of a breathing cycle***

This phrase is found in Claim 23 of the '575 Patent.

Phrase: at least a portion of a breathing cycle

Construction: anywhere from a part of either the inspiratory or expiratory phase of the breathing cycle to an entire two-phase breathing cycle, and anything in between.

Reasoning: The dispute between the parties as to this phrase is difficult to discern. However, regardless, the proper construction of this phrase is elementary once the term breathing cycle is properly defined. There is no reasonable dispute that a breathing cycle is defined by the patent to be the expiratory phase and the inspiratory phase of a complete breath. '575 Patent, cl. 1, ln. 64; cl. 2, ln. 7; cl. 7, lns. 1-12. Therefore, "at least a portion of a breathing cycle", means anywhere from part of the inspiratory phase or part of the expiratory phase, to an entire expiratory-inspiratory cycle.

(b) ***controlling said supply of gas ... based on said fluid characteristic signal and said first gain***

This phrase is found in Claim 23 of the '575 Patent.

Phrase: controlling said supply of gas ... based on said fluid characteristic signal and said first gain

Construction: The supply of gas is controlled based on the flow rate signal and a constant value that is applied to either boost or reduce the delivered pressure.

Reasoning: There is little dispute remaining regarding the proper construction of this phrase. We have previously defined fluid characteristic to mean flow rate. The first gain is simply a constant value. The patent defines gains as constant values that, when applied to other values or signals, are used to either reduce or boost pressure. '575 Patent, cl. 13, lns. 36-52; cl. 15, lns. 8-35. We reject defendant's argument that this phrase is limited to any particular formula or illustration of its concepts.

6. ***Minimally Sufficient Pressure***

This phrase is found in Claim 23 of the '575 patent.

Phrase: Minimally sufficient pressure

Construction: A summation of the pressure necessary to prevent airway collapse in the absence of respiratory efforts (collapse due to airway structure, muscle tone, and body position) and the pressure necessary to overcome the collapsing and splinting effects of respiratory efforts.

Reasoning: The real dispute between the parties as to the appropriate construction of this phrase stems from a disagreement as to how many of the claim elements, and how much of the patent specification, must be read into this phrase. Defendant contends that illustrative equations from the patent specification must be used to define this phrase and that claim language relating to proportionality, fluid characteristic, and first gain, must be read into the phrase. Plaintiffs argue that this phrase has been used consistently throughout the family of patents, and has a clearly established meaning. We agree with plaintiffs.

While the formulas urged by defendant may help illustrate the phrase, the phrase is not limited to them. Any additional limitations from the remainder of this Claim regarding proportionality, fluid characteristic, or gains can be addressed in the infringement analysis. However, in terms of construing the disputed phrase "minimally sufficient pressure", we find that the phrase is given a clear and consistent definition throughout the family of patents.

7. ***prevent airway collapse, wherein said minimally sufficient pressure is a summation ...***

This phrase is found in Claim 23 of the '575 patent.

Phrase: prevent airway collapse, wherein said minimally sufficient pressure is a summation of a pressure needed to prevent airway collapse and pressure needed to overcome respiratory effort

Construction: prevent airway collapse, wherein said minimally sufficient pressure is a summation of a pressure needed to prevent airway collapse and pressure needed to overcome respiratory effort.

Reasoning: This phrase requires no construction by the court.

8. ***Further Comprising a Step of Setting ...***

This phrase is found in claim 44 of the '575 patent.

Phrase: Further comprising a step of setting at least one of a magnitude and a duration of said pressure profile

Construction: Further comprising the step of setting a magnitude, a duration, or both, of said pressure profile.

Reasoning: The real dispute between the parties regarding this claim element is whether the shape of the predetermined pressure profile includes its magnitude and duration. As we have already resolved that issue, there is no need to further construe this claim element.

9. ***controlling a pressure of the flow of breathing gas delivered to a patient based on a product of ...***

This phrase is found in Claims 29 and 32 of the '517 Patent.

Phrase: controlling a pressure of the flow of breathing gas delivered to a patient based on a product of the expiratory gain and the fluid characteristic during at least a portion of an expiratory phase of such a patient's breathing cycle, so that a pressure of the flow of breathing gas delivered to the patient during at least a portion of the expiratory phase varies with fluctuations of the fluid characteristic.

Construction: controlling the pressure of breathing gas delivered to a patient during at least part of the expiratory phase so that it fluctuates in relation to the patient's flow rate, by multiplying the constant expiratory gain value by the flow rate.

Reasoning: The dispute between the parties as to the meaning of this phrase centers around whether and how the step-plusfunction limitation applies to it under 35 U.S.C. s. 112, para. 6. However, we can see no validity in defendant's argument on this point. The portions of the prosecution history on which defendant relies do not even address the claims that are being asserted in this case. For instance, defendant cites to an amendment to Claim 45, which corresponds to claim 1 in the final published patent. That claim specifically recites a "processing means". Claims 29 and 32 are not discussed in the office action response on which defendant relies.

Construing this claim element is straightforward after dispensing of defendant's step-plus-function argument, and considering previous constructions that this court has given to the term "gain" and the phrase "fluid characteristic."

IV. ***CONCLUSION***

The parties shall proceed in this case in accordance with the above constructions.

W.D.Pa.,2006.
Respironics, Inc. v. Invacare Corp.

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