United States District Court,
D. Minnesota.

ADVANCED RESPIRATORY, INC,
Plaintiff.
v.
ELECTROMED, INC,
Defendant.

No. Civ. 00-2646(DWF/SRN

Jan. 10, 2003.

Edward F. Fox, Edward M. Laine, Cyrus A. Morton, and David J. McKinley, Oppenheimer Wolff & Donnelly, LLP, Minneapolis, MN, for Plaintiff.

Richard J. Bartz, and Richard O. Bartz, Bartz & Bartz, Edina, MN, Karl L. Cambronne, Chestnut and Cambronne, Minneapolis, MN, William J. George, George Law Office, Wayzata, MN, and Paul A. Koches, McLean Group, Washington, DC, for Defendant.

MEMORANDUM OPINION AND ORDER

FRANK**, J.**

Introduction

The above-entitled matter came on for hearing before the undersigned United States District Judge on November 13, 2002, on the issue of patent claim construction pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996).

Background

This litigation involves a claim by Plaintiff Advanced Respiratory, Inc. ("ARI"), formerly known as American Biosystems, Inc. (collectively, "Plaintiff"), that certain high frequency chest wall oscillation ("HFCWO") units manufactured by Defendant Electromed, Inc. ("Defendant"), infringe Plaintiff's patent rights.

Plaintiff owns the rights to United States Patent Nos. 6,036,662 (the " '662 Patent") and 5,769,797 (the " '797 Patent"). In addition, Plaintiff has exclusive license rights, including enforcement rights, to United States Patent No. 4,838,263 (the " '263 Patent"), such patent which is owned by the University of Minnesota.

Generally, Plaintiff's device consists of a vest with an inflated air bladder. The device employs a diaphragm to oscillate the air pressure in the vest, creating pulsing blows that loosen lung secretions and thereby assist in their expulsion. Plaintiff's '662 and '263 Patents relate to this technology. A brief history of those two

patents follows.

Plaintiff and the University of Minnesota entered into a licensing agreement on November 2, 1988, whereby the University granted Plaintiff an exclusive license to commercialize the technology from U.S. Patent application No. 045,888 (the " '888 Patent application") and gave Plaintiff the right to bring suit to enforce these patent rights against third parties. The '263 Patent issued from the '888 Patent application. Plaintiff sold its Model 102 product pursuant to this licensing agreement.

During the course of its licensing agreement with the University of Minnesota, Plaintiff developed the Model 103 product. Plaintiff alleges that Model 103 resulted from improvements to the '263 Patent designs and the Model 102 product. In approximately December 1996, Plaintiff and the University set out to determine whether the Model 103 product was covered by the '263 Patent owned by the University. Both the University and Plaintiff concluded that it was not.

Plaintiff's '662 Patent application was filed on March 16, 1998. The '662 Patent was based upon Plaintiff's advancements made in the Model 103 device. The '662 Patent matured from an application that was filed as a continuation of an earlier-filed parent application. That parent application resulted in the '797 Patent.

Plaintiff alleges that Defendant has infringed upon the '662 and '263 Patents by manufacturing and distributing a device, the Medpulse 2000, that uses the same oscillating pressure technology as the '662 and '263 Patents.

Discussion

1. Claim Construction

Patent claim construction, *i.e.,* the interpretation of the patent claims that define the scope of the patent, is a matter of law exclusively for the Court. Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed.Cir.1995) *aff'd* 517 U.S. 370 (1999).

Proper claim construction requires an examination of the intrinsic evidence of record, including the claims of the patent language, the specification, and the prosecution history. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). Such types of intrinsic evidence are the most significant source of the legally operative meaning of the disputed claim language and should be considered in that order. *Id*. The claim interpretation "begins with the language of the claim itself." National Recovery Technologies, Inc. v. Magnetic Separation Systems, Inc., 166 F.3d 1190, 1195 (Fed.Cir.1999) (*citing* Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 619 (Fed.Cir.1995)). The terms of a claim are given their ordinary meaning as understood by one of ordinary skill in the art, unless the inventor intended the terms to be construed otherwise. Hockerson-Halberstatdt, Inc. v. Avia Group Intern., Inc., 222 F.3d 951, 955 (Fed.Cir.2000); Karlin Technology, Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 971 (Fed.Cir.1999). Claim language also must be construed in the light of the specifications. Vitronics, 90 F.3d at 1582; *Markman,* 52 3d at 979.

In most situations, intrinsic evidence will resolve any ambiguity in a disputed claim term, and it is improper to rely upon extrinsic evidence when intrinsic evidence serves to resolve such ambiguity. *Vitronics,* 90 3d at 1582. Extrinsic evidence may be used, however, when the claim language remains genuinely ambiguous after consideration of the intrinsic evidence. *Pitney Bowes, Inc. v. Hewlett-Packard Co.,* 182 3d 1298, 1308 (Fed.Cir.1999). "The court may receive extrinsic evidence to educate itself about the invention and the

relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." *Karlin Technology,* 177 3d at 1195.

The Federal Circuit recently held that in construing the claims, "[d]ictionaries are always available to the court to aid in the task of determining meanings that would have been attributed by those of skill in the relevant art to any disputed terms used by the inventor in the claims." *Texas Digital Systems, Inc. v. Telegenix, Inc.,* 308 3d 1193, 1202 (Fed.Cir.2002). The dictionary definition may be used to determine the meaning that one ordinarily skilled in the art would attach to a claim term. *Id.* at 1203-4. Dictionaries, treatises, and encyclopedias are appropriately used even prior to reviewing the prosecution history and specifications of the patent, so long as such use is consistent with the intrinsic record of the patent. *Id.* at 1204.

2. Claim Construction of the '263 Patent

The '263 Patent is entitled "Chest Compression Apparatus." It includes eight claims that describe an oscillatory chest compression device that aids in loosening and eliminating mucus from the lungs of a cystic fibrosis patient. The invention includes a vest fitted with an air bladder. A mechanical apparatus hooked to the vest and bladder by hoses provides pulses of air to the vest bladder. Such pulses stimulate coughing and thus assist the user with expelling mucus buildup in the user's lungs. This device was intended to take the place of manual methods of stimulating mucus expulsion, such as having a trained individual perform daily physical pounding on the back or chest of a person with cystic fibrosis, thus allowing the user of the apparatus more freedom and flexibility.

Specifically, the '263 Patent consists of a single independent claim and seven dependent claims. Claim 1, the independent claim allegedly infringed by Electromed, reads:

Oscillatory chest compression apparatus for a person, comprising:

means for applying a force to the chest of such person, said force applying means including a bladder for receiving pressurized air;

means for supplying a continuous regular pattern of pulses of said pressurized air to said bladder at a frequency irrespective of and greater than the breathing frequency of said person;

means for venting said pressurized air from said bladder; and

means for controlling said pressurized air in said bladder so that the pressure therein can be increased and decreased in correspondence with the expiration and inspiration breathing frequency of said person wherein said force is applied by said applying means at the pulse frequency of said supplying means with greater impact when said controlling means allows increased air pressure in said bladder and with lessor impact when said controlling means allows decreased air pressure in said bladder.

('263, c. 7, 11: 38-58; c. 8, 11: 1-2.)

The parties do not dispute that the individual elements of Claim 1 of the '263 Patent are in means-plus-function form and thus subject to 35 U.S.C. s. 112, para. 6, which states:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specifications and equivalents thereo

35 U.S.C. s. 112, para. 6.

Use of the term "means" creates a presumption that the inventor used the term to trigger s. 112, para. 6. *Sage Products, Inc. v. Devon Indus., Inc.,* 126 3d 1420, 1427 (Fed.Cir.1997). This presumption may be rebutted, however, if the claim elaborates sufficient structure, material, or acts within the claim element to perform the recited function. *Kemco Sales, Inc. v. Control Papers Co., Inc.,* 208 3d 1352, 1361 (Fed.Cir.2000). Once it is established that a means-plus-function limitation is present, the limitation must be construed, thereby determining what the claimed function is and what structures that are disclosed in the written description correspond to the means for performing that function. *Id.* at 1360. The description of some structure in a means-plus-function element does not preclude the applicability of s. 112, para. 6. *Laitram Corp. v. Rexnord, Inc.,* 939 2d 1533, 1536 (Fed.Cir.1991). The structure disclosed in the specification is "corresponding structure" pursuant to s. 112, para. 6 " 'only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim." ' *Texas Digital Sys., Inc. v. Telegenix, Inc.,* 308 3d 1193, 1208 (Fed.Cir.2002), *quoting B. Braun Med., Inc. v. Abbot Labs.,* 124 3d 1419, 1424 (Fed.Cir.1997).

a. Force Applying Means

The use of the word "means" in the first element of Claim 1 of the '263 Patent invokes a presumption that s. 112, para. 6 applies. The function of the force-applying means is for applying a force to the chest of a person. The claim element fails to recite sufficient structure, material, or acts for performing the function of applying force. Thus, the presumption that s. 112, para. 6 applies is not rebutted.

Regarding the force-applying means, Defendant argues that the limitation is incomplete because it does not include a means for providing a supply of pressurized air to the bladder. Plaintiff contends that the means of supplying pressurized air is defined in the second means clause of the '263 Patent, and thus need not be interpreted as to the first means clause of Claim 1.

It appears to the Court that the patent specification describes one structure for supplying all of the pressurized air to the bladder. Specifically, the two alternate embodiments of the patent describe structures that allow the bladder to fill with air to apply force to the chest of a person. In one embodiment of the patent, the patient closes a switch which opens a solenoid valve to supply pressurized air flow to the bladder. ('263, c. 5, ll: 10-14.) In the second embodiment, a bellows system provides pressurized air flow to the bladder. The patient closes a vent hole and a switch controlling a solenoid valve to fill the bladder with pressurized air. ('263, c. 6, ll: 20-26.)

Under either of these embodiments, it appears to the Court that any air that remains in the bladder to establish the "base pressure," as it is referred to by Plaintiffs, is a result of the patient having not evacuated all of the pressurized air from the bladder according to the venting means, as described below. The specification and the two alternate embodiments only describe one means of supplying pressurized air to the bladder; there is no separate structure to create a so-called "base pressure." Because the Court interprets the

means for supplying all of the pressurized air to the bladder in its discussion of the supplying means clause of Claim 1, the Court need not include the means for supplying air to the bladder in the Court's construction of the first means clause.

Thus, the structure of the first means clause of Claim 1 that corresponds to the function of applying force to the chest of a person is construed as a bladder for receiving pressurized air, and its equivalent structures.

b. Supplying Means

The use of the word "means" in the second element of Claim 1 of the '263 Patent invokes a presumption that s. 112, para. 6 applies. As stated in this means clause, the function of the supplying means is for supplying a continuous regular pattern of pulses of pressurized air to the bladder at a frequency irrespective of and greater than the breathing frequency of a person. The claim element fails to recite sufficient structure, material, or acts for performing the function of supplying pulses of pressurized air. Thus, the presumption that s. 112, para. 6 applies is not rebutted.

The parties appear to agree that the structure for supplying the pattern of pulses to the bladder is described by the two embodiments of the specification. In the first embodiment, the pulses of pressurized air are supplied by a blower that provides air to a rotary valve that is rotated with a motor. The alternate embodiment uses a bellows that is expanded and contracted to provide air pressure pulses to the bladder.

Thus, the Court construes the structure of the second means clause of Claim 1 corresponding to the function of supplying pulses of pressurized air to the bladder to mean that pulses are supplied by two alternate structures and their equivalent structures. In one alternate embodiment, a blower provides air to a rotary valve that is rotated with a motor, and the rotary valve in turn supplies a regular pattern of pulses of air to the bladder; the frequency of such pulses is determined by the speed of the motor. In another embodiment, a bellows is expanded and contracted to supply the air pressure pulses via a hose connected to the bladder. The construction of the supplying means includes the equivalent structures of these two embodiments.

c. Venting Means

The use of the word "means" in the third clause of Claim 1 of the '263 Patent invokes a presumption that s. 112, para. 6 applies. The function of the venting means is for venting pressurized air from the bladder. The claim element fails to recite sufficient structure, material, or acts for performing the function of venting pressurized air. Thus, the presumption that s. 112, para. 6 applies is not rebutted.

The specification of the '263 Patent confirms that the device requires, as part of its structure, a person's hand to support the venting function. In both embodiments, the pressurized air is vented from the bladder by means of the user regulating the air pressure by either flipping a switch that releases air (*see* '263 c. 5, ll: 48-50) or by means of the user manipulating a tube to vent the bladder (*see* '263 c. 6, ll: 3-26, 46-50).

The prosecution history of the '797 Patent also supports this construction. FN1 In the prosecution history for the '797 Patent, Plaintiff states:

FN1. The '797 Patent resulted from the same parent application that resulted in the '662 Patent at issue here.

Warwick et al. is an open loop system where the user *must* manipulate switch 162 and tube 116 during each

and every breathing cycle. At column 6, lines 3-26, Warwick et al. clearly discloses that the user must manipulate tube 116 to decrease vest pressure during each inhalation and manipulate switch 162 to increase vest pressure during each exhalation.... Requiring the user to manipulate a tube and switch for each breathing cycle has clear disadvantages.
See Response to First Office Action for '797 Patent at 5 (*emphasis in original*). In light of the language of the specification and the language of later statements made by Plaintiff, it is not appropriate for Plaintiff to claim now that user manipulation of the tube or switch is not required.
The Court therefore construes the structure that corresponds to the venting function to require human interaction with a tube, hose, or switch, or an equivalent structure, in order to vent pressurized air from the bladder.

d. Controlling Means

The use of the word "means" in the fourth clause of Claim 1 of the '263 Patent invokes a presumption that s. 112, para. 6 applies. The function of the supplying means is for controlling the pressurized air in the bladder so that the pressure accommodates the breathing expiration and inspiration frequency of the user. The claim element fails to recite sufficient structure, material, or acts for performing the function of controlling pressurized air. Thus, the presumption that s. 112, para. 6 applies is not rebutted.

Plaintiff asserts that the overall structures which are necessary to carry out the function are a valve, a vent opening, and a control for the valve such as a switch, and the equivalents of such structures. Defendant contends that this means is limited only to the structure described in the specification, and that the structure should not include any equivalent structures. Because Defendant has provided nothing in its briefs to support such an argument, the Court declines to adopt the Defendant's position.

The Court finds support for Plaintiff's proposed construction in the specification. In one embodiment, the specification states that the patient uses a switch that controls a solenoid valve. ('263, c. 5, ll: 20-3.) The switch "must be held down during expiration and released during inspiration so as to provide pulsing during expiration and evacuation during inspiration." (Id.) The alternate embodiment also provides for a means to control the air pressure to accommodate breathing. In this embodiment, the patient manipulates a vent hole and a switch, and the patient in turn controls the solenoid valve that allows for the air to be pressurized appropriately to accommodate breathing. ('263, c. 6, ll: 17-26.) Notably, the specification describes a system that requires human interaction to control the pressurized air in the bladder to accommodate breathing.

The prosecution history also supports such a construction. In its Response to the First Office Action for the '263 Patent, the applicant stated:

In addition, the apparatus of claim 1 includes manual means for alternately controlling the pulse supplying means and the venting means so that air pressure in the bladder can be increased and decreased in correspondence to the breathing frequency of the person. In this way, pressure to the bladder increases and decreases with the breathing frequency of the person. The pulses of the supplying means have a frequency greater than the breathing frequency and are continuous, but are really only felt by the person when there is pressure in the bladder. The apparatus of claim 1 has pulses of a high frequency superimposed on the pressure build up and release occurring as a result of the manual controlling means operated by the person at his slower breathing rate.

Response to First Office Action for '263 Patent at 4. In addition, the Response to the Second Office Action

provides:

a second element of claim 1 in the form of controlling means is provided to specifically allow for an increase and decrease of pressurized air to the bladder in correspondence with expiration and inspiration such that the pulses from the pulse supplying means are superimposed on such increased and decreased pressure.

Response to Second Office Action for '263 Patent at 5.

Consistent with the specification and file history, the Court construes the structure corresponding to the function of controlling pressurized air in the bladder to accommodate breathing as: a valve, a vent opening, and a control for the valve, such as a switch, that is manipulated by a person. Such construction includes any equivalents of these structures.

3. Claim Construction of the '662 Patent

The '662 Patent is entitled "Oscillatory Chest Compression Device." It consists of a single independent claim and eleven dependent claims that describe an oscillatory chest compression device similar to the '263 Patent. The device aids in loosening and eliminating mucus buildup from the lungs of a person with a respiratory disorder such as cystic fibrosis. Generally, the invention includes a vest containing a bladder that is secured to a person's torso. Tubes connect the bladder with two air flow generators. The first oscillatory air flow generator supplies pulses to the vest in accordance with user-selected settings. The second continuous air flow generator maintains pressure in the system. The device also includes two feedback control means: one that maintains the oscillatory frequency at a user-selected setting and another that maintains the pressure in the air chamber at a user-selected setting.

Claim 1 of the patent, allegedly infringed by Electromed, reads:

An apparatus for generating oscillatory air pulses in a bladder positioned about a person, comprising:

an oscillatory air flow generator, comprising an air chamber;

a reciprocating diaphragm operably connected with the air chamber,

a rod having a first end and a second end, the first end operably connected with the diaphragm, and the rod extending generally orthogonal to the diaphragm;

a crankshaft operably connected with the second end of the rod and extending generally orthogonal to the rod; and

a first motor operably connected with the crankshaft;

a continuous air flow generator operably connected with the oscillatory air flow generator;

a first feedback and control means operably connected with the oscillatory air flow generator for maintaining the frequency of the oscillatory air flow generator at a predetermined value;

and a second feedback and control means operably connected with the continuous air flow generator for continuously varying the output pressure of the continuous air flow generator in order to maintain the peak pressure generated by the positive air flow generator at a predetermined value.

a. Air Chamber

The parties do not dispute that an air chamber is "a space containing air." However, Electromed argues that the Court should construe "air chamber" in Claim 1 of the '662 Patent more narrowly to include the walls and seal that are described in the specification. (*See* '662, c. 3, 11: 48-50.) The Court will not add limitations to the claim that appear only in the specification. *Electro Medical Sys., S.A. v. Cooper Life Sciences, Inc.,* 34 3d 1048, 1054 (Fed.Cir.1994). Furthermore, the Court notes that in Defendant's brief, Defendant concedes that the common meaning of an air chamber is a space containing air. *See* Defendant Electromed's Markman Memorandum Regarding Scope and Content of Claims of U.S. Patent No. 4,838,263 and U.S. Patent No. 6,036,662 at 14.

Thus, the Court construes the phrase "air chamber" to mean a space containing air.

b. Operably Connected

Claim 1 of the '662 Patent describes several components that are "operably connected" to other components of the invention. Plaintiff asserts that "operably connected" should be defined uniformly throughout the patent to mean that one component is connected to another component, either directly or indirectly, so that the components may interact with each other. Defendant, on the other hand, contends that the term "operably connected" is indefinite and not supported by structure and, thus, that the drawing and specification must be used to determine the structure and meaning of the term "operably connected" as to each connected set of components.

The Court agrees with Plaintiff that the common meaning of the term "operably connected" is that one component is connected to another component in such a manner that the components may interact with each other. In construing the term in that manner, the Court notes the principle that claim terms should be construed consistently. *See Phonometrics, Inc. v. Northern Telecom, Inc.,* 133 3d 1459, 1465 (Fed.Cir.1998) ("A word or phrase used consistently throughout a patent claim should be interpreted consistently."). Here, the language is used consistently throughout the patent to generically mean that the specified components interact with each other. Nothing in the language of the claims or specifications, or the prosecution history, urges the Court to reach a different result. Furthermore, Defendant's own witness has testified that this term means "[t]hat the interface between two components will serve the function causing one component to interact with respect to one another." *See* Plaintiff's Claim Construction and Brief Regarding '263 and '662 Patents at 14, *citing* Deposition Testimony of Paul Cross. The Court finds no reason to further narrow the term as the claims, not the specifications, should limit the scope of the patent.

Thus, the Court construes the language "operably connected" to mean that one component is connected to another component in such a manner that the components may interact with each other.

c. Orthogonal

Plaintiff has requested that the Court construe the term "orthogonal" according to its dictionary definition. This term does not appear to be in dispute among the parties, however, the Court agrees with Plaintiff that the term should be construed so as to avoid confusion as to the meaning of the term. According to the

Academic Press Dictionary of Science and Technology, "orthogonal" is defined, among other things, as "perpendicular." Academic Dictionary of Science and Technology at 1534 (Christopher Morris, ed .) (1992). The Court sees no reason to diverge from this dictionary definition, as it is consistent with the patent specifications. Thus, the term "orthogonal" should be construed to mean perpendicular.

d. Rod and Crankshaft

Plaintiff asserts that the term "rod" in Claim 1 of the '662 Patent should be construed to mean "a rigid member for connecting and transferring mechanical force from one portion of a device to another portion of a device." Further, Plaintiff contends that "the term would include a connecting rod which is any rigid member for connecting and transferring mechanical force to other portions of a device, including a member that transmits power from one rotating portion of a machine to another in reciprocating motion." Defendant asserts that "rod" should be construed merely as "a one-piece member having a first end and a second end." Furthermore, Defendant argues that the first end of the rod should be construed to be pivotally connected to the crankshaft and the second end of the rod should be construed to be pivotally connected to the diaphragm.

First, the Court notes that it has already construed the term "operably connected" to mean that one component is connected to another component in such a manner that the components may interact with each other. Thus, the Court need not address Defendant's argument that a pivotal connection be read into the "operably connected" language in Claim 1 of the '662 Patent. Claim 1 states, generally, that one end of the rod is operably connected with the diaphragm, the second end of the rod is operably connected to the crankshaft, and the crankshaft is operably connected to the first motor. Consistent with the Court's previous discussion of the term "operably connected," the Court construes these terms to mean that these components are connected in such a manner that the components may interact with each other.

Second, the Court finds that Plaintiff is correct in asserting that the term "rod," as used in the '662 Patent, means "connecting rod." "Connecting rod" is commonly defined as "a rod that transmits motion from a reciprocating part of a machine (as a piston) to a rotating part or vice versa." Merriam Webster's Collegiate Dictionary 245 (10th ed.1998). The McGraw-Hill Encyclopedia of Science and Technology defines a connecting rod as, among other things, "a link in several kinds of mechanisms ... any straight link that transmits motion or power from one linkage to another within a mechanism." McGraw-Hill Encyclopedia of Science and Technology, vol. 4 at 625 (9th ed.2002). As described in the specification of the '662 Patent, the term "rod" is used to describe the diaphragm's mechanical connection to the crankshaft. (*See* '662, c. 4, 11:9-13 ("Diaphragm 19 is mechanically connected through rod 33 to a crankshaft 34, which is driven by a motor 35").) As noted by Plaintiff, the prosecution history also supports the definition of a rod as a connecting rod. Specifically, in the Response to the First Office Action for the '797 Patent, the applicant stated as follows:

Additionally, in the claimed invention, the crankshaft moves the diaphragm through a cycle that is sinusoidal with respect to time. Consequently, the sinusoidal pulses are generated at an oscillation frequency between about 5 and 25 Hz, which is generally below the human audible range. These sinusoidal pulses contain no undesirable high frequency components which would act on the walls of a bladder as a sounding board, creating undesirable noise. Also, the crankshaft is counterbalanced, which offsets the dynamic vibration forces of the reciprocating motion of the diaphragm and connecting rod. The benefits of offsetting these dynamic vibration forces include less noise, less vibration, and increased reliability.

See Response to First Office Action for '797 Patent at 5. Thus, in the context of the '662 Patent, a rod performs the function of transmitting power from the crankshaft to the motor within the mechanism.

Consistent with this definition, the specification, and the prosecution history, the Court construes the term "rod" to mean any straight link that transmits motion or power from one linkage to another within a mechanism.

e. Continuous Air flow Generator

Plaintiff proposes the following construction for "continuous air flow generator" in Claim 1 of the '662 Patent:

The word "continuous" in the term "continuous air flow generator" refers to dynamic adjustments being made so that there will be a continuous or consistent baseline pressure based on the user selected amount. The continuous air flow generator is used to supply air pressure to the system to compensate for leaks in the system and repeated inhalation and exhalation of the user. Together with the pressure compensation feedback system, about which the Court will instruct you in a moment, the continuous air flow generator provides continuous, or dynamic, adjustments so that the user selected pressure can be continuously maintained.

To support such a construction, Plaintiff points to the specification and the prosecution history. Specifically, Plaintiff asserts that the specification and prosecution history discuss dynamic adjustments that are made in the device to maintain a user-selected level of pressure in the air bladder. Plaintiff also contends that the term "continuous air flow generator" is synonymous with "positive air flow generator."

Defendant contends that "continuous air flow generator" must be construed as a generator that produces continuous or non-stop air flow.

In the context of the '662 Patent, the Court rejects Defendant's proposed construction because it disregards the specification language that describes the continuous air flow generator as one that provides dynamic adjustments to maintain a user-selected air pressure. The specification and the prosecution history point to such a construction.

First, the Summary of the Invention equates the continuous air flow generator with a "positive air flow generator" and provides that such mechanism compensates for leakage:

The present invention includes a positive air flow generator operably connected with the oscillatory air flow generator. The positive air flow generator compensates for any leakage in the system, including the hoses and bladder. Also, the positive air flow generator, in connection with a feedback system, maintains the desired peak pressure delivered by the bladder, independent of variations in the bladder and the patient.

('662, c. 2, ll: 24-36.) Further, the specification provides:

Although diaphragm 19 approximates a perfect system in terms of displacement of air into and out of bladder 2 on each stroke, remaining parts of the closed system are less perfect. For example, bladder 2 typically leaks air at a variable rate that is difficult to model. The amount of air leakage is influenced by many factors, including variations in production of the bladder, age, use, and other factors.

Also, tubes 3 and the various connections within the system may leak. Additionally, the air pressure delivered to bladder 2 must be varied due to the repeated inhalation and expiration of the user during treatment, and also due to the size of the particular user. Therefore, positive air pressure generator 16 is used to supply positive air pressure to the system to compensate for the above-identified variables.

('662, c. 5, ll: 226-40.) The specification also provides:

Positive air flow generator 16 and pressure-compensation feedback system 50 provide several advantages. First, positive air flow generator 16 dynamically adjusts the peak pressure in air chamber 17 to provide a consistent peak pressure based on the user selected peak pressure, independent of leaks in the system, size of the user, condition of the bladder, and the repeated inhalation and expiration of the user. Maintaining a constant peak pressure provides for increased efficacy of treatment.

('662, c. 6, ll: 1-9.)

The prosecution history provides additional support for an interpretation of the term "continuous air flow generator" that encompasses dynamic adjustments. Specifically, the prosecution history's differentiation from the '263 Patent is instructive:

Applicants respectfully submit that claim 1, as amended, is patentable over Warwick, et al. (U.S. Patent No. 4,838,263). Claim 1 as amended, includes limitations not found in Warwick et al. First, Warwick does not disclose a "continuous air flow generator ...". Warwick et al. only discloses a storage tank 130 for use in reinflating the vest during the expiration cycle of a breath when the user actuates switch 162 (column 6, lines 12-26). Storage tank 130 does not provide, and is not capable of providing, a continuous, baseline pressure as does the continuous air flow generator of the present claimed invention. As stated in the specification of the present application as originally filed, air flow generator 16 dynamically adjusts the pressure in air chamber 17 to provide a consistent pressure based on the user selected pressure, independent of leaks in the system, size of the user, condition of the bladder, and the repeated inhalation and expiration of the user. Maintaining the pressure also provides for increased efficacy of treatment. (See page 11, lines 3-11 of the specification.) The storage tank 130 of Warwick et al. does not perform this function and, consequently, does not provide the advantages of the present claimed invention.

Response to First Office Action for '797 Patent at 4.

Thus, the Court finds that the specification and the prosecution history determine the construction of the term "continuous air flow generator" in this claim. In so holding, the Court acknowledges Defendant's contention that the term "positive air flow generator" in the claim was modified and renamed "continuous air flow generator" during the prosecution of the patent. *See* Response to First Office Action for '662 Patent at 4-5. It appears to the Court that this amendment was made to clarify the connection between the positive air flow generator and the associated feedback and control means and, thus, to distinguish the invention from prior art. *See* id. Thus, in the context of the '662 Patent, the terms "continuous air flow generator" and "positive air flow generator" are used somewhat synonymously. The continuous air flow generator is a positive air flow generator that is connected to a feedback and control system to provide dynamic adjustments in order to maintain a user-selected air pressure.

Therefore, the Court construes the term "continuous air flow generator" to mean a mechanism that is used to

supply and maintain a user-selected air pressure in the air chamber, thus compensating for leaks in the system and for repeated inhalation and exhalation of the user. Together with the pressure compensation feedback system, the continuous air flow generator provides dynamic adjustments in order to maintain such a user-selected air pressure.

f. Feedback and Control Means

The parties dispute whether the feedback and control mechanism is a means-plus-function clause. As noted above in the Court's discussion of the '263 Patent, use of the term "means" in a claim limitation creates a presumption that s. 112, para. 6 has been invoked, but such presumption may be rebutted if the properly construed claim limitation recites a sufficiently definite structure to perform the claimed function. *See* Kemco Sales, Inc. v. Control Papers Co., Inc ., 208 F.3d 1352, 1361 (Fed.Cir.2000). Here, the claim uses the term "means." The Court finds that the claim does not recite sufficient structure to rebut the presumption that the claim is in a means-plus-function form.

Plaintiff contends that these two feedback and control means should be construed to be feedback and control systems, and not construed as to their individual components. Defendant, on the other hand, asserts a component-by-component construction of the structure. The Court finds Plaintiff's proposed construction more persuasive.

The claim defines two separate feedback and control means. The function of the first feedback and control means is for maintaining the frequency of the oscillatory air flow generator at a predetermined value. The function of the second feedback and control means is for continuously varying the output pressure of the continuous air flow generator in order to maintain the pressure generated by the positive air flow generator at a predetermined value.

The structure that supports the first feedback and control means is described in the specification as a system. The frequency-compensation feedback system 38 serves to maintain the oscillation frequency at a user-selected value. ('662, c. 5, ll: 18-20.) This system maintains a relationship between the frequency set by the user and the output of the oscillatory airflow generator. As noted by Plaintiff, this system functions in a manner similar to the way a heating or cooling thermostat functions in a room, where a user can set a temperature and the system produces heat or cooling output to maintain the room temperature at the user-selected value. Here, the user sets the frequency at a certain level, and the system compensates for leakage and other variables to maintain the oscillation frequency at that user-selected value.

The structure that supports the second feedback and control means is the pressure-compensation feedback system 50. This system serves to maintain the pressure generated by the continuous airflow generator at a predetermined value. ('662, c. 5, ll: 46-48; c. 6, ll: 1-9.) Specifically, this system maintains a relationship between the pressure selected by the user and the output of the positive air flow generator to dynamically adjust the pressure in the air chamber and to maintain the user-selected pressure. ('662, c. 6, ll: 2-9.) Like the frequency-compensation feedback system, this system functions in a manner similar to a room thermostat, which can be adjusted by a person to maintain a constant room temperature.

These two systems distinguish the '662 invention from open-loop system of the prior art, as noted by the applicants in the prosecution history:

Next, Warwick et al. [the '263 Patent] does not disclose either the first or second feedback and control

means found in claim 1. Warwick et al. is an open loop system where the user *must* manipulate switch 162 and tube 116 during each and every breathing cycle. At column 6, lines 3-26, Warwick et al. clearly discloses that the user must manipulate tube 116 to decrease vest pressure during each inhalation and manipulate switch 162 to increase vest pressure during each exhalation. This scheme is also shown in Figure 1. Requiring the user to manipulate a tube and switch for each breathing cycle has clear disadvantages. First, it requires training and good coordination for the patient to master this constant manipulation of tube and switch. Even with training and experience, it is unlikely that a typical user could ever be as efficient in maintaining the desired pressure setting compared to the feedback and control means' [sic] of the present invention. Next, the user must focus on the machine throughout the treatment to manipulate the tube and switch. Finally, an ill or weak person, or young child, is unlikely to be able to use the machine of Warwick et al. due to weakness, lack or [sic] coordination, or immaturity.

The first and second feedback and control means found in claim 1, allow the user to make the desired settings and do nothing more with the apparatus. The user can then watch TV, converse with others, etc. Also, the apparatus of claim 1 can be used with young, weak, or ill patients, where a family member or health care provider can make the predetermined settings for the user. This person can then go on with other tasks.

Response to First Office Action for '662 Patent at 5 (*emphasis in original*).

A dictionary definition also leads the Court to the result that the structure supporting the feedback and control means described in the '662 Patent are closed loop or feedback and control systems. Van Nostrand's Scientific Encyclopedia defines feedback control as:

A basic form of automatic control action in which a measured variable is compared with its desired value to produce an actuating error signal which is acted upon in such a way as to reduce the magnitude of the error.... By contrast, an open loop or *open-loop control* may be defined as a single path without feedback. For example, a process or machine that is preprogrammed to function on a time basis and does not take into consideration continuous measurements of the end results as a criterion for adjusting the control system is open loop. In such a system, no information is fed back to alter the action of the controller.

Van Nostrand's Scientific Encyclopedia at 1151 (6th ed.1983) (*emphasis in original*). The McGraw-Hill Encyclopedia of Science & Technology also contrasts an open loop with a closed loop system:

A closed-loop control system utilizes an additional measure of the actual output in order to compare the actual output with the desired output response. A standard definition of a feedback control system is a control system which tends to maintain a prescribed relationship of one system variable to another by comparing functions of these variables and using the difference as a means of control.

McGraw-Hill Encyclopedia of Science & Technology at 684 (9th ed.2002) (*internal citation omitted*). These definitions are consistent with the Plaintiff's construction of the structure corresponding to the feedback and control means as a closed-loop or feedback control system.

In addition, the Court finds that it is not necessary to construe the structure of this means clause under a component-by-component analysis, as Defendant contends. In *Odetics, Inc. v. Storage Technology Corp.,* the Federal Circuit held that such a component-by-component analysis is not required. 185 F.3d 1259, 1268 (Fed.Cir.1999). Specifically, the *Odetics* court noted that the individual components of an overall structure

corresponding to the claimed function do not limit the claim. *Id*. "Rather, the claim limitation is the overall structure corresponding to the claimed function." *Id*. Under this rule, the Court need not construe the individual components of the structures supporting the function of maintaining the frequency of the oscillatory air flow generator at a predetermined value; nor need the Court construe the individual components of the structures supporting the function of continuously varying the output pressure of the continuous air flow generator in order to maintain the pressure generated by the positive air flow generator at a predetermined value. Instead, the Court need only construe the overall structure which corresponds to those claimed functions.

Therefore, the Court construes the overall structure corresponding to the function of maintaining the frequency of the oscillatory air flow generator as a feedback and control system that acts in the same manner as a room thermostat. With a room thermostat, the user selects a room temperature and the heating or cooling system measures the actual temperature, compares the selected temperature to the actual temperature, and then adjusts to maintain that selected temperature. Here, the user defines a setting for the frequency of oscillations, and the frequency-compensation feedback system 38 measures the oscillation rate, compares it to the user-selected oscillation rate, and adjusts to maintain the user-selected oscillation rate. The Court construes the overall structure corresponding to the function of maintaining the user-selected pressure of the continuous air flow generator as a feedback and control system that also acts in the same manner as a room thermostat, as described above. The user defines a setting for the pressure, and the pressure-compensation feedback system 50 measures the pressure, compares it to the user-selected pressure, and adjusts to maintain the user-selected pressure value. This construction includes the functional equivalents of these structures.

Conclusion

For the reasons stated, IT IS HEREBY ORDERED that the '263 and '662 Patents are construed as set forth in this Order.

D.Minn.,2003.
Advanced Respiratory, Inc. v. Electromed, Inc.

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