NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

RESPIRONICS, INC., AND RIC INVESTMENTS, LLC, Plaintiffs-Appellants,

v.

INVACARE CORP., Defendant-Cross Appellant.

2010-1447,-1505

Appeal from the United States District Court for the Western District of Pennsylvania in case no. 04-CV-0336, *Chief Judge* Gary L. Lancaster.

Decided: July 8, 2011

W. THOMAS MCGOUGH, JR., Reed Smith, LLP, of Pittsburgh, Pennsylvania, argued for plaintiffs-appellants. With him on the brief were GENE A. TABACHNICK and JOSHUA S. BISH.

CHARLES B. LYON, Calfee, Halter & Griswold, LLP, of Cleveland, Ohio, argued for defendant-cross appellant. With him on the brief were MITCHELL G. BLAIR, NENAD PEJIC and JENNIFER B. WICK.

Before BRYSON, MAYER, and DYK, *Circuit Judges*. BRYSON, *Circuit Judge*.

Ι

Respironics, Inc., owns two patents through its wholly owned subsidiary, RIC Investments, LLC. The patents, U.S. Patent No. 6,609,517 ("the '517 patent"), and U.S. Patent No. 6,105,575 ("the '575 patent"), share a common specification. Both are entitled "Method and Apparatus for Providing Positive Airway Pressure to a Patient." The '517 patent is a continuation-in-part of the '575 patent.

Respironics sued Invacare for infringement of the '575 patent, the '517 patent, and other patents not relevant to this appeal. Early in the proceedings, the district court entered summary judgment that Invacare's "Commercial Device" did not infringe the asserted claims of the '575 Respironics' allegation that Invacare's "Trade patent. Show Device" infringed the '517 patent was tried before a jury, which found that the Trade Show Device infringed the asserted claims of that patent. The district court granted Respironics' motion for summary judgment as to anticipation of the asserted claims of the '517 and '575 patents, holding that those claims were not anticipated by a 1987 article by Dr. Magdy K. Younes entitled "An Apparatus for Altering the Mechanical Load of the Respiratory System."

Respironics appealed issues relating to infringement, and Invacare cross-appealed issues relating to both infringement and validity. In *Respironics I*, this court modified the district court's construction of some of the appealed claim terms. *Respironics, Inc. v. Invacare Corp.*, 303 F. App'x 865 (Fed. Cir. 2008) (*Respironics I*). This court vacated the summary judgment of noninfringement of the '575 patent and remanded the case to the district court to consider infringement under the modified claim construction. On Invacare's cross-appeal of the summary judgment of no anticipation, this court noted that neither Respironics nor the district court had identified any claim limitation that was not disclosed in the asserted reference. This court remanded so that Respironics could more clearly articulate the differences between that reference and the asserted claims.

On remand, both Invacare and Respironics filed crossmotions for summary judgment as to the validity of both patents and infringement of the '575 patent. Invacare's anticipation defense again focused on the article by Dr. Younes, a physician and researcher specializing in respiratory therapy. Dr. Younes served as Respironics' expert witness on validity. Invacare's expert witness on validity was Jeffrey L. Orth, a biomedical engineer. The district court reopened the record and allowed both Mr. Orth and Dr. Younes to submit updated declarations setting forth each expert's opinion on anticipation under the amended claim construction. The court also allowed each side to depose its opponent's expert for a second time.

Following that supplementary discovery, Respironics argued that Dr. Younes had identified eight elements that distinguished his 1987 article from the asserted claims. The district court agreed with Invacare, however, that the elements that Dr. Younes identified did not distinguish the asserted claims from the Younes article. Nonetheless, the court held that Invacare had not shown that the article disclosed all of the elements "as arranged" in the claims. Accordingly, the court held that no reasonable jury could find that the Younes article anticipated the asserted claims and entered summary judgment in favor of Respironics on the issue of invalidity of the claims of the '575 and '517 patents. After construing the term "predetermined" in the claims of the '575 patent, a term this court did not squarely address in *Respironics I*, the district court entered summary judgment that the accused Commercial Device does not infringe the asserted claims of the '575 patent.

Respironics has again appealed the judgment as to infringement, and Invacare has again cross-appealed the judgment as to anticipation. Because we hold that the asserted claims of the two patents are anticipated by the Younes reference, we reverse the summary judgment of no anticipation. In light of that ruling, it is not necessary for us to address Respironics' appeal relating to the construction of "predetermined," as the dispute over the construction of that term is relevant only to infringement and not to validity.

Π

A device embodying Respironics' claimed invention provides "positive pressure support therapy" to patients suffering from sleep apnea, a condition characterized by a collapse in the soft tissue of the airway. Traditional CPAP (continuous positive airway pressure) therapy supplies a steady stream of positive air pressure to a sleeping patient. The delivered pressure is constant, regardless of whether the patient is inhaling or exhaling. When the patient is inhaling, the direction of the airflow assists the patient's efforts to inhale and holds the airway open, preventing it from collapsing. When the patient is exhaling, however, the flow of air is in opposition to the patient's breath. Many patients found exhaling against the stream of air uncomfortable and consequently discontinued CPAP therapy. Respironics' patents are directed to a method and a device that reduces the magnitude of the positive pressure that is provided to the patient during the expiratory phase of the breathing cycle as compared to the magnitude of the pressure that is delivered during the inspiratory phase.

Both patents describe two embodiments of the invention: the "proportional" embodiment and the "predetermined" embodiment. The asserted claims of the '517 patent (claims 29, 30, and 32) are directed to the "proportional" embodiment, whereas the asserted claims of the '575 patent (claims 21, 43, and 44) are directed to the "predetermined" embodiment.

A device that practices the "proportional" embodiment measures physiological aspects of the patient's breathing habits, such as the rate at which the patient inhales and exhales, the volume of air that the patient moves with each breath, or the "pressure gradient between the inlet of the patient's airway and his lungs." '517 patent, col. 9, ll. 31-41. The device uses a formula, discussed in *Respi*ronics I, to control the reduction in expiratory pressure in response to those monitored characteristics.

In contrast, a device that practices the "predetermined" embodiment decreases the pressure during exhalation based not on the patient's monitored breathing habits, but instead on a function that the patent refers to as a "pressure profile." '575 patent, col. 7, ll. 5-17. We construed that term in *Respironics I*, in which we held that a "pressure profile" has three components: duration, magnitude, and shape. We explained that duration is "the time difference measured from the start to the end of the profile"; magnitude is "the pressure difference between the profile's maximum and minimum pressures"; and the profile's shape is "the contour along which the pressure changes over time, describing the way in which the profile drops off to arrive at the minimum pressure and then rises up to arrive back at the maximum pressure, independent of the particular magnitude and duration of the profile."

Invacare contends that Dr. Younes's 1987 article anticipates the "predetermined" and the "proportional" claims. The article describes an apparatus for altering the "load" of the respiratory system, which refers to the air pressure that a patient must work against while breathing. The respiratory support device disclosed in the Younes article can deliver both positive and negative pressure. That is, the apparatus can function both as a ventilator and as a positive pressure support apparatus. For the reasons discussed below, we agree with Invacare that no reasonable jury could conclude that the Younes article is not anticipatory.

А

Respironics argues that eight features of the '517 and '575 patents are not disclosed in the Younes article. We agree with the district court that those features are not actually limitations of the claims. Because every claim limitation is found in the Younes reference, Invacare has met its burden to make a prima facie showing of anticipation. See Orion IP, LLC v. Hyundai Motor Am., 605 F.3d 967, 977 (Fed. Cir. 2010). We further conclude that Respironics has not pointed to any contrary evidence that would raise a genuine issue of material fact as to whether the Younes article anticipates the claims. See Leggett & Platt, Inc. v. VUTEk, Inc., 537 F.3d 1349, 1352 (Fed. Cir. 2008). We therefore hold that the asserted claims are invalid as anticipated.

1. The '517 Patent

The validity of claims 29, 30, and 32 is at issue. Claim 29 reads as follows:

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.

Dr. Younes's article unquestionably discloses an apparatus that generates a flow of a breathing gas. It also discloses "sensing a fluid characeristic associated" with that flow of breathing gas. In *Respironics I*, we construed "fluid characteristic" as "flow or volume," and the Younes article explicitly discloses a sensor for the flow of gas, stating that "[f]low is measured by use of a pneumatograph, and airway pressure is sampled at the breathing valve." Dr. Younes agreed during his deposition on remand that the apparatus disclosed in his article includes appropriate sensors to measure the flow rate and volume of the breathing gas and to generate a signal corresponding to those parameters. The expiratory gain is a constant

that is used to change the delivered pressure depending on the flow rate. '517 patent, col. 11, ll. 11-14 ("[G]ain is the constant used to augment pressure based on the flow rate."). The greater the gain, the greater the reduction in expiratory pressure. Dr. Younes agreed that his apparatus discloses selecting gain and multiplying the signal by the gain.

In seeking to show that the Younes article does not anticipate claim 29, Respironics argues that the Younes article "does not describe anything having to do with preventing the collapse of the 'airway of the patient." Respironics argues that claim 29 (and every asserted claim) is directed to the treatment of obstructive sleep apnea and that treating that disorder requires preventing the collapse of the upper airway in particular, not the "airway" in general. According to Respironics, in the context of these patents "everyone knows that the 'airway' referred to is the upper airway." Respironics then asserts that the Younes article does not specifically disclose providing positive pressure to prevent the collapse of the upper airway in a patient suffering from obstructive sleep apnea.

As the district court recognized, the distinction that Respironics seeks to draw between the Younes article and claim 29 is wholly unsupported. In *Respironics I*, we noted that the claims of the '517 and '575 patents are "not limited to the treatment of any particular condition or disease state, but recite 'delivering pressurized breathing gas to an airway of a patient." The '517 specification acknowledges that the system disclosed in Younes applies pressure "directly to the subject's airway." '517 patent, col. 3, ll. 58-60. The Younes article therefore plainly discloses the claim limitation of "delivering pressurized breathing gas to the airway of a patient."

Respironics also argues that the Younes article does not teach "controlling a pressure of the flow of breathing gas," the last step in the method of claim 29. In particular, Respironics argues that the system disclosed in Dr. Younes's article does not measure and control for air leakage that inevitably occurs between the patient interface (a mask, for example) and the patient. Respironics' position is that a system that does not account for leakage cannot accurately calculate a "fluid characteristic" and therefore cannot vary the applied pressure in response to that parameter. Because the apparatus disclosed in Younes does not have that capability, Respironics argues that the article cannot anticipate claim 29. Respironics made the same argument in Respironics I, in response to which we noted that "leak detection is not recited in the claims" of the '517 and '575 patents. The same point applies here—the absence of a disclosure of leak detection in the Younes article does not defeat anticipation, because leak detection is not a limitation of the asserted claims.

Claim 30 of the '517 patent reads as follows:

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

Claim 30 adds the step of reducing the delivered pressure by venting gas from the conduit that carries the pressurized gas from the apparatus to the patient. The Younes article discloses the inclusion of "logic circuits" that direct the position of a "spirometric piston" to control the release of breathing gas from the patient—apparatus conduit to attain a predetermined pressure. Although the article states that this aspect of the disclosed breathing apparatus was not actually built, a reference is anticipatory if it enables one skilled in the art to practice the invention. The prior inventor need not have reduced his invention to practice. *Verizon Servs. Corp. v. Cox Fibernet Va., Inc.,* 602 F.3d 1325, 1337 (Fed. Cir. 2010). There is no dispute that the Younes disclosure is enabling. Thus, as with Claim 29, the Younes article clearly discloses each of the limitations of claim 30.

Claim 32 of the '517 patent reads as follows:

The method of 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 patent'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.

Claim 32 differs from claim 29 only in that it specifically recites the step of applying positive pressure to the patient's airway during inspiration ("IPAP"). The specification of the '517 patent defines IPAP as a constant value. '517 patent, col. 2, ll. 20-27. The specification states that the Younes system "may load or unload during inspiration, expiration, or both[.]" *Id.* at col. 3, ll. 56-57. Dr.

Younes agreed that the apparatus disclosed in his article can provide a constant positive pressure. He also agreed that the apparatus can include a gating circuit and rectifier that allow for deviation from that constant pressure during one phase of the breathing cycle. That is, he agreed that his article enables one skilled in the art to maintain constant pressure during inspiration and to reduce that pressure during expiration (and only during expiration) based on the product of a gain and a measured fluid characteristic. Thus, Invacare met its burden to show clear and convincing evidence that each of the limitations of claim 32 was found in the Younes article.

2. The '575 Patent

From the '575 patent, claim 21 provides as follows:

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.

The Younes article discloses all of the limitations of claim 21. The "gas flow generator" is disclosed for the same reasons as in the '517 patent. So is the "sensor." The Younes article discloses a pneumotachograph to measure the flow and means to measure pressure; that signal is fed to a gating circuit, "which identifies positive or negative zero crossing of the flow signal" and thus distinguishes between inhalation and exhalation.

Respironics argues that four limitations of claim 21 are missing from the Younes article: (1) "airway of a patient"; (2) "patient interface"; (3) "predetermined pressure profile"; and (4) "shape."

As to the first limitation, we reject Respironics' argument with respect to the term "airway of a patient" for the same reason that we rejected the same argument made with respect to claim 29 of the '517 patent.

As to "patient interface," Respironics argues that the term means "a mask (or nasal cannulae) strapped to the patient while he sleeps." According to Respironics, the Younes article does not disclose either of those specific interfaces and therefore does not anticipate the claim. The specification undermines Respironics' argument, however. In one embodiment, "the patient interface is either a nasal mask or a full face mask." '575 patent, col. 9, ll. 8-9. But other embodiments refer to the interface as being "a mouthpiece, a nasal seal, nasal prongs or cannulae, an endotrachial tube, a trachea adapter or any other suitable appliance for interfacing between a source of breathing gas and a patient." Id. at col. 9, ll. 11-14. The specification continues: "Also, the phrase 'patient interface' can encompass more than the interface worn by the patient. For example, the patient interface can include . . . any other structures that connect the source of pressurized breathing gas to the patient." Id. at col. 9, ll. 14-18. In his deposition testimony on remand, Dr. Younes stated that the pressure-support apparatus disclosed in his article and a commercial CPAP machine use fundamentally different types of patient interfaces, with the interface of his article being more invasive than a typical CPAP interface. But he did not suggest that the Younes article fails to disclose a "patient interface" as that term is broadly used in the '575 patent. Because Respironics' proposed interpretation of that term conflicts with its own specification, there is no disputed issue of fact as to whether the Younes article discloses a "patient interface" as the term is used in the '575 patent.

The third and fourth limitations that Respironics suggests are missing from the Younes article are the related terms "predetermined pressure profile" and "shape." The Younes article states that the applied pressure can be "made to change in proportion to any external function," for example, a sinusoidal function. Dr. Younes acknowledged that his article fully enables an apparatus and a method in which the pressure controller delivers "a continuous positive airway pressure in inhalation, and a pre-determined pressure profile in exhalation, reducing the pressure of the CPAP."¹ He agreed that the

¹ The dispute between Invacare and Respironics regarding the construction of "predetermined pressure profile" does not affect the invalidity analysis. In the

pressure profile disclosed in his article has "a shape in which the pressure changes over time," and he further agreed that the disclosed shape of the pressure profile "describes the way the profile drops off to arrive at the minimum pressure, and then rises up to arrive back at the maximum pressure, independent of the exact values of magnitude and duration." *See Respironics I*, 303 F. App'x at 872-73 (construing "pressure profile" and "shape").

After making that concession, Dr. Younes stated that he never reduced that particular aspect of his invention to practice. As noted, however, anticipation does not require

In *Respironics I*, we held that "the predetermined pressure profile reduces the constant pressure of CPAP or the reduced EPAP pressure of bi-level therapy once the device detects the expiratory breathing phase." That is the construction Respironics favors, and it was the governing construction when Dr. Younes acknowledged that his article discloses and enables a "predetermined pressure profile."

After Dr. Younes made that concession, the district court ruled that "predetermined" means "chosen in advance, before operation." The Younes article discloses a "function generator" that can generate a sine wave with a fixed (i.e., "predetermined") shape, magnitude, and duration. The article plainly anticipates that element under the district court's construction of "predetermined." We need not decide, therefore, whether the district court's construction was in error, because on this record, the article anticipates either way.

order on appeal, the district court held that "predetermined" means "chosen in advance, before operation." The court therefore required that each of the three characteristics of the "pressure profile"—duration, magnitude, and shape—must be selected in advance. Respironics argues that this construction conflicts with the specification and violates the mandate in *Respironics I*. Invacare disagrees.

that the prior art reference was reduced to practice, as long as it was enabled. Dr. Younes conceded that his article provides an enabling disclosure of the contested claim limitations.

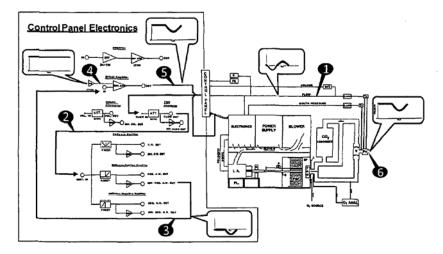
For the same reasons, there is no dispute that the article discloses all of the limitations of claim 43 of the '575 patent, which recites the method that corresponds to apparatus claim 21.

Claim 44 of the '575 patent depends on claim 43 and adds the additional step of "setting at least one of a magnitude and duration of said pressure profile." The Younes article discloses that element by describing a control panel that includes the ability to select "magnitude, pattern, duration, and time of application (in relation to the respiratory cycle) of the altered load."

В

Although the district court rejected the distinguishing features that Respironics identified, the court accepted Respironics' position that the Younes article does not disclose all the limitations "as arranged" in the claim. Respironics continues to press that argument as a basis for upholding the district court's ruling. The "rearrangement" argument relies mainly on the way that Invacare's expert, Mr. Orth, presented the figures from the Younes article in his expert report. The diagram in Mr. Orth's expert report corresponding to the proportional embodiment appears below. Mr. Orth prepared a similar diagram for the predetermined embodiment. Those diagrams match elements of the underlying circuitry of Younes, as illustrated in Figure 3 of Younes (left), with the schematic version of the apparatus, as illustrated in Figure 1 of Younes (right). Mr. Orth added the arrows

indicated by callouts (1) through (6). The diagram presented in Mr. Orth's report did not include the numerical callouts. Those were included in Invacare's brief, but they do not affect the substance of the diagrams.



Mr. Orth did not have to combine features from unrelated embodiments in the Younes article to generate the above diagram, which depicts the claimed invention. Moreover, contrary to Respironics' contention that the diagram is "fabricated and self-serving," the diagram was presented to Dr. Younes during his deposition on remand and Dr. Younes acknowledged that it fairly and accurately represents the teaching of his 1987 article.

The first callout illustrates the connection between the pneumotachograph, which measures the patient's breathing habits, and the flow attenuator. Dr. Younes agreed:

Q. First, with respect to the flow rate signal, the pneumotachograph provides a flow rate signal, isn't that correct?A. That's correct.

Q. [I]n figure three, you indicate flow in, in the flow attenuator?A. Right.Q. So, as it is set up in figure three, it means that the flow rate signal is going into the flow attenuator?A. Only if you connected this way.

Q. [Y]ou will agree that the way the flow rate is shown . . . as going into the control panel and the flow in, is one of the ways that is described in the Younes article[.]

A. That yes, that this is something that can be done with the Younes article, yeah, it is the Younes apparatus.

The second callout illustrates the connection between the flow attenuator, where the signal is multiplied (i.e., reduced) by a preselected gain, and the rectifier. Again, Dr. Younes agreed that the annotation in Dr. Orth's diagram accurately presents that aspect of his article:

Q. And with respect to the Younes apparatus . . . once it enters the flow in of the flow attenuator, it is multiplied by a gain in the attenuator, correct? A. Attenuators usually reduce the signal as opposed to increasing it, but that's fine.

Q. It is still a multiplication of a gain?

A. Right, right, right.

The rectifier allows the apparatus to apply or to vary the applied pressure during only one part of the breathing cycle; for example, it permits the apparatus to reduce the pressure only during expiration. With reference to the diagram, Dr. Younes agreed:

Q. [T]he signal coming out of the flow attenuator is shown as going into the rectifier. That's certainly something disclosed and described in the Younes article, is it not?

A. Yes, that's only if you want to apply, to change the pressure in proportion to the flow during one part of the cycle. The rectifier is only useful if you want to say I want to apply it only during inspiration or only during expiration, then you go through the rectifier.

The third callout represents the connection between the rectifier and an offset amplifier, a connection the Younes article plainly discloses: "The rectifier output is then connected to the amplifier input and from there to the drive input." Again, Dr. Younes agreed:

Q. [I]f you want to combine, is there a way to combine flow rate with any other parameter described in your article?

A. Yes, you can go with the—you can go into the opposite amplifier and dial in an additional constant signal.

Q. And that would be described [in the Younes article] where you say: "If flow, volume, or other external function are additionally inputted into the offset amplifier, combined loads can be applied."

A. Right.

Q. So the arrow going up to the offset amplifier would be in accordance with what I just read.

A. Yes.

The fourth callout is the other input to the offset amplifier, a constant voltage signal. The fifth callout represents the connection between the amplifier and the pressure generator. Dr. Younes agreed that those connections and callouts are entirely consistent with his disclosure:

Q. And what is the other input to the offset amplifier?

A. Its own input, it is just a constant voltage generator.

Q. So showing a straight line coming into the voltage source . . . is consistent with what is described and illustrated in the Younes article . . . correct?

A. Yeah. In practice, the output of the offset amplifier, which in this case would also contain the flow signal, would go into the input of the top circuit, which has an amplifier. And then it would go to the device itself, to the pressure.

Finally, the sixth callout represents the physical connection between the patient and the pressure generator, i.e., the "patient interface."

Mr. Orth chose to annotate the figures in order to facilitate his presentation of a highly technical reference to the district court. We see no indication that he picked and chose from multiple disclosed embodiments or otherwise altered the figures in a way that would suggest that the article does not disclose all the elements of the invention as arranged in the claims.

С

In sum, we agree with the district court that the features that Respironics argues distinguish its claims from Dr. Younes's article do not correspond to elements of the claims and therefore cannot distinguish the claims from the prior art. However, we disagree with the district court's conclusion that the elements of the Younes article were not "arranged" in a manner that rendered the article anticipatory. For that reason, we reverse the district court's grant of summary judgment to Respironics on the issue of anticipation. Moreover, as the above analysis indicates, the Younes article discloses every element of the asserted claims and it does so in a manner that does not require rearrangement of the disclosed elements to obtain the invention of the asserted claims. Because we conclude that a reasonable jury would necessarily find that the asserted claims are anticipated by the Younes article, we hold that the claims are anticipated as a matter of law. We therefore direct the entry of judgment in favor of Invacare on the issue of anticipation. In light of our holding as to invalidity, Respironics' appeal of the court's construction of the term "predetermined" and summary judgment of noninfringement is moot.

Each party shall bear its own costs for this appeal.

REVERSED and REMANDED