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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DOUGLAS S. MCNAIR[1]

Appeal 2017-011482
Application 12/688,593
Technology Center 3700

Before RICHARD M. LEBOVITZ, RYAN FLAX, and TAWEN CHANG, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims directed to methods of optimizing aerosolization and administration of an inhaled drug to a patient via a vibratory inhaler device. The Examiner rejected the claims as obvious under 35 U.S.C. § 103. Pursuant to 35 U.S.C. § 134(a), Appellants appeal the Examiner's determination that the claims are unpatentable. We have jurisdiction under 35 U.S.C. § 6(b). The rejection is reversed.

STATEMENT OF THE CASE

Claims 1, 3–9, and 11–16 stand rejected under pre-AIA 35 U.S.C.

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[1] The Appeal Brief ("Br."; entered March 2, 2017) identifies Cerner Innovation, Inc., as the real party in interest.

§ 103(a) as obvious in view of Burnell et al. (US 2007/0225587 A1, published Sep. 27, 2007) ("Burnell") and Dunsmore et al. (US 2009/0126731 A1, published May 21, 2009) ("Dunsmore"). Ans. 2.

DISCUSSION

Claim 1

Claim 1 is reproduced below (with annotations [1]–[4] added to number each step of the claim):

> 1. A method of optimizing an aerosolization and administration of an inhaled drug to a patient via a vibratory inhaler device to facilitate the aerosolization as a plume of fine particles and to inhibit agglomeration or coagulation of particles within the plume, the method comprising:
>
> [1] collecting time-domain response measurements by performing acoustic pulse reflectometry on a patient, the measured time-domain response corresponding to acoustic and anatomical properties associated with the patient's mouth, pharynx, and upper airway;
>
> [2] identifying a frequency spectrum of acoustic vibrations that are specific to the patient's mouth, pharynx, and upper airway, wherein the frequency spectrum identified is based on the time-domain response measurements collected by performing acoustic pulse reflectometry on the patient; and
>
> [3] identifying a vibratory inhaler device having a first dispersal configuration, wherein the vibratory inhaler device having the first dispersal configuration is specifically identified based on a determination that the first dispersal configuration produces the frequency spectrum of acoustic vibrations that are specific to the patient's mouth, pharynx, and upper airway, wherein the first dispersal configuration includes a size of the vibratory inhaler device and a geometry of the vibratory inhaler device.

As indicated above, claim 1 has three recited steps of 1) "collecting time-domain response measurements by performing acoustic pulse reflectometry on a patient," 2) "identifying a frequency spectrum of acoustic vibrations that are specific to the patient's mouth, pharynx, and upper airway," and 3) "identifying a vibratory inhaler device having a first dispersal configuration." The "first dispersal configuration" of step 3) is based on "the frequency spectrum of acoustic vibrations that are specific to the patient's mouth, pharynx, and upper airway."

The Examiner found that Burnell discloses the three claimed steps "substantially as claimed except for identifying a frequency spectrum of acoustic vibrations that are specific to the patient," which corresponds to step 3) of claim 3. Final Act. 2. For this limitation, the Examiner cited Dunsmore as describing the frequency spectrum of a patient's airway. *Id.* at 2–3. The Examiner determined that it would have been obvious to one of ordinary skill in the art to have "to have identified the frequency spectrum of the patient's airway as taught by Dunsmore et al. in order to determine the most effective therapy." *Id.*

Appellant states that Dunsmore describes locating the resonance frequency of the patient's lungs when running a test utilizing a continuous positive airway pressure (CPAP) machine to deliver percussive therapy to keep patient airways open. Br. 10. Appellant contends, however, that Dunsmore does not determine the acoustic vibrations that are specific to the patient's mouth, pharynx, and upper airway as required by steps 2) and 3) of claim 1. *Id.* at 11. Appellant also argues that neither of "Burnell nor Dunsmore make any statements regarding the identification of a frequency

spectrum produced by a vibratory inhaler device" as required by step 3) of the rejected claim. *Id.* at 12.

We agree with Appellant that the Examiner did not meet the burden of establishing that claim 1 is obvious based on the Burnell and Dunsmore publications.

Burnell explains that pre-lung deposition is undesirable when using inhaler devices to deliver medication to the lung because such deposition in the pre-lung upper respiratory tract results in the delivery of medication that "never reaches its primary therapeutic delivery target point at the lung." Burnell ¶ 4. For this reason, Burnell states that "[c]onsiderable effort has therefore been directed towards understanding pre-lung deposition to enable the design of improved in vitro laboratory performance testing apparatus. . . that more effectively simulates what happens in vivo." *Id.* To address the problem of pre-lung deposition, Burnell teaches utilizing acoustic reflecting imaging "to map the internal geometry of the mouth, throat and upper respiratory tract of each patient in the sample group." *Id.* at ¶ 6. Burnell further teaches:

> matching said at least one internal physical parameter of the airway of the first patient's throat with a dataset comprising pre-determined data relating to the corresponding internal physical parameter for the throat of at least one other patient,

Burnell ¶ 12. Data from the patient's throat is thus matched to pre-determined throat data obtained from at least one other patient.

Burnell teaches that the matching step "enables prediction of the tendency of particles to deposit within a first-patient's throat when said particles are orally inhaled through said first throat." *Id.* at ¶ 13. Burnell teaches that this information is "suitable for use in the assessment of

inhalation-type medicament dispenser devices." *Id.* at ¶ 146. Burnell's method enables the determination of how much drug will be deposited in the throat of the patient and therefore how much will ultimately reach the lung, the desired destination.

While Burnell utilizes acoustic reflecting imaging as does the claimed method ("acoustic pulse reflectometry"), Burnell does not use this technique to measure "a frequency spectrum of acoustic vibrations that are specific to the patient's mouth, pharynx, and upper airway" as required by the claims, but rather uses it to measure the internal *geometry* of the mouth, throat and upper respiratory tract to determine how much drug is deposited in these regions before reaching the lung. *Id.* at ¶ 6.

Dunsmore does not compensate for this deficiency. In paragraph 43 cited by the Examiner, Dunsmore describes programming a controller of a respiratory device "to perform an example routine in which a resonant frequency (where the most effective therapy is likely to occur) of the patient's lungs is 'located.'" Dunsmore ¶ 43. Dunsmore explains:

> Throughout the example routine, the patient is monitored for chest wiggle, as is information signaled from the pressure sensors **67, 120,** to determine the pulse rate frequency that best fits the resonant frequency, or "sweet spot," for a particular patient. In one embodiment, an accelerometer can be coupled to the patient's chest and provide a signal indicative of chest movement. This chest movement signal can be monitored based on the rate of frequency pulses delivered to identify an optimal frequency.

Id. at ¶ 44. Thus, Dunsmore describes locating a resonant frequency of the lung, but not the resonant frequency of the patient's mouth, pharynx, and upper airway as required by all the claims ("a frequency spectrum of acoustic vibrations that are specific to the patient's mouth, pharynx, and

upper airway"). The Examiner did not explain why one of ordinary skill in the art would have used Burnell's acoustic imaging, which is utilized to measure the *geometry* of the throat, to determine "a frequency spectrum of acoustic vibrations that are specific to the patient's mouth, pharynx, and upper airway." Dunsmore determined resonance frequency, but of the lungs. The Examiner did not provide an adequate reason why one of ordinary skill would have reached, from the teachings in Burnell and Dunsmore, the claimed step of "[2] identifying a frequency spectrum of acoustic vibrations that are specific to the patient's mouth, pharynx, and upper airway, wherein the frequency spectrum identified is based on the time-domain response measurements collected by performing acoustic pulse reflectometry on the patient."

Because the Examiner did not meet the burden of establishing the claims are prima facie obvious in view of Burnell and Dunsmore, the rejection of claim 1, and dependent claims 3–8, is reversed.

Claim 9

Independent claim 9 is reproduced below:

> 9. Non-transitory computer readable media having computer-executable instructions embodied thereon that, when executed, perform a method for identifying an optimal configuration of a vibratory inhaler device for a patient, the method comprising:
>
> collecting time-domain response measurements by performing acoustic pulse reflectometry on a patient;
>
> storing the time-domain response measurements of the patient as acoustic reflectometry data in a medical record of the patient;
>
> identifying a frequency spectrum of acoustic vibrations that are specific to the acoustic reflectometry data

> corresponding to the patient and spirometry data corresponding to the patient; and
>
> selecting a vibratory inhaler device having a first dispersal configuration, wherein the vibratory inhaler device having the first dispersal configuration is selected based on a determination that the first dispersal configuration that produces a frequency spectrum that matches (i) the frequency spectrum of acoustic vibrations that are specific to the acoustic reflectometry data corresponding to the patient and (ii) the spirometry data corresponding to the patient, wherein the first dispersal configuration increases deep-lung drug deposition rates in the patient based on the matching frequency spectrum produced via the first dispersal configuration, wherein the first dispersal configuration includes a size of the vibratory inhaler device and a geometry of the vibratory inhaler device; and
>
> initiating an order of the vibratory inhaler device having the first dispersal configuration for the patient.

Independent claim 9 is not limited to identifying a frequency spectrum of acoustic vibrations that are specific to the patient's mouth, pharynx, and upper airway as in claim 1, but rather does not specify where the frequency is ascertained ("the frequency spectrum of acoustic vibrations that are specific to the acoustic reflectometry data corresponding to the patient"). However, as argued by Appellant, the Examiner did not provide adequate evidence that the "selecting" step of claim 9 is met by either cited publication alone, or in combination.

Independent claim 9 comprises a step of "selecting a vibratory inhaler device having a first dispersal configuration." The selection is based on two criteria: "i) the frequency spectrum of acoustic vibrations that are specific to the acoustic reflectometry data corresponding to the patient and (ii) the spirometry data corresponding to the patient."

The Examiner found that "Burnell et al. discloses a method comprising measuring time-domain response by acoustic pulse reflectrometry . . . and identifying a device type," i.e., the "selecting" step of claim 9. Ans. 2. The Examiner also found that Burnell does not disclose initiating an order of the vibratory inhaler device for the patient as required by the last step of claim 9. *Id.* However, the Examiner found Burnell "discloses the method is suitable for assessment of inhalation-type medicament dispenser devices for delivery of medicaments for treatment of respiratory disorders ([0146])." *Id.* The Examiner determined that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the step of initiating an order of the inhaler device in order to provide treatment of respiratory disorders." *Id.*

As indicated above, claim 9 requires "selecting" a device "based on a determination" that the frequency spectrum of the device matches the frequency spectrum and spirometry data corresponding to the patient. Burnell performs "assessment of inhalation-type medicament dispenser devices" (Burnell ¶ 146) based on the geometry of the patient's airway, but does not describe *selecting* a device based on matching the device's characteristics to the patient's airway. The device is already selected in Burnell. Dunsmore describes finding a pulse rate frequency of a device that "best fits" the resonance frequency of the lung. Dunsmore ¶ 44. Dunsmore does not "select" a device either, but rather operates the valve of the pre-selected device to change the frequency pulses to match the lung resonance.

> More particularly, the example routine includes the controller **28** operating the electronic valve **40** to initially generate higher frequency pulse rates (e.g., 20 Hz) and gradually decrease to a lower rate (e.g., 2 Hz). The process is then repeated at

> incrementally higher pressures. The rate can also decrease, if desired, by starting at a high frequency pulse rate and decreasing to a lower rate.

Dunsmore ¶ 43.

The issue in the rejection of claim 9 boils down to whether one of ordinary skill in the art would have had reason to have *selected* a device having a frequency spectrum that "best fits" the resonance frequency of the lung, rather than proceeding through the example routine described by Dunsmore. The Examiner found that Burnell discloses identifying a device type, citing paragraphs 15, 17, 87, and 134 of Burnell. Ans. 2. However, we have reviewed these paragraphs and do not find the Examiner's finding to be supported by these disclosures in Burnell.

Paragraph 15 of Burnell describes the "predictive assessment of particle deposition within a patient's throat to which particulate product is delivered by a delivery system (e.g. from an inhaler device)." Paragraph 17 describes "the particles are deliverable by means of an inhaler-type delivery device (e.g. a dry powder inhaler (DPI) device for the delivery of dry powdered medicament or medicament formulation; or metered dose inhaler (MDI) device for the delivery of aerosol medicament formulation)." Neither of these paragraphs refer to selecting or identifying the device. Rather, the disclosure refers generally to characterizing the device or using a specific kind of device, but not selecting it based on its delivery characteristics. Paragraph 87 refers to using "a more active delivery system, in which the inhaler provides initial energy (e.g. kinetic energy) to the medicament to be inhaled (e.g. release of aerosolised medicament from a metered dose inhaler)." However, again, it does not describe selecting the device to match characteristics "corresponding to patient" as required by claim 9. Finally,

paragraph 134 refers to "relevant data (obtained for a particular inhalation device and formulation) for each of Throats A to F." Thus, paragraph 134 does not describe selecting an inhaler, but rather it shows what kind of deposition to expect using a specific device.

In sum, none of the portions of Burnell cited by the Examiner describe "selecting a vibratory inhaler device having a first dispersal configuration" where the configuration is "selected based on" characteristics of the patient as required by claim. Rather, in Burnell, the device is *assessed*, but not selected:

> It is a further object of the present invention to provide improved laboratory testing apparatus for use in predicting pre-lung deposition of medicament delivered by an inhaler device.

Burnell ¶ 9.

The Examiner did not meet the burden of establishing that Burnell and Dunsmore describe or suggest the recited "selecting" step of claim 9. Accordingly, the obviousness rejection of claim 9, and dependent claims 10–16, is reversed.

REVERSED