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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JAIME F. MATA, KAI RUPPERT, and
JOHN P. MUGLER[1]

Appeal 2014-004170
Application 12/771,767
Technology Center 3700

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and
JACQUELINE T. HARLOW, *Administrative Patent Judges*.

PER CURIAM

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to systems and methods for assessing structural changes in a volume of interest. The claims are rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] According to Appellants, the Real Party in Interest is the University of Virginia Patent Foundation (App. Br. 2).

STATEMENT OF THE CASE

The Specification describes "a system, computer program product and method to detect and assess in a single breath-hold the physiologic, morphologic and structural changes in multiple organs" that use polarized Xe-129 gas and chemical shift imaging (Spec. ¶ 44). Claims 1, 4–9, 12–17, and 20–24 are on appeal. Claim 1 is illustrative and reads as follows (emphasis added):

> 1. A method for assessing structural changes in a volume of interest, the method comprising:
>
> (a) polarizing Xe-129 gas to form hyperpolarized Xe-129 gas;
>
> (b) introducing the hyperpolarized Xe-129 gas into the volume of interest;
>
> (c) acquiring *multiple spatially oriented spectra* from the volume of interest, using a magnetic resonance pulse sequence capable of producing said multiple spatially oriented spectra within a predetermined time;
>
> (d) post-processing the multiple spatially oriented spectra in a computing device to obtain magnetic resonance spectra and chemical shift maps; and
>
> (e) evaluating the magnetic resonance spectra, the chemical shift maps, or the magnetic resonance spectra and the chemical shift maps to assess the structural changes in the volume of interest;
>
> wherein the volume of interest is in a lung of a patient, and *wherein the predetermined time is less than a breath hold of the patient*.

The claims stand rejected as follows:

I. Claims 1, 4, 5, 9, 12, and 13 stand rejected under 35 U.S.C. § 103(a) as being obvious based on Swanson[2] and Driehuys '516.[3]

II. Claims 6 and 14 stand rejected under 35 U.S.C. § 103(a) as being obvious based on Swanson, Driehuys '516, and Albert.[4]

III. Claims 7 and 15 stand rejected under 35 U.S.C. § 103(a) as being obvious based on Swanson, Driehuys '516, and Hatabu.[5]

IV. Claims[6] 17, 18, 20, 21, and 24 stand rejected under 35 U.S.C. § 103(a) as being obvious based on Swanson, Driehuys '516, and Driehuys '846.[7]

V. Claim 22 stands rejected under 35 U.S.C. § 103(a) as being obvious based on Swanson, Driehuys '516, Driehuys '846, and Albert.

VI. Claim 23 stands rejected under 35 U.S.C. § 103(a) as being obvious based on Swanson, Driehuys '516, Driehuys '846, and Hatabu.

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[2] Swanson et al., *Distribution and Dynamics of Laser-Polarized ^{129}Xe Magnetization In Vivo*, 42 MAGNETIC RESONANCE IN MEDICINE 1137–1145 (1999).
[3] Driehuys et al., US 2003/0152516 A1, published Aug. 14, 2003.
[4] Albert et al., US 6,845,262 B2, issued Jan. 18, 2005.
[5] Hatabu et al., *Pulmonary Perfusion and Angiography: Evaluation with Breath-Hold Enhanced Three Dimensional Fast Imaging Steady-State Precession MR Imaging with Short TR and TE*, 167 AJR 653–655 (1996).
[6] We note that the Examiner identified claim 19 as being rejected (Ans. 8). Appellants identified claim 19 as being canceled (Appellants' Claims Appendix). Therefore, we do not include claim 19 in our deliberations.
[7] Driehuys et al., US 2008/0089846 A1, published Apr. 17, 2008.

I.

We have considered Appellants' arguments, but are not persuaded that the Examiner erred in rejected claims 1, 4, 5, 9, 12, and 13 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Swanson and Driehuys '516. Because the claims are not separately argued, we focus our discussion on claim 1, which is representative.

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of the prior art (Ans. 3–10; FF 1–9), and agree that the claims are rendered obvious by Swanson and Driehuys '516. We address Appellants' arguments below.

Findings of Fact

FF 1. Swanson discloses "magnetic resonance imaging studies of laser-polarized ^{129}Xe, dissolved in the blood and tissue of the lungs and the heart of Sprague-Dawley rats" (Swanson Abstract; *see also* Ans. 3–4, 8).

FF 2. Swanson discloses that "[a]ll experiments were performed on a 2.0 T Omega CSI . . . and equipped with self-shielded gradients. A doubly-tuned, slotted-cylinder NMR probe was constructed to resonate at the ^{129}Xe and ^{1}H frequencies, enabling registration of xenon chemical-shift imaging (CSI) data with proton images" (Swanson 1138, 1st col.; *see also* Ans. 3–4, 8).

FF 3. Swanson discloses that "[a]ll spectra and images in these studies were cardiac gated and acquired with an effective repetition time (TR) of 428 ms (two cardiac cycles at 280 beats per minute)" (Swanson 1138, 2nd col.; *see also* Ans. 3–4, 8).

FF 4. Swanson discloses that

> [t]he data were then Fourier transformed along each dimension and the magnitude was calculated. Summing the two-dimensional (2D) planes across each resonance (blood, tissue, and gas) created images shown in Figs. 4 and 5. Cardiac-gated proton images, with an appropriate FOV, were collected for spatial registration of the ^{129}Xe signal.

(Swanson 1139, 2nd col.; *see also* Ans. 3–4, 8.)

FF 5. Driehuys '516 discloses

> MR spectroscopy and imaging methods for imaging pulmonary and cardiac vasculature and the cardiac region and evaluating blood flow or circulatory deficits use dissolved phase polarized ^{129}Xe gas and large flip angle excitation pulses. Pulmonary and cardiac vasculature MRI images are obtained by delivering gas to a patient via inhalation such as with a breath-hold delivery-procedure, exciting the dissolved phase gas with a large flip angle pulse, and generating a corresponding image. Preferably, the image is obtained using multi-echo imaging techniques. Blood flow is quantified using low field MR spectroscopy and an RF excitation pulse with a frequency which corresponds to the resonance of the dissolved phase ^{129}Xe.

(Driehuys '516 Abstract; *see also* Ans. 4, 8, 10.)

FF 6. Driehuys '516 discloses that "[t]he excitation repetition rate should be fast enough to capture the ^{129}Xe before it flows out of the chest region. Such an imaging method can provide useful two (2) and three (3) dimensional dissolved phase images of the pulmonary and cardiac vasculature" (Driehuys '516 ¶ 21; *see also* Ans. 4, 8, 10).

FF 7. Driehuys '516 discloses that "[t]he patient inhales a (predetermined) quantity of polarized ^{129}Xe gas into the pulmonary region (i.e., lungs and trachea). Preferably, after inhalation, the patient holds his or her breath for a predetermined time such as 5–20 seconds. This can be

described as a 'breath-hold' delivery" (Driehuys '516 ¶ 39; *see also* Ans. 4, 8, 10).

FF 8. Driehuys '516 discloses that "[i]n one embodiment, for single echoes, the repetition time between excitation pulses is set at 78 ms or less" (Driehuys '516 ¶ 58; *see also* Ans. 4, 8, 10).

FF 9. Driehuys '516 discloses that "[i]n a preferred embodiment, an entire perfusion image (MR image directed to the dissolved phase polarized gas) is generated in a single breath-hold period ('T_B')" (Driehuys '516 ¶ 60; *see also* Ans. 8). Driehuys '516 further discloses that "[t]he number of RF pulses ('N_{rf}') which can be generated in a single breath-hold time is related to repetition time (T_R) and breath-hold time (T_B), and can be expressed by: $N_{rf} = \frac{T_B}{T_R}$" (Driehuys '516 ¶ 61; *see also* Ans. 8).

FF 10. The Specification discloses "acquisition of multiple spatially oriented spectrums, localized in the same plane (2D), in multiple different planes (3D) or in 3D plus at multiple time intervals (4D)" (Spec. ¶ 44; *see also* Ans. 10).

FF 11. The Examiner finds that "imaging conducted within a breath hold are well known in the art and suitable for use in the method of pulmonary imaging using hyper-polarized gas" (Ans. 4). The Examiner additionally finds that an ordinarily skilled artisan would have been motivated to combine Swanson and Driehuys '516 because such combination "provides [] less discomfort of holding breath for patients while obtaining necessary data" (*id.*).

FF 12. The Examiner finds that "scan parameters such as MR pulse sequence and associated repetition time are scan parameters that can be adjusted in each imaging mode to optimize the imaging product. Therefore,

Swanson can adjust its imaging parameters when the imaging acquisition is performed under predetermined time of Drieuhuys ['516] with predictable results" (*id.* at 10).

Analysis

We have considered, but do not find persuasive, Appellants' contention the Examiner has not identified any teaching in Driehuys '516 that would have assisted an ordinarily skilled artisan in overcoming Swanson's requirement for multiple breath-holds (App. Br. 5). Rather, we agree with the Examiner that Driehuys '516 explicitly teaches imaging the lung and heart using polarized ^{129}Xe in a predetermined time that is less than a breath-hold of the patient, i.e., 5–20 seconds (FF 5–9; Ans. 10). We further agree with the Examiner that an ordinarily skilled artisan would have been motivated, with an expectation of success to modify Swanson to perform imaging in a single breath-hold as taught by Driehuys '516 in order to improve patient comfort during image acquisition (FF 11–12; Ans. 4, 10).

We are likewise unpersuaded by Appellants' assertion that the cited references teach away from the combination proposed by the Examiner because they utilize different techniques and disclose different repetition times (*see* App. Br. 5; Reply Br. 2–3). We instead agree with the Examiner that the "MR pulse sequence and associated repetition time are scan parameters that can be adjusted in each imaging mode to optimize the imaging product . . . with predictable results" (FF 12; Ans. 10). *In re Aller*, 220 F .2d 454, 456 (CCPA 1955) ("where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation"). "[T]he discovery of an optimum value of a variable in a known process is usually obvious." *Pfizer,*

Inc. v. Apotex, Inc., 480 F.3d 1348, 1368 (Fed. Cir. 2007). The rationale for determining the optimal parameters for prior art result effective variables "flows from the 'normal desire of scientists or artisans to improve upon what is already generally known.'" *Id.* (quoting *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003)). In this regard, we additionally note that Driehuys '516 discloses the relationship between breath-hold time, repetition time, and the number of pulses that can be generated in a single breath-hold (FF 9).

Moreover, Appellants have not identified any disclosure in Swanson or Driehuys '516 sufficient to support a determination that either reference teaches away from the proposed combination. *See In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) ("[A]ttorney argument [is] not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). For example, Appellants do not point us to any portion of Swanson that discredits, criticizes, or disparages the predetermined time being less than one breath-hold (FF 1–4). *See DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1364 (Fed. Cir. 2006) ("We will not read into a reference a teaching away from a process where no such language exists.").

In addition, disclosure by Driehuys '516 that "*[i]n one embodiment*, for single echoes, the repetition time between excitation pulses is set at 78 ms or less" (FF 8; emphasis added) does not foreclose additional embodiments having different repetition times (*see, e.g.*, FF 9), or otherwise teach away from combination with Swanson. *See Merck & Co. Inc. v. Biocraft Labs. Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) ("the fact that a specific [embodiment] is taught to be preferred is not controlling, since all

disclosures of the prior art, including unpreferred embodiments, must be considered") (quoting *In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976)).

We have also considered, but remain unpersuaded by, Appellants' contention that the proposed combination fails to render obvious the production of three- and four-dimensional information from a single breath-hold acquisition, as is possible using the claimed invention (App. Br. 5). As an initial matter, we note that Appellants' arguments fail to account for the disclosure in Driehuys '516 of "two (2) and three (3) dimensional dissolved phase images" (FF 6). Moreover, and critically, claim 1 does not require three- or four-dimensional information (Ans. 10; *see also* FF 10). "[L]imitations are not to be read into the claims from the specification." *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993). *See also In re Self*, 671F.2d 1344, 1348 (CCPA 1982) ("[A]ppellant's arguments fail from the outset because . . . they are not based on limitations appearing in the claims.").

Appellants' assertions that the image acquisition process taught by Driehuys '516 requires at least two separate breath holds and inhalations, cannot acquire RBC and tissue images when dissolved chemical shift frequencies are too close to each other, and is based on the Dixon method differs from Appellants' techniques (App. Br. 5–6) are similarly unavailing. Claim 1 does not require chemical shift frequencies that are close to each other for acquiring RBC and tissue images, and Appellants do not provide any evidentiary basis to support that conclusion that Swanson's method cannot be modified based on the teachings of Driehuys '516. *See In re Self*, 671F.2d at 1348 and *In re Geisler*, 116 F.3d at 1470.

Neither do we find persuasive Appellants' contentions that the methods disclosed by Swanson require "long and risky breathing maneuvers" not possible in human subjects, utilize only one- and two-dimensional CSI techniques, and are not specifically optimized for hyperpolazized gas imaging, while Appellants' invention is specific to intrinsic properties as well as external nuclear magnetization (*id.* at 6–7). In particular, we observe that Appellants do not provide evidence to support the conclusion that Swanson's method cannot be modified based on the teachings of Driehuys '516 because of the above-alleged characteristics of that method. *See In re Geisler*, 116 F.3d at 1470. We further note that Appellants arguments relate to limitations not present in claim 1. *See In re Van Geuns*, 988 F.2d at 1184.

Conclusion of Law

A preponderance of the evidence of record supports the Examiner's conclusion that Swanson and Driehuys '516 render claim 1 obvious. Claims 4, 5, 9, 12, and 13 fall with claim 1.

II.

The Examiner has rejected claims 6 and 14 under 35 U.S.C. § 103(a) as being obvious based on Swanson, Driehuys '516, and Albert. Appellants present no additional argument based on the teachings of Albert, and rely on the same arguments addressed above with regard to Swanson and Driehuys '516 (*see* App. Br. 8). For the reasons discussed above, therefore, we affirm the rejection of claims 6 and 14, which depend from claims 1 and 9, respectively.

III.

The Examiner has rejected claims 7 and 15 under 35 U.S.C. § 103(a) as being obvious based on Swanson, Driehuys '516, and Hatabu. Appellants present no additional argument based on the teachings of Hatabu, and rely on the same arguments addressed above with regard to Swanson and Driehuys '516 (*see* App. Br. 8). For the reasons discussed above, therefore, we affirm the rejection of claims 7 and 15, which depend from claims 1 and 9, respectively.

IV.

The Examiner has rejected claims 17, 18, 20, 21, and 24 under 35 U.S.C. § 103(a) as being obvious based on Swanson, Driehuys '516, and Driehuys '846. Similar to claim 1, independent claim 17 recites, in pertinent part:

> acquiring multiple spatially oriented spectra from the volume of interest after hyperpolarized Xe-129 gas has been introduced into the volume of interest, using a magnetic resonance pulse sequence capable of producing said multiple spatially oriented spectra within a predetermined time . . .
>
> such that the predetermined time is less than a breath hold of the patient.

Appellants present no additional argument based on the teachings of Driehuys '846, and rely on the same arguments addressed above with regard to Swanson and Driehuys '516 with respect to this aspect of claim 17 (*see* App. Br. 8). For the reasons discussed above, therefore, we affirm the rejection of claim 17. Because they are not separately argued, we also affirm the rejection of claims 18, 20, 21, and 24, which depend from claim 17.

V.

The Examiner has rejected claim 22 under 35 U.S.C. § 103(a) as being obvious based on Swanson, Driehuys '516, Driehuys '846, and Albert. Appellants present no additional argument based on the teachings of Driehuys '846 and Albert, and rely on the same arguments addressed above with regard to Swanson and Driehuys '516 (*see* App. Br. 8). For the reasons discussed above, therefore, we affirm the rejection of claim 22, which depends from claim 17.

VI.

The Examiner has rejected claim 23 under 35 U.S.C. § 103(a) as being obvious based on Swanson, Driehuys '516, Driehuys '846, and Hatabu. Appellants present no additional argument based on the teachings of Driehuys '846 and Hatabu, and rely on the same arguments addressed above with regard to Swanson and Driehuys '516 (*see* App. Br. 8). For the reasons discussed above, therefore, we affirm the rejection of claim 23.

SUMMARY

We affirm the rejection of claims 1 and 9 under 35 U.S.C. § 103(a) based on Swanson and Driehuys '516. Claims 4 and 5 fall with claim 1, and claims 12 and 13 fall with claim 9.

We affirm the rejection of claims 6 and 14 under 35 U.S.C. § 103(a) based on Swanson, Driehuys '516, and Albert.

We affirm the rejection of claims 7 and 15 under 35 U.S.C. § 103(a) based on Swanson, Driehuys '516, and Hatabu.

We affirm the rejection of claims 17, 18, 20, 21, and 24 under 35 U.S.C. § 103(a) based on Swanson, Driehuys '516, and Driehuys '846.

We affirm the rejection of claim 22 under 35 U.S.C. § 103(a) based on Swanson, Driehuys '516, Driehuys '846, and Albert.

We affirm the rejection of claim 23 under 35 U.S.C. § 103(a) based on Swanson, Driehuys '516, Driehuys '846, and Hatabu.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED