NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

IN RE: HANI KAYYALI, CRAIG A. FREDERICK, CHRISTIAN MARTIN, ROBERT N. SCHMIDT, BRIAN M. KOLKOWSKI,
Appellants

2016-1081

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. 11/811,156.

Decided: June 14, 2016

BRIAN M. KOLKOWSKI, Flocel Inc., Cleveland, OH, for appellants. Also represented by MARK PENNINGTON, NeuroWave Systems Inc., Cleveland Heights, OH.

THOMAS W. KRAUSE, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, for appellee Michelle K. Lee. Also represented by BENJAMIN T. HICKMAN, FRANCES LYNCH.

Before TARANTO, CLEVENGER, and CHEN, *Circuit Judges*.

PER CURIAM.

Hani Kayyali, Craig A. Frederick, Christian Martin, Robert N. Schmidt, and Brian M. Kolkowski (collectively, Kayyali) filed an application for a patent on methods of conducting an at-home sleep analysis. As relevant here, an examiner rejected Kayyali's claims for obviousness based on the prior-art reference Westbrook, either alone or in combination with another prior-art reference, Fey. The Patent Trial and Appeal Board affirmed.

Kayyali appeals, arguing that an ordinarily skilled artisan would not have been motivated to modify Westbrook, that Westbrook actually teaches away from the modification, that Fey is not analogous art, and that an ordinarily skilled artisan would not have been motivated to combine Westbrook and Fey. We reject those arguments and therefore affirm.

BACKGROUND

Kayyali's patent application describes "a method of conducting a sleep analysis by collecting physiologic and kinetic data from a subject, preferably via a wireless in-home data acquisition system, while the subject attempts to sleep at home." J.A. 69. The in-home sleep test "provides more accurate data for the sleep diagnosis" than would a sleep test conducted in a laboratory, subjects being "generally more comfortable sleeping at home." J.A. 73. Kayyali describes applying at least two sensors to the subject to collect physiological, kinetic, or environmental signals. For example, electrodes may be placed on the subject's scalp to measure brain waves or on the subject's torso to measure electrical currents generated by the heart. The application also calls for a pulse oximeter to measure respiration and oxygenation of the subject's blood. The various sensors are connected to a data acquisition system, which is preferably light-weight, easily transported, and capable of collecting and transmitting data from the sensors. Sleep-test data is transmitted,

preferably in real time, to allow for a sleep-trained technician to monitor and analyze the test results remotely.

Pending claims 1–7 and 34–47 are at issue in this appeal. Claims 1 and 7 are illustrative for present purposes:

> 1. A method of conducting an at-home sleep analysis comprising the steps of:
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> applying at least two sensors and a pulse oximeter to a subject,
>
> connecting the at least two sensors and the pulse oximeter before or after application to the subject to a data acquisition system including a patient interface box with wireless radio frequency transmission capability, the patient interface box being capable of receiving signals from the at least two sensors and the pulse oximeter, digitizing the signals, and retransmitting the digitized signals, or transmitting another digitized signal based at least in part on at least one of the sensor signals by bidirectional wireless radio frequency transmission,
>
> collecting and digitizing the signals from the at least two sensors and the pulse oximeter applied to the subject while the subject is sleeping at home with the patient interface box,
>
> transmitting the digitized signals or transmitting the other digitized signal based at least in part on the sensor signals to a remote location, at least in part by wirelessly transmitting the digitized signals utilizing a bidirectional radio frequency signal transmission, and
>
> analyzing the retransmitted digitized signals or the transmitted other digitized signal by a sleep trained individual to diagnose whether the subject has a sleeping disorder.

J.A. 4.

> 7. The method in claim 1, including the further steps of having the subject visit a physician's or clinician's office or place of business;
>
> providing the subject at the physician's or clinician's office or place of business with the portable patient interface and three sensors;
>
> providing the subject or the subject's care provider with direct face-to[-]face demonstration with instruction and guidance regarding use and application of the portable patient interface box and the three sensors;
>
> sending the subject home or to another location remote from the physician's or clinician's office or place of business with the portable patient interface box and the three sensors and having the subject or the subject's care provider use the instruction and guidance to apply and connect the sensors and to use the patient interface box;
>
> analyzing the transmitted data at a location remote from both the physician's or clinician's office or place of business and the subject's home or other remote location to make the diagnosis of whether the subject has the sleep disorder;
>
> sending the diagnosis of the collected data to the physician or clinician;
>
> and determining a treatment if required for the subject.

J.A. 5. Claim 38 further requires the subject to "return the portable patient interface box and the sensors . . . after the data is collected." J.A. 7.

The examiner rejected claims 1–7 and 34–47 for obviousness: claims 1–3, 6, 34, and 41 over Westbrook; claim 4 over Westbrook in view of Thompson; claim 5 over Westbrook in view of Auphan; and claims 7, 35–40, and 42–47 over Westbrook in view of Fey. Only Westbrook and Fey are now pertinent, because Kayyali has not independently challenged the rejection of claims 4 and 5.

U.S. Patent Application Publication No. 2005/0027207 to Westbrook et al. describes a monitoring system for collecting and analyzing physiological signals to detect sleep apnea. The system includes a small, light-weight device that is attached to the subject's forehead and contains several sensors, including a pulse oximeter. The system collects data, which "may be directly transmitted to an offsite facility for processing and report generation." Westbrook, ¶ 78. Although Westbrook recognizes that "[t]he current 'gold standard' for the diagnosis of [sleep apnea] is an . . . overnight sleep study . . . administered and analyzed by a trained technician," *id.* ¶ 8, the described system automatically generates a report based on the sleep data that can include "a full-disclosure presentation of the physiological recordings from the entire session" for physicians to analyze, *id.* ¶ 156.

U.S. Patent Application Publication No. 2007/0143151 to Fey et al. describes a system to manage and analyze electronic medical records. After undergoing medical testing, a patient receives a smart drive that contains test results and other information. The patient can plug the smart drive into her computer to input data and to interact with data already stored on the device. "[T]he user-inputted information can be transmitted to the centralized system and one or more health care professionals for evaluation and feedback," allowing health plans to be revised and updated. Fey, ¶ 40.

Kayyali appealed the rejection of claims 1–7 and 34–47 to the Board. Kayyali argued that the examiner did

not identify any motivation a relevant skilled artisan would have had to modify Westbrook to have a remotely located sleep-trained technician analyze sleep data and that Westbrook teaches away from using a sleep-trained individual altogether. Kayyali further argued that Fey is not analogous art because, contrary to the examiner's finding, it does not describe an "ambulatory physiological monitor."

The Board affirmed the examiner's rejection of claims 1–7 and 34–47. The Board adopted the factual findings and analysis of the examiner's answer, which concluded that "[i]t would have been obvious to one of ordinary skill in the art to substitute one known method for another to achieve the expected results of diagnosing sleep disorders, such as using a board-certified clinician to analyze collected data as taught by Westbrook in place of the computerized analysis used in the invention of Westbrook." J.A. 619. In denying Kayyali's request for rehearing, the Board elaborated: "it was well known at the time of the invention to use sleep trained individuals to review sleep data and additionally well known that sleep data could be forwarded to a remote location in view of Westbrook, to have sleep trained individuals to review sleep data at a remote location." J.A. 688–89.

Kayyali appealed to this court, and because the Board did not address Kayyali's arguments regarding Fey, this court granted the Director's motion to remand the case for further proceedings. On remand, the Board again affirmed the examiner's rejection of claims 1–7 and 34–47. The Board repeated its analysis that it would have been obvious to use a sleep-trained individual to analyze the sleep data generated in Westbrook. With respect to Fey, the Board explained that Fey shows "the well-known rudimentary business practice of examining a patient in a medical center, providing the patient with a medical recording device, returning home to use the device, and returning the device to the physician." J.A. 24. The

Board found that Fey is both within the field of the inventor's endeavor—"ambulatory physiological monitoring"—and reasonably pertinent to solving the inventor's problem.

Kayyali appeals under 35 U.S.C. § 141(a), challenging the Board's rejection of claims 1–7 and 34–47 for obviousness. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

We review the Board's ultimate determinations of obviousness de novo. *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013). Underlying factual findings, including findings as to whether a reference is analogous art and the presence or absence of a motivation to combine or modify with a reasonable expectation of success, are reviewed for substantial evidence. *Id.*; *In re Bigio*, 381 F.3d 1320, 1324 (Fed. Cir. 2004).

Kayyali first challenges the Board's rejection of claims 1–3, 6, 34, and 41 for obviousness over Westbrook; in so doing, Kayyali treats claim 1 as representative. Kayyali argues that a relevant skilled artisan would not have been motivated to modify the computer-automated analysis described in Westbrook to allow a sleep-trained individual to perform the diagnosis. But Westbrook explicitly states that diagnosis by a sleep-trained clinician is the current "gold standard," thus confirming that a skilled artisan would have a motivation to replace computer-automated diagnosis with diagnosis by a specialist (at least some of the time) to achieve better diagnosis of the patient.

Kayyali also argues that Westbrook teaches away from the modification because it disparages the use of a sleep-trained individual. Westbrook suggests that an overnight sleep study conducted by a sleep-trained clinician is expensive and that detection can vary by clinician

because professional organizations have provided limited guidelines. At most, those suggestions indicate some advantages for computer analysis that may make such analysis preferable in many circumstances. That is not enough to teach skilled artisans away from the alternative that Westbrook identifies and calls the "gold standard." *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009). The Board, therefore, did not err in finding that Westbrook does not teach away from using sleep-trained individuals.

In addition, Kayyali challenges the Board's rejection of claims 7, 35–40, and 42–47 on the ground that Fey is not analogous art; in so doing, Kayyali treats claim 7 as representative. To be analogous art, a prior-art reference must (1) be reasonably pertinent to the particular problem with which the inventor is involved or (2) be from the same field of endeavor. *See Innovention Toys, LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1321 (Fed. Cir. 2011). The Board found that Fey qualifies under both of the alternatives. Kayyali argues that Fey qualifies under neither.

The Board properly found that Fey is reasonably pertinent to the problem at hand, as "Fey would logically have commended itself to an inventor's attention in considering the problem of medical device portability, data transfer and ambulatory physiological monitoring." J.A. 26. Fey discloses a device that the patient can take home to "input and manage information pertaining to one or more health/intervention plans" and that can "include a plan revision component for updating the one or more health plans based upon the user-inputted information." Fey, ¶ 40. The device allows both the patient and physician to observe and review the patient's physiological health data. Therefore, as the Board found, Fey is reasonably pertinent to the problem faced by Kayyali—providing a patient with a medical device, sending the

device home for the patient to use, and returning the device after use. Because substantial evidence supports the Board's finding that Fey is reasonably pertinent to the particular problem of the claimed invention, and therefore analogous art, we need not reach Kayyali's argument that Fey is not in the same field of endeavor.

Finally, Kayyali contends that a relevant skilled artisan would not have been motivated to combine the in-home sleep-test device of Westbrook with the teachings of Fey. The Board found that "Fey solves the known problem of providing patient care using an ambulatory medical device by giving the patient the portable device in person, and sending [the patient] home to use the device, and later returning the device." J.A. 29. The Board determined that Fey's method itself provides a motivation to combine Fey with Westbrook—to achieve the benefits of "providing patient care using an ambulatory medical device." J.A. 27. The Board did not err in reaching this conclusion.

CONCLUSION

For the foregoing reasons, we affirm the Board's rejection of the claims at issue.

AFFIRMED