NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

IN RE: RONALD S. KARPF,
Appellant

2018-2090

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. 11/645,067.

Decided: January 30, 2019

RONALD S. KARPF, Corvallis, OR, pro se.

THOMAS W. KRAUSE, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, for appellee Andrei Iancu. Also represented by MONICA BARNES LATEEF, JOSEPH MATAL, MEREDITH HOPE SCHOENFELD.

Before LOURIE, O'MALLEY, and REYNA, *Circuit Judges.*

LOURIE, *Circuit Judge.*

Ronald S. Karpf ("Karpf") appeals from a decision of the Patent Trial and Appeal Board ("the Board") affirming the rejection in the U.S. Patent and Trademark Office ("the PTO") of pending claims 23 and 25 of U.S. Patent

Application 11/645,067 ("the '067 application") as obvious over U.S. Patent 5,845,255 ("Mayaud") in view of U.S. Patent 6,270,456 ("Iliff"). Because the Board's decision was supported by substantial evidence, we *affirm*.

I. BACKGROUND

A. The '067 application

The '067 application discloses an electronic medical records ("EMR") system accessible to a patient, so that the patient may review his or her records, including the treatment instructions that have been provided to the patient by the medical practitioner. In addition, the disclosed EMR system may determine the patient's compliance with a treatment regimen and send compliance reminders to non-compliant patients as needed.

In order to give patients control over the identity of individuals who may access their records in the EMR system, the '067 application discloses giving them two passwords: (1) a patient password that each patient uses to log in to the system; and (2) a patient PIN that the patient can share with healthcare providers to provide them with access to the patient's records.

At issue in this appeal are claims 23 and 25. Independent claim 23 recites:

> 23. An article of manufacture comprising at least one non-transitory machine-readable storage medium having stored therein indicia of a plurality of machine executable control program steps, the control program comprising the steps of:
>
> a) storing patient data, including patient identification data, and patient password;
>
> b) storing medical encounter data relating to at least one medical encounter between a medical personnel and a patient, wherein the medical encounter data includes at least one reason for the

> medical encounter, and at least one diagnosis by medical personnel corresponding to the medical encounter; and
>
> c) storing medical condition data relating to at least one medical condition that may be deemed by medical personnel to relate to a patient as a result of a medical encounter, wherein medical condition data includes general information about a given medical condition.
>
> d) storing treatment information for at least one medical encounter of a given patient
>
> e) determining compliance by the given patient with the treatment information stored in said storing step (d) for a given medical encounter; and
>
> f) issuing a notification based on a determination of non-compliance in said determining step (e).

SAppx4. Claim 25 depends from claim 23 and is further limited to:

> 25. The article of manufacture as recited in claim 23, wherein:
>
> said storing step (b) includes storing data regarding: a medical encounter in the form of a doctor's office visit, medical personnel in the form of a doctor who examined the patient during the office visit, and a patient complaint as a reason for the office visit;
>
> the treatment information in said storing step (d) includes medication regimen issued by the doctor who examined the given patient during a given office visit; and
>
> said issuing step (f) includes issuing a notification in the form of a reminder message sent to the giv-

> en patient to comply with the medication regimen issued by the doctor.

SAppx17–18.

B. Prior Art

Mayaud, the primary reference relied upon to reject the instant application, discloses an electronic prescription management system, where prescribers can access patient information through desktop computers or mobile devices. Mayaud col. 7 ll. 57–67. The system stores patient data, *id.* col. 1 ll. 46–51, and identification information, *id.* col. 17 ll. 44–53. It also teaches securing the patient's information by use of a password or an access code, which may be provided directly by the patient. *Id.* col. 10 ll. 12–27. The stored information may comprise medical encounter data, *id.* col. 13 l. 31–col. 15 l. 6, including diagnosis, *id.* col. 14 ll. 38–55, and the reason for the medical encounter, *id.* col. 13 l. 45. The data stored may be medical condition data or treatment information, including prescriptions. *Id.* col. 5 ll. 9–12. Mayaud further discloses electronically readable dosing indicator devices that detect when medications have not been taken and issue audible or visual notifications to patients accordingly. *Id.* col. 30 ll. 10–56.

Iliff discloses a computerized medical diagnostic system that allows patients to perform an examination on themselves and then consult the system to refine their diagnosis. Iliff col. 1 l. 63–col. 2 l. 10. Patients gain access to this system by entering a PIN or password. *Id.* col. 21 ll. 24–31. The examiner further relied on Iliff as disclosing a patient password.

C. Procedural History

Karpf, along with his late co-inventor, Dr. Arthur B. White, filed the instant application on December 26, 2006. During prosecution, the examiner rejected then-pending claims, including previous versions of the instant

claims, as anticipated by Mayaud. Karpf argued before the Board that Mayaud does not disclose a system to which a patient has access or a patient password which allows a patient to gain access to the system, but only a patient-held password or access code that a patient can disclose to a medical professional to use. Nonetheless, the Board affirmed the rejection, *Ex parte Ronald S. Karpf & Arthur B. White*, No. 2010-9172, 2013 WL 1225722 (P.T.A.B. Mar. 18, 2013), and Karpf appealed to this court.

We vacated the Board's decision and remanded for further proceedings. *In re Karpf*, 576 F. App'x 968 (Fed. Cir. 2014). With respect to claims 23 and 25, we noted that neither the examiner nor the Board ever offered a ground of rejection specific to these claims. *Id.* at 972–73. We held that, while the claims do not expressly require that a patient be able to access his or her own records, the Board erred by failing to clearly address Karpf's argument that the patient password limitation inherently requires patient access. *Id.*

The Board in turn remanded to the examiner to reopen prosecution. The examiner rejected claims 23 and 25 as obvious over Mayaud in view of Iliff. In the examiner's view, Mayaud discloses all the limitations of claims 23 and 25 except a patient password, which is disclosed in Iliff. The examiner concluded that, since Mayaud and Iliff concern the same field of endeavor, treatment management programs, an ordinary artisan would have had reason to integrate the patient password of Iliff into Mayaud's system, and therefore rejected claims 23 and 25 as obvious.

Karpf appealed the rejection of claims 23 and 25 to the Board. He argued that Mayaud's dosing indicator device does not disclose the claimed feature of a control program that determines patient compliance with a treatment regimen and sends reminders to the patient

because the claims require that the *control program* perform this function, not a standalone device. Karpf further contended that the rejection was in error because the examiner failed to explain the motivation to combine Mayaud with Iliff and because Mayaud does not disclose patient access to its EMR system.

The Board affirmed. *Ex parte Ronald S. Karpf & Arthur B. White*, No. 2016-5324, 2018 WL 1773794 (P.T.A.B. Mar. 30, 2018) ("*Board Decision*"). It found that the alerts issued by Mayaud's dosing indicator device met the compliance and reminder limitations. *Id.* at *6. The Board further concluded that an ordinary artisan would have had reason to combine Mayaud with Iliff because both are from the same field of endeavor and because Mayaud discloses limited patient access to the EMR system in the form of a patient interface at medical facilities. *Id.* at *6–7; Mayaud col. 46 ll. 41–49.

Karpf timely appealed to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

II. DISCUSSION

We review the Board's legal determinations *de novo*, *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004), but we review the Board's factual findings underlying those determinations for substantial evidence, *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). A finding is supported by substantial evidence if a reasonable mind might accept the evidence as adequate to support the finding. *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). The ultimate judgment of obviousness is a legal conclusion, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007), but it is premised on underlying findings of fact, *Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 752 F.3d 967, 972 (Fed. Cir. 2014). The Supreme Court has held that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art,"

but "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 550 U.S. at 416–18.

On appeal, Karpf argues that Mayaud's system does not teach a patient's access to his own records stored in the system. Second, Karpf contends that Mayaud's system does not teach sending non-compliance notifications directly to patients. Instead, Karpf asserts that Mayaud's system only notifies physicians of patient noncompliance, and the physicians in turn must notify the patients themselves; he further distinguishes Mayaud's dosing indicator devices as not meeting the limitation of a "control program." Karpf also argues that there is no motivation to add Iliff's patient password feature to Mayaud because Mayaud's system only concerns prescriptions, and to give patients access to the system through the patient password would lead to patients prescribing themselves medication or viewing other patients' confidential information. Finally, Karpf argues that there was a long-felt, unmet need for better patient compliance with prescribed treatment regimens which weighs against finding obviousness of the claimed methods.

The PTO responds that the claims at issue, unlike previous claims, do not require patient access to the system. The PTO further argues that Mayaud's system discloses the limitation of sending a patient a notice of non-compliance, including as a message, through the audio or visual alerts sent by the dosing indicator device. Finally, the PTO argues that the Board properly found that a person of skill would have had reason to modify Mayaud's system by adding a patient password as disclosed in Iliff to support a patient's access to his own records. The PTO does not respond to Karpf's argument on the long-felt, unmet need for better patient compliance with treatment regimens.

We agree with the PTO that the rejected claims would have been obvious at the time the invention was made.[1] While Karpf points to our previous opinion for the proposition that Mayaud does not teach patient access or use of a patient password, claims 23 and 25 at issue here do not require that a patient have direct access to his or her own medical records. In addition, Mayaud does disclose a patient-held access code or password, *id.* col. 10 ll. 11–27, as the claims do require, and the Board further found that an ordinary artisan would have had reason to modify Mayaud's system to allow patients to use the password, as disclosed in Iliff. *Board Decision*, 2018 WL 1773794, at *6–7.

We also conclude that substantial evidence supports the Board's finding that Mayaud discloses a system that sends reminder messages to non-compliant patients. Karpf asserts that Mayaud does not disclose a "control program determin[ing] compliance and issu[ing] reminder messages." But the Board found that Mayaud's EMR system can print out a patient's medication regimen, *Board Decision*, 2018 WL 1773794, at *6–7, which can be inserted into an electronic pill container that issues "audio or visual" alerts when the patient has not complied with the medication regimen. Mayaud col. 28 ll. 50–62, col. 30 ll. 11–16. We note that the claimed program requires "*at least one* non-transitory machine readable storage medium" (emphasis added), so we find Karpf's argument that the claims exclude an electronic pill container from performing the reminder function

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[1] The '067 application was filed in 2006, so pre-AIA § 103 applies. *See* Leahy–Smith America Invents Act, Pub. L. No. 112–29, sec. 3(c), 125 Stat. 284 at 293 (2011) (explaining that the pre-AIA version of the Patent Act generally applies to patents with effective filing dates before March 16, 2013).

unpersuasive. *Cf. In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984) ("The PTO broadly interprets claims during examination of a patent application since the applicant may amend his claims to obtain protection commensurate with his actual contribution to the art.") (citation omitted).

Karpf argues that an ordinary artisan would not have combined Mayaud with Iliff because Mayaud's system manages prescriptions, and allowing patients to have access to that system could result in patients self-prescribing or viewing other patients' information. However, we agree with the PTO that, because Mayaud discloses tailoring access to different professionals (including non-prescribers), *id.* col. 10 ll. 11–19, col. 18 ll. 53–57, this concern is misplaced. We hold that substantial evidence supports the Board's conclusion that an ordinary artisan would have combined Iliff's patient password functionality with Mayaud.

Finally, we conclude that Karpf's claim of a long-felt, unmet need for improved patient compliance technology does not render claims 23 and 25 nonobvious. Karpf provides extensive documentation showing that patient non-compliance is a prevalent and costly issue. However, he does not provide evidence, other than attorney argument, that the claimed invention meets that need. *See In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) ("For objective evidence of secondary considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention.") (citation omitted). Thus, we conclude that the nexus between the claimed invention and the purported long-felt, unmet need is too attenuated to provide a persuasive rationale for nonobviousness.

III. CONCLUSION

We have considered Karpf's other arguments but do not find them persuasive. We conclude that substantial

evidence supports the Board's conclusion that claims 23 and 25 properly stand rejected as obvious. We therefore *affirm*.

AFFIRMED