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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte EUGENE DANTSKER

Appeal 2018-007352
Application 14/697,483
Technology Center 3700

Before MICHAEL J. FITZPATRICK, MICHELLE R. OSINSKI, and JILL D. HILL, *Administrative Patent Judges*.

HILL, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Eugene Dantsker ("Appellant")[1] appeal under 35 U.S.C. § 134(a) from the Examiner's final decision rejecting claims 1–3, 6–9, 15–18, 21–27, 29 and 30.[2] We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

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[1] Appellant identifies Applicant and Assignee Qualcomm Incorporated as the real party in interest. Appeal Br. 3.

[2] Claims 4, 5, 10–14, 19, 20 and 28 have been withdrawn from consideration. Final Act. 1.

BACKGROUND

Independent claims 1, 18, and 27 are pending. Independent claim 1, reproduced below, illustrates the claimed invention:

> 1. A system comprising:
> an adhesive patch, wherein the adhesive patch comprises:
> a flexible substrate having an adhesive backing for adhering the flexible substrate to a person's skin, the flexible substrate having one or more openings, each opening indicating a post-adhesion, designated injection site for subcutaneous medication delivery when the adhesive patch is adhered to the person's skin, and
> a first short-range wireless communications interface;
> a first subcutaneous medication delivery applicator (SMDA), wherein the first SMDA includes:
> a mechanism configured to subcutaneously deliver an amount of medication through the person's skin,
> a second short-range wireless communications interface configured to receive and transmit information from and to, respectively, at least the first short-range wireless communications interface, and
> a safety interlock that prevents the mechanism from dispensing the medication when the safety interlock is engaged and that allows the mechanism to dispense the medication when disengaged; and
> control logic operatively connected with the first short-range wireless communications interface, the second short-range wireless communications interface, and the safety interlock, wherein:
> the control logic includes a first portion that is included in the adhesive patch and a second portion that is included in the first SMDA,
> the first portion of the control logic and the second portion of the control logic are configured to communicate with each other via the first short-range wireless communications interface and the second short-range wireless communications

> interface, respectively, and the control logic is configured to:
>
> determine whether subcutaneous injection of the medication from the first SMDA is authorized at a first time based, at least in part, on information indicating that the first SMDA is pre-associated with identifier information that identifies the first SMDA and that is pre-associated with the adhesive patch and transmitted via the first short-range wireless communications interface, the second short-range wireless communications interface, or the first short-range wireless communications interface and the second short-range wireless communications interface, and
>
> cause the safety interlock to disengage responsive to a determination that the subcutaneous injection of the medication is authorized.

App. Br. 29–30 (Claims Appendix).

REJECTIONS

I. Claims 1, 2, 6–8, 14, 16–18, 21, 22, 24, 26, 27, 29, and 30 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Ulrich ’705 (WO 2013/070705 A1, pub. May 16, 2013), Deberadine (US 2014/0128842 A1, pub. May 8, 2014), and Yodfat (US 2011/0118694 A1, pub. May 19, 2011). Final Act. 2.

II. Claim 3 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Ulrich '705, Deberadine, Yodfat, and Curry (US 2014/0247109 A1, pub. Sept. 4, 2014).[3] Final Act. 8.

III. Claims 9 and 23 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Ulrich '705, Deberadine, Yodfat, and Zhang (US 2001/0037104 Al A1, pub. Nov. 1, 2001).[4] Final Act. 8.

IV. Claim 25 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Ulrich '705, Deberadine, Yodfat, and Ulrich '715 (WO 2013/070715 A1, pub. May 16, 2013). Final Act. 9.

ANALYSIS

Rejection I

Appellant makes no argument that claims 1, 2, 6–8, 14, 16–18, 21, 22, 24, 26, 27, 29, and 30 are patentable over Ulrich '705, Deberadine, and Yodfat. Therefore, we summarily sustain Rejection I.

Rejection II

Claim 3 depends from claim 1 and recites the adhesive patch being configured to short-circuit itself upon removal from the person's skin. Appeal Br. 30 (Claims App.) The Examiner finds this disclosure in Curry. Final Act. 8 (citing Curry ¶¶ 38, 64). The Examiner concludes that it would

[3] Claim 3 depends from claim 1, which was rejected over Ulrich '705, Deberadine, and Yodfat. We understand the omission of Yodfat in the Examiner's statement of the rejection to be a typographical error.
[4] Claim 9 depends from claim 1, and claim 23 depends from claim 18 which was rejected over Ulrich '705, Deberadine, and Yodfat. We understand the omission of Yodfat in the Examiner's statement of the rejection to be a typographical error.

have been obvious to short circuit the device of Ulrich '705, "as Curry teaches this is beneficial for disabling the device and would prevent unwanted use after the device should no longer be used to ensure safety." *Id*.

Appellant argues that the cited references fail to teach the limitations of dependent claim 3. Appeal Br. 10. Regarding Curry, which the Examiner finds discloses the limitations of claim 3, Appellant argues that Curry implements disablement or functionality impairment/downgrade in medical devices "based on the status of a condition of conveyance," such as late installment payments. *Id.* at 12 (Curry ¶ 81). Curry contemplates that "'[t]he disabling or impairing of ... functionality of the device ... may be in such a way as to permanently disable or impair the functionality ... [f]or instance, electronic components may be deliberately destroyed by creating a short circuit in the device 102 . . . .'" *Id*. (quoting Curry ¶ 64). Appellant argues that Curry's short circuit is not, however, based on removing the device from the patient. *Id*. at 12, 14. According to Appellant, the Examiner has provided no evidentiary support for the finding that it is well known to prevent re-use of an adhesive patch, and "preventing use or re-use of a medical device usually focuses on devices that contain medication or that are designed to be inserted into a person's body, i.e., devices other than [an] adhesive patch." *Id.* at 14–15.

The Examiner responds that: (1) the claim does not explicitly require patch removal to *cause* short-circuiting, because "the term 'upon in the claim is taken to mean on or thereafter in relation to" timing rather than causation; (2) the claim does not recite how patch removal would cause short circuiting; (3) Curry's short circuiting, though triggered to prevent

delivery/use for other reasons, could be done concurrently with removal and satisfy the claim (when "upon" is construed as a term of timing, rather than causation); and (4) "preventing re-use of a device is well-known and the short-circuiting as taught by Curry prevents such re-use." Ans. 2–4.

Appellant replies that (1) "[t]he word 'upon' is commonly understood to imply a causative link," and the Examiner's position that "upon" should be construed as merely a time measure of "on or thereafter" is unreasonable; (2) it is immaterial that the claim does not recite the exact manner in which removal of the adhesive patch would cause short-circuiting; and (3) "there has been no evidentiary showing that it is well known to 'prevent re-use' of an adhesive patch." Reply Br. 3–4.

Appellant has the better argument. The Specification states that "the adhesive patch 102 may also be configured to disable itself upon removal from the patient's skin. For example, . . . the first processor 172 [of the adhesive patch] may cause the adhesive patch 102 to short-circuit various critical components . . . ." Spec. ¶ 70. While, during examination, claims are given their broadest reasonable interpretation, that interpretation must be consistent with the specification to be reasonable. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005). Because Appellant's Specification speaks explicitly and only to adhesive patch removal causing short circuiting, the Examiner's interpretation of the term "upon" to mean on or thereafter in relation to timing rather than causation (Ans. 3) is unreasonable. We interpret the term "upon" in claim 3 to indicate causation. Curry does not disclose adhesive patch removal causing short circuiting, and the Examiner does not explain adequately why it would have been obvious

for removal of an adhesive patch to cause short circuiting, and we therefore do not sustain the rejection of claim 3.

Rejection III

Claims 9 and 23 depend respectively from claims 1 and 18, and recite, *inter alia*, the adhesive patch including a transdermal medication dispenser (depicted in Fig. 12), and the control logic being "configured to adjust a rate of transdermal medication dispensation from the transdermal medication dispenser based, at least in part, on a determination that the subcutaneous injection of the medication is authorized." Appeal Br. 33, 38 (Claims App.). The Examiner finds this disclosure in Zhang. Final Act. 8. According to the Examiner, Zhang discloses "controlling delivery of anesthetic to accommodate different patient needs." *Id*. (citing Zhang ¶¶ 8, 18, 23, 80, 81). The Examiner concludes that it would have been obvious to control delivery of the anesthetic as in Zhang "to accommodate different patient needs." *Id*.

Appellant argues that the Examiner's reasoning "fails to address a key feature," because Zhang's medication delivery depends on a "setting selected by the patient or the physician based on the patient's degree of pain," rather than being based on "a determination that the subcutaneous injection of the medication [via the first SMDA] is authorized" as claimed. Appeal Br. 19 (claim 9), 25 (claim 23). Appellant contends that modifying Ulrich '705 and Deberadine with Zhang's delivery controller "would simply result in an adhesive patch that had Ulrich's and Deberadine's injection-authorization features (for authorizing a separate medication injector to unlock in order to administer an injection)" and "allow the patient or physician to manually increase the transdermal medication delivery rate

based on patient pain." Appeal Br. 20, 26. The proposed modification would not result in adjusting a rate of medication dispensation "at least in part, on a determination that the subcutaneous injection of the medication is authorized,' as recited in claim 9." *Id.* at 20–21 ("Zhang's medication delivery is ultimately governed . . . by the patient or physician's active selection of [a] medication delivery rate."), 26.

The Examiner responds that Zhang "provides rate control to the patch" that, combined with the teachings of Ulrich '705 and Deberadine, "would result in this rate adjustment being at least in part on the authorization because" the device and its rate control adjustment would not be used if the device usage is not authorized. Ans. 3 (emphasis omitted).

Appellant replies that the Examiner "artificially generalizes" Yodfat's or Deberadine's unlocking of injection systems *not* adhered to the patient's body as being authorized device usage, and then "artificially narrows" device usage to apply to Zhang's transdermal medication delivery dispenser. Reply Br. 5, 6. According to Appellant, "[a]bsent the guidance of [their] [S]pecification, there is no suggestion or teaching in the record that would cause a person of ordinary skill in the art to modify the combination of Ulrich ['705], Deberadine, and Yodfat to include Zhang's transdermal medication delivery dispenser and accompanying user-controllable medication delivery rate adjustment functionality" so that a patch of the combined teachings is configured to adjust a medication dispensation rate "based, at least in part, on a determination that the subcutaneous injection of the medication is authorized," as claimed. *Id*.

Appellant has the better argument. Appellant's Specification discloses an embodiment (*see* Fig. 12) with the adhesive patch having an

opening 1220 through which an authorized SMDA can deliver medication subcutaneously, and also a transdermal medication delivery dispenser 1226. Spec. ¶ 87. The Specification contemplates "adjust[ing] the rate of transdermal medication delivery in response to a medication injection being performed," for example if the transdermal medication interferes with the injected medication, or if mixing the medications may produce an undesirable side effect. *Id*. Thus, the control logic of the adhesive patch may cause the transdermal medication dispenser to adjust its delivery rate — "for example, the transdermal delivery rate may be decreased or turned off entirely." *Id.*

While the references disclose both (1) adhesive patch control logic permitting subcutaneous medication delivery only when authorization results from pre-association of the SMDA and the patch, and (2) adjusting a transdermal medication dispensation rate, the Examiner fails to explain adequately how the references would be combined to teach or suggest transdermal delivery being adjusted based on authorization of the subcutaneous medication delivery. Lacking such an explanation or support in the prior art, the Examiner has not established prima facie obviousness of claims 9 and 23.

Rejection IV

Claim 25 depends from claim 18, via claim 24, and recites SMDA-adhesive patch pre-association information "includes information identifying SMDAs from at least two different medication manufacturers or at least two different SMDA manufacturers." Appeal Br. 38–39 (Claims App.). The Examiner finds this disclosure in Ulrich '715. Final Act. 9. According to the Examiner, Ulrich '705 discloses transmitting various information

"including device ID and medication ([0038], [0042])," but does not disclose transmitting "manufacturer information." *Id*. The Examiner finds, however, that Ulrich '715 discloses that "device information includes the manufacturer ([0241])." *Id*. The Examiner concludes that it would have been obvious to include manufacturer information in Ulrich '705 "as this aids in further ensuring the appropriate device and medication is delivered." *Id*.

Appellant notes that Ulrich '715 discloses:

> All of the various injection devices described herein may contain various electronic components for communicating with other medical instruments. For example, the injection device might contain a RFID tag that contains information such as the dose amount, a time stamp for the injection, the manufacturer, the batch from which the medication was manufactured, the device serial number, and other tracking information.

Appeal Br. 27–28 (citing Ulrich ¶ 241). According to Appellant, this paragraph of Ulrich '715 merely suggests that "injection devices may have RFID tags" identifying the injection device manufacturer, rather than disclosing or suggesting an adhesive patch being "preassociated with SMDAs from at least two different medication manufacturers or . . . SMDA manufacturers." *Id.* at 28. According to Appellant, "the Examiner focuses on information preassociated with injection devices rather than information pre-associated with the adhesive pad." *Id*.

The Examiner responds that "the base references already pre-associate the adhesive patch and the (SMDA) [with certain information,]" and Ulrich '715 discloses manufacturer information ensuring safe usage and tracking, such that the combination would suggest manufacturer information being a

useful addition to the information used for pre-association in the base references. Ans. 4.

Appellant replies that the Examiner's response does not address Appellant's contention that Ulrich '715 "'does not suggest that an adhesive patch is preassociated with SMDAs from at least two different medication manufacturers or at least two different SMDA manufacturers.'" Reply Br. 6 (emphasis omitted).

Again, Appellant has the better argument. Although Ulrich '715 discloses its injection device information including the manufacturer, the Examiner makes no finding or conclusion that the combined references disclose or render obvious "information identifying SMDAs from "*at least two different* SMDA manufacturers" as claimed. Lacking such a finding or conclusion, prima facie obviousness has not been established.

DECISION

We AFFIRM the rejection of claims 1, 2, 6–8, 14, 16–18, 21, 22, 24, 26, 27, 29, and 30 as unpatentable over Ulrich '705, Deberadine, and Yodfat.

We REVERSE the rejection of claim 3 as unpatentable over Ulrich '705, Deberadine, Yodfat, and Curry.

We REVERSE the rejection of claims 9 and 23 as unpatentable over Ulrich '705, Deberadine, Yodfat, and Zhang.

We REVERSE the rejection of claim 25 as unpatentable over Ulrich '705, Deberadine, Yodfat, and Ulrich '715.

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). *See*

37 C.F.R. § 41.50(f).

AFFIRMED-IN-PART