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EXAMINER	
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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL C. SCHMITZ,
DALE F. SEELEY, and
KEITH R. HILDEBRAND

Appeal 2019-006659
Application 13/953,108
Technology Center 3700

Before STEFAN STAICOVICI, MICHAEL L. HOELTER, and
LEE L. STEPINA, *Administrative Patent Judges*.

HOELTER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1, 3–11, 18, 20, 21, 25, and 26, which

[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. We understand the real party in interest is "Medtronic, Inc. of Minneapolis, Minnesota, the assignee of record, and Medtronic plc of Dublin, Ireland, the ultimate parent entity of Medtronic. Inc." Appeal Br. 3.

constitute all the claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

CLAIMED SUBJECT MATTER

The disclosed subject matter "generally relates to, among other things, titration of dosing of medicaments delivered by medical infusion devices and systems and methods associated therewith." Spec. ¶ 1. Apparatus claim 1 and method claim 18 are the sole independent claims. Claim 1 is representative of the claims on appeal and is reproduced below.

> 1. A medical infusion device, comprising:
>
> a reservoir for housing a liquid composition comprising a medicament;
>
> a pump mechanism configured to drive the liquid composition from the reservoir to a patient;
>
> input apparatus configured to receive input indicative of a patient side effect of the medicament; and
>
> control electronics operably coupled to the pump mechanism and to the input apparatus, wherein the control electronics are configured to:
>
> (a) cause the pump mechanism to drive the liquid composition from the reservoir to the patient at an initial rate;
>
> (b) automatically cause the pump mechanism to drive the liquid composition from the reservoir to the patient for a predetermined period of time at a rate increased relative to a preceding rate if no input indicative of a patient side effect has been received during a period of time in which the pump mechanism drove the liquid composition from the reservoir to the patient at the preceding rate; and
>
> (c) repeat step (b) until a maximum predetermined rate has been achieved or until input indicative of a patient side effect is received, wherein if input indicative of a patient side effect is received, the control electronics cause the pump mechanism to drive the liquid composition from the reservoir to

> the patient at a decreased rate relative to a rate in a time period in which the input indicative of a patient side effect is received but at a rate equal to or greater than the initial rate if no input indicative of a patient side effect was received during a period of time in which pump mechanism drove the liquid composition from the reservoir to the patient at the initial rate.

EVIDENCE

Name	Reference	Date
Spencer	US 6,010,483	Jan. 4, 2000
Bui et al. ("Bui")	US 6,231,560 B1	May 15, 2001
Dang et al. ("Dang")	US 2003/0069318 A1	Apr. 10, 2003
Flaherty et al. ("Flaherty")	US 2005/0203461 A1	Sept. 15, 2005

REJECTIONS

Claims 1, 3–7, 18, 20, 21, 25, and 26 are rejected under 35 U.S.C. § 103 as unpatentable over Spencer and Bui.

Claims 8 and 9 are rejected under 35 U.S.C. § 103 as unpatentable over Spencer, Bui, and Dang.

Claims 10 and 11 are rejected under 35 U.S.C. § 103 as unpatentable over Spencer, Bui, and Flaherty.

ANALYSIS

The rejection of claims 1, 3–7, 18, 20, 21, 25, and 26 as unpatentable over Spencer and Bui

Appellant argues claims 1, 3–7, 18, 20, 21, 25, and 26 together. *See* Appeal Br. 10–22.[2] We select claim 1 for review, with the remaining claims

[2] After presenting arguments with respect to independent claim 1, Appellant states, "[t]he same or similar arguments apply to claim 18." Appeal Br. 22.

(i.e., claims 3–7, 18, 20, 21, 25, and 26) standing or falling with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

The Examiner relies primarily on Spencer for teachings the various limitations of claim 1, including pump operation. *See* Final Act. 2–3. However, the Examiner acknowledges that Spencer "fails to specifically disclose *that the control electronics* are configured to cause the pump" to operate as recited. Final Act. 3 (emphasis added). To be clear, Spencer addresses "a single button for a patient to push when more pain medicine is needed." Spencer 2:29–30. The Examiner relies on Bui for disclosing "control electronics (Fig. 2) . . . configured to cause the pump" to operate, and to do so "automatically." Final Act. 3, 4; *see also* Ans. 3 ("but the control electronics of Spencer fails to perform step (b) in an automatic manner"), 4 ("with regards to the word 'automatically', a second reference is used in the action"). The Examiner's stated reason to combine Spencer and Bui is that it would have been obvious to a skilled artisan "for the purpose of automatically adjusting . . . the patient's medications in [the] absence of [a] caregiver." Final Act. 4, Ans. 4 (both referencing Bui 13:30–62) ("The invention allows the pump to automatically adjust basal rate and/or bolus rate to alleviate patient pain in the absence of the caregiver's intervention."); *see also* Bui, Abstract ("automatically adjusts the amount of medication to optimize the treatment of pain").

Appellant initially contends, "***the Office Action appears to contradict itself when discussing Spencer***." Appeal Br. 13. Appellant states, "the Office Action contended that Spencer *disclosed* step (b) of claim 1 but simultaneously acknowledged that Spencer *failed to disclose* step (b) of claim 1." Appeal Br. 14. This is not a correct interpretation of the

Examiner's rejection. As noted above, the Examiner acknowledged that Spencer did not specifically disclose that the "control electronics" operate the pump in a certain manner, and relied on Bui for automatic operation thereof. Thus, Appellant's contention that the Examiner issued contradictory statements regarding step (b) is not a proper reading of the Examiner's rejection. Accordingly, we do not find error in the Examiner's analysis or conclusion.

Appellant also contends, "***Spencer failed to disclose increasing the pump rate if there is no patient side effect***." Appeal Br. 15. This is not a correct reading of Spencer. Spencer clearly addresses monitoring "patient parameters," and provides such examples as "respiratory rate, respiratory depth, hemoglobin oxygen saturation, and patient movement." Spencer 2:54–57. Spencer also states, "such parameters may be used to provide both sensitive and specific feedback to the pump regarding possible overdose." Spencer 2:57–59. Spencer also teaches "having the continuous infusion flow rate step up to a higher rate" but that patient feedback may also result in "discontinuation of the infusion." Spencer 2:31–50. Accordingly, Appellant's contention above that Spencer does not disclose increasing pump rate if there is no patient side effect is not a correct reading of the teachings of Spencer.[3]

Appellant also contends that Spencer does not teach the automatic operation of the pump. *See* Appeal Br. 16–17. Appellant provides a

[3] Appellant also appears to agree that Spencer monitors for side effects stating, "Although Spencer also described determining an effective baseline infusion rate if the patient's background pain is controlled without side-effects, there is *no affirmative step* to increase in the absence of patient side effects described." Appeal Br. 18.

definition of "automatically" as "(of a device or process) working by itself **with little or no direct human control**." Reply Br. 2. Hence, as per Appellant, "claim 1 recites to, *with little or no direct human control*, cause the pump mechanism to" operate. Reply Br. 2. However, it is clear from the Examiner's rejection that Bui was relied on for such automatic operation, not Spencer. *See* Final Act. 3–4. This would be the case even abiding by Appellant's definition above.[4] Accordingly, Appellant's contentions are not persuasive of Examiner error.

Appellant further states, "***Bui failed to disclose increasing the pump rate if there is no patient side effect***." Appeal Br. 19. This contention is not persuasive because Bui was not relied on for this teaching, but instead for disclosing electronic controls that operate automatically.[5] Final Act. 3–4. It would appear that Appellant is improperly arguing the art individually when the rejection is predicated upon a combination of prior art disclosures. *See In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

In addition to the above, Appellant seeks to distinguish Bui by stating, "Bui described a PCA [pain controlled analgesic] modification routine in which *the patient is queried before modifying the PCA*. Appeal Br. 19. Appellant contends that because of such querying, "Bui describes a process that is not automatic." Reply Br. 2. In other words, "Bui did not disclose at least step (b)," which includes the limitation of "automatically" causing the pump to operate, because Bui queries first. Appeal Br. 19. Appellant does

[4] Further, regarding Spencer's teaching of pushing a button, such action would also appear to be in accordance with Appellant's proffered definition of "little or no direct human control."
[5] However, Bui also teaches adjusting infusion rate based on side effects. *See* Bui 2:52–58; 11:34–42; 13:44–49.

not explain how, because Bui's pump may be programmed to first ascertain whether a predetermined value needs modification, this act serves to detract from Bui's clear teaching of the automatic operation of the pump to provide medication. *See* Appeal Br. 19, Reply Br. 2 (both referencing Bui 13:39–54); *see also* Bui, Title, Abstract, 1:6–8; 2:52–58, 4:15–16, etc.

Accordingly, and based on the record presented, we are not persuaded the Examiner erred in rejecting claims 1, 3–7, 18, 20, 21, 25, and 26 as unpatentable over Spencer and Bui.

The Examiner's rejection of (a) claims 8 and 9 as unpatentable over Spencer, Bui, and Dang and (b) claims 10 and 11 as unpatentable over Spencer, Bui, and Flaherty

Appellant does not dispute the Examiner's additional reliance on Dang or Flaherty in rejecting these claims, but instead relies on the arguments presented above regarding the combination of Spencer and Bui. *See* Appeal Br. 23. Because we are not persuaded by Appellant's arguments regarding Spencer and Bui, we sustain (a) the rejection of claims 8 and 9 as unpatentable over Spencer, Bui, and Dang and (b) the rejection of claims 10 and 11 as unpatentable over Spencer, Bui, and Flaherty.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 3–7, 18, 20, 21, 25, 26	103	Spencer, Bui	1, 3–7, 18, 20, 21, 25, 26	
8, 9	103	Spencer, Bui, Dang	8, 9	
10, 11	103	Spencer, Bui, Flaherty	10, 11	

Overall Outcome			1, 3–11, 18, 20, 21, 25, 26	

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

AFFIRMED