

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CAREFUSION CORPORATION,
Petitioner,

v.

BAXTER INTERNATIONAL, INC.,
Patent Owner.

Case IPR2016-01463
Patent 6,231,560 B1

Before RICHARD E. RICE, ROBERT J. WEINSCHENK, and
AMANDA F. WIEKER, *Administrative Patent Judges*.

RICE, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Petitioner, CareFusion Corporation, filed a Petition requesting an *inter partes* review of claims 1–18 of U.S. Patent No. 6,231,560 B1 (Ex. 1001, “the ’560 Patent”). Paper 1 (“Pet.”). In response, Patent Owner, Baxter International, Inc., filed a Preliminary Response. Paper 7 (“Prelim. Resp.”).

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted “unless . . . the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” Upon considering the Petition and the Preliminary Response, and for the reasons set forth below, we determine that Petitioner has shown a reasonable likelihood that it would prevail with respect to claims 1–3, 6, 7, and 16, but not claims 4, 5, 8–15, 17, and 18.

Accordingly, we institute an *inter partes* review of claims 1–3, 6, 7, and 16.

A. Related Matters

According to the parties, the ’560 Patent is involved in *Baxter Int’l, Inc. v. CareFusion Corp.*, No. 1:15-cv-09986 (N.D. Ill.). Pet. 2; Paper 4, 1.

B. The ’560 Patent

The ’560 Patent is directed to a method and apparatus for adjusting automatically the medication level for a patient, including the basal (i.e., constant) and bolus rates of administration in a pain controlled analgesic (“PCA”) mode during which an infusion pump periodically infuses boluses of an analgesic in response to requests by the patient. Ex. 1001, 1:6–35, 2:36–48. According to the Specification, an object of the invention is “automatically adjusting the medication level in response to input from a

patient regarding his pain level, side effects and impairment of functionalities, without having to contact the caregiver or physician.” *Id.* at 2:41–44. Another object of the invention is “automatically adjusting the medication level in patient control analgesia using a predetermined set of criteria which is patient specific, yet provides the patient the ability to have his medication adjusted without having to contact a caregiver or physician.” *Id.* at 2:45–49.

In a preferred embodiment, infusion pump 10 provides automatic adjustment of a patient’s medication. *Id.* at 4:15–16. Operation of the infusion pump is controlled by a computer program stored in EPROM 204 and executed by controller 200. *Id.* at 6:29–31. The infusion pump has five basic modes, including a PCA mode during which the pump periodically infuses boluses of analgesic in response to periodic requests by the patient. *Id.* at 7:6–20.

“Prior to assigning a particular infusion pump to a patient, the physician or caregiver programs in the patient’s algorithm for automatically changing his PCA dose.” *Id.* at 11:34–36. The patient’s algorithm defines the range of values for the basal dose, the bolus dose, and the maximum amount of drug to be administered, and “can increase or reduce the amount or duration of any of the PCA elements, depending on the patient’s pain level, side effects and any impairment of the patient’s functionalities.” *Id.* at 11:36–42. In one embodiment, percent of “Successful Bolus Request” data is stored by the pump along with other pump information, accessed from memory, and used as an indirect measure of pain level. *Id.* at 12:39–43. For example, if the patient makes “bolus requests after the maximum number has already been administered, this is an indication that the patient is

in pain and needs either a higher basal rate, higher bolus dose or greater number of bolus doses, or a combination thereof.” *Id.* at 12:43–47.

C. Illustrative Claim

Claims 1, 8, 9, and 16 are independent. Claim 1 is illustrative of the claimed subject matter and is reproduced below.

1. A method for automatically controlling the level of a patient’s medication administered from a programmable infusion pump, comprising:

programming the infusion pump with a medication algorithm;

initiating an evaluation of the patient’s medication;

obtaining information pertaining to the patient’s condition;

obtaining information pertaining to the patient’s current medication;

evaluating the patient’s current medication and condition with the medication algorithm; and

controlling administration of the patient’s medication based on the evaluation.

Id. at 14:6–20.

D. Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable based on the following specific grounds (Pet. 14):

References	Basis	Claims Challenged
Bollish ¹	§ 102(e)	1–3 and 9–11
Bollish	§ 103(a)	1–18

¹ US 5,957,885 to Bollish et al., which issued Sept. 28, 1999 from an application filed Nov. 6, 1996 (Ex. 1004, “Bollish”).

References	Basis	Claims Challenged
Bollish and TITRATOR ²	§ 103(a)	1–18

To support the Petition, Petitioner relies on the Declaration of Stephen J. Bollish (Ex. 1003).³ In its Preliminary Response, Patent Owner relies on the Declaration of Warren P. Heim (Ex. 2001).

II. ANALYSIS

A. Level of Skill in the Art

Petitioner contends based on the testimony of its declarant, Dr. Bollish, that “[a] person of ordinary skill in the art [“POSA”] . . . would have been someone with at least a bachelor’s or graduate degree in pharmacy, medicine, biomedical engineering, or a related field, and at least 8 years of combined clinical and infusion pump design experience.” Pet. 9 (citing Ex. 1003 ¶ 15). Patent Owner disagrees. Patent Owner contends based on the testimony of its declarant, Mr. Heim, that a POSA would have been

an individual having at least a bachelor’s degree in engineering who is familiar with mechanical, electronic, and software engineering as it was practiced for medical devices before or during 1999, and who had been actively involved in the engineering and design of infusion pumps for at least six years. Prelim. Resp. 5–6 (citing Ex. 2001 ¶ 43).

“The person of ordinary skill in the art is a hypothetical person who is

² *Directions for Use: TITRATOR™, Sodium Nitroprusside Closed Loop Module – Model 10K*, IVAC Corp., San Diego, CA (1990) (Ex. 1005).

³ Dr. Bollish testifies that he is the “lead inventor” of Petitioner’s “PCA Pause technology,” which is “disclosed and claimed” in the Bollish reference. Ex. 1003 ¶ 13.

presumed to know the relevant prior art.” *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citation omitted). Pertinent to determining this skill level are factors such as problems encountered in the relevant art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field. *See id.* For the purposes of this Decision, we determine that a person of ordinary skill in the art would have had at least an undergraduate degree in pharmacy, medicine, engineering, or a related field, and at least six years of experience in the design of infusion pumps.⁴

B. Claim Interpretation

1. *“controlling administration of the patient’s medication”* (claims 1 and 16), *“modifying delivery of the patient’s medication”* (claim 8), and *“changing the rate and amount of the liquid medicant to be administered to the patient”* (claim 9)

Claims 1 and 16 recite “controlling administration of the patient’s medication.” Claim 8 recites “modifying delivery of the patient’s medication.” And claim 9 recites “changing the rate and amount of the liquid medicant to be administered to the patient.” Petitioner contends that these terms each require “increasing or decreasing the amount or duration of the patient’s ongoing delivery of medication,” that is, “*changing* the delivery rate, not stopping it.” Pet. 11 (citing Ex. 1001, 1:49–52, 11:32–42; Ex. 1003 ¶¶ 9–11).

Patent Owner disagrees. Patent Owner argues that Petitioner improperly limits the “controlling,” “modifying,” and “changing” terms to

⁴ We have taken into account that the educational background of Dr. Bollish is pharmacy and the educational background of Mr. Heim is engineering. *See* Ex. 1003 ¶ 2; Ex. 2001 ¶ 9.

merely increasing or decreasing the amount or duration of a patient's medication. Prelim. Resp. 8. Patent Owner further argues that "Petitioner also improperly limits these terms to 'ongoing delivery of medication,' requiring the pump to continually administer medication." *Id.* According to Patent Owner, Petitioner's construction is inconsistent with the Specification, which teaches, for example, "intermittently delivering medication or delivering unique infusion rates over multiple time periods." *Id.* at 9–11 (citing Ex. 1001, 3:33–42; 4:15–16; 7:6–19, 8:52–63, 9:25–30, 9:45–51).⁵

At this stage of the proceeding, Petitioner has not persuaded us that a proper interpretation of these terms "requires *changing* the delivery rate, not stopping it." *See* Pet. 11. Petitioner relies on the "Background of the Invention" portion of the Specification, which discloses a conventional infusion pump that "prevent[s] PCA doses in excess of the maximum set by the physician." *See id.* (citing Ex. 1001, 1:49–52). Petitioner has not argued or shown, however, that the Specification disavows that feature. *See Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1024 (Fed. Cir. 2015) (stating that "disavowal requires that 'the specification [or prosecution history] make[] clear that the invention does not include a particular feature'" (quoting *SciMed Life Sys. Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001))).

Petitioner argues that, in contrast with the conventional infusion pump, which prevents PCA doses in excess of the maximum set by the physician, the preferred embodiment as described in the Specification only

⁵ Patent Owner proposes no claim construction of its own. *See* Prelim. Resp. 11 n.3 ("reserv[ing] the right to further construe the terms at issue in this IPR and in the related District Court Litigation").

changes the patient's dosage rate. Pet. 11 (citing Ex. 1001, 1:49–52, 11:32–42). But Petitioner bases its characterization of the preferred embodiment's functionality on a single passage in the Specification, and that passage does not provide clear support for Petitioner's argument. The passage states simply that “[t]he patient algorithm can increase or reduce the amount or duration of any of the PCA elements, depending on the patient's pain level, side effects and any impairment of the patient's functionalities.” Ex. 1001, 11:39–42. Other portions of the Specification more clearly indicate that, contrary to Petitioner's argument, the preferred embodiment does have the capability to prevent PCA doses in excess of the maximum set by the physician.

For example, the “Summary of the Invention” portion of the Specification describes two methods for determining a patient's pain level. *Id.* at 3:7–17. In one of those methods, “the programmable infusion pump stores the number of bolus requests by the patient and whether or not they resulted in delivery of a bolus over a prescribed period of time.” *Id.* at 3:8–11 (emphasis added). The number of patient bolus requests in excess of the total number of boluses delivered is used in that method as an indication of the patient's pain level. *Id.* at 3:11–14. The method thus depends on operating the programmable infusion pump such that it prevents delivery of bolus doses in excess of the maximum.

Further, under the broadest reasonable interpretation standard, a claim term generally is given its ordinary and customary meaning as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). At this stage of the proceeding, we are persuaded that the

ordinary and customary meanings of the “controlling,” “modifying,” and “changing” terms are each broader than “increasing or decreasing the amount or duration of the patient’s ongoing delivery of medication.” *See* Prelim. Resp. 8–11; Pet. 11. Petitioner has not explained sufficiently why we should give the claim terms a meaning that is different from, and narrower than, their ordinary and customary meanings.

For the purposes of this Decision, we determine that the broadest reasonable interpretation consistent with the Specification of each of the claim terms set forth above includes stopping the delivery rate of the patient’s medication. No further construction is required. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

2. “*modification of a basal delivery rate, a bolus dose, and a number of bolus allowed within a certain time frame*”

Claim 3 recites “controlling administration of the patient’s medication includes *modification of a basal delivery rate, a bolus dose and a number of bolus allowed within a certain time frame*” (emphasis added). Petitioner argues that the broadest reasonable construction of this “modification” term is “increasing or decreasing the amount or duration of the ongoing basal delivery rate, increasing or decreasing the amount or duration of the available bolus doses, and increasing or decreasing the number of allowed future bolus doses.” Pet. 12. Petitioner further argues that this term is not met by “simply shutting down or pausing the pump if a dosage limit is exceeded or the patient’s oxygen saturation or respiration fall below safe levels.” *Id.* (citations omitted).

For the reasons discussed above with respect to the “controlling” term in claim 1, from which claim 3 depends, we do not agree with Petitioner’s

proposed claim construction at this stage of the proceeding. *See supra* Section II.A.1. Rather, we determine that for the purposes of this Decision the broadest reasonable interpretation consistent with the Specification of “modification of a basal delivery rate, a bolus dose and a number of bolus allowed within a certain time frame” not only includes increasing or decreasing a basal delivery rate, a bolus dose, and a number of bolus doses allowed within a certain time frame, but also stopping or pausing delivery of the patient’s basal dose and bolus dose. No further construction is required. *See Vivid*, 200 F.3d at 803.

3. “*obtaining information . . .*”

Claim 1 recites “obtaining information pertaining to the patient’s condition” and “obtaining information pertaining to the patient’s current medication.” Claim 2 recites “[t]he method of claim 1, wherein the step of obtaining information pertaining to the patient’s current medication comprises storing information pertaining to the amount of medication administered to the patient over a predetermined period of time.” Claim 8 recites “obtaining information pertaining to the patient’s pain level,” “obtaining information pertaining to the patient’s side effects,” “obtaining information pertaining to the patient’s impairment of functionalities,” and “obtaining information pertaining to the patient’s current medication.” Claim 9 recites “a data acquiring routine for obtaining information pertaining to the patient’s pain level, side effects and impairment of functionalities.”

Petitioner argues that “for the purposes of evaluating the claims under their broadest reasonable interpretation, it is appropriate for the Board to consider [Patent Owner’s] infringement positions when comparing these

elements to the prior art.” Pet. 13.⁶ Remarkably, however, Petitioner states that it “*disagrees that [Patent Owner’s] constructions are correct,*” but “does not dispute [Patent Owner’s] interpretation of these terms for the purpose of this Petition, though [Petitioner] may subsequently do so in the district court lawsuit.” *Id.* (emphasis added).

Patent Owner responds, and we agree, that Petitioner has not provided a sufficient statement of how the “obtaining information . . .” terms are to be construed as required under the Board’s rules. *See* 37 C.F.R. § 42.104(b)(3); Prelim. Resp. 16. Not only has Petitioner failed to indicate that it agrees with, proposes, or adopts the constructions attributed to Patent Owner, Petitioner states, without qualification, that the constructions are incorrect. *See* Pet. 13.

In this case, we reject Petitioner’s argument that it would be appropriate for the Board to consider Patent Owner’s infringement positions with respect to the “obtaining information . . .” terms. Rather, we determine that no construction is required for the purposes of this Decision.

⁶ According to Petitioner, Patent Owner contends in the related litigation that: (1) “‘obtaining information pertaining to the patient’s current medication’ is satisfied by ‘keep[ing] track of the patient’s current medication by *e.g.*, tracking when the last dose of medication was delivered’”; and (2) “‘obtaining information pertaining to the patient’s condition’ and ‘obtaining information pertaining to the patient’s pain level, side effects and impairment of functionalities’ [are] satisfied by either registering the patient’s PCA bolus dose requests or monitoring the patient’s respiration or oxygen saturation.” Pet. 13 (citations omitted). Patent Owner “denies that it has offered any such constructions, or taken any particular position with regard to construing any of the claims in [the related] litigation.” Prelim. Resp. 16–18.

C. Asserted Anticipation by Bollish

To anticipate a patent claim under 35 U.S.C. § 102, “a single prior art reference must expressly or inherently disclose each claim limitation.”

Finisar Corp. v. DirecTV Group, Inc., 523 F.3d 1323, 1334 (Fed. Cir. 2008).

Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claim limitations, it anticipates, even though artisans of ordinary skill may not have recognized the inherent characteristics or functioning of the prior art. *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (citation omitted); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349–50 (Fed. Cir. 2002).

Petitioner contends that Bollish anticipates claims 1–3 and 9–11 under 35 U.S.C. ¶ 102(e). Pet. 14–33.

1. Overview of Bollish

Bollish discloses a patient care system that comprises a PCA unit, a pulse oximetry unit, and an interface between the two units. Ex. 1004, 3:19–21. The pulse oximetry unit determines a patient’s percentage blood oxygen saturation and pulse rate. *Id.* at 3:27–29. Upon detection and recognition of respiratory depression by the pulse oximetry unit, the system automatically shuts-off the PCA unit, sounds visual and audio alarms, and delivers appropriate feedback to medical personnel. *Id.* at 3:36–40.

2. Claims 1–3

With respect to claims 1–3, Petitioner contends that Bollish inherently discloses “obtaining information pertaining to the patient’s current medication.” Pet. 19. Petitioner relies on Bollish’s disclosure that “*whether the patient actually receives a requested dose depends upon the patient request dosing limits, if any.*” *Id.* at 19–20 (citing Ex. 1004, 8:11–25); *see*

id. at 22–24. Petitioner argues that “[c]omparing the requested PCA dose of narcotics to the ‘patient request dosing limits’ inherently teaches that the device has stored and retrieved information regarding the patient’s current medication level.” *Id.* at 20 (citing Ex. 1003 ¶ 18). Petitioner further supports its inherency theory with testimony from Dr. Bollish:

A person of ordinary skill in the art in 1999 would have understood that by comparing the requested dose to “the patient request dosing limits, if any,” my ’885 patent is *inherently* referring to the well-known ability of infusion pumps to track the delivered medication dose over a period of time (stored in the pump’s memory) and compare it against the dosing limits for that time period programmed by the caregiver (also stored in the pump’s memory).

Ex. 1003 ¶ 18 (emphasis added).

Patent Owner responds that Petitioner’s inherency argument is conclusory, and fails to show that Bollish’s infusion pump *necessarily* stores and retrieves information regarding the patient’s current medication level. Prelim. Resp. 20–28. Patent Owner argues that, instead of storing and retrieving information regarding the patient’s current medication level, Bollish’s device alternatively could have employed one or more electronic or mechanical counters:

For example, one alternative to determining whether to administer a bolus dose is for one or more electronic or mechanical counters to track the number of boluses requested during one or more intervals, regardless of the amount of medication that has been delivered to the patient, and for electronics other than a microprocessor to evaluate that request against a fixed or variable threshold value stored either electronically or mechanically to determine whether or not to administer the requested PCA dose. (Ex. 2001 ¶¶ 75–77.) The threshold value could be set to a standard value suitable for a group of patients and not be patient specific, and could be

utilized by either a microprocessor or one or more resistor-capacitor timing circuits driving single bipolar junction transistors in determining whether to administer a dose or not. (Ex. 2001 ¶ 78.) One example of a mechanical non-microprocessor solution would be a clock mechanism, which could be driven electrically or mechanically, such as with a wound spring, that continuously moves a sliding contact toward a position that allows a bolus to be delivered, and pushed incrementally away from that position whenever a bolus has been delivered. (Ex. 2001 ¶ 79.) Such a system could determine whether to administer a PCA dose without any information relating to the patient's current medication. (Ex. 2001 ¶¶ 75, 79.)

Id. at 26–27.

We agree with, and adopt, Patent Owner's argument that Petitioner has failed to establish that Bollish inherently discloses "obtaining information pertaining to the patient's current medication." For the reasons given, we determine that Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing that Bollish anticipates claims 1–3.

3. Claims 9–11

With respect to claims 9–11, Petitioner asserts that Bollish expressly discloses "a data acquiring routine for obtaining information pertaining to the patient's pain level, side effects and impairment of functionalities." Pet. 29–33. Petitioner relies on Bollish's disclosure that "whether the patient actually receives a requested dose depends upon . . . the *patient's current percent blood oxygen saturation and pulse rate relative to the minimum levels set by the clinician.*" *Id.* at 30 (citing Ex. 1004, 8:11–25). Petitioner also relies on the disclosure in Bollish that the system monitors the patient's

oxygen saturation and pulse rate and initiates measures to protect the patient if the monitored levels are too high or too low:

“[i]n the event that *the patient’s percent blood oxygen saturation and pulse rate* is outside of the maximum and minimum levels set by the clinician, central interface unit 100 immediately shuts-off PCA unit 150A, and . . . [i]n addition, central interface unit 100 activates audio alarm 260, *displays visual alarm on information display 102, flashes ALARM indicator 164 on PCA unit 150A and/or pulse oximetry unit 150B*, and sends an emergency signal via interface ports 122 and external communications controller 274 in order to alert appropriate medical personnel.

Id. at 30–31 (citing Ex. 1004, 8:42–55); *see also id.* at 29–30 (citing Ex. 1001, 7:26–45). Petitioner argues that: “Thus, to the extent that monitoring a patient’s bolus requests, pulse, and/or oxygen saturation can be considered ‘obtaining information pertaining to the patient’s pain level, side effects and impairment of functionalities,’ as [Patent Owner] contends, Bollish teaches this limitation.” *Id.* at 31 (citing Ex. 1003 ¶¶ 12–13, 18–19; also citing the claim construction section of the Petition and Patent Owner’s infringement contentions).

Petitioner has failed to persuade us that Bollish discloses the required “data acquiring routine for obtaining information pertaining to the patient’s pain level, side effects and impairment of functionalities.” Petitioner’s conclusory argument improperly relies on Patent Owner’s infringement positions rather than a proper claim construction. *See supra* Section II.B.3. Moreover, Petitioner has not explained sufficiently why “monitoring a patient’s bolus requests, pulse, and/or oxygen saturation” corresponds to “obtaining information pertaining to the patient’s pain level, side effects and impairment of functionalities” as required by claims 9–11.

We have considered the testimony of Dr. Bollish that a POSA “would have understood that the PCA pump described in [the Bollish reference] stores the digital information described in the patent (such as programmed doses, historical dose information, and monitored patient information) in its memory (*see, e.g.*, element 250 in Figure 3).” Ex. 1003 ¶ 21. The only portion of the Bollish reference that Dr. Bollish cites to support his testimony, however, is memory 250 in Figure 3. Dr. Bollish does not point to any discussion in Bollish explaining the function of memory 250, and we have found none. Accordingly, we give little weight to his testimony that the Bollish reference expressly discloses storing programmed doses, historical dose information, and monitored patient information in its memory. *See* 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”). Dr. Bollish’s testimony also does not clarify Petitioner’s argument that “monitoring a patient’s bolus requests, pulse, and/or oxygen saturation” somehow corresponds to “obtaining information pertaining to the patient’s pain level, side effects and impairment of functionalities.”

For the reasons given, we determine that Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing that Bollish anticipates claims 9–11.

4. *Summary*

We determine that Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing that Bollish anticipates claims 1–3 and 9–11.

D. Asserted Obviousness over Bollish

A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations, if in evidence. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Petitioner contends that Bollish renders obvious claims 1–18 under 35 U.S.C. ¶ 103(a). Pet. 33–46.

1. Claims 1–3

Relying on its anticipation arguments, Petitioner contends that claims 1–3 would have been obvious because “anticipation is the epitome of obviousness.” *Id.* at 33–34 (citing *In re McDaniel*, 293 F.3d 1379, 1385 (Fed. Cir. 2002)). Petitioner also argues that: “Should the Board conclude that Bollish does not inherently require [information regarding the patient’s medication dosage levels] to be stored in the device . . . , it certainly would have been obvious to a person of ordinary skill in the art to store the patient’s medication information in order to perform the calculations taught

by Bollish.” *Id.* at 34 (citing Ex. 1003 ¶¶ 18–21). In support of that argument, Dr. Bollish testifies that “it certainly would have been obvious to [a] person of ordinary skill designing infusion pump systems to store this information using well-known digital memory.” Ex. 1003 ¶ 21.

In its Preliminary Response, Patent Owner argues that Petitioner has failed to show that its obviousness ground is not redundant. Prelim. Resp. 28–29 n.6. Patent Owner asserts, as it did in connection with Petitioner’s anticipation ground, that Bollish does not disclose inherently the “obtaining information . . .” terms of claims 1–3. *Id.* at 35–39. Patent Owner also argues that Petitioner has failed to identify the differences between the claimed subject matter and the prior art, and that Petitioner relies for obviousness on merely conclusory statements. *Id.* at 28–35.

In its claim charts, Petitioner provides citations to portions of Bollish that correspond to the limitations of claims 1–3. Pet. 16–24, 34. While we agree with Patent Owner that Bollish does not *disclose* expressly or inherently the “obtaining information . . .” terms, we are persuaded at this stage of the proceeding that claims 1–3 nevertheless would have been *obvious* over Bollish based on the knowledge of a person of ordinary skill in the art at the time of the invention. In particular, we are persuaded by Petitioner’s arguments and Dr. Bollish’s testimony showing that: (1) the Bollish reference teaches using information display 102 to input or recall values for patient bolus dosage, patient request dosing limits, and a background continuous infusion dosage; (2) a POSA would have understood that these dosing values, like any other information stored in a digitally-programmable device, are stored in memory, such as memory 250; (3) a POSA would have understood that the Bollish reference teaches storing

information relating to programmed doses, doses delivered to the patient, and monitored vital signs of the patient; and (4) it would have been obvious to a POSA designing infusion pump systems to store this information using well-known digital memory. Pet. 14–24, 34; Ex. 1003 ¶¶ 20–21; Ex. 1004, Fig. 3.

We have considered Patent Owner’s arguments, but at this stage of the proceeding we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that claims 1–3 would have been obvious over Bollish.

2. Claim 4

Claim 4 recites “[t]he method of claim 1, wherein the step of obtaining information pertaining to the patient’s condition further comprises storing the number of bolus requests made by the patient which exceed the maximum number of permitted boluses.” In support of Petitioner’s contention that claim 4 would have been obvious, Dr. Bollish testifies:

As discussed, a person of ordinary skill in the art in the late 1990’s would have understood that the PCA pump described in [the Bollish reference] stores the number of bolus requests made by the patient and the maximum number of allowed boluses. [The Bollish reference] further discloses the well-known practice of comparing those two numbers to determine if a further bolus dose is allowed. It would have been a trivial modification of the PCA pump described in [the Bollish reference] to also specifically store the number of bolus doses made in excess of the allowed maximum — that number is simply the difference between the actual number of requests and the number of allowed requests. Such a trivial modification would have been obvious to a person of ordinary skill in the art.

Ex. 1003 ¶ 22. Petitioner’s argument in the Petition relies on this testimony.

Pet. 35 (citing Ex. 1003 ¶ 22).

We are not persuaded that claim 4 would have been obvious over Bollish. Neither Petitioner nor Dr. Bollish provides a reason why a POSA would have modified Bollish's PCA pump to store the number of bolus requests made by the patient that exceed the maximum number permitted. *See In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”). Dr. Bollish's conclusory testimony that such a modification would have been trivial to implement is insufficient.

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing that claim 4 would have been obvious over Bollish.

3. Claim 5

Claim 5 requires “querying the patient regarding the patient's pain level, side effects and impairment of functionalities.” Petitioner has not shown sufficiently that Bollish teaches “querying the patient.” *See* Pet. 35–36 (citing Ex. 1003 ¶¶ 18–19). Specifically, the Petition does not explain why “the number of bolus requests, the patient's blood oxygen saturation, and the patient's pulse rate would have been indicative of the patient's pain level,” and, even if so, how such any such “indicati[on] of pain level corresponds to “querying the patient” as claimed. *See id.*

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing that claim 5 would have been obvious over Bollish.

4. Claim 6

Claim 6 requires “providing an evaluation of the patient's side effects.” Petitioner argues that a person of ordinary skill in the art would

have understood that shutting off the PCA pump in response to an out-of-limit blood oxygen saturation corresponds to “providing an evaluation of the patient’s side effects” as required by claim 6. Pet. 37 (citing Ex. 1003 ¶¶ 18–19). On the current record, we agree with Petitioner’s argument. Bollish teaches monitoring for the potential side effect of respiratory depression and, upon detection and recognition of that side effect, automatically shutting-off the PCA unit. Ex. 1004, 3:30–40.

Accordingly, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that claim 6 would have been obvious over Bollish.

5. Claim 7

Claim 7 recites “[t]he method of claim 1, wherein the step of obtaining information pertaining to the patient’s condition further comprises the step of providing an evaluation of the patient’s impairment of functionalities.” Petitioner argues that a person of ordinary skill in the art would have understood that shutting off the PCA pump in response to an out-of-limit blood oxygen saturation corresponds to “providing an evaluation of the patient’s impairment of functionalities” as required by claim 7. Pet. 38 (citing Ex. 1003 ¶¶ 18–19). On the current record, we agree with Petitioner’s argument for essentially the same reasons as discussed above with respect to claim 6. At this stage of the proceeding, we are persuaded that detecting and recognizing respiratory depression involves evaluating the patient’s impairment of functionalities. *See* Ex. 1004, 3:30–40.

Accordingly, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that claim 7 would have been obvious over Bollish.

6. *Claim 8*

Independent claim 8 requires, *inter alia*, “a procedure for obtaining information pertaining to the patient’s pain level and storing the patient’s pain level information automatically” and “a procedure for evaluating stored information of the patient’s current medication, pain level, side effects and impaired functionalities” For those requirements, Petitioner relies on its arguments with respect to claim 5. Pet. 41–42. As discussed above in connection with claim 5, we do not agree with Petitioner’s arguments.

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing that claim 8 would have been obvious over Bollish.

7. *Claims 9–15*

Petitioner relies on its anticipation arguments to show obviousness of claims 9–11. Pet. 43. As discussed above, we do not agree with Petitioner’s anticipation arguments, and thus we are not persuaded that claims 9–11 would have been obvious over Bollish. *See supra* Section II.C.3. For the same reasons, we are not persuaded that claims 12–15, which depend indirectly from claim 9, would have been obvious over Bollish.

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing that claims 9–15 would have been obvious over Bollish.

8. *Claim 16*

Claim 16 recites:

16. A method for automatically controlling the level of a patient's medication administered from a programmable infusion pump, comprising:
 - programming the infusion pump with a set of patient specific, predetermined ranges of medication;
 - evaluating the patient's current medication and recording the patient's current medication in the infusion pump;
 - evaluating the patient's physiological conditions and recording the patient's physiological conditions in the infusion pump; and
 - controlling administration of the patient's medication based on the evaluation of the patient's current medication and physiological conditions as compared with the programmed predetermined ranges of medication.

The limitations of claim 16 are similar to those of claims 1 and 2. For the reasons discussed above with respect to claims 1 and 2, we determine at this stage of the proceeding that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that claim 16 would have been obvious over Bollish.

9. Claims 17 and 18

Claim 17 requires evaluating the patient's pain level, and claim 18 requires querying the patient. For the reasons discussed above with respect to claims 5 and 8, we determine that Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing that claims 17 and 18 would have been obvious over Bollish.

10. Summary

For the reasons given, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that claims 1–3, 6, 7, and 16 are obvious over Bollish, but not claims 4, 5, 8–15, 17, and 18.

E. Asserted Obviousness over Bollish and TITRATOR

Petitioner contends that Bollish and TITRATOR render obvious claims 1–18 under 35 U.S.C. ¶ 103(a). Pet. 46–64.

1. Overview of TITRATOR

TITRATOR contains directions for using the TITRATOR™ control device in a system for regulating a patient’s mean arterial pressure (“MAP”) through controlled infusions of the vasoactive drug Sodium Nitroprusside (“SNP”). Ex. 1005, 5.⁷ The system comprises the TITRATOR™ device, a dedicated SNP infusion pump, and an arterial pressure transducer. *Id.* The TITRATOR™ device monitors patient MAP, computes infusion rates, and sends control signals to the dedicated infusion pump through a serial data link. *Id.* User-selectable displays show infusion rate and systolic/diastolic pressure or heart rate. *Id.* at 8. The device can limit SNP dosage rate and total dosage delivered through a toxicity limiting feature when solution concentration, total drug dose, and patient weight values are entered into the system. *Id.* “In the AUTO mode, the TITRATOR^[TM] device will automatically adjust the infusion rate as necessary when the infusion is being delivered.” *Id.* at 23.

2. Rationale for Combining the References

Petitioner contends that a POSA would have combined “the automatic dosage modification features of the TITRATOR^[TM] module with the PCA infusion pump disclosed by Bollish” because modification of TITRATOR’s control module for connection to the Bollish infusion pump would have been

⁷ We cite to the page numbers of Exhibit 1005 that begin with page 1 (actually marked “CF000040_0001”). In the Petition, Petitioner cites to another set of numbers, in which “APP0211” corresponds to page 1.

“merely a combination of prior art elements according to known methods to yield predictable results.” Pet. 49 (citing Ex. 1003 ¶¶ 23–26). In support of Petitioner’s rationale, Dr. Bollish testifies that such a modified pump could have adjusted automatically the patient’s medication level in response to pulse oximetry readings and the number of bolus requests — rather than merely deactivating the pump in response to out-of-limit readings and denying bolus requests in excess of the allowed maximum. Ex. 1003 ¶ 26.

Patent Owner argues that Petitioner has failed to provide a sufficient rationale for combining the references. Prelim. Resp. 43–57. For example, Patent Owner argues that TITRATOR teaches a specialized system that is used to deploy a vasoactive drug in a closed loop control system, while Bollish teaches a PCA pump that is used to deploy bolus doses of pain control medicine at the request of the patient. *Id.* at 51. Patent Owner also points to TITRATOR’s use restriction, and argues that “TITRATOR thus not only fails to overcome any shortcoming of Bollish, it *specifically teaches away* from the alleged combination Petitioner is attempting to make.” *Id.* at 52. Patent Owner also points to the technical difficulty of combining the references, and argues that extensively modifying the TITRATOR™ device for use with Bollish’s PCA pump would change its basic principles of operation. *Id.* at 53–54 (citing Ex. 2001 ¶¶ 95–99).

We have considered Patent Owner’s arguments, but we are persuaded at this stage of the proceeding that Petitioner has provided a sufficient rationale for combining the automatic dosage modification features of the TITRATOR™ module with the PCA infusion pump disclosed by Bollish. The TITRATOR™ use restriction states that the TITRATOR™ device may be used only for delivery of SNP with an IVAC Model 560i pump, but does not

criticize, discredit, or otherwise discourage modification of the device for use in other applications, for example, with a PCA infusion pump. *See id.* at 52; *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (requiring for a reference to “teach away” that it “criticize, discredit, or otherwise discourage the solution claimed”). At this stage of the proceeding, we do not discern that the asserted modifications to Bollish’s PCA pump would have been beyond the skill of a POSA. *See KSR*, 550 U.S. at 417 (“[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.”).

3. *Claims 1–3, 6, 7, and 16*

Petitioner cites both Bollish and TITRATOR for every limitation of claims 1–3, 6, 7, and 16. *See Pet.* 49–63. In its Preliminary Response, Patent Owner argues unpersuasively that Petitioner’s claim chart generally commingles citations without ever describing which specific elements are being combined, in what manner, or why one of ordinary skill in the art would have been motivated to do so. *Prelim. Resp.* 40. We note, for example, that Petitioner relies on inherency and obviousness to show that Bollish alone teaches the “obtaining information . . .” limitations of claims 1–3, but asserts with respect to the combination of Bollish and TITRATOR that those limitations are disclosed expressly by TITRATOR. *See Pet.* 20, 22–23, 34, 51–53. Further, with respect to claim 3, Petitioner explains how and why elements of Bollish and TITRATOR would have been combined:

As discussed in connection with claim 1, TITRATOR teaches automatically adjusting the drug infusion rate, within a limited range, to maintain desired arterial pressure. (Ex. 1005 at

APP0218.) Thus, TITRATOR expressly discloses automatically controlling administration of the patient's medication by modification of a basal delivery rate.

It would have been obvious to a person of ordinary skill in the art to use the teachings of TITRATOR to modify the patient-controlled analgesia (PCA) infusion pump taught by Bollish. (*See* 1003 at ¶¶ 23–26.) In such a combination, it would have been obvious to a person of ordinary skill in the art to modify the bolus dose and allowed number of boluses in the same manner that TITRATOR teaches modifying the basal dose. (*See id.*)

Thus, the combination of Bollish and TITRATOR satisfies this claim element, regardless of what construction is applied.

Pet. 53. Although Patent Owner argues that Bollish and TITRATOR do not render obvious claims 1–3, 6, 7, and 16, we already have determined, as discussed above, that those claims would have been obvious over Bollish alone. *See supra* Section II.D.10.

Accordingly, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that claims 1–3, 6, 7, and 16 would have been obvious over Bollish and TITRATOR.

4. Claims 4, 5, 8–15, 17, and 18

We already have determined, as discussed above, that claims 4, 5, 8–15, 17, and 18 would not have been obvious over Bollish alone. *See supra* Section II.D.10. Petitioner has not persuaded us that TITRATOR cures any of Bollish's deficiencies.

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing that claims 4, 5, 8–15, 17, and 18 would have been obvious over Bollish and TITRATOR.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on its challenges to: (a) claims 1–3, 6, 7, and 16 as obvious over (a) Bollish and (b) Bollish and TITRATOR, but Petitioner has not demonstrated a reasonable likelihood of prevailing on any of its challenges to claims 4, 5, 8–15, 17, and 18. At this stage of the proceeding, the Board has not made a final determination with respect to the patentability of any of the challenged claims, nor with respect to claim construction.

IV. ORDER

In consideration of the foregoing, it is ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted based on the following grounds:

- A. claims 1–3, 6, 7, and 16 of U.S. Patent No. 6,231,560 B1 as unpatentable under 35 U.S.C. § 103(a) for obviousness over Bollish; and
- B. claims 1–3, 6, 7, and 16 of U.S. Patent No. 6,231,560 B1 as unpatentable under 35 U.S.C. § 103(a) for obviousness over Bollish and TITRATOR;

FURTHER ORDERED that no other ground of unpatentability asserted in the Petition is authorized for this *inter partes* review; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; the trial will commence on the entry date of this Decision.

IPR2016-01463
Patent 6,231,560 B1

PETITIONER:

Kurt J. Niederluecke
Adam R. Steinert
Nikola L. Datzov
FREDRIKSON & BYRON, P.A.
kniederluecke@fredlaw.com
asteinert@fredlaw.com
ndatzov@fredlaw.com

PATENT OWNER:

Denis J. Sullivan
Thomas Hoehner
BARCLAY DAMON, LLP
dsullivan@barclaydamon.com
thoehner@barclaydamon.com