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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 ROBERT J. WEINSCHENK, TIMOTHY J. GOODSON, and AMANDA F. WIEKER, *Administrative Patent Judges.*

GOODSON, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

CareFusion Corporation ("Petitioner") filed a petition (Paper 1, "Pet.") requesting *inter partes* review of claims 1–18 of U.S. Patent No. 6,231,560 B1 (Ex. 1001, "the '560 patent"). Baxter International, Inc. ("Patent Owner") filed a preliminary response. Paper 7 ("Prelim. Resp."). We instituted an *inter partes* review of claims 1–3, 6, 7, and 16 on the following grounds:

Reference(s)	Basis	Claims
Bollish[1]	§ 103	1–3, 6, 7, and 16
Bollish and TITRATOR[2]	§ 103	1–3, 6, 7, and 16

See Paper 9 ("Dec. on Inst.").

After institution of trial, Patent Owner filed a Patent Owner Response (Paper 22, "PO Resp."), and Petitioner filed a Reply (Paper 23, "Reply"). Patent Owner filed a motion to exclude evidence (Paper 27), to which Petitioner filed an opposition (Paper 28) and Patent Owner filed a reply (Paper 29). Patent Owner's motion to exclude is discussed below in Section IV. A combined oral hearing for this proceeding and Case IPR2016-01460 was held on October 17, 2017, and a transcript of the hearing is included in the record. Paper 37 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown by a

[1] U.S. Patent No. 5,957,885, Sept. 28, 1999, Ex. 1004.
[2] *Directions for Use: TITRATOR, Sodium Nitruprusside Closed Loop Module – Model 10K*, IVAC Corp., Ex. 1005.

preponderance of the evidence that claims 1–3, 6, 7, and 16 of the '560 patent are unpatentable. *See* 35 U.S.C. § 316(e).

A. Related Matter

The parties identify only one proceeding that involves the '560 patent: *Baxter Int'l, Inc. v. CareFusion Corp.*, Case No. 1:15-cv-09986, in the U.S. District Court for the Northern District of Illinois. *See* Pet. 2; Paper 4, 1.

B. The '560 Patent

The '560 patent relates to a method and apparatus for automatically adjusting the medication level for a patient, including the basal rate (i.e., constant rate) and bolus rate 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. Claims Challenged in Instituted Grounds

As noted above, we instituted trial as to claims 1–3, 6, 7, and 16. *See* Dec. on Inst. 28. Of these, only claims 1 and 16 are independent claims. *See* Ex. 1001, 14:6–29, 14:39–46, 16:18–32. Claims 1 and 16 are reproduced below, with labels added in brackets for convenient reference:

> 1. [a] A method for automatically controlling the level of a patient's medication administered from a programmable infusion pump, comprising:
>
> [b] programming the infusion pump with a medication algorithm;
>
> [c] initiating an evaluation of the patient's medication;
>
> [d] obtaining information pertaining to the patient's condition;

[e] obtaining information pertaining to the patient's current medication;

[f] evaluating the patient's current medication and condition with the medication algorithm; and

[g] controlling administration of the patient's medication based on the evaluation.

16. [a] A method for automatically controlling the level of a patient's medication administered from a programmable infusion pump, comprising:

[b] programming the infusion pump with a set of patient specific, predetermined ranges of medication;

[c] evaluating the patient's current medication and recording the patient's current medication in the infusion pump;

[d] evaluating the patient's physiological conditions and recording the patient's physiological conditions in the infusion pump; and

[e] 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.

Id. at 14:6–20, 16:18–32.

II. CLAIM CONSTRUCTION

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard). Under that standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed.

Cir. 2007). Only those terms in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

A. "controlling administration of the patient's medication"

In our Decision on Institution, we determined that this phrase, which appears in claims 1 and 16, includes stopping the delivery rate of the patient's medication. *See* Dec. on Inst. 6–9. In reaching that determination, we explained why we found unpersuasive Petitioner's argument that the phrase requires changing the delivery rate, but does not include stopping it:

> 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 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"[3] 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.

Id. at 7–9.

The parties' post-institution briefing does not present any reason to modify the construction in our Decision on Institution. Patent Owner argues that the Board correctly determined that Petitioner's construction is incorrect. PO Resp. 21. Petitioner "maintains that its proposed

[3] The "modifying" and "changing" terms referred to here are phrases in claims 8 and 9, which claims are not included in the instituted grounds. *See* Dec. on Inst. 6, 28.

constructions . . . are correct, for the reasons stated in the Petition," but argues that under the construction adopted in the Decision on Institution, the limitations are present in Bollish. Reply 10. Based on the complete record present now, we maintain our determination that this phrase includes stopping the delivery rate of the medication, for the reasons we explained in the Decision on Institution.

B. "modification of a basal delivery rate, a bolus dose, and a number of bolus allowed within a certain time frame"

In our Decision on Institution, we determined that this phrase, which appears in claim 3, 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. Dec. on Inst. 9–10. We considered Petitioner's argument 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." Pet. 12 (citations omitted). However, we explained:

> 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. . . . 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.

Dec. on Inst. 9–10. As with the claim term discussed in the immediately preceding section, the parties' post-institution briefing does not present any reason to modify the construction in our Decision on Institution. Patent Owner argues that the construction in the Decision on Institution was correct, and Petitioner maintains that the construction it advocated in its initial Petition was correct but does not offer any new argument. *See* PO Resp. 23–24; Reply 10. Thus, based on the complete record present now, we maintain the construction stated in the Decision on Institution.

C. "programming the infusion pump with a medication algorithm"

The phrase "programming the infusion pump with a medication algorithm" appears in claim 1. During the preliminary phase of this proceeding, neither party proposed a construction of this phrase and no express construction was adopted in the Decision on Institution. *See* Pet. 9–13; Prelim. Resp. 6–16; Dec. on Inst. 6–11.

In its Patent Owner Response, Patent Owner proposes that this phrase should be construed to mean "storing in non-volatile memory a computer program that provides a step-by-step set of instructions used by a controller to operate the infusion pump to deliver medication." PO Resp. 5, 11. Patent Owner argues that the specification supports this proposed construction because it describes that the infusion pump's operation "is controlled by a computer program in the EPROM 204 and executed by controller 200." *Id.* at 5 (quoting Ex. 1001, 6:29–31). Patent Owner also finds support for its proposed construction in Figures 3–5, which are flowcharts illustrating the operation of the infusion pump. *See id.* at 7–10. In addition, Patent Owner argues that its proposal is in accord with the dictionary definition of "algorithm," which is "a step-by-step problem solving procedure, esp. an

established, recursive computational procedure with a finite number of steps." *Id.* at 10 (quoting 2018, 34). Patent Owner further argues that initial pump setup and data entry activities performed by a caregiver are not within the scope of this claim phrase. *Id.* at 11–21. According to Patent Owner, "the specification delineates between initial pump setup activities and the algorithm that controls administration of medication." *Id.* at 12.

In reply, Petitioner argues that Patent Owner's proposal is incorrect and that to the extent construction is necessary, the broadest reasonable interpretation "must include a clinician setting up the pump with parameters that define the infusion protocol." Reply 9. According to Petitioner, "[e]very time the specification uses the word 'program' as a verb, it refers to setting up the parameters that control the patient's dosing regimen." *Id.* at 5–6 (citing Ex. 1001, 2:59–3:3, 1:36–37, 1:41–44, 2:10–11, 6:31–33, 7:35–41, 11:34–36). Concerning "algorithm," Petitioner argues that the specification refers to a table of configuration parameters as an algorithm, thereby establishing that a set of parameters describing the behavior of the infusion pump is an algorithm, as that term has been used in the context of the '560 patent, regardless of the term's ordinary dictionary meaning. *Id.* at 7–8 (citing Ex. 1001, 11:65–12:30). Petitioner proposes that the phrase should be construed to mean "configuring the pump to deliver medication according to the prescribed treatment plan." *Id.* at 5.

Looking first at the "programming the infusion pump" portion of the disputed phrase, we agree with Petitioner that the broadest reasonable interpretation includes a clinician's entry of infusion protocol parameters as part of pump setup. As Petitioner correctly notes, the specification repeatedly refers to a clinician's entry of infusion parameters as

"programming" the pump. *See, e.g.*, Ex. 1001, 2:59–3:3, 1:36–37, 1:41–47, 2:10–11, 6:31–33, 6:54–59, 8:1–6. In at least two instances, the specification refers to such entry of infusion protocol parameters by the caregiver as programming an algorithm. *Id.* at 7:35–41 ("In Pain Control Analgesic (PCA) mode, the caregiver programs the patient's algorithm as provided by the physician . . . ."), 11:34–36 ("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.").

Moreover, Patent Owner agrees that "programming the pump" has an accepted meaning in the field that includes pump setup and data entry activities, and that the specification's usage of the phrase is consistent with that accepted meaning. *See* PO Resp. 11 ("[T]he '560 Patent utilizes the vernacular common among clinical professionals who use infusion pumps, and refers to initial pump setup and data entry activities as 'programming the pump.'"); Tr. 82:11–83:2 (Patent Owner's counsel explaining that programming the pump is "a term of art in the use of an infusion pump. Sometimes clinicians will refer to programming the pump as entering programming values"); *see also* Ex. 2014 ¶ 64 (Patent Owner's declarant testifying that "[f]ollowing the convention of the industry, the '560 Patent uses the word 'program' to mean 'setup.'").

The intrinsic evidence of the '560 patent and Patent Owner's expressions of the "vernacular" meaning of programming an infusion pump within this field are inconsistent with Patent Owner's claim construction arguments. Specifically, the specification and the evidence of how "programming" an infusion pump is understood by clinicians run counter to Patent Owner's positions that initial pump setup and data entry activities

performed by a caregiver are outside the scope of the disputed claim phrase, and that programming the pump as used in claim 1 requires storing a program on the processor before a user starts running the pump. *See* PO Resp. 11–21; Tr. 84:1–6. At the hearing, Patent Owner criticized Petitioner's proposed construction as overbroad because "it would cover basically doing anything to set up a pump that a clinician would do prior to using it to administer medication. So it would include putting the IV tubing into the pump. . . ." Tr. 88:17–20. This criticism of Petitioner's proposed construction has merit, in that it notes the potentially expansive breadth of Petitioner's construction, but it does not detract from the persuasiveness of Petitioner's more general point that programming an infusion pump includes a clinician setting up the pump with parameters that define the infusion protocol. Again, this more general point appears to be recognized by Patent Owner as well. PO Resp. 11.

Turning to the "medication algorithm" portion of the claim phrase, we observe that, as Patent Owner agreed at the hearing, "medication algorithm" does not appear anywhere in the specification, other than in claim 1. Tr. 79:4–6. The word "algorithm," however, does appear in the specification, and its usage is inconsistent with Patent Owner's proposal that an algorithm requires a step-by-step set of instructions. Specifically, the specification describes a "patient algorithm" that is programmed in by the caregiver "for automatically changing his PCA dose. The patient's algorithm defines the range of values for the basal dose, the bolus dose, the maximum amount of drug to be administered." Ex. 1001, 11:31–39. The specification further describes that after taking into account the patient's condition, pain medication, and other factors, "[t]he physician determines

the course of therapy for the individual patient by changing the patient algorithm. For PCA, the patient algorithm includes a number of input parameters to control the basal rate and the bolus dose." *Id.* at 11:48–52.

Table 3 is reproduced below:

TABLE 3

Input			Output	
% of Successful Bolus Request	Side Effects	Restoration of Function	% Change to Basal Rate	% Change to Bolus Dose
100	No	No	−30	0
100	No	Yes	−30	−20
100	Yes	No	−30	0
100	Yes	Yes	−50	−20
50	No	No	+10	+20
50	No	Yes	+20	+20
50	Yes	No	0	+10
50	Yes	Yes	0	+20

Id. at 12:1–16. Table 3 shows "[o]ne embodiment of a patient algorithm for controlling basal rate and bolus dose." *Id.* at 11:65–67.

Table 4 is reproduced below:

TABLE 4

Input Pain Level	Output Side Effects	Restoration of Function	% Change to Basal Rate	% Change to Bolus Dose
2	No	No	−30	0
2	No	Yes	−30	−20
2	Yes	No	−30	0
2	Yes	Yes	−50	−20
10	No	No	+10	+20
10	No	Yes	+20	+20
10	Yes	No	0	+10
10	Yes	Yes	0	+20

Id. at 12:19–40. Table 4 shows "[o]ne embodiment of a patient algorithm for controlling basal rate and bolus dose." *Id.* at 11:65–67.

This description of the patient algorithm does not reflect a computer program that provides a step-by-step set of instructions used by a controller to operate the infusion pump, as in Patent Owner's proposed construction. Instead, it describes an infusion protocol entered by the clinician—specifically, a range of dosage values (basal, bolus, and maximum amount) and variations based on particular conditions. *See id.* at 11:36–42; *see also* Ex. 2014 ¶ 95 (Patent Owner's declarant testifying that "[t]he example embodiments [in] Tables 3 and 4 illustrate that the patient algorithm is a table of input data used by the program that controls the pump for automatically changing the patient's medication.").

Patent Owner argues that the "medication algorithm" in claim 1 is distinct from the "patient algorithm" described in the specification. *See* PO Resp. 11; Tr. 77:12–16. Patent Owner equates the claimed "medication algorithm" with the operating system of the pump. *See* PO Resp. 8–10; Tr. 77:24–78:18. Yet Patent Owner does not provide any persuasive evidence or explanation for why the pump's operating system should be considered the claimed "medication algorithm." The specification does not describe the operating system as an algorithm. Indeed, the only appearances of the word "algorithm" in the specification are in connection with the "patient algorithm" discussed above (*see* Ex. 1001, 7:35–42, 11:30–12:35, 13:47–52) or the apparently synonymous term "pain relief algorithm" used in the Summary of the Invention (*see id.* at 3:3–6, 3:33–42).

The term "medication algorithm" was introduced to the claim in an amendment during prosecution. *See* Ex. 1002, APP0125. In particular, claim 1 was amended such that "medication algorithm" replaced the phrase "set of patient-specific, predetermined ranges of medication." *Id.* Other

independent claims then pending in the application, which also included the phrase "set of patient-specific, predetermined ranges of medication," were not amended to recite "medication algorithm." *Id.* at APP0126. The remarks accompanying the amendment do not explain the meaning of the term "medication algorithm," or whether or to what it extent it differed from the phrase it replaced. *See id.* at APP0127–132.

At the hearing, Patent Owner argued that the amendment signifies that the applicant was "moving entirely away from the patient algorithm/infusion parameter type medication to the medication algorithm" and intended to "focus[] on not the user data that's entered into the pump but what the pump actually does." Tr. 86:17–18, 87:2–4; *see also* PO Resp. 19 (arguing that through this claim amendment, "Patent Owner distinguished between mere patient-specific ranges of medication (the 'patient algorithm'), such as those in Tables 3 and 4, from the broader medication algorithm running on the controller"). But that understanding of the prosecution history is not apparent from the amendment itself, and is difficult to square with the Office Action Response as a whole. Specifically, the other pending independent claims were not amended to introduce the "medication algorithm" term, yet the applicant's remarks accompanying the amendment presented the same arguments over the pending prior art rejection for claim 1 as for the other, un-amended independent claims. *See* Tr. 86:19–87:12; Ex. 1002, APP0127–132. Patent Owner acknowledged at the hearing that its briefing in this proceeding did not point to any portion of the prosecution history that clarifies what was meant by "medication algorithm." Tr. 88:4–7. Accordingly, the prosecution history sheds little light on the meaning of "medication algorithm," and does not support Patent Owner's interpretation

that the medication algorithm is the pump's operating system. Patent Owner provides no other persuasive evidence to support its construction.

In view of the foregoing, we generally accept Petitioner's arguments regarding the proper construction of this phrase and conclude that the broadest reasonable interpretation of "programming the infusion pump with a medication algorithm" encompasses a clinician entering parameters into the pump for an infusion protocol to govern administration of medication to the patient.

III. OBVIOUSNESS ANALYSIS

A. Legal Standards

In *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), the Supreme Court set out a framework for assessing obviousness under 35 U.S.C. § 103 that requires consideration of four factors: (1) the "level of ordinary skill in the pertinent art," (2) the "scope and content of the prior art," (3) the "differences between the prior art and the claims at issue," and (4) "secondary considerations" of nonobviousness such as "commercial success, long felt but unsolved needs, failure of others, etc." *Id.* at 17–18; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007).

In this case, neither party has introduced evidence or argument relating to secondary considerations of nonobviousness. Accordingly, our analysis focuses on the first three *Graham* factors.

B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom*

Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 962 (Fed. Cir. 1986); *Orthopedic Equip. Co., Inc. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner argues, with citation to the declaration of Dr. Stephen Bollish, that a person of ordinary skill in the art would have had "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 with Petitioner's definition of the level of ordinary skill in the art insofar as it does not require an engineering degree. PO Resp. 3–4. According to Patent Owner, Dr. Bollish admitted in his deposition that infusion pump design requires engineering skills. *Id.* (citing Ex. 2013, 21:25–22:23). With citation to the declaration of Mr. Warren Heim, Patent Owner argues that an ordinarily skilled artisan would have "at least a bachelor's degree in engineering [and would be] familiar with mechanical, electronic, and software engineering as it was practiced for medical devices before or during 1999, and [would have] been actively involved in the engineering and design of infusion pumps for at least six years." PO Resp. 4 (citing Ex. 2001 ¶ 43).

In reply, Petitioner argues that Patent Owner's definition that requires an engineering degree "would exclude not only Dr. Bollish, the lead inventor of the asserted prior art, but also two of the named inventors of the '560 patent itself, Devon Levitas and Stephen Axel, who are not engineers." Reply 3 (citing Ex. 1016, 29:13–31:19). Here, Petitioner's argument overstates the evidence upon which it relies. The cited evidence is the deposition testimony of Mr. Tuan Bui, one of the inventors of the '560

patent, indicating that he does not know whether the other inventors had a technical background. Ex. 1016, 29:22–30:5, 31:2–3. The record does not include evidence supporting Petitioner's assertion that two of the inventors of the '560 patent do not have engineering degrees. *See* Tr. 55:7–12.

The primary dispute regarding the level of ordinary skill in the art is whether an engineering degree is required. With the full record now before us, we agree with Patent Owner that this dispute is "a bit of a red herring." Tr. 103:8–9; *see also id.* at 102:25–103:1 ("We think what a person of ordinary skill is in the context of this IPR is, frankly, irrelevant. . . ."). The question of whether an engineering degree is necessary for the ordinary level of skill in the art is a predicate for Patent Owner's challenge to the reliability of Petitioner's expert, Dr. Bollish, who does not have an engineering degree. *See* PO Resp. 49–50. As the analysis below indicates, this is not a case that hinges on expert testimony. Expert testimony can be a crucial aid to fact-finding in cases involving complex technologies. *See Idemitsu Kosan Co., Ltd. v. SFC Co. Ltd.*, 870 F.3d 1376, 1381 (Fed. Cir. 2017). But here, the technology described in the challenged patent and cited prior art references is straightforward and easy to understand. *See Wyers v. Master Lock Co.*, 616 F.3d 1231, 1242 (Fed. Cir. 2010). Further, the main aspect of Dr. Bollish's testimony that Patent Owner attacks is his analysis of the obviousness of combining the Bollish and TITRATOR references. *See* PO Resp. 48–61. But as explained below in Section III.D.2., Petitioner's challenge based on the combination of Bollish and TITRATOR is deficient for other reasons.

In any event, complete overlap between a witness's technical qualifications and the field of the invention is not necessary for the witness's

testimony to be admissible under Federal Rule of Evidence 702. *See SEB S.A. v. Montgomery Ward & Co., Inc.*, 594 F.3d 1360, 1372–73 (Fed. Cir. 2010) (upholding a district court's admission under Rule 702 of the testimony of a witness who lacked experience in the design of the patented invention, but had experience with materials selected for use in the invention). Dr. Bollish has two degrees in pharmacy and has significant experience with the design and development of infusion pumps. *See* Ex. 1003 ¶¶ 2, 4–10; Ex. 2013, 20:16–28:3. Thus, even if Patent Owner is correct that the level of ordinary skill in this art requires an engineering degree, Dr. Bollish's lack of an engineering background would detract from the weight to be given his testimony on engineering-related matters, but would not make the entirety of his testimony inadmissible under Rule 702.

For these reasons, the parties' dispute over the level of ordinary skill in the art does not impact our ultimate conclusions regarding obviousness below. Nevertheless, to provide a clear record, based on our review of the '560 patent, the types of problems and solutions described in the '560 patent and in the cited prior art references, and the testimony of Dr. Bollish and Mr. Heim, 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.

C. Obviousness Ground Based on Bollish

1. Summary of Bollish

Bollish relates to a system "for centrally interfacing and controlling administration of analgesics in a patient controlled analgesia methodology while monitoring the patient to prevent central nervous system and

respiratory depression associated with administration of analgesics." Ex. 1004, 1:7–11. Bollish's system 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. "The clinician may specify a minimum or maximum percentage of blood oxygen saturation and a minimum or maximum pulse rate." *Id.* at 6:53–55; *see also id.* at 7:23–25. In addition, the clinician can enter bolus dosage parameters and continuous infusion dose. *Id.* at 7:50–8:10. Once the setup is completed,

> PCA unit 150A begins background continuous infusion, if one has been selected. In addition, the patient may now request a dose of narcotic analgesics at any time by means of patient dose request actuation device 135. Of course, whether the patient actually receives a requested dose depends upon the patient request dosing limits, if any, as well as the patient's current percent blood oxygen saturation and pulse rate relative to the minimum levels set by the clinician.

Id. at 8:17–25. If the patient's blood oxygen saturation or pulse rate pass outside the limits set by the clinician, the system can activate alarms and automatically shut off the PCA unit. *Id.* at 3:36–40, 6:55–66, 8:42–47.

2. Claim 1

Petitioner contends that claim 1 would have been obvious based on the teachings of Bollish. *See* Pet. 14–22, 33–34. Patent Owner disputes Petitioner's contentions regarding limitations [b], [f], and [g]. *See* PO Resp. 26–33.

a. Preamble [a]: "A method for automatically controlling the level of a patient's medication administered from a programmable infusion pump"

Assuming that the preamble constitutes a limitation, we are persuaded by Petitioner's contention, which Patent Owner does not dispute, that Bollish discloses what is recited in the preamble. Pet. 16–17. Specifically, Bollish describes "a programmable patient care system" that "control[s] administration of analgesics in a patient controlled analgesia methodology," which is "commonly administered via a stand-alone type of infusion device." Ex. 1004, 1:5–23.

b. Limitation [b]: "programming the infusion pump with a medication algorithm"

As discussed above in Section II.C., we have determined that the broadest reasonable interpretation of "programming the infusion pump with a medication algorithm" encompasses a clinician entering parameters into the pump for an infusion protocol to govern administration of medication to the patient. Applying that construction, we are persuaded by Petitioner's contention that Bollish teaches this limitation. Pet. 17 (citing Ex. 1004, 7:46–8:10). In particular, Bollish teaches that a clinician can select bolus dosing parameters, such as dosing limits, and continuous infusion dose. Ex. 1004, 7:55–60, 8:4–7.

Patent Owner's arguments concerning this limitation are unpersuasive because they are based primarily on Patent Owner's proposed claim construction, which we have not adopted. *See* PO Resp. 26–29. Specifically, Patent Owner argues that the portion of Bollish upon which Petitioner relies "fails to disclose an algorithm of any kind, and instead describes initial clinician pump setup activities and data entry." *Id.* at 26.

Patent Owner urges that the parameters entered by the clinician are input values used by software running on the pump, and they do nothing without the pump's firmware. *Id.* at 27 (citing Ex. 2013, 65:22–66:9). Under the construction we have adopted, these arguments do not identify any aspect of limitation [b] that is not taught in Bollish.[4]

Patent Owner also argues that when asked in his deposition where the Bollish reference discloses a medication algorithm, Dr. Bollish pointed to a different portion of the reference than that relied upon by Petitioner. *Id.* at 27–28 (citing Ex. 71:14–73:19). Patent Owner further argues that Dr. Bollish admitted that what he identified as the algorithm is not the same as the medication algorithm disclosed in the '560 patent. *Id.* at 28–29 (citing Ex. 2013, 74:14–23, 77:6–11, 133:17–21). In reply, Petitioner counters that the testimony Patent Owner quotes "relates to the commercial embodiment of the Bollish reference," but that "Dr. Bollish explained that the teaching of the Bollish reference itself is broader." Reply 13 (citing Ex. 2013, 141:6–143:1). In addition, at the hearing, Petitioner argued that Dr. Bollish's deposition occurred before Patent Owner filed its Response proposing a construction of "medication algorithm." *See* Tr. 115:17–116:3. Consequently, according to Petitioner, Dr. Bollish was not "sensitive to that claim construction debate, and I think that may have made his testimony a bit confusing in light of the debate that subsequently sprung up." *Id.* at

[4] Moreover, even if we were to agree with Patent Owner's claim construction argument that the medication algorithm refers to the pump's operating system, it is unclear how or why Patent Owner's proposed construction would distinguish Bollish. As Petitioner correctly notes, Bollish discloses a microprocessor that controls the operations of the infusion pump and coordinates the activities of the PCA unit and the pulse oximetry unit. *See* Reply 11; Ex. 1004, 6:24–7:6.

116:3–6.

The excerpts of Dr. Bollish's testimony regarding this limitation cited by Patent Owner are somewhat confusing. That confusion may be explained to some extent by the fact that Dr. Bollish's deposition occurred before either party proposed a construction for limitation [b] and, therefore, before the claim construction dispute regarding the "medication algorithm" came into focus. Importantly, we note that in the Petition, Petitioner's contentions regarding why the Bollish reference teaches this limitation rely solely on the Bollish reference, without any citation to testimony of Dr. Bollish. *See* Pet. 17–18 (citing Ex. 1004, 7:46–8:10). Despite the confusing testimony from Dr. Bollish regarding this limitation cited by Patent Owner, ultimately Patent Owner's arguments do not undermine the arguments and evidence presented in the Petition. In our view, the description in the reference itself, relied upon in the Petition, shows that under the construction of limitation [b] we have adopted, the limitation is taught by Bollish.

c. Limitation [c]: "initiating an evaluation of the patient's medication"

We are persuaded by Petitioner's contention, which Patent Owner does not dispute, that Bollish discloses limitation [c] because it describes determining whether to administer a medication dose after a patient requests one by considering the dosing limits. Pet. 18–19; Ex. 1004, 8:19–25.

d. Limitation [d]: "obtaining information pertaining to the patient's condition"

We are persuaded by Petitioner's contention, which Patent Owner does not dispute, that Bollish discloses limitation [d] because it describes monitoring the patient's percent blood oxygen saturation and pulse rate. Pet. 18–19; Ex. 1004, 7:26–45.

e. Limitation [e]: "obtaining information pertaining to the patient's current medication"

Regarding this limitation, Petitioner points to Bollish's description that after a clinician enters medication dosage limits, the patient can request a dose of analgesics at any time through a dose request actuation device, but "whether the patient actually receives a requested dose depends upon the patient request dosing limits." Pet. 19–20 (quoting Ex. 1004, 8:11–25). Petitioner contends, as part of an anticipation ground on which we did not institute, that this description "inherently teaches that the device has stored and retrieved information regarding the patient's current medication level." *Id.* at 20. In our Decision on Institution, we found that inherency argument unpersuasive, in view of Patent Owner's rebuttal argument that it would have been possible to use mechanical counters to track bolus requests instead. *See* Dec. on Inst. 13–14. However, we determined that Petitioner had presented a sufficient showing that limitation [e] would have been obvious because:

> (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.

Id. at 18–19 (citing Pet. 14–24, 34; Ex. 1003 ¶¶ 20–21; Ex. 1004, Fig. 3). In its Patent Owner Response, Patent Owner does not present any argument concerning limitation [e]. Thus, for the same reasons explained in our

Decision on Institution, we determine that limitation [e] would have been obvious to an ordinarily skilled artisan in view of Bollish's teachings.[5]

f. Limitation [f]: "evaluating the patient's current medication and condition with the medication algorithm"

We are persuaded by Petitioner's contention that Bollish discloses limitation [f] because it describes that whether the patient receives a requested bolus is based on dosing limits and pulse oximetry data, which means that the unit is evaluating the patient's medication level and physical condition relative to the parameters set by the clinician. Pet. 20–21; Ex. 1004, 8:11–25.

Patent Owner argues that Petitioner did not establish that the "algorithm the Petition relies on for the claimed medication algorithm also evaluates the patient's current medication and condition" because the "medication algorithm identified in the Petition simply discloses initial pump setup and data entry activities." PO Resp. 30. This argument is unpersuasive because it is based on Patent Owner's claim construction argument that information entered by a clinician during pump setup to control the administration of medication cannot be a medication algorithm, a construction we have not adopted for the reasons discussed above in

[5] We note Patent Owner's argument that Petitioner failed to provide an obviousness analysis under *Graham* and instead merely relied on anticipation arguments. *See* PO Resp. 33–34. However, Petitioner did identify potential differences between the claimed subject matter and the prior art insofar as it explained why claim 1 would have been obvious even if limitation [e] was not disclosed inherently. *See* Pet. 34 (citing Ex. 1003 ¶¶ 18–21); *see also CRFD Research, Inc. v. Matal*, __ F.3d __, slip op. at 28 (Fed. Cir. Dec. 5, 2017) ("Even if a reference's teachings are insufficient to find anticipation, that same reference's teachings may be used to find obviousness.").

Section II.C. Bollish describes that during pump setup, the clinician can specify bolus dosage limits and maximum and minimum pulse rate and blood oxygen saturation levels. *See* Ex. 1004, 6:53–55, 7:23–25, 7:50–8:10. Whether a patient receives a requested dose depends on an evaluation that compares the patient's medication and pulse oximetry data to the parameters set by the clinician. *Id.* at 8:11–25.

Patent Owner also argues that Dr. Bollish admitted, during his deposition, that the Bollish reference does not disclose this limitation. *See* PO Resp. 30–31 (citing Ex. 2013, 77:14–25). In the cited testimony, Dr. Bollish notes that the Bollish reference discloses that doses are denied if dosing limits are exceeded. Ex. 2013, 77:17–18; *see also id.* at 76:12–20. Thus, the testimony does not cast any doubt on our understanding of the Bollish reference. However, for reasons that are unclear, Dr. Bollish indicated that this functionality did not involve an evaluation of the patient's current medication. *Id.* at 77:20–25. As with limitation [b], although Dr. Bollish's testimony is confusing and gives us some pause, we have considered the entirety of the evidence before us and we conclude that the description in the reference itself shows that limitation [f] is taught by Bollish.

g. Limitation [g]: "controlling administration of the patient's medication based on the evaluation"

We are persuaded by Petitioner's contention that Bollish discloses limitation [g] because it describes that whether a requested bolus dose is administered depends on dosing limits and pulse oximetry data relative to minimum levels set by the clinician. Pet. 21–22; Ex. 1004, 8:11–25, 8:42–55. Patent Owner's arguments concerning this limitation refer back to the arguments for limitation [f]. *See* PO Resp. 32 ("[B]ecause the Petition fails

to show that Bollish discloses the claimed evaluation limitation, it follows that the Petition also fails to disclose the limitation 'controlling administration. . . .'"). For the reasons just discussed, those arguments are unpersuasive.

h. Conclusion

For the reasons discussed above, we determine that Petitioner has shown by a preponderance of the evidence that claim 1 would have been obvious to a person of ordinary skill in the art in view of Bollish.

3. Claims 2, 3, 6, 7, and 16

Petitioner explains how the limitations of these claims are taught by Bollish. *See* Pet. 22–24, 36–38, 44–45. Patent Owner does not dispute Petitioner's contentions, separate from the arguments it presented concerning claim 1. *See* PO Resp. 25–34.

We are persuaded by Petitioner's contentions. Claim 2 depends from claim 1 and adds that "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." Ex. 1001, 14:21–25. We find persuasive Petitioner's argument that Bollish's description of determining whether to administer a requested PCA dose of analgesics by considering the patient request dosing limits indicates that the device has stored information regarding the amount of the drug the patient has received over the relevant period of time. Pet. 22–23 (citing Ex. 1004, 8:11–25; Ex. 1003 ¶¶ 18, 20).

Claim 3 depends from claim 1 and further recites that "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." Ex. 1001, 14:26–29. Under the construction we have adopted, this limitation includes stopping or pausing delivery of the patient's basal dose and bolus dose. *See supra* § II.B. Bollish discloses that a requested bolus dose will not be administered if dosing limits are exceeded or if the patient's blood oxygen saturation and pulse rate are outside the limits set by the clinician. Ex. 1004, 8:11–25; Pet. 23. Bollish also discloses that administration of any background infusion and bolus doses is stopped if the patient's blood oxygen saturation and pulse rate is outside the maximum and minimum levels set by the clinician. Ex. 1004, 8:42–55; Pet. 23–24. Thus, Bollish discloses the subject matter of this claim.

Claim 6 depends from claim 1 and additionally recites "providing an evaluation of the patient's side effects." Ex. 1001, 14:39–42. We find persuasive Petitioner's argument 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). 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.

Claim 7 depends from claim 1 and adds that "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." Ex. 1001, 14:43–46. We find persuasive Petitioner's argument 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. *See* Pet. 38 (citing Ex. 1003 ¶¶ 18–19). Similar to the discussion above regarding claim 6, we are persuaded

that detecting and recognizing respiratory depression involves evaluating the patient's impairment of functionalities. *See* Ex. 1004, 3:30–40.

Claim 16 includes limitations similar to those of claims 1 and 2, and Petitioner's arguments regarding claim 16 simply refer back to its arguments for earlier claims. *See* Pet. 44–45. The preamble of claim 16 is the same as the preamble of claim 1. To the extent it is limiting, it is disclosed by Bollish for the reasons discussed in Section III.C.2.a. Regarding limitation [b], Bollish teaches that a clinician can select bolus dosing parameters, such as dosing limits, and continuous infusion dose. Ex. 1004, 7:46–8:10. With respect to limitation [c], Bollish's description of determining whether to administer a requested PCA dose of analgesics by considering the patient request dosing limits indicates that the device has stored information regarding the amount of the drug the patient has received over the relevant period of time. Ex. 1004, 8:11–25; Ex. 1003 ¶¶ 18, 20; Pet. 22–23. Concerning limitation [d], Bollish teaches that the system monitors the patient's pulse rate and blood oxygen saturation rate. Ex. 1004, 5:50–61, 6:50–55, 8:13–15. We credit Dr. Bollish's testimony that an ordinarily skilled artisan would have understood that the pump

> stores the digital information described in the patent (such as . . . monitored patient information) in its memory (*see, e.g.*, element 250 in Figure 3). Regardless, even if it were somehow possible for the pump to utilize this information without storing it in digital memory, it certainly would have been obvious to person of ordinary skill designing infusion pump systems to store this information using well-known digital memory.

Ex. 1003 ¶ 21. Finally, with respect to limitation [e], Bollish teaches that a requested bolus dose will not be administered if dosing limits set by the clinician are exceeded or if the patient's blood oxygen saturation and pulse

rate are outside the limits set by the clinician. Ex. 1004, 8:11–25. Bollish also discloses that administration of any background infusion and bolus doses is stopped if the patient's blood oxygen saturation and pulse rate is outside the maximum and minimum levels set by the clinician. Ex. 1004, 8:42–55.

Accordingly, we determine that Petitioner has shown by a preponderance of the evidence that claims 2, 3, 6, 7, and 16 would have been obvious to a person of ordinary skill in the art in view of Bollish.

D. Obviousness Ground Based on Bollish and TITRATOR

1. Summary 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, APP0215. 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 APP0218. 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 device will automatically adjust the infusion rate as necessary when the infusion is being delivered." *Id.* at APP0233.

2. TITRATOR's Status as Prior Art

A threshold question for this ground is whether Petitioner has presented sufficient evidence to show that TITRATOR qualifies as prior art to the '560 patent. For the reasons discussed below, we determine that Petitioner has not carried its burden to show that the version of the TITRATOR manual upon which Petitioner relies (i.e., the document in Exhibit 1005) was publicly accessible within the prior art period.[6]

As the party relying on TITRATOR for its obviousness case, Petitioner bears the burden to establish that TITRATOR qualifies as prior art. *See Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1349 (Fed. Cir. 2016). That burden includes a burden of persuasion as well as a burden of production. *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1379 (Fed. Cir. 2015).[7] The analysis of whether a reference constitutes a printed publication under § 102 focuses on whether the reference was publicly accessible, specifically whether "it was 'disseminated

[6] The '560 patent issued from an application filed on February 10, 1999, and does not claim priority to any earlier application. *See* Ex. 1001, [22]. Petitioner does not specify under which statutory provision TITRATOR qualifies as prior art (*see* Pet. 46–47; Reply 16–17), but we determine that the TITRATOR reference would qualify under pre-AIA 35 U.S.C. § 102(b) if it were published before February 10, 1998. Alternatively, given that Patent Owner has not introduced evidence to establish an invention date earlier than the actual filing date of the '560 patent, TITRATOR would qualify as prior art under pre-AIA 35 U.S.C. § 102(a) if it were published before February 10, 1999.

[7] *Dynamic Drinkware* explains that the burden of production can shift, but this case does not present a burden-shifting scenario because Patent Owner is only challenging the sufficiency of Petitioner's showing and is not attempting to antedate TITRATOR. *See In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1376 (Fed. Cir. 2016).

or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it.'" *Blue Calypso*, 815 F.3d at 1348 (quoting *Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1350 (Fed. Cir. 2008)).

To establish that TITRATOR is prior art to the '560 patent, Petitioner cites the "COPYRIGHT 1990" markings in TITRATOR. Pet. 47 (citing Ex. 1005, APP0213, APP0263). Petitioner also points to a paper bearing the notation "© 1988 IEEE," which describes the regulatory approval process for the TITRATOR device, which Petitioner argues corroborates the release of the TITRATOR device. *Id.* (citing Ex. 1010). Further, Petitioner relies on the declaration of Mr. Chuck Willhite, who "began working at CareFusion's predecessor IVAC Corporation in March 1982" and is currently an employee of Patent Owner's parent company with responsibility for the sales of Patent Owner's products. Pet. 47; Ex. 1009 ¶ 1. Mr. Willhite states that he "was personally involved in sales of the TITRATOR product." Ex. 1009 ¶ 6. Mr. Willhite testifies that in December 1987, IVAC received premarket approval from the FDA for the TITRATOR device. *Id.* ¶ 3. Mr. Willhite further testifies as follows:

> Submitted herewith as Exhibit 1005 is a true and correct copy of the TITRATOR Directions for Use, bearing a copyright date of 1990. This manual is consistent with my recollection of the operation of the TITRATOR device throughout its product life. In my experience, a copy of the TITRATOR Directions for Use was provided with every TITRATOR unit sold.

Id. ¶ 7.

Patent Owner responds that Petitioner failed to present evidence that the particular TITRATOR reference upon which Petitioner relies was publicly accessible because "Petitioner provided no evidence that a single

TITRATOR product was ever sold in or after 1990, the date that appears on the TITRATOR [reference]." PO Resp. 35–36 (emphasis omitted). Relatedly, Patent Owner argues that Petitioner's evidence that the TITRATOR device received FDA approval in 1987 and Petitioner's assertion that the device was sold in the late 1980s are irrelevant to the question of whether the TITRATOR reference, having a 1990 copyright date, was publicly accessible. *Id.* at 37–38. Patent Owner also submits two technical articles and the testimony of Petitioner's expert, Dr. Bollish, indicating that the TITRATOR device was marketed for only a short period after its FDA approval in 1987. *Id.* at 39 (citing Ex. 2010, 2; Ex. 2019, 387; Ex. 2013, 117:15–18).

In reply, Petitioner argues that Patent Owner is "flat-out wrong" that the TITRATOR product was discontinued soon after its release. Reply 16. Petitioner cites printouts from the FDA's website showing that regulatory filings continued to be submitted for the TITRATOR device until 1993. *Id.* at 16–17 (citing Ex. 1018–1024).

After considering the arguments and evidence summarized above, we agree with Patent Owner that Petitioner has not shown that TITRATOR qualifies as a prior art printed publication. Petitioner does not present adequate evidence to establish that the version of the TITRATOR manual in Exhibit 1005 was publicly disseminated or otherwise made available such that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could locate it. Mr. Willhite testifies that Exhibit 1005 is "consistent with [his] recollection of the operation of the TITRATOR device throughout its product life" and that "a copy of the TITRATOR Directions for Use was provided with every TITRATOR sold."

Ex. 1009 ¶ 7. However, that a reference is consistent with the operation of the device throughout its product life does not support that this reference itself—i.e., the reference shown as Exhibit 1005—was publicly available throughout the product's life or at any particular point in the product's life. Mr. Willhite "was personally involved in sales of the TITRATOR product" (*id.* ¶ 6), but he does not state when the device was sold, and does not demonstrate that the manual presented as Exhibit 1005 accompanied those sales.

Petitioner submits evidence that the TITRATOR device received FDA premarket approval in 1987. Ex. 1009 ¶¶ 3–4; Ex. 1010. Petitioner asserts, without citation to record evidence, that the device was sold soon after. *See* Pet. 5 (describing that the TITRATOR device was "sold in the late 1980s"); Reply 16 (referring to the TITRATOR product's "release in 1987"). However, Petitioner acknowledged at the hearing that the TITRATOR manual changed over the course of time (*see* Tr. 71:23–72:2), an admission that is consistent with the purported 1987 commercial release of the TITRATOR device and the 1990 copyright date in Exhibit 1005. Petitioner argued at the hearing that the aspects of the reference on which it relies for its obviousness arguments were also present in earlier versions of the manual (*see id.* at 72:2–4), but there is no evidence in the record describing what changes were made to the manual, or identifying what content in the version in Exhibit 1005 was also present in earlier versions.

Petitioner relies on the 1990 copyright date for TITRATOR, but as Patent Owner correctly notes, Petitioner has not presented any evidence of sales of the TITRATOR device from 1990 onward, wherein those sales included the TITRATOR manual at issue here. *See* Tr. 67:24–68:2 ("Where

Baxter has complained that we don't have sales record from 1990 saying this version of the manual was attached to this Titrator product, that's right. From 1990, multiple corporate mergers ago, we do not still have those sales records. . . ."). To attempt to fill that gap, Petitioner filed with its Reply FDA website printouts (*see* Ex. 1018–1024), but Petitioner does not present any evidence describing the significance of these FDA website printouts or connecting them to actual sales in 1990 or later, or to the document presented as Exhibit 1005. *See* Tr. 70:19–71:18. On their face, the FDA website printouts simply indicate that various documents were submitted to the FDA between 1990 and 1993.[8] Moreover, Patent Owner's evidence tends to show that the TITRATOR device was sold only for a short period. Ex. 2010, 2; Ex. 2019, 387; Ex. 2013, 117:15–18. Absent evidence of sales from 1990 onward, Mr. Willhite's testimony that the manual was included with the TITRATOR device does not support a finding that the version of the manual in Exhibit 1005 was publicly disseminated.

The shortcomings of Petitioner's evidentiary showing are all the more apparent given that the TITRATOR device was sold by Petitioner's predecessor company. *See* Pet. 5. Petitioner is the entity in the best position to adduce evidence that the TITRATOR reference was publicly accessible in the prior art period. It was unable to do so in this case, even with its Reply

[8] Petitioner's Reply also argued that "Baxter and its expert Mr. Heim were fully aware that the TITRATOR was subject to PMA regulation." Reply 17 (citing Ex. 2001 ¶¶ 100–02; Ex. 1017 at 58:5–61:9). It is unclear how Mr. Heim's testimony that the TITRATOR device had received premarket approval has any bearing on the issue of whether and when the TITRATOR manual in Exhibit 1005 became publicly accessible.

after Patent Owner challenged Petitioner's showing in the Patent Owner Response.

Because Petitioner has not established that TITRATOR qualifies as prior art, Petitioner has not carried its burden on the obviousness challenges based on Bollish in combination with TITRATOR.

E. Conclusions Regarding Petitioner's Obviousness Challenges

Petitioner has shown by a preponderance of the evidence that claims 1–3, 6, 7, and 16 would have been obvious over Bollish. Petitioner has not shown by a preponderance of the evidence that claims 1–3, 6, 7, and 16 would have been obvious over Bollish and TITRATOR.

IV. PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE

Patent Owner moves to exclude the copyright notice in Exhibit 1005 (i.e., the TITRATOR reference) on the basis that the copyright date constitutes inadmissible hearsay for the purpose of proving the date when the document was created. Paper 27, 3–6. Patent Owner also moves to exclude Exhibit 1005 in its entirety on the ground that Petitioner did not authenticate it as a manual that was included with the TITRATOR device. *Id.* at 6–7. Petitioner opposes the motion, arguing that the copyright date constitutes prima facie evidence to establish that TITRATOR is prior art, that TITRATOR qualifies for the ancient document exception to the hearsay rule, and that Patent Owner's motion "mischaracterizes the Board's precedent." *See* Paper 28, 2–14.

It is unnecessary for us to resolve Patent Owner's motion to exclude because, as discussed above in Section III.D.2., even without excluding all or any part of TITRATOR, we determine that Petitioner's showing is

insufficient to establish that TITRATOR qualifies as prior art to the '560 patent. Accordingly, we dismiss as moot Patent Owner's motion to exclude.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–3, 6, 7, and 16 have been shown to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude is dismissed as moot; and

FURTHER ORDERED that parties to the proceeding seeking judicial review of this Final Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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