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Paper 63
Date: April 29, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BECTON, DICKINSON AND COMPANY,
Petitioner,

v.

BAXTER CORPORATION ENGLEWOOD,
Patent Owner.

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IPR2019-00120
Patent 9,662,273 B2

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Before ROBERT A. POLLOCK, MICHAEL L. WOODS, and PAUL J. KORNICZKY, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge.*

# JUDGEMENT

Final Written Decision
Determining Challenged Claims Unpatentable
*35 U.S.C. § 318(a)*

Denying Patent Owner's Revised Motion to Amend to Substitute Claims 22–42
*35 U.S.C. § 318(a)*

Denying Petitioner's Motion to Exclude Evidence
*37 C.F.R. § 42.64*

# I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–21 of U.S. Patent No. 9,662,273 B2 (Ex. 1001, "the '273 patent"). We have jurisdiction under 35 U.S.C. § 6.

Petitioner has the burden of proving unpatentability of a claim by a preponderance of the evidence. 35 U.S.C. § 316(e). Having reviewed the arguments of the parties and the supporting evidence, we find that Petitioner has demonstrated by a preponderance of the evidence that claims 1–21 are unpatentable. We also deny Patent Owner's motion to amend and Petitioner's motion to exclude.

## A. Procedural History

Becton, Dickinson and Company ("Petitioner") filed a Petition for an *inter partes* review of claims 1–21 of the '273 patent. Paper 1 ("Pet."). Baxter Corporation Englewood ("Patent Owner" or "Baxter") timely filed a Preliminary Response. Paper 9 ("Prelim. Resp."). We subsequently issued an Order inviting additional briefing on whether one of Petitioner's asserted references, Alexander,[1] is prior art under 35 U.S.C. § 102(e) and/or § 102(g)(2).[2] Paper 11. In accord with that Order, Petitioner submitted a

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[1] Alexander, US 8,374,887 B1, issued Feb. 12, 2013. Ex. 1008.
[2] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '131 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. §§ 102 and 103 throughout this Final Written Decision.

Reply to the Preliminary Response (Paper 13) and Patent Owner submitted a corresponding Sur-reply (Paper 14).

In view of the then-available record, we concluded that Petitioner satisfied the burden, under 35 U.S.C. § 314(a), to show that there was a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims. Accordingly, on behalf of the Director (37 C.F.R. § 42.4(a)), and in accordance with *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018), we instituted an *inter partes* review of all the challenged claims, on all the asserted grounds. Paper 15 ("Inst. Dec.").

After institution, Patent Owner filed a Response. Paper 26 ("PO Resp."). Petitioner filed a Reply. Paper 31 ("Reply"). Patent Owner filed a revised Sur-reply. Paper 50 ("Sur-reply"). Petitioner filed a Supplemental Reply directed to Exhibit 2026 as referenced in Patent Owner's Revised Sur-reply (Paper 51 ("Suppl. Reply")), and an additional Supplemental Reply (Paper 48) addressing the corrected version of Dr. Brittain's deposition transcript.

Patent Owner submitted a first Contingent Motion to Amend. Paper 27 ("Motion" or "Mot."). Petitioner filed an Opposition to the Motion. Paper 32 ("Opposition" or "Opp."). We further provided Preliminary Guidance to Patent Owner's first contingent Motion. Paper 39 ("Guidance").

Patent Owner further submitted a Revised Contingent Motion to Amend. Paper 41 ("Revised Motion to Amend" or "Rev. Mot."). Petitioner filed an Opposition to the Revised Motion. Paper 52 ("Opposition to the Revised Motion" or "Opp. Rev. Mot."). Patent Owner further filed a Reply

to Petitioner's Opposition to the Revised Motion (Paper 56, "Rev. Mot. Reply") and Petitioner filed a Sur-reply (Paper 61 "Rev. Mot. Sur-reply").

Petitioner also filed a Motion to Exclude Exhibit 2026. Paper 57 ("Mot. Excl."). Patent Owner filed an Opposition to the Motion to Exclude (Paper 59 ("Opp. Mot. Excl.")) and Petitioner filed a Reply (Paper 60 ("Reply Mot. Excl.")).

On February 26, 2020, the parties presented arguments at oral hearing, the transcript of which is of record. Paper 62 ("Tr.").

B. Real Parties-in-interest

Petitioner identifies itself as the real party-in-interest. Pet. 2. According to Patent Owner, the real parties-in-interest are Baxter Corporation and its licensee, Baxter Healthcare Corporation. Paper 5, 1.

C. Related Proceedings

In addition to the '273 Patent at issue here, Petitioner requested, and this panel instituted, *inter partes* review of U.S. Patent Nos. 8,554,579 and 9,474,693 in IPR2019-00119 and IPR2019-00121, respectively. According to the parties, these three patents are at issue in *Baxter Healthcare Corporation and Baxter Corporation Englewood v. Becton, Dickinson and Company,* Case No. 17-cv-02186 (S.D. Cal., filed October 26, 2017), which is presently stayed. Pet. 2; Paper 5, 1; Tr. 8:8–14.

D. The '273 Patent and Relevant Background

The '273 patent is titled "Work Station for Medical Dose Preparation System" and is generally directed to work stations for use in medical dose preparation management systems. Ex. 1001, code (54), Abstract. Figures 1 and 2 of the '273 patent are reproduced below.

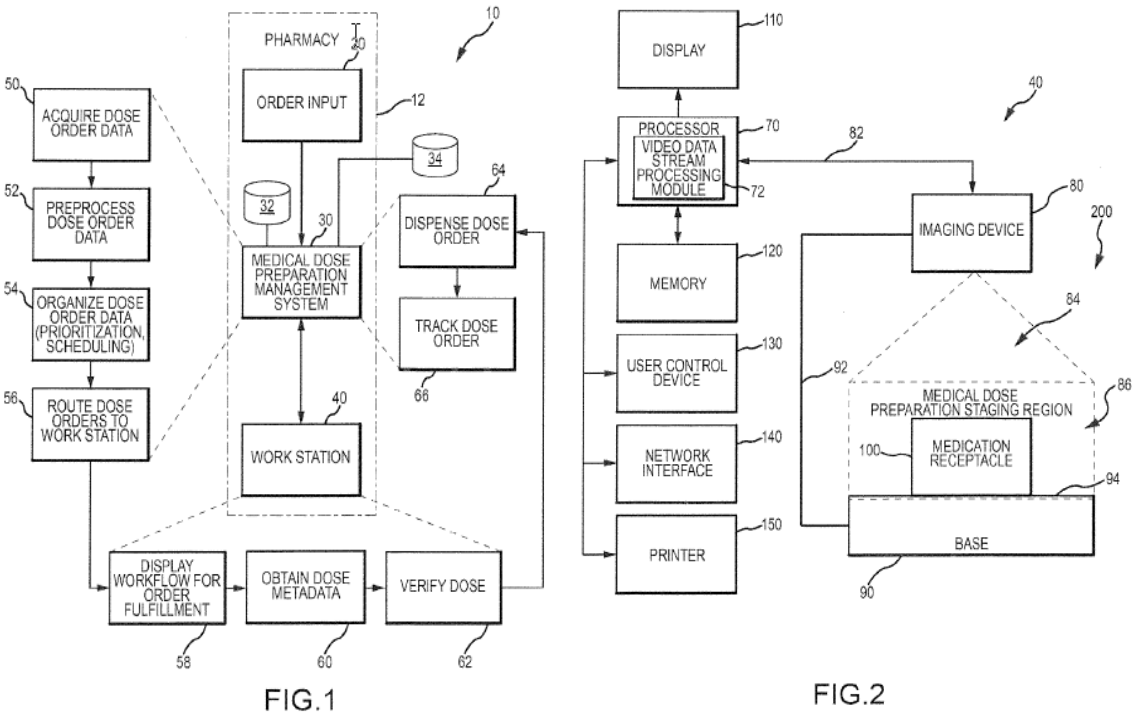


Figure 1 illustrates medical dose preparation management system 30 in communication with workstation 40. *Id.* at 8:36–38, 12:50–13:3. Figure 2 provides further details of a representative workstation including imaging device 80 in communication with processor 70 and disposed relative to medical dose preparation staging region 86. *Id.* at 8:39–41, 14:21–56. The dose preparation staging region may also include base 90 and a scale, wherein "weight measured by the scale may be captured substantially

simultaneously as the capture of a medical dose preparation image by the imaging device 80." *Id.* at 24:26–31. Processor 70 "may perform a gravimetric analysis using a weight measured by the scale to, for example, compare the measured weight to an anticipated weight for the medical dose." *Id.* at 24:31–38.

E. Challenged Claims

Petitioner challenges claims 1–21 of the '273 Patent, of which only claim 1 is independent. Claim 1 recites:[3]

> 1. A work station for use in a system for medical dose preparation management, the work station comprising:
>
> a base having a support platform to support at least one medication receptacle within a medication preparation staging region, and a scale operable to output weight data corresponding to at least one medication receptacle supported on the support platform within the medication preparation staging region;
>
> an imaging device having an imaging field encompassing at least a portion of the medication preparation staging region, wherein the imaging device is operable to output image data of at least one medication receptacle supported on the support platform within the medication preparation staging region;
>
> a processor in operative communication with the scale to receive the weight data, and in operative communication with the imaging device to receive the image data; and,
>
> [1g] *a memory in operative communication with the processor,* [1h] *wherein a weight and a medical dose preparation image*

[3] We adopt Petitioner's convention in referring to the italicized language as Elements [1g] and [1h] as shown in the bracketed insertions. *See* Pet. 18–19.

> *of at least one medication receptacle supported on the support platform within the medication preparation staging region are associatively stored in the memory.*

Ex. 1001, 26:5–27 (emphasis added).

F. Asserted Grounds of Unpatentability

Petitioner asserts six grounds of unpatentability (Pet. 12–13):

| Ground | Claim(s) | Basis (35 U.S.C. §) | Reference(s) |
|---|---|---|---|
| 1 | 1, 3–8, 10, 11, 16–21 | 102(b) | Fioravanti[4] |
| 2 | 1–14, 16–21 | 103(a) | Fioravanti |
| 3 | 1–14, 16–21 | 103(a) | Fioravanti and Alexander[5] |
| 4 | 1–14, 16–21 | 103(a) | Fioravanti, Alexander, and Eliuk[6] |
| 5 | 2 | 103(a) | Fioravanti, Alexander, Eliuk, and Claypool[7] |
| 6 | 13–15 | 103(a) | Fioravanti, Alexander, Eliuk, and Bear[8] |

In support of its patentability challenges, Petitioner relies on the testimony of Dr. Marc Young. *See* Exs. 1004, 1021, 1025 (first, second, and third Declarations, respectively); Ex. 1005 (curriculum vitae); Exs. 2021, 2022, 2031 (deposition transcripts). Jeffrey R. Brittain, PharmMD, BCPS.

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[4] Fioravanti, US 2011/0191121 A1, published Aug. 4, 2011. (Ex. 1006).
[5] Alexander, US 8,374,887 B1, issued Feb. 12, 2013. (Ex. 1008).
[6] Eliuk et al., US 7,783,383 B2, issued Aug. 24, 2010. (Ex. 1009).
[7] Claypool, US 2009/0205877 A1, published Aug. 20, 2009. (Ex. 1010).
[8] Bear et al., US 2008/0119958 A1, published May 22, 2008. (Ex. 1011).

Ex. 2008 (Declaration); Ex. 2009 (curriculum vitae); Ex. 1018 (deposition transcript); Ex. 2032 (replacement version of Ex. 1018).[9] Patent Owner further relies on the testimony of Robert L. Stevenson, Ph.D. *See* Ex. 2010 (Declaration); Ex. 2011 (curriculum vitae).

## II. ANALYSIS

### A. Principles of Law

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

To anticipate a 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). Accordingly, "'the dispositive question regarding anticipation [i]s whether *one skilled in the art* would reasonably understand or infer from the [prior

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[9] We authorized Patent Owner to submit a replacement version of Dr. Brittain's deposition transcript and authorized Petitioner to file supplemental briefing to address the differences between the two versions. Paper 42, 3.

art reference's] teaching' that every claim element was disclosed in that single reference." *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003)(quoting *In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991)).

A claim is unpatentable 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 that subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).[10] The question of obviousness is resolved based on 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 ordinary skill in the art; and (4) objective evidence of nonobviousness, if present. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

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 . . . known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish

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[10] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '273 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. §§ 102 and 103 throughout this Decision.

obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (internal quotation marks and citations omitted). Under the proper inquiry, "obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007).

We analyze the instituted grounds of unpatentability in accordance with these principles.

B. Person 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. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

The parties agree that a person of ordinary skill in the art as of the relevant date would have several years of experience with remote pharmacy

work supervision and verification systems and a familiarity with basic pharmacy processes and have been aware of relevant regulations. Pet. 8; PO Resp. 13. As noted by Petitioner, the Board previously applied this definition in an *inter partes* review of the Alexander reference asserted here. Pet. 8 (referencing *Baxter International Inc. v. Becton, Dickinson And Company*, IPR2015-00883, Paper 29 at 43 (PTAB July 11, 2016)). As the parties' undisputed proposed definition is not inconsistent with the cited prior art, we adopt it here. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

C. Claim Construction

In this *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b) (2018).[11] Under that standard, we presume that a claim term carries its

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[11] The broadest reasonable interpretation ("BRI") construction standard applies to *inter partes* reviews filed before November 13, 2018. Changes to Implement Inter Partes Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents; Final Rule, 77 Fed. Reg. 48680, 48727 (Aug. 14, 2012) (codified at 37 C.F.R. § 42.100(b)), as amended at Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 81 Fed. Reg. 18750, 18766 (Apr. 1, 2016); *see also* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial

"ordinary and customary meaning," which "is the meaning that the term would have to a person of ordinary skill in the art in question" at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed.Cir.2005)); *see also Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016) ("Under a broadest reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification and prosecution history."). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Limitations, however, may not be read from the specification into the claims (*In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993)), nor may the Board "construe claims during [an *inter partes* review] so broadly that its constructions are unreasonable under general claim construction principles" (*Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015), *overruled on other grounds by Aqua Products, Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017)).

We address below the claim terms provisionally construed in our Institution Decision. No other terms require express construction. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)

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and Appeal Board, 83 Fed. Reg. 51340 (Oct. 11, 2018) (changing the standard for interpreting claims in *inter partes* reviews filed on or after November 13, 2018). Because the instant Petition was filed prior to this date, on October 29, 2018, the BRI construction standard applies.

("[O]nly those terms need be construed that are in controversy and only to the extent necessary to resolve the controversy.").

1. "work station"

In our Institution Decision, we construed "work station" as "a combination of physical components for the preparation and measurement of a medication dose." Inst. Dec. 10–11. As neither party provides additional argument or evidence for a different construction, we apply it here.

2. "at substantially the same time"

Claim 5 recites that "the processor is operable to record the weight at substantially the same time as the capture of the medical dose preparation image." Ex. 1001, 26:39–42. As noted in our Institution Decision, the parties agree that the phrase "at substantially the same time," as used therein, should be construed as "sufficiently close in time that the medication dose preparation image has not changed since the time the weight was recorded." Inst. Dec. 11 (citations omitted). For clarity, we adopt this construction.

3. "base"

Petitioner proposes that "base" as used in claim 1 means "the bottom of something considered as its support." Pet. 10 (citing Ex. 1001, 3:53–58; Ex. 1004 ¶¶ 24–25). Patent Owner does not dispute this definition, but argues that "base" is used in its ordinary sense. PO Resp. 8. Neither party provides argument or evidence suggesting that the inventors used this term in anything other than its ordinary meaning, and we discern none from the intrinsic evidence. Accordingly, and because this term does not appear to be in dispute, an express construction for this term is not necessary.

4. "metadata"

Petitioner proposes that we construe "metadata" as used in claim 19 to mean "data regarding a medical dose order." Pet. 11–12 (citing Ex. 1001, 2:42–57. In the Preliminary Response, Patent Owner argued that "the '273 patent uses the term 'metadata' in accordance with its ordinary meaning" and, thus, "no further construction of this limitation is required." Prelim. Resp. 23; *see* PO Response 8. Although we agree with Petitioner that "metadata" includes data regarding a medical dose order (*see* Ex. 1001, 2:45–47 ("[W]ork order stations may be used to capture, collect, or compile data (e.g., metadata) regarding the medical dose. . . .")), the Specification's use of "e.g." indicates that it is not so limited. Consistent with a broader meaning, the Specification further recites, "metadata may include data regarding the prepared dose order, a component of the dose order, or the manner in which the prepared dose order or a component of the dose order was prepared." *Id*. at 2:52–55; *see id*. at 10:52–12:49.

Accordingly, we agree with Patent Owner that the ordinary meaning applies and no further construction is required.

5. "associatively stored in the memory"

Claim 1 recites Elements [1g], "a memory in operative communication with the processor," modified by Element [1h]: "wherein a weight and a medical dose preparation image of at least one medication receptacle supported on the support platform within the medication preparation staging region are associatively stored in the memory." *See* Ex. 1001, 26:23–27; Pet 18–19.

Prior to our Institution Decision, neither party set forth an express definition for any portion of either element. We, nevertheless, interpreted "associatively stored," in Element [1h], to mean that "data for a particular medication receptacle (e.g., a vial or syringe) is stored in memory such that the processor can match that data to the medication receptacle or relevant dose order." Inst. Dec. 15. We further stated that "[i]n practice, this may mean that weight and/or image data for a particular medication receptacle contains metadata linking it to the relevant dose order, and thus the medication receptacle associated with that order," and noted that "the intrinsic evidence . . . places no restriction on the type, duration, or location" of the recited memory. *Id.* at 14–15 & n.9. We revisit our initial determination in light of additional arguments and evidence adduced at trial.

Petitioner agrees with our initial determination of "associatively stored" and proposes no additional construction for claim 1. Reply 1–3. Patent Owner, in contrast, argues that our initial construction "goes beyond the plain and customary meaning of storing an image and weight in relation to one another" and that we ignore "express claim language mandat[ing] that the memory itself be capable of storing the weight and dose preparation image for sufficient duration to permit remote access and verification." PO Resp. 11–12. Instead, considering Elements [1g]/[1h] as a whole, Patent Owner proposes that we construe this language as "a weight and a medical dose preparation image of at least one medication receptacle supported on the support platform within the medication preparation staging region are stored in relation to one another in memory such that the data can be

retrieved and reviewed later." *Id*. at 12 (citing Ex. 2010 ¶¶ 30–32, 34); Sur-reply 3–5. Petitioner opposes Patent Owner's construction. Reply 3–8.

As noted in our Institution Decision, the prosecution history sheds no light on the meaning of "associatively stored." Inst. Dec. 13 (citing Pet. 7–8; Ex. 1002, 539; Ex. 1003, 418–19).[12] The Specification also provides no express definition of the term but suggests a link to the storage of metadata associated with a medical dose order. In particular, it discloses that workstations

> may be used to capture, collect, or compile data (e.g., metadata) regarding the medical dose order. In this regard, metadata associated with the medical dose order may be stored in corresponding relation to the medical dose order such that the metadata may be accessible to a care provider before or after administration of the medical dose associated with the medical dose order to the patient. The metadata may include data regarding the prepared dose order, a component of the dose order, or the manner in which the prepared dose order or a component of the dose order was prepared. Accordingly, metadata captured, collected, or compiled at the work station may be used to organize, track, or otherwise manage medical dose orders.

Ex. 1001, 2:42–57. In one embodiment, a work station may include a scale and an imaging device in communication with a processor. *See id*. at 7:46–8:17.

> [U]pon capture of a medical dose preparation image, the weight of the medication receptacle may be recorded by the processor from the scale at substantially the same time that the medical

[12] We also do not find Petitioner's discussion regarding the allowance of the '273 patent over US 2013/0279774 particularly enlightening. *See* PO Resp. 43–44; Ex. 2010 ¶¶ 32–33.

> dose preparation image is captured. In other words, the processor may be operable to and/or adapted to—upon receipt of a user input—record the weight from the scale at substantially the same time that the medical dose preparation image is captured. In this regard, the work station may also include a memory in operative communication with the processor for storing the weight and the medical dose preparation image. For example, the weight and the medical dose preparation image may be associatively stored in the memory. As such, the processor may be operable to compare the measured weight of the medication receptacle to an anticipated weight of the medication receptacle (e.g., provided in metadata of the order).

*Id*. at 7:55–8:4.

Accordingly, the Specification does not indicate that "associatively stored" refers to a specific data base structure, but instead uses the term to indicate that information is accessible or available such that a "processor may be operable to compare the measured weight of the medication receptacle to an anticipated weight of the medication receptacle (e.g., provided in metadata of the order)," presumably by accessing the metadata associated with the weight data. *Id*. at 8:1–4.

As noted by Petitioner, a substantial portion of Patent Owner's proposed construction repeats the language of Element [1h], such that "[o]nly the intended use language of PO's definition 'such that the data can be retrieved and reviewed later' is new." Reply 3. Although we acknowledge Petitioner's "intended use" argument with respect to retrieval of data, we understand Patent Owner to focus instead on the meaning of "memory" as used in the '273 patent and, thus, on its meaning in Elements [1g]/[1h]. In this respect, Patent Owner asserts that a person of ordinary skill in the art "would understand that the memory in the '273 Patent must

be capable of storing data for a duration allowing for remote access and verification, i.e., beyond local real time display." PO Resp. at 10–11 (citing Ex. 2010 ¶ 29).

In support of its construction, Patent Owner points to claims 19 and 21, depending from claim 1, as requiring that associatively stored weight and image data are stored in memory for "remote access and verification," conditions inherently requiring that the stored data have some temporal permanence. PO Resp. 10; Ex. 2010 ¶ 28. Although claim differentiation does not require all memory recited in claim 1 be capable of the storage required in claims 19 and 21, Patent Owner points to additional support in the Specification, which variously states that:

> "*During and/or after* the preparation of the dose order, the work station 40 may be used to assist in obtaining 60 dose order metadata related to the medical dose order" (Ex. 1001, 13:34–36 (emphasis added);
>
> "metadata associated with the medical dose order may be stored in corresponding relation to the medical dose order *such that the metadata may be accessible to a care provider before or after administration of the medical dose*" (*Id.* at 2:45–52 (emphasis added);
>
> "metadata collected at the work station 40 may be made available to a pharmacist via a network" (*Id.* at 13:47–53); and
>
> "[t]he verifying 62 may include inspection of the medical dose preparation images, obtained information, or other data regarding the medical dose order by the pharmacist" (*Id.* at 13:62–65).

PO Resp. 10; Ex. 2010 ¶¶ 27–28.[13]

[13] In addition, and consistent with Patent Owner's argument, the idea that

Despite the above, our reading of the Specification and prosecution history alone leaves unresolved whether, and to what extent, the memory and associative storage elements of claim 1 have temporal permanence. Accordingly, we look to the testimony of the parties' experts in determining how one of ordinary skill in the art would understand the disputed claim language. *See, e.g.*, Ex. 2008 ¶¶ 50–51, 70–78, 92–97; Ex. 1021 ¶¶ 5–20; Ex. 2010 ¶¶ 19, 24–34, 81–86.

Of the three experts in this case, we find Dr. Stevenson's testimony particularly helpful on this issue. Although not himself one of ordinary skill in the art as defined in section II(B), above, we recognize Dr. Stevenson's expertise in computer system design, particularly with respect to digital signal and image processing, computer memory, and data storage. *See* Ex. 2010 ¶¶ 7–16; Ex. 2011. Considering the Specification of the '273 patent, Dr. Stevenson testifies that

> [n]ot only does the memory need to store the weight and image data until at least drug administration (which is at least some time after verification of dose completion), the data must also be associatively stored until that point. If it is not, the association is lost and the ability to use the association, such as for reviewing the work performed to capture the weight and image data, is eliminated.

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data in memory must be accessible for at least some minimum duration is further reflected by the disclosure that the workstation stores "metadata associated with the medical dose order may be stored in corresponding relation to the medical dose order such that the metadata may be accessible to a care provider before or after administration . . . [and] may be used to organize, track, or otherwise manage medical dose orders." Ex. 1001, 2:47–61.

Ex. 2010 ¶ 30. Moreover,

> real-time display of data on a computer screen does not necessarily equate to or mandate the storage of the displayed data for later review. Instead, a discrete step for storing the data in memory (and for storing some indication of the association in memory) must be performed so that this later review is possible." *Id.* ¶ 31. In sum, Dr. Stevenson opines that "the memory in the '273 Patent must be capable of storing data for a duration allowing for remote access and verification, *i.e.,* after formulation, and certainly meaningfully longer than what is required for real time display.

*Id.* ¶ 29.

We do not find persuasive Petitioner's contention that Patent Owner's construction of "memory" renders claim 1 ambiguous. *See* Reply 5–8. Petitioner focuses on what may or may not be done with metadata stored in the memory and on the potentially open-ended duration of this information under Patent Owner's proposed construction. *Id.* But as we understand Patent Owner's proposal, the memory recited in Elements [1g]/[1h] must be capable of storing data in a sufficiently non-transitory state that it can be made available "for remote access and verification, i.e., beyond local real time display." *See* PO Resp. 10–11 (citing Ex. 2010 ¶ 29). This definition merely sets some minimum duration on the *capability* of the memory to associatively store weight and a medical dose preparation image data, i.e., the time necessary for remote access and verification—a duration longer than that required for real time display. That remote access and verification may, in fact, occur at some later, undetermined time, as Petitioner contends, does not render the term ambiguous. *See* Reply 5–7.

Considering the record before us and based on the representations of both parties as to its construction, we construe "associatively stored in the memory" in the context of Element [1g]/[1h], to mean that data for a particular medication receptacle (e.g., a vial or syringe) is stored in memory such that the processor can match that data to the medication receptacle or relevant dose order, and wherein the memory is capable of storing data for a duration sufficient to allow for remote access and verification, i.e., beyond local real time display.

No other terms require express construction. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.").

D. Anticipation in view of Fioravanti (Ground 1)

In Ground 1, Petitioner challenges claims 1, 3–8, 10, 11, and 16–21 as anticipated by Fioravanti. Pet. 13–29. In support, Petitioner provides a detailed claim chart mapping the teachings Fioravanti to each of the claim elements. *Id.* at 15–29. Patent Owner opposes. PO Resp. 33–49. We begin with an overview of Fioravanti.

1. Overview of Fioravanti (Exhibit 1006)

According to Fioravanti, liquid pharmaceutical compositions are typically prepared "by medical or pharmaceutical operators . . . using doses, i.e., preset amounts/weights of one or more active principles prescribed in a medical prescription." Ex. 1006 ¶ 3. The process involves "selecting and taking from a store the vials containing the active principles present in the

medical prescription; drawing from the vials, using sterile syringes, the preset doses of active principles; and fitting each syringe to the administration instrument to introduce therein the dose of active principle." *Id.* ¶ 4. Because the process is performed manually, it "may be subject to accidental errors, i.e., ones deriving from incorrect aspiration/dosage of the active principles in the syringes by the operator." *Id.* ¶ 5. Accordingly, Fioravanti discloses a system or "[d]igital assistant appliance for assisting an operator in the manual preparation of a liquid pharmaceutical composition." *Id.* at Abstract. The disclosed system includes:

> (1) "a user interface, through which the operator imparts selection commands of a pre-stored medical prescription and which displays to the operator himself, step by step, messages indicating the operations to be performed";
>
> (2) "a gravimetric control device for measuring the weight of the vials containing the active principles and the sterile syringes used for transfer of the active principle"; and
>
> (3) "an electronic processing unit, which, on the basis of the weights of the vials and of the syringes, measured before and after the transfer of the active principle from the vials to the syringes, calculates the effective dose of active principle drawn in/dosed by the operator to point out any possible discordance between the dose of active principle effectively drawn in and the dose prescribed in the medical prescription."

*Id.* ¶ 6; *see id.* ¶ 12, claim 4.

Fioravanti Figures 1 and 2, respectively, disclose a schematic of a representative physical digital assistant and flowchart of its operation. *Id.* ¶¶ 16–17. Figure 1 shows cameras 9, 10, 13, and 19, which we address in turn.

"[V]ideocamera 9 . . . is set above the scale 8 of the electronic balance 7 in such a way as to acquire images containing the view from above of the vial or of the syringe set on the scale 8; and at least one front photographic camera or videocamera 10 . . . is set facing a preset side 7*a* of the scale 7 to acquire the image of the front side of the vial or of the syringe." Ex. 1006 ¶ 23. "[B]iometric-recognition photographic camera or videocamera 13 [is] designed to acquire the images of the operator." *Id.* ¶ 25. "Remote monitoring system 18 comprises a field photographic camera or videocamera 19 set in the workstation 30 to acquire the images regarding the different steps of preparation of the liquid pharmaceutical composition by the operator so as to produce a video film." *Id.* ¶ 33. "[C]ommunication module 21 connected to the remote-surveillance station 31 through a data-communication network 32 . . . transmit[s] the video film acquired [by camera 19] to the remote-surveillance station 31; and a processing module 22 that controls the video field camera 19, issues a command for storage of the video film in the memory device 15." *Id.*

Memory device 15 "contain[s] the data for identification of the operator . . . [and] a database designed to contain the medical prescriptions associated to the pharmaceutical compositions to be administered to the patients." *Id.* ¶ 36, *see also id.* ¶¶ 37–39. Medical prescription in the database contain information regarding, for example, "data regarding the active principle or principles to be used for the preparation of the liquid pharmaceutical composition[,] the dose, i.e., the weight or amount of each active principle," and information regarding the shape and capacity of each syringe or vial to be filled. *Id.* ¶ 37.

"The memory device 15 moreover contains, for each type of syringe, a syringe sample image and, for each type of vial, a vial sample image." *Id.* ¶ 38. Processing system 6 compares the image data with the syringe or vial positioned on scale 8 "to verify whether the syringe [or vial] identified corresponds or not to one of the types of syringes [or vials] . . . that can be selected." *Id.* ¶¶ 58–61, 71–74. The processing system also determines whether an operator has accurately filled the medication container by, for example, "calculat[ing] the difference . . . between the weight PS2b of the syringe S2 measured subsequently to drawing-in of the active principle and the weight PS2a thereof measured prior to drawing in." *Id.* ¶ 92; Ex. 1004 ¶ 49.[14] Based on this calculation, the system notifies the operator to take up more liquid into the syringe, expel the excess amount, or print a label. *See* Ex. 1006, Fig. 2, ¶¶ 92–95; *see also id.* ¶¶ 84–91 (corresponding disclosure for vials from which medication is withdrawn); Ex. 1004 ¶ 34. Insofar as memory device 15 is the only memory recited in Fioravanti, we infer that memory device 15 stores at least the initial syringe and vial weights to compare its weight after drawing/withdrawing the active principle. *See* PO Resp. 44 ("Fioravanti does not disclose any memory other than memory device 15 . . . ." (citing Ex. 2010 ¶ 78)); Ex. 1017, 66:2–8 (Dr. Stevenson

[14] Patent Owner concedes that Fioravanti discloses storing initial syringe and vial weights, but there is no express teaching in Fioravanti to store other weight data from the gravimetric device. *See* PO Resp. 30 (citing Ex. 2010 ¶ 56; Ex. 2008 ¶¶ 75–78); *see also* Ex. 1017, 66:16–68:13 (Dr. Stevenson testifying that "current" weight in Figure 10 temporarily resides in display memory).

presuming that memory device 15 is "the only place data is stored in the database."); Ex. 1004 ¶ 36 (Dr. Young's testimony that "the processing system performs these comparisons of weight and image data for the steps of filling a particular prescription by storing and retrieving the data associated with the prescription from the database in memory device 15").

Figures 3–10 show "graphic interfaces displayed by the digital assistant appliance illustrated in FIG. 1 during preparation of the liquid pharmaceutical composition" where, for example, Figures 4 and 10, show a "[c]urrent camera image" from videocamera 9 of hypodermic syringe S2 on a scale with the respective instructions to "weigh a new empty syringe" and "[c]heck final syringe weight." *Id.* ¶¶ 18, 23. Figure 10 is reproduced below.

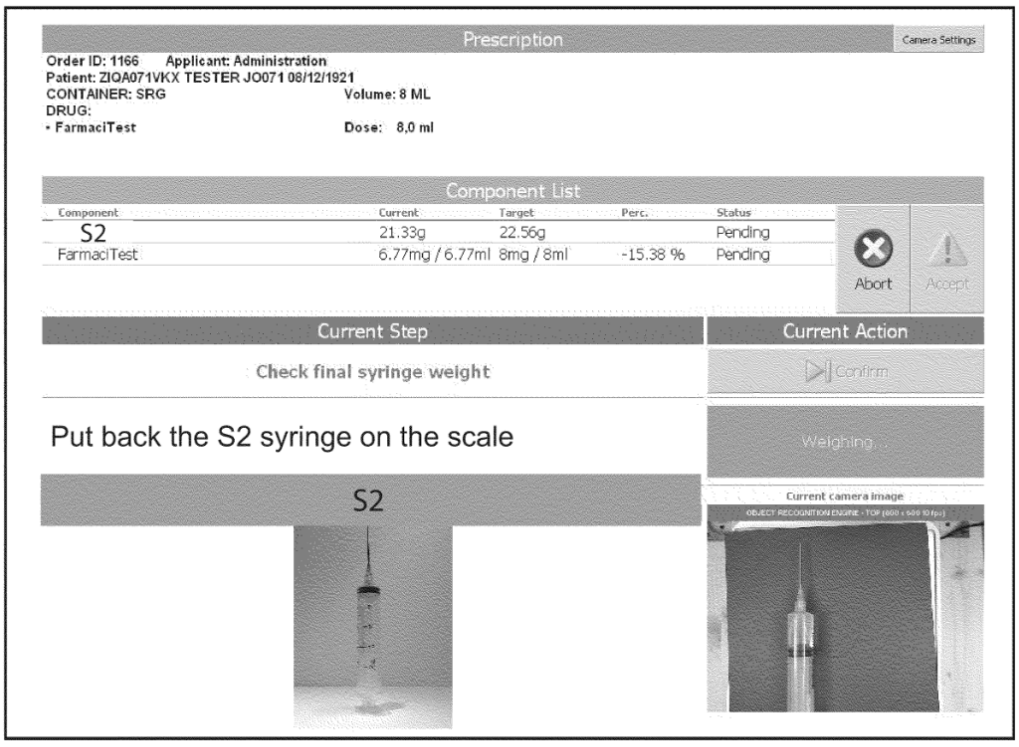


***Fig. 10***

Figure 10 further shows the "current" and "target" weights of syringe S2 and the percent deviation ("Perc") between the current and target weights of the drug composition contained therein. Fioravanti's system, thus, calculates the weight of the syringe contents and notifies the operator to take up more liquid into the syringe, expel the excess amount, or print a label, depending on whether the contents' weight is below, above, or within a set tolerance range. *See id.* Figs. 2, 10, ¶¶ 92–95.

In view of the above, Petitioner reasonably characterizes Fioravanti as disclosing a "system [that] aids drug dose preparation by comparing captured images and weights to . . . expected images and weights of the vial and syringe to ensure correct vessels are used and the correct dose is transferred between them." Pet. 13–14 (citing Ex. 1006 ¶¶ 59–61, 73–74, 80–81, 84–85, 90–92, 95).

2. Analysis of Independent Claim 1

We focus on claim 1, from which claims 3–8, 10, 11, and 16–21 depend. In its element-by-element comparison showing where each recited element is found in Fioravanti, Petitioner asserts, in part, that the reference discloses:

> workstation 30 which corresponds to the recited "work station" (citing Ex. 1006 ¶¶ 1, 21);
>
> bottom portion of balance 7 which corresponds to the recited "base" (citing Ex. 1006 ¶ 22; Ex. 1007, Fig. 1);
>
> gravimetric control system, scale 8, and vial or syringe to be weighted, which corresponds to the recited "scale" and "medication receptacle supported on the support platform" (citing Ex. 1006 ¶ 22; Ex. 1007, Fig. 1);

> camera/videocameras that acquire real-time images of the vial/syringe (cameras 9, 10), and different steps of preparation (camera 19), which correspond to the recited "imaging device" (citing Ex. 1006 ¶¶ 23, 33);
>
> processing system 6 comprising processing device 26 which corresponds to the recited "processor in operative communication with the scale" (citing Ex. 1006 ¶¶ 41, 60, 58, 59); and

Pet. 15–30. Patent Owner does not contest that Fioravanti discloses these limitations and we the evidence showing their disclosure them persuasive. *See* PO Resp. 33–46. We address next, Patent Owner's contention that Petitioner fails to establish that Fioravanti discloses data for a weight and a medical dose preparation image "associatively stored in the memory" as required under elements [1g]/[1h]. *See id.* at 35–47; Sur-reply 5–9.

With respect to elements [1g]/[1h], Petitioner points to memory device 15 of processing system 6, as including a database of "medical prescriptions associated to the pharmaceutical compositions to be administered to the patients." Pet. 18 (quoting Ex. 1006 ¶ 36.). According to Petitioner, "the processing system uses the image and weight data in association with each other to determine whether the steps of preparing a medication dose have been followed correctly." Pet. 19; *see* Ex. 1006 ¶¶ 37–38, 59–61, 73–74, 80–85, 89–95. Petitioner further explains that a person of ordinary skill "would have understood from the teachings of Fioravanti that the processing system performs these comparisons of weight and image data for the steps of filling a particular prescription by storing and retrieving the data associated with the prescription from the database in memory device 15." *Id.* (citing Ex. 1004 ¶¶ 32–34, 43–46).

Patent Owner argues that although Figure 10 may display weight and dose preparation images side-by side on a single screen, Fioravanti does not teach *associating* the weight and dose preparation images for a particular medication preparation. *See* PO Resp. 44–45. According to Patent Owner, "[c]reating an association between the video and weight data of the type displayed in Figure 10 for later remote access and verification would require specific intent in the programming to do so, about which Fioravanti is entirely silent," and "*Fioravanti* is silent on this issue would signal to an ordinarily skilled person that that reference did not contemplate associating video and weight data." *Id.* at 45 (citing Ex. 2010 ¶ 84).

We do not find Patent Owner's argument persuasive. Although we agree with Patent Owner that Fioravanti does not teach storing weight and dose preparation images "for later retrieval and review," Fioravanti's display, on its face, creates an "association" between the weight and preparation images, at least temporarily for the real-time display. *See* Ex. 1006, Figs. 2, 10.

Fioravanti teaches that "memory device 15 . . . contains, for each type of syringe, a syringe sample image and, for each type of vial, a vial sample image." *Id.* ¶ 38. Processing system 6 compares the image data with the syringe or vial positioned on scale 8 "to verify whether the syringe [or vial] identified corresponds or not to one of the types of syringes [or vials] . . . that can be selected." *Id.* ¶¶ 58–61, 71–74. Fioravanti also teaches, for example, that "the processing system . . . calculates the difference . . . between the weight PS2b of the syringe S2 measured subsequently to drawing-in of the active principle and the weight PS2a thereof measured

prior to drawing-in." *Id.* ¶ 92. Based on this calculation, the system notifies the operator to take up more liquid into the syringe, expel the excess amount, or print a label. *See id.* at Fig. 2, ¶¶ 92–95. As illustrated in Figures 4 and 10, Fioravanti's system also displays a "[c]urrent camera image" before and after inspiration of a pharmaceutical compound. *Id.* ¶ 18. Figure 10 further shows a current image of the hypodermic syringe in association with its current and target weight.

Patent Owner argues that such comparisons do not equate to an "association," but does not explain how the system could use the image data in association with the weight data without, at some point, having that data associated together in memory 15—the only memory disclosed in Fioravanti. *See* PO Resp. 44–45. Dr. Young, for example, testifies that:

> Fioravanti teaches that the processing system 6 measures and stores the weight measured by the gravimetric control system 4. (*See, e.g.*, Ex. 1006 at 0079.) Fioravanti also provides that processing system 6 includes a memory device 15, which can be used to store image data and medical prescriptions. (*See, e.g.*, *Id.* at 0033, 0036.) As discussed, Fioravanti teaches that the processing system uses the image and weight data in association with each other to determine whether the steps of preparing a medication dose have been followed correctly. (*See, e.g.*, *Id.* at 0059–61, 0073–74, 0080–81, 0084–85, 0090–92, 0095.)

Ex. 1004 ¶ 35. That the image and weight data were stored, and subsequently identified by the processing system as associated with a single medication receptacle or dose order, is sufficient to establish that they are "associated" together. Accordingly, we agree with Petitioner that Fioravanti "teaches that the processing system uses the image and weight data in

association with each other to determine whether the steps of preparing a medication dose have been followed correctly." Pet. 19 (citing Ex. 1006 ¶¶ 37–38, 59–61, 73–74, 80–85, 89–95). This does not, however, end our analysis.

In section II(C)(5), above, we construed "associatively stored in the memory," in the context of Element [1g]/[1h], to mean that "data for a particular medication receptacle (e.g., a vial or syringe) is stored in memory such that the processor can match that data to the medication receptacle or relevant dose order, and wherein the memory is capable of storing data for a duration sufficient to allow for remote access and verification, i.e., beyond local real time display." Applying this construction, we agree with Patent Owner that Petitioner's has not established that Fioravanti anticipates claim 1 of the '273 patent.

Fioravanti discloses that processing system 6 captures the weight and dose preparation images in memory so they can be displayed in real-time on a display. *See* Ex. 1006, Figs. 3–10. Petitioner has not established that this data is associatively stored in memory such that it can be retrieved and reviewed at a later time, or that the memory is even *capable* of storing data for a duration sufficient to allow for remote access and verification, as required under our construction. *See, e.g.*, PO Resp. 41–43 (arguing that "Figure 10's simultaneous display of weight and real-time video from the syringe/vial recognition system cameras is not sufficient to disclose that a weight and image data are 'associatively stored in the memory,' particularly in view of the foregoing discussion that the memory claimed in the '273 Patent must be capable of associatively storing such data for later retrieval

and review") (citing, *e.g.*, Ex. 2010 ¶¶ 79–85); *id.* at 44–47 (arguing the simultaneous display of weight and image data in Fioravanti's Figure 10 does not equate to "associatively stored") (citing Ex. 2010 ¶¶ 31, 78, 82–85)); *see also id.* at 19–26.

In sum, we agree with Patent Owner that Fioravanti stores weights so that it may "compar[e] the stored weights to other weights during dose preparation" (*id.* at 47 (citing Ex. 2010 ¶ 58; Ex. 2008 ¶ 96)), and the "stated purpose in *Fioravanti* for the storage and transmission of the video film is to enable viewing at the remote-surveillance station of the operations carried out at the workstation" (*id.* (quoting Ex. 2010 ¶ 86)). Petitioner does not identify any explicit teaching in Fioravanti that any image or video from cameras 9, 10, or 19, including the real-time images displayed in Figures 3–10 are stored, or could be stored, for later retrieval and review. Pet. 13–29; Reply 8–12.

In view of the above, Petitioner has not shown by a preponderance of the evidence that claim 1 is unpatentable as anticipated by Fioravanti.

3. Analysis of Dependent Claims 3–8, 10, 11, and 16–21

Petitioner provides a detailed analysis explaining where Fioravanti teaches the limitations in claims 3–8, 10, 11, and 16–21, which depend from independent claim 1. Pet. 19–29. Patent Owner argues that, if independent claim 1 is not anticipated by Fioravanti, depending claims 3–8, 10, 11, and 16–21 cannot be anticipated by Fioravanti. PO Resp. 49. Patent Owner is correct. Petitioner has not shown by a preponderance of the evidence that claims 3–8, 10, 11, and 16–21 are unpatentable as anticipated by Fioravanti.

4. Conclusion as to Ground 1

On the record as a whole, and for the reasons set forth above, Petitioner has not shown by a preponderance of the evidence that claims 1, 3–8, 10, 11, and 16–21 of the '273 patent are unpatentable as anticipated by Fioravanti.

E. Obviousness in view of Fioravanti (Ground 2)

In Ground 2, Petitioner challenges claims 1–14 and 16–21 as obvious in light of Fioravanti. Pet. 30–33; Reply 14–15. In support, Petitioner relies on its claim chart with respect to Ground 1 and further provides a detailed claim chart mapping the teachings of Fioravanti to the elements of claims 1–14 and 16–21. *Id.* at 31–33. Patent Owner opposes. PO Resp. 49–54; Sur-reply 13–14. As Patent Owner does not challenge Petitioner's obviousness contentions with respect to the dependent claims, we focus our analysis on claim 1. *Id.* In light of Patent Owner's contentions regarding anticipation, however, we separately address elements of claims 5, 19, and 21. We find persuasive Petitioner's contentions regarding all other elements of the claims challenged under this ground. We address the elements found lacking in the anticipation analysis in our obviousness analysis as follows.

1. Analysis of Independent Claim 1

As discussed in Ground 1, Petitioner has shown that Fioravanti teaches all of the limitations of claim 1 except for limitation [1g]/[1h], which requires that "the weight and the medical dose preparation image are . . . associatively stored in the memory." Petitioner, relying on the testimony of Dr. Young, contends that, "[t]o the extent that Fioravanti does not explicitly

teach associatively storing a captured image and weight measurement of a syringe or vial (*see* element 1h), it would have been obvious from Fioravanti's teaching to store these pieces of information together as part of the database record for a medication dose order." Pet. 30 (citing Ex. 1004 ¶¶ 35–36); *see also id*. at 30–31 (further relying on Dr. Young's testimony with respect to elements of claims 4–6, 11, 16, 19, and 21). Having reviewed the competing testimony and evidence of record, we agree with, and credit, Dr. Young's testimony that it would have been obvious to "associatively store" the weight and medical dose preparation image information. Petitioner's reasoning is sufficiently articulated and supported by rational underpinnings. *KSR*, 550 U.S. at 418.

Dr. Young testifies, and we agree, "Fioravanti teaches utilizing a scale and camera or video camera to provide several verification checks during the preparation of a medical dose order." Ex. 1004 ¶ 34 (citing Ex. 1006 ¶¶ 22–23). He explains how Fioravanti uses syringe samples images to insure that the correct vial is used:

> First, the operator places a syringe on the scale and "the artificial viewing system 4 identifies the syringe by comparing the image of the syringe acquired by the top videocamera 9 . . . with the syringe sample images associated to the types of syringe S1 and S2" to determine whether the operator placed the correct syringe on the scale. ([Ex. 1006 ¶] 0059–61.) Then, the operator removes the syringe and places a vial on the scale so that the artificial viewing system 4 can capture an image of the vial and compare it to a sample vial image to determine the presence of the correct vial. (*Id.* at 0073–74.)

Young Decl. ¶ 34.

Dr. Young also explains how Fioravanti insures that the correct weight of the prescribed dose is achieved:

> After the operator has drawn a dose of the medication from vial F2 using syringe S2, the operator utilizes the system to measure the weight of the vial, and the system confirms whether the difference between the two weight measurements of the vial corresponds to the weight of the prescribed dose. ([Ex. 1006 ¶¶] 0080–81, 0084–85.) If the difference in the weight is within a tolerance range, the operator removes the vial and places the syringe on the scale. The system again performs an image analysis confirmation to ensure the correct syringe was placed on the scale, and then weighs the syringe to determine if the difference in the two syringe weight measurements corresponds to the weight of the prescribed dose. (*Id.* at 0090–92, 0095.) The procedure described by Fioravanti in sequentially weighing the medication containers is one that would have been known and commonly used to compound pharmaceuticals during the relevant time frame.

Young Decl. ¶ 34.

Dr. Young testifies that Fioravanti "teaches that the processing system 6 measures and stores the weight measured by the gravimetric control system 4," and this "processing system 6 includes a memory device 15, which can be used to store image data and medical prescriptions." Ex. 1004 ¶ 35 (citing Ex. 1006 ¶¶ 79, 33, 36). He states, "Fioravanti teaches that the processing system uses the image and weight data in association with each other to determine whether the steps of preparing a medication dose have been followed correctly." *Id.* (citing Ex. 1006 ¶¶ 59–61, 73–74, 80–81, 84–85, 90–92, 95).

Dr. Young further testifies that "[t]o determine whether the correct amount of medication has been drawn into a syringe, the system would need

to have a reference or target weight," and a "common way to provide such a value during the relevant time frame would have been for the scale to be connected to a pharmacy system or database that included the medication order." Ex. 1004 ¶ 36. Dr. Young reasons that a person of ordinary skill in the art would have understood from the teachings of Fioravanti that "the processing system performs these comparisons of weight and image data for the steps of filling a particular prescription by storing and retrieving the data associated with the prescription from the database in memory device 15." *Id.*

In light of Dr. Young's testimony, it would have been obvious to a person of ordinary skill in the art to store data for a particular medication receptacle (e.g., a vial or syringe) in memory so that the processor can match that data to the medication receptacle or relevant dose order for a duration sufficient to allow for remote access and verification, i.e., beyond local real time display, as recited in claim limitation [1g]/[1h]. According to Dr. Young, for example, Fioravanti's "memory device 15 . . . comprises a database designed to contain the medical prescriptions associated to the pharmaceutical compositions to be administered to the patients." Ex. 1004 ¶ 45 (citing Ex. 1006 ¶ 36). Dr. Young states, and we agree, that a person of ordinary skill in the art would have understood from the teachings of Fioravanti that "memory device 15 can be used to store and retrieve the data associated with the prescription," and "would have expected information related to a prescription to become part of the pharmacy record for preparing the medication dose order." *Id.* Accordingly, "it would have been at least obvious for a person of ordinary skill in the art to store such captured

information as part of the record for the medication dose order." *Id.*[15]

We further credit Dr. Young's testimony that the "metadata described by Fioravanti would have been typical of the data captured in the process of compounding pharmaceuticals during the relevant time frame," and a person of ordinary skill in the art would have understood that "pharmacy systems and other electronic health records would capture various metadata regarding a medical dose order from connected systems and peripherals." Young Decl. ¶ 46. He reasons that a person of ordinary skill in the art would have understood that "the captured weight and images can be stored in memory device 15 as data corresponding to the dose order," and "[a]t a minimum, it would have been obvious to a person of ordinary skill in the art to do so based on the teachings of Fioravanti." *Id.*

We agree with Dr. Young's articulated reasoning. Fioravanti already teaches to store in memory, at least temporarily for the real-time display, associated images and weight related to medication dose preparation. *See, e.g.*, Ex. 1006, Fig. 10. Moreover, as set forth in section II(D)(1), above, Fioravanti further teaches that memory device 15 may contain a medical prescription database, image data of syringes and vials for comparison with the syringe or vial positioned on scale 8, and weight data regarding the positioned syringe or vial. We also agree with Dr. Young that the weight

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[15] Although not necessary to our determination, Dr. Young's testimony that, "[i]n certain respects, information used during the compounding process may legally be required to be stored with the patient's record as those products would be used for patient care," further supports Petitioner's position. Ex. 1004 ¶ 45.

and image data captured in Fioravanti's process of compounding pharmaceuticals also would be useful to pharmacy systems and other electronic health records, and a person of ordinary skill in the art "would have expected information related to a prescription to become part of the pharmacy record for preparing the medication dose order." Ex. 1004 ¶¶ 43–45.

Patent Owner does not address persuasively Dr. Young's articulated reasoning or show why it lacks rational underpinning or persuasively explain why it would not have been obvious to an ordinary skilled artisan to store Fioravanti's data for a particular medication receptacle in memory for a duration sufficient to allow for remote access and verification, i.e., beyond local real time display. PO Resp. 49–53. Rather, Patent Owner argues, that the "paragraphs from Dr. Young's declaration cited in the Petition say *nothing* about associative storage." PO Resp. 52 (citing Ex. 1004 ¶¶ 32–34, 43–46). Patent Owner further argues that, at most, "Dr. Young opines about *Fioravanti's* alleged teachings of associated 'use' ([Ex. 1004] ¶ 35) and data comparisons (*Id.*, ¶ 34)," and "Dr. Young's careful wording (and avoidance of the claim term 'storage') is telling, and is insufficient to show the purported obviousness of claim 1." PO Resp. 52. Patent Owner's arguments are not persuasive because, as discussed above, Dr. Young reasonably explains that a person of ordinary skill in the art would have understood that Fioravanti's "memory device 15 can be used to store and retrieve the data associated with the prescription," and "would have expected information related to a prescription to become part of the pharmacy record for preparing the medication dose order." Ex. 1004 ¶¶ 43–45.

Patent Owner also argues that an ordinarily skilled person reading Fioravanti would not be motivated to store image data in association with weight data as required by claim 1 in light of "a) the different purposes for storing weight and image data; b) the storage of weight and image data at different locations; c) and the absence of any mention of the discrete programming necessary to associate weight data with the video data displayed in Figure 10 at a later time." PO Resp. 50–51 (citing Ex. 2010 ¶ 89; Ex. 2008 ¶¶ 98–101).

Patent Owner similarly argues that only though hindsight would one of ordinary skill in the art reading Fioravanti implement the changes required to arrive at the claims of the '273 patent. *Id*. (citing Ex. 2008 ¶ 100). In particular, Patent Owner's expert, Dr. Brittain, testified that this would involve five "non-trivial" changes—so called because "they are significantly different than what is described by Fioravanti" and "that's not something that would happen by accident." Ex. 1018, 75:5–20. These are:

> (1) chang[ing] which camera view is being stored in the memory (from camera 19 to cameras 9/10), so that it is of the medication receptacle supported on the support platform (since the actual view and angle of camera 19 is unknown); (2) determining what weight data to store, e.g., whether the stored weight data includes discrete weight(s), a continuous stream of weights, one or more weight calculations, or combinations of those, and then how to store the weight data; (3) implement[ing] storing of the weight data that is being output from the scale; (4) determining how the weight data will be stored in relation to the output from cameras 9/10, such that they can be retrieved later; and (5) associatively stor[ing] the weight data with the output from cameras 9/10.

Ex. 2008 ¶ 100.

We do not find Dr. Brittain's testimony persuasive because he does not address evidence that Fioravanti already teaches storing, at least temporarily for real-time displays, images and weight in memory. *See, e.g.*, Ex. 1004 ¶ 35; Ex. 1006, Fig. 10. Similarly, Dr. Brittain does not address Dr. Young's testimony that it would have been obvious to an ordinary skilled artisan "to store and retrieve the data associated with the prescription," and "would have expected information related to a prescription to become part of the pharmacy record for preparing the medication dose order." Ex. 1004 ¶ 45. Patent Owner's "hindsight" argument (PO Resp. 51–52) is similarly unpersuasive because Patent Owner does not address Petitioner's articulated reasoning which we found, as discussed above, supported by rational underpinning.

Finally, Patent Owner argues that "*Fioravanti* lacks an express teaching of associative storage, and . . . Dr. Young has failed to provide <u>any</u> evidence that such feature would have been obvious to one ordinarily skilled in the art reading that reference." PO. Resp. 52–53. Patent Owner's arguments is not persuasive because an express teaching or motivation in Fioravanti is not required. *KSR*, 550 U.S. at 418. Instead, Petitioner need only articulate a reason to combine the references with some rational underpinning to support the legal conclusion of obviousness. *Id.* As set forth above, we find ample evidence of such in the record.

Accordingly, Petitioner has shown by a preponderance of the evidence that independent claim 1 is unpatentable as obvious in light of Fioravanti.

2. Dependent Claims 2–14 and 16–21

Having addressed the parties' arguments with respect to independent claim 1, we turn to claims 2–14 and 16–21, which depend from claim 1. In sum, we find reasonable Petitioner's arguments with respect to these claims. *See* Pet. 30–33. Patent Owner does not independently address claims 2–14 and 16–21 under Ground 2. To the extent Patent Owner does not address the merits of any of Petitioner's assertions regarding claims 2–14 and 16–21, Patent Owner's arguments are waived. *See* Scheduling Order, Paper 16, 8 (cautioning Patent Owner that "any arguments for patentability not raised in the response will be deemed waived"); *cf In re Nuvasive*, 842 F.3d 1376, 1381 (Fed. Cir. 2016) (explaining that a patent owner waives an argument presented in the preliminary response if it fails to renew that argument in the patent owner response after trial is instituted). Because a preponderance of the evidence supports Petitioner's arguments relating to the teachings of the prior art, we adopt Petitioner's arguments as our own. *See* Pet. 30–33; *see also In re Nuvasive*, 841 F.3d 966, 974 (Fed. Cir. 2016) (explaining that the Board need not make specific findings as to claim limitations that Patent Owner does not dispute are disclosed in the prior art)."

But because Patent Owner does address elements of claims 5, 19, and 21 under Ground 1, we address them below. *See* PO Resp. 48–49.

a) Claim 5

Claim 5 requires that, "upon receipt of the user input the processor is operable to record the weight at substantially the same time as the capture of the medical dose preparation image." As set forth in the Petition, "Fioravanti teaches that the system is capable of capturing an image of the

syringe or vial at substantially the same time as the scale weighs the syringe or vial." Pet. 21–22 (citing Ex. 1007, Figs. 7 and 2). Petitioner further notes that blocks 150 and 180 of Fioravanti's Figure 2 "teach[] 'identification of vial with artificial vision/gravimetric electronic system' as a single step in the process," thereby "indicat[ing] that the weighing and image capture are occurring at substantially the same time." Pet. 22 (citing Ex. 1004 ¶¶ 40–41).

Patent Owner argues, however, that "[n]owhere does Petitioner identify the requisite user input occasioning the recordation of weight and the capture of the preparation image." PO Resp. 48. But Figure 7, as illustrated in the Petition, instructs an operator to "Pick and weight a vial" according to the steps: "1. Pick a vial choosing from [those pictured] below"; "2. Remove the cap"; and "3. Place the vial on the scale in front of the camera." Such steps alone would appear to satisfy the "upon receipt" requirement of claim 5. Moreover, as Petition points out, Figure 7 further shows the "Weighing" prompt highlighted, which underscores that Fioravanti's system captures weight and image data at substantially the same time. In sum, we do not find Patent Owner's argument persuasive. *See* Pet. 22, 30–31 (citing Ex. 1004 ¶¶ 35–43, 45, 46, 51); Reply 12 (citing Ex. 1004 ¶¶ 37–41).

b) Claim 19

Claim 19 requires that "said weight and said medical dose preparation image are stored in said memory as part of metadata corresponding to a medication dose order." Petitioner cites to paragraph 38 and Figures 3–10 of Fioravanti as support for this language, further stating that one of ordinary

skill in the art "would have understood from the teaching of Fioravanti that the system stores such metadata in the database in memory device 15." Pet. 28 (citing Ex. 1004 ¶¶ 45–46).

Patent Owner responds that paragraph 38 contains "no mention of weight," whereas displaying weight information in Figure 10 "is not the same as storing that information, let alone storing that information associatively with image information." PO Resp. 48 (citing Ex. 2010 ¶¶ 87–88); *see* Sur-Reply 20–21. We do not find Patent Owner's argument persuasive.

We note first, Petitioner's argument that claim 19, recitation of "said weight" references the weight earlier addressed in independent claim 1. Reply 13. We also addressed the obviousness of associatively storing information in section E(1), above, noting, for example, Dr. Young's testimony that a person of ordinary skill in the art would have understood from the teachings of Fioravanti's processing system 30 "performs . . . comparisons of weight and image data for the steps of filling a particular prescription by storing and retrieving the data associated with the prescription from the database in memory device 15." Ex. 1004 ¶ 36. We also credit Petitioner's evidence that "to the extent Fioravanti does not explicitly teach storing weight and images as metadata and making them available for remote access and verification (*see* claims 19 and 21), it would have been obvious to do so." Pet. 31 (citing Ex. 1004 ¶¶ 45–46, 51).

c) Claim 21

Claim 21 recites that "said metadata is stored for remote access and verification." Patent Owner argues that Petitioner's challenge fails because

"there is no teaching in *Fioravanti* to store any weight data remotely." PO Resp. 49. We do not find Patent Owner's argument persuasive.

Citing paragraphs 32, 34 of Fioravanti, Petitioner argues that one of ordinary skill in the art would have understood "that remote surveillance station 31 can remotely access any metadata associated with the preparation of a medical dose." Pet. 29 (citing Ex. 1004 ¶ 51). Moreover, relying on the testimony of Dr. Young, Petitioner asserts, "to the extent Fioravanti does not explicitly teach storing weight and images as metadata and making them available for remote access and verification (*see* claims 19 and 21), it would have been obvious to do so." Pet. 31 (citing Ex. 1004 ¶¶ 45–46, 51).

3. Conclusion as to Ground 2

On the record as a whole, and for the reasons set forth above, Petitioner has shown by a preponderance of the evidence that claims 1–14 and 16–21 of the '273 patent are unpatentable as obvious in light of Fioravanti.

F. Obviousness in view of Fioravanti and Alexander (Ground 3)

In Ground 3, Petitioner challenges claims 1–14 and 16–21 as obvious over the combination of Fioravanti and Alexander. Pet. 33–48. In support, Petitioner provides a rationale to combine the teachings of Fioravanti and Alexander (*id.* at 25–36) and a detailed claim chart mapping the teachings of the asserted references to the challenged claims (*id.* at 37–49). Patent Owner opposes. PO Resp. 54–68; Sur-reply 14–22. We have reviewed the evidence of record including the Petition and Petitioner's expert declarations and Patent Owner's arguments and evidence, including its experts'

declarations. Below, we present an overview of Alexander, address whether Alexander is prior art, and then we address Petitioner's and Patent Owner's contentions for this obviousness ground in detail.

1. Overview of Alexander (Exhibit 1008)

Alexander discloses an application of telepharmacy in which a pharmacist can remotely direct and oversee the compounding of a patient's medication. In particular, Alexander discloses a system and method

> for providing certain pharmacy services to institutionalized patients at an institution where a live pharmacist is not available. The institutional pharmacy and a remotely located pharmacist are linked via wired or wireless telecommunication systems in a manner that enables the pharmacist to remotely supervise and verify that pharmacy functions are properly performed by non-pharmacist personnel.

Ex. 1008, 2:13–20; *see id.* at Abstract. The disclosed system includes an

> image capture device located in the institutional pharmacy . . . to capture images of work performed by nonpharmacist personnel. The image(s) and corresponding documentation are transmitted from the institutional pharmacy to a remotely located computer system, where a pharmacist supervises and verifies the work, and subsequently authorizes non-pharmacist personnel to further process the work.

*Id*. at 2:46–53. In one aspect, the system is illustrated by Figure 5, reproduced below.

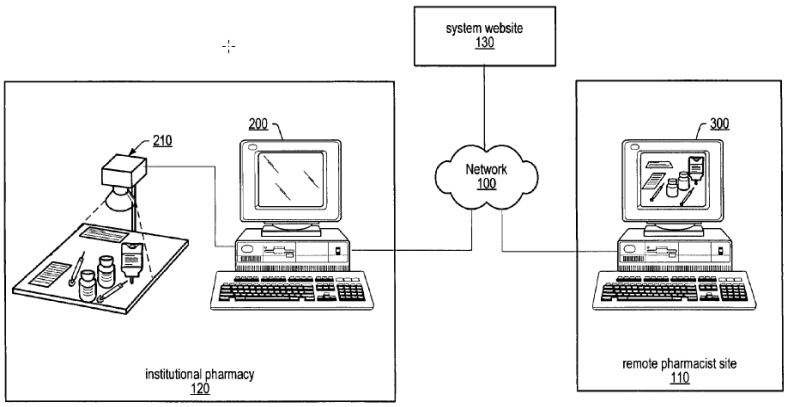


***FIG. 5***

Figure 5 depicts "an exemplary system for remotely supervising and verifying pharmacy functions," wherein

> an image captured on image capture device 210 at institutional pharmacy 120 being sent and viewed at remote pharmacist site 110, in one embodiment. For example, a nurse, or other non-pharmacy personnel, at institutional pharmacy Site 120 may enter the pharmacy and compound a sterile intravenous product that was ordered for a patient after pharmacy hours and was not available outside of the pharmacy department. A pharmacist may have entered the mediation order into the patient's medication profile and may also have generated a label for the intravenous product via the pharmacy's order entry software. According to one embodiment, after visually inspecting the final product, such as for particulate matter, the nurse may place the labeled sterile intravenous product, with label and base solution content clearly visible, on image capture device 210's display area.
>
> * * *
>
> The captured image(s) may be transmitted from the workstation at institutional pharmacy 120 to system website 130 and may be downloaded by a workstation at remote pharmacist site 110 . . . .

> A pharmacist at remote pharmacist site 110 may view the pharmacy work performed at institutional pharmacy 120, as well as any other information necessary to conduct process checks and verify that the medication in the captured image(s) was correctly and accurately prepared, labeled, compounded, and/or packaged.

*Id.* at 3:1–2, 9:55–10:47. Alexander further explains that:

> Image capture device 210 may be any of a number of different types of image capture devices configured to capture still and/or video images or clips, according to various embodiments. For example, in one embodiment, image capture device 210 may be an off-the-shelf digital camera mounted appropriately to capture images of pharmacy work. In another embodiment, image capture device 210 may be a visual presenter, while in other embodiments, image capture device may be a web cam configured to capture still and/or video images or clips. In yet other embodiments, image capture device 210 may be a custom image capture device configured specifically for capturing images of pharmacy functions.
>
> * * *
>
> The captured images may, in some embodiments, include images of all work and documentation required to properly supervise and verify the correct and accurate preparation, labeling, compounding, prepackaging and/or packaging, of any pharmacy work performed.

*Id.* at 6:11–23, 39–43.

In some embodiments, "[s]erver 700 may also provide an interface for review of images by pharmacists." *Id.* at 14:11–12. "[I]mages may be transmitted via FTP or another network file transfer protocol. Server 700 may then store the received images for later access by a remote pharmacist. In some embodiments, the images may be associated with a job or task identifier that may be used by a pharmacist to reference the images for

review." *Id.* at 14:5–10. "Server 700 may store received images in any of variety of manners and formats. . . . Images may be stored as individual files on a file server, as records in an image database, or multiple images may be compacted and stored together in a single file, such as in a .ZIP file." *Id.* at 15:16–21.

2. Prior Art Status of Alexander

In the Institution Decision, we determined that Alexander is prior art under § 102(e)(2), but not under § 102(g)(2) or § 102(e)(1). Inst. Dec. 26–32. Patent Owner maintains that Alexander is not prior art under § 102(e)(2). PO Resp. 54–61; Sur-reply 21–22. We address the parties' contentions below.

a) 35 U.S.C. § 102(g)(2)

Title 35, United States Code, section 102(g)(2), provides in relevant part that a person shall be entitled to a patent unless "before [the applicant's] invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." Petitioner argues that the filing of the patent application resulting in the issuance of Alexander was a "'constructive reduction to practice . . . [that] evidenced a prior invention, which deprives a later invention of patentability' under § 102(g)." Paper 13, 5 (quoting *Rexam Indus. Corp. v. Eastman Kodak Co.*, 182 F.3d 1366, 1371 (Fed. Cir. 1999)). *Rexam*, however, merely references § 102(g) in explaining that an abandoned, non-allowable patent application "is not a new class of prior art" and, thus, has little bearing on Petitioner's argument. *See Rexam,* 182 F.3d at 1370–71.

More to the point, subsection (g) of pre-AIA 35 U.S.C. § 102 is the basis of interference practice for determining priority of invention between two parties. *See Bigham v. Godtfredsen,* 857 F.2d 1415, 1416 (Fed. Cir. 1988). Contrary to Petitioner's argument, "the disclosure in a reference United States patent does not fall under 35 U.S.C. § 102(g) but under 35 U.S.C. § 102(e)." *In re Zletz*, 893 F.2d 319, 323 (Fed. Cir. 1989).

We also credit Patent Owner's argument in the Preliminary Response that the filing of the application leading to the issuance of the Alexander patent is insufficient to prove that the invention was previously actually reduced to practice as required under § 102(g)(2):

> [35 U.S.C §] 102(g)(2) requires that there be evidence that an invention was actually reduced to practice; conception alone is not sufficient. 35 U.S.C. § 102(g)(2); *see also* Manual of Patent Examining Procedure ("MPEP"), § 2138 (citing *Kimberly-Clark v. Johnson & Johnson*, 745 F.2d 1437, 1445 (Fed. Cir. 1984)). While the filing of an application for patent is a constructive reduction to practice, such filing does not itself provide evidence of an actual reduction to practice.

Prelim. Resp. 7–8.

Nevertheless, to the extent the filing of the application resulting in the issuance of Alexander would evidence prior invention under § 102(g)(2), our governing statute provides that "[a] petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications." 35 U.S.C § 311(b). Although Alexander is a printed publication, Petitioner does not seek to use

it as such under § 102(g)(2) but, instead, as evidence of prior invention, which is not a legitimate basis for challenge in *inter partes* review.

For the above reasons, and as set forth at pages 26–28 of our Institution Decision, Alexander is not available as prior art in this proceeding under 35 U.S.C § 102(g)(2).

b) 35 U.S.C. § 102(e)

Under 35 U.S.C § 102(e), a person shall be entitled to a patent "unless the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent . . . or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent." As noted in our Institution Decision, Alexander is not prior art under 35 U.S.C § 102(e)(1) because the applicant expressly requested that the application that matured into Alexander "not be published under 35 U.S.C 122(b)" and was, therefore, never published under that section. Inst. Dec. 28 (citing Prelim. Resp. 8; Ex. 2005, 58).

With respect to 35 U.S.C § 102(e)(2), Patent Owner does not dispute that Alexander was granted on February 12, 2013 from a U.S. application filed on February 11, 2005, by another, before the earliest filing date of the '273 patent. *See* Ex. 1008, codes (22), (45), (76). Instead, Patent Owner raises the novel argument that, because all of Alexander's claims were found unpatentable in IPR2015-00883—and subsequently cancelled—Alexander no longer qualifies as a "granted" patent pursuant to the statute. *See* PO Resp. 54–61; Reply 21–22; Ex. 2005, 399–400 (*Inter Partes* Review Certificate dated Feb. 15, 2018, cancelling claims 1–27 of Alexander). In

other words, Patent Owner argues that not only is the Alexander patent unenforceable, but the cancelation of claims retroactively stripped it of any prior art status—which even Patent Owner has admitted "may seem illogical." *See, e.g.*, PO Resp. 57–58; Prelim. Resp. 12. Patent Owner's attempt to remove Alexander as prior art because its claims were subsequently invalidated, however, is contrary to public policy and unsupported by its cited case law.

Patent Owner relies on *Fresenius* as evidence of "Congressional intent that claims so canceled be void *ab initio*." PO Resp. 55 (citing *Fresenius USA, Inc. v. Baxter Intern., Inc.*, 721 F.3d 1330, 1346 (Fed. Cir. 2013)). But the passage Patent Owner relies on is directed to the retroactive effect cancellation has on *enforceability* not prior art status. The same applies to Patent Owner's citation to *Peck v. Collins*, 103 U.S. 660, 664 (1880), for the proposition that "patent claims canceled in reissue are void *ab initio*, as if '[t]he patentee was in the same situation as he would have been if his original application for a patent had been rejected.'" PO Resp. 55. As with Fresenius, the cited passage in *Peck* refers to *the patentee's* right to enforce patent rights, and not to *the public's* right to rely on information disclosed in the underlying application.

Patent Owner's reliance on *Oil States* and *Cuozzo* is similarly misplaced because neither case addresses the prior art status of a cancelled patent. *Id.* at 57 (citing *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1374 (2018); *Cuozzo Speed Tech., LLC v. Lee*, 136 S. Ct. 2144 (2016)).

Contrary to Patent Owner's argument for the evanescence of Alexander as prior art, "[t]he use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Lemelson,* 397 F.2d 1006, 1009 (CCPA 1968). Accordingly, we do not find Patent Owner's arguments persuasive. We, instead, adopt Petitioner's reasoning on this issue. *See* Paper 13, 1–5; Reply 15–17. As Petitioner explains,

> [A] patent application acts a "self-authenticating instrument establishing a date of disclosure" that is later publicized by the PTO through either a published application or through the issuance of a granted patent.

Reply 16–17. Accordingly,

> [w]hen Alexander filed her patent application on February 11, 2005, she delivered a self-authenticating instrument to the PTO, establishing a disclosure date for everything it taught. When the PTO issued the Alexander patent, it engaged in a "publication event" that delivered Alexander's disclosure to the public. From that moment on, Alexander's prior art status was set.

Paper 13, 4. Patent Owner's attempt to remove Alexander as prior art because its claims were subsequently invalidated is contrary to public policy and the case law relied on by Petitioner in the Reply.

Further,

> section 103 forbids issuance of a patent when "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 said subject matter pertains."

*KSR*, 550 U.S. at 406 (emphasis added). The scope and content of prior art is, therefore, measured as of the filing date of the challenged invention.

In the present case, the critical date of the '273 patent is no later than March 15, 2013, the filing date of the non-provisional parent application. Ex. 1001, code (22).[16] Patent Owner does not dispute that Alexander was filed on February 11, 2005,[17] before the critical date, and that Alexander's claims were not cancelled until February 15, 2018, long after that critical date. Ex. 1008, code (22). Despite Patent Owner's contention that "one of ordinary skill in the art would not have even known that Alexander existed" as of the filing date of the '273 patent, these facts are sufficient to establish Alexander as prior art under 35 U.S.C § 102(e)(2) as of the critical date. *See* PO Resp. 60–61 (emphasis omitted).

For the above reasons, we agree with Petitioner that Alexander qualifies as prior art to the '273 patent under 35 U.S.C § 102(e)(2).

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[16] Although we need not consider whether the '569 patent is further entitled to the benefit of the October 26, 2012, provisional application, Patent Owner asserts that "the specification of the provisional application (Ex. 2012, 8–64 is identical to the specification filed in the application that led to the '273 Patent." PO Resp. 60, n.7.

[17] Patent Owner's reliance on the issue date of Alexander (February 12, 2013) is misplaced because relevant date under § 102(e)(2) for determining prior art status is Alexander's filing date, not the issue date. *See* PO Resp. 60–61. We similarly fail to see the relevance to § 102(e)(2) of Patent Owner's assertion that "[t]he majority of time between Alexander's issuance and cancellation were spent in proceedings before the PTO." *See Id.* at n.8.

3. Motivation to Combine

According to Petitioner, Fioravanti and Alexander each describes—and touts the advantages of—"computer systems for use in a pharmacy to aid the operator in preparing a medication dose more efficiently and with fewer errors." Pet. 35 (citations omitted). Petitioner asserts, therefore, that one of ordinary skill in the relevant art would have been motivated to combine the teachings of these references because they "are easily compatible and . . . disclos[e] . . . similar structures and components to achieve similar goals." Pet. 36 (citing Ex. 1004 ¶ 83). "Such a combination merely combines prior art elements according to known methods to yield predictable results." *Id.* (citing Ex. 1004 ¶¶ 84–85). As summarized by Dr. Young, "[a] person of ordinary skill in the art designing [a system such as those of Fioravanti or Alexander] also would have looked to other prior art references for ideas in improving the design of a telepharmacy or dose preparation system." Ex. 1004 ¶ 84.

As we understand Patent Owner's counter-argument, one of ordinary skill in the art might consider combining Alexander with Fioravanti "if there was an appreciated deficiency in the image capturing solution taught in Fioravanti," but both references already teach the capture and use of images and "there is nothing in Dr. Young's declaration describing such a deficiency." PO Resp. 61–62 (citing Ex. 2010 ¶ 91; Ex. 2008 ¶¶ 102–105). We do not find Patent Owner's argument persuasive.

Rather, as we understand Dr. Young's testimony, one of ordinary skill in the art would be motivated to combine Fioravanti's dose preparation assistance system with Alexander's system for remote verification "to aid

the operator in preparing pharmaceutical doses with greater efficiency and protection against errors in compounding medication." *See* Ex. 1004 ¶ 83. As further articulated by Petitioner,

> [a] POSITA would have found it obvious to modify *Fioravanti* in view of *Alexander*'s explicit teaching of a job/task identifier so that weight and image information could be associated as taught by *Alexander*. Ex. 1004, ¶¶62, 65. Both *Fioravanti* and *Alexander* describe computer systems that aid the operator in preparing a medication dose more efficiently and with fewer errors. Petition, 35 (citing Ex. 1004, ¶83; Ex. 1006, 0006, Ex. 1008, 12:32-38).

Reply 18–19.

We also are not persuaded by Patent Owner's assertion that Dr. Young contradicted himself on this issue during cross examination. *See* PO Resp. 61–62 (citations omitted). Consistent with Petitioner's response, the cited statements are directed to features of individual references, and not to how one of ordinary skill would have viewed the combination. *See* Reply 17–18.

Patent Owner also argues that Dr. Young's opinions on motivation to combine are "contradicted by pre-litigation evidence coming from the Petitioner itself." PO Resp. 62–63 (citing Ex. 2003 ¶¶ 7–8).[18] This evidence refers to "*a current system* that combines information from an image verification system and a gravimetric verification system." *Id.*. (emphases

[18] Patent Owner's further reliance on prosecution history regarding the Rodgers reference merely reflects an argument that an Examiner had not properly articulated a rationale for a rejection, which Patent Owner does not establish as a contradiction. *Id.* (citing Ex. 2006, 602–603).

altered). Absent additional context and explanation, we do not find Patent Owner's argument persuasive. Nor—to the extent the statements may be inconsistent—has Patent Owner established that Petitioner's statement in an unrelated patent application estoppes it from relying on Dr. Young's testimony. *See SkyHawke Techs., LLC v. Deca Int'l Corp.,* 828 F.3d 1373, 1376 (Fed. Cir. 2016) ("[J]udicial estoppel only binds a party to a position that it advocated *and successfully achieved* . . . .") (emphasis added) (citation omitted).

Considering the evidence as whole, Petitioner has established that one of ordinary skill in the art would have been motivated to combine the teachings of Fioravanti and Alexander.

4. Claim 1: "associatively stored in the memory"

Patent Owner argues that Petitioner has not shown that either Fioravanti or Alexander teaches or suggests that weight and image data are associatively stored in the memory as required by Elements [1g]/[1h]. PO Resp. 64–67. For at least the reasons discussed above in section II(E)(1), above, we do not find this argument persuasive in light of Fioravanti alone.

With respect to Alexander, Petitioner contends that the reference teaches that a server may receive images of pharmacy work, store the received images in an image database for later access and retrieval, and that those "images may be associated with a job or task identifier that may be used by a pharmacist to reference the images for review." Pet 41–42 (citing Ex. 1008, 15:9–21, 14:6–10) (emphasis omitted). In light of the construction set forth in section II(C)(5), and on record as a whole, we also agree with Petitioner that Alexander's image data is associatively stored in an image

database. Indeed, it seems self-evident that Alexander would not store image data in a database unless that data could be associated with the preparation of a particular dose or dose order.

Patent Owner argues, however, that Alexander cannot teach "weight and image data being 'associatively stored,'" because the portion of Alexander Petitioner relies on "does not mention weight." PO Resp. 64 (citing Ex. 2010 ¶ 93). We, nevertheless, focus on what one of ordinary skill in the art would understand from the combination of references cited. In this respect, and relying on the testimony of Dr. Young, Petitioner asserts that one of ordinary skill in the art would have found it obvious to associate the weight information recorded by the Fioravanti system with the task identifier disclosed by Alexander. Pet. 42 (citing Ex. 1004 ¶¶ 62, 65). Referencing Petitioner's reliance on paragraph 65 of Dr. Young's declaration, Patent Owner responds that this portion of Dr. Young's declaration "says nothing about associative storage between weight and an image, but rather discusses storing 'the deviation between the captured weight [of a syringe or vial positioned on scale 8] and the calculated anticipated weight,'" as set forth in Fioravanti. PO Resp. 65 (quoting Ex. 1004 ¶ 65). Given that claim 1 broadly recites "wherein *a weight* . . . [is] associatively stored in the memory," we do not find the distinction persuasive. *See also* Ex. 1006, Fig. 10 (further displaying current and target weight of syringe S2); section II(E)(1), above.

5. Claims 19 and 21

Patent Owner further argues that nothing in Alexander discloses or renders obvious the elements of claims 19 and 21. PO Resp. 67. Ground 3,

however, relies on the combined teachings of Alexander and Fioravanti. Insofar as the elements of claims 19 and 21 are taught or rendered obvious by Fioravanti, as set forth in sections II(E)(2)(b) and (c), above, we do not find persuasive Patent Owner's arguments regarding any lack of additional evidence in Alexander.

6. Conclusion as to Ground 3

Patent Owner presents no additional arguments with respect to claims 2–14, 16–18, or 20 and, thus, waives and any arguments with respect to the non-disputed elements. *See* PO Resp. 68. Because a preponderance of the evidence supports Petitioner's arguments relating to the teachings of the prior art, we adopt Petitioner's arguments as our own in view of the analysis set forth with respect to Ground 2. *See* Pet. 33–48; *see also In re Nuvasive*, 841 F.3d at 974 (explaining that the Board need not make specific findings as to claim limitations that Patent Owner does not dispute are disclosed in the prior art)."

On the record as a whole, and for the reasons set forth above, Petitioner has shown by a preponderance of the evidence that claims 1–14 and 16–21 of the '273 patent are unpatentable as obvious in light of Fioravanti and Alexander.

G. Obviousness in view of Fioravanti, Alexander, and Eliuk (Ground 4)

In Ground 4, Petitioner challenges claims 1–14 and 16–21 as obvious over the combination of Fioravanti, Alexander, and Eliuk. Pet. 49–62. In support, Petitioner provides rationale to combine the teachings of Fioravanti, Alexander, and Eliuk (*id.* at 51–52) and a detailed claim chart mapping the

teachings of the asserted references to the challenged claims (*id*. at 52–62). Patent Owner opposes. PO Resp. 68–69; Sur-reply 22–26.

We have reviewed the evidence of record including the Petition and Petitioner's experts' declarations, and Patent Owner's arguments and evidence, including its experts' declarations. We are persuaded that Petitioner has shown by a preponderance of the evidence that claims 1–14 and 16–21 are unpatentable as obvious over Fioravanti, Alexander, and Eliuk. The teachings of Fioravanti and Alexander have been discussed above. Below, we present an overview of Eliuk and address the parties' contentions.

1. Overview of Eliuk (Exhibit 1009)

Eliuk discloses "an automated Pharmacy Admixture System (APAS)… [that] transport[s] medical containers such as bags, vials, or syringes in a compounding chamber . . . . embodiments may include a controller adapted to actuate the manipulator system to bring a fill port of an IV bag, vial, or syringe into register with a filling port at a fluid transfer station in the chamber." Ex. 1009 at Abstract. A "drug order record in the APAS database 4340 may be associated with images of the drugs and/or diluent used to process the drug order as well as images of the final order in

its delivery container." *Id.* at 49:39–42. Accordingly, the APAS may include a vial ID station, as illustrated in Figure 50, reproduced below.

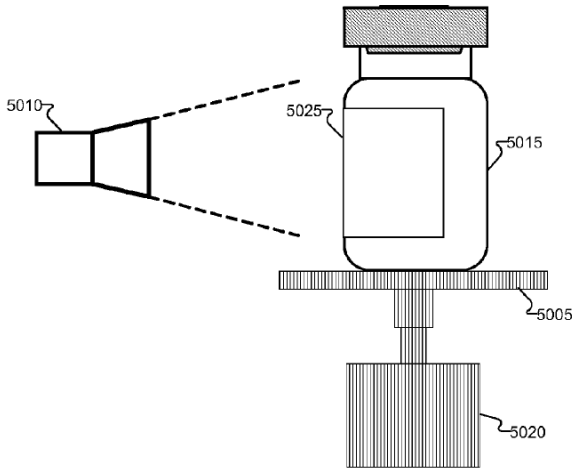


Figure 50 shows a vial ID station with camera system 5010, which is used to take images of vial 5015 (including label 5025) positioned on rotating platform 5005. *Id.* at 66:13–22.

> [P]attern matching software checks each image for matches of the key label fields[, e.g., "the drug name, the drug manufacturer, and/or the drug code (e.g., NDC or DIN)"]. . . . [A]t least two unique patterns per label may be used to identify a medical container (e.g., vial, syringe, IV bag). The APAS cell may store images of the vial ensuring that the key fields are captured, as well as the vial's lot number and expiration date. The software can then create logical links to associate the images and the drug orders that used the vial.

*Id.* at 66:13–42. Once a vial has been verified through image capture, it is transported to a scale "where it can be weighed and the vial's weight can be compared to the expected weight for that vial." *Id.* at 66:57–62; *see also id.* at 9:60–10:5 ("[T]he IV bag is identified by bar code or pattern matching and its weight is recorded. . . . [I]t may be weighed multiple times, such as before, during, and/or after each fluid transfer step . . . to determine if the

change in weight is within an expected range.").

> [A] drug order record for each drug order . . . may be stored in the APAS database 4340. Each drug order record may be associated with . . . a unique dose *ID*. . . . Each dose ID may be associated with process measurements, such as measurements of weights at different processing stages, captured images (e.g., bitmap, .gif, .jpeg, or .mpeg video clips) . . . .

*Id*. at 49:5–32.

2. Motivation to Combine

Petitioner relies on Dr. Young's testimony that it would have been obvious to a person of ordinary skill in the art to combine the teachings of Eliuk with Fioravanti and/or Alexander. Pet. 51, 56 (citing Ex. 1004 ¶¶ 77, 86). According to Dr. Young, "[l]ike Fioravanti and Alexander, Eliuk teaches a system for compounding and preparing pharmaceutical doses and relies on image captures and weight measurements to ensure the correct medication dose is prepared." Ex. 1004 ¶ 86 (citing Ex. 1009, 66:13–62). Dr. Young testifies that Eliuk "notes the importance of providing error checks to ensure the correct medication and doses are being used," and "is directed to automating functions traditionally performed by pharmacy staff." *Id*. (citing 9:62–64). Dr. Young reasons that a person of ordinary skill in the art would have recognized that "the teachings and benefits in automatically preparing and compounding medications would equally apply to systems directed to the manual preparation of medications, particularly those that rely on computer technology in assisting during the preparation process as a means to reduce errors," and "[c]ombining Eliuk's teachings with the system of Fioravanti and Alexander would have further enhanced the workflow for

medical dose preparation and furthered the common goals of all three systems" because it "would provide complementary technologies that provide a more complete system and allow the capability of additional pharmacy functions in an improved way." *Id.* Dr. Young concludes that, for the same reasons that it would have been obvious to combine the Alexander and Fioravanti systems, a person of ordinary skill in the art would have been motivated, and found it obvious, to combine Eliuk with either or both of the Alexander and Fioravanti systems. *Id.*

Patent Owner argues that, "[o]ther than to simply recap Eliuk's teachings, Dr. Young provides no rationale for [his] conclusion." PO Resp. 68. According to Patent Owner, Dr. Young's testifies that "instead of combining the systems into one machine, they would instead be *separately* used in the same pharmacy, thus failing to accomplish the goal of the invention of the '273 Patent." *Id.* (citing Ex. 2021, 224:16–21). Patent Owner also argues, "given that both *Fioravanti* and *Eliuk* teach taking weight measurements, there is no good reason to conclude, without further explanation, that one would have thought to combine the teachings of those two references." *Id.* at 69. Moreover, "[a]utomation such as taught in *Eliuk* would decrease, rather than increase, the need for associatively stored data to be used for verification purposes." *Id.* at 70 (citing Ex. 2008 ¶¶ 107–109).

As we understand its position, Patent Owner appears to assert that it is "especially problematic" that Dr. Young does not explain specifically how the automated system taught by Eliuk would have enhanced or complemented the systems of Fioravanti and Alexander because "[b]enefits from automation . . . do not translate into the claimed associative storage of

weight and image data" and "[i]t is counterintuitive that combining the automation of Eliuk with Fioravanti and Alexander would have somehow resulted in associative storage of weight and image data." *Id.* at 69–70.

Patent Owner's arguments are not persuasive. To the contrary, Dr. Young's rationale for combining the teachings of Fioravanti, Alexander, and Eliuk is supported by rational underpinnings. As discussed above, Fioravanti teaches that it is desirable to store in real-time weight and associated dose preparation images but does not explicitly teach this information should be stored for later retrieval and review. Alexander teaches that it is desirable for dose preparation images and related dose preparation data to be associatively stored for later retrieval and review, but does not explicitly state that related dose preparation data includes weight. Eliuk discloses that it is desirable to associatively store weight, dose preparation image, and related dose preparation data. We agree with Dr. Young that, taking these teachings together, it would have been obvious to a person of ordinary skill in the art to use the teachings of Eliuk to modify Fioravanti and/or Alexander so that the weight and the medical dose preparation image are associatively stored in the memory, as recited in claim 1. Ex. 1004. ¶¶ 85, 90.

Patent Owner further argues that Eliuk is not combinable with Fioravanti and Alexander because Dr. Young admitted on cross-examination that in combination, Eliuk's system would be used separately. PO Resp. 68; Sur-reply 22 (citing Ex. 2021, 224:16–21). We do not find the cited passage sufficiently clear to justify discounting Dr. Young's declaration testimony. Moreover, to the extent Patent Owner's interpretation is correct

> [t]o justify combining reference teachings in support of a rejection it is not necessary that a device shown in one reference can be physically inserted into the device shown in the other. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art."

*In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (citations omitted).

In sum, Dr. Young provided a detailed rationale with rational underpinnings for combining the teachings of Fioravanti, Alexander, and Eliuk. We agree with Dr. Young that, taking the teachings of Fioravanti, Alexander, and Eliuk together, it would have been obvious to a person of ordinary skill in the art to use the teachings of Eliuk to modify Fioravanti and/or Alexander so that the weight and the medical dose preparation image are associatively stored in the memory, as recited in Elements [g]/[1h].

3. Claim 1: "associatively stored in the memory"

For Ground 4, Patent Owner specifically addresses only Petitioner's contentions with respect to claim 1. *See* PO Resp. 70 ("Because claim 1 is not rendered obvious by this prior art combination, the claims depending from that claim are also not obvious in view of these references."). As set forth in section II(E)(1), above, Petitioner reasonably relies on Fioravanti for the associatively stored in memory limitation of Elements [1g]/[1h]. Although not necessary to our finding that claim 1 is obvious under this ground, we further find that Petitioner's reliance on Eliuk provides additional support for the obviousness of Elements [1g]/[1h] and, in fact,

expressly discloses at least some elements of the associative storage limitation.

The Petition expressly relies on Eliuk in support of the obviousness of Elements [1g]/[1h]. Pet. 55–56 (citing Ex. 1009, 49:5–10, 25–32). As quoted in part at page 35 of our Institution Decision, the relied-upon portion of Eliuk states:

> [A] drug order record for each drug order… may be stored in the APAS database 4340. Each drug order record may be associated with . . . a unique dose *ID*. . . . Each dose ID may be associated with process measurements, such as measurements of weights at different processing stages, captured images (e.g., bitmap, .gif, .jpeg, or .mpeg video clips).

*Id*. (quoting Ex. 1009, 49:5–32). Petitioner argued that one of ordinary skill in the art would have found it obvious "to associate the weight information recorded by the Fioravanti system with the dose ID disclosed by Eliuk." Pet. 56 (citing Ex. 1004 ¶ 77). Having determined, above, that one of ordinary skill in the art would have been motivated to combine Eliuk with Fioravanti and Alexander, we find Petitioner's position reasonable.

In the Reply, Petitioner takes the further position that "*Eliuk* provides an explicit disclosure of associative storage recited in the claims." Reply 21; *see id*. at 22–23 ("*Eliuk* provides an explicit disclosure of associative storage and explicitly says that this associative storage is weight and medical dose preparation images, just as recited in the claims"). Patent Owner contends that we should ignore Petitioner's argument that Eliuk itself discloses the "associatively stored" limitation because "Petitioner never argued, and the Board never considered" this argument in the Petition. Sur-reply 22. While we agree with Patent Owner that this argument was not expressly set forth in

the Petition, Patent Owner responded to this argument on the merits. *See* Sur-reply 24–26; Tr. 109:10–110:4. Having considered Patent Owner's counter arguments, we agree with Petitioner that, at a minimum, the plain language of Eliuk cited above teaches "weight and a medical dose preparation image of at least one medication receptacle . . . associatively stored in the memory," as required by claim 1.

4. Conclusion as to Ground 4

Patent Owner presents no additional arguments with respect to claims 2–14 and 16–21 and, thus, waives and any arguments with respect to the non-disputed elements. *See* PO Resp. 70. Because a preponderance of the evidence supports Petitioner's arguments relating to the teachings of the prior art, we adopt Petitioner's arguments as our own in view of the analysis set forth with respect to Grounds 2 and 3. *See* Pet. 49–62; *see also In re Nuvasive*, 841 F.3d at 974 (explaining that the Board need not make specific findings as to claim limitations that Patent Owner does not dispute are disclosed in the prior art)."

On the record as a whole, and for the reasons set forth above, Petitioner has shown by a preponderance of the evidence that claims 1–14 and 16–21 of the '273 patent are unpatentable as obvious in light of the combined teachings of Fioravanti, Alexander, and Eliuk.

H. Obviousness in view of Fioravanti, Alexander, Eliuk, with Claypool or Bear (Grounds 5 and 6)

In Ground 5, Petitioner challenges claim 2 as obvious over the combination of Fioravanti, Alexander, Eliuk, and Claypool. Pet. 62–65. In support, Petitioner provides a rationale to combine the teachings of

Fioravanti, Alexander, Eliuk, and Claypool and a detailed claim chart mapping the teachings of the asserted references to the challenged claims. *Id*. at 63–65

In Ground 6, Petitioner challenges claims 13–15 as obvious over the combination of Fioravanti, Alexander, Eliuk, and Bear. *Id*. at 65–70. In support, Petitioner provides rationale to combine the teachings of Fioravanti, Alexander, Eliuk, and Claypool and a detailed claim chart mapping the teachings of the asserted references to the challenged claims. *Id*. at 66–70.

1. Overview of Claypool (Ex. 1012)

Claypool is titled "Digital Scale with Detachable Platform." Ex. 1012, code (54). Claypool's "digital scale 20 has a number of components integrated within an instrumentation unit or housing 22 to perform a number of weight measurement and other functions in connection with a load applied to a platform assembly 24" (*id*. ¶ 30) because "it may be useful at times to disengage the platform 168 for cleaning, maintenance, replacement, etc., . . . the platform 168 is configured to releasably engage one or more components of the instrumentation unit 154." *Id*. ¶ 72.

2. Overview of Bear (Ex. 1010)

Bear is titled "Medication Dispenser With Integrated Monitoring System." Ex. 1011, code (54). Bear is directed to devices, systems, and methods for remote visualization of the storage compartments in a medication dispenser device, to monitor a patient's compliance with a medication dosage schedule and for verifying the proper loading of medication into the patient's medication dispenser device. *Id*. at code (57).

Bear's medical dispenser includes "a plurality of storage compartments, wherein each storage compartment has an interior space for storing at least one medication" and "an image capturing device positionable to capture an image of the interior space of each of the plurality of storage compartments." *Id.* ¶ 9. "[E]ach storage compartment may be selectively lighted (e.g., by an LED 328) to provide illumination for digital visual image capture . . . ." *Id.* ¶ 24. It also includes "a communication module for electronically transmitting the image captured by the image capturing device to a central monitoring station," which "can provide verification that appropriate medications have been loaded in the dispenser, removed from the dispenser, and/or remain loaded in the dispenser." *Id.* ¶¶ 6, 18.

5. Analysis and Conclusion with respect to Grounds 5 and 6

Petitioner reasonably relies on Claypool as disclosing a "support platform . . . removably disposed relative to the base" as recited in claim 2. Pet. 64–65. Petitioner reasonably relies on Bear with respect to the "light source" limitations of claims 13–15. *Id.* at 67–70. Other than for the reasons presented in Grounds 1–4, Patent Owner does not contest the contentions supporting Grounds 5 and 6. PO Resp. 70 (arguing that "for the reasons discussed above, claim 1 [from which claims 2 and 13–15 depend] is not invalid [and] these challenge[d] grounds must fail").

Patent Owner presents no additional arguments with respect to claims 2 and 13–15 as challenged under Grounds 5 and 6 and, thus, waives and any new arguments with respect to these grounds. *See* PO Resp. 70. Because a preponderance of the evidence supports Petitioner's arguments relating to the teachings of the prior art, we adopt Petitioner's arguments as our own in

view of the analysis set forth with respect to Grounds 2–4. *See* Pet. 62–65; *see also In re Nuvasive*, 841 F.3d at 974 (explaining that the Board need not make specific findings as to claim limitations that Patent Owner does not dispute are disclosed in the prior art)."

On the record as a whole, and for the reasons set forth above, Petitioner has shown by a preponderance of the evidence that claim 2 of the '273 patent is unpatentable as obvious in light of the combined teachings of Fioravanti, Alexander, Eliuk, and Claypool, and that claims 13–15 are obvious over the combination of Fioravanti, Alexander, Eliuk, and Bear.

## III. PATENT OWNER'S CONTINGENT MOTION TO AMEND

Pursuant to 35 U.S.C. § 316(d)(1) and 37 C.F.R. § 42.121(a), Patent Owner contingently moved to replace claims 1–21 of the '273 patent with a first set of proposed substitute claims 22–42. Mot. Subsequent to our Preliminary Guidance regarding those claims, Patent Owner submitted a Revised Motion to Amend, seeking to replace claims 1–21 of the '273 patent with a second set of proposed substitute claims 22–42,[19] contingent on our determination as to whether a preponderance of the evidence establishes that claims 1–21 of the '273 patent are unpatentable. Rev. Mot. As discussed in detail above, Petitioner has shown by a preponderance of the evidence that

[19] Patent Owner repeatedly refers to claim 43 in the text of its Revised Motion (Rev. Mot. 8–9, 22–23), but provides text and support for only proposed claims 22–42 (*id.* at 4–6, A12–A52), and states that proposed claim 42 is cancelled (*id.* at A12). Presuming that the cancellation of proposed claim 42 is a typographical error, we address proposed claims 22–42, as does Petitioner. *See, e.g.*, Opp. Rev. Mot. 9.

original claims 1–21 of the '273 patent are unpatentable as obvious under one or more of Grounds 2–6. Accordingly, we address Patent Owner's Revised Motion to Amend.

A. Applicable Law

In an *inter partes* review, amended claims are not added to a patent as of right, but rather must be proposed as a part of a motion to amend. 35 U.S.C. § 316(d). The Board must assess the patentability of proposed substitute claims "without placing the burden of persuasion on the patent owner." *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1328 (Fed. Cir. 2017) (en banc); *see also Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 3–4 (PTAB Feb. 25, 2019) (precedential). Subsequent to the issuance of *Aqua Products*, the Federal Circuit issued a decision in *Bosch Automotive Service Solutions, LLC v. Matal*, 878 F.3d 1027 (Fed. Cir. 2017) ("*Bosch*"), as well as a follow-up order amending that decision on rehearing. *See Bosch Auto. Serv. Sols., LLC v. Iancu*, No. 2015-1928 (Fed. Cir. Mar. 15, 2018) (Order on Petition for Panel Rehearing).

In accordance with *Aqua Products*, *Bosch*, and *Lectrosonics*, Patent Owner does not bear the burden of persuasion to demonstrate the patentability of the substitute claims presented in the motion to amend. Rather, ordinarily, "the petitioner bears the burden of proving that the proposed amended claims are unpatentable by a preponderance of the evidence." *Bosch*, 878 F.3d at 1040 (as amended on rehearing); *Lectrosonics,* Paper 15 at 3–4. In determining whether a petitioner has proven unpatentability of the substitute claims, the Board focuses on

"arguments and theories raised by the petitioner in its petition or opposition to the motion to amend." *Nike, Inc. v. Adidas AG*, 955 F.d 45, 51 (Fed. Cir. 2020). The Board itself also may justify any finding of unpatentability by reference to evidence of record in the proceeding. *Lectrosonics*, Paper 15 at 4 (citing *Aqua Products*, 872 F.3d at 1311 (O'Malley, J.)). "Thus, the Board determines whether substitute claims are unpatentable by a preponderance of the evidence based on the entirety of the record, including any opposition made by the petitioner." *Id.*

Notwithstanding the foregoing, Patent Owner's proposed substitute claims 22–42 must meet the statutory requirements of 35 U.S.C. § 316(d) and the procedural requirements of 37 C.F.R. § 42.121. *Lectrosonics*, Paper 15 at 4–8. Accordingly, Patent Owner must demonstrate: (1) the amendment proposes a reasonable number of substitute claims; (2) the amendment responds to a ground of unpatentability involved in the trial, (3) the proposed claims are supported in the original disclosure (and any earlier filed disclosure for which the benefit of filing date is sought); and (4) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter. *See* 35 U.S.C. § 316(d); 37 C.F.R. § 42.121.

B. Proposed Substitute Claims

Patent Owner's proposed substitute claims 23 and 25–42 are not substantively different from the claims they seek to replace. *See* Rev. Mot., Appendix A. Accordingly, we focus on substitute claims 22 and 24, which replace original claims 1 and 3, respectively. Proposed substitute claims 22 and 24 are reproduced below with bracketing indicating text deleted, and

underlining indicating text added, as compared to original claims 1 and 3, respectively.

22. A work station for use in a system for medical dose preparation management, the work station comprising:

a base having a support platform to support at least one medication receptacle within a medication preparation staging region, and a scale operable to output weight data corresponding to at least one medication receptacle supported on the support platform within the medication preparation staging region;

an imaging device having an imaging field encompassing at least a portion of the medication preparation staging region, wherein the imaging device is operable to output image data of at least one medication receptacle supported on the support platform within the medication preparation staging region;

a processor in operative communication with the scale to receive the weight data, and in operative communication with the imaging device to receive the image data; and,

a memory in operative communication with the processor, wherein a weight and a medical dose preparation image of at least one medication receptacle supported on the support platform within the medication preparation staging region are associatively stored in the memory; and,

wherein said memory is capable of associatively storing said weight and said medical dose preparation image corresponding to a medication dose order at least until administration of a medication dose corresponding to the medication dose order.

24. A work station according to claim [[1]]22, wherein the imaging device is operable to capture at least one of still digital images and a video data stream; and,

wherein said weight and said medical dose preparation image are displayed remotely for review and verification.

C. Statutory and Regulatory Requirements

"Before considering the patentability of any substitute claims, . . . the Board first must determine whether the motion to amend meets the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121." *Lectrosonics*, Paper 15, at 4–8.

1. Claim Listing

The motion to amend includes a claim listing, as required by 37 C.F.R. § 42.121(b). Rev. Mot. 4, Appendix A; *Lectrosonics*, Paper 15 at 8.

2. Claim Listing

The motion to amend includes a claim listing, as required by 37 C.F.R. § 42.121(b). Rev. Mot. 4, Appendix A; *Lectrosonics* at 8.

3. Reasonable Number of Substitute Claims

"There is a rebuttable presumption that a reasonable number of substitute claims per challenged claim is one (1) substitute claim." *Lectrosonics*, Paper 15 at 4–5 (citing 37 C.F.R. § 42.121(a)(3)). The Petition challenges 21 claims, and the Revised Motion to Amend proposes one substitute claim for each challenged claim. Rev. Mot. 1. We determine that the number of proposed claims is reasonable.

4. Respond to Ground of Unpatentability

We next consider whether the proposed substitute claims respond to a ground of unpatentability involved in this trial. *Lectrosonics*, Paper 15 at 5–6. Patent Owner argues the motion to amend is responsive to the instituted grounds insofar as the language underlined in claims 22 and 24, above,

responds to our assessment that original claim 1 "places no restriction on the type, duration, or location of the 'memory in operative communication with the processor.'" Rev. Mot. 1–2 (quoting Inst. Dec. 15–16, n.9). Patent Owner also highlights the added limitations in asserting that the proposed substitute claims are patentable over the references in the instituted grounds. *See id*. at 13–25.

Petitioner argues substitute claims 22–42 are improper for failing to further limit the issued apparatus claims, which we understand to mean the amendment does not respond to a ground of unpatentability. *See* Opp. Rev. Mot. 2–3. The proposed substitute claims differ from the issued claims of the '273 patent by requiring, via substitute claim 22 from which all subsequent claims depend, that the "memory is capable of associatively storing said weight and said medical dose preparation image corresponding to a medication dose order at least until administration of a medication dose corresponding to the medication dose order." *Compare* Rev. Mot. A1 (issued claim 1), *with id*. at A6–A7 (proposed substitute claim 22). Petitioner contends that the "capable of" language of proposed claim 22 merely requires the ability to do something and not that such thing has to be performed. Opp. Rev. Mot. 2 (citing Ex. 1026). Petitioner further argues that, because all memories are inherently "capable of" storing data for any desired duration, "capable of" fails to limit the claimed apparatus. *Id*. at 2–3.

Although we agree with Petitioner that the "capable of" limitation means that the apparatus need only have the ability to perform the subsequent 'associatively storing' limitation, we do not agree that the

substitute claims are improper for failing to further limit the issued apparatus claims. Functional limitations in an apparatus claim are interpreted as requiring the claimed apparatus to possess the capability of performing the recited functions. *See In re Schreiber*, 128 F.3d 1473, 1478–79 (Fed. Cir. 1997). Here, the proposed amendment further limits the apparatus in that the claimed memory must possess the capability "of associatively storing said weight and said medical dose preparation image corresponding to a medication dose order at least until administration of a medication dose corresponding to the medication dose order." Petitioner has not established that this is an inherent property of all memory. Nor has Petitioner argued that the proposed limitation of claim 24, "wherein said weight and said medical dose preparation image are displayed remotely for review and verification," fails to further limit the apparatus.

In light of the above, we determine that the amended language in the proposed substitute claims is responsive to the grounds of unpatentability involved in this trial.

5. Scope of Amended Claims

"A motion to amend may not present substitute claims that enlarge the scope of the claims of the challenged patent." *Lectrosonics,* Paper 15 at 6–7 (citing 35 U.S.C. § 316(d)(3); 37 C.F.R. § 41.121(a)(2)(ii)). Patent Owner argues that "[s]ubstitute claims 22 and 24 retain all the features of corresponding original claims 1 and 3 and are narrowing because they clarify that the weight and medical dose preparation image must be associatively stored in the memory at least until administration," whereas the amendments to substitute claims 23 and 25–43 merely address the

dependency from independent claim 22. Rev. Mot. 2. Petitioner does not argue that the proposed amendments enlarge claim scope.

We determine that the limitations added to proposed claims 22–43 do not enlarge the scope of the original claims.

6. New Matter/Written Description

"A motion to amend may not present substitute claims that . . . introduce new subject matter." *Lectrosonics*, Paper 15 at 6–7 (citing 35 U.S.C. § 316(d)(3); 37 C.F.R. § 41.121(a)(2)(ii)). Accordingly, "the Board requires that a motion to amend set forth written description support in the originally filed disclosure of the subject patent for each proposed substitute claim, and also set forth support in an earlier filed disclosure for each claim for which benefit of the filing date of the earlier filed disclosure is sought." *Id.* at 7 (citing 37 C.F.R. § 42.121(b)(1)–(2)). For this requirement, Patent Owner must cite "to the original disclosure of the application, as filed, rather than to the patent as issued." *Id.* at 8.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to a person of ordinary skill in the art that the inventor had possession of the claimed subject matter at the time of filing, rather than the presence or absence of literal support in the specification for the claim language. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983).

The '273 patent claims benefit of priority to at least U.S. Provisional Patent Application No. 61/719,256 ("the '256 application"), filed on October

26, 2012 (*see* Ex. 2012); U.S. Patent Application No. 14/696,175, which issued as U.S. Patent No. 9,474,693 on October 25, 2016; U.S. Patent Application No. 15/289,343, which issued as the '273 patent on May 30, 2017. *See* Ex. 1001, code (21), (63). Patent Owner points to support for the proposed substitute claims in the original disclosure of the '273 patent, the original disclosure of the '693 patent, and the '256 application. Rev. Mot. 4–9, A12–52.

Petitioner sets forth a number of arguments for why the proposed amendments lack written description support. *See* Opp. Rev. Mot. 2–9; Rev. Mot. Sur-reply 1–8. Bearing directly on whether proposed claim 22 is adequately described, the parties disagree on the meaning we should ascribe to "associatively storing" in the proposed claim language:

> wherein said memory is capable of associatively storing said weight and said medical dose preparation image corresponding to a medication dose order at least until administration of a medication dose corresponding to the medication dose order.

At core, the issue is whether "associatively storing" refers to the *process* of storing data in memory, or to the static *arrangement* of data in the memory.

Petitioner takes the position that "memory . . . capable of associatively storing" the recited data should be read as "self-managed memory" having the capability of "associatively stor[ing] the weight and the medical dose preparation image, independent of a control subsystem or any 'discrete programming.'" Opp. Rev. Mot. 3 (citing Guidance 5–6).[20] Petitioner notes

[20] For the reasons set forth at pages 5 and 6 of our Preliminary Guidance, we determined that similar language lacking the "capable of" limitation was "directed to a self-managed memory, which lacks written description

that even "PO's expert explained that there is no such thing as a self-managed memory because discreet programming steps are required to manage memories in combination with a memory control sub-system" (*id.* (citing Ex. 1017, 39:20–40:4, 40:17–41:3), and though substitute claim 22 recites a processor, "the processor does not participate in memory management, storage timing, or data acquisition." *See id.* at 4. Applying this interpretation, Petitioner argues that "[t]here is no description of how the claimed *memory* would itself manage the claimed capability." *Id.*

In contrast, Patent Owner focuses not on the act of "memory . . . associatively storing" weight and image data, but on the relationship between such data when it is stored in the memory, specifically, that the memory is capable of storing weight and image data "*in relationship to one another*." Rev. Mot. 10 (citing Ex. 1001, 2:45–52, 10:52–55, 11:20–22, 60–63, 13:35–41, 47–53, 62–65; Ex. 2010 ¶ 29).

The portions of the '273 patent Specification cited by Patent Owner disclose that medical dose preparation images may be stored locally in the workstation memory, which is in operative communication with the processor. *Id.*; *see also id.* at A23 (citing Ex. 1002, 27 (file history of the '273 patent); Rev. Mot. Sur-reply 4–5 (citing Ex. 1001, 7:57–60 ("a memory in operative communication with the processor" is responsible for "storing the weight and the medical dose preparation image"); 15:66–16:2 ("the video data stream processing module 72 may be stored in a memory 120 in operative communication with the processor 70"), 24:32–34 ("[t]he

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support in the '273 patent Specification."

processor 70 at the work station 40 may associatively store the anticipated weight and the measured weight")). Further, the medical dose preparation images may be communicated to a remote location by way of a network interface in operative communication with the processor, such that the images may be reviewed and verified. Rev. Mot. 7–8, A23 (citing Ex. 1001, 16:2–15; Ex. 1002, 38). Thus, the '273 patent Specification discloses that the processor, not the memory, stores data to the memory and controls access to the data stored in the memory. We, therefore, agree with Petitioner that the proposed limitation, as currently written, is directed to a "self-managed" memory, which lacks written description support in the '273 patent Specification.

For these reasons, and considering the entirety of the record, we find by a preponderance of the evidence that Patent Owner's proposed substitute claim 22 does not find adequate support in the original disclosure of the patent for proposed substitute claim 22. Depending from that claim, claims 23–42 suffer the same infirmity. Accordingly, we deny Patent Owner's Revised Contingent Motion to Amend for lack of sufficient written description/new matter.[21]

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[21] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related

Having addressed the statutory and regulatory requirements, we consider whether Petitioner has shown that the proposed amended claims are unpatentable as non-enabled and/or unpatentable over the prior art of record in this proceeding.

D. Enablement

We next address Petitioner's contention that the Revised Contingent Motion to Amend fails for lack of enablement. *See* Opp. Rev. Mot. 4–5. As with our new matter/written description analysis, we expressly apply the construction of Elements [1g]/[1h] set forth in section II(C)(5), above.

"The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). "[A] patent specification complies with the statute even if a 'reasonable' amount of routine experimentation is required in order to practice a claimed invention." *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999). Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

In parallel with its written description argument, Petitioner argues a person of ordinary skill in the art "would not have been enabled to make and use an invention reciting a self-managing memory," because the

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matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2) (2019).

Specification fails to describe a "memory subsystem or processor including the 'discrete programming' steps Dr. Stevenson testifies as being necessary." Opp. Rev. Mot. 4–5; *see* Rev. Mot. Reply 6 ("Petitioner essentially repeats its written description challenge regarding a self-managing memory."). Patent Owner sets forth no specific rebuttal, merely asserting that the enablement challenge should fail "for the same reasons as with written description.´ Rev. Mot. Reply 6. Patent Owner has, thus, waived any argument specific to enablement. Accordingly, and for essentially the reasons set forth above with respect to written description, we agree with Petitioner that one of ordinary skill "would not have been able to make and use an invention reciting a self-managing memory that "is capable of associatively storing said weight and said medical dose preparation image corresponding to a medication dose order at least until administration of a medication dose corresponding to the medication dose order," as required by proposed independent claim 22 and its dependent claims. *See also In re Nuvasive*, 841 F.3d at 974 (explaining that the Board need not make specific findings as to claim limitations that Patent Owner does not dispute are disclosed in the prior art)."

In light of the above, we further deny Patent Owner's Revised Contingent Motion to Amend for lack of enablement under 35 U.S.C. § 112 ¶ 1.

E. Patentability Over the Prior Art of Record

Having considered the record as a whole, we discern in the proposed amendments little or no patentable distinction as compared to the claims

they are intended to replace. Accordingly, our analysis and conclusions are substantially similar to that set forth in sections II(D)–(H), which we adopt with respect to all limitations not substantially the same as those of the originally challenged claims. The discussion below addresses the newly-added limitations of claims 22 and 24.

1. Anticipation in view of Fioravanti

Petitioner contends that claims 22–42 are anticipated by Fioravanti. Opp. Rev. Mot. 11–18. Among the proposed substitute claims, the sole independent claim, claim 22, recites that the memory in operative communication with the processor "is capable of associatively storing said weight and said medical dose preparation image corresponding to a medication dose order at least until administration of a medication dose corresponding to the medication dose order." Petitioner contends that Fioravanti discloses "the memory device 15 having a database storing medical prescriptions for each drug, sample images for various syringes and vials, and sample images of syringe-spike configurations." *Id.* at 16–17. According to Petitioner, "FIG. 10 [depicts] an interface with the current weight and a current camera image obtained from a gravimetric control system and from a camera," and a person of ordinary skill in the art would understand Fioravanti's "disclosure of memory, storing the database in the memory, storing sample images in the memory, and displaying the weight and image data to mean that the *Fioravanti* memory is capable of associatively storing weight and image data for a period of time." *Id.* at 17 (citing Ex. 1025 ¶¶ 14, 18, 22).

As discussed above with respect to Ground 1, Fioravanti discloses that the processor captures the weight and dose preparation images at substantially the same time in memory so they can be displayed in real-time, for example, on the display shown in Figures 3–10 of Fioravanti (*see* Ex. 1006, Figs. 2, 10), but does not explicitly disclose that these weight and images are associatively stored in memory so that they can be retrieved and reviewed at later time. Petitioner does not identify any explicit teaching in Fioravanti alone that any image or video from cameras 9 and 10, including the real-time images displayed in Figures 3–10, are stored for later retrieval and review. Pet. 13–29; Reply 8–12.

Because claim 22 is not anticipated by Fioravanti, depending claims 23–42 cannot be anticipated by Fioravanti.

2. Obviousness in view of Fioravanti

Petitioner contends that claims 22–42 are unpatentable as obvious over Fioravanti alone. Opp. Rev. Mot. 18–23.

As an initial matter, Petitioner does not argue that claims 22–42 are obvious under our construction that independent claim 22 requires a self-managed memory. We, nonetheless, address obviousness under the presumption that Patent Owner *intended* claim 22 to recite that *a processor* in operative communication with a memory *associatively stores* the weight and medical dose preparation image corresponding to a medication dose order. Under such a construction, proposed independent claim 22 and its dependent claims would remain obvious over Fioravanti alone.

As discussed above in Ground 2, we agree with Petitioner that, to the extent that Fioravanti does not explicitly teach associatively storing a

captured image and weight measurement of a syringe or vial, it would have been obvious from Fioravanti's teaching to store these pieces of information together as part of the database record for a medication dose order. *See* section II(E)(1), above. We agree with Dr. Young that it would have been obvious to a person of ordinary skill in the art to store data for a particular medication receptacle (e.g., a vial or syringe) in memory so that the processor can match that data to the medication receptacle or relevant dose order for a duration sufficient to allow for remote access and verification, i.e., beyond local real time display. *Id.*

Patent Owner argues that Fioravanti's memory does not store images and weight. Rev. Mot. Reply 8–9. For the reasons discussed in Ground 2, Patent Owner's argument is not persuasive. Fioravanti discloses that the processor captures the weight and dose preparation images at substantially the same time in memory so they can be displayed in real-time, for example, on the display shown in Figures 3–10 of Fioravanti. *See* Ex. 1006, Figs. 2, 10.

Depending from claim 22, claim 24 newly recites that "said weight and said medical dose preparation image are displayed remotely for review and verification." Petitioner contends, and we agree, that Fioravanti discloses "a monitoring system 18 that allows for remote monitoring from a computer 33 connected to a data communication network 32," and "[u]sing the computer, remote monitoring of the workstation 30, and/or viewing of the film regarding preparation of a given liquid pharmaceutical composition; and/or monitoring in real time of the state of advance of the preparation of said composition" is possible." Opp. Rev. Mot. 18 (citing Ex. 1006 ¶¶ 32–

34 (monitoring system 18 enables viewing from a remote-surveillance station; Ex. 1025 ¶¶ 14, 18, 22).

Thus, Petitioner has shown that claims 22–42, including the amended limitations, are obvious over Fioravanti.

3. Obviousness—Fioravanti and Alexander

Petitioner contends that claims 22–42 are unpatentable as obvious over Fioravanti and Alexander. Opp. Rev. Mot. 23–24.

As discussed above in Ground 3, Alexander's server 700 associatively stores images of pharmacy work for later access in an image database with a job/task identifier. Ex. 1008, 15:9-21, 14:6-10; Pet., 40; Ex. 1004 ¶¶ 59, 64. Although Alexander does not explicitly address storing weight data, Petitioner contends, and for the reasons discussed in sections II(F)(3) and (4), above, we agree, that it would have been obvious to a person of ordinary skill in the art "to associate the weight information recorded by the Fioravanti system with the task identifier disclosed by Alexander." Pet. 42 (citing Ex. 1004 ¶¶ 62, 65). In this respect, we credit Dr. Young's testimony that one of ordinary skill in the art would have considered such an association useful in providing a record for later reference or verification, for example, if an adverse event occurs after the dose has been administered. Ex. 1002 ¶ 65.

Petitioner further argues that that a person of ordinary skill in the art would have found it obvious "to modify the *Fioravanti* system with the teachings of *Alexander* regarding *how* a specific image may be associated with other information to permit later access and processing," and "*Alexander*'s job/task identifier, in addition to providing a reference for a

pharmacist to review the images, could be used to reference other data corresponding to the same job or task." Opp. Rev. Mot. 23–24. For the reasons identified in the Petition, we find Petitioner's argument persuasive. *See Id*. (citing Pet., 40; Ex. 1004 ¶¶ 59, 64; Ex. 2021, 146:7–12 ("[O]ne purpose … would be to record the person doing the work for the record, retrospectively if you needed to go back and see who performed it, like an error had occurred."), 177:5–10 ("[T]he person involved, their image, all the recognition. So when you want to go through this record . . . the metadata is everything they did and all the little data points is what you're looking at.").

Thus, the combined teachings of Fioravanti and Alexander teach or suggest that "said memory is capable of associatively storing said weight and said medical dose preparation image corresponding to a medication dose order at least until administration of a medication dose corresponding to the medication dose order," as recited in claim 22.

As to claim 24, and as discussed above, Fioravanti discloses the limitations in claim 24.

Thus, Petitioner has shown that claims 22–42, including the amended limitations, are obvious over Fioravanti and Alexander.

4. Obviousness *in view of Fioravanti, Alexander, and Eliuk*

Petitioner contends that claims 22–42 are unpatentable as obvious over Fioravanti, Alexander, and Eliuk. Opp. Rev. Mot. 24–25.

As discussed above in Ground 4, Eliuk explicitly describes association of weight information and captured images using a dose *ID*. Ex. 1009, 49:5–32 ("[A] drug order record for each drug order . . . may be stored in the APAS database 4340 . . . [e]ach dose ID may be *associated* with process

measurements, such as *measurements of weights at different processing stages*, *captured images . . . expected and actual image data*.") (emphases added); *see* Opp. Rev. Mot. 24–25 (citing Pet. 50–51, 55–56; Ex. 1004 ¶77).

Petitioner contends, and we agree, that a person of ordinary skill in the art would have found it obvious "to modify *Fioravanti* so that the captured weight and medical dose preparation image are associated using a dose ID as taught by *Eliuk*" to achieve the "benefits linked with associating weight and medical dose preparation images." *Id.* at 25. For the reasons cited by Petitioner, and as set forth in sections II(G)(2)–(4), above, we find this argument persuasive. *See id.* (citing Pet. 55–56; Ex. 1004 ¶ 77).

Thus, Petitioner has shown that claims 22–42, including the amended limitations, are obvious over Fioravanti, Alexander, and Eliuk.

## IV. PETITIONER'S MOTION TO EXCLUDE EXHIBIT 2026

Petitioner moved to exclude "Exhibit 2026 in its entirety, and any reference to or reliance on it, without limitation." Mot. Excl. 1. Patent Owner opposed the motion (Resp. Mot. Excl.) and Petitioner filed a Reply (Reply Mot. Excl.).

Exhibit 2026 appears to be a July 29, 2019 email thread between Petitioner and Patent Owner's counsel containing Patent Owner's request for documents containing alleged "critical customer and market insights." Ex. 2026, 3. As we do not rely on Exhibit 2026, we dismiss Petitioner's motion as moot with respect to this exhibit.

## V. CONCLUSION

For the foregoing reasons, Petitioner has not shown by a preponderance of the evidence that any of the challenged claims of the '273 Patent are unpatentable, as summarized in the following table:

| Claims | 35 U.S.C § | Reference(s) / Basis | Claims Shown Unpatentable | Claims Not Shown Unpatentable |
|---|---|---|---|---|
| 1, 3–8, 10, 11, 16–21 | 102(b) | Fioravanti | | 1, 3–8, 10, 11, 16–21 |
| 1–14, 16–21 | 103(a) | Fioravanti | 1–14, 16–21 | |
| 1–14, 16–21 | 103(a) | Fioravanti, Alexander | 1–14, 16–21 | |
| 1–14, 16–21 | 103(a) | Fioravanti, Alexander, Eliuk | 1–14, 16–21 | |
| 2 | 103(a) | Fioravanti, Alexander, Eliuk, Claypool | 2 | |
| 13–15 | 103(a) | Fioravanti, Alexander, Eliuk, Bear | 13–15 | |

| | | | | |
|---|---|---|---|---|
| Overall Outcome | | | 1–21 | |

| Motion to Amend Outcome | Claims |
|---|---|
| Original Claims Cancelled by Amendment | |
| Substitute Claims Proposed in the Amendment | 22–42 |
| Substitute Claims: Motion to Amend Granted | |
| Substitute Claims: Motion to Amend Denied | 22–42 |
| Substitute Claims: Not Reached | |

## VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–21 of U.S. Patent No. 9,662,273 B2 have been shown to be unpatentable;

FURTHER ORDERED that Patent Owner's Revised Contingent Motion to Amend is denied;

FURTHER ORDERED that Petitioner's motion to exclude Exhibit 2026 is denied;

FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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