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Paper 51
Entered: April 29, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY,
Petitioner,

v.

BAXTER CORPORATION ENGLEWOOD,
Patent Owner.

IPR2019-00119
Patent 8,554,579 B2

Before BARRY L. GROSSMAN, ROBERT A. POLLOCK, and PAUL J. KORNICZKY, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge.*

JUDGMENT

Final Written Decision
Determining No Challenged Claims Unpatentable
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 1–13 and 22 of U.S. Patent No. 8,554,579 B2 (Ex. 1001, "the '579 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 not demonstrated by a preponderance of the evidence that claims 1–13 and 22 are unpatentable.

A. Procedural History

Becton, Dickinson and Company ("Petitioner") filed a Petition for an *inter partes* review of claims 1–13 and 22 of the '579 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 Reply to the Preliminary Response (Paper 13) and Patent Owner submitted a corresponding Sur-reply (Paper 14).

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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 '579 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.

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 Inst., 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 28 ("Reply"). Patent Owner filed a revised Sur-reply. Paper 43 ("Sur-reply"). Petitioner filed a Supplemental Reply directed to Exhibits 2025 and 2030 as referenced in Patent Owner's Sur-reply. Paper 44 ("Suppl. Reply").

Petitioner also filed a Motion to Exclude Exhibits 2025 and 2030. Paper 45 ("Mot. Excl."). Patent Owner filed a Response to the Motion to Exclude (Paper 46 ("Resp. Mot. Excl.")) and Petitioner filed a Reply (Paper 47 ("Reply Mot. Excl.")).

On February 26, 2020, the parties presented arguments at oral hearing, the transcript of which has been entered in the record. Paper 49 ("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 '579 Patent at issue here, Petitioner requested, and this panel instituted, *inter partes* review of U.S. Patent Nos. 9,662,273 and 9,474,693 in IPR2019-00120 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 Oct. 26, 2017), which is presently stayed. Pet. 2; Paper 5, 1; Tr. 8:8–14. According to Patent Owner, claim 8 of the '579 patent and its dependent claims (i.e., claims 9–13) are at issue in that litigation. PO Resp. 4; Tr. 57:3–6

D. The '579 Patent and Relevant Background

The '579 patent, titled "Management, Reporting and Benchmarking of Medication Preparation" is generally directed to the "management of medication dose orders and medication dose preparation," including "remote dose inspection for facilitating the practice of telepharmacy." Ex. 1001, 1:14–20. The patent discloses "[s]ystems for preparing patient-specific doses and a method for telepharmacy in which data captured while following [a protocol specifying a set of steps to fill the drug order] are provided to a remote site for review and approval by a pharmacist." *Id.* at Abstract. Such systems may involve a "dose preparation station . . . in bidirectional communication with [an] order processing server [having] and has an interface for providing an operator with a protocol associated with each received drug order and specifying a set of steps to fill the drug order." *Id.*

Relevant portions of the prosecution history of the '579 patent are accurately summarized on pages 7–10 of the Petition. In allowing the claims to issue, the Examiner stated that certain references overcome in prosecution did not "provide information as to whether a discrete step (of a recipe) was completed" or were "not directed to capturing and later presenting a specific image that corresponds to a discrete event (step) performed (in order to allow subsequent validation of the step) during the compounding process." Ex. 1002, 415–416.

E. Challenged Claims

Petitioner challenges claims 1–13 and 22 of the '579 Patent. Claims 2–7 and 22 depend, directly or indirectly, from independent claim 1. Claims 9–13 depend, directly or indirectly, from independent claim 8. The challenged independent claims are reproduced below with bracketed identifiers and italics added to indicate elements addressed with specificity in Patent Owner's Response. *See* PO Resp. i–iii.

> 1. A method for performing telepharmacy comprising the steps of:
>
> receiving and processing a dose order;
>
> preparing a dose at a medication preparation station based on the dose order including following a recipe, wherein the dose is a reconstituted drug and the recipe having one or more drug preparation steps including using a diluent for reconstitution;
>
> displaying the recipe on [1d] *an interactive screen that includes prompts that can be highlighted by an operator to receive additional information relative to one particular step* and includes areas for entering an input;
>
> capturing one or more images of a plurality of the drug preparation steps, each of the images being captured at,

corresponding to, and confirming a performance of one discrete drug preparation step of the recipe, one captured image displaying a result of a discrete isolated event performed in accordance with one drug preparation step, the drug preparation steps including at least one step that is an intermediate step involving the diluent that shows the dose prior to completing the dose preparation and obtaining a completed dose that is in a state that is suitable for delivery to a patient, [1f] *wherein one input comprises an input that is prompted by the performance of the drug preparation steps*;

storing each image associated with the drug preparation steps of the recipe that has been collected together in a data record of a database, thereby allowing the captured image to be later retrieved for inspection;

accessing the data record including the images from a remote site using a portal in communication with the database;

inspecting the data record through the portal;

reviewing the images in the data record in order to verify that each of the captured drug preparation steps was properly completed; and

approving release of the dose to the patient if the reviewing step confirms that each of the captured drug preparation steps was properly completed.

8. A system for preparing and managing patient-specific dose orders that have been entered into a first system, comprising:

an order processing server executing software on a processor thereof and connected by a network to the first system and configured to receive the patient-specific dose orders from the first system, the order processing server including a database configured to store the dose orders and images that relate to the dose orders, [8d] *the order processing server being configured to generate a dose order queue listing all dose orders received by the order processing server*;

a dose preparation station for preparing a plurality of doses based on received dose orders, the dose preparation station being in bi-directional communication with the order processing server and having an interface for providing an operator with [8e] *a protocol associated with each received drug order and specifying a set of drug preparation steps to fill the drug order*, the dose preparation station including [8f] *an interactive screen that includes prompts that can be highlighted by an operator to receive additional information relative to one particular step* and includes areas for entering an input;

[8g] *the dose preparation station being configured to present the protocol* and having one or more data input devices to capture images of a plurality of the set of drug preparation steps that are part of the protocol and are followed to fill the drug order, wherein each image associated with the drug preparation steps of the protocol is stored together in a data record of the database, wherein at least one captured image is captured at, corresponds to, and confirms a performance of one discrete drug preparation step in which the dose is not completely prepared and ready for delivery to the patient and [8j] *wherein each of the steps must be verified as being properly completed before the operator can continue with the other steps of drug preparation process*, the captured image displaying a result of a discrete isolated event performed in accordance with one drug preparation step, wherein verifying the steps includes reviewing all of the discrete images in the data record; and

[8l] *a display communicatively coupled to the order processing server and positionable independently of the dose preparation station, the display outputting the dose order queue and metrics concerning activity at the dose preparation station*.

F. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 14):

Ground	Claims Challenged	35 U.S.C §	References
1	1–12, 22	103(a)	Alexander, Liff[3]
2	1–12, 22	103(a)	Alexander, Liff, Morrison[4]
3	3–6, 11–13	103(a)	Alexander, Liff, Morrison, Peoples[5]

In support of its patentability challenges, Petitioner relies on the testimony of Dr. Marc Young. *See* Ex. 1003 (Declaration); Ex. 1004 (curriculum vitae); Ex. 2022 (deposition transcript). Patent Owner relies on the testimony of Jeffrey R. Brittain, PharmMD, BCPS. Ex. 2008 (Declaration); Ex. 2009 (curriculum vitae); Ex. 1011 (deposition transcript); Ex. 2032 (corrected version of Ex. 1011).[6]

II. ANALYSIS

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is

[3] Liff et al., US 6,581,798 B2, issued June 24, 2003. Ex. 1006.
[4] Morrison et al., US 2005/0080651 A1, published Apr. 14, 2005. Ex. 1007.
[5] Peoples, Jr., US 6,098,892, issued Aug. 8, 2000. Ex. 1008.
[6] In Paper 34, we authorized Patent Owner to submit a revised version of Dr. Brittain's deposition transcript in each of the related IPRs. As the revisions are potentially relevant to only to IPR2019-00120 and IPR2019-00121, we authorized Petitioner to file supplemental briefing in those cases addressing the differences between the two versions. *See* Paper 34, 3.

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).

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). 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 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.

A. 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. 10–11; PO Resp. 6 (referencing Inst. Dec. 9). As noted by Petitioner, the Board

previously applied this definition in an *inter partes* review of the Alexander reference asserted here. Pet. 10–11 (referencing IPR2015-00883, Paper 29 at 43). As the parties' undisputed proposed definition is consistent with the cited prior art, we adopt it consistent with our Institution Decision. *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, 163–164 (Fed. Cir. 1985)).

B. 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).[7] Under that standard, we presume that a claim term carries its "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); *see also Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir.

[7] The broadest reasonable interpretation ("BRI") construction standard applies to *inter partes* reviews filed before November 13, 2018. 77 Fed. Reg. 48680, 48727 (Aug. 14, 2012) (codified at 37 C.F.R. § 42.100(b)), as amended at 81 Fed. Reg. 18766 (Apr. 1, 2016); *see also* 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.

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 two claim terms provisionally construed in our Institution Decision, as well as element [8j], subsequently raised by the parties. 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.").

1. "medication/dose preparation station"

Petitioner argues that "[w]hile the specification and claims include various components that may be part of a particular medication or dose preparation station," we should construe the "medication preparation station" of claim 1 and the "dose preparation station" of claim 8 to "refer generically to a location within a pharmacy where medication doses are prepared." Pet. 12–13 (emphasis omitted) (citing Ex. 1001, 3:24–4:15). We

read the Specification, however, as generally referring to a medication or dose preparation station as a physical entity rather than a location. *See e.g.*, Ex. 1001, Abstract ("The dose preparation station is in bidirectional communication with the order processing server"), 3:24–31 (referencing automated or manual workstations).

Noting that claim 8 recites a dose preparation station having particular physical structure (e.g., "an interactive screen" and "one or more data input devices") and functional elements (e.g., "being in bi-directional communication with the order processing server"), Patent Owner argued in its Preliminary Response that we should construe the "medication/dose preparation station" terms to mean "a physical automated or manual workstation at which a dose of medication is prepared, which contains the claimed equipment having the claimed functionality." Prelim. Resp. 19–20.

In our Institution Decision, we found Patent Owner's proposal consistent with the Specification, but "because it is axiomatic that the 'medication preparation station' and 'dose preparation station' will encompass the specific limitations recited in their respective claims, we [found] Patent Owner's full definition unnecessary and potentially subject to confusion where a 'medication/dose preparation station' appears in multiple claims with different subsidiary limitations." Inst. Dec. 12–13. In the interests of clarity and simplicity, we provisionally construed these terms as meaning "a physical automated or manual workstation at which a dose of medication is prepared." *Id.* at 13. Neither party disputes our construction, and we apply it here. *See, e.g.*, PO Resp. 6.

2. "hands-free device"

In our Institution Decision, we provisionally adopted Petitioner's definition of "hands-free device" as "a device that operators can interact with using something other than their hands." Inst. Dec. 12; Pet. 13. Patent Owner does not dispute this definition for the purpose of this proceeding. PO Resp. 6. As this definition is both undisputed, and consistent with the Specification, we apply it here.

3. [8j] "wherein each of the steps must be verified as being properly completed before the operator can continue with the other steps of the drug preparation steps"

The system for preparing and managing patient-specific dose orders of claim 8, and its dependent claims 9–13, involves a plurality of drug preparation steps followed to fill a drug order. Element [8j] requires that, "each of the steps must be verified as being properly completed before the operator can continue with the other steps of the drug preparation steps." The parties agree that we should construe this element, designated [8j], according to its plain and ordinary meaning, but have different views on what that meaning is. *See, e.g.*, Sur-reply 3 (citing Pet. 11; PO Resp. 5).

Whereas the plain language of element [8j] mandates that each step "*must be verified* before the operator can continue," the parties initially appear to disagree about who—or what—is responsible for the verification. Patent Owner contends that element [8j] embodies the concept of a "hard stop," wherein "the system will not allow the operator to proceed to the next step until the prior step has been verified." PO Resp. 24; Sur-reply 1. To

the extent Patent Owner uses the term "hard stop" as a short hand for the words of element [8j], we agree with this portion of its construction.[8]

As we further understand Patent Owner's position, however, verification that a step is properly completed requires input from a remote pharmacist overseeing the operator. *See* PO Resp. 27 (distinguishing Alexander as not requiring "the remote pharmacist ***must*** verify each and every step ***before*** the operator is allowed to proceed"). But reading claim 8 (directed to a system) to require a method step performed by a pharmacist would appear to "combine . . . two separate statutory classes of invention." *See IPXL Holdings, L.L.C. v. Amazon.com, Inc.,* 430 F.3d 1377, 1384 (Fed. Cir. 2005). Moreover, claim 8 makes no mention of a pharmacist and Patent Owner fails to explain adequately why we should import such a limitation from the Specification into the claim. Accordingly, we decline to apply Patent Owner's construction of element [8j] to the extent it requires input from a remote pharmacist. We, nevertheless, note that in the Sur-reply, Patent Owner indicates that element [8j] may be satisfied where "*the workstation* . . . captur[es] the image and scan[s] the barcode in order to verify the step has been performed." Sur-reply 6 (emphasis added).

[8] Although Patent Owner initially defined "hard stop" as an action that "halts the progress or prescribing, dispensing, or administering a medication that would likely be dangerous to a patient, with further execution of the order blocked" (PO Resp. 26 (citing Ex. 2008 ¶ 70, Ex. 2011, 1)), Patent Owner subsequently clarified, and we accept, that "hard stop" is merely a short hand for element [8j] and does not impute any additional meaning to the claim term (*see* Sur-reply 3–4 & fn.2; Tr. 67:13–68:14).

Petitioner, in contrast, contends that element [8j] does not mandate input from a remote pharmacist, but "embraces an operator confirmation that a step is completed properly." Reply 4. In support, Petitioner reasonably contends that Figure 9 of the '579 patent and select passages in the specification describe an "operator-initiated click-through verification process." *Id.* (citing Ex. 1001, 18:47–52, 56–58, Fig. 9; Ex. 1011, 102:4–22).

Petitioner further points to the prosecution history of the '579 patent in which the then-applicant amended claims to avoid rejection over DiGianfilippo. Reply 6 (citing Ex. 1002, 235–236, 267, 297, 324, 359, 387; Ex. 1012 ¶ 128). Petitioner asserts that "DiGianfilippo describes a click-through process where the operator is merely prompted to confirm that a step has been completed before a later step can be started." *Id.*[9] According to the Examiner, DiGianfilippo discloses:

> a pharmaceutical compounding system where an operator must confirm and verify that specific steps have been properly completed before the next step in the preparation of the drug can commence (para. 128). DiGianfilippo further teaches to prevent[] the operator from continuing in the process until the steps have been properly completed (para. 128).

Ex. 1002, 236, 297.

Petitioner cites the above prosecution history as evidence that Patent Owner disavowed a construction of element [8j] as requiring a hard stop, which we find neither clear, nor relevant to our construction of element [8j].

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[9] Although Petitioner provides no citation for this assertion, it appears to refer to Exhibit 1012 (DiGianfilippo et al., US 2008/0125897 A1, published May 29, 2008).

See Reply 6; Sur-reply 6–7. We, nevertheless, agree with Petitioner, that the Specification supports an "operator-initiated click-through verification process" because the plain language of element 8[j] is agnostic regarding the source of any input required to trigger verification (whether from, e.g., a remote pharmacist, local operator, or automatic system function).

For the above reasons, we construe element 8[j] as requiring that "the system will not allow the operator to proceed to the next step until the prior step has been verified."

C. Obviousness in view of Alexander and Liff (Ground 1)

In Ground 1, Petitioner challenges claims 1–12 and 22 as obvious over Alexander and Liff. Pet. 14–47. In support, Petitioner provides a detailed claim chart mapping the teachings of Alexander and Liff to each of the claim elements (*id.* at 19–47) and posits a rationale for combining their respective teachings (*id.* at 17–19). Patent Owner opposes on grounds that Alexander does not qualify as prior art (PO Resp. 11–18; Sur-reply 19) and on the merits of the combination (PO Resp. 18–46, 60–61; Sur-reply 14–17). We begin with an overview of the asserted references.

1. Overview of Alexander (Exhibit 1005)

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. 1005, 2:13–20; *see* 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.

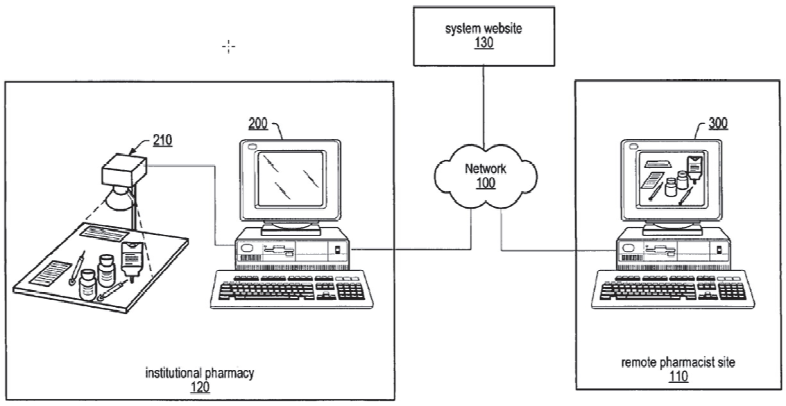

FIG. 5

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 medication 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.
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> * * *
>
> 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.
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> * * *
>
> 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.

2. Overview of Liff (Exhibit 1006)

Liff discloses an application of telepharmacy in which a pharmacist or other medical practitioner can remotely direct the dispensing of a patient's medication. In particular, Liff discloses an "automated drug dispensing system" that "combines computer hardware and software, a telecommunications capability, and a medication container dispensing cabinet to form a complete in office dispensing system." Ex. 1006, Abstract, 2:8–11.

The Liff system dispenses prepackaged drugs — identified by bar codes — from the medication container dispensing cabinet directly to a patient in response to remote commands received from "a physician, pharmacist, or other licensed practitioner." *See id.* at 2:8–38. According to Liff, "[t]he system provides a convenient, safe, automated, and low cost drug delivery system for the patient." *Id.* at 2:15–16.

3. Prior Art Status of Alexander

Petitioner asserts that Alexander is prior art under 35 U.S.C § 102(g)(2) and 102(e)(2). Pet. 5; Paper 13; Reply 16–18. 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. 15–20. Patent Owner maintains that Alexander is not prior art under § 102(e)(2). PO Resp. 11–18; Sur-reply 19. 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. *Id*.

Prelim. Resp. 7.

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.[10]

For the above reasons, and as set forth at pages 15–17 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

[10] Accordingly, we find irrelevant Patent Owner's implication that Petitioner has not satisfied its burden to show that that the Alexander invention was not abandoned, suppressed or concealed as set forth in section 102(g). *See* Sur-reply. 5 & n.3.

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. 18 (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 '579 patent. *See* Ex. 1008, at [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. 11–18; Prelim. Resp. 8–14; Paper 14, 1–3; 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 '579 patent unenforceable, but the cancelation of claims retroactively stripped it of any prior art status—which even Patent Owner admits "may seem illogical." *See, e.g.*, PO Resp. 12–13; 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 the case law relied on by Patent Owner.

Patent Owner relies on *Fresenius* as evidence of "Congressional intent that claims so canceled be void *ab initio*." PO Resp. 12–13 (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.'" *Id.* at 17. 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.

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 16–18. 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 17. Accordingly,

> When 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.

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). Accordingly, the scope and content of prior art is measured as of the filing date of the challenged invention.

In the present case, the critical date of the '579 patent is no later than January 23, 2009, the filing date of the non-provisional parent application. Ex. 1001 at [22].[11] Alexander was filed on February 11, 2005, before the critical date, and that Alexander's claims were not cancelled until February 15, 2018, long after that critical date. Ex. 1008 at [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 '579 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. 18 (emphasis omitted).[12]

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[11] Although we need not consider whether the '579 patent is further entitled to the benefit of the October 13, 2008, provisional application, Patent Owner asserts that "the specification of the provisional application (Ex. 2014, 10–67) is identical to the specification filed in the application that led to the '579 Patent." PO Resp. 17, fn.5.

[12] We also 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

For the above reasons, Alexander qualifies as prior art to the '579 patent under 35 U.S.C § 102(e)(2).

4. Motivation to Combine Alexander and Liff

According to Petitioner, Alexander and Liff describe—and tout the advantages of—"telepharmacy systems that use computer networks to allow a remote pharmacist to supervise the dispensing of drugs in a facility where no on-site pharmacist is available, for example at a hospital after hours, a nursing home, or at a clinic located in an area with insufficient licensed pharmacists." Pet. 17 (citations omitted). Accordingly, Petitioner contends, "the combination of Liff and Alexander is use of a known technique to improve similar devices in the same way." *Id.* at 18 (citing Ex. 1003 ¶¶ 79–82; *see e.g.* Ex. 1003 ¶¶ 79–81 (testifying that Liff and Alexander share the "common objective" of "us[ing] computer networks to allow a remote pharmacist to supervise the dispensing of drugs in a facility where no on-site pharmacist is available.").

Relying on the testimony of Dr. Young, Petitioner asserts that one of ordinary skill in the art would have been motivated to combine the teachings of Alexander and Liff because they "provide complementary partial solutions to the same overall problem, and each can be enhanced by combining it with the other." Pet. 17 (citing Ex. 1003 ¶ 82). For example, whereas Liff provides for the remote dispensing of stable, prepackaged drugs, it "is not, by itself, well suited for dispensing drugs that must be

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cancellation were spent in proceedings before the PTO." *See* PO Resp. 18 n.6.

mixed shortly before administration." *Id.* at 18 (citing Ex. 1003 ¶¶ 81–82). "Combining the Liff dispensing system with the Alexander remote supervision system overcomes this shortcoming of Liff, because the Alexander system enables a non-pharmacist to dispense a drug in stable form from the Liff cabinet and then reconstitute it under the remote supervision of a licensed pharmacist." *Id.* (citing Ex. 1003 ¶ 82).

Petitioner further argues that one of ordinary skill in the art would have been motivated to combine the teachings of Alexander and Liff because it would have been advantageous to have a system for storing prepackaged drugs (as taught by Liff) as well as a method for remotely supervising the compounding of drugs that cannot be prepackaged (as taught by Alexander). *Id.* (citing Ex. 1003 ¶ 83). According to Petitioner, the skilled artisan "would have been motivated to implement both systems with as many shared elements as possible to reduce cost, simplify the pharmacy workflow, and reduce potential errors." *Id.* Petitioner further assets that in combining the two systems, the skilled artisan would have "found it obvious to implement the user interface taught by Liff into the remote supervision system provided by Alexander to display information for filling a prescription" and "matching user interfaces would have simplified the workflow for the staff using the equipment, reducing staff frustration and the likelihood of errors." *Id.* at 18–19 (citing Ex. 1003 ¶¶ 82–84); *see* Reply 13.

Pointing to allegedly inconsistent statements by Petitioner during the *inter partes* review of Alexander (IPR2015-00883), Patent Owner contends that the two references are not combinable because Liff fails to teach the remote supervision of a non-pharmacist and we should, therefore, disregard

"Dr. Young's opinion that *Alexander* and *Liff* 'have a common objective'" because it is "contrary to the goals of each reference." PO Resp. 19–22. (citations omitted). We do not find Patent Owner's argument persuasive.

In particular, Patent Owner focuses on Petitioner's prior statement that "Liff merely discloses that a pharmacist operating a remote workstation can cause the cabinet to dispense a pre-packaged pharmaceutical . . . . Liff does not in any way disclose or suggest remote supervision of a non-pharmacist." *Id.* at 19 (citing Ex. 2007, 16) (emphasis removed). But Petitioner's statements are not irreconcilable. As we read the earlier statement, Petitioner conveys that Liff discloses that a pharmacist operating a remote workstation can cause a medication container dispensing cabinet to dispense a pre-packaged pharmaceutical to a non-pharmacist—which we understand as a form of supervision or oversight over the non-pharmacist—but Liff does not disclose a pharmacist also remotely supervising the compounding of drugs as is taught in Alexander.

Accordingly, we find no fault with Dr. Young's assertion that Liff and Alexander "have a common objective" in that "each describe telepharmacy systems that use computer networks to allow a remote pharmacist to supervise the dispensing of drugs in a facility where no on-site pharmacist is available." Ex. 1003 ¶¶ 79–80. The pertinent distinction being that the pharmacist in Liff supervises the dispensing of prepackaged drugs, whereas Alexander provides a system for supervising the compounding of drugs that are not prepackaged for administration. Both references teach the delivery of pharmaceutical products in response to remotely transmitted instructions from a pharmacist or other licensed practitioner.

We also do not find persuasive Patent Owner's argument that Petitioner fails to establish any "reason to combine a remote surveillance type review system as in *Alexander* with the automated dispensing system of *Liff* since there is no need to remotely supervise the dispensing of readymade drugs." PO Resp. 20 (citing Ex. 2008 ¶¶ 58–61, 78). To the contrary, we agree with Petitioner's characterization of this position as a strawman argument, in that rather than modifying Liff to include Alexander's remote supervision system for drug compounding, as Patent Owner appears to argue, Petitioner proposes "modifying Alexander's remote supervision system with the user interface taught by Liff." *See* Reply 13–14; PO Resp. 20–21.

For the reasons above, we find Petitioner has established motivation to combine the teachings of Liff and Alexander.

5. Secondary Considerations

Focusing on the "hard stop" element [8j], Patent Owner presents evidence for nexus between claim 8 and its DoseEdge product, as well as evidence of commercial success and industry praise of the DoseEdge system. PO Resp. 53–60; Sur-reply 19–22. Petitioner opposes. Reply 19–24; Supp. Reply 1–5. For the reasons below, and on the record before us, we accord little weight to Patent Owner's secondary considerations evidence.

In determining whether the challenged claims would have been obvious over Petitioner's asserted combinations, we must consider Patent Owner's objective evidence of nonobviousness. *See Graham* 383 U.S. at 17–18. "In order to accord substantial weight to secondary considerations in an obviousness analysis, the evidence of secondary considerations must have

a nexus to the claims, i.e., there must be a legally and factually sufficient connection between the evidence and the patented invention." *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (internal quotations omitted). A nexus is rebuttably presumed when "the patentee shows that the asserted objective evidence is tied to a specific product and that product 'embodies the claimed features, and is coextensive with them.'" *Id.* (quoting *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 Fed. Cir. 2018)). "[E]vidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art." *Stratoflex, Inc. v. Aeroquip Corp.,* 713 F.2d 1530, 1538 (Fed. Cir. 1983).

a) Nexus

With respect to nexus, Patent Owner relies on Dr. Brittain's element-by-element comparison of claim 8 to exemplary embodiments of DoseEdge. PO Resp. 54–55; Ex. 2008 ¶¶ 101–115 (citing Ex. 2018, 1; Ex. 2034; Ex. 2024) (concluding that "DoseEdge practices claim 8 of the '579 Patent"). Patent Owner emphasizes that "DoseEdge includes the step-specific hard stop feature as part of verifying the processing of a dose order, which is claimed by the '579 Patent. This hard stop prevented patients from receiving [the] wrong drug, which is the main reason for DoseEdge's commercial success." PO Resp. 55 (citations omitted). "While there have been updates, or versions, of DoseEdge since its first release [in 2008], the key feature of claim 8, the 'hard stop.' has remained the same." Sur-reply

19 (citing Ex. 2018, 1).

Petitioner attacks Dr. Brittain's testimony regarding nexus as, for example, not identifying specific versions of DoseEdge, not specifying how marketing material touting error prevention necessarily discloses a "hard stop" or "patient-specific" dose preparation, and failing to illustrate prompts or highlighting functionality. Reply 20. Notably, however, Petitioner proffers no countervailing document or expert testimony to Dr. Brittain's detailed opinion on why DoseEdge practices claim 8 of the '579 Patent. At best, these assertions reflect the weight we should accord Dr. Brittain's opinions on secondary considerations. Considering Dr. Brittain's extensive familiarity with the DoseEdge system, and his testimony as a whole, we find that Petitioner's assertions do not rebut the presumption of nexus.

b) Commercial success

Patent Owner bases its commercial success argument on a publication, nominally dated 2014, showing the release date and number of "live installations"[13] of various sterile compounding systems in the United States. *See* PO Resp. 56 (citing Ex. 2019). Pointing to Exhibit 2018, Patent Owner further contends that "[a]dvertisements for DoseEdge detail that the key feature was DoseEdge's ability to identify wrong drugs and intercept those errors by stopping the technician from completing the compounding process and releasing the prepared dose." *Id.* (citing Ex. 2018). Referencing this

[13] Although Petitioner criticizes Exhibit 2019 for not defining "live installations" (*see* Reply 21–22), we understand the term to refer to all active systems installed irrespective of the ownership terms recited in the table (i.e., capital purchase, lease, license, or rent).

same advertisement, Dr. Brittain similarly testifies: "This hard stop feature has prevented countless patients from receiving the wrong drug, thus contributing to why DoseEdge is a successful product." Ex. 2008 ¶ 112 (citing Ex. 2018, 1). We note, however, that the advertisement depicted in Exhibit 2018 merely states: "nearly 40% of errors identified as wrong drug," and makes no mention of a "hard stop" or any feature identifiable as element [8j]. In sum, this evidence is insufficient to establish that a showing of commercial success could be attributed to claim element [8j].

Petitioner argues that Exhibit 2019 is "incomplete and misleading," because, for example, it does not account for the 2008 release date of DoseEdge, and/or address financial factors that might affect the relative number of installations between competing systems, e.g., profit margins, marketing, and administrative expenses. Reply 21–22 & fn.7.

Petitioner's arguments are well taken. A "patentee must establish a nexus between the evidence of commercial success and the patented invention." W*yers v. Master Lock Co.*, 616 F.3d at 1246 (citations omitted). Exhibit 2019 compares sales of DoseEdge, launched in 2008, with other products launched as late as 2013. Patent Owner makes no attempt to normalize live installation numbers with release dates, or address the effect of early market entry. Patent Owner similarly fails to address marketing efforts, relative system costs, or other financial incentives that may account for the higher number of DoseEdge installations shown in Exhibit 2019. Beyond the raw numbers of Exhibit 2019, Patent Owner can only point to Dr. Brittain's opinion that "DoseEdge is a successful product." Ex. 2008 ¶ 112. But Patent Owner does not attempt to qualify Dr. Brittain as having

expertise in sales, economics, marketing, or other discipline relevant to these issues. Nor does Dr. Brittain's background evidence such. *See* Ex. 2008 ¶¶ 8–13; Ex. 2009; *see also* Reply 23, fn.8 ("PO's expert had no idea of Baxter's market share (Ex. 1011, 83:5–11) or the marketing budget relating to DoseEdge when he drafted his declaration. (*Id.,* 83:12–13)").

Considering the evidence before us, we find Patent Owner's evidence of commercial success weak.

c) Industry Praise

Patent Owner asserts that "DoseEdge received overwhelming awards and praise. . . for its innovative safety technology." PO Resp. 57. Patent Owner provides no evidence of the any awards and cites to a single, three-page excerpt from a KLAS report[14] as evidence of industry praise. *Id.* at 57–59.[15] Petitioner contends that citations to "barcoding technology" and "image capture features" in the KLAS report merely refer to features known in the prior art, and that its praise for safety enhancements "cannot be attributable to DoseEdge, or any claimed feature, because the 'solutions' encompass many different products with many different features." Reply 24.

Patent Owner responds that the KLAS reports recitation of "errors [] being prevented," and of DoseEdge "preventing countless patients from

[14] "U.S. IV Automation Robots and workflow solutions in 2012," KLAS Research Performance Report (October 2012) (excerpt). Exhibit 2012.
[15] As noted by Petitioner, Patent Owner only provides three pages of the KLAS report, leaving us to wonder whether competing systems received similar reviews. *See* Reply 23–24.

receiving the wrong drug," are the direct result of the "hard stop" of element [8j], which, as Dr. Brittain attests, prevents the operator from proceeding without verification and "has prevented countless patients from receiving the wrong drug." Sur-reply 22; Ex. 2008 ¶ 112.

Although we note Dr. Brittain's opinion of the "hard stop" feature of element [8j] as "contributing to why DoseEdge is a successful product," (Ex. 2008 ¶ 112 (citing Ex. 2018, 1)), we do not read the passages of the KLAS report quoted by Patent Owner as referring to any feature that prevents the operator from proceeding to the next step as required by this element. To the contrary, the quoted passage provides: "I can go back at any point in time in DoseEdge System and be able to see what they really did," implies verification *after* the operator has completed compounding. *See* PO Resp. 59 (quoting Ex. 2012, 111–112). Similarly, the passage: "Now we have a photograph on record so if there is ever a doubt about what we had . . . I have a picture of it," clearly indicates a post-compounding verification. See *id.*

Considering the evidence before us, we find Patent Owner's evidence of industry praise weak.

d) Conclusion

Patent Owner's evidence of secondary considerations is weak. We, nonetheless, weigh that evidence in determining whether Petitioner has established obviousness under Grounds 1–3.

6. Disputed Claim Elements

Petitioner provides a detailed claim chart mapping the teachings of Alexander and Liff to each element of claims 1–12 and 22. Pet. 19–47. Patent Owner contends that the asserted combination of references fails to teach or suggest elements of claims 1, 3, 6, and 8, which we address below.

a) Element [8j]: "wherein each of the steps must be verified as being properly completed before the operator can continue with the other steps of the drug preparation process"

As set forth in section II(B)(3) above, element [8j] requires that "the system will not allow the operator to proceed to the next step until the prior step has been verified." According to Petitioner, this verification is satisfied by Alexander. *See* Pet. 41 (referencing *id.* at 24, 28 and citing Ex. 1005:5:4–11, 8:62–64, 9:47–54, 11:21–45; Ex. 1003 ¶¶ 36–37, 43, 45–46). In particular, Alexander teaches:

> Remote verification of pharmacy functions performed by non-pharmacists may additionally include, in some embodiments, one or more legally required in-progress checks. In general, remote pharmacist verification of pharmacy work performed by non-pharmacists may include supervision and/or verification of the pharmacy work in various stages of completion as well as verification of any and/or all results of the pharmacy work.

Ex. 1005, 5:4–11.

> [I]n some embodiments, a remote pharmacist may supervise pharmacy work as it is being performed. For example, in one embodiment, a remote pharmacist may verify each step as it is performed and may provide an indication to a non-pharmacist performing the pharmacy that the step was performed correctly. In such an example, the remote pharmacist may provide

> verification feedback via the same collaboration software, or via another method, such as by telephone.

Id. at 9:47–54.

Reflecting Alexander's teaching that a remote pharmacist may supervise pharmacy work as it is being performed, Dr. Young testifies that:

> A person of ordinary skill in the art would have understood that in order for a remote pharmacist to successfully verify that each step was performed correctly in real time, each step would need to be verified before the pharmacy staff member could continue with the next step in the preparation process. At a minimum, it would have been obvious from the teachings of Alexander for the remote pharmacist to verify each step before the operator can continue on to the next step.

Ex. 1003 ¶ 45.

Patent Owner responds that "*Alexander* only discusses that 'a remote pharmacist *may* verify each step' (Ex. 1005, 9:49–52); not that the remote pharmacist *must* verify each and every step *before* the operator is allowed to proceed." PO Resp. 27 (citing Ex. 2008 ¶ 76). Relying on the testimony of its expert, Dr. Brittain, Patent Owner contends that one of ordinary skill in the art would not have contemplated the "hard stop" of element 8[j], and would have read Alexander as disclosing an electronic version of "the typical procedure for final verification by a pharmacist[] involved the technician putting in a basket all of the components used to compound the final dose, then the pharmacist would review and provide a signature as verification, and a label finalized so that the dose could be dispensed." *See* PO Resp. 26–28; Ex. 2008 ¶ 70–72. Applying this logic, Alexander's teaching that a "remote pharmacist may provide verification feedback via the same collaboration software, or via another method, such as by

telephone" (Ex. 1005, 9:52–54), does not mandate that the operator is prevented from continuing on with subsequent dosage steps before receiving verification that each step is performed correctly, as required by element [8j]. Accordingly, Patent Owner argues, "nothing in *Alexander* prevents the operator from continuing on with subsequent dose preparation steps irrespective of a verification that previous steps have been performed." (Sur-reply 7–8 (citations omitted)). We find Patent Owner's argument persuasive.

Considering the record as whole, including the testimony of the parties' respective experts, we find that Petitioner has not demonstrated by a preponderance of the evidence that Alexander teaches or renders obvious element [8j]. And although Petitioner is correct that element [8j] encompasses "a click-through process where the operator is . . . prompted to confirm that a step has been completed before a later step can be started," as allegedly described in DiGianfilippo (*see* section II(B)(3) above; Reply 6), Petitioner does not rely on DiGianfilippo in its asserted Grounds, and we do not apply it here. Nor does Petitioner otherwise establish sufficiently that one of ordinary skill in the art would find it obvious to apply click-through verification to ensure that *each* drug preparation step is verified as being properly completed before the operator can continue with the other steps as required by element [8j]. *See Sirona Dental Sys. GMBH v. Institut Straumann AG*, 892 F.3d 1349, 1356 (Fed. Cir. 2018) (citing *SAS*, 138 S.Ct. at 1356–57) (because "the petitioner's contentions, not the Director's discretion, define the scope . . . [i]t would . . . not be proper for the Board to deviate from the grounds in the petition and raise its own obviousness

theory").

For the above reasons, and in view of the record as a whole, Petitioner has not made the requisite showing that element [8j], and thus, claim 8, and its dependent claims 9–13, are obvious under Ground 1.

b) Element [8d] "the order processing server being configured to generate a dose order queue listing all dose orders received by the order processing server"

Alexander teaches that a remote pharmacist may verify medication dose records "on a first-come first-served basis . . . in the order they notified the remote pharmacist that images were available for verification." Ex. 1005 at 4:39–43. Relying on the testimony of Dr. Young, Petitioner contends that one of ordinary skill in the art "would have found it obvious that in order to verify orders on a first-come first-served basis, the server should generate a queue tracking the sequence in which orders were received," as required by element [8d]. Pet. 34–35 (citing Ex. 1003 ¶¶ 48–51).

With respect to Ground 1,[16] Patent Owner, contends "Dr. Young fails to explain how a remote pharmacist, verifying already prepared dose orders 'on a first-come first –served basis' upon notification 'that images were available for verification,' somehow translates into *the order processing server*, which is not being used by the remote pharmacist, generating a[n] order queue of yet-to-be prepared doses." PO Resp. 33–34 (citing Ex. 2008 ¶ 83); *see* Sur-reply 10–11. Petitioner responds, that the broadest reasonable construction of element [8d] encompasses *both* "a queue of 'yet-to-be

[16] Patent Owner does not dispute that Morrison discloses element [8d] in Ground 2. *See* Pet. 55 (further citing Ex. 1007 ¶¶ 27, 29); Reply 11.

prepared-doses' for technicians and a queue of 'yet-to-be-verified doses' for pharmacists." Reply 10. We agree.

Patent Owner further contends that we should disregard Dr. Young's testimony as inconsistent because a system could insert orders at the front of a queue on a "stat" basis, or require a condition precedent before a technician prepares a queued dose. PO Resp. 34–36. Neither situation, however, is inconsistent with an "order processing server being configured to generate a dose order queue listing all dose orders received by the order processing server," as recited in element [8d]. Nor is either contingency incompatible with Dr. Young's testimony that one of ordinary skill would look to such queueing information to ensure the timely completion of orders in the system. *See* Ex. 1003 ¶¶ 49–52.

Considering the record as whole, we find that Alexander's teaching to verify medication dose records "on a first-come first-served basis," in conjunction with Dr. Young's testimony, establishes that element [8d] is obvious over the prior art.

> c) Elements [8e]/[8g]: "a protocol associated with each received drug order and specifying a set of drug preparation steps to fill the drug order . . . the dose preparation station being configured to present the protocol"

Petitioner relies on "Alexander's workstation for drug preparation as modified by Liff's user interface of displaying instructions to an operator" as teaching or suggesting "a protocol associated with each received drug order and specifying a set of drug preparation steps to fill the drug order . . . the dose preparation station being configured to present the protocol" as set forth in elements [8e] and [8g]. *See* Pet. 19, 35–40; Reply 9–10.

Patent Owner contends Petitioner's citations to Alexander highlight a workstation for "'implementing [the] *remote supervision and verification* of pharmacy functions,' not for supplying a set of drug preparation steps." PO Resp. 28–29 (citing Ex. 1005, 5:65–67; Ex. 2008, ¶74). According to Patent Owner, Alexander fails to disclose a recipe for drug preparation and one of ordinary skill in the art would not have looked to the remote monitoring system described in *Alexander* as the means for providing such a recipe." *Id.* (citing Ex. 2008 ¶¶ 73–74, 77). Consistent with our understanding of Liff as a system for dispensing prepacked pharmaceuticals, Patent Owner similarly argues that Liff fails to disclose instructions for a technician to prepare a dose. *Id.* at 29–33.

In response, Petitioner points to Alexander's disclosure of "pharmacy functions performed at institutional pharmacy 120 that may be remotely supervised and verified may include . . . Medication preparation . . . pursuant to medication orders . . . ." Reply 9–10 (citing Ex. 1005, 4:44–53, 12:50–55, Fig. 6). Petitioner further relies on the testimony of Dr. Young that

> During the relevant time frame, conventional computers were ubiquitous and their use in telepharmacy systems was well-known. A person of ordinary skill in the art would have understood that displaying the medication dose order, a recipe for the dose order, or the steps to be performed in preparing the dose on a computer screen rather than a printed reference would simply have been a design or implementation choice in any system for preparing pharmaceutical doses. A person of ordinary skill in the art also would have understood that any conventional user interface, displayed on a conventional computer, could be used to present the medication dose order or the steps to be performed, which were already available to the pharmacy staff member.

Ex. 1003 ¶ 36.

Despite Patent Owner's arguments to the contrary (*see* Sur-reply 8–11), we agree with Petitioner that one of ordinary skill in the art would have understood that the disputed elements were rendered obvious by Alexander in view of Liff, and that in implementing an electronic system for preparing medications, one of ordinary skill in the art would have considered it obvious to provide a set of drug preparation steps on a computer, likewise rendering obvious elements [8e]/[8g]. Reply, 10 (citing Ex. 1003 ¶ 36).

> d) Elements [8f]/[1d]: "an interactive screen that includes prompts that can be highlighted by an operator to receive additional information relative to one particular step"

Patent Owner challenges the sufficiency of Petitioner's arguments with respect to the requirement of claims 1 and 8 for "an interactive screen that includes prompts that can be highlighted by an operator to receive additional information relative to one particular step." PO Resp. 36–39, 43.

Relying on the testimony of Dr. Young, Petitioner contends that "[a] POSITA would have found it obvious to present the dose preparation recipe disclosed by Alexander using the interface disclosed by Liff." Pet. 24 (citing Ex. 1003 ¶¶ 36, 59–66). According to Petitioner, one of ordinary skill in the art would have looked to the data entry in Liff, "for example by selecting items previously stored in a database from a drop-down menu, which will cause 'the relevant data [to] automatically appear in the data windows,'" and that "a person of ordinary skill would have found it obvious to display the directions for compounding a pharmaceutical in the user interface taught by Liff on a conventional personal computer, such as the

computer described in the Alexander system." *See* Pet. 21–24; Ex. 1003 ¶¶ 36, 59–66.

Patent Owner challenges Dr. Young's opinion for "fail[ing] to explain what 'relevant data' is," but admits that such data "likely includes 'the patient including name, address, phone numbers, age, sex, weight, identification numbers, basic health information, and employer information.'" PO Resp. 36–37 (citing Pet. 22–23; Ex. 1006, 17:65–67; Ex. 2008 ¶ 86–87). Patent Owner takes the position, however, that all this information is unrelated to dose preparation, and thus irrelevant to step [8f]/[1d]. We do not find Patent Owner's argument persuasive.

Claim 8 is not directed to the generic drug preparation but to "preparing and managing patient-specific dose orders," which are "prepared and [made] ready for delivery to the patient." Claim 8 is similarly directed to the "preparing a dose . . . based on the dose order [and] . . . approving release of the dose to the patient." Implicit in such language is the identification of the referenced patient. To this end, we find it reasonable to use common identifiers such as the patient's "name, address, phone numbers, age, sex, weight, identification numbers" because, absent this type of relevant data, a dose would not be patient-specific, i.e., a dose would not be prepared based on a dose order and made ready for delivery to a particular patient.

With respect to "prompts that can be highlighted by an operator" in elements [8f]/[1d], Petitioner relies on Dr. Young's testimony that Figure 14B of Liff

> illustrates an interactive user interface screen with multiple areas for entering user inputs and displaying information relating to the patient for whom the prescription is being filled. Liff explains that the user can be prompted to enter data in various ways, for example by selecting items previously stored in a database from a drop-down menu, which will cause "the relevant data [to] automatically appear in the data windows." ([Ex. 1006,] 17:55-18:13.) **Liff also teaches that the user can highlight various inputs and information displayed on the screen, as illustrated in Figure 14F.**

Ex. 1003 ¶ 63 (cited at Pet. 24) (emphasis added).

Patent Owner argues that Figure 14F of Liff merely highlights a patient's allergies and "does not even suggest formulation steps." PO Resp. 39. Although Petitioner argues that "the content of [Liff's] menus is irrelevant" (Tr. 117:3–12), we agree with Patent Owner that Dr. Young's opinions "do not address any particular step of drug formulation, let alone the ability to highlight a portion of the computer screen to receive additional information about such [a] step." PO Resp. 39.

Although this presents a close case, we agree with Patent Owner that Petitioner's evidence is insufficient. Dr. Young fails to explain why Liff's teaching to highlight patient characteristics when dispensing a prepackaged medication would lead one of ordinary skill to highlight prompts in a drug formulation context to receive additional information relative to one particular step in that process, or even what additional information might be relevant.

For the reasons set forth above, Petitioner has failed to establish sufficiently that the combination of Alexander and Liff discloses or renders obvious element [8f]/[1d]. Accordingly, Petitioner has not made the

requisite showing that claim 8, and its dependent claims 9–13, or claim 1, and its dependent claims 2–7 and 22, are obvious under Ground 1.

> e) Element [8l]: "a display communicatively coupled to the order processing server . . . outputting the dose order queue and metrics concerning activity at the dose preparation station"

Claim 8 requires "a display communicatively coupled to the order processing server . . . outputting the dose order queue and metrics concerning activity at the dose preparation station." With respect to such metrics, Petitioner points to Liff as "teach[ing] that 'an operator may at any time monitor inventory in an RCD unit by selecting the 'inventory' option shown in Fig. 14T[, which] . . . shows the number of bottles in each RCD bin or column.'" Pet. 42 (citing Ex. 1006, 22:3–6, 7:60–62, Fig. 14T). Petitioner further relies on the testimony of Dr. Young who states that, in addition to displaying information regarding the dose order queue,

> information regarding the status of the dose preparation also would have been relevant and important to the remote pharmacist. As such, it would have been obvious to a person of ordinary skill in the art to present additional information regarding the status of the dose preparation on a display connected to the remote pharmacist workstation and/or a display connected to the server.

Ex. 1003 ¶ 52 (cited at Pet. 42).

On behalf of Patent Owner, Dr. Brittain responds, that "*Liff* is not directed to dose preparation in any manner; *Liff* discloses dispensing ready-to-use drugs." Ex. 2008 ¶ 88 (citing *id*. at ¶¶ 51, 78–81). But this attack on an individual reference does not address the combination as a whole. *See In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Considering the

record as a whole, we find that Petitioner has established sufficiently that the combination of Alexander and Liff discloses or renders obvious element [8l].

In light of the above, we find Petitioner has established that element [8l] is obvious over the combination of Alexander and Liff.

f) Element [1f]: "wherein one input comprises an input that is prompted by the performance of the drug preparation steps"

In seeking to establish that the prior art teaches or suggests element [1f], Petitioner relies on Dr. Young's explanation of how one of ordinary skill in the art would have understood the prior art, including Alexander's teaching to capture an image of an intermediate step in the compounding process and Liff's teaching to prompt an operator for input. Pet. 25–26; Reply 11 (collectively citing Ex. 1003 ¶¶ 38–39, 44, 47; Ex. 1005, 5:4–11, 8:62–66, 10:3–18, 12:56–58, Fig. 4; Ex. 1006, 17:55–18:3).

Patent Owner responds that Dr. Young's opinion is conclusory and "relies upon the flawed presupposition that one would combine the teachings of *Alexander* and *Liff*." PO Resp. 43. As set forth in section II(C)(4), above, however, we find ample motivation to combine *Alexander* and *Liff*. We do not find Dr. Young's opinion unduly conclusory, and note that Patent Owner offers no opposing testimony from Dr. Brittain on this issue. Considering the record as a whole, Petitioner has established element [1f] is obvious in view of Alexander and Liff.

g) Claim 3: "scanning a label on the diluent that is to be combined with the drug product"

Depending from claim 1, claim 2 is directed to "steps of preparing the dose and capturing information" including the step of "confirming the identity of a diluent that is combined with the drug product." Depending from claim 2, claim 3 further includes the step of "scanning a label on the diluent that is to be combined with the drug product; and capturing an image of the diluent."[17]

In addressing claim 3, Petitioner points to Alexander's teaching that "one or more of the following items may also be placed on a display area of image capture device 210:1. A vial of sterile water, with label clearly visible, which was used to reconstitute the medication vial added to the final product." Pet. 31 (quoting Ex. 1005, 10:3–8) (emphasis removed)). Relying on the testimony of Dr. Brittain, Patent Owner argues that "[c]apturing an image of a label does not equate to scanning a label. There is no evidence that capturing an image of a label accomplishes the same thing, or that it would have occurred to one reading *Alexander* to replace image capture with scanning." PO Resp. 45 (citing Ex. 2008 ¶¶ 90–91); *see* Ex. 2008 ¶ 91 ("While *Alexander* may capture images of the preparation steps, capturing an image is not the same as 'scanning a label' to confirm what is in the

[17] Although the parties do not address directly whether "scanning" is different or narrower than "capturing an image," we need not address that here. Rather, we apply the parties' presumption that "scanning" refers to interpreting information encoded in a bar code rather than merely acquiring an image of it.

bottle. . . . solely capturing an image is not a replacement for scanning the barcode on the bottle.").

In response, Petitioner argues persuasively that one of ordinary skill in the art would understand Alexander to teach or disclose "scanning a label on the diluent that is to be combined with the drug product," as required by claim 3:

> Alexander discloses capturing an image of the label on a diluent (Ex. 1005, 10:3–14), and Liff discloses scanning a label on an item to identify its content (Ex. 1005, 21:18–23). PO's expert admits that barcoding was in the prior art and provides a great way to identify a product. (Ex. 1011, 42:3–44:2). As part of the verification process, the diluent must be verified; accordingly, it would have been obvious to scan the label to identify the diluent. (Ex. 1003, ¶ 47).

Reply 12.[18]

Considering the record as a whole, Petitioner has established that claim 3 is rendered obvious by Alexander, as understood by one of ordinary skill in the art.

> h) Claim 6: "scanning a label on the completed dose container"

Claim 6 depends from claim 5, which depends from claim 2, which depends from claim 1. Claim 2 is directed to "steps of preparing the dose and capturing information" including the step of "capturing an image of the

[18] Although not necessary to our determination, Petitioner's citation to Peoples' as disclosing "scanning the label on a medication bottle with a bar-code scanner to verify that a correct medication was dispensed," provides additional, and persuasive, support. *See id.* (citing Ex. 1008, 1:39–40, 1:49–54, 7:17–21, Figs. 6–7).

completed drug product." Depending from claim 2, claim 5 further includes the steps of "applying a label to a dose container . . . and capturing an image of the completed dose container." Depending from claim 5, claim 6 still further includes the step of "scanning a label on the completed dose container."

With respect to claim 6, Petitioner relies on Alexander's teaching to "place the labeled sterile intravenous product, with label and base solution content clearly visible, on image capture device 210's display area." Pet. 32 (quoting Ex. 1005, 10:3–14) (emphasis omitted). Petitioner further points to Liff as teaching: "Each time a package 74 is dispensed from the cabinet 20, the package bar code label 98 is scanned by the bar code reader 40 to verify that the correct pharmaceutical has been dispensed." Pet. 32–33 (quoting Ex. 1006, 7:28–32) (emphasis omitted).

Referencing its arguments regarding claim 3, Patent Owner argues that "the image capture teaching of *Alexander* . . . is unrelated to scanning." PO Resp. 45. For the reasons discussed above with respect to claim 3, we do not find Patent Owner's argument persuasive here.

Patent Owner further contends that "the scanning step taught by *Liff* has nothing to do with dose preparation," and that Petitioner does not explain "why teachings regarding drug *dispensation* would suggest anything to a skilled person regarding drug *formulation*." *Id.* We do not find Patent Owner's argument persuasive. To find obviousness, it is not necessary that all features of a secondary reference are "bodily incorporated into the structure of the primary reference." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). "Rather, the test is what the combined teachings of the references

would have suggested to those of ordinary skill in the art." *Id.* "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *KSR*, 550 U.S. at 417.

In the present case, Alexander teaches image capture in the context of dose preparation, including the labeled finished product, whereas Liff teaches that such products are scanned by a "bar coder reader . . . to verify that the correct pharmaceutical has been dispensed." *See* Ex. 1005, 10:3–10; Ex. 1006, 7:28–32. Moreover, in the context of the intermediate reagents, Dr. Young reasonably testifies that "a person of ordinary skill in the art would have understood that the label for a vial of medication or a diluent such as a vial of sterile water would allow a pharmacist, or other medical professional, to verify the contents of the drug product or diluent." Ex. 1003 ¶ 47. Considering the combination as a whole, we find that that one of ordinary skill in the art would similarly find it obvious to scan the label of Alexander's finished product to verify its identity. Accordingly, the record as a whole supports a finding that Alexander in combination with Liff renders obvious "scanning a label on the completed dose container," as recited in claim 6.

7. Conclusion as to Ground 1

For the reasons set forth above, Petitioner has failed to establish that the combination of Alexander and Liff discloses or renders obvious elements [8j] and [8f]/[1d]. Accordingly, Petitioner has not made the requisite showing that claim 8, and its dependent claims 9–13, or claim 1, and its

dependent claims 2–7 and 22 would have been obvious under Ground 1.

D. Obviousness in view of Alexander, Liff, and Morrison (Ground 2)

In Ground 2, Petitioner challenges claims 1–12 and 22 as obvious over the combination of Alexander, Liff, and Morrison. Pet. 47–60. In support, Petitioner provides a detailed claim chart mapping the teachings of the asserted references to each of the claim elements (*id.* at 50–60) and posits a rationale for combining their respective teachings (*id.* at 48–49). Patent Owner opposes. *See* PO Resp. 46–50; Sur-reply 17–18; section II(C), above. We begin with an overview of Morrison.

1. Overview of Morrison (Ex. 1007)

Morrison discloses "[a] system and method for remote pharmacy order processing" "in which pharmacy personnel at remote pharmacy facilities access pharmacy information systems of multiple healthcare facilities to review and authorize their pharmacy orders." Ex. 1007, Abstract, ¶ 1. "The pharmacist functions as if physically on-site at the hospital. . . . Nurses at remote hospital facilities dispense medications based on pharmacy orders that have been reviewed and authorized by a pharmacist prior to being dispensed to a patient." *Id.* ¶ 7. "Orders are transmitted from a plurality of hospital pharmacy information systems 120, 122, 124 to a central order queuing site where they are received at or entered into a server 126 (e.g., a fax server, document server, etc.) and organized in hospital queues." *Id.* ¶ 27. More particularly:

> Orders from hospitals are transmitted to a site for centralized order queue management. Each order is identified and added to a queue for the originating hospital. Orders are reviewed and

> authorized at remote order processing centers by licensed pharmacy personnel. Computers at the remote order processing centers are linked to hospital pharmacy information systems. A pharmacist at a remote order processing center selects a hospital, reviews orders from the queue for the selected hospital, and enters them directly into the hospital's pharmacy information system.

Id. at Abstract.

Morrison defines an "order server" as "any single software server or combination of software servers (e.g., fax server, email server, or other order receiving server and document management server) that provide features and functionality for receiving orders, digitizing or producing images of orders, and organizing orders in queues." *Id.* ¶ 29. Morrison further teaches that:

> The remote order processing centers provide seamless order processing service by linking their computers directly to pharmacy information systems at hospitals and emulating those systems. Using technology such as a virtual private network, dial up connections, high-resolution fax servers with archiving capability, scanners and other technologies, the pharmacy orders are transmitted (via fax, email, or scanner) for centralized queue management, and then are accessed via a secure connection at the remote order processing centers for processing by pharmacists.

Id. ¶ 7.

Morrison's system includes an order view display that "displays the electronic image of the order in addition to the following annotated fields: patient identifier, total orders on sheet, total orders completed . . . comment fields are also included as well as buttons to indicate the next screen that should appear once the order image is completed." *Id.* ¶ 70. Morrison further teaches a "master hospital queue," which displays "the total number

of orders in the hospital queue and the time of the oldest order in the queue." *Id.* ¶ 55. In some embodiments, "hospital service level tracking . . . alerts for aging orders and provides operational and clinical metrics related to order volume, processing time and clinical consultation activity." *Id.* ¶ 9.

2. Motivation to Combine Alexander and Liff with Morrison

Petitioner asserts that one of ordinary skill in the art would have been motivated to combine Alexander, Liff, and Morrison for essentially the same reasons as discussed for Alexander and Liff in section II(C)(4), above. *See* Pet. 48–49 (citing Ex. 1003 ¶¶ 85–87). Relying on the testimony of Dr. Young, Petitioner additionally argues that "a person of ordinary skill in the art would have found it obvious to use Morrison's servers to communicate between remote pharmacy personnel and systems to achieve the objectives of Alexander and Liff." *Id.* (citing Ex. 1003 ¶ 88).

Patent Owner argues that "Morrison is directed to interfacing with a cabinet dispensing system like Liff, so there would be no need to use the system in Morrison with the system in Alexander wherein a remote pharmacist is already involved." Sur-reply 18 (emphasis omitted). Relying on the testimony of Dr. Brittain, Patent Owner concludes that "[a]s with *Liff,* there is no reason to believe that one skilled in the art would have combined the teachings of *Morrison* with those of *Alexander*." PO Resp. 46 (citing Ex. 2008 ¶¶ 92–94). But Dr. Brittain's opinions on this matter are conclusory and we accord them little weight. At best, Dr. Brittain states:

> *Morrison* describes how a remote pharmacist is used to dispense drugs to supplement efforts of the on-site hospital and pharmacy staff. There is no teaching in *Morrison* that its system could be use to oversee and monitor sterile compounding.

> Therefore, a person of skill in the art would not have looked to a system like *Alexander* to further supplement the efforts described by *Morrison*.

Ex. 2008 ¶ 93. Neither Dr. Brittain nor Patent Owner address, for example, Dr. Young's opinion that:

> Morrison provides details on the use of servers to transfer data between systems and users. A person of ordinary skill in the art would have found it obvious to use Morrison's servers to communicate data between different pharmacy personnel and pharmacy systems. Given Alexander and Liff's disclosure of databases and remote workstations, a person of ordinary skill in the art would have looked to Morrison's servers to achieve the objectives of the verification system of Alexander and the dispensing system of Liff. Such a combination would have combined prior art elements according to known methods to yield predictable results in filling a prescription order.

Ex. 1003 ¶ 88.

Considering the record before us, Petitioner has established that one of ordinary skill in the art would have been motivated to further combine Alexander and Liff with Morrison.

3. Contested Claim Elements

a) Element [8j]: "wherein each of the steps must be verified as being properly completed before the operator can continue with the other steps of the drug preparation steps"

With respect to element [8j], both parties refer to their arguments made in Ground 1. As set forth in section II(C)(6)(a), above, Petitioner has not made the requisite showing that claim 8, and its dependent claims 9–13, are obvious.

b) Elements [8e]/[8g]: "a protocol associated with each received drug order and specifying a set of drug preparation steps to fill the drug order . . . the dose preparation station being configured to present the protocol"

In Ground 2, Petitioner further relies on Morrison with respect to element [8e]. Pet. 56–57. Patent Owner reasonably asserts that "the cited portion of *Morrison* is actually referring to general hospital and pharmacy policies, *not* protocols that specify a set of drug preparation steps." PO Resp. 47–48 (citations omitted). As noted in section II(C)(6)(c), above, however, Petitioner has satisfied its burden with respect to this element based on Alexander and Liff.

c) Element [8f]/[1d]: "an interactive screen that includes prompts that can be highlighted by an operator to receive additional information relative to one particular step"

As noted in section II(C)(6)(d), above, Petitioner has not satisfied its burden with respect to Ground 1, because it does not explain adequately why highlighting a patient's allergies in the context of filling a prescription renders obvious "prompts that can be highlighted by an operator to receive additional information relative to one particular [drug formulation] step," as required by element [8f]/[1d]. For Ground 2, Petitioner further supports its contention with reference to Morrison. Pet. 50–52 (citing Ex. 1007 ¶¶ 46, 70, 76, Fig. 14; Ex. 1003 ¶¶ 36, 72, 74).

Patent Owner opposes on the grounds that the cited passages "say nothing about prompts or highlighting, let alone highlightable prompts 'to receive additional information relative to one particular step.'" PO Resp. 49. We agree. Petitioner's arguments with respect to Morrison do not address

the deficiency in its position based on Alexander and Liff. Accordingly, Petitioner has failed to establish that the combination of Alexander, Liff, and Morrison discloses or renders obvious element [8f]/[1d].

> d) Element [8l]: "a display communicatively coupled to the order processing server . . . outputting the dose order queue and metrics concerning activity at the dose preparation station"

As discussed in section II(C)(5)(e), Petitioner has established sufficiently that element [8l] is obvious over the combination of Alexander and Liff.

In Ground 2, Petitioner further relies on Morrison with respect to this element. Pet. 49. Morrison discloses a "master hospital queue" that displays "the total number of orders in the hospital queue and the time of the oldest order in the queue" and "hospital service level tracking[, which] alerts for aging orders and provides operational and clinical metrics related to order volume, processing time and clinical consultation activity." Ex. 1007 ¶¶ 9, 55; *see also* section II(D)(1), above.

According to Patent Owner, Petitioner does not explain how Morrison's "'master hospital queue' translates into a metric concerning activity at a *dose preparation station*, *i.e.*, a single station within a hospital." PO Resp. 49–50. We do not find Patent Owner's argument persuasive in light of Dr. Young's well-reasoned testimony regarding industry standards for security at the relevant time. *See* Ex. 1003 ¶¶ 56–58. Dr. Young notes, for example, that Alexander discloses a requirement for "'secure login credentials, such as a username and password." *Id.* ¶ 57 (citing Ex. 1005, 5:43–45). "A person of ordinary skill art would have understood that the

login credentials would identify a specific user and that such credentials could be acquired by prompting the user to input their credentials into a user interface." *Id.* "It was also an industry standard that any access to the system be recorded, for example in a records database, that maintained a history of which users accessed the system." *Id.* ¶ 56. "At a minimum, it would have been obvious to a person of ordinary skill in the art to prompt the operator to provide his or her initials or signature as part of the record in preparing the dose order." *Id.* ¶ 58. Accordingly, Morrison further teaches or renders obvious "outputting the dose order queue and metrics concerning activity at the dose preparation station," as recited in element [8l].

e) Element [1f]: "wherein one input comprises an input that is prompted by the performance of the drug preparation steps"

In support of its arguments for the unpatentability of element [1f] under Ground 2, Petitioner refers to its prior arguments under Ground 1. Pet. 52. Patent Owner similarly refers to its arguments "with regard to the first challenged ground." PO Resp. 50. For the reasons set forth in section II(C)(6)(f), above, Petitioner has established sufficiently element [1f] is obvious under Ground 2.

f) Conclusion as to Ground 2

Petitioner has failed to establish that the combination of Alexander, Liff, and Morrison discloses or renders obvious elements [8j] and [8f]/[1d]. Petitioner has, therefore, not made the requisite showing that claim 8, and its dependent claims 9–13, or claim 1, and its dependent claims 2–7 and 22, would have been obvious under Ground 2.

E. Obviousness in view of Alexander, Liff, Morrison, and Peoples (Ground 3)

1. Overview of Peoples (Ex. 1008)

Peoples is directed to a "device and method . . . for converting products specific identification numbers associated with bar code indicia on pharmaceutical products to an industry standard identification number." Ex. 1008, Abstract. According to Peoples:

> The National Drug Code (NDC) was developed as a universal identification system for pharmaceutical products distributed in the U.S. . . . The NDC for prescription pharmaceuticals is the single basic identifier for all forms of pharmaceutical products in the health industry. Pharmacy computer systems, third-party prescription claims processing, and sale tracking, reporting and industry support services typically use the NDC to identify, describe and pay for pharmaceutical services. For pharmacy providers, legislation now mandates the use of the NDC for all Medicaid claims.

Id. at 2:20–39; *see id*. at 3:18–24.

According to Peoples, an NDC number may be presented in multiple formats and "[p]roblems have arisen in the various bar code types have different character lengths which do not correspond to the ten-digit NDC number." *Id.* at 3:1–39. To address this problem, Peoples teaches a system and method for converting various NDC formats into standard bar code formats. *See, e.g.*, *id.* at 3:39–55.

2. Motivation to Combine Alexander, Liff, and Morrison with Peoples

According to Petitioner, one of ordinary skill in the art would have been motivated to further combine Alexander, Liff, and Morrison with Peoples

> [b]ecause the use of NDCs to identify drugs was mandatory (and ubiquitous) well before the 2005 time frame, a POSITA would have been motivated to implement the methods taught by Peoples in order to read NDCs with the bar code readers disclosed in Alexander, Liff, and Morrison and to utilize those NDCs to identify and track the medications prepared and dispensed using the Alexander, Liff, and Morrison systems.

Pet. 62 (citing Ex. 1003 ¶ 89).

Further to its arguments regarding motivation to combine Alexander, Liff, and Morrison (discussed in section II(D)(2), above), Patent Owner argues that "[t]here also would not have been a reason to use a bar code scanner, such as disclosed in *Peoples*, with the automated dispensing system disclosed by *Liff*, or with the order processing system of *Morrison* because the pharmaceuticals being dispensed are already in an automated medication dispensing system, so no scanning would be necessary. PO Resp. 51 (citing Ex. 2008, ¶¶ 56–57, 97–98, 100).

But as Petitioner points out, Liff teaches that such scanning is needed "to verify that the correct pharmaceutical has been dispensed." Reply 15 (citing Ex. 1006, 7:28–32; Ex. 1011, 43:16–44:2). Petitioner similarly points to evidence that one of ordinary skill in the art reading Alexander "would have understood that the label for a vial of medication or diluent such as a vial of sterile water would allow a pharmacist, or other medical

professional, to verify the contents of the drug product or diluent." *Id.* at 15–16 (citing Ex. 1005, 10:3–14, Ex. 1003 ¶ 47). Accordingly, and in light of the evidence of record, we find that Petitioner has established that one of ordinary skill in the art would have been motivated to combine Alexander, Liff, and Morrison, with Peoples.

3. Element [3c]: "scanning a label on the diluent that is to be combined with the drug product; and capturing an image of the diluent"

With respect to Ground 3, Petitioner relies on the teachings Alexander and Liff as teaching or rendering obvious this element. *See e.g.*, Pet. 63–64. For Ground 3, Patent Owner revisits its arguments, discussed above, that there is no need to scan components used to prepare a dose in Alexander, Liff, or Morrison. PO Resp. 52–53. As set forth in section II(C)(6)(f), Petitioner has established that element [3c] is rendered obvious by Alexander alone. In particular, we find persuasive Petitioner's argument, supported by the testimony of Dr. Young that, one of ordinary skill in the art reading Alexander "would have understood that the label for a vial of medication or diluent such as a vial of sterile water would allow a pharmacist, or other medical professional, to verify the contents of the drug product or diluent" and that "the use of such label for a vial of medication/diluent is precisely for identification and tracking purposes." Reply 15–16 (citing Ex. 1005, 10:3–14; Ex. 1003 ¶¶ 47, 89).

4. Elements of Independent Claims 1 and 8.

In Ground 3, Petitioner raises no additional arguments with respect to element [8j] or element [8f]/[1d]. *See* Pet. 62–67. Claims 3–6 and 11–13

challenged under this ground all depend from independent claims 1 or 8 and, thus, incorporate all elements of the respective independent claims. Petitioner has not established that elements [8j] or [8f]/[1d] are rendered obvious by the combination of Alexander, Liff, and Morrison, and has provided no evidence that Peoples fills these gaps. Accordingly, Petitioner has not made the requisite showing that the claims challenged under Ground 3, claims 3–6 and 11–13, are obvious under Ground 3.

5. Conclusion as to Ground 3

Petitioner has failed to establish that the combination of Alexander, Liff, Morrison, and Peoples discloses or renders obvious elements [8j] and [8f]/[1d]. Petitioner has, therefore, not made the requisite showing that claim 8, and its dependent claims 9–13, or claim 1, and its dependent claims 2–7 and 22 would have been obvious under Ground 3.

F. Motion to Exclude

Petitioner moved to exclude "Exhibits 2025 and 2030 in their entirety, and any reference to or reliance on them." Mot. Excl. 1. Patent Owner opposed the motion (Resp. Mot. Excl.) and Petitioner filed a Reply (Reply Mot. Excl.).

Exhibit 2030 appears to be a blog article discussing two Board rulings on design choice. As we do not rely on Exhibit 2030, we dismiss Petitioner's motion as moot with respect to this exhibit.

Patent Owner submitted Exhibit 2025 in connection with its Sur-reply to buttress its arguments that claim 8 requires a "hard stop." Sur-reply 3–4. Patent Owner's argument concerning Exhibit 2025 directly addresses

Petitioner's arguments in the Reply regarding the meaning of element [8j]. *See id.* Although the Panel considered Patent Owner's argument, we did not find it particularly informative, and accept Patent Owner's explanation that "hard stop" is merely a short hand designation for the words of element [8j], which we construe according to its plain and ordinary meaning without reference to Exhibit 2025. *See* section II(B)(3), above.

Patent Owner also relies on Exhibit 2030 in response to Petitioner's contention "that there is not a nexus between barcode scanning and 'right drug' statistics from DoseEdge." Sur-reply 20–21. Although we find Patent Owner's response justified, we did not rely on Exhibit 2030 in determining that Petitioner had not rebutted Patent Owner's presumption of nexus. *See* section II(C)(5)(a), above. In any event, we afforded Petitioner an opportunity to respond to Patent Owner's Sur-reply exhibits, which it did. *See* Suppl. Reply.

For the above reasons, we do not find persuasive Petitioner's generalized implication that it was prejudiced by Patent Owner's submission of the Exhibit 2025 in its Sur-reply for lack of "an opportuning to cross-examine PO's expert on the new evidence and present rebuttal evidence." *See* Mot. Excl. 1, 4; Reply Mot. Excl. 1–3. Accordingly, we deny on the merits, Petitioner's motion to exclude Exhibit 2025.

III. CONCLUSION

For the foregoing reasons, Petitioner has not shown by a preponderance of the evidence that any of the challenged claims of the '579 Patent are unpatentable, as summarized in the following table:

Claims	35 U.S.C §	References/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–12, 22	103(a)	Alexander, Liff		1–12, 22
1–12, 22	103(a)	Alexander, Liff, Morrison		1–12, 22
3–6, 11–13	103(a)	Alexander, Liff, Morrison, Peoples		3–6, 11–13
Overall Outcome				1–13, 22

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–13, and 22 of the '579 patent have not been shown to be unpatentable;

FURTHER ORDERED that Petitioner's motion to exclude Exhibit 2030 is dismissed as moot;

FURTHER ORDERED that Petitioner's motion to exclude Exhibit 2025 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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Exhibit 1001