No. 20-1937

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BECTON, DICKINSON AND COMPANY,

Appellant,

v.

BAXTER CORPORATION ENGLEWOOD,

Appellee.

Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board in *Inter Partes* Review No. IPR2019-00119

PETITION FOR REHEARING EN BANC BY APPELLEE BAXTER CORPORATION ENGLEWOOD

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July 12, 2021

CERTIFICATE OF INTEREST

Counsel for the Appellee Baxter Corporation Englewood certifies the following:

1. **Represented Entities**. Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

   Baxter Corporation Englewood.

2. **Real Party in Interest**. Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

   Baxter Healthcare Corporation.

3. **Parent Corporations and Stockholders**. Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

   Baxter International, Inc.

4. **Legal Representatives**. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

   None/Not Applicable.

5. **Related Cases**. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

   Baxter Healthcare Corporation and Baxter Corporation Englewood v. Becton, Dickinson and Company, No. 3:17-cv-02186 (S.D. Cal.).

6. **Organizational Victims and Bankruptcy Cases**. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None/Not Applicable.

July 12, 2021

/s/ George C. Summerfield
Signature of Counsel

George C. Summerfield
Printed Name of Counsel

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STATEMENT PURSUANT TO FED. CIR. R. 35(b)(2)

Based on my professional judgment, I believe the panel decision is contrary to the following decisions:

Apple Inc. v. Samsung Electronics Co., Ltd., 839 F.3d 1034, 1039 (Fed. Cir. 2016) (*en banc*);

Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 138 S. Ct. 1365, 1374-75 (2018); and

Cuozzo Speed Tech., LLC v. Lee, 136 S. Ct. 2140, 2144 (2016)).

July 12, 2021

/s/ George C. Summerfield
Signature of Counsel

George C. Summerfield
Printed Name of Counsel

I. INTRODUCTION

The Court's *en banc* decision in *Apple Inc. v. Samsung Electronics Co., Ltd.* made clear that, in reviewing a jury verdict, "it is beyond [the Court's] role to reweigh the evidence or consider what the record might have supported, or investigate potential arguments that were not meaningfully raised." 839 F.3d 1034, 1062 (Fed. Cir. 2016) (*en banc*). The panel in *Apple* and this Panel, in reversing a decision below, have in common that they: addressed a claim construction issue not appealed by either party; relied on extra-record evidence; and dismissed substantial evidence supporting the decision in favor of evidence purportedly supporting the losing party—all found to be problematic in *Apple.*

Baxter now seeks *en banc* rehearing of the Panel's precedential decision in order to restore the Board's decision on patentability, and to confirm that the *en banc* decision in *Apple* regarding the limits of appellate review apply even more so to administrative appeals, given the limits imposed by the Administrative Procedures Act ("APA") and the America Invents Act ("AIA"), which collectively proscribe each of the afore-referenced actions by the Panel. Vacating the Panel's findings as to any one of the issues on which it reversed the Board, and for any aspect of appellate review exceeding the scope set forth in *Apple*, the APA, and/or the AIA, warrants reinstating the decision below.

Separately, Baxter respectfully submits that the Panel misapplied the law regarding what qualifies as prior art under Section 102(e)(2), *i.e.*, that a canceled patent is not void *ab initio* and may nonetheless qualify as a "patent granted" under this section. As Alexander is cited in every challenge ground, the Panel's decision finding the claims of the '579 Patent obvious should be vacated.

II. PROCEDURAL BACKGROUND

Independent claim 8 of the '579 Patent requires a "dose preparation station … wherein each of the [drug preparation] steps must be verified as being properly completed before the operator can continue with the other steps of the drug preparation process" ("the Verification Limitation"). Appx96 at cl. 8. The entirety of BD's argument in its IPR petition regarding the Verification Limitation was: "*See* [claim] element 1e, 1f-k." Appx5044. However, as the Panel noted, "the 'verification' limitation . . . appears in claim 8 but not claim 1." Panel Decision at 2. The Board found that BD had not demonstrated by a preponderance of the evidence that the prior art teaches or renders obvious the Verification Limitation. *See* Appx37. The Panel reversed the Board's decision based in part on extra-record evidence from the appeal argument. Panel Decision at 7 & 9.

Independent claims 1 and 8 further contain the limitation "an interactive screen that includes prompts that can be highlighted by an operator to receive additional information relative to one [drug formulation] step" ("the Highlighting

Limitation"). Appx96-97 at cls. 1 & 8. The Board found that BD had failed to prove that the prior art renders the Highlighting Limitation obvious. Appx43. Again, the Panel reversed. Panel Decision at 14.

III. THE PANEL EXCEEDED THE PROPER SCOPE OF REVIEW SET IN THE *APPLE* DECISION

A. As in *Apple*, the Panel *Sua Sponte* Raised and Decided Undisputed Claim Construction Issues

The *en banc* Court in *Apple* found it problematic that, in reviewing a jury verdict, the panel *sua sponte* construed the term "analyzer server," an issue that had not been appealed by either party. *Apple,* 839 F.3d at 1043–44. In this matter, the Board construed the Verification Limitation to mean "*the system* will not allow the operator to proceed to the next step until the prior step has been verified," which neither party appealed. Appx17 (emphasis added). Further, neither party ever proposed a construction of the Highlighting Limitation.

The Panel construed the unappealed Verification Limitation to not require "a mechanical stop as opposed to requiring authorization from a pharmacist to continue." Panel Decision at 8. The Panel went on to discuss the intrinsic evidence supporting its view of this construction.[1] *See id*. (citing Appx87 at 15:39-45). This

[1] Although the Panel should not have reviewed an unappealed construction, having done so, the Panel failed to consider the plain and ordinary meaning of the language "a dose preparation station," which qualifies the Verification Limitation, and requires a mechanical stop by the system. *See, e.g., Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1362 (Fed. Cir. 2007) (the plain and

new claim construction was central to the Panel's finding that Alexander taught the Verification Limitation by "requiring authorization from a pharmacist." *See id.*

Similarly, the Panel *sua sponte* construed the Highlighting Limitation as including "clicking [a] box" labeled "[d]etail." *Id.* at 13. Again, this new construction predicated the Panel's finding that the Highlighting Limitation was obvious in light of Liff's teachings of "basic computer functionality." *See id.* at 12.

Under the reasoning in *Apple*, appellate review should not include undisputed issues. That prohibition is mandated in the APA, which statutorily limits appeals to issues "when presented." 5 U.S.C. §706. This "when presented" language prohibits a reviewing court from taking up an issue on review that has been waived, which BD did when it failed to: appeal the Board's Verification Limitation construction; and propose a construction of the Highlighting Limitation below. *See Elbit Sys. of Am., LLC v. Thales Visionix, Inc.*, 881 F.3d 1354, 1359 (Fed. Cir. 2018) (failure to raise argument on appeal constitutes waiver); *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1075 (Fed. Cir. 2017) ("the general rule is that any argument not raised before the Board is waived on appeal."). Given these waivers, the Panel exceeded its statutory authority in addressing these claim construction issues.

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ordinary meaning of a claim limitation controls unless the specification sets forth a specialized meaning).

B. As in *Apple,* the Panel Resorts to Extra-Record Evidence

In *Apple,* the Court noted the panel's resort to "extra-record extrinsic evidence" in the form of counsel's admission at the appeal argument "to modify [an] agreed upon and unappealed construction" of the "analyzer server" limitation. *See Apple,* 839 F.3d at 1042–43. The Court reiterated that it limits its "appellate review to the record before the district court" when reviewing a jury verdict. *See id.* at 1044.

The Panel here cited to a purported concession from Baxter's counsel made during appellate argument, that "a non-pharmacist who, without authorization to proceed, did not stop processing work would likely be disciplined," as the sole non-patent evidence supporting its Verification Limitation findings. Panel Decision at 7. This, according to the Panel, addressed the portion of the Verification Limitation wherein verification is required "before the operator can continue with the other steps of the drug preparation process." *See id.*[2]

The AIA mandates that appellate review is conducted "on the record before the Patent and Trademark Office." 35 U.S.C. §§ 144, 319; *accord Camp v. Pitts*, 411 U.S. 138, 143–44 (1973) ("the focal point should be the administrative record already in existence, not some new record made initially in the reviewing court").

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[2] Further, Baxter respectfully disagrees with the Panel's factual finding. Because any disciplinary action would take place only *after* the drug formulation process has been completed, that necessarily means the step was not "verified as being properly completed *before* the operator can continue with the other steps of the drug preparation process," as required by claim 8.

That the Panel relied upon extra-record evidence in contravention of the statute here is at least as improper as the panel having done so in the context of a jury verdict review.

C. As in *Apple,* the Panel Departed from the Substantial Evidence Review Standard

The *Apple* decision affirmed that this Court reviews the facts underlying an obviousness determination for substantial evidence. *Apple,* 839 F.3d at 1047. That review does not include reweighing the evidence, considering what the record might have supported, or investigating potential arguments that were not meaningfully raised. *Id.* at 1062. Indeed, "[i]f two inconsistent conclusions may reasonably be drawn from the evidence in record, the PTAB's decision to favor one conclusion over the other is the *epitome* of a decision that must be sustained upon review for substantial evidence." *Elbit Sys. of Am.*, 881 F.3d at 1356 (emphasis added) (internal citation omitted); *In re Jolley*, 308 F.3d 1317, 1329 (Fed. Cir. 2002) (same); *see also Consolo v. Federal Maritime Com.*, 383 U.S. 607, 620 (1965) ("the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence"). For the reasons discussed below, despite the Panel in this Appeal having characterized its review as one of substantial evidence, that review for the two separate claim limitations on which it reversed the Board was anything but.

1. The Verification Limitation

In its IPR petition, BD's entire argument regarding Alexander's purported teaching of the Verification Limitation was "[*s*]*ee* element 1e, 1f-k," *i.e.,* elements e through k of claim 1. *See* Appx5044. As the Panel noted, however, "the 'verification' limitation . . . appears in claim 8 but not claim 1." Panel Decision at 2. Accordingly, there is no evidence or argument in BD's IPR petition specifically addressing the Verification Limitation in claim 8.

The following is the extent of BD's relevant discussion regarding Alexander's teachings as concerns claim 1:

> Alexander explains that such images are captured to allow for confirming the performance of each discrete step: 'a remote pharmacist ***may verify each step*** as it is performed and may provide an indication to a non-pharmacist performing the pharmacy [*sic*] that the ***step was performed correctly***.' (*Id.* at 9:49-52)
>
> A POSITA would have understood that in order for a remote pharmacist to successfully verify that each step was performed correctly (i.e., in accordance with the recipe), each captured image would need to display the result of a discrete isolated event performed in accordance with one preparation step. (Ex. 1003, ¶¶ 36-37, 43, 45-46.) It would have been at least obvious to provide a remote pharmacist with captured images displaying a result of a discrete isolated event performed in accordance with one preparation step. (*Id.*)

Appx5028 (emphasis in original). Importantly, at no point in the IPR petition did BD explain how the foregoing teach or suggest that "each of the [drug preparation] steps must be verified as being properly completed *before the operator can continue with the other steps of drug preparation process*," as claim 8 requires.

Baxter, in arguing that the Verification Limitation is absent, presented expert testimony from Dr. Brittain, that: (1) claim 8 of the '579 Patent provides for a "hard stop;" (2) a hard stop "halts the progress of prescribing, dispensing, or administering a medication that would likely be dangerous to a patient, with further execution of the order blocked;" and (3) "[t]he system of Alexander provides neither a hard stop or a soft stop; it only sends the images of preparation process to an off-site pharmacist for verification." Appx3006–3007, ¶70. Baxter also presented evidence that "Alexander only discusses that 'a remote pharmacist *may* verify each step' (Ex. 1005, 9:49-52); not that the pharmacist *must* verify each and every step *before* the operator is allowed to proceed." Appx36 *citing* Appx3009–3010, ¶76 (emphasis in original).

Dr. Brittain also discussed the electronic version of the pull-back verification method taught in Alexander, which occurs at the end of the drug compounding process, as an "embodiment" of that reference. Appx3007, ¶71. That embodiment supports his ultimate conclusion that "[t]he system of Alexander provides neither a hard stop or a soft stop; it only sends the images of preparation process to an off-site pharmacist for verification." Appx3006–3007, ¶70.

Relying upon "the record as a whole," including "the testimony of the parties' respective experts," the Board held that "BD has not demonstrated by a preponderance of the evidence that Alexander teaches or renders obvious [the

Verification Limitation]." *See* Appx37. As the *Apple* decision noted, "what a reference teaches is a question of fact." 839 F.3d at 1051.

The Panel, in reviewing the Board's decision on the Verification Limitation, omitted any discussion of Baxter's evidence that "[t]he system of Alexander provides neither a hard stop or a soft stop." *See* Appx3006–3007, ¶70. Rather, the Panel began its review by interpreting *de novo* the meaning of the term "may" in Alexander, drawing a purported distinction between that term and "occasionally," and stating that Alexander's teaching is actually that "one 'may' choose to systematically check each step." *See* Panel Decision at 6. The Panel then goes on to discuss several passages from Alexander that supposedly support its interpretation of Alexander's teachings on this point, including the abstract—a section of Alexander that BD did not cite. *See id.* at 6–7. Further, as noted above, the Panel cited the purported concession from Baxter's counsel from the appeal argument that "a non-pharmacist who, without authorization to proceed, did not stop processing work would likely be disciplined." Panel Decision at 7.[3] The Panel did not discuss BD's losing argument and evidence or, more specifically in this case, the lack thereof.

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[3] Ironically, the Panel did cite to an admission from BD's expert, Dr. Marc Young, actually supporting *Baxter's* position that, when using the system taught in Alexander, "an improperly prepared dose 'could go out to the patient and cause harm.'" Panel Decision at 7.

Finally, the Panel characterized Baxter's arguments on which the Board relied as conflating the embodiment from Alexander wherein "a remote pharmacist may verify each step as it is performed" and the embodiment comprising an electronic version of the pull-back method of verification. Panel Decision at 9.

Per this Court's *en banc* decision in *Apple*, the Panel was not permitted to ignore Baxter's expert evidence, which the Board found credible, under a substantial evidence review. Appx37; *Apple*, 839 F.3d at 1062 (expert testimony qualifies as substantial evidence). Nor was the Panel permitted to consider or make arguments that BD did not make below, "review whether [BD's] losing position was also supported by substantial evidence or [] weigh the relative strength of [BD's] evidence against [Baxter's] evidence." *Apple*, 839 F.3d at 1052.[4] And while the *Apple* case arose in the context of a jury verdict, those same appellate missteps are statutorily prohibited under the AIA and APA.

For instance, in an appellate review under the APA, a "substantial evidence" review—not a *de novo* review of evidence—is statutorily mandated. 5 U.S.C. §706(2)(E). Similarly, the Panel's resort to evidence and argument beyond the scope

[4] To that end, if the Alexander reference does not qualify as "substantial evidence" sufficient to support the Board's decision, it should not qualify as "substantial evidence" sufficient to support BD's losing position either. *Consolo*, 383 U.S. at 620; 86 S. Ct. at 1026 ("the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence").

of BD's IPR petition is problematic given the statutory mandate that an IPR petition "identifies, in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim." 35 U.S.C. §312(a). Also, "the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence." 35 U.S.C. §316(e). As such, the IPR petition is to be "the centerpiece of the proceeding both before and after institution." *SAS Institute, Inc. v. Iancu*, __ U.S. __, 138 S. Ct. 1348, 1358 (2018); *see also Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.,* 821 F.3d 1359, 1369 (Fed. Cir. 2016) ("the expedited nature of IPRs bring with it an obligation for petitioners to make their case in their petition to institute."). The Panel's reversal based on evidence and arguments outside BD's IPR petition violates the AIA, including its Due Process and burden protections for the patentee.

2. The Highlighting Limitation

With regard to the Highlighting Limitation, BD's IPR petition cited its expert, Dr. Young, opining that the Liff reference "teaches that the user can highlight various inputs and information displayed on the screen, as illustrated by Figure 14F." Appx43 (quoting Appx1496–1497, ¶63). Baxter's opposing position, which the Board adopted, was that Liff Figure 14F "merely highlights a patient's allergies and 'does not even suggest formulation steps.'" Appx43. The Board also found that

"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 preparation context to receive additional information relative to one particular step in that process, or even what additional information might be relevant." *Id.* As a result, the Board found that BD had failed to prove that Liff teaches or suggest the Highlighting Limitation. *Id.*

The Panel, reviewing the Board's findings, began by referencing Liff's Figure 10—a figure not cited by BD for the Highlighting Limitation. *See* Panel Decision at 9–10. The Panel then acknowledged BD's failure to show "that Liff 'directly discloses highlighting to receive additional language about a drug preparation step.'" *Id.* at 11–12.

Still, the Panel noted BD's argument that "Liff discloses basic computer functionality—i.e., using prompts that can be highlighted by the operator to receive additional information—that would render the highlighting limitation obvious when applied in combination with other references." Panel Decision at 12. The Panel cites pages 4, 24 and 25 of BD's brief as the source of this argument. *Id.* Those pages cite <u>no</u> evidence for either the proposition that highlighting was "basic computer functionality" at the time of application for the '579 Patent, or that such functionality would have rendered obvious the particular concept of highlighting to obtain additional information about a drug preparation step. *See* Opening Brief at 4

& 24–25. It is pure attorney argument, which "is not evidence and cannot rebut other admitted evidence." *Elbit Sys. of Am.*, 881 F.3d at 1359.

Beyond Liff's teaching of highlighting patient information, BD cited to Dr. Young's testimony making the pedestrian point that Liff's interface could have included a tab containing information including "the text of the order itself, information relating to who or how the order should be prepared, or where the order should be dispensed." *See* Panel Decision at 12 (quoting Appx1497). The Panel went on to repeat that testimony twice more. *See id.* at 13.

From there, the Panel concluded; "[t]hat Liff's teaching was 'to highlight patient characteristics when dispensing a prepackaged medication' does not suggest that a person or ordinary skill would not have used highlighting . . . for other information in the pharmacy field." *Id.* Of course, *the Board had concluded the opposite*, making the factual finding that highlighting information about a patient suggests nothing about the obviousness of highlighting to receive additional information about a drug preparation step. Appx43.

Accordingly, per this Court's *en banc* decision in *Apple*, the Panel was not permitted to ignore Baxter's expert evidence, which the Board found credible, under a substantial evidence review. Appx43; *Apple*, 839 F.3d at 1062 (expert testimony qualifies as substantial evidence). Nor was the Panel permitted to consider or make arguments that BD did not make below, "review whether [BD's] losing position was

also supported by substantial evidence or [] weigh the relative strength of [BD's] evidence against [Baxter's] evidence." *Apple*, 839 F.3d at 1052. Indeed, as discussed above, these actions are prohibited under the APA and AIA statutes. 5 U.S.C. §706(2)(E) (substantial evidence review); 35 U.S.C. §312(a) (IPR limited to evidence and argument in the petition); 35 U.S.C. §316(e) (petitioner bears the burden of proving unpatentability); *SAS Institute,* 138 S. Ct. at 1358 (IPR petition is "the centerpiece of the proceeding both before and after institution."); *see also Intelligent Bio-Sys., Inc.*, 821 F.3d at 1369 ("the expedited nature of IPRs bring with it an obligation for petitioners to make their case in their petition to institute.").

IV. ALEXANDER IS NOT PRIOR ART

Baxter argued that Alexander does not qualify as prior art under pre-AIA Section 102(e)(2) because of its cancellation following *inter partes* review. Panel Decision at 14–15. The effect of cancellation is *ab initio*—as if the grant never occurred—and therefore, Alexander is not a "granted" patent as required under Section 102(e)(2).[5] *See* Response Brief at 35–36 (citing *Peck v. Collins*, 103 U.S. 660, 664 (1880); *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1374-75 (2018), *Cuozzo Speed Tech., LLC v. Lee*, 136 S. Ct. 2140, 2144 (2016)). The Panel did not address the issue of *ab initio* cancellation at all. Rather,

[5] Alexander would still generally qualify as prior art under other sections of 102 upon publication; however, in this case, publication occurred several years after the challenged patent's critical date.

the Panel addressed the prior art status of Alexander in two sentences: "The text of the statute requires only that the patent be 'granted,' meaning the 'grant[]' has occurred. The statute does not require that the patent be currently valid." Panel Decision at 15 (internal citation omitted).

This decision runs counter to, *inter alia*, the Supreme Court decisions above. *See Peck*, 103 U.S. at 664 (canceled patent claims 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"). It also runs counter to the Patent Statute's infringement sections. Section 271(a) provides: "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any *patented* invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a) (emphasis added). Section 281 provides: "[a] patentee shall have remedy by civil action for infringement of his patent." 35 U.S.C. § 281. Neither provision expressly requires that a patent be "currently valid," only that it was "patented." Thus, under the Panel's reasoning, a patentee could bring and maintain a suit for patent infringement that occurred before cancellation. Of course, this is not the law. *See, e.g.*, *Fresenius USA, Inc. v. Baxter Intern., Inc.*, 721 F.3d 1330, 1346 (Fed. Cir. 2013) (barring suit for pre-cancellation damages a because "cancelled claims were void *ab initio*"). Additionally, section 102(e)(2) presupposes a legal fiction - that an issued patent not actually in the public

domain prior to the priority date is nonetheless prior art. Once that patent is canceled, that fiction is destroyed.

V. CONCLUSION

For the foregoing reasons, the Panel's decision should, after rehearing, be vacated and the Board's decision affirmed.

Dated: July 12, 2021

Respectfully submitted,

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ADDENDUM

United States Court of Appeals for the Federal Circuit

BECTON, DICKINSON AND COMPANY,
Appellant

v.

BAXTER CORPORATION ENGLEWOOD,
Appellee

2020-1937

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2019-00119.

Decided: May 28, 2021

THOMAS SAUNDERS, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, DC, argued for appellant. Also represented by OMAR KHAN, New York, NY; KATHERINE P. KIECKHAFER, Boston, MA.

BENJAMIN EDWARD WEED, K&L Gates LLP, Chicago, IL, argued for appellee. Also represented by KATHERINE ALLOR, GEORGE C. SUMMERFIELD, JR.; MICHAEL IRA COHEN, Baxter International Inc., Deerfield, IL.

Before PROST*, CLEVENGER, and DYK, *Circuit Judges*.

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* Sharon Prost vacated the position of Chief Judge on May 21, 2021.

DYK, *Circuit Judge*.

Becton, Dickinson and Company ("Becton") appeals a decision from the Patent Trial and Appeal Board ("Board"), determining that certain claims of U.S. Patent No. 8,554,579 ("the '579 patent") were not invalid as obvious. We reverse.

BACKGROUND

Baxter Corporation Englewood ("Baxter") is the owner of the '579 patent, which is directed to "[s]ystems for preparing patient-specific doses and a method for telepharmacy in which data captured while following [a protocol associated with each received drug order and specifying a set of steps to fill the drug order] are provided to a remote site for review and approval by a pharmacist." '579 patent, Abstract.

Becton petitioned for inter partes review of 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 parties agree that claims 1 and 8 of the '579 patent are illustrative.

There are two contested limitations on appeal. The first is the "verification" limitation, which appears in claim 8 but not claim 1. The second is the "highlighting" limitation, which appears in both claims 1 and 8. The relevant portion of claim 8, containing both limitations, states:

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

Id. col. 32 l. 52–col. 33 l. 30 (highlighting and verification limitations emphasized). Claims 1 and 8 are set forth in full in an Attachment to this opinion.

In asserting that the challenged claims were invalid, Becton relied primarily on three prior art references: U.S. Patent No. 8,374,887 ("Alexander"), U.S. Patent No. 6,581,798 ("Liff"), and U.S. Patent Publication No. 2005/0080651 ("Morrison").

The Board found that Becton had established that one of ordinary skill in the art would have been motivated to combine Alexander and Liff, as well as Alexander, Liff, and Morrison. The Board also determined that Baxter's "evidence of secondary considerations [was] weak." J.A. 34.

However, the Board determined that Alexander did not teach or render obvious the verification limitation and that combinations of Alexander, Liff, and Morrison did not teach or render obvious the highlighting limitation. The

Board concluded that, as a result, none of the challenged claims (1–13, 22) was shown to be unpatentable.[1]

Becton appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § 141(c).

DISCUSSION

> A patent may not be obtained . . . 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 said subject matter pertains.

35 U.S.C. § 103(a).[2] In reviewing the Board's determination on the question of obviousness, "[w]e review the Board's legal conclusions de novo and its factual findings for substantial evidence." *MCM Portfolio LLC v. Hewlett-Packard Co.*, 812 F.3d 1284, 1293 (Fed. Cir. 2015).

I

We first address the verification limitation, "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." '579 patent, col. 33 ll. 18–21. The Board construed the limitation under the broadest

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[1] The Board also found that the challenged claims were not shown to be unpatentable on a separate third ground asserted by Becton, which Becton does not appeal.

[2] Congress amended § 103 when it enacted the Leahy-Smith America Invents Act ("AIA"). Pub. L. No. 112-29, § 3(c), 125 Stat. 284, 287 (2011). However, because the challenged claims of the '579 patent have an effective filing date before March 16, 2013, the pre-AIA version of § 103 applies. *See id.* § 3(n)(1), 125 Stat. at 293.

reasonable interpretation standard.[3] Under the Board's construction, which neither party appeals, the verification limitation requires that "the system will not allow the operator to proceed to the next step until the prior step has been verified." J.A. 17. The Board further determined that the plain language of the verification limitation does not require "automatic system function" to "trigger verification." *Id.*[4]

The Board determined that Alexander does not teach or render obvious the verification limitation. Specifically, the Board found persuasive Baxter's argument that Alexander "only discusses that 'a remote pharmacist may verify each step'; not that the remote pharmacist must verify each and every step before the operator is allowed to proceed." *See id.* at 36–37 (quoting *id.* at 5284) (citation and emphasis omitted). We conclude that the Board's determination is not supported by substantial evidence.

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[3] Because the filing date of the petition for inter partes review, October 29, 2018, was before November 13, 2018, the broadest reasonable interpretation standard applies. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (codified at 37 C.F.R. § 42.100); *see also Personalized Media Commc'ns, LLC v. Apple Inc.*, 952 F.3d 1336, 1340 n.2 (Fed. Cir. 2020).

[4] Baxter refers to the verification limitation as a "hard stop," Appellee's Br. 25, as opposed to a "soft stop," which, according to Baxter, "provides information to the clinician about a potential drug safety or efficacy problem and may offer alternative suggestions for the clinician to consider." J.A. 5283 (citation omitted). Under the Board's construction, "'hard stop' is merely a short hand for [the verification limitation] and does not impute any additional meaning to the claim term." *Id.* at 15 n.8.

The passage from Alexander on which the Board relied states:

> [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.

Alexander, col. 9 ll. 47–54 (emphasis added).

In the context of Alexander, "may" does not mean "occasionally," but rather that one "may" choose to systematically check each step. This is quite clear from the context of Alexander.

Alexander is directed to "[a] system and method for remotely supervising and verifying pharmacy functions performed by a non-pharmacist at an institutional pharmacy." *Id.* Abstract. Alexander discloses that "software may be installed at both an institutional pharmacy site and at a remote pharmacist site allowing a pharmacist to view in real-time, or near real-time, images of the pharmacy work being performed." *Id.* col. 9 ll. 31–34. "Captured images and corresponding documentation may be transmitted from institutional pharmacy to the remotely located pharmacist, either directly or via a web site accessible to both." *Id.* Abstract. The purpose is to allow the pharmacist to "authorize" the work. *See id.*

In this process, the Alexander specification provides that the non-pharmacist is not authorized to proceed absent verification by the pharmacist. The abstract states that "[r]eceiving the pharmacist's verification may authorize the non-pharmacist to further process the work." *Id.*

Likewise, column two of the specification provides that "a pharmacist supervises and verifies the work, and subsequently authorizes non-pharmacist personnel to further process the work." *Id.* col. 2 ll. 51–53. Plainly, Alexander discloses systematic step-by-step review and authorization by the pharmacist.

It is also clear that, without the pharmacist's verification of "each step as it is performed," *id.* col. 9 ll. 49–50, the non-pharmacist is not "authorize[d]" to "further process the work," *id.* col. 2 ll. 52–53; *see also id.* Abstract. There is no significant difference between that teaching of Alexander and the '579 patent's verification requirement, which the Board construed as requiring that "the system will not allow the operator to proceed to the next step until the prior step has been verified." J.A. 17.

Baxter attempts to sustain the Board on two grounds not adopted by the Board. Baxter first contends that "Alexander does not disclose a system that would stop the operator from proceeding if a prior step was unverified, and that such an improperly prepared dose 'could go out to the patient and cause harm,'" quoting from the deposition testimony of Becton's expert witness, Dr. Marc Young. Appellee's Br. 29 (quoting J.A. 3376). Requiring authorization before proceeding necessarily stops the work if the authorization is not forthcoming. The remote operator cannot further process the work without authorization. Counsel for Baxter conceded at oral argument that, in Alexander's system, a non-pharmacist who, without authorization to proceed, did not stop processing work would likely be disciplined. Oral Arg. 25:55–26:40, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=20-1937_04082021.mp3.

Baxter also contends that Alexander's disclosure is insufficient because the verification limitation requires a "mechanical . . . prohibition" on continuing the work absent verification. *Id.* at 23:37–24:01. The Board's construction

requires that "the system will not allow the operator to proceed to the next step until the prior step has been verified," J.A. 17 (emphasis added), and Baxter contends that the use of the word "system" implies a mechanical stop.

Nothing in the construction requires a mechanical stop as opposed to requiring authorization from a pharmacist to continue. Nor does the specification of the '579 patent indicate that the "stop" cannot be in the form of an instruction from a pharmacist. *See, e.g.*, '579 patent, col. 15 ll. 39–45 ("If during any step, a verification error arises and there is a question as to whether the step was properly performed, the dose order processing is prevented from continuing to the next step until the step is verified as being properly performed or until the dose order is flagged as being not completed due to an error." (emphasis added)); *id.* col. 18 ll. 25–27, 56–58 (similar).

Finally, Baxter presents the '579 patent as an improvement to the "'pull-back' method" of pharmacist verification in sterile compounding. *See* Appellee's Br. 4. "Often a pharmacy technician (a non-pharmacist) performs the sterile compounding under a pharmacist's supervision, with the pharmacist responsible for final verification of the prepared dose." *Id.*

> According to the "pull-back" method, after combining ingredients using one or more syringes, the technician pulls each syringe back to the position it was in when it was full of the added component, but since the ingredients have already been combined, the syringe would be filled with air. The pulled-back syringe(s) along with other dose preparation materials would be in a basket, which the pharmacist would then use to reconstruct the process and verify that the technician had properly prepared the dose.

Id. (citations omitted).

According to Baxter, the pull-back method "left a lot of room for error in dose preparation of sterile compounds." *Id.* Baxter contends that the '579 patent improved the prior art by disclosing a "a system for dose preparation flow and verification of preparation steps, whereby the system prevents the dose preparer from proceeding to the next preparation step if the previous step has not been verified." *Id.* at 5.

The embodiment of Alexander, in which "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," Alexander, col. 9 ll. 49–52, is not the pull-back method (or an electronic version thereof). The Board's suggestion to the contrary, *see* J.A. 36–37, is not supported by substantial evidence.

We conclude that the Board's determination that Alexander does not teach the verification limitation is not supported by substantial evidence.

II

We next address the highlighting limitation, which requires "an interactive screen that includes prompts that can be highlighted by an operator to receive additional information relative to one particular step." '579 patent, col. 31 ll. 55–57, col. 33 ll. 4–6. Figure 10 of the '579 patent, "an exemplary display of a product preparation screen and procedure," *id.* col. 5 ll. 47–48, shows

> an interactive screen in that the user can simply highlight different areas either to receive more information or to enter information. For example, there is a Detail button 622 near the drug identification and if additional information is needed concerning this particular drug order, the user can simply highlight this particular button (as by "clicking" the box).

Id. col. 15 l. 58–col. 16 l. 3.

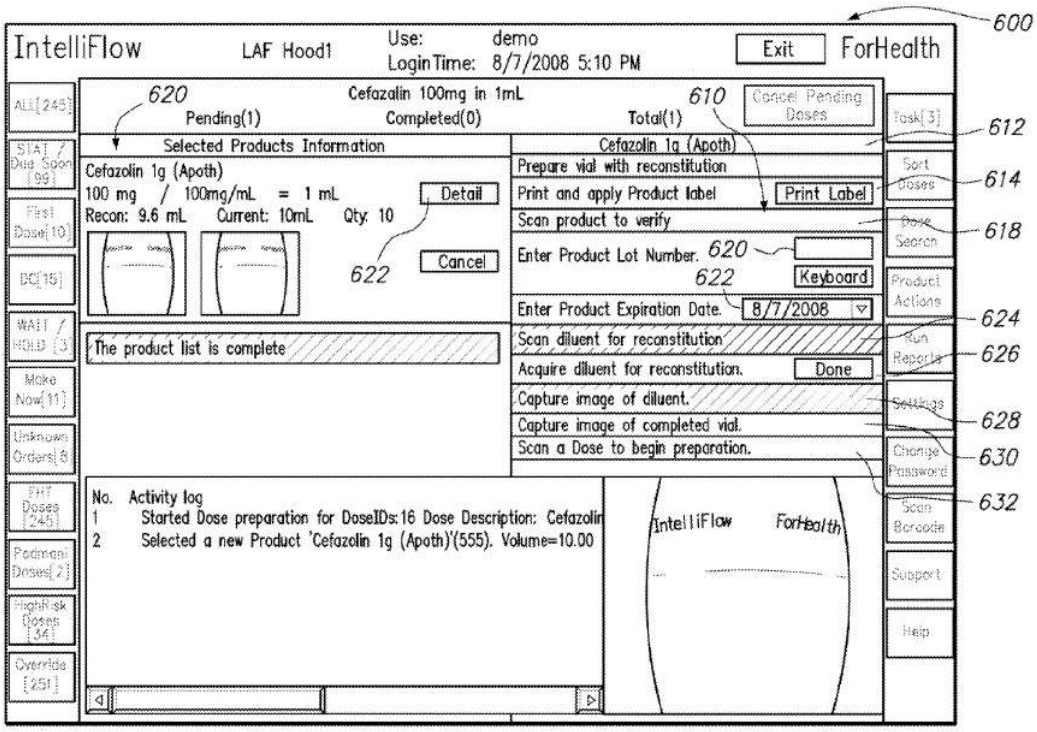

FIG. 10

Id. fig. 10.

The Board determined "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." J.A. 41. Given that determination, the only missing element of this limitation is the ability to highlight prompts to receive more information concerning drug preparation steps.

The Liff reference teaches highlighting in the pharmacy context. *See id.* at 1496–97 (declaration of Dr. Marc Young in support of petition for inter partes review). Liff is directed to "[a]n automated drug dispensing system [that] includes a cabinet adapted to store a variety of

prepackaged pharmaceuticals in a plurality of bins for filling patient prescriptions." Liff, Abstract. Liff teaches a user interface for a workstation, *see id.* col. 4 ll. 5–9, figs. 14A–14V, which provides the operator with options, such as "entering a new prescription" and "refilling a prescription." *Id.* col. 17 ll. 28–31 (referring to fig. 14A).

As Dr. Young testified in his declaration, Liff "teaches that the user can highlight various inputs and information displayed on the screen, as illustrated in Figure 14F." J.A. 1496–97. More specifically, the Board found that Liff taught "highlight[ing] patient characteristics when dispensing a prepackaged medication," *id.* at 43, and Baxter does not contend that this aspect of the Board's decision was in error.

Figure 14F of Liff is below:

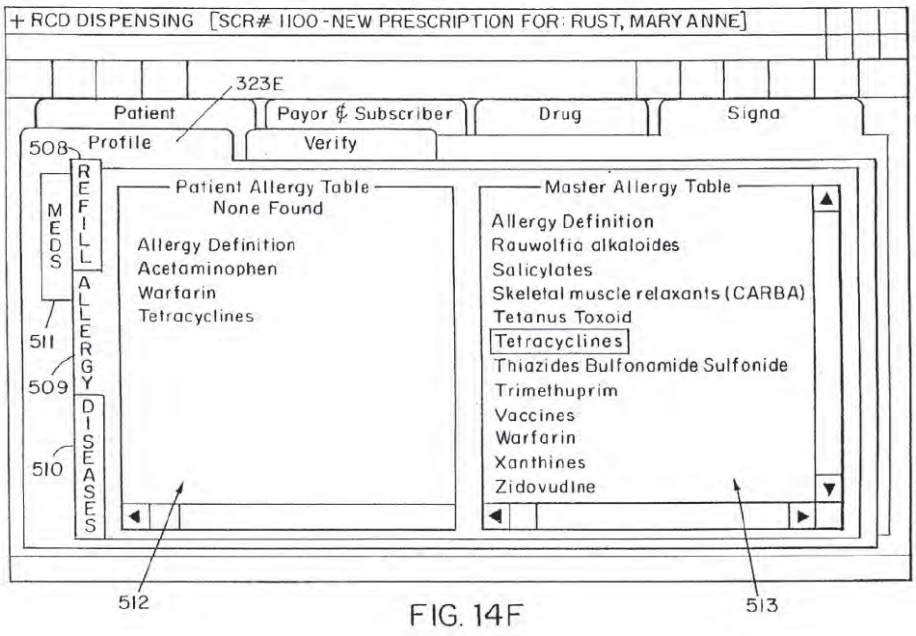

FIG. 14F

Liff, fig. 14F.

Becton does not argue that Liff "directly discloses highlighting to receive additional language about a drug

preparation step." Appellant's Br. 4. Becton instead argues that "Liff discloses basic computer functionality—i.e., using prompts that can be highlighted by the operator to receive additional information—that would render the highlighting limitation obvious when applied in combination with other references," primarily Alexander. *Id.* at 4 (emphasis omitted); *see also id.* at 24–25.

Becton relies on the following testimony of Dr. Young:

> A person of ordinary skill in the art would have understood that additional information could be displayed on the tabs taught by Liff and that additional tabs, with additional information, could also be displayed in the user interface, depending on the design needs and expected use of the software. For example, a person of ordinary skill in the art would have found it obvious to include in the user interface taught by Liff a tab for the prescription order and information regarding the prescription order that the operator was fulfilling. Such information could have included the text of the order itself, information relating to who or how the order should be prepared, or where the order should be dispensed.

J.A. 1497. The testimony of Baxter's expert, Dr. Jeffrey Brittain, was not to the contrary.

The Board found that "this present[ed] a close case." *Id.* at 43. As noted above, the Board agreed that, in light of Alexander and Liff, "one of ordinary skill in the art would have considered it obvious to provide a set of drug preparation steps on a computer." *Id.* at 41. Nevertheless, the Board determined that

> Dr. Young fail[ed] 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.

Id. at 43. The Board found that Becton's arguments with respect to Morrison did not address the deficiency in its position based on Alexander and Liff.

The Board's determination is not supported by substantial evidence. That Liff's teaching was "to highlight patient characteristics when dispensing a prepackaged medication," *id.*, does not suggest that a person of ordinary skill would not have used highlighting (accomplished in the '579 patent by "'clicking' [a] box" labeled "[d]etail," '579 patent, col. 15 l. 64–col. 16 l. 3) with respect to other information in the pharmacy field. Dr. Young, without contradiction, testified to the opposite, stating that "a person of ordinary skill in the art would have found it obvious to include in the user interface taught by Liff a tab for the prescription order and information regarding the prescription order that the operator was fulfilling." J.A. 1497. As the Supreme Court has made clear, "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

The Board erred in looking to Liff as the only source a person of ordinary skill would consider for what "additional information might be relevant." J.A. 43. "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. at 421. Dr. Young testified that "[a] person of ordinary skill in the art would have understood that additional information could be displayed on the tabs taught by Liff" and that "such information could have included the text of the order itself, information relating to who or how the order should be prepared, or where the order should be dispensed." J.A. 1497. Dr. Young further

testified that "[a] medication dose order for compounding a pharmaceutical would have been accompanied by directions for how the dose should be prepared, including step-by-step directions for preparing the dose." *Id.* Baxter points to no contrary testimony.

We conclude that the highlighting limitation would have been obvious to one of ordinary skill in the art in view of Alexander and Liff. The Board's determination that the highlighting limitation is not obvious over Alexander and Liff is not supported by substantial evidence. We need not reach Becton's arguments regarding Morrison.

III

As an alternative ground to affirm the Board's determination of non-obviousness, Baxter argues that the Board erred in determining that Alexander is prior art under 35 U.S.C. § 102(e)(2) (pre-AIA).[5] This section provides that "[a] person shall be entitled to a patent unless . . . the invention was described in . . . a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent." 35 U.S.C. § 102(e)(2).[6] It is undisputed that the filing date of the

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[5] Congress amended § 102 when it enacted the AIA. Pub. L. No. 112-29, § 3(b)(1), 125 Stat. at 285–87. However, because the application that led to the '579 patent was filed before March 16, 2013, the pre-AIA version of § 102 applies. *See id.* § 3(n)(1), 125 Stat. at 293.

[6] The Board noted that "Alexander is not prior art under 35 U.S.C § 102(e)(1)." J.A. 23. That section provides that "an application for patent, published under [35 U.S.C. § 122(b)], by another filed in the United States before the invention by the applicant for patent," is prior art. 35 U.S.C § 102(e)(1) (pre-AIA). The Board found that "the applicant [for Alexander] expressly requested that the application that matured into Alexander 'not be published under

application for Alexander is February 11, 2005, which is before the earliest filing date of the application for the '579 patent, October 13, 2008; that the Alexander claims were granted; and that the application for Alexander was filed by another.

Baxter contends that Alexander nonetheless is not prior art because all claims in Alexander (granted on February 12, 2013) were cancelled on February 15, 2018, following inter partes review. Baxter argues that "because the Alexander 'grant' had been revoked, it can no longer qualify as a patent 'granted' as required for prior art status under Section 102(e)(2)." Appellee's Br. 35.[7]

The text of the statute requires only that the patent be "granted," meaning the "grant[]" has occurred. 35 U.S.C. § 102(e)(2) (pre-AIA). The statute does not require that the patent be currently valid.

IV

Finally, we address "secondary considerations" of nonobviousness. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966). The Board found that Baxter's evidence of secondary considerations was "weak." J.A. 33–

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35 U.S.C 122(b)' and was, therefore, never published under that section." J.A. 23 (citation omitted). On appeal, Becton does not argue that Alexander is prior art under grounds other than 35 U.S.C. § 102(e)(2).

[7] Baxter also argues that "even assuming that Alexander's prior art status is evaluated at the time of patent filing, a person of skill in the art would not have considered Alexander to be prior art as of October 2008 [the '579 patent's priority date], or even known of Alexander, because Alexander was not made public until issuance on February 12, 2013." Appellee's Br. 36. The Supreme Court's decision in *Hazeltine Research, Inc. v. Brenner*, 382 U.S. 252, 254–56 (1965), forecloses this argument.

34.[8] Baxter does not argue that the Board's determination in this respect was in error. "[W]eak evidence of secondary considerations . . . simply cannot overcome the strong showing of obviousness." *ZUP, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1375 (Fed. Cir. 2018). Baxter does not meaningfully argue that the weak showing of secondary considerations here could overcome the showing of obviousness based on the prior art.

CONCLUSION

The Board's determination that the verification and highlighting limitations are not obvious is not supported by substantial evidence. We reverse.

REVERSED

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[8] Baxter presented evidence of secondary considerations focusing primarily on the verification limitation.

ATTACHMENT

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 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, 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.

'579 patent, col. 31 l. 47–col. 32 l. 18.

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, 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 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 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;

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 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

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.

Id. col. 32 l. 52–col. 33 l. 30.

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

1. The foregoing Petition complies with the type-volume limitation of Federal Rule of Appellate Procedure 35(b)(2)(A) because it contains 3,738 words, excluding the parts of the Petition exempted by Federal Circuit Rule 32(b)(2).

2. This brief complies with the type-face requirements and type-style requirements of Federal Rules of Appellate Procedure 32(a)(5) and 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14-point font.

Dated: July 12, 2021

Respectfully submitted,

/s/ George C. Summerfield
George C. Summerfield

Attorney for Appellee Baxter Corporation Englewood

CERTIFICATE OF SERVICE

I hereby certify that on July 12, 2021, a true and correct copy of the foregoing **PETITION FOR REHEARING EN BANC BY APPELLEE BAXTER CORPORATION ENGLEWOOD** was filed with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

/s/ George C. Summerfield
George C. Summerfield