

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BAXTER INTERNATIONAL INC.,
Petitioner,

v.

BECTON, DICKINSON AND COMPANY,
Patent Owner.

Case IPR2015-00883
Patent 8,374,887 B1

Before MICHAEL W. KIM, ERICA A. FRANKLIN, and
JAMES A. WORTH, *Administrative Patent Judges*.

KIM, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. *Background*

Baxter International Inc. (“Petitioner”) filed a Petition (“Pet.”) for *inter partes* review of claims 1–27 of U.S. Patent No. 8,374,887 B1 (“the ’887 patent”) (Ex. 1001) pursuant to 35 U.S.C. §§ 311–319. Paper 1. Becton, Dickinson and Company (“Patent Owner”) filed a Patent Owner Preliminary Response. Paper 5 (“Prelim. Resp.”). On August 13, 2015, we instituted an *inter partes* review of claims 1–27 on certain grounds of unpatentability set forth in the Petition. Paper 8 (“Dec.”). After institution of trial, Patent Owner filed an Amended Patent Owner Response (Paper 16, “PO Resp.”) and Petitioner filed a Reply (Paper 20, “Pet. Reply”). An oral hearing was held on April 6, 2016. Paper 28 (“Tr.”).

The Board has jurisdiction under 35 U.S.C. § 6(c). In this Final Written Decision, issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73, we determine that Petitioner has shown by a preponderance of the evidence that all claims for which trial is instituted, claims 1–27 of the ’887 patent, are unpatentable.

B. *The ’887 patent*

The ’887 patent relates to “remotely supervising and verifying technical pharmacy functions performed by a non-pharmacist located in an institutional pharmacy.” Ex. 1001, 1:9–12. A pharmacist’s scope of practice in institutions, such as hospitals or correctional facilities, includes preparing, packaging, compounding, and labeling medication, compounding sterile products, as well as other medication related activities. Ex. 1001, 1:14–17. Many technical functions involving the preparation and distribution of drugs may be performed in the pharmacy by non-pharmacist

personnel, usually a pharmacy technician or licensed nurse. Ex. 1001, 1:18–21. When a non-pharmacist performs such functions a pharmacist must generally verify their work. Ex. 1001, 1:21–22. The majority of institutional pharmacies do not have pharmacists on duty 24 hours, 7 day per week, yet patients frequently require medications that are only available in the pharmacy department of an institution when no pharmacist is on duty. Ex. 1001, 1:40–44. “Under such circumstances, no pharmacist can supervise or verify the performance of the pharmacy functions performed.” Ex. 1001, 1:44–46. In such circumstances, the ’887 discloses that the tradeoff is between availability and safety of the pharmacist. Ex. 1001, 1:46–2:8.

To remedy such alleged problems, the ’887 patent discloses a system and method of providing certain pharmacy services to institutionalized patients at an institution where a live pharmacist is not available. Ex. 1001, 2:13–15. The institutional pharmacy and a remotely located pharmacist are linked via wired or wireless telecommunication systems in a manner that enables the pharmacist to supervise remotely and verify that pharmacy functions are performed properly by non-pharmacist personnel. Ex. 1001, 2:15–20.

C. *Related Matters*

Petitioner and Patent Owner identify the following related district court proceeding between Petitioner and Patent Owner that involves the ’887 patent: *Becton, Dickinson and Co. v. Baxter International Inc.*, Case No. 14-cv-00222-LY (W.D. Tex.). Pet. 9; Paper 4, 2–3. Petitioner and Patent Owner identify also the following related patent applications: U.S. Patent

Application No. 13/747,231; U.S. Patent Application No. 14/677,322. Pet.
9; Paper 4, 3.

D. Illustrative Claim

Independent claim 16 is reproduced below:

16. A method for remote supervision and verification of pharmacy functions that are performed by a non-pharmacist person, comprising:

in response to performance, by a non-pharmacist person, of pharmacy work to prepare a medication at an institutional pharmacy, wherein the pharmacy work requires pharmacist verification of the pharmacy work, wherein performing the pharmacy work comprises the non-pharmacist person performing, at a workstation in the institutional pharmacy, a sterile compounding process to prepare the medication, wherein the medication is compounded from a plurality of material components at the workstation within the institutional pharmacy:

capturing, via an image capture device at the workstation in the institutional pharmacy, one or more images of the pharmacy work performed by the non-pharmacist person as the work is performed by the non-pharmacist person at the institutional pharmacy, wherein at least one of the images is an image of the sterile compounding process performed by the non-pharmacist person that requires verification by a pharmacist for medications to be placed into pharmacy stock;

wherein capturing the one or more images comprises capturing two or more images of the sterile compounding process of the sterile compounded medications as the sterile compounded medications are prepared, wherein at least one of the two or more images is captured at a different stage of the compounding of the sterile compounded medications than at least one other of the two or more images;

implementing verification software, via one or more computers at the institutional pharmacy, to remotely verify the

work performed by the non-pharmacist person, wherein remote verification of the work performed by the non-pharmacist person comprises:

- transmitting the one or more images captured by the image capture device of the sterile compounding process performed by the non-pharmacist person at the workstation to a remote pharmacist for review;
- receiving an indication of the remote pharmacist's verification of the correct performance of the sterile compounding process by the non-pharmacist person; and
- providing, in response to the indication of the remote pharmacist's verification, an indication at the institutional pharmacy that the remote pharmacist has verified the sterile compounding process performed by the non-pharmacist person.

E. Prior Art References Applied by Petitioner and Instituted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–27 on the basis of the following grounds and prior art (Pet. 13–59):

References	Basis	Challenged Claims
Texas Pharmacy Code, ¹ Reese, ² and Liff ³	§ 103(a)	16–18, 20, 22–24, and 27

¹ Title 22, Part 15, Chapter 291, Rules 20, 36 and 71 to 74 of the Texas Administrative Code as published and in effect on Feb. 10, 2004 (“the Texas Pharmacy Code”), including certification that the included Rules were in effect on Feb. 10, 2004 (Ex. 1005; “TPC”).

² US 6,711,460 B1, issued Mar. 23, 2004 (Ex. 1006).

³ US 6,581,798 B2, issued June 24, 2003 (Ex. 1007).

References	Basis	Challenged Claims
Texas Pharmacy Code, Reese, Liff, and ND Telepharmacy Project ⁴	§ 103(a)	19 and 21
Texas Pharmacy Code, Reese, Liff, and Morrison ⁵	§ 103(a)	1–3, 5–15, 25, and 26
Texas Pharmacy Code, Reese, Liff, Morrison, and ND Telepharmacy Project	§ 103(a)	4, 14, and 26

Petitioner also cites the Declaration of Mr. Brian T. Hart (Ex. 1003; “the Hart Declaration”), and the Declaration of Dr. Wayne H. Grant (Ex. 1004; “the Grant Declaration”).

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, a claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, No. 15-446, 2016 WL 3369425, at *12 (U.S. June 20, 2016) (holding that 37 C.F.R. § 42.100(b) “represents a reasonable exercise of the rulemaking authority that Congress delegated to the . . . Office”). Under the

⁴ Charles D. Peterson & Howard C. Anderson Jr., “*The North Dakota Telepharmacy Project: Restoring and Retaining Pharmacy Services in Rural Communities*” (“ND Telepharmacy Project”), 20 J. OF PHARMACY TECH. 1, 28–39, received by the Pharmacy Library at the University of Wisconsin on Feb. 13, 2004 (Ex. 1009).

⁵ US 2005/0080651 A1, published Apr. 14, 2005 (Ex. 1008).

broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

No express claim constructions are necessary in rendering this Decision.

B. Claims 16–18, 20, 22–24, and 27 as Unpatentable over the Texas Pharmacy Code, Reese, and Liff

Petitioner contends that claims 16–18, 20, 22–24, and 27 are unpatentable over a combination of the TPC, Reese, and Liff. Pet. 13–38 (citing Exs. 1003–1007). Patent Owner disagrees. PO Resp. 20–54 (citing Exs. 1003–1007, 1017, 2001–2003). Petitioner replies. Pet. Reply 1–21 (citing Exs. 1003–1007, 1027, 1030–1032, 2001, 2002). Claim 16 is independent.

1. The Texas Pharmacy Code (Ex. 1005)

The TPC is a portion of the Texas Administrative Code that concerns pharmacy operations. The TPC discloses regulations for a remote pharmacy system using telepharmacy systems. Ex. 1005 § 291.20(c). A remote site is a facility not located at the same location as a Class A or Class C pharmacy, at which remote pharmacy services are provided using telepharmacy dispensing system. Ex. 1005 § 291.20(c)(2)(F). The TPC discloses that a remote site shall be under the continuous supervision of a provider pharmacy pharmacist, for example, electronically through the use of the following types of technology: (I) audio and video; (II) still image capture; and (III) store and forward. Ex. 1005 § 291.20(c)(4)(C)(i). The TPC discloses that “dispense” is defined as “[p]reparing, packaging, compounding, or labelling

for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.” Ex. 1005 § 291.20(c)(2)(B).

The TPC also discloses regulations for compounding sterile pharmaceuticals. Ex. 1005 § 291.36(a). Compounding of sterile pharmaceuticals may be performed by a pharmacy technician, provided that certain requirements are met, for example, that the pharmacy technician is supervised by a pharmacist who (1) has completed the requisite training, (2) conducts in-process and final checks, and (3) affixes his or her initials to the appropriate quality control records. Ex. 1005 § 291.36(c)(4)(B).

2. *Reese (Ex. 1006)*

Reese is directed to delivery of personalized care by a single pharmacist to outpatients in multiple pharmacies. Ex. 1006, 1:15–16. Reese discloses compounding robot 348 receiving and executing instructions from a remote pharmacist, including detailed directions for compounding a particular medication. Ex. 1006, 11:32–38. The remote pharmacist may monitor aspects of the compounding process performed by compounding robot 348 via cameras 332, 334, 336, 349. Ex. 1006, 11:53–63. If a remote pharmacist has any concerns about whether a packaged product matches a prescription or order, the remote pharmacist has access to the prescription transmission data, a video recording of the compounding process, and visual images from the compounding process as captured by the cameras. Ex. 1006, 20:10–21. If the concerns cannot be resolved, the remote pharmacist may direct that the medication be placed in a holding area for appropriate disposal or restocking at a later time, and to refill the prescription. Ex. 1006, 20:35–38.

3. *Liff (Ex. 1007)*

Liff is directed to enabling drug prescription dispensing in volume by a physician, pharmacist, or other licensed practitioner directly to the patient at a clinic, group practice, or other location outside a pharmacy or hospital. Ex. 1007, 2:11–14. When a patient approaches a technician, the technician initiates a dispensing process by entering relevant patent data into host computer 564. Ex. 1007, 23:1–3. If the dispensing process requires expertise of a pharmacist, then the technician at host computer 564 issues a request to an available pharmacist operating at a remote location. Ex. 1007, 23:3–11. Relevant data is exchanged and video teleconferencing is enabled between the technician and the pharmacist or prescribing physician if appropriate. Ex. 1007, 23:11–13. When the pharmacist receives the data, the pharmacist conducts the relevant tests and makes a determination regarding dispensing the pharmaceutical. Ex. 1007, 23:27–29. Host computer 570 receives the determination from the pharmacist via the internet, unpacks the data, and dispenses the pharmaceutical automatically, in real time. Ex. 1007, 23:27–29.

4. *Petitioner's Position*

Petitioner asserts that claims 16–18, 20, 22–24, and 27 are unpatentable over a combination of the TPC, Reese, and Liff. Pet. 13–38. For example, independent claim 16 requires capturing two or more images of a sterile compounding process performed by a non-pharmacist person that requires verification by a pharmacist. Petitioner cites the TPC for disclosing that compounding of sterile pharmaceuticals may be performed by a pharmacy technician, provided that the pharmacy technician is supervised by a pharmacist. Ex. 1005 § 291.36(c)(4)(B). Petitioner also cites the TPC for

disclosing that a remote site shall be under the continuous supervision of a provider pharmacy pharmacist, for example, electronically through the use of the following types of technology: (I) audio and video; (II) still image capture; and (III) store and forward. Ex. 1005 § 291.20(c)(4)(C)(i).

Petitioner additionally cites Reese and Liff for the technical aspects of monitoring remote pharmacies.

Independent claim 16 further requires implementing verification software that transmits the two or more images to a remote pharmacist. Petitioner cites Reese for disclosing that if a remote pharmacist has any concerns about whether a packaged product matches a prescription or order, the remote pharmacist has access to the prescription transmission data, a video recording of the compounding process, and visual images from the compounding process as captured by the cameras. Ex. 1006, 20:10–21.

Independent claim 16 also requires receiving an indication of verification by the remote pharmacist that the non-pharmacist correctly performed the sterile compounding, and providing a further indication in response to the verification indication. Petitioner cites the TPC for disclosing that compounding of sterile pharmaceuticals may be performed by a pharmacy technician who is supervised by a pharmacist, and that a remote site shall be under the continuous supervision of a provider pharmacy pharmacist. Ex. 1005 §§ 291.36(c)(4)(B), 291.20(c)(4)(C)(i). Petitioner also cites the TPC for disclosing that only a pharmacist can authorize printing of a prescription label at a remote site and perform a final check of the dispensed prescription. Ex. 1005 § 291.20(c)(4)(D)(iii). Petitioner further cites the TPC for disclosing that, during sterile compounding, the pharmacist conducts in-process and final checks, and affixes his or her

initials to the appropriate quality control records. Ex. 1005
§ 291.36(c)(4)(B).

Petitioner sets forth similar analyses for claims 17, 18, 20, 22–24, and 27. Citing the Hart Declaration, Petitioner provides several rationales for combining the aforementioned disclosures of the TPC, Reese, and Liff. Pet. 17–19 (citing Ex. 1003 ¶¶ 108–121); Ex. 1005 §§ 291.36(c)(4)(B).

5. *Prohibition*

Patent Owner’s asserts that the TPC does not disclose or suggest remote supervision of sterile compounding, as required by each independent claim, because, (1) even if the TPC discloses such activity, it is prohibited, and (2) it would not have been obvious to modify one portion of the TPC in view of another, if the resulting combination is prohibited.⁶ After contemplating this issue, in light of the factual record of this case, we determine that the proper framework for evaluation of “prohibition” differs depending on whether the relevant issue is “disclosure” or “modification.”

i. “disclosure”

Concerning the proper treatment of a reference that discloses explicitly that an activity is prohibited, we determine that “prohibition” has little practical relevance. This is because, in our view, “prohibition” of an activity requires two separate realizations: (1) that the activity exists; and (2) that it is prohibited. Within that framework, the logical position concerning “disclosure” and “prohibition” becomes clear; in that because prohibition of

⁶ For the purposes of this section and the next, we refer in the aggregate to all assertions concerning specific claim language at issue as “remote supervision of sterile compounding.” Specific assertions concerning particular claim limitations will be addressed individually in subsequent sections.

an activity first requires an acknowledgement of its existence, a reference's disclosure of a "prohibited activity" is the same as disclosure of the activity itself. To hold otherwise would unreasonably indicate that prohibition of a known activity somehow renders that same activity to then be unknown. By analogy, if a reference discloses "swimming," and then later discloses "swimming is prohibited," we are unpersuaded that the latter disclosure renders unknown the former.

ii. "modification"

The analysis changes for modification, however, i.e., whether one of ordinary skill would have modified an activity disclosed in a reference, where the resulting modified activity is prohibited activity. To that end, Patent Owner appears to be advancing two interrelated positions: (a) that a modification that results in something prohibited is categorically an impermissible modification; and (b) that "prohibition" of a "modification" is a logical equivalent of "teaching away" from that modification.

For (a), we decline to adopt any categorical rules concerning "prohibition" and "modification." "The Supreme Court has cautioned [] that an obviousness determination cannot be confined by formalistic rules. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007). Rather, courts must take an 'expansive and flexible approach' to the question of obviousness. *Id.* at 415." *Dome Patent L.P. v. Lee*, 799 F.3d 1372, 1380 (Fed. Cir. 2015). In view of that guidance, we conclude that "prohibition," and any supporting facts, should be evaluated, as factors to be weighed in an overall obviousness analysis as to whether the proffered modification would have been made by one of ordinary skill.

For (b), we agree with Patent Owner, but that agreement does not alter appreciably our above conclusion in the preceding paragraph. Specifically, “[a] reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). To that end, we agree that “prohibition” can be properly characterized as “discouragement.” A finding of a teaching away, however, is not dispositive, as “there is no rule that a single reference that teaches away will mandate a finding of nonobviousness.” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed.Cir.2006). Indeed, “[t]he degree of teaching away will of course depend on the particular facts.” *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Similarly, we consider a finding of prohibition is actually a weighing of the underlying facts supporting that finding, and, thus, is no different than our conclusion above with respect to (a).

To that end, an analysis of Patent Owner’s analogy concerning the United States Pharmacopeia (“USP”) is instructive. The USP requires a purity level of 95% for a particular medication. Thus, the prohibition against purity levels of less than 95% for that particular medication is a finding that the USP teaches away from modifying that particular medication to have a purity level below 95%. That finding, however, is only as persuasive as the underlying facts as to why there is a prohibition against purity levels of less than 95%. For example, there may be underlying facts indicating that ingesting anything less than a 95% purity level for that particular medication is toxic to humans. Conversely, there may be

underlying facts indicating that the 95% purity level is an arbitrary designation unrelated to any particular advantages or consequences. The persuasive weight of the above will vary widely depending on which set of underlying facts are present.

iii. Patent Owner's Positions Concerning "Prohibition"

In view of this analytical framework, Patent Owner, as noted above, appears to have taken two separate positions: (1) even if the TPC discloses such activity, it is prohibited, and (2) it would not have been obvious to modify one portion of the TPC in view of another, if the resulting combination is prohibited. As set forth above in our analytical framework with respect to (1) "disclosure," both positions cannot coexist; either the TPC prohibits remote supervision of sterile compounding, in which case remote supervision of sterile compounding is disclosed, or the TPC does not disclose remote supervision of sterile compounding at all. As we assume that Patent Owner would prefer to take a position that does not undermine their assertion that the challenged claims are patentable over the cited references, we do not evaluate further Patent Owner's assertions concerning disclosure and "prohibition," for such an assertion is tantamount to an admission that the TPC discloses that which is prohibited. Instead, we reframe (1) to "the TPC does not disclose such activity, prohibited or not," and leave undisturbed (2) as "it would not have been obvious to modify one portion of the TPC in view of another, if the resulting combination is prohibited."

6. *Analysis of Patent Owner's Positions Concerning
"Remote Supervision of Sterile Compounding" and the TPC*

Patent Owner asserts that the TPC does not disclose expressly remote supervision of sterile compounding. We agree. Indeed, at oral argument, Petitioner conceded the same.⁷ The inquiry, thus, shifts to whether remote supervision of sterile compounding would have been obvious in view of the cited sections of the TPC, an inquiry that first requires two predicate findings as to whether the TPC discloses each of "remote supervision of dispensing" and "remote supervision of compounding."

1. *"remote supervision of dispensing"*

Here, obviousness would be the result of a combination of multiple express disclosures. To that end, we begin with the basic overarching fact, not disputed by either party, that Section 20 of the TPC discloses remote supervision of dispensing.⁸ We agree that this finding is supported by the express provisions of Section 20 cited by Petitioner. We find further that the express provisions of Section 20 cited by Petitioner disclose the basic infrastructure for remote supervision of dispensing, namely, a pharmacist at a provider pharmacy supervising a licensed healthcare provider or certified pharmacy technician at a remote site using electronic imaging technology. Ex. 1005 §§ 291.20(c)(3)(F), (c)(3)(H), (c)(4)(C)(i), (c)(4)(D).

⁷ Given this concession, Patent Owner's assertions as to whether or not Mr. Hart and Dr. Grant admitted that the TPC does or does not disclose expressly remote supervision of sterile compounding are inapposite.

⁸ The finding here is with respect to "remote supervision of dispensing," and not "remote supervision of ***sterile compounding***."

2. “remote supervision of compounding”

To those express findings, Petitioner asserts that Section 20(c)(2)(B) defines “dispensing” as including “compounding,” and, thus, that Section 20 of the TPC discloses or suggests remote supervision of compounding. Patent Owner disputes that this assertion is credible, because Section 20(c)(4)(D)(ii) discloses that the only type of dispensing authorized at the remote site is of pre-packaged drugs, which would not include compounding. We agree with Petitioner. Section 20(c) discloses remote pharmacy services and Section 20(c)(2)(H) discloses that remote sites dispense prescription drugs. *See also* Ex. 1005 §§ 291.20(c)(3)(B), (c)(4)(D). Given that Section 20(c)(2)(B), as well as all the other portions referenced above, are in Section 20(c), we have no trouble in finding that Section 20(c) of the TPC discloses remote supervision of compounding.⁹ And as this is a disclosure, we determine that Patent Owner’s assertions concerning the relevance of the prohibition on certain types of dispensing in Section 20 are unpersuasive for the reasons set forth above.¹⁰

⁹ The finding here is with respect to “remote supervision of compounding,” and not “remote supervision of ***sterile*** compounding.”

¹⁰ Even if we were to weigh this evidence, however, we are unclear that any alleged prohibition would outweigh the self-evident rationale for this modification, namely, that there are only a certain number of ways to meet the demand for prescription drugs in areas lacking pharmacists, a problem articulated in the “Description of Related Art” section of the ’887 patent and Sections 20(a), (b), and (c) of the TPC. *See KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007) (“When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.”).

3. *“remote supervision of sterile compounding”*

To the above finding that Section 20(c) of the TPC discloses remote supervision of compounding, Petitioner asserts that the “compounding” in Section 20 should be modified to include the “sterile compounding” in Section 36. In support of this modification, Petitioner identifies several ties between Sections 20 and 36. First, Petitioner asserts that because the TPC discloses expressly that dispensing includes compounding (Ex. 1005 § 291.20(c)(2)(B)), one of ordinary skill would have recognized that “dispense” also encompassed a narrower form of compounding, for example, the sterile compounding set forth in Section 36. Pet. 21 (citing Ex. 1004 ¶ 25). Petitioner makes a similar assertion concerning “reconstitution.” Ex. 1005 § 291.20(c)(4)(D)(ix). Additionally, Petitioner identifies the following portion of Section 36:

A Class A (Community) pharmacy compounding sterile pharmaceuticals which is engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provision of § 291.20 of this title (relating to Remote Pharmacy Services).

Ex. 1005 § 291.36(d)(1)(J). *See also* Ex. 1005 §§ 291.74(a)(11), (b)(1)(B), (b)(2)(A)(ii), (f)(5).

Patent Owner sets forth many arguments and corresponding evidence that it asserts, in the aggregate, outweigh Petitioner’s proffered arguments and evidence for the proposed modification. We disagree with Patent Owner for the reasons set forth below.

Patent Owner asserts that the picking and choosing of different arbitrary and disparate sections of the voluminous TPC to piece together a disclosure of remote supervision of sterile compounding is unreasonable, and could only be the product of hindsight. We disagree. Specifically, we

are persuaded that Petitioner has identified sufficient links between the disclosures of Sections 20 and 36 in the TPC that would have led a person of ordinary skill in the art to consider those disclosures together. For example, Section 36(d)(1)(J) describes “sterile compounding at a remote site,” and further provides, by its own express terms, a link between sterile compounding and the remote pharmacy services of Section 20.

Furthermore, Petitioner also relies on the following testimony of Dr. Grant:

The term “dispense” is a common term in the pharmacy industry. It generally describes the act of providing medications or drugs to an end user, such as a patient. In my experience, the term “dispense” is understood by pharmacists to encompass sterile compounding activities.

Ex. 1004 ¶ 25. We find Dr. Grant’s testimony on this point credible based on the following factors: his background as a pharmacist and, thus, his familiarity with the abilities of one of ordinary skill at the time of the invention (Ex. 1004 ¶¶ 5–10; Ex. 1022); his depth of knowledge concerning sterile compounding (Ex. 1004 ¶¶ 11–24); and the rather basic conclusion Dr. Grant makes, namely, that dispensing includes sterile compounding, a conclusion confirmed independently by the aforementioned portions of Sections 20 and 36. Thus, we are unpersuaded the connections articulated by Petitioner between Sections 20 and 36 are arbitrary or the product of improper hindsight.

Patent Owner asserts that any remote supervision of dispensing in the TPC is limited to the following, none of which contemplates remote supervision of sterile compounding:

(ii) Drugs may be dispensed by the provider pharmacy through a telepharmacy system at a remote site only in unit-of-use containers that are:

- (I) prepackaged in suitable containers at the provider pharmacy and appropriately labeled as specified in § 291.33(c)(4) of this title; or
- (II) in original manufacturer's containers.

Ex. 1005 § 291.20(c)(4)(D)(ii). Patent Owner asserts essentially that by limiting any remote supervision of dispensing to the aforementioned activities, one of ordinary skill would not contemplate making any modifications to remote supervision of dispensing that falls outside of these limitations, such as remote supervision of sterile compounding. While we agree that Patent Owner's assertions have some merit, we are unpersuaded that the weight of the evidence supports Patent Owner's position.

Accordingly, we agree that certain portions of Section 20(c)(4)(D) may arguably provide restrictions on remote supervision of "dispensing" that could plausibly be read as precluding remote supervision of sterile compounding. We are unpersuaded, however, that such a conclusion¹¹ outweighs the evidence identified herein that modifying remote supervision of dispensing to include remote supervision of sterile compounding was, nevertheless, known. Indeed, we discern that it is precisely because all

¹¹ This is especially so, given that no underlying facts are provided in the TPC as to why remote supervision of sterile compounding are precluded. Furthermore, while we have considered Dr. Ginsburg's testimony that such preclusions are related to patient safety, we are unpersuaded that it outweighs the evidence of record to the contrary that the purportedly precluded modification was known.

forms of remote supervision of dispensing, including remote supervision of sterile compounding, were known generally, that restrictions are necessary.¹²

Along similar lines, Patent Owner asserts that Sections 36 and 74 disclose that sterile compounding can only be conducted at a Class A or Class C pharmacy, while Section 20 discloses that remote telepharmacy services can only be provided at a healthcare facility that is not a Class A or Class C pharmacy. The principle portion of the TPC relied on by Patent Owner concerning this assertion is Section 20(c)(3)(B), which reads as follows:

A provider pharmacy may not provide remote pharmacy services if a Class A (Community) or Class C (Institutional) pharmacy that dispenses prescription drug orders to out-patients is located in the same community.

Ex. 1005 § 291.20(c)(3)(B). Patent Owner asserts that by limiting any sterile compounding to a Class A or Class C pharmacy, one of ordinary skill would not contemplate making any modifications to move such sterile compounding to a non-Class A or non-Class C pharmacy, which would be required to make a showing of remote supervision of sterile compounding. We disagree with Patent Owner for several reasons. First, the above cited portion of the TPC is limited to remote sites where “a Class A (Community) or Class C (Institutional) pharmacy that dispenses prescription drug orders to *out-patients is located in the same community.*” Thus, if a remote site dispenses drugs to (1) in-patients or (2) is located in a community without

¹² Extending the analogy set forth *supra*, if a reference discloses “swimming,” and then later discloses “swim after eating is prohibited,” we are persuaded that the references disclose that each of the following were known: swimming, generally; swimming after not eating; and even swimming after eating.

Class A or Class C pharmacy, the aforementioned provisions do not apply. Moreover, another portion of Section 20 cited by Petitioner recites the following:

The purpose of this section is to provide standards for the provision of pharmacy services by *a Class A or Class C pharmacy in a healthcare facility that is not at the same location as a Class A or Class C pharmacy* through a telepharmacy system

Ex. 1005 § 291.20(c)(1) (emphasis added). In other words, Section 20(c) contemplates expressly remote pharmacy services being provided at a remote site, which may itself be a Class A or Class C pharmacy, in which case, there is no prohibition under Section 36 for providing sterile compounding at that remote site. Furthermore, Section 36 discloses the following:

A Class A (Community) pharmacy compounding sterile pharmaceuticals which is engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provision of § 291.20 of this title (relating to Remote Pharmacy Services).

Ex. 1005 § 291.36(d)(1)(J). As set forth above, we found that the aforementioned portion of the TPC discloses explicitly “sterile compounding at a remote site.” We are unclear as to why Section 36 would disclose expressly that a Class A pharmacy can be used as a remote site for sterile compounding, if it was, in practice, prohibited by Section 20. Accordingly, based on all of the above, we are unpersuaded that Patent Owner’s underlying factual premise, that Section 20 discloses that remote telepharmacy services can only be provided at a healthcare facility that is not a Class A or Class C pharmacy, is correct. Furthermore, even if Patent Owner were correct, we still would not be persuaded based on the same

logic as set forth above in the aforementioned analysis concerning Section 20(c)(4)(D)(ii) and pre-packaged drugs.

Patent Owner asserts additionally that sterile compounding cannot be considered as being encompassed by the word “dispense,” because Section 36 provides many indications that sterile compounding is a specialized pharmacy task that requires specific equipment, training, and precautions. In support of this position, Patent Owner cites the Declaration of Dr. Diane B. Ginsburg. We are unpersuaded by Patent Owner’s assertion, because we are unclear as to Patent Owner’s logic. By the express definition set forth in TPC, “compounding” is a narrower form of “dispensing.” Ex. 1005 § 291.20(c)(2)(B). By the addition of the word “sterile” to “compounding,” the evidence shows, and we agree, that “sterile compounding” is a narrower of form of “compounding,” which itself is a narrower form of “dispensing.” Patent Owner has not established how narrowing an activity (sterile compounding) takes it out of the realm of the broader activity (dispensing).¹³ Accordingly, even though we are persuaded that the relevant portions of Dr. Ginsburg’s testimony generally (Ex. 2001 ¶¶ 39–50) should be given some weight, we are unpersuaded that the testimony supports Patent Owner’s position that “dispensing” does not encompass “sterile compounding.” And

¹³ At oral argument, Patent Owner agreed with the analogy proffered by the Board that “sterile compounding” was some form of “super-species” that cannot be fairly said to be encompassed by the genus of “dispensing.” When pressed for the reasons as to what distinguishes a “species” from a “super-species,” however, Patent Owner merely asserted again its points concerning “narrowing,” and we are unpersuaded that the amount of “narrowing” contemplated here would take the species of “sterile compounding” outside the genus of “dispensing.” See also Ex. 1031, 66:10–67:8, 71:4–73:19, 75:13–76:19, 82:16–86:7, 103:17–21, 118:12–119:9.

in any case, we found above that the TPC discloses expressly remote supervision of compounding. Accordingly, when Patent Owner's assertions are reframed as opposing modifying "compounding" to "sterile compounding," we remain unpersuaded.

Patent Owner identifies additionally Sections 73(e)(2)(A) and (B) as support for their differentiation between "compounding" and "sterile compounding," in that Sections 73(e)(2)(A)(ii) and (iii) refer to "compounding" and "bulk compounding," respectively, while Section 73(e)(2)(B) is directed solely to "[s]terile pharmaceuticals," indicating that "compounding" and "sterile compounding" are sufficiently different that the former does not encompass the latter. We are unpersuaded by Patent Owner's argument. Section 73(e)(2)(A) discloses that it is directed to "[g]eneral [d]uties." Accordingly, when read in conjunction with Section 73(e)(2)(B), we discern that all of the requirements of Section 73(e)(2)(A) are applicable to those of Section 73(e)(2)(B), with Section 73(e)(2)(B) merely enumerating additional requirements for sterile pharmaceuticals. We are unpersuaded that this supports Patent Owner's position that "compounding" does not encompass "sterile compounding."

Patent Owner identifies also several other portions of the TPC to support its assertion that the TPC requires in-person supervision of sterile compounding. Most specifically, Patent Owner identifies Section 36(c)(4)(B)(ii)(II), which recites "pharmacy technicians are under the direct supervision of and responsible to a pharmacist." *See also* Ex. 1005 §§ 291.36(c)(4)(B), 291.73(e)(2)(A). According to Patent Owner, "direct" is the same as "in-person," and cites paragraphs 79–82 of Dr. Ginsburg's

Declaration in support, which in turn relies on pages 16–18¹⁴ of Exhibit 1017,¹⁵ i.e., Sub-Exhibit 2 of Exhibit 1017 (Texas Pharmacy Board Task Force Report reviewing and making a recommendation to the Board regarding a petition for a pilot project to evaluate the potential benefits of an electronic supervision of pharmacy technicians in hospital facilities during the absence of a pharmacist). As an initial matter, we are unpersuaded that the word “direct” is the same as “in-person,” especially when considered in conjunction with Section 20(c)(3)(F), which reads “[t]he pharmacist-in-charge of the provider pharmacy is responsible for all operations at the remote site including supervision of the telepharmacy system and compliance with this section.” *See also* Ex. 1005 § 291.20(c)(4)(C)(i); Ex. 1030, 124:1–11. Furthermore, turning again to Dr. Ginsburg’s Declaration, we note that her testimony is largely an analysis of pages 16–18 of Exhibit 1017. Patent Owner, however, does not specify how Dr.

¹⁴ Patent Owner appears to use the pagination at the top of the page, referring to these as pages 17–19. The actual pagination, however, is at the bottom of the page, and so pages 17–19 are actually pages 16–18. We will use the actual pagination in this Decision.

¹⁵ Exhibit 1017 is an exhibit containing multiple Sub-Exhibits A, 1, 2, 3, 4, and 5. Of those, Sub-Exhibit A is a Declaration of Dr. Roger W. Anderson, purportedly explaining the other Sub-Exhibits 1–5. In an Order entered November 17, 2015 (Paper 14), we indicated that if Patent Owner desired to rely substantively on the contents Dr. Anderson’s Declaration, Patent Owner must make Dr. Anderson available for cross-examination. Patent Owner did not do so. Accordingly, for substantive purposes, Sub-Exhibit A of Exhibit 1017 is given little or no weight. *See IBG LLC v. Trading Techs. Int’l, Inc.*, Case CBM2015-00179 (PTAB Apr. 15, 2016) (Paper 39); *Altaire Pharm., Inc. v. Paragon Biotech, Inc.*, Case PGR2015-00011 (PTAB Apr. 1, 2016) (Paper 29). The contents of Sub-Exhibits 1–5 of Exhibit 1017, however, not being testimony, are entitled to more weight.

Ginsburg came to know or be familiar with the content pages 16–18 of Exhibit 1017. Specifically, Patent Owner does not assert, and we are unable to discern independently, that Dr. Ginsburg had first-hand knowledge concerning the preparation of pages 16–18. Accordingly, as Dr. Ginsburg’s opinions concerning pages 16–18 of Exhibit 1017 appear to be based on no more than an evaluation of the content of the pages themselves, we assign little weight to Dr. Ginsburg’s analysis of pages 16–18 of Exhibit 1017, and instead put more of an emphasis on the disclosures of Exhibit 1017 itself, other than Sub-Exhibit A.

Concerning the substantive contents of pages 16–18 of Exhibit 1017, Petitioner asserts, and we agree, that the content should be assigned little weight. Patent Owner has not provided any background, other than the contents of the document itself and attorney argument, as to what the document is, when it was generated it, who generated it, who it was submitted to, whether it was approved, and whether it was approved with or without modifications. Absent such context, we can, of course, evaluate the document itself, but decline to assign much persuasive weight to the content of the document given its lack of foundation. *See Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 856 (1982) (“Determining the weight and credibility of the evidence is the special province of the trier of fact.”); *cf.* Fed. R. Evid. 901 (“To satisfy the requirement of authenticating or identifying an item of evidence, the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is.”).

Moreover, in evaluating the document, it is apparent why the lack of context concerning pages 16–18 of Exhibit 1017 is problematic.

Specifically, Patent Owner cites pages 16–18 of Exhibit 1017 to support its position that “direct” and “in-person” supervision are co-extensive. The most vaguely relevant portion we are able to identify that recites anything concerning “direct” and “in-person” is the interplay between the following two disclosures: “Board Rule 291.73(e)(2) requires pharmacy technicians to work under the direct supervision of a pharmacist as follows:” (Ex. 1017, 16); and “[w]aiving these two rules will allow Ebar Telepharmacy LLC to provide electronic supervision of pharmacy technicians performing duties in a Class C pharmacy located in a small hospital (100 beds or less)” (Ex. 1017, 18). Based solely on the express text of Exhibit 1017 and attorney argument, Patent Owner asks us to determine that (1) it was clear that prior to the submission of this proposal, remote supervision of pharmacy technicians performing duties in a Class C pharmacy located in a small hospital (100 beds or less) was prohibited; and that (2) waiver of the rules was directed solely, or at least primarily, at this aspect. We decline to do so.

We discern that there are too many inferences that must be made, and intervening questions asked, in order to persuasively link this disclosure and “direct” vs. “in-person.” For example, one inference required is that explicitly permitting something now is an indication that it was explicitly prohibited previously, as opposed to the result of some other consideration such as improving or providing more clarity to the TPC, an inference for which no analysis, or evidence, has been provided. Pet. Reply 13–14 (citing Ex. 1030, 65:19–66:6, 91:21–92:3). In another example, one intervening question is the scope of what the waiver of the rules actually allowed as compared to what was prohibited previously, i.e., just electronic supervision

of pharmacy technicians, that plus Class C pharmacy, that plus small hospitals, or any permutation thereof. Again, no evidence or analysis has been provided concerning these questions.

Which brings us back to Dr. Ginsburg's Declaration. Patent Owner may assert that the aforementioned inferences and questions are addressed by Dr. Ginsburg. To that end, while we agree that Dr. Ginsburg's imprimatur on the connection, between Sub-Exhibit 1–5 of Exhibit 1017 and Patent Owner's assertions concerning "direct" vs. "in-person," perhaps provides a little more weight than attorney argument itself, we are unpersuaded it provides an adequate connection, as paragraph 81 states the conclusion, where the evidentiary basis for that conclusion in paragraph 82 is merely a citation to the above, without any further analysis. Furthermore, even if Patent Owner were correct, we still would not be persuaded based on the same logic as set forth in the above analysis concerning Section 20(c)(4)(D)(ii) and pre-packaged drugs.

Patent Owner identifies further Section 36(d)(2)(D), which Patent Owner asserts restricts non-pharmacists to performing only six actions in the absence of a pharmacist. The referenced second is titled "Temporary absence of pharmacist." Insofar as Patent Owner is asserting that a pharmacist's remote presence is an "absence," we are unpersuaded because we discern that "absence" indicates a complete lack of supervision, whereas a remote pharmacist still provides supervision.

Patent Owner asserts further that based on the above, even if certain disparate portions of Sections 20 and 36 can perhaps be cobbled together to suggest remote supervision of sterile compounding, when all of the provisions of the TPC are taken in the aggregate, one of ordinary skill

ultimately would not have been persuaded to do that which was prohibited. As an initial matter, we note that the only portion of the TPC identified by Patent Owner that we view as actually supporting its position that the TPC prohibits the proffered modification is Section 20(c)(4)(D)(ii) concerning pre-packaged drugs. In light of that, we are unpersuaded that one section outweighs all of the evidence and analysis identified above to the contrary.

Patent Owner asserts additionally that Exhibit 1017 supports its position that the TPC prohibited the proffered modification, because Sections 72–73 of the TPC were amended in 2008 to *permit*, for the first time, remote supervision of sterile compounding. PO Resp. 28–30 (citing Ex. 1017). There are several problems with Patent Owner’s reliance on Exhibit 1017. First, we determined that because Dr. Roger W. Anderson was not made available for cross-examination, the portions of Exhibit 1017 containing his Declaration (Ex.1017, 1–13) would be given no weight. Without that Declaration the evidentiary basis for the rest of Exhibits 1017 are cast in doubt, in varying degrees, for the reasons set forth *supra* concerning our evaluation of pages 16–18 of Exhibit 1017.

Second, Patent Owner was permitted to rely on the non-Declaration portions of Exhibit 1017. The portions of Exhibit 1017 relied on by Patent Owner, however, do not state directly that the proffered modification was prohibited, so, at best, Patent Owner asks us to draw inferences along those lines, namely, that the 2008 amendments indicate that the previous versions of the TPC prohibited Petitioner’s proffered modification. We discern, however, that such inferences are anything but self-evident, and so require substantial analysis and evidentiary backing. The main analysis provided, however, is attorney argument, which we are not persuaded by, and the only

non-attorney argument support for those inferences is provided at paragraphs 76–89 of Dr. Ginsburg’s Declaration concerning pages 16–18 of Exhibit 1017. Generally, those paragraphs assert that the TPC does not disclose remote supervision of sterile compounding (Ex. 1017 ¶¶ 84, 88, 89), for which there is no dispute, and the other paragraphs are not persuasive for the reasons set forth *supra* concerning “direct” vs. “in-person.” The only other citations are to redlining on pages 60–66; however, we are unpersuaded that unexplained redlining by itself supports adequately the inferences that the proffered modification was prohibited, and, indeed, suffers from at least the same, if not more, “inferences” and “intervening questions” problems as pages 16–18 of Exhibit 1017.

Patent Owner advances similar assertions concerning “reconstituting” and “sterile compounding.” Those assertions are unpersuasive for the same reasons as set forth above with respect to “dispensing.” See Ex. 1031, 104:4–20.

7. *Analysis of Patent Owner’s Positions Concerning
Certain Claim Limitations*

Patent Owner asserts that the TPC does not disclose or suggest verification software that performs “receiving an indication of the remote pharmacist’s verification of the correct performance of the sterile compounding process by the non-pharmacist person” and “providing, in response to the indication of the remote pharmacist’s verification, an indication at the institutional pharmacy that the remote pharmacist has verified the sterile compounding process performed by the non-pharmacist person,” as recited in independent claim 16. Petitioner asserts that the “remote pharmacy” of the TPC corresponds to the recited “institutional

pharmacy,” and that the recited “remote pharmacist” is present at the “provider pharmacy” of the TPC. Accordingly, in order to meet the aforementioned claim limitations, the TPC must disclose (1) sending a verification via software to the remote pharmacy, and (2) providing an indication via software in response to that verification at the remote pharmacy.¹⁶ Patent Owner asserts that none of these aspects are met by the TPC alone. We agree.¹⁷

As an initial matter, we note that the indication in (2) is met by the disclosure in the TPC concerning authorizing the telepharmacy system to print a prescription label at the remote site, with the exception of the fact that the indication is not in response to a verification sent via software, as required by (1). Specifically, Section 20(c)(2)(K) discloses that monitoring the dispensing of prescription drugs *at* the remote pharmacy is done via (i) audio and video, (ii) still image capture, or (iii) store and forward. While Section 20(c)(2)(I) and (J) disclose that each of (ii) still image capture and (iii) store and forward involve electronic capture, which we are persuaded would involve software, verification requires transmission of the verification *to* the remote pharmacy. Not only do these Sections not disclose verification at all, but the only transmissions necessary to implement this provision would have been *from* the remote pharmacy, and not *to*, as required by (1).

Petitioner cites further Sections 20(c)(2)(D)(iii)(VI) and (VII) as authorizing the performance of certain actions at the remote pharmacy by the

¹⁶ We have already addressed above the aspects of the claim limitations related to the interplay between remote supervision and sterile compounding, and, thus, do not focus on those aspects here.

¹⁷ As set forth later, however, our agreement with Patent Owner on this assertion is not dispositive as to the claim limitation at issue.

provider pharmacy, which presumably correspond to the recited verification in (1), but those Sections do not disclose how such a verification is sent *to* the remote pharmacy. Specifically, Patent Owner asserts, and we agree, that such verifications need not be sent using software, as required by the claims, and Petitioner has not shown it would have been inherent to do so. Section 20(c)(2)(D)(vi) is a bit more specific, in that a final check is disclosed as being done “through a visual check using electronic methods.” Again, however, the “visual check using electronic methods” is concerning information flowing *from* the remote pharmacy, and while some indication of the final check must be sent back to the remote pharmacy, and could have been done using software, as required by the claims, the actual method of such a transmission is not disclosed, and Petitioner has not shown it would have been inherent to do so.¹⁸

Petitioner also cites the following:

If the remote site has direct access to the provider pharmacy’s data processing system, only a pharmacist or a certified pharmacy technician may enter prescription information into the data processing system. The original prescription shall be sent to the provider pharmacy and a pharmacist shall verify the accuracy of the data entry.

¹⁸ Patent Owner asserts that the final check cannot correspond to the recited verification, because the action in the TPC corresponding to the indication, the printing of the prescription label, occurs *before* the final check. We do not read Section 20(c)(4)(D) so rigidly, as we are persuaded that rearranging the order would have been obvious. Moreover, we are persuaded that disclosure of a *final* check at least suggest *in-process* checks, especially in view of Section 36(c)(4)(B), which discloses that compounding sterile pharmaceuticals by pharmacy technicians are supervised by a pharmacist who conducts in-process and final checks.

Ex. 1005 § 291.20(c)(4)(D)(viii). Here, again, however, all information flows to the *provider* pharmacy, and not to the *remote* pharmacy, as required by the claims.¹⁹

Our inquiry does not end there, however, as Petitioner also cites Liff for disclosing the aforementioned claim limitations. Specifically, for “receiving an indication of the remote pharmacist’s verification of the correct performance of the sterile compounding process by the non-pharmacist person,” we discern that the only portion missing from the TPC is that the infrastructure for verification in (1) is via software. For that, Petitioner cites Liff for disclosing data transfer protocols where “a signal from the pharmacist’s workstation to host 570 or servers 584/585 for eventual provision to cabinets (RCDs) indicating that the prescription can be dispensed.” Pet. 31 (citing Ex. 1007). The proffered rationale to combine is the following:

Liff discloses a pharmacist electronically supervising another location using telecommunication systems. (Ex. 1007 at 23:27–38). An artisan would have understood Texas Pharmacy Code’s “store and forward” could have been achieved by sending data packets as in Liff. (*Id.*; Ex. 1003 at ¶ 120). An artisan would have understood that Liff’s data packets could deliver indications of pharmacist verifications to a system at the remote site for label printing as in Texas Pharmacy Code. (Ex. 1007 at 23:27–38; Ex. 1003 at ¶ 120). Since Liff discloses a data transfer protocol to

¹⁹ Petitioner presents evidence concerning Rendezviewer, purportedly a part of the Texas Tech Pharmacy Project, on the theory that because Rendezviewer had to comply with the TPC, it is evidence of what was purportedly disclosed by the TPC. *See, e.g.*, Pet. Reply 10–11, 23–25 (citing Exs. 1029–1030). At oral hearing, however, Petitioner asserted that Rendezviewer was merely relied on to rebut testimony of Patent Owner’s experts. In any case, we discern that it is improper to rely on Rendezviewer to “fill-in gaps” with respect to the TPC.

achieve the functionality of Texas Pharmacy Code, an artisan would have made the combination. (Ex. 1003 at 111, 120).
Pet. 19; *see also* Pet. 17–18.

Patent Owner asserts that Liff is inadequate to cure any deficiencies of the TPC concerning (1) sending a verification via software to the remote pharmacy, because the verification in Liff has nothing to do with “correct performance of the sterile compounding process by the non-pharmacist person,” as recited in independent claim 16. Patent Owner’s assertions are misplaced, as Petitioner cites the TPC for disclosing this limitation. As set forth above, we find that the TPC discloses “receiving an indication of the remote pharmacist’s verification of the correct performance of the sterile compounding process by the non-pharmacist person,” with the exception that the infrastructure for verification is done via software. We find that Liff discloses software being used to send data packets signaling a drug dispensing verification between the pharmacist and a remote cabinet. Ex. 1007, 16:46–63, 23:1–43, Figs. 16, 17. And based on Petitioner’s rationale for modification, we are persuaded that providing the software infrastructure of Liff to effect the verification of the TPC would have been within the abilities of one of ordinary skill.

Patent Owner asserts further that Liff is inadequate to cure any deficiencies of the TPC concerning (2) providing an indication via software in response to that verification at the remote pharmacy, as required by independent claim 16, because, in Liff, nothing occurs automatically in response to a pharmacist providing a verification. Patent Owner’s assertions are misplaced, as we found *supra* that the TPC discloses providing an indication in response to that verification at the remote pharmacy.

Alternatively, Patent Owner may be asserting that, at best, modification of the TPC to include the software infrastructure of Liff is still insufficient to meet the aforementioned claim limitation, because it is unclear from the proffered combination whether a human takes the verification, from the software infrastructure of Liff, and effects that verification by printing a prescription label at the remote site. If so, according to Patent Owner, the claim limitation is not met because software is required to perform the link between the verification and indication. We disagree, to the extent that Patent Owner is asserting that every aspect of those claim limitations should be construed as being required to be fulfilled by software, and without human intervention. Based on the express claim language, we construe the relevant limitations as requiring some software to be used in each step, which the proffered combination does, but decline to construe them as requiring the use of software exclusively for implementing every aspect of those steps.

Patent Owner asserts additionally that Liff is non-analogous art, in that it is directed to automated pharmacy systems, while the relevant portions of the TPC and the claimed invention are directed to telepharmacy systems. As evidence supporting their position, Patent Owner notes that automated pharmacy systems are set forth in Section 20(a) of the TPC, while telepharmacy systems are set forth in Section 20(c). We are unpersuaded. The '887 patent is titled "System and Method for Remotely Supervising and Verifying Pharmacy Functions." Liff is titled "Method for Controlling a Drug Dispensing System." As noted by Patent Owner, Section 20 of the TPC is titled "Remote Pharmacy Services," and encompasses both automated pharmacy systems and telepharmacy systems. Accordingly, we

find that the '887 patent, Liff, and the TPC are in the same field of remote pharmacy services, and, thus, are analogous art. We are unpersuaded further that Liff and the claimed invention are so far afield, that one of ordinary skill in one would not have been familiar with features of the other, especially when both relate to using video equipment for pharmacy services.

Patent Owner asserts also that the TPC does not disclose the capture of “one or more images of the pharmacy work performed by the non-pharmacist person as the work is performed,” or use of images captured to monitor “in-process” steps of sterile compounding procedures, as required in independent claim 16. Patent Owner’s assertions are misplaced, as Petitioner cites both the TPC and Reese as corresponding to the aforementioned claim limitation. Specifically, Petitioner asserts that Reese discloses all aspects of the aforementioned claim limitations, with the exception of the fact that the work at the remote site is being performed by the non-pharmacist. For that, Petitioner relies on the TPC, with the rationale for modification being the following:

Reese confirms that compounding was one type of pharmaceutical work amenable to being remotely supervised and verified using cameras and computers. (Ex. 1006 at 20:10–21; Ex. 1003 at ¶¶ 82, 114). It provides detail on which images to transfer, the layout of workstations and cameras, and the technologies used for remote verification. (Ex. 1006 at 20:10–21). Particularly, since Reese discloses that tasks performed by a machine could also be performed by humans, (Ex. 1006 at 22:45–58), an artisan reviewing Texas Pharmacy Code would have supplemented its disclosure with Reese’s discussion of the details of supervising such compounding work. (Ex. 1003 at ¶ 118). Moreover, Texas Pharmacy Code’s image transfer and store-and-forward (Ex. 1005 at p. 815, §291.20(c)(2)(I)–(K)) are enabled by Reese, (Ex. 1006 at 6:15-24, 11:52-67), so an artisan

making the combination would have expected success. (Ex. 1003 at ¶¶ 116, 117, 110).

Pet. 18. We are persuaded that Petitioner's position is reasonable and supported by the evidence. Relatedly, Patent Owner asserts that Reese does not disclose capturing images of work done "by a non-pharmacist person." These assertions are unpersuasive for the same reasons as set forth *supra*.

8. *Dependent Claim 27*

Dependent claim 27 recites "for each of at least two steps in the sterile compounding process of the sterile compounded medications, the remote pharmacist provides to the institutional pharmacy, on a step-by-step basis, a verification of the step using at least one captured image for the step." Patent Owner asserts that Reese does not disclose providing verification for each step, as required by dependent claim 27, because in Reese the pharmacist is controlling the robot, and, thus, any verification of their own actions would only be a mental one. Patent Owner's assertions are misplaced, in that a combination of the TPC and Liff are cited for an electronic verification corresponding to a particular step, i.e., the data packet of Liff including the verification of the TPC. Reese is cited merely for an explicit disclosure of multiple images each associated with one of multiple steps, and we are persuaded that this disclosure of Reese, with the TPC's disclosure of in-process and final checks and Liff's disclosure of electronic verification, supports adequately at least two images associated with two different steps with at least two corresponding electronic verifications.

9. *Conclusion*

For the foregoing reasons, we are persuaded that Petitioner has shown, by a preponderance of the evidence, that claims 16–18, 20, 22–24, and 27 are obvious in view of the TPC, Reese, and Liff.

C. Claims 19 and 21 as Unpatentable over the Texas Pharmacy Code, Reese, Liff, and the ND Telepharmacy Project

Petitioner contends that claims 19 and 21 are unpatentable over a combination of the Texas Pharmacy Code, Reese, Liff, and the ND Telepharmacy Project. Pet. 38–41 (citing Exs. 1001, 1003, 1005, 1006, 1009, 1023). Patent Owner disagrees. PO Resp. 54–55 (citing Ex. 1009). Petitioner replies. Pet. Reply 22–23.

1. The ND Telepharmacy Project (Ex. 1009)

The ND Telepharmacy Project discloses information and guidelines for pharmacists and rural communities on how to implement a telepharmacy program designed to serve small rural communities that have lost their pharmacy services, are about to lose their pharmacy services, or have had no pharmacy services. Ex. 1009, 28. The ND Telepharmacy Project discloses a NetMeeting video conferencing system, which allows a pharmacist to monitor continuously the technician’s work, and allows constant communication. Ex. 1009, 34.

2. Analysis

Petitioner asserts that claims 19 and 21 are unpatentable over a combination of the Texas Pharmacy Code, Reese, Liff, and the ND Telepharmacy Project. Pet. 38–41. For example, claim 19 depends from independent claim 16, and recites “wherein said transmitting the one or more images comprises transmitting the one or more images via email or via a real-time collaboration tool.” Petitioner cites the ND Telepharmacy Project for disclosing a real-time collaboration tool, and then provides a rationale for combining the Texas Pharmacy Code, Reese, Liff, and the ND Telepharmacy Project at pages 38–39 of the Petition, with support from the

Hart Declaration. Petitioner sets forth a similar analysis for dependent claim 21.

Patent Owner asserts that the ND Telepharmacy Project does not disclose or suggest a system capable of remotely supervising and verifying the sterile compounding of a pharmaceutical product by a non-pharmacist technician. Patent Owner's assertions are misplaced, as the Texas Pharmacy Code, Reese, and Liff are cited for disclosing the aforementioned system for the reasons set forth *supra*.

3. Conclusion

For the foregoing reasons, we are persuaded that Petitioner has shown, by a preponderance of the evidence, that claims 19 and 21 are obvious in view of the TPC, Reese, Liff, and the ND Telepharmacy Project.

D. *Claims 1–3, 5–15, 25, and 26 as Unpatentable over the Texas Pharmacy Code, Reese, Liff, and Morrison*

Petitioner contends that claims 1–3, 5–15, 25, and 26 are unpatentable over a combination of the Texas Pharmacy Code, Reese, Liff, and Morrison, and claims 4, 14, and 26, are unpatentable over a combination of the Texas Pharmacy Code, Reese, Liff, Morrison, and the ND Telepharmacy Project. Pet. 41–49 (citing Exs. 1003–1009). Patent Owner disagrees. PO Resp. 20–59 (citing Exs. 1003–1009, 1017, 2001–2003). Petitioner replies. Pet. Reply 1–23 (citing Exs. 1003–1009, 1027, 1029–1032, 2001, 2002). Claim 1 is independent.

1. *Morrison (Ex. 1008)*

Morrison relates to remote processing of pharmacy orders in which pharmacy personnel at remote pharmacy facilities access pharmacy information systems of multiple healthcare facilities to review and authorize

their pharmacy orders. Ex. 1008 ¶ 1. Morrison discloses a web-based hospital pharmacy information system where access may be obtained through the web. Ex. 1008 ¶ 34. Morrison discloses that orders may be digitized into order images and transmitted to a document management server. Ex. 1008 ¶ 39.

2. *Petitioner's Position*

Petitioner asserts that claims 1–3, 5–15, 25, and 26 are unpatentable over a combination of the TPC, Reese, Liff, and Morrison, and claims 4, 14, and 26 are unpatentable over a combination of the TPC, Reese, Liff, Morrison, and the ND Telepharmacy Project. Pet. 41–49. For example, independent claim 1 requires capturing one or more images of a sterile compounding process performed by a non-pharmacist person that requires verification by a pharmacist. Petitioner cites the TPC for disclosing that compounding of sterile pharmaceuticals may be performed by a pharmacy technician, provided that the pharmacy technician is supervised by a pharmacist. Ex. 1005 § 291.36(c)(4)(B). Petitioner also cites the TPC for disclosing that a remote site shall be under the continuous supervision of a provider pharmacy pharmacist, for example, electronically through the use of the following types of technology: (I) audio and video; (II) still image capture; and (III) store and forward. Ex. 1005 § 291.20(c)(4)(C)(i). Petitioner additionally cites Reese and Liff for the technical aspects of monitoring remote pharmacies.

Independent claim 1 further requires implementing verification software that transmits the one or more images to a remote pharmacist, where the images are stored on a website. Petitioner cites Reese for disclosing that if a remote pharmacist has any concerns about whether a

packaged product matches a prescription or order, the remote pharmacist has access to the prescription transmission data, a video recording of the compounding process, and visual images from the compounding process as captured by the cameras. Ex. 1006, 20:10–21. Petitioner cites Morrison for disclosing storage of images related to pharmacy information on a web-based system. Ex. 1008 ¶¶ 34, 39.

Independent claim 1 also requires receiving an indication of verification by the remote pharmacist that the non-pharmacist correctly performed the sterile compounding, and providing a further indication in response to the verification indication. Petitioner cites the TPC for disclosing that compounding of sterile pharmaceuticals may be performed by a pharmacy technician who is supervised by a pharmacist, and that a remote site shall be under the continuous supervision of a provider pharmacy pharmacist. Ex. 1005 §§ 291.36(c)(4)(B), 291.20(c)(4)(C)(i). Petitioner also cites the TPC for disclosing that only a pharmacist can authorize printing of a prescription label at a remote site and perform a final check of the dispensed prescription. Ex. 1005 § 291.20(c)(4)(D)(iii).

Petitioner sets forth similar analyses for claims 2–15, 25, and 26. Citing the Hart Declaration, Petitioner provides several rationales for combining the aforementioned disclosures of the TPC, Reese, Liff, Morrison, and the ND Telepharmacy Project on pages 41, 42, and 48 of the Petition.

3. *Patent Owner's Positions*

Patent Owner asserts that Morrison does not remedy the aforementioned deficiency of the TPC, Liff, and Reese with respect to the following limitations of independent claim 1:

(1) remote supervision and verification by a pharmacist of a sterile compounding process performed by a non-pharmacist person; (2) capturing one or more images of the pharmacy work performed by the non-pharmacist person as the work is performed by the non-pharmacist person at the institutional pharmacy; and (3) implementing verification software to remotely verify the work performed by the non-pharmacist person with the remote verification of the work performed by the non-pharmacist person including: receiving an indication of the remote pharmacist's verification of the correct performance of the sterile compounding process by the non-pharmacist person and providing an indication at the institutional pharmacy that the remote pharmacist has verified the sterile compounding process performed by the non-pharmacist person.

PO Resp. 56. Patent Owner's assertion is misplaced, as we determined *supra* that Petitioner had shown sufficiently that the TPC, Liff, and Reese did disclose or suggest the similarly worded corresponding limitations of independent claim 16. That same analysis is applicable here to independent claim 1.

Dependent claim 6 recites "receiving an indication comprises: storing the indication of the pharmacist's verification of the correct performance of the sterile compounding process on the website; and the non-pharmacist accessing the indication of the pharmacist's verification on the website." Patent Owner asserts that the architecture disclosed in disparate sections of the TPC is not for transferring indications of verification of sterile compounding and storage/access of the same on/from a website. Patent Owner assertions are misplaced, as we discern that Morrison is cited as disclosing every aspect of dependent claim 6, except for "the indication of the pharmacist's verification of the correct performance of the sterile compounding process." As set forth above in our analysis of independent

claim 16, we are persuaded that a combination of the TPC and Liff discloses or suggests “sending a verification via software to the remote pharmacy.”

Patent Owner asserts additionally the following:

Morrison is silent as to compounding of any type, or of images of compounding being viewed by a pharmacist using a website. Indeed, Mr. Hart admitted in his deposition that Morrison discloses that verifications for the orders are remotely stored, which is different than storing them on a website as required by dependent claim 6 (Ex. 2003 at 197:22–197:2).

PO Resp. 58. Insofar as Patent Owner is asserting that Morrison does not disclose compounding, those assertions are misplaced for the reasons set forth *supra*. Furthermore, we find that Morrison discloses remotely storing orders on a website. Ex. 1008 ¶¶ 34, 39, 50. Insofar as Patent Owner is asserting that Mr. Hart’s above testimony casts doubt on that finding from Morrison, we are unpersuaded, as we read Mr. Hart’s testimony as asserting that orders can be stored on a remote server for a website.

4. *Dependent Claim 15*

Dependent claim 15 recites “wherein, for each of at least two steps in the sterile compounding process of the sterile compounded medications, the remote pharmacist provides to the institutional pharmacy, on a step-by-step basis, a verification of the step using at least one captured image for the step.” Patent Owner’s assertions, and our analysis, is the same as set forth above with respect to identically worded dependent claim 27, with the additional elaboration that Petitioner additionally relies on Morrison, but in a way that does not affect the analysis of dependent claim 15.

5. *Conclusion*

For the foregoing reasons, we are persuaded that Petitioner has shown, by a preponderance of the evidence, that claims 1–3, 5–15, 25, and 26 are

unpatentable over a combination of the TPC, Reese, Liff, and Morrison, and claims 4, 14, and 26, are unpatentable over a combination of the TPC, Reese, Liff, Morrison, and the ND Telepharmacy Project.

E. Other Issues

1. Level of Ordinary Skill in the Art

Petitioner asserts that one of ordinary skill in the art would have had “several years of experience with remote pharmacy work supervision and verification systems and a general familiarity with pharmacy operations.” Pet. 10 (citing Ex. 1003 ¶¶ 23); Pet. Reply 23–25. Patent Owner asserts that Petitioner’s proffered skill level does not recognize sufficiently that one of ordinary skill in the art would have had several years of experience as a pharmacist or in the field of pharmacy, so as to have familiarity with telepharmacy technology and relevant codes and regulations. PO Resp. 21–22 (citing Ex. 2001 ¶¶ 18–21; Ex. 2003). We agree to an extent. Dr. Ginsburg testifies that an artisan should have been familiar with basic pharmacy processes and aware of relevant regulations. Ex. 2001 ¶ 21. Accordingly, we modify Petitioner’s proffered skill level to read “several years of experience with remote pharmacy work supervision and verification systems and a familiarity with basic pharmacy processes and aware of relevant regulations.” Petitioner’s assertions are, nevertheless, largely consistent with this modified level of skill.

2. Hart Declaration

Patent Owner seeks to discount the testimony of Mr. Hart on several bases. PO Resp. 49–52. First, Patent Owner seeks to modify the level of ordinary skill to explicitly include “pharmacist” so that the Board would discount Mr. Hart’s testimony, as Mr. Hart admits he is not a pharmacist.

PO Resp. 49–50 (citing Ex. 1003 ¶ 11). Our review of Mr. Hart’s background (Ex. 1003 ¶¶ 8–13; Ex. 1021), however, indicates that Mr. Hart would appear to meet the above-articulated level of one of ordinary skill. Accordingly, we decline to discount Mr. Hart’s testimony solely because he is not, and never has been, a pharmacist.

Patent Owner asserts further that Mr. Hart has no experience in sterile compounding, and no experience in the type of telepharmacy system relevant to the present claims. Regarding sterile compounding, Patent Owner’s assertions are misplaced, as Petitioner relies primarily on the TPC and Dr. Grant’s testimony for sterile compounding. *See* Pet 20–22 (citing Ex. 1004 ¶¶ 13, 15, 18–25, 27, 31, 33–35). Concerning telepharmacy system relevant to the present claims, Patent Owner’s assertions are unpersuasive for the same reasons as set forth above with respect to Patent Owner’s assertions concerning non-analogous art. Indeed, we discern Mr. Hart’s testimony is more credible concerning the infrastructure of telepharmacy systems, and it is this area where we have accorded Mr. Hart’s testimony the most weight, for example, in the rationales to modify the TPC in view of Liff and Reese.

Patent Owner asserts further that much of Mr. Hart’s testimony appears to be based on his personal experience, and not on the documents themselves. Insofar as this is correct, they have been discounted accordingly, for example, as set forth in the footnote above concerning Rendezviewer.

Patent Owner also takes issue with Mr. Hart’s references to Dr. Emily Alexander, the inventor of the ’887 patent, and her relationship with Texas Tech University. Specifically, Patent Owner asserts that Mr. Hart’s

testimony concerning this issue has no relevance in this proceeding. We agree, and have not considered it in rendering our Decision.

Patent Owner asserts further that Mr. Hart's testimony at paragraph 58 should not be given any weight, because it opines, in a conclusory manner, only as to what could be performed based on the TPC, which is not a sufficient basis for obviousness. Patent Owner's assertions are misplaced, in that we found explicitly that the TPC discloses remote supervision of compounding, and that modifying that disclosure by adding the word "sterile" would have been within the abilities of one of ordinary skill, for the extensive reasons set forth *supra*. Accordingly, even if Mr. Hart's testimony on this basis was given little weight, it would not be outcome altering. In any case, while we agree that the conclusory statement "these rules disclose that sterile compounding was a type of pharmacy function that could be remotely supervised or provided as a remote pharmacy service," without more, should be given very little weight, we note that both Mr. Hart and Petitioner provide additional evidence to support that conclusion, namely, the specific citations to references set forth above, as well as the testimony of Dr. Grant (Ex. 1004 ¶¶ 26–32).

Patent Owner asserts that numerous other paragraphs of Mr. Hart's Declaration should be discounted for lacking adequate underlying factual bases. Insofar as Patent Owner is correct, we have done so in rendering this Decision.

3. *Grant Declaration*

Patent Owner seeks to discount the testimony of Dr. Grant because (1) Dr. Grant doesn't state that the TPC permits remote supervision and verification of sterile compounding, and (2) Dr. Grant only opines that

“nothing would prohibit supervision of sterile compounding using a camera and computers,” which is a purely hindsight conclusion insufficient to support Petitioner’s proffered modification. PO Resp. 52–54 (emphasis omitted). For (1), we agree, but nevertheless determine that the TPC discloses explicitly remote supervision of compounding, and that modifying that disclosure by adding the word “sterile” would have been within the abilities of one of ordinary skill, for the extensive reasons set forth *supra*. For (2), we are unpersuaded that it is a purely hindsight conclusion, as Dr. Grant provides some bases in the paragraphs preceding his conclusion in paragraph 32, but, in any case, as set forth extensively *supra*, it was not the only basis on which we were persuaded that Petitioner’s proffered modification would have been within the abilities of one of ordinary skill.

Patent Owner asserts that numerous other paragraphs of Dr. Grant’s Declaration should be discounted for lacking adequate underlying factual bases. Insofar as Patent Owner is correct, we have done so in rendering this Decision.

4. *Exhibit 1017*

Petitioner asserts that the Exhibit 1017 should not be accorded any weight. We have considered Exhibit 1017 above to the extent that it is relevant.

III. CONCLUSION

Petitioner has demonstrated, by a preponderance of the evidence, that claims 1–27 of the ’887 patent are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–27 of the '887 patent are held unpatentable;
and

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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