IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

SKEDO, INC., an Oregon corporation,

Plaintiff,

v.

STRATEGIC OPERATIONS, INC., a California corporation,

Defendant.

No. 3:13-cv-00968-HZ

OPINION & ORDER

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HERNANDEZ, District Judge:

Plaintiff Skedco, Inc. brings this action against Defendant Strategic Operations, Inc., alleging that Defendant infringes Claims 18, 19, and 20 of United States Patent No. 8,342,652 ("the '852 Patent") which discloses a system for simulating hemorrhages in the training of first responders.[1] The United States, through the Secretary of the Army, owns the '852 Patent. Plaintiff is the sole and exclusive licensee of the '852 Patent under an agreement which also gives Plaintiff the right to bring this action in its own name.

In 2015, after claim construction disputes were resolved, both parties moved for summary judgment on the issues of infringement, validity, and unenforceability based on inequitable conduct. In a December 8, 2015 Opinion, I granted summary judgment to Defendant on the issue of infringement, denied Plaintiff's motion on that issue, and denied all remaining motions as moot. *Skedco, Inc. v. Strategic Ops., Inc.*, 154 F. Supp. 3d 1099 (D. Or. 2015). Judgment was entered that day. ECF 153. Plaintiff appealed. In an April 24, 2017 Opinion, the Court of

[1] A copy of the '852 Patent is found at Exhibit A to the Second Amended Complaint, ECF 17-1. All further references to the '852 Patent will be to this Exhibit and will be denoted simply by reference to the patent and the column and line number cited as appropriate.

Appeals for the Federal Circuit (CAFC), reversed the summary judgment determination, concluding that I erred in construing certain claim elements. *Skedco., Inc. v. Strategic Ops., Inc.*, 685 F. App'x 956 (Fed. Cir. 2017). The CAFC vacated the underlying judgment and remanded the case to this Court. *Id.* The mandate was filed on May 31, 2017. ECF 197.

The parties have now filed new summary judgment motions, again raising issues of infringement, validity, and unenforceability based on inequitable conduct. I grant Plaintiff's motion and deny Defendant's motion on the issue of literal infringement. I deny as moot both parties' motions on infringement under the doctrine of equivalents. I deny both parties' motions on obviousness and on inequitable conduct. I grant Plaintiff's motion addressed to all of Defendant's affirmative defenses except for obviousness and inequitable conduct.

Following the recitation of summary judgment standards, this Opinion has four parts: (1) Infringement; (2) Obviousness; (3) Inequitable Conduct; and (4) Remaining Issues. My December 8, 2015 Opinion includes an overview of the '852 Patent, the then-operative claim constructions, and an overview of the allegedly infringing BPS System. 154 F. Supp. 3d at 1101-03. I do not repeat the overviews here. I do not revisit the claim constructions other than those addressed by the CAFC in its April 24, 2017 Opinion.

STANDARDS

Summary judgment is appropriate if there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The moving party bears the initial responsibility of informing the court of the basis of its motion, and identifying those portions of "'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence

of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (quoting former Fed. R. Civ. P. 56(c)).

Once the moving party meets its initial burden of demonstrating the absence of a genuine issue of material fact, the burden then shifts to the nonmoving party to present "specific facts" showing a "genuine issue for trial." *Fed. Trade Comm'n v. Stefanchik*, 559 F.3d 924, 927-28 (9th Cir. 2009) (internal quotation marks omitted). The nonmoving party must go beyond the pleadings and designate facts showing an issue for trial. *Bias v. Moynihan*, 508 F.3d 1212, 1218 (9th Cir. 2007) (citing *Celotex*, 477 U.S. at 324).

The substantive law governing a claim determines whether a fact is material. *Suever v. Connell*, 579 F.3d 1047, 1056 (9th Cir. 2009). The court draws inferences from the facts in the light most favorable to the nonmoving party. *Earl v. Nielsen Media Research, Inc.*, 658 F.3d 1108, 1112 (9th Cir. 2011).

If the factual context makes the nonmoving party's claim as to the existence of a material issue of fact implausible, that party must come forward with more persuasive evidence to support his claim than would otherwise be necessary. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

INFRINGEMENT

I. Prior Decision/Claim Construction & CAFC Opinion

Most of the claim constructions from the 2014 *Markman* hearing and *Markman* Opinion which were controlling before the 2015 summary judgment motions, remain unchanged. Of the six terms or phrases this Court construed, the CAFC expressly rewrote only one. In the December 8, 2015 Opinion resolving the 2015 summary judgment motions, I added to the

previous claim constructions. The CAFC concluded that my additional limitations were unsupported by the patent.

Based on the prior claim constructions, particularly the construction of "valve," "pump," and "a controller connected to said pump and said at least one valve," I granted Defendant's motion for summary judgment on literal infringement. 154 F. Supp. 3d at 1104-1112. The CAFC's Opinion primarily concerned two claim elements in Claim 18: (1) "at least one valve in fluid communication with said pump," and (2) "a controller connected to said pump and said at least one valve." *Skedco*, 685 F. App'x at 957-58. As the CAFC noted, I construed "at least one valve in fluid communication with said pump" to require the pump and the valve to be physically separate structures. *Id.* at 959 (citing 154 F. Supp. 3d at 1112). The CAFC did not disagree with the construction of "pump" as a "device that moves or transfers fluid by mechanical action," or the construction of "valve" as "a device that regulates, directs, or adjusts the flow of fluid through a passageway by opening, closing, or restricting that passageway." *Id.* But, the CAFC rejected my conclusion that the pump and the valve had to be physically separate structures:

> [N]othing in the claims requires the pump and the valve to be physically separated. The claimed valve need only be "in fluid communication with" the claimed pump. '852 patent, 14:9. Nothing prevents a pump from being "in fluid communication with" an internal valve.
>
> * * *
>
> Our construction is also consistent with the district court's construction of the individual terms "pump" and "valve." To paraphrase the district court, a "pump" moves fluid and a "valve" regulates fluid flow. *See Skedco*, 154 F.3d at 1102. . . . We see no reason why a device that moves fluid cannot contain another device that regulates flow within it. A pump does not cease moving fluid - *i.e.*, being a "pump" - just because an internal valve adjusts fluid flow.
>
> * * *

> We therefore hold that the district court erred in construing the limitation "at least one valve in fluid communication with said pump" as requiring a physically separate pump and valve.

685 F. App'x at 959, 960.

The CAFC then addressed the limitation of "a controller connected to said pump and said at least one valve." *Id.* at 960-61. Following the *Markman* hearing, I construed the phrase "controller connected to" as "an activation mechanism joined, united, or linked to" establishing the meaning of the entire phrase as "an activation mechanism joined, united, or linked to said pump and said at least one valve." 154 F. Supp. 3d at 1102. During my 2015 summary judgment infringement analysis, I further construed the phrase as requiring the controller to have "direct," "independent," and "physical" connections to the pump and the valve so that the pump and valve "were controlled by the controller." *Id.* at 1105-06. The CAFC concluded that including these additional limitations into Claim 18 was error.

Instead of requiring a physical connection, the CAFC held that "the term 'connected to' in the context of the '852 patent contemplates both direct and indirect connections." 685 F. App'x at 961. The CAFC further determined that there was no reason to "import" a "physical" limitation into Claim 18. *Id.* The CAFC explained that the claimed "'controller' is merely 'an activation mechanism'" and "nothing limits this activation to physical channels." *Id.* (citing embodiments of the patent where a remote controller activates a valve and noting that "[t]his activation must occur at least in part through a nonphysical connection."). According to the CAFC, it "was error to limit the claimed connection to physical connections." *Id.*

The court agreed that my analysis that the valve and the pump must be "controlled by the controller" was "essentially correct." *Id.* The CAFC explained, "[i]n the context of claim 18, the

controller is 'an activation mechanism' for controlling the components connected to it." *Id.* Then, while the CAFC agreed with Plaintiff that Claim 18 "expects interaction between the controller and the components connected to it," it rejected Skedco's proposed construction of "connected to" to mean "interacts directly or indirectly with" because the "'852 patent describes the relationship between the controller and the pump and the valve as being one of control or activation, not 'interaction' more generally." *Id.*

Based on this discussion, the CAFC held that the "correct construction of "a controller connected to said pump and said at least one valve' is 'an activation mechanism configured to control a pump and a valve to which it is directly or indirectly joined, united, or linked.'" *Id.* According to the CAFC, "[t]his construction reflects the parties' agreement that 'controller' means 'an activation mechanism.'" *Id.* And, "[i]t is consistent with the plain meaning of 'connected to' as 'joined, united, or linked to.'" *Id.*

II. Infringement Standards Generally

A patent holder has the right "to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States[.]" 35 U.S.C. § 154(a)(1). A party infringes a patent if, "without authority," it "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[.]" 35 U.S.C. § 271(a).

A device can infringe a patent literally or under the doctrine of equivalents. *E.g.*, *Energy Transp. Grp., Inc. v. William Demant Holding A/S*, 697 F.3d 1342, 1352 (Fed. Cir. 2012) (noting that a device that does not literally infringe a claim may still infringe under the doctrine of equivalents). Infringement analysis involves two steps. *Grober v. Mako Prods, Inc.*, 686 F.3d

1335, 1344 (Fed. Cir. 2012). First, the court determines the scope and meaning of the patent claims through the claim construction process and second, the claims as construed are compared to the allegedly infringing device. *Id.* (citing *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc)). The two-step analysis applies to both literal infringement and infringement under the doctrine of equivalents. *Deering Precision Instruments, LLC v. Vector Distrib. Sys., Inc.*, 347 F.3d 1314, 1322 (Fed. Cir. 2003). As indicated above, the step one claim construction occurred in this case in 2014 and was revised by the CAFC in its April 2017 Opinion. As to step two, "[p]atent infringement, whether literal or by equivalence, is an issue of fact, which the patentee must prove by a preponderance of the evidence." *Siemens Med. Sols. USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1279 (Fed. Cir. 2011).

III. Literal Infringement

To establish literal infringement, "every limitation set forth in a claim must be found in an accused product, exactly." *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1356 (Fed. Cir. 2012) (internal quotation marks omitted). As in the 2015 summary judgment motions, Defendant focuses its argument on Claim 18 and then asserts that the allegedly infringing BPS System does not infringe Claims 19 and 20 because those claims depend from Claim 18. A dependent claim cannot be infringed if the independent claim is not infringed. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989).

Defendant does not contest that the BPS System meets Elements 1, 2, or 5 of Claim 18. As it did previously, Defendant focuses on Elements 3 and 4 of Claim 18 and contends that the BPS System does not have the requisite valve or that such valve is not "connected to" a

controller.

A. Element 3: "at least one valve in fluid communication with said pump"

My prior claim construction, confirmed by the CAFC, requires a valve to regulate, direct, or adjust the flow of fluid through a passageway by opening, closing, or restricting the passageway. 154 F. Supp. 3d at 1102; 685 F. App'x at 959. Both parties' experts opine that the internal valves of the three pumps used in the BPS System at any given time (Pump A, Pump B, and Pump C), regulate, direct, or adjust the flow of fluid through a passageway by opening. closing, or restricting the passageway and thus meet the claimed element. Stevick Dec. 19, 2014 Infring. Rep. ¶¶ 53-63, ECF 98-3; Guentzler Jan. 2015 Rebuttal Infring. Rep. ¶¶ 47-50 (Pump A); ¶¶ 53-54 (Pump B); ¶¶ 60-61 (Pump C), ECF 98-10. The same is true for what the parties refer to as "Pump D" although Pump D is a different type of device. Stevick Dec. 19, 2014 Infring. Rep. ¶¶ 64-66, ECF 98-3; Guentzler July 21, 2015 Dep. 153:17-154:11, ECF 98-15.

Defendant does not seriously contest that the valve components within each of the four pumps meet the controlling definition of "valve" because the components "regulate[], direct[], or adjust[] the flow of fluid through a passageway by opening, closing or restricting the passageway."[2] Defendant argues however, that the current claim constructions require that the valve be a separate and distinct device from the pump, even if it may be physically housed within the pump, and because the internal valves of Pumps A, B, C, and D are nothing more than components of the pump that exist solely to allow each pump to function properly, there is no actual "valve." Thus, Defendant continues, none of the four pumps used in the BPS System meets

[2] At the December 12, 2017 oral argument on the motions, Defendant argued that Pump D did not meet the limitation. Based on the testimony of its expert Dr. William Guentzler cited above, I reject this argument.

Element 3 of Claim 18.

In my December 8, 2015 Opinion, I stated that the claim language supported a conclusion that the pump and the valve were separate devices. 154 F. Supp. 3d at 1108 ("[b]y disclosing a 'pump' in Element 2 and separately disclosing a 'valve' in Element 3, the language in Claim 18 suggests that these are two independent devices"). I also stated that the claim construction further supported a conclusion that these were separate devices because they perform distinct functions. *Id.* ("By defining each of these claim components as a 'device' and by defining each as performing a distinct function different from the other, the claim construction indicates that the pump and the valve disclosed in Claim 18 are separate devices").

I recognized the competing expert opinions regarding the independence of the internal valves that reside within the pumps used in the BPS System. *Id.* at 1108-09. I noted that Plaintiff's expert Dr. Glen Stevick asserted that Pumps A-D were "structures that contain internal components which satisfy both the 'pump' and 'valve' limitations[.]" *Id.* at 1108. Stevick, I explained, deconstructed each of the four pumps and asserted, essentially, that each of them had "valve" components that operated independently from the "pump" components such that the "pump" components moved fluid by mechanical action and the "valve" components regulated fluid flow. *Id.* In contrast, Dr. William Guentzler, Defendant's expert, opined that Pumps A-D could not function to move fluid and perform as intended with the "valve" components removed. *Id.* at 1109. The valve components were not independent of the pump.

For the purposes of the December 8, 2015 Opinion, I accepted Stevick's opinion that Pumps A-C had valve components that could be separated from the pump components and that Pump D's gear teeth acted as backflow-preventing valves. *Id.* I further credited Stevick's opinion

that even with these valve components removed, the pumps could operate. *Id.* Nonetheless, I explained:

> The valve components of Pumps A-D "regulate" the fluid only within the pumps themselves. The valve disclosed in Claim 18 is separate from the pump because the valve, as discussed above, is separately and independently connected to the controller/activation mechanism. And, while the components of Pumps A-D may be disassembled for the purposes of testing the operation of those pumps absent the "valve" portion, the BPS System does not use Pumps A-D with the components taken apart. Thus, even though the components can be separated for testing, the "valve" portions of Pumps A-D actually function as part of the pump. Each Pump A-D is a single device that has internal components that prevent backflow into the pump so that the pump will function efficiently to move fluid by mechanical action. Pumps A-D do not have an independent valve.

Id.; *see also id.* at 1112 ("Pumps A-D do not satisfy the independent functions of the two devices (the valve and the pump) because the design of each of those pumps is that the internal valve and pump work together to make the pump work efficiently to move or transfer the fluid").

The CAFC concluded that I erred in my analysis and determined that nothing in the patent claims or specification required that the valve be physically separate from the pump. 685 F. App'x at 959-60. Although the CAFC accepted my claim constructions for "valve" and "pump," agreed that each device performed a distinct function ("a 'pump' moves fluid and a 'valve' regulates fluid flow"), and expressly recognized that "a 'pump' is not a 'valve,'" it nonetheless found that the claim language contained no limitation on the "structural relationship between the pump and the valve" other than that the valve be in fluid communication with the pump. *Id.* at 959-60. Nothing prevented the pump from being "in fluid communication with" an internal valve and "nothing in the claims or specification prohibits a valve from residing within a pump." *Id.* Further, in rejecting Defendant's argument that because the pump and the valve are separately listed claim elements they are presumptively distinct, the CAFC stated that "nothing in the

agreed-upon constructions of 'pump' and 'valve' forbids a pump from housing an internal valve." *Id.* at 960.

Defendant's argument here poses the question of whether "components" which perform the function of a valve as defined in the claim construction, but which do so solely as part of the pump and are integral to the movement of fluid by mechanical action, are nonetheless not "valves" as defined because, by virtue of their indispensability to pump function, they are not an independent "device" and they perform no separate function. That is, even though the CAFC concluded that a "valve" may reside inside a "pump" consistent with the claim language, are these internal components nonetheless inconsistent with the claim language because they perform no discrete "valve" function and are not functionally an independent device?

I am constrained by the CAFC's decision to answer the question with a "no," the internal components are not inconsistent with the claim language. The CAFC's holding is directed to the physical separation of the pump and valve. But, its discussion reflects a determination that the "valve" components residing inside each version of the pump meet the Element 3 limitation even if they are integral to the effective functioning of the pump. This is seen by the fact that this issue was addressed in my December 8, 2015 Opinion, by the fact that Defendant raised the issue in its brief to the CAFC, by the questioning of Defendant's counsel during oral argument, and by statements in the CAFC's opinion.

My December 8, 2015 Opinion, as seen from the discussion above, unambiguously set forth a discussion regarding how the valve components of Pumps A-D performed no independent function and instead operated *with the pump* to make the pump satisfy its required function of moving or transferring fluid by mechanical action. Defendant raised the issue in its brief on

appeal. *See Skedco, Inc. v. Strategic Ops., Inc.*, No. 16-1349, ECF 39 (Fed. Cir. July 15, 2016) (Def.'s Appellee Br.). Beginning in the Introduction, Defendant discussed what it called Plaintiff's "deconstructed pump theory" and explained why the argument failed. Def.'s Appellee Br. 5-6. Defendant later explained why Claim 18 required a valve to be a separate device from the pump and thus could not be something that is part of the "internal, integral structure of the pump." *Id.* at 20. Defendant framed the dispute as "not whether a 'valve' can be 'in fluid communication' with a 'pump' when that valve and pump are housed in the same single structural element[,]" but "whether each Pump A-D, as used in the BPS, performs the separate and independent functions of the two separately claimed devices, a 'pump' and a 'valve.'" *Id.* at 41; *see also id.* at 42 (quoting portion of December 8, 2015 Opinion set out above explaining that the "valve" portions of Pumps A-D function as part of the pump).

During oral argument before the CAFC, Judge Chen and Judge Prost both questioned Defendant's counsel as to why the valve could not be inside the pump. Stevick Aug. 15, 2017 Supp'l Reb. Infring. Rep. 2-3, ECF 224-4. Judge Chen asked why "can't the valve be inside the pump?" *Id.* at 2. Defendant's counsel tried to explain that there was no valve because it was just a pump device with many components within that device. *Id.* But, Judge Chen asked directly: "Is one of the components a valve?" to which Defendant's counsel answered "[y]es." *Id.* Defendant's counsel persisted in trying to communicate that the valve component just "functions in the pump." *Id.* Judge Chen responded by asking still, why could that valve not meet the claim limitation for the valves? *Id.* Citing *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221 (Fed. Cir. 2011), which I had discussed in my December 8, 2015 Opinion, Judge Chen explained that although there were two claim limitations in *Powell*, the CAFC had nonetheless affirmed the

jury's verdict that the accused product's single box met both limitations. *Id.* Judge Chen wondered "why couldn't that also potentially be applicable here, or at least at a minimum, raise a factual question for a jury or a district court to decide as a factual matter?" *Id.* at 3. Judge Chen was not persuaded that *Powell* was distinguishable, noting that here, there "are two specific devices[,]" "[j]ust like in *Powell*." *Id.* Still, Defendant's counsel pressed in his position that in *Powell*, there were specific teachings in the specification envisioning that the two devices could be integrated into one. *Id.* At that point, Judge Prost remarked that if the claim language is broad enough to allow it, then even without teaching in the specification, it would be allowed, absent a disclaimer. *Id.*

The CAFC was aware of the issue present here and posed questions to counsel during oral argument suggesting that despite Defendant's contentions that a valve was not a pump and that the valve components function only as part of the pump, the valve components still met the limitation for valves. The CAFC's statements in its decision confirm this. In particular, I note the court's determination that "Claim 18 contains no other limitation [aside from "in fluid communication with"] governing the structural relationship between the pump and the valve." 685 F. App'x at 959. Additionally, even in the face of the December 8, 2015 Opinion and Defendant's arguments on appeal, the court still stated that "nothing in the agreed-upon constructions of 'pump' and 'valve' forbids a pump from housing an internal valve." *Id.* at 960. Then, well aware of how an internal valve functions, the court concluded that the internal valve components were consistent with the constructions of "pump" and "valve." Finally, the court's observation that "[a] pump does not cease moving fluid - *i.e.*, being a 'pump' - just because an internal valve adjusts fluid flow[,]" shows that the court, fully cognizant of the separate functions

of the valve and the pump, nonetheless held that these functions could be performed by components housed together in a pump. *Id.* at 959. With that, the CAFC's opinion requires that I conclude that as long as the components perform the function as defined, the valve limitation in Element 3 is satisfied.

Even assuming that Guentzler's opinion is correct, and that the internal valves in Pumps A-D are not independent from the pumps, that does not mean that they do not satisfy the limitation of a "valve." Because Guentzler's reports and testimony show that components within each of Pumps A-D "regulate, direct, or adjust the flow of fluid through a passageway by opening, closing, or restricting the passageway," there is no dispute that the components meet the definition of a "valve." Therefore, the "valves" in Pumps A-D of the BPS System meet Element 3 of Claim 18.

B. Element 4: "a controller connected to said pump and said at least one valve"

As noted above, the CAFC revised my claim construction of this phrase to mean "an activation mechanism configured to control a pump and a valve to which it is directly or indirectly joined, united, or linked." 685 F. App'x at 961. It contemplates both that the activation mechanism "control" the pump and the valve and that the activation mechanism be directly or indirectly joined, united, or linked to the pump and the valve. There is no dispute that the BPS System activation mechanism controls the pump and that the activation mechanism is directly joined to the pump via wiring. The issue is whether the internal valves in Pumps A-D meet the limitation.

Plaintiff argues that Pumps A-D each meet this element because both a wireless key fob and a wired activation mechanism responsive to the key fob (a) control the pump and the valve

within the pump, and (b) are indirectly joined, united, or linked to the pump and to the valve within the pump. Pl.'s Mot. for Sum. J. 12, ECF 223. Plaintiff argues that "[e]ach of Pumps A-D has a valve component controlled by the action of the pump and thus, [the valve] is indirectly controlled by and connected to the controller." *Id.*; *see also* Pl.'s Reply 6, ECF 238; Pl.'s Opp. 7-9, ECF 233.

Defendant contends that the BPS controller system is configured to control only the pump, not the valve. Defendant focuses on the CAFC's rejection of Plaintiff's proposed construction of "connected to" as "interacts directly or indirectly with." Defendant argues that Plaintiff's contentions regarding how the BPS System meets Element 4 of Claim 18 describe only an "indirect interaction" between the controller/activation mechanism and the valve, which the CAFC rejected. Defendant suggests that a more direct connection is required.

The evidence in the record from both parties' experts establishes that when the controller turns on electric power to the pump, the pump creates hydraulic pressure that activates the internal valves in each pump. Plaintiff refers to this as an "electric-over-hydraulic connection." Pl.'s Reply 6, ECF 238. Stevick opines that the BPS System controller is directly connected to each pump and indirectly connected to the valve components, and that when activated, the controller starts the pump which causes the valve to cyclically open and close. Stevick Claim Chart 15-17, ECF 98-2 (citing to (a) Ex. 1 to Stevick Dec. 19, 2014 Infring. Rep., ECF 98-3 (BPS Product Descrip.); (b) Stevick Dec. 19, 2014 Infring Rep. ¶¶ 67-69, ECF 98-3; and (c) Guentzler Dep. 158:25-159:9, 163:9-20, ECF 98-15); *see also* Stevick Aug. 15, 2017 Supp'l Reb. Infring. Rep. 11, ECF 224-4 ("In each version of the BPS, the controller activates the pump electrically, and indirectly activates the valve via the pump and the fluid pressure that the pump

creates"); *see also* Guentzler July 21, 2015 Dep. 158:25-159:9, 163:9-20, ECF 98-15 (testifying that when the BPS controller is turned on, it sends 12 volts to the model of the pump and that when the pump starts to pump, the movement of the plunger controls the valves).

To the extent Defendant suggests that a physical connection between the activation mechanism and the valve is required, Defendant's contention is foreclosed by the CAFC's opinion which specifically held that the term "connected to" contemplated both direct and indirect connections. The court expressly rejected the contention that Claim 18 required a physical connection. 685 F. App'x at 961. To the extent Defendant argues that the valve must be activated independently from the pump, nothing in the construction of Element 4 or the CAFC's opinion suggests that is necessary.

During oral argument at the CAFC, Judge Chen, in asking about an "indirect or direct connection," stated that "connected to" could be "an indirect connection in the sense that you have to go through some other component in order to, you know, activate that downstream component." Stevick Aug. 15, 2017 Supp'l Reb. Infring. Rep. 5, ECF 224-4. And, in the decision itself, the CAFC explicitly pointed to an indirect connection in the '852 Patent. 685 F. App'x at 960-61 ("The patent describes *activating* valve 124 'though [sic] a controller (or remote control switch) 126' despite a lack of direct connection between the controller and the valve. . . . Using 'connected to' to cover indirect connections is also more consistent with the term's plain meaning"; "'controller' is merely 'an activation mechanism,' . . . and nothing limits this activation to physical channels. Indeed, the '852 patent includes several embodiments where a remote controller 160 activates a valve. . . . This activation must occur at least in part through a nonphysical connection.") (emphasis added).

The CAFC's acknowledgment that indirect connection includes activating a downstream component by going through another component and its example of indirect control support a conclusion that going through the "other component" of the pump to activate the valve satisfies the limitation in Element 4 as construed by the CAFC. Given that the valve is a subdevice/component of the pump and it is undisputed that the activation mechanism activates the pump, the valve is also activated by the mechanism, albeit indirectly, and thus the BPS System and each one of Pumps A-D meets the required limitation of having an activation mechanism configured to control a pump and a valve to which it is directly or indirectly joined, united, or linked.

C. Stevick's Opinion

In its Memorandum in Opposition to Plaintiff's Summary Judgment Motion, Defendant argues that Plaintiff has presented no post-CAFC Opinion expert opinion setting forth an infringement analysis using the proper construed claim language. Thus, Defendant argues, Plaintiff cannot sustain its burden of proving infringement. Def.'s Opp. 1, ECF 234. Defendant objects to any testimony by Stevick related to the post-CAFC Opinion claim constructions because he provided no expert opinion on those issues. Because Stevick issued no new report after the CAFC revised the construed claim terms, Defendant argues that Stevick offers no opinion on these terms on which this Court can rely.

Following the issuance of the CAFC mandate, I set a new case schedule. June 20, 2017 Am. Min. Ord., ECF 203. I denied Defendant's request to reopen fact discovery but I allowed reopening of expert discovery. *Id.* I set a schedule for disclosure of initial expert reports as follows: August 1, 2017 for initial expert reports; August 15, 2017 for supplemental/rebuttal

reports; and September 1, 2015 for the close of expert discovery. *Id.*

Plaintiff did not tender a new infringement report to Defendant on August 1, 2017. *See* Def.'s Mot. to Strike, ECF 207. Plaintiff did provide a Supplemental Report from Stevick on August 15, 2017. *Id.* On September 6, 2017, Defendant moved to strike Stevick's August 15, 2017 Supplemental Report because several of the initial pages were not, in Defendant's opinion, rebuttal to an August 1, 2017 Supplemental Infringement Report by Guentzler, but were instead an initial report which was untimely. As a result, Defendant argued it was deprived of the opportunity to rebut Stevick's infringement opinion. *Id.*

In a September 8, 2017 Order, I denied Defendant's motion to strike:

> ORDER: The Court has reviewed Defendant's Motion to Strike Plaintiff's "Supplemental Expert Report of Glen Stevick in Rebuttal to Supplemental Expert Report of William D. Guentzler" 207. The Court has also reviewed Dr. Stevick's report that is at issue in Defendant's motion. According to Defendant, the first portion of Dr. Stevick's report (pages 2-6) to which the motion to strike is addressed is not actually a rebuttal to Dr. Guentzler's report but is an untimely new expert report on infringement offered by Dr. Stevick. (Defendant's motion does not address pages 7 - 15 of Dr. Stevick's report which is clearly delineated as a rebuttal to Dr. Guentzler's report)[.] Based on the Court's reading of this portion of Dr. Stevick's report, Dr. Stevick opines that the Federal Circuit's decision clarified the original claim construction this Court rendered in 2014. Dr. Stevick further states that the "concepts described" by the Federal Circuit are as he described in earlier reports or are consistent with his understanding of the 2014 claim construction issued by this Court.
>
> I DENY the motion to strike the report 207 because the opinion offered by Dr. Stevick is not a new opinion regarding infringement but is a reassertion of his prior infringement opinion based on his conclusion that the Federal Circuit's decision clarified the claim construction consistent with the claim construction that Dr. Stevick previously relied on. Dr. Stevick's interpretation of the Federal Circuit's opinion is not controlling on this Court, however, and Plaintiff may or may not be successful in defending Dr. Stevick's interpretation going forward. At this point, because Dr. Stevick does not appear to be offering a new opinion on infringement, there is no basis to strike his August 15, 2017 report as untimely.

ECF 208.

Stevick's pre-CAFC infringement opinions are sufficient to sustain Plaintiff's burden of proof. Stevick's original opinions remain valid unless they are inconsistent with the post-CAFC Opinion claim constructions. Stevick's opinions were based on the 2014 claim constructions which are set forth in the December 8, 2015 Opinion. 154 F. Supp. 3d at 1102. As the CAFC noted, the December 8, 2015 Opinion added claim limitations not previously announced in the 2014 *Markman* hearing or the *Markman* Opinion. 685 F. App'x at 960. Before the December 8, 2015 Opinion, nothing in the prior claim constructions suggested that the "in fluid communication with" limitation required physically separate pump and valve structures. Before the December 8, 2015 Opinion, nothing in the prior claim constructions suggested that the "controller connected to" limitation required a direct, physical connection. It was not until the December 8, 2015 Opinion was issued that these additional limitations were rendered. I even acknowledged in a footnote in that decision that to the extent the additional limitations were viewed as changed claim constructions, the law supported my authority to do so. *Id.* at 1108 n.6.

I read the CAFC decision as addressing and rejecting the *additional* limitations I provided in the December 8, 2015 Opinion. I do not read that decision as fundamentally altering the 2014 claim constructions. As a result, Stevick's original infringement opinions are based on claim constructions which still govern, albeit with some clarification by the CAFC. And, those clarifications are consistent with the interpretations of the 2014 claim constructions that Plaintiff and Stevick have had since they were issued in 2014. Defendant's objection to Stevick's infringement opinions is overruled.

/ / /

D. Summary re: Literal Infringement

Plaintiff meets its burden of establishing that the BPS System literally infringes all elements of Claim 18 of the '852 Patent. The record presents no material disputed issues of fact as to the literal infringement of this claim.

As to Claims 19 and 20, Defendant offers no evidence or argument specifically addressed to those claims. Claims 19 and 20 depend from Claim 18. Claim 19 discloses a trauma training system as disclosed in Claim 18 but with two wound sites. Claim 20 discloses a trauma training system disclosed in Claim 18 with a container housing the reservoir, pump, and at least one valve. Stevick opines that the BPS System meets all elements of Claims 19 and 20. Stevick Claim Chart 19-21, 23, ECF 98-2; Stevick Dec. 19, 2014 Infring. Rep. ¶¶ 74-76, 77-78, ECF 98-3; Ex. D to Stevick Dec. 19, 2014 Infring. Rep. 51-52, ECF 98-3 (BPS Product Description). Guentzler's opinion is not inconsistent with Stevick's. Guentzler Jan. 2015 Rebuttal Infring. Rep. ¶ 43 (describing four separate blood supply lines), ¶ 73 (describing wound sites), ECF 98-10. There are no disputed issues of fact regarding the literal infringement of Claims 19 or 20.

I grant summary judgment on literal infringement of Claims 18, 19, and 20 to Plaintiff and deny Defendant's motion on that issue. By granting summary judgment to Plaintiff on the issue of literal infringement, I need not address Plaintiff's alternative contention that the BPS System infringes Claims 18, 19, and 20 of the '852 Patent under the doctrine of equivalents. Thus, I deny both parties' motions addressed to the doctrine of equivalents, as moot.

OBVIOUSNESS

I. Legal Standards

United States patents are presumed valid by statute. 35 U.S.C. § 282. Defendant bears

the burden of establishing invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 100-01, 110-13 (2011); *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1293 (Fed. Cir. 2015). The presumption mandated by Section 282 applies to validity challenges based on obviousness. *See Senju Pharm. Co. v. Lupin Ltd.*, 780 F.3d 1337, 1350 (Fed. Cir. 2015). While the clear and convincing burden of proof always applies to the patent validity challenger, if "a challenger introduces evidence that might lead to a conclusion of invalidity—what we call a prima facie case," the patentee is "well advised to introduce evidence sufficient to rebut that of the challenger[.]" *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1360 (Fed. Cir. 2007) (explaining that "the presumption of validity remains intact and the ultimate burden of proving invalidity remains with the challenger throughout the litigation," and further that the "trial court has the responsibility to determine whether the challenger has met its burden by clear and convincing evidence by considering the totality of the evidence, including any rebuttal evidence presented by the patentee.") (internal quotation marks omitted).

A patent is rendered invalid for being obvious if "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. "Obviousness is a question of law based on underlying factual findings: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective considerations of nonobviousness." *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068 (Fed. Cir. 2012). These four factors are referred to as the "*Graham* factors" after *Graham v. John Deere Co.*, 383 U.S. 1, 17-

18 (1966). *E.g.*, *ABT Sys., LLC v. Emerson Elec. Co.*, 797 F.3d 1350, 1357 (Fed. Cir. 2015).

Additionally, to establish obviousness, there must be evidence of a motive to combine as well as a reasonable expectation of success in doing so:

> Generally, a party seeking to invalidate a patent as obvious must demonstrate by clear and convincing evidence that a skilled artisan would have had reason to combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so.

In re Cyclobenzaprine, 676 F.3d at 1068-69 (internal quotation marks omitted). The burden also includes showing that the skilled artisan would have chosen the particular references asserted in support of the obviousness argument. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1337 (Fed. Cir. 2016). As with the four *Graham* factors, whether there is a reason or motive to combine prior art references is a question of fact. *In re Van Os*, 844 F.3d 1359, 1360 (Fed. Cir. 2017).

In 2007, the Supreme Court rejected a "rigid approach" of the CAFC's "teaching, suggestion, or motivation" (TSM) test. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 415, 419 (2007). Before *KSR*, the court required

> that a patent challenger show that a person of ordinary skill in the art would have had motivation to combine the prior art references and would have had a reasonable expectation of success in doing so [and] that the reason, suggestion, or motivation to combine may be found explicitly or implicitly: 1) in the prior art references themselves; 2) in the knowledge of those of ordinary skill in the art that certain references, or disclosures in those references, are of special interest or importance in the field; or 3) from the nature of the problem to be solved.

Wyers v. Master Lock Co., 616 F.3d 1231, 1238 (Fed. Cir. 2010) (citations and internal quotation marks omitted). But, *post-KSR*, the CAFC, and thus, district courts analyzing obviousness, must take a more "expansive and flexible approach" in determining whether a patented invention was obvious at the time it was made. *Id.*

Additionally, *KSR* reiterated the Supreme Court's previous caution in granting patents on inventions which are combinations of prior art elements:

> For over half a century, the Court has held that a patent for a combination which only unites old elements with no change in their respective functions obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men. This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

KSR, 550 U.S. at 415-16 (citation, internal quotation marks, and ellipsis omitted). The Court further explained:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. . . . [A] court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

Id. at 417.

It is clear that post-*KSR*, "common sense" plays a role in the obviousness analysis. But, the CAFC has made equally clear that "the mere recitation of the words 'common sense' without any support adds nothing to the obviousness equation." *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1377 (Fed. Cir. 2012). The *KSR* Court itself acknowledged that even through the lens of "common sense," it is still important to identify a reason that prompted the inventor to combine references. *KSR*, 550 U.S. 418-19. The Court explained:

> Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have

> prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Id.

Recent CAFC cases confirm that evidence of a motivation to combine is part of the obviousness inquiry. *E.g.*, *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1366 (Fed. Cir. 2017) ("In determining whether there would have been a motivation to combine prior art references to arrive at the claimed invention, it is insufficient to simply conclude the combination would have been obvious without identifying any reason why a person of skill in the art would have made the combination"). Nonetheless, according to *KSR,* in "determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103." *KSR*, 550 U.S. at 419.

Finally, obviousness may not be based on hindsight. The statute requires that obviousness be assessed at the time the invention was made. 35 U.S.C. § 103 (requiring that the obviousness determination be made as of the time of the invention's effective filing date); *see also KSR*, 550 U.S. at 421 (warning against "the distortion caused by hindsight bias" and advising caution in the face of "arguments reliant upon *ex post* reasoning"); *Senju Pharm. Co.*, 780 F.3d at 1356 ("Obviousness is a matter of foresight, not hindsight.").

II. *Graham Factors* - Underlying Factual Findings

A. Scope & Content of the Prior Art

Defendant relies on several pieces of prior art in support of its obviousness argument: (1)

the Simulaids Arterial Blood Action Simulator (SABAS) Device; (2) the Simulaids Humerus - Compound Fracture (SH-CF) Device; (3) two patents by Niiranen; (4) the Zelenak Patent; and (5) the Sirhan Patent. Other than an argument directed at the SABAS Device and noted later in this Opinion, Plaintiff does not contest that all of the asserted prior references are either patents or devices which existed or were on the market before the relevant application date of the '852 Patent.[3]

A prior art reference is analogous and thus available to be used in an obviousness argument "if it is from the same field of endeavor, regardless of the problem addressed or is reasonably pertinent to the particular problem with which the inventor is involved, even if it is not within the inventor's field of endeavor." *Tinnus Enters., LLC v. Telebrands Corp.*, 846 F.3d 1190, 1207 (Fed. Cir. 2017) (internal quotation marks omitted); *see also In re GPAC Inc.*, 57 F.3d 1573, 1577-78 (Fed. Cir. 1995) ("prior art relevant to an obviousness determination necessarily encompasses not only the field of the inventor's endeavor but also any analogous arts."). A "reference is reasonably pertinent if it, as a result of its subject matter, logically would have commended itself to an inventor's attention in considering his problem." *K-TEC, Inc. v. Vita-Mix Corp.*, 696 F.3d 1364, 1371 (Fed. Cir. 2012) (internal quotation marks omitted). The scope of prior art is construed broadly. *Wyers*, 616 F.3d at 1238.

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[3] Defendant asserts that the earliest application in which the limitations of Claims 18, 19, and 20 of the '852 Patent are fully supported is Provisional Patent Application 60/822,888, filed on August 18, 2006. Def.'s Am. Mot. for Sum. J. 24, ECF 227; *see also* Eastman Oct. 2, 2017 Decl., Ex. 8, ECF 211-8 (copy of provisional patent application). Although Plaintiff has contended that the correct invention and priority dates are earlier, for purposes of these summary judgment motions, Plaintiff does not appear to dispute that all references (other than the SABAS Device), are "prior" to Plaintiff's asserted invention/priority date.

1. Simulaids Products - SABAS and SH-CF Devices

Both of these products are made by Simulaids, a manufacturer of simulation training aids for healthcare and rescue workers. Guentzler Jan. 2015 Supp'l Inv. Rep. ¶ 16, ECF 210-3. The SABAS Device has a pump, a reservoir, several moulages, a power supply, a five-gallon rigid reservoir for simulated blood, multiple supply lines, one by-pass return line, and one main blood supply line. Eastman Oct. 2, 2017 Decl., Ex. 27, ECF 213-7 (Instructor's Guide); *see also id.*, Ex. 28 at 9, ECF 213-8 (photo of device); *id.*, Ex. 29 at 8, ECF 213-9 (photo of device). Plaintiff does not dispute that the SABAS Device is within the same field of endeavor as the '852 Patent which is teaching aids/simulation devices for hemorrhage control or trauma training devices. As a matter of law, it is analogous prior art.[4]

The SH-CF Device includes a collapsible reservoir, a hand pump, a moulage, a main supply line connecting the collapsible reservoir with the hand pump, a blood supply line connecting the hand pump to the moulage, and a manual valve attached to the exterior of the main supply line. Guentzler Jan. 2015 Supp'l Inv. Rep. ¶¶ 45, 46, ECF 210-3; *Id.*, Ex. 3 at 43, ECF 210-3 at 43 (photo of SH-CF Device).

Defendant argues that like the SABAS device, the SH-CF Device is in the same field of endeavor as the '852 Patent, meaning teaching aids for injury, hemorrhage, or trauma simulation. Further, Defendant argues that the SH-CF Device is reasonably pertinent to the particular problem the '852 Patent was intended to solve, meaning a realistic bleeding simulation that allows for hands-on practice. Plaintiff contends that the SH-CF Device is non-analogous prior

[4] As a result of my conclusion on literal infringement, the fact that the SABAS Device uses a positive displacement pump with internal valves is no longer relevant to a determination of its status as prior art for purposes of the obviousness analysis.

art because it is only a "wound simulator."

As one of the four *Graham* factors, the scope of the prior art is a fact question for the jury. Construing the evidence in Defendant's favor, the SH-CF Device is analogous prior art because it is a teaching aid for the treatment of bleeding wounds and is intended to provide a realistic simulation of pulsing blood. The realistic wound, supplied by fake blood, activated by a hand pump, and which is worn by human subjects, all combine to make this device in the same field of endeavor - trauma training.

Even construing the evidence in Plaintiff's favor, a jury could not reach the opposite conclusion. Describing this device as being in the field of "wound simulators" is a general observation, and more importantly, it does not remove the SH-CF Device from being either in the same field of endeavor of trauma training devices or at least reasonably pertinent to the problem to be solved. The SH-CF Device allows for hands-on practice of treating a bleeding wound, appears to be non-fragile in the sense that it does not use software, does not appear to require pre-programming, and given its simplicity, is undoubtedly cost-effective. Plaintiff fails to create a material issue of fact as to the SH-CF Device. As a matter of law, it is analogous prior art.

2. The Niiranen Patents

Two patents were issued to John V. Niiranen in 1959 and 1960. The first, United States Patent No. 2,871,579 ("the '579 Niiranen Patent No. 1"), is entitled "Surgical Body-Member Simulacrum For Teaching First Aid." Brunette Oct. 2, 2017 Decl., Ex. 8, ECF 224-8. The second, U.S. Patent No. 2,945,304 ("the '304 Niiranen Patent No. 2"), is entitled "Periosomatic Training Devices." *Id.*, Ex. 7, ECF 224-7.

Defendant contends that both Niiranen patents are within the same field of endeavor as

the '852 Patent and reasonably pertinent to the particular problem the '852 Patent was intended to solve because both patents disclose a teaching-aid device designed to provide realistic simulation of wounds. *See* '579 Niiranen Patent No. 1, 1:19-28, ECF 224-8 ("The present invention relates to a surgical body-member simulacrum for teaching first aid and more particularly to an artificial body-member, such as an abdomen or the like with simulated layers of skin, adipose tissue, and blood vessels arranged in combination with a motor for simulating 'arterial' and 'venous' pressure and pulse-beat, and a reservoir for simulated blood, for training advanced first aid students, doctors, nurses, and medical technicians in the various wound closure and blood vessel clamping techniques"); '304 Niiranen Patent No. 2, 1:19-22, ECF 224-7 ("This invention relates to a training means for simulating early emergency casualty care and particularly to moulages which are fitted around the 'patient' to provide realistic simulation of wounds.").

Plaintiff does not contest that both Niiranen patents are in the same field of endeavor as the '852 Patent. As a matter of law, they are analogous prior art references.

3. The Zelenak Patent

A patent obtained by John Zelenak in 1997, United States Patent No. 5, 645, 404 ("the Zelenak Patent"), discloses a "Personal Fluid Dispensing Device." Oct. 2, 2017 Brunette Decl., Ex. 6, ECF 224-6. It contains a fluid reservoir, a delivery tube, an electronic pump, a power supply, and an actuating device. *Id.* at 1 (abstract description). The invention "relates generally to personal fluid dispensing devices, and more particularly to an electrically powered hand-portable dispensing device for potable beverages." *Id.*, 1:5-7. The drawings indicate that it is

worn as a backpack, similar to what many people refer to as a camelback.[5]

Defendant asserts that the Zelenak Patent is acceptable prior art because Plaintiff disclosed it in the '852 Patent prosecution. '852 Patent at 2. However, the relevant federal regulation indicates that a patent applicant's citation of a reference during prosecution is not an admission that the reference is prior art. 37 C.F.R. § 1.97(h) ("The filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability[.]"). Thus, such disclosure of the Zelenak Patent does not conclusively establish it as analogous prior art in an obviousness inquiry.

The question remains, however, whether the Zelenak Patent is either in the same field of endeavor as the '852 Patent or reasonably pertinent to the problem to be solved. Plaintiff argues that the personal fluid dispensing device in the Zelenak Patent is not in the same field of endeavor as a trauma training or wound simulation system. According to Plaintiff, trauma training and the replenishment of personal bodily fluids are completely different fields of endeavor. I agree with Plaintiff that no reasonable juror could conclude that the Zelenak Patent and the '852 Patent are devices within the same field of endeavor.

But, analogous prior art includes prior art that is reasonably pertinent to the problem to be solved. The '852 Patent was trying to overcome problems of previous hemorrhage training methods which were not dynamic or realistic enough because they were either too limited in scope of training (such as CPR mannequins), too complex for mass training with attendant problems of being too costly and fragile for use in the field, or too restricted in the type of wound

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[5] "Camelbak" is a particular brand but the term "camelback" is often used as a generic reference to a hydration backpack.

they could simulate (such as humans with cards). '852 Patent 1:19-67 - 2:1-5; *see also* Pl.'s Opp. 35-36, ECF 233 (describing problems limiting realism of prior art devices including that they were too delicate, too expensive, and "too tethered (mobility, and hence realism, limited by cords or cables attached to training device") (citing ECF 129-7 at 6 (FEBSS ad), 17 (U.S. Army publication))). Even though Lynn King, the '852 Patent's inventor, knew about the Zelenak Patent and disclosed it, Plaintiff argues that the Zelenak Patent would not have logically commended itself to the inventor's attention in considering the problem he was addressing. Stevick states that individuals in the field of emergency medical and critical care training, and in particular hemorrhage control simulations and training, would not have thought of beverage dispensers as potential components of a realistic and robust hemorrhage simulation tool. Stevick Aug. 15, 2017 Supp'l Reb. Inv. Rep. 18, ECF 224-5.

KSR indicates that relevant prior art is *not* limited to prior art designed to solve the same problem as the claimed invention. "Common sense teaches . . . that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *KSR*, 550 U.S. at 420 ("The second error of the Court of Appeals lay in its assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem"); *Wyers*, 616 F.3d at 1238 (noting that *KSR* directs that the scope of analogous prior art must be construed broadly and quoting *KSR* in regard to familiar items having obvious uses beyond their prior purposes). Thus, the fact that the Zelenak Patent is not designed as a trauma training device is not conclusive as to whether it is analogous prior art.

There are reasonable competing inferences that the Zelenak Patent is reasonably pertinent

to the problems confronting King, who cited it in his patent application. Because the Zelenak Patent discloses a portable, lightweight system easily worn by a person as a backpack and which mechanically pumps fluid from a collapsible reservoir into a tube and then out of a nozzle, it could be reasonably concluded that it would have logically commended itself to King's attention in attempting to create a more dynamic and realistic trauma training device. On the other hand, given that it has no relation to wound simulation or hemorrhage control, a jury could reasonably conclude that it is not reasonably pertinent to the problems King was attempting to solve. This issue is to be resolved by a jury.

4. The Sirhan Patent

In 1990, Eddie Sirhan obtained a patent for a "Glove Amusement Device," United States Patent No. 4, 903, 864 ("the Sirhan Patent"). Brunette Oct. 2, 2017 Decl., Ex. 11, ECF 224-11. It squirts liquid. *Id.* at 1. It has a liquid storage apparatus which includes a pump and an activation mechanism, a glove, and an umbilical cord connecting the two. *Id.* The field of the invention "relates to amusement devices and more particularly to amusements [sic] devices for squirting liquids." *Id.*, 1:5-8.

Plaintiff argues that the Sirhan Patent is not analogous prior art because it is of a completely different field of endeavor and would not have logically commended itself to the attention of King, who was concerned with solving problems in realistic trauma training. Stevick states that individuals working in the field of emergency and critical casualty care training and in particular hemorrhage control simulations and training, would not have thought of novelty squirt gun toys as potential components of a realistic and robust hemorrhage simulation tool to train medical personnel, first responders, or combat medics to deal with life-threatening injuries.

Stevick Aug. 15, 2017 Supp'l Reb. Inv. Rep. 14, ECF 224-5.

The Sirhan Patent, like the Zelenak Patent, is not in the same field of endeavor as the '852 Patent. But, in contrast to the Zelenak Patent, I agree with Plaintiff that as a matter of law, no reasonable juror could determine that the Sirhan Patent is reasonably pertinent to the problems King was solving to solve. The Sirhan Patent does have some features which overlap with the Zelenak Patent, including a storage container for liquid, a pump, an activation trigger, and a tube connecting the liquid to a dispensing hole. But, the storage container is not disclosed as being collapsible, the patent does not disclose a nozzle capable of dispensing fluid but only a pinhole designed to squirt fluid, and use of the device may require a belt to which the liquid container is attached as well as velcro straps attached to the tube so the user can strap the tube to his or her clothes to prevent the tube from becoming an obstacle during water competition. *See* Sirhan Patent 3:44-45 (container preferably made of high impact plastic); 3:64-65 ("container **24** is made from hard, high impact plastic"); 3:65-68 (liquid container unlikely to cause injury to user or water competition participant because it is attached to the user's belt); 4:22 (end cap has a pin hole opening); 4:35-39 (use of velcro straps); 5:11-12 (claim element claiming a glove opening "for squirting liquid"); 5:46-51 (claim element claiming tube with an end cap having a pin hole opening); 6:20-13 (claim element claiming container made from hard, high impact plastic). All of these elements combine to create a distinct device, limited in scope, which would not have commended itself to the problems King was trying to solve.

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B. Differences Between the Claimed Invention & the Prior Art

1. The Simulaids Products

a. The SABAS Device

As described in a 1980 publication by the United States Army, the SABAS Device, which has the same components as the '852 Patent except for a collapsible reservoir, functions as follows:

> Principal components of the device are the six plastic moulages of a wounded forearm which is bleeding from the artery. Each of these moulages is life-size and realistically colored. They may be placed on foam rubber in trays, which are provided, or strapped onto dummies or human "subjects" during the first-aid training. The six moulages may be operated separately or simultaneously.
>
> Simulated blood, mixed from a powder provided with the device, is stored in the 5-gallon reservoir provided. Manifold valves control the blood flow to the desired moulage(s) so that it flows into the moulage and out of the wound, as it would on a wounded person.
>
> Control of the simulated blood is accomplished by means of a pump and power-supply unit, six blood supply lines, a bypass return line, and a main blood-supply line.

Eastman Oct. 2, 2017 Decl., Ex. 28 at 9, ECF 213-8.

The photos of the SABAS Device show that it is a considerably larger device than the "Field Expedient Bleeding Simulation System" (FEBSS) product Plaintiff makes and markets as the patented invention. *Compare id.*, ECF 213-8 (photo of SABAS Device) *and id.*, Ex. 29 at 8, ECF 213-9 (photo of SABAS Device), *with* King Aug. 14, 2015 Decl. ¶¶ 6-9, ECF 99 (description of the invention with accompanying photo of Plaintiff's Hydrasim or FEBSS product), *and* Ex. 7 to Lovett Sept. 4, 2015 Decl., ECF 129-7 at 6 (photo of FEBSS in advertisement).

Plaintiff argues that the size difference between the SABAS Device and the patented

invention renders the SABAS Device irrelevant as prior art. Plaintiff contends that given the size of the SABAS Device, it is not portable, distinguishing it from the '852 Patent invention. *See* Stevick July 25, 2015 Dep. 231-47, ECF 219-2 (stating that a device that is "luggable" can be moved but is not designed for movement whereas the configuration of the '852 Patent is very portable).

Although the difference in size is notable, the components and overall function of the SABAS Device are strikingly similar to the components and practice of the '852 Patent. Thus, the size discrepancy is essentially a relevance question with an impact on the motivation inquiry. The weight to be given to the SABAS Device in that determination is an issue for the factfinder.

b The SH-CF Device

The SH-CF Device has similar components to those claimed in the '852 Patent in that it has a collapsible reservoir, a valve, and a conduit connecting the reservoir to a wound site. It uses a hand pump, however, and lacks a controller.

2. The Niiranen Patents

Plaintiff argues that there are significant differences between the Niiranen patents and the '852 Patent claimed invention, including that the Niiranen patents, like the SABAS Device, have a rigid supply tank. Defendant contends that the Niiranen patents disclose a collapsible reservoir.

a. The '579 Niiranen Patent No. 1.

The '579 Niiranen Patent No. 1 has "four major portions": the body-member simulacrum, the motor-driven pump system for producing both simulated "arterial" and "venous" pressure, the supply tank or reservoir for simulated blood, and a supporting base and housing. '579 Niiranen Patent No. 1, 2:35-39, ECF 224-8. The drawings and description show all components contained

in a single structure, but with distinct components of the supply tank, the simulacrum, hoses, and the motor assembly. *Id.*, Figs. 1-3. In the drawings, the simulacrum is made to resemble an abdomen such that one would practice wound closing directly on that component while it is housed in the structure with the simulated blood flowing. *Id.*

As for the supply tank, the '579 Niiranen Patent No. 1 discloses a "closed unit with a removable air-tight opening" which Defendant argues discloses a collapsible reservoir. Def.'s Am. Mot. for Sum. J. 42, ECF 227.[6] In support, Defendant cites to Exhibit 3 of Guentzler's August 1, 2017 Third Supplemental Expert Report re: Invalidity. Def.'s Am. Mot. for Sum. J., ECF 227. Exhibit 3 is a Claim Chart in which Guentzler asserts that the '579 Niiranen Patent No. 1 has a collapsible reservoir because the disclosed supply tank is a closed unit with removable air-tight opening. Guentzler Aug. 1, 2017 Supp'l Inv. Rep., Ex. 3, ECF 210-7 at 36.

In opposing Plaintiff's motion, Defendant more clearly states that "[b]ecause the reservoir described in the Niiranen Patent No. 1 has an 'air-tight opening,' the reservoir must necessarily flex or fold as the volume of the container of fluid is drawn out." Def.'s Opp. 24, ECF 234. For support, Defendant cites to Exhibit 6 to Guentzler's January 2015 Invalidity Report which is a Claim Chart that states that the '304 Niiranen Patent No. 2, not the '579 Niiranen Patent No. 1, satisfies the "collapsible reservoir" element of Claim 18 of the '852 Patent because it "[i]ncorporates by reference a description of an air tight supply tank." Guentzler Jan. 2015 Supp'l Inv. Rep., Ex. 6, ECF 210-3 at 49.

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[6] Plaintiff notes that in the prior round of summary judgment motions in 2015, Defendant and its expert admitted that the Niiranen patents lacked a collapsible reservoir. Pl.'s Opp. 23-24, ECF 233; *see* Guentzler July 21, 2015 Dep. 182:5-193:1, 185:18-20, ECF 97-6 (testifying that the Niiranen patents disclosed a rigid tank and neither disclosed a collapsible reservoir).

The '579 Niiranen Patent No. 1 discloses that the "supply tank **12** is a closed unit with a removable air-tight opening **45** for replenishing the colored synthetic blood." '579 Niiranen Patent No. 1, 3:24-26. Earlier, the patent states that the "tank **12** may be supplied with a continual steady air pressure, through inlet **31** by means of conduit **32** from a small air compressor **33** driven by electric motor." *Id.*, 3:3-6. The drawings show the supply tank as a rigid box.

While the claims themselves in the '579 Niiranen Patent No. 1 do not expressly recite a rigid storage tank or alternatively, a collapsible reservoir, each one of them discloses that the liquid in the tank is pressurized, thereby forcing the liquid out of the tank for use in the simulation. '579 Niiranen Patent No. 1, 4:14-75 (claiming a pressurized tank in each of five separate claims). With these disclosures, no reasonable juror could accept Defendant's argument that the disclosure of the tank being "air tight" necessitates the disclosure of a collapsible reservoir when each claim in the '579 Niiranen Patent No. 1 recites a pressurized system for storage of the liquid. That is, Defendant's argument that the recitation of "air tight" necessarily discloses a collapsible reservoir is untenable in the presence of a pressurized system. The '579 Niiranen Patent No. 1 does not teach a collapsible reservoir in the context of the pressurized system disclosed by the claims of that patent.

b. The '304 Niiranen Patent No. 2

Defendant makes the same assertion as to the '304 Niiranen Patent No. 2, contending that its "closed unit with a removable air-tight opening" discloses a collapsible reservoir. Def's Am. Mot. for Sum. J. 42, ECF 227. The '304 Niiranen Patent No. 2 is addressed to "a training means for simulating early emergency casualty care" and particularly to "moulages which are fitted

around the 'patient' to provide realistic simulation of wounds." '304 Niiranen Patent No. 2, 1:19-22, ECF 224-7; *see also id.*, 2:40, 2:45-46 (describing moulages "adapted to be fitted on a volunteer" which are "connected by rubber tubing to a central fluid supply."). The claims themselves are primarily directed to the moulages, providing only for "a supply of simulated blood" without further elaboration. *Id.*, 6:21-47.

The patent description, however, makes clear that the supply tank disclosed in the '579 Niiranen Patent No. 1 is to be used in the '304 Niiranen Patent No. 2. The '304 Niiranen Patent No. 2 states that the "fluid supply system contains a fluid storage tank **12** which is adapted to store venous and arterial blood flow." *Id.*, 2:46-48. Figure 1 shows what appears to be a box as the tank. Later, the '304 Niiranen Patent No. 2 refers to the '579 Niiranen Patent No. 1 when it states that the "simulated blood supply unit has been more fully described in the co-pending application, Serial No. 588,584 and will not be further described here." *Id.*, 3:2-5. It also states that "CO_2 supply and solenoid have been substituted for the air compressor in order to make the pressure producing means portable." *Id.*, 3:5-9.

As with the '579 Niiranen Patent No. 1, the '304 Niiranen Patent No. 2 discloses a pressurized tank system. Accordingly, Defendant's contention that the recitation of an air-tight supply tank necessarily discloses a collapsible reservoir is without support in the '304 Niiranen Patent No. 2. No reasonable juror could conclude otherwise.

3. The Zelenak Patent

Plaintiff contends that in contrast to the '852 Patent, the Zelenak patented device lacks both a wound site and a valve connected to a controller. Plaintiff also argues that it is not a "trauma training system." As to the valve, Plaintiff argues that Defendant provides no evidence

that one exists in the device. There is no dispute that it has a pump, but Stevick states that there is no evidence that the pump used in that device has an internal valve. Stevick Aug. 15, 2017 Supp'l Reb. Inv. Rep. 17-18, ECF 224-5. Guentzler, however, explains that consistent with Plaintiff's infringement contentions, if the pump of the Zelenak device includes internal valves, then the device has a valve in fluid communication with the pump. Guentzler Aug. 1, 2017 Supp'l Inv. Rep., Ex. 3, ECF 210-7 at 36. Plaintiff is correct that there is no affirmative evidence of the existence of a valve. However, the disclosure of a pump creates a reasonable inference that the pump possesses an internal valve. Thus, there is an issue of fact as to this component.

During claim construction I construed "wound site," as used in Claim 18, to mean "a simulated injury having an opening through which fluid can flow to simulate a hemorrhage." 154 F. Supp. 3d at 1102. The parties' experts offer contradictory opinions as to whether the nozzle in the Zelenak device satisfies the claim limitation of "wound site." Guentzler Aug. 1, 2017 Supp'l Inv. Rep., Ex. 3, ECF 210-7 at 37-38 (stating that the valve or nozzle is "used to direct a flow fluid, which when inserted into a mouth may simulate a bleeding mouth"); Stevick Aug. 15, 2017 Supp'l Reb. Inv. Rep. 17, ECF 224-5 (the drinking nozzle of the Zelenak personal hydration system is not a wound site because the nozzle is not a simulated injury and does not simulate hemorrhaging).

I agree with Plaintiff that no reasonable juror could conclude that the nozzle used in the Zelenak device is a "wound site" as defined. It simply lacks a simulated injury. Claim 18 of the '852 Patent discloses a separate wound site element which means that Claim 18 includes a component specifically designed to look like an injury. The Zelenak device nozzle is not such a component.

Plaintiff also argues that the Zelenak device is not a "trauma training system" as required by the preamble to Claim 18. Claim 18 recites that it is a "trauma training system for replicating at least one hemorrhage, said system comprising: [reciting elements]." '852 Patent, 14:3-4. Plaintiff notes that the '852 Patent consistently describes the invention not as a mere collection of components such as a pump, valve, and controller, but as a trauma training system. It is the title of the '852 Patent. It is noted in the abstract to be a "system for simulating one or more hemorrhages." '852 Patent at 1. The preamble to two of the three independent claims discloses that it is a "trauma training system for replicating at least one hemorrhage[.]" '852 Patent, 11:43-44 (Claim 1), 14:3-4 (Claim 18). All dependent claims also disclose a "trauma training system." *Id.*, 11:54, 58, 65, 12:1, 4, 16, 19, 31, 39, 41, 44, 54, 65, 13:1, 4, 14:15, 22. Plaintiff argues that nothing in the Zelenak Patent teaches use of its beverage-supplying personal hydration system as a trauma training system, and no reasonable factfinder could find otherwise.

Defendant argues that the preamble language is not limiting. Defendant acknowledges that a preamble can be limiting when it serves as an antecedent basis for limitations in the claim body. *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003) ("When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention. On the other hand, if the body of the claim sets out the complete invention, then the language of the preamble may be superfluous.") (citation, internal quotation marks, and brackets omitted). Defendant argues that Claim 18's preamble provides no antecedent element for the asserted claims. Further, Defendant notes that there is no evidence in the prosecution history where the patent examiner relied on the preamble to limit a claim element. Defendant argues that the preamble provides

only a purpose or an intended use for the device, and thus, cannot be limiting.

Plaintiff argues that the "trauma training system" language in the preamble supplies a fundamental characteristic of the assembled elements and thereby breathes "life, meaning, and vitality" into the claims. *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1357 (Fed. Cir. 2012) (internal quotation marks omitted). Plaintiff contends that the express inclusion of "wound site" in Claim 18 confirms that "trauma training system" is limiting.

Determining whether a preamble is limiting is part of claim construction which is a matter of law for the court. *See Poly-Am., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1309 (Fed. Cir. 2004) (in reviewing jury's determination on obviousness, district court's determination regarding limiting nature of language in preamble was analyzed on appeal as a claim construction issue). The *Poly-America* court explained that

> [w]hether to treat a preamble as a limitation is a determination resolved only on review of the entire patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim. No litmus test defines when a preamble limits claim scope. On the one hand, a preamble is a claim limitation if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim. On the other hand, a preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention. Further, when reciting additional structure or steps underscored as important by the specification, the preamble may operate as a claim limitation.

Id. at 1309-10 (citations, internal quotation marks, brackets, and ellipsis omitted).

In *Poly-America*, the court agreed with the district court that the preamble language was limiting. *Id.* at 1310. The court noted that (1) the specification is "replete with references to the invention as a 'blown-film' liner, including the title of the patent itself and the 'Summary of the Invention'"; (2) the phrase was repeatedly used to describe the preferred embodiments; and (3)

the entire preamble "blown-film textured liner" was restated in each of the patent's seven claims. *Id.* The court concluded that the inventor considered the "blown-film" preamble language to represent an important characteristic of the claimed invention. *Id.* Therefore, the court affirmed the district court's conclusion that, when the entire patent was reviewed, the preamble language relating to "'blown-film' does not state a purpose or an intended use of the invention, but rather discloses a fundamental characteristic of the claimed invention that is properly construed as a limitation of the claim itself." *Id.*

In addition to *Poly-America*, other cases cited by Plaintiff support a conclusion that "trauma training system" is limiting, even if it was not used in the patent's prosecution. In *Deere & Co.*, the patent at issue disclosed an "easy clean dual wall deck" for a rotary cutter pulled behind a tractor to cut or mow large swaths of ground. 703 F.3d at 1352. The court considered whether the recitation of "rotary cutter deck" in the preamble was limiting and concluded it was. *Id.* at 1357-58. The court explained that the "recitation of a 'rotary cutter deck' in Claim 1 is necessary to understand the subject matter encompassed by the claim, which otherwise generally recites deck walls that 'define a box section having torsional stiffness.'" 703 F.3d at 1358. The court found that the term did not merely state a name or use for the claimed box section but described a "characteristic of the claimed invention that informs one of skill in the art as to the structure required by the claim." *Id.* (internal quotation marks omitted). As a specific example, it explained that the limiting effect of the preamble phrase was found because "rotary cutter deck" informed the meaning of the "torsional stiffness" limitation. *Id.* That is, the claimed structure had to possess sufficient stiffness to withstand the torsional loads imposed by the operation of a rotary cutter. *Id.*

Similarly, in a 2013 unpublished case, the CAFC considered claims related to a patent directed to infant socks with "gripper" surfaces that provided traction for crawling and walking. *Piggy Pushers, LLC v. Skidders Footwear, Inc.*, 544 F. App'x 984, 988-89 (Fed. Cir. 2013). There, the district court found that the preamble limited the claims. The CAFC affirmed, concluding that "[t]he requirement that the combined elements form a 'sock' is a fundamental characteristic of the claimed invention." *Id.* at 989 (internal quotation marks omitted). The court noted that the specification "uniformly describe[d] what results from combining the sock member with the gripper member as itself remaining a sock." *Id.* It further noted that the specification distinguished a sock from a shoe, which could be undesirable or difficult to put on an infant, and thus, the addition of the gripper could not transform the sock into a shoe. *Id.*

In *Piggy Pushers*, *Poly America*, and *Deere & Co.*, the court found preamble language limiting even though there was no evidence that the patentee relied on the preamble in the patent prosecution. Thus, that factor is not determinative. Similar to the torsional stiffness element in *Deere & Co.*, the presence of the "wound site" element in Claim 18 is informed by the preamble limitation of "trauma training system." The "wound site" limitation in Claim 18, even with the claim construction definition of "a simulated injury having an opening through which fluid can flow to simulate a hemorrhage" has little or no context without the presence of "trauma training system." Thus, the preamble is essential to understanding the term in the claim body. Further, as in *Poly America*, "trauma training system" is the title of the '852 Patent and is recited in the preamble to every claim but one. The background of the invention establishes that the invention was conceived as a response to needs for a more dynamic and realistic trauma training system. Three of the four exemplary embodiments describe the invention as a trauma training system.

'852 Patent, 2:9-36. The fourth discloses its use for a "simulation." *Id.*, 2:34-36. The specification thus shows the importance of the additional "structure" recited in the "trauma training system" preamble language. I agree with Plaintiff that the preamble language "trauma training system" is limiting because it provides a "fundamental characteristic" of the assembled elements and thereby "breathes life, meaning, and vitality" into the claims.

In summary in regard to the Zelenak Patent's comparison to Claim 18 of the '852 Patent, the Zelenak device has a storage reservoir (preferably collapsible), an activation mechanism, and a pump which moves liquid from the storage reservoir through a tube to the nozzle to be dispensed. There is a fact issue as to whether it has an internal valve located within the pump. It does not have a wound site. It is not a trauma training system.

C. Person of Ordinary Skill in the Art (POSA)

As stated in the statute, the obviousness determination is adjudged through the lens of a "person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. As with the other *Graham* factors, the level of skill in the art is a factual determination. *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007) (citing *Graham*, 383 U.S. at 17). "The person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art." *In re GPAC Inc.*, 57 F.3d at 1579. "In determining this skill level, the court may consider various factors including" (1) the types of problems encountered in the art; (2) prior art solutions to those problems; (3) rapidity with which innovations are made; (4) sophistication of the technology; and (5) educational level of active workers in the field. *Id.* "In a given case, every factor may not be present, and one or more factors may predominate." *Id.*

The parties dispute the level of ordinary skill in the art. Defendant contends that a POSA

at the relevant time was "a person having familiarity with the appearance and treatment of trauma conditions, and a basic understanding of electrical and mechanical systems." Guentzler Jan. 2015 Supp'l Inv. Rep. ¶ 34, ECF 210-3. In forming this opinion, Guentzler notes the experience of "active workers" in the field by stating that Niiranen was a Navy physician who was known in his era as a pioneer in the field of realistic trauma training and related products and was an innovator in the field for the United States military and that King was an Army medic. *Id.* ¶¶ 29, 31. He also relies on what he considers the lack of sophisticated technology of the '852 Patent. *Id.* ¶ 34 (stating that the technology claimed in the '852 Patent is "basic, rudimentary technology already in existence as evidenced by the '304 Niiranen Patent and the Simulaids bleeding injury simulations products.").

Stevick opines that the appropriate POSA in this case is a person possessing at least an emergency medical technician (EMT) certificate and high school degree (or similar educational background) and with a year of hands on experience in EMT training or similar work history. Stevick Dec. 19, 2014 Infring. Rep.¶ 41, ECF 98-3. Stevick explains that he formed his opinion by considering factors such as the educational level and years of experience not only of the person who developed the products that are the subject of the '852 Patent but also of others working in the field of training front-line medical personnel and other first responders, the types of problems encountered in the art and publications of other persons or companies, and the sophistication of the technology. *Id.* ¶ 39, ECF 98-3. He states that the "art" at issue here, as implicated by the '852 Patent, is equipment and techniques for training front-line medical personnel and other first responders. *Id.* ¶ 40. Given that, he opines that a POSA would be "an individual possessing at least an emergency medical technician (EMT) certificate and a high

school degree (or similar educational background) and with a year of hands-on experience in EMT training or a similar work history." *Id.* ¶ 41.

Under Federal Rule of Evidence 702, Plaintiff seeks to strike certain portions of Guentzler's testimony, including his opinions related to the level of skill in the art. Specifically, Plaintiff seeks to strike all portions of Guentzler's reports "in which Dr. Guentzler purports to assert what a person of ordinary skill in the art of trauma training would know, think, or understand." Pl.'s Opp. 45, ECF 233; *see also* Pl.'s Reply 38-39, ECF 238 (seeking to strike Guentzler's testimony that "consists of speculation by extending beyond his area of relevant technical expertise, including his speculation as to what would have been known, understood, or thought by a person of ordinary skill in the field of trauma training[.]").

The basis for Plaintiff's objection is that Guentzler admittedly is not an expert in trauma training devices. *E.g.*, Guentzler July 21, 2015 Dep. 56, ECF 235-2 (testifying that he had no expertise in trauma training). Plaintiff contends that because Guentzler is not an expert in the pertinent art, he may not testify as to what a POSA would know, think, or understand. As a result, Plaintiff objects to more than two dozen paragraphs scattered throughout Guentzler's various expert reports on infringement and invalidity. Pl.'s Opp. 48, ECF 233. Included in those objections are certain statements and opinions contained in Guentzler's January 2015 Supplemental Invalidity Report pertaining to the level of ordinary skill in the art. *Id.*[7]

[7] The challenged testimony includes Guentzler's opinion as to the proper POSA even though the argument is directed to testimony regarding what the proper POSA would know or understand. The argument does not appear to include Guentzler's underlying opinion as to who the proper POSA is in the first place. Nonetheless, because Guentzler's opinion regarding the proper POSA is included in the challenged paragraphs, I address the argument.

(challenging ¶¶ 28-34 of Guentzler's Jan. 2015 Supp'l Inv. Report).[8]

The CAFC has explained that

> it is an abuse of discretion to permit a witness to testify as an expert on the issues of noninfringement or invalidity unless that witness is qualified as an expert in the pertinent art. Testimony proffered by a witness lacking the relevant technical expertise fails the standard of admissibility under Fed. R. Evid. 702. Indeed, where an issue calls for consideration of evidence from the perspective of one of ordinary skill in the art, it is contradictory to Rule 702 to allow a witness to testify on the issue who is not qualified as a technical expert in that art.

Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1363 (Fed. Cir. 2008). In *Sundance*, the court considered the admissibility of expert testimony by a patent attorney on noninfringement and invalidity, among other issues. The court observed that the defendant, proponent of the testimony, failed to explain how the attorney was an expert in the pertinent art of tarps or covers. *Id.* at 1362. Nor did the defendant establish that the attorney's experience was "sufficiently related" to the pertinent art. *Id.* Thus, he was unqualified to offer expert testimony on the topic of invalidity. *Id.*

Sundance offers two ways an expert may testify on issues of invalidity under Rule 702. First, the witness is qualified if he or she has expertise in the precise pertinent art at issue. Alternatively, the witness's testimony may still be admissible if the expertise possessed by the witness is "sufficiently related" to the pertinent art. *See Sport Dimension, Inc. v. The Coleman Co., Inc.*, No. CV1400438BROMRWX, 2015 WL 12732710, at *5 (C.D. Cal. Jan. 29, 2015) (concluding that under *Sundance*, "an expert need not have an expertise in the specific pertinent art to be qualified as an expert [under Rule 702], but the expert must nevertheless demonstrate

[8] Plaintiff submits a version of this expert report in which the challenged testimony is highlighted in blue. *See* ECF 235-9.

that his or her technical background is sufficiently related to that pertinent art"), *aff'd*, 820 F.3d 1316 (Fed. Cir. 2016). While Guentzler is admittedly not an expert in trauma training, hemorrhage control, or wound simulation systems, his testimony may still be admissible if his knowledge and expertise is sufficiently related to such systems. Plaintiff does not address this issue, focusing instead only on the lack of actual expertise in the pertinent art. Therefore, because Guentzler's industrial technology and engineering education and experience, including experience with pumps and valves, could be sufficiently related to the pertinent art, Plaintiff's motion to strike is denied.[9] *See* Ex. 1 to Def.'s Exp. Designation, ECF 210-1 at 5-24 (Guentzler curriculum vitae).

Defendant argues that a specific finding on the level of ordinary skill in the art is unnecessary in this case because the technology is easily understandable and the prior art provides all that is required for determining the appropriate POSA. *E.g.*, *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163-64 (Fed. Cir. 1985) ("A specific finding on the level of skill in the art is not . . . . required where the prior art itself reflects an appropriate level

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[9] I resolve this motion to strike based only on the summary judgment record and only in the context of resolving the summary judgment motions. I note that although Defendant does not expressly challenge Stevick's opinions under Rule 702, Stevick's background suggests that he is not a trauma training device expert either. While he has some experience with medical devices, none of that experience is related to trauma training systems. Thus, similar to Guentzler, the summary judgment record does not qualify Stevick as a trauma training device expert. *See* Stevick Aug. 15, 2015 Decl. ¶ 1, ECF 98 (reciting that his "areas of technical expertise include the design, performance, and analysis of mechanical, fluid, and dynamic systems common to a wide variety of products and industries, including medical devices, construction, and oil and gas" including "extensive work with the engineering and analysis of medical devices (including arterial stent, heart valve components, pacemaker leads, spinal implants, surgical tools), blood pressure and flow, and pump and valve systems"); *Id.*, Ex. 1 (Stevick curriculum vitae). Whether Stevick's experience is "sufficiently related" to the pertinent art to qualify him as an expert under Rule 702 is not at issue in these motions.

and a need for testimony is not shown.").

Defendant argues that based on the parties' proposed definitions of a POSA, both agree that the scientific and engineering principles applicable to the pertinent art are not difficult and are easily understandable. I agree with Defendant that both parties' proposed POSA definitions suggest that the scientific and engineering principles are not complex. But, even with that consensus, I reject Defendant's argument that no expert testimony is needed on the issue.

Plaintiff's proposed definition focuses on the EMT experience both in terms of having an EMT certificate and having provided EMT training or the equivalent. It includes a basic high school education or equivalent which supports a conclusion that the scientific and engineering principles are not difficult. Defendant's proposed definition includes a person who has "a basic understanding of electrical and mechanical systems." The reference to "basic" suggests that the skill level is not high, but, because the proposal singles out electrical and mechanical systems, it suggests a greater skill level than Plaintiff's proposal which more generally requires a high school or equivalent education without mentioning anything about electrical or mechanical processes. And, in contrast to Plaintiff's proposed definition emphasizing trauma treatment skills, Defendant's proposal requires only that the person have familiarity with the appearance and treatment of trauma conditions. Overall, Plaintiff's proposed POSA has more experience in trauma training than Defendant's proposed POSA and Defendant's proposed POSA has more specific requirements for mechanical and electrical systems knowledge than Plaintiff's proposed POSA.

Defendant suggests that no specific POSA finding is required because "the prior art discloses all of the elements of the asserted claims and teaches how the components work

together to create a training device." Def.'s Am. Reply 29, ECF 240. I disagree. While the prior art informs the finding, the prior art does not resolve the dispute between the parties regarding how much experience in EMT training or in mechanical and electrical knowledge the POSA must have. The prior art references indicate that a POSA is someone with some trauma training experience. The prior art references also indicate a need for a basic understanding of mechanical and electrical systems. But, the prior art references do not dictate the *precise level* of experience in trauma training or the *precise level* of knowledge of the scientific principles. Thus, the dispute between the parties about the proper POSA is material and is unresolved on summary judgment because a reasonable juror examining the evidence in a light most favorable to the non-moving party could credit either party's proposed POSA.

D. Secondary/Objective Considerations of Nonobviousness

Objective considerations of nonobviousness constitute "independent evidence" which "may often be the most probative and cogent evidence of nonobviousness in the record." *Mintz*, 679 F.3d at 1378 (internal quotation marks omitted). The objective criteria "help innoculate the obviousness analysis against hindsight." *Id.* As the *Mintz* court explained:

> These objective criteria thus help turn back the clock and place the claims in the context that led to their invention. Technical advance, like much of human endeavor, often occurs through incremental steps toward greater goals. These marginal advances in retrospect may seem deceptively simple, particularly when retracing the path already blazed by the inventor. For these reasons, this court requires consideration of these objective indicia because they provide objective evidence of how the patented device is viewed in the marketplace, by those directly interested in the product.

Id. (internal quotation marks omitted). Relevant considerations include unexpected results, expert skepticism, copying, commercial success, praise by others, failure by others, and long-felt

need. *Id.* at 1379.

Plaintiff contends that commercial success, industry praise, long-felt need, the failure of others, and copying by others establish nonobviousness, or at least create an issue of fact precluding summary judgment for Defendant on obviousness.

1. Commercial Success

To establish nonobviousness, commercial success must relate to the claimed invention. *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011) ("nexus must exist between the commercial success and the claimed invention"). A "prima facie case of nexus is made when the patentee shows both that there is commercial success, and that the product that is commercially successful is the invention disclosed and claimed in the patent." *Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1310–11 (Fed. Cir. 2010).

Plaintiff relies on sales data for its FEBSS products (basic and deluxe models) to support its commercial success argument. The FEBSS is a commercial embodiment of the '852 Patent. King Aug. 14, 2015 Decl. ¶¶ 6-9, ECF 99. For the period of January 2013 - August 2014, Plaintiff sold 173 "units" for a total price of $424,801.55. Serena Morones Aug. 27, 2015 Decl., ¶18 & Ex. 1 (Morones Exp. Rep.) at Sch. 2, ECF 122 & 122-1. Defendant characterizes these sales figures as minimal given that since January 2013, Plaintiff has sold only 173 units amounting to less than $500,000 in sales revenue. Defendant also notes that there is no evidence of the total sales in the relevant market, rendering the sales data for this product alone not especially probative of commercial success. *See, e.g.*, *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996) ("bare sales numbers" are a "weak showing" of commercial success) (citing *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1026-27 (Fed. Cir. 1983) (sales of five million

units was a minimal showing of commercial success because without additional economic evidence, it is "improper to infer that the reported sales represent a substantial share of any definable market"), *overruled on other grounds*, *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999)).

Plaintiff responds by noting that these sales figures include data for only the first one and one-half years of sales, not the entirety of sales to date. But, the record does not appear to include any updated sales figures. Plaintiff also suggests that its sales figures must be viewed in the context of Defendant's "copying" and infringing sales. Pl.'s Reply 35, ECF 238 (noting Defendant's "nearly immediate copying of the invention, resulting in [Defendant] offering the invention in direct competition with Skedco."); *see also* Bud Calkin Jan. 21, 2016 Decl. ¶ 3, ECF 183 (stating that Plaintiff and Defendant communicated between October 2007 and January 2011 to discuss Plaintiff's supplying its FEBSS product to Defendant but failed to reach agreement). Plaintiff's argument is that having obtained information about its product from Calkin in the process of attempting to negotiate an agreement, Defendant then used that information to unfairly compete against Plaintiff in the marketplace, diminishing Plaintiff's sales figures. While this is essentially a damages argument, I accept for the purposes of the summary judgment motions that Plaintiff's sales figures would have been higher but for Defendant's competition.[10]

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[10] Morones opines that Defendant sold 27 BPS units from January 1, 2013 through August 2014 and an additional 53 BPS units that were components in Defendant's "Cut Suit" product during that same period, for a total of 80 units. Morones Ex. Rep. ¶¶ 13-17 & Ex. 1, Schs. 1b, 1a, ECF 122-1. Assuming that Plaintiff had made those sales, Plaintiff would have seen an additional $155,934 is sales revenue. This figure assumes that 69 basic FEBSS units were sold (based on Morones's opinion that Defendant sold 16 BPS basic units, 11 BPS deluxe units, and sold 53 unidentified BPS units as components in the Cut Suit; without additional evidence, I assume the 53 unidentified units were the basic model for a total of 69 basic units sold). Given that during the period, Plaintiff's FEBSS basic unit sold for $1,664 and its deluxe

Defendant also argues that Plaintiff fails to show that any commercial success it has had is related to the claimed invention. Defendant first contends that Plaintiff has sold its FEBSS as a common hydration backpack, which is no different from the system disclosed in the Zelenak Patent. Thus, Defendant argues, any success from selling the FEBSS is not related to the claimed invention but only to a prior art device. In support, Defendant relies on an advertisement for the FEBSS which asserts that the FEBSS

> recreates active bleeding on real people while doubling as a common hydration backpack. [The FEBSS] can be worn on the outside of the uniform while the simulated drink tube is routed underneath the uniform. The entire system is self contained and allows for independent wireless control of two venous and two arterial bleeds.

Eastman Oct. 23, 2017 Decl., Ex. 4 at 3, ECF 231-4.

This advertisement does not market the system as only a common hydration pack. It markets a device that simulates bleeding but which can be worn like a common hydration backpack. It indicates that the bleeding apparatus is disguised as a common hydration backpack. While commercial success, as one of the secondary considerations, is a factual issue, no reasonable juror would construe the advertisement as one for a common hydration pack.

Defendant still more generally argues that to the extent Plaintiff shows commercial success, such commercial success is attributable only to the non-patented portable and concealable nature of the product. That is, any commercial success is not related to the claimed invention because Claims 18, 19, and 20 do not disclose any limitation regarding size,

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unit sold for $3,738, Plaintiff would have sold $114,816 in basic units and $41,118 in deluxe units had it made the sales Morones claims were made by Defendant. Thus, the total sales figure assumed for the purposes of the summary judgment motions is $580,735.55 based on the sale of 253 units.

concealability, or portability. *See Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006) ("if the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant"); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1377 (Fed. Cir. 2000) (explaining that to counter obviousness, the party must show that "commercial success of the product results from the claimed invention"; indicating that sales related to feature not actually claimed would not meet that standard) (internal quotation marks omitted).

Plaintiff responds that first, the objective evidence identifies that the trauma training system as a whole is commercially desirable, and second, portability is one of the merits of the claimed invention contemplated in the specification which results from practicing the invention as a whole. Thus, Plaintiff contends, commercial success related to sales of the system and which are related to its portability is relevant evidence. Pl.'s Reply 34, ECF 238.

Plaintiff relies on various publications in support of this argument: (1) an article from "Technology for Today," ECF 129-7 at 13-14; (2) a 2008 Defense Department Press Release, ECF 129-7 at 18; (3) the June 2009 issue of the Journal of Emergency Medical Services, ECF 129-7 at 15; (4) a May 14, 2009 article from the "News Leader," ECF 129-7 at 16; and (5) a publication from the United States Army Medical Research and Material Command's Office of Research and Technology Applications, ECF 129-7 at 17.

Most of the evidence cited supports Plaintiff's position that the system as a whole has received industry praise and is commercially desirable. The Defense Department press release notes that the FEBSS system has had "great value in preparing medics to treat combat casualties." ECF 129-7 at 18. The Journal of Emergency Medical Services recognized the FEBSS as one of the top thirty "Hot Products" for 2009. ECF 129-7 at 15 (describing the FEBSS

as an "extremely effective simulator that can be used with any simulation mannikin" with each bleed capable of simulating any combination of capillary, venous, or arterial bleeds to create the chaos of a major trauma bleed at the touch of a button). The "News Leader" article contains remarks from the former director of Emergency Medical Training for the United States Army regarding the FEBSS, noting that compared to the prior art, the FEBSS is "very inexpensive," is "relatively indestructible," and "adds a realism that even the higher fidelity mannequin cannot offer." ECF 129-7 at 16. The Office of Research and Technology Applications publication describes the FEBSS, mentions King, and notes that a high percentage of fatalities occurs from delayed hemorrhage treatment in the field. ECF 129-7 at 17. It discusses that prior trauma training tools to address that issue had been unable to recreate the stress and difficulty of real life hemorrhage control in the field. *Id.* It notes that mannequins hooked up to a laptop were cumbersome and impractical for training. *Id.* In contrast, the FEBSS can simulate several concurrent wounds, from mild to severe, suited for mannequins or worn by personnel in a role-playing exercise. *Id.*

Even if the system as a whole is commercially desirable, commercial success related to an unclaimed feature or "external" or "extraneous" factor does not assist a party attempting to show nonobviousness. Success, however, may be "linked to an individual element or, in other circumstances, it could be linked to the inventive combination of known elements." *WBIP*, 829 F.3d at 1332. The issue in an obviousness inquiry is "whether the '*claimed invention as a whole*' would have been obvious." *Id.* at 1331-32 (quoting 35 U.S.C. § 103) (emphasis in *WBIP*). As discussed above, "trauma training system" is limiting on Claim 18. This system, based on reading the '852 Patent in its entirety, is one that must be adaptable to several uses and practices,

including mass casualty training. While there is no express reference to "portability" in Claims 18, 19, or 20, the '852 Patent's recitation of the limitations of the prior art and the patent's discussion of several different embodiments support a conclusion that "portability" is not an "extraneous factor."

The '852 Patent recites that it was intended to provide a more realistic and dynamic bleeding simulation and thus a more realistic and dynamic training experience. *E.g.*, '852 Patent at 1 (abstract), 1:18-21, 2:3-5. The patent discloses the problems in the prior art as (1) specific-purpose mannequins which cannot be used to simulate other types of medical situations; (2) complex devices reliant on software which are not suited for large training exercises because of the need to "train the trainers" on the system, are fragile because of the software components, and are expensive; and (3) human actors who can provide only static injuries. *Id.*, 1:28-67.

The '852 Patent indicates that it was intended to solve these problems because it is easy to use, requires minimal training, and provides flexibility. *Id.*, 2:34-36 (noting these features in at least one embodiment). Demonstrating the flexibility of the system, various embodiments are disclosed including mannequins, body suits, bag enclosures, and backpacks for housing part or all of the system. *Id.*, 4:12-14; *see also id.*, 6:63-67 (reciting that the system "may be utilized in many embodiments, including cooperating with, housed in, or integrated with, for example, a mannequin, a bag or backpack, a belt, or a bodysuit. The system can be retrofitted into an existing mannequin or other housing."). Discussion of the mannequin embodiment expressly refers to the portability of the system, even with a mannequin *Id.*, 7:52-54. Such portability is achieved through the use of a rechargeable battery which "lacks power cords and provides a more realistic simulation." *Id.*, 7: 57-60. Another exemplary embodiment is placement of the system

in a "portable container" which may be a backpack, shoulder bag, or the like, allowing live participants to attach the system to their bodies and locate the simulated wounds at a variety of locations. *Id.*, 9:48-60. This "allows for a more realistic simulation of a live casualty by enabling the live participant to provide more meaningful feedback to the trainee." *Id.*, 9:61-63.

Defendant is correct that neither size nor portability is expressly claimed in Claims 18, 19, or 20 of the '852 Patent. Nonetheless, when the '852 Patent is read as a whole, the claimed "trauma training system," in order to provide a "more realistic and dynamic" training experience, is a system that is flexible and adaptable to many different uses. Portability is achieved when the invention as a whole is considered and practiced. As a result, portability is not "an extraneous factor" and commercial success related to that feature is relevant to nonobviousness.

Plaintiff has established a prima facie case of nexus by virtue of the FEBSS sales figures, which, while minimal absent market share context, are for sales of the claimed invention. There is also evidence of commercial desirability of the entire system. Defendant fails to rebut the prima facie presumption of nexus.

2. Long-Felt Need

Evidence of a long-felt but unresolved need shows nonobviousness because it is reasonable to infer the need would not have persisted had the solution been obvious. Plaintiff argues that while prior art devices addressed the need for more realistic hemorrhage control training, no prior trauma training system allowed a hemorrhage in a live action training scenario as is possible with the patented device's particular arrangement of components including the controller, pump, valve, and wound site(s). Stevick opines that there was a long-felt need for a powered bleeding simulation system that was portable and concealable and which could be worn

by a trainer patient to simulate traumatic hemorrhage on demand in a live action environment. Stevick June 2015 Inv. Rep. ¶ 27, ECF 98-5.[11]

Stevick's opinion creates an issue of fact as to the long-felt but unresolved need satisfied by the '852 Patent. Even without Stevick's testimony, however, the long-felt need for more realistic trauma training is found in the prior art. *E.g.* '304 Niiranen Patent No. 2, 1:23-38, ECF 224-7 (stating that "[t]he existing methods for teaching early emergency casualty care, or first aid, are unsatisfactory in the realism obtained by the simulation" and reciting problems with existing methods as unsatisfactory in the realism obtained because (1) tags on subjects describing wound type provided only minimal realism; (2) painted wound on subject increased realism but provided inadequate simulation; and (3) moulages painted with wounds improved realism but complete realism unobtainable without a flow of blood through open wounds). The prior art attempted to address that need. *E.g.*, *id.*, 1:57-59 ("[a]n object of the invention is to provide realistic simulation of injury whereby training in first aid is provided under conditions closely analogous to actual injury"). Thus, the '304 Niiranen Patent No. 2, issued in 1960, along with the '579 Niiranen Patent No.1, issued in 1959, provided for a simulacrum containing an artificial body member with simulated layers of skin and blood vessels along with a simulated blood supply reservoir. *Id.*, 1:39-42.

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[11] In a footnote, Defendant objects to Stevick's opinion on this issue, contending that Stevick "lacks personal knowledge of the industry, is not qualified to make such a statement, and is incompetent to testify as an expert in this regard." Def.'s Opp. 41 n.12, ECF 234. I do not consider this objection because it is conclusory and not developed enough for consideration. Additionally, as noted previously, a witness may testify as an expert on invalidity issues under Rule 702 if the witness's experience is "sufficiently related" to the pertinent art. No "sufficiently related" argument about either party's expert has been made in connection with the summary judgment motions.

Defendant is correct that the prior art resolved the need for more realistic training systems. *E.g.*, the Niiranen patents, the SABAS Device. However, the record also lacks a prior art device that increased the realism through use of a collection of components as disclosed in Claim 18 of the '852 Patent which allows, as Plaintiff notes, for on-demand hemorrhage simulation in a live action environment using backpacks, mannequins, etc. Accordingly, Plaintiff produces evidence of long-felt but unmet need.

3. Failure of Others

Failure of others to find a solution to the problem is objective evidence of nonobviousness. *E.g., In re Cyclobenzaprine*, 676 F.3d at 1080 ("evidence of a longfelt need for an extended-release formulation and the failure of others to formulate one strongly support a conclusion of nonobviousness"); *see also Reiner v. I. Leon Co.*, 285 F.2d 501, 504 (2d. Cir. 1960) (Hand, J.) (The failure of others to create an invention while having the means to do so and knowing of a need is evidence that the invention "demanded more intuition than was possessed by the ordinary workers in the field.").

Guentzler contends that Kevin Sweeney, Simulaids's former president, was one of ordinary skill in the art of trauma training devices and probably highly skilled in that art. Guentzler July 21, 2015 Dep. 224:19, ECF 97-6. Given that Simulaids is in the business of making simulation training aids for medical workers, it is reasonable to infer that Simulaids and Sweeney would have recognized the need for increasingly realistic training systems and would be motivated to improve upon their products. *See Pro-Mold & Tool Co. v. Great Lake Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996) (court recognized "self-evident proposition that mankind, in particular, inventors, strive to improve that which already exists"). Yet, even though

Simulaids already made the SABAS and SH-CF Devices, it did not manufacture a device equivalent to that disclosed in Claim 18 of the '852 Patent. This supports a finding of nonobviousness.

4. Copying

Copying of the invention is evidence of nonobviousness. *E.g., Crocs, Inc.*, 598 F.3d at 1311. Plaintiff notes that Defendant released its BPS in late 2011, after learning about King's invention in 2010. Kit Lavell Sept 24, 2014 Dep.76:8-23, 80:17-18, ECF 129-11. This creates an inference of copying.

5. Summary re: Objective Factors of Nonobviousness

Plaintiff has evidence of industry praise. It has minimal evidence of commercial success. Plaintiff's evidence supports a finding of nexus. Defendant fails to rebut that finding. Plaintiff has evidence of a failure of others, namely Simulaids, to create the device. Plaintiff raises an inference of copying with the timing of Defendant learning of Plaintiff's device before releasing its own. A juror, however, could reasonably conclude that the timing does not establish copying.

The record, when construed in Defendant's favor, suggests that prior art did address the long-felt need to provide more realistic trauma training. However, when construed in Plaintiff's favor, the record is capable of suggesting that the use and particular arrangement of the components satisfied an unmet need for a more realistic hemorrhage simulator used to train first responders that was sturdier, less expensive, and more flexible in its uses than previously existed

Overall, when viewed in Plaintiff's favor, the objective, secondary considerations of nonobviousness support Plaintiff. But, when viewed in Defendant's favor, some of these considerations do not show nonobviousness.

E. Summary of *Graham* Factors

There are issues of fact as to whether the Zelenak Patent is analogous prior art, as to whether the Zelenak Patent discloses a valve, as to the proper POSA, and as to some of the secondary considerations of nonobviousness. These are to be resolved by the factfinder.

F. Motive to Combine

While motive to combine is not one of the four *Graham* factors, it is a relevant inquiry. Though *KSR* held that "neither the particular motivation nor the avowed purpose of the patentee controls," it also held that when determining whether there is an "apparent reason to combine the known elements in the fashion claimed by the patent in suit[,]" a court should look at the "interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art[.]" *KSR*, 550 U.S. at 418, 419.

As noted previously, the motivation inquiry is directed to the motive to select the particular references, the motive to combine, and a reasonable expectation of success. *WBIP*, 829 F.3d at 1337 ("[w]hether a skilled artisan would be motivated to make a combination includes whether he would select particular references in order to combine their elements"); *In re Cyclobenzaprine*, 676 F.3d at 1068 ("party seeking to invalidate a patent as obvious must demonstrate by clear and convincing evidence that a skilled artisan would have had reason to combine the teaching of the prior art references to achieve the claimed invention and that the skilled artisan would have had a reasonable expectation of success from doing so") (internal quotation marks omitted). And, whether there is a reason or motive to combine prior art references is a question of fact. *In re Van Os*, 844 F.3d at 1360.

In its motion, Defendant posits three possible combinations of prior art references which it argues invalidate Claim 18 of the '852 Patent as obvious. Def.'s Am. Mot. for Sum. J. 36-39, 42-43, ECF 227. In opposing Plaintiff's motion, Defendant adds four more. Def.'s Opp. 35-39, ECF 234. Defendant's primary argument is that the combination of the SABAS and SH-CF Devices would have been obvious to a POSA. Def.'s Am. Mot. for Sum. J. 36-39, ECF 227; Def's Opp. 18-22, ECF 234. It also relies on the combination of either Niiranen Patent with the SH-CF Device, the Zelenak Patent with the SH-CF Device, the combination of the SABAS and SH-CF Devices with the '304 Niiranen Patent No. 2, and either Niiranen Patent combined with the Zelenak Device. Def.'s Am. Mot. for Sum. J. 42-43, ECF 227; Def.'s Opp. 36-39, ECF 234.[12]

1. SABAS and SH-CF Devices

In support of the SABAS and SH-CF Device combination, Defendant argues that it was "simple" and that the replacement of the storage tank of the SABAS Device with the collapsible reservoir of the SH-CF Device was just a "simpl[e] . . . rearrangement of the old elements to achieve the functions already known and achieved by these prior art devices." Def.'s Am. Mot. for Sum. J. 36, ECF 227. Because the technical expertise required is minimal, there are no engineering challenges. It is, Defendant suggests, as simple as cutting the tube from the rigid tank in the SABAS Device and replacing it with the tube from the collapsible reservoir of the SH-CF Device. *Id.* at 37 (citing to screen shot of Stevick's videotaped deposition when he inserted the SH-CF Device reservoir tube into the SABAS Device pump inlet tube).

Guentzler opines that the combination of the SABAS and SH-CF Devices is

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[12] A fourth combination offered in opposition to Plaintiff's motion relies on the Sirhan Patent. Def.'s Opp. 35-36, ECF 234. Given my conclusion that the Sirhan Patent is non-analogous prior art, I do not consider that combination.

"rudimentary." Guentzler Jan. 2015 Supp'l Inv. Rep. ¶ 37, ECF 210-3. He reviews the components of each device, *id.* ¶¶ 38-46, and then offers this opinion:

> The combination of the [SABAS Device] and the collapsible reservoir from the [SH-CF Device] is shown in Exhibit 4 (with the collapsible reservoir filled with simulated blood for contrast). The combination replaces the reservoir for simulated blood of the [SABAS Device] with the collapsible reservoir of the [SH-CF Device]. Simply, this combination would have been obvious to a person of ordinary skill in the art.

Id. ¶ 47. He also provides a claim chart showing the elements of Claim 18 and each device's corresponding structure for each element. *Id.* ¶ 48 & Ex. 5.

I agree with Plaintiff that Guentzler's testimony is conclusory and thus insufficient to create an issue of fact regarding motive. But, the law does not require expert testimony to establish obviousness. *See Wyers*, 616 F.3d at 1239 (Fed. Cir. 2010) ("*KSR* and our later cases establish that the legal determination of obviousness may include recourse to logic, judgment, and common sense, in lieu of expert testimony"). Defendant offers several rationales which it contends support its motivation contention without expert testimony.

Defendant argues that motive is demonstrated because with all of the claimed elements known in the prior art, one skilled in the art could have combined the elements by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. *See KSR*, 550 U.S. at 416 ("[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result"). A reasonable juror could determine that at the time of the invention, a POSA would have been motivated to make this combination by a desire to improve similar

devices to satisfy the design and market need for more realistic, durable, cost effective trauma training devices which could be used in the field for mass casualty live training simulations. *See KSR*, 550 U.S. at 420 ("any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed"); at 421 (explaining that when there is a design need or market pressure to solve a problem, and there are a finite number of identified, predictable solutions, a POSA has motivation to "pursue the known options within his or her technical grasp" and if this leads to anticipated success, it is likely not the product of innovation but of ordinary skill and common sense); *Tokai Corp.*, 632 F.3d at 1371 ("We have consistently stated that courts may find a motivation to combine prior art references in the nature of the problem to be solved and this form of motivation to combine evidence is particularly relevant with simpler mechanical technologies") (internal quotation marks and brackets omitted).

The SABAS Device contains all of the components of the '852 Patent as claimed in Claim 18 except for a collapsible reservoir. The SH-CF Device contains all of the components of the '852 Patent as claimed in Claim 18 except for a controller/activation mechanism. Both devices are in the same field of endeavor as the '852 Patent. A reasonable juror could conclude that to create more realistic trauma or hemorrhage control training simulations and to overcome the problems in the prior art (*e.g.*, motive created by design need and/or nature of the problem to be solved), a POSA would have looked at devices in the same field of endeavor including those with mechanical blood pumping systems, collapsible reservoirs, and moulages/wound sites. Thus, a reasonable juror could find, even without expert testimony, a motive to choose these two prior art devices and combine them.

Plaintiff argues that a skilled artisan would not have relied on the SABAS Device as a prior art reference because it had a five-gallon supply tank, a car battery, and a desk-sized wooden crate housing the entire device. And, Plaintiff contends that given these features of the SABAS Device, a skilled artisan would not have expected success in achieving an adaptable, flexible, or portable training device simply by substituting the collapsible reservoir of the SH-CF Device for the rigid tank of the SABAS Device. Plaintiff also argues that a POSA at the time of the invention would not have been motivated to combine the SABAS and SH-CF Devices because the combination would compromise the functionality of the SABAS Device. That device has lengthy hoses and multiple moulages used to train up to six people simultaneously. According to Stevick, the combination would provide an inadequate supply of simulated blood to fill the hoses in the SABAS Device needed to function as a trauma training device for teaching hemorrhage control. Stevick Aug. 2017 Supp'l Reb. Inv. Rep. 7, ECF 224-5. According to Plaintiff, there is no evidence or logical explanation to show why a POSA would abandon the SABAS Device's functionality in order to combine it with the tiny reservoir of the SH-CF to arrive at an inoperable device.

The CAFC has affirmed a determination of nonobviousness when the alleged combination would have destroyed a basic objective of how the prior art reference would have functioned. *E.g., Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016). The court has recognized, however, that although "[t]he fact that features of one reference cannot be substituted into the structure of a second reference may indicate that the claims were nonobvious in view of the combined teachings of the two references," that is not necessarily always the case. *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1013 (Fed. Cir. 1983). There, the court

explained that "[c]laims may be obvious in view of a combination of references, even if the features of one reference cannot be substituted physically into the structure of the other reference." *Id.* The court recognized the "distinction between trying to physically combine the two separate apparatus disclosed in two prior art references on the one hand, and on the other hand trying to learn enough from the disclosures of the two references to render obvious the claims in suit." *Id.* (further recognizing that a technological incompatibility that prevented the combination could be "telling on the issue of nonobviousness" but the lack of economic feasability resulting from the combination would not).

Other cases have explained that "[t]o justify combining reference teachings in support of a rejection it is not necessary that a device shown in one reference can be physically inserted into the device shown in the other." *In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981). Instead, "the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *Id.*; *see also Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1076 (Fed. Cir. 2015) ("[a] reference must be considered for everything it *teaches* by way of technology and is not limited to the particular *invention* it is describing and attempting to protect") (internal quotation marks omitted); *In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983) (rejecting argument that a prior art reference should not be considered "because it deals with collapsible hose rather than flexible plastic pipe and teaches that rolling 600 feet of 4 inch, noncollapsible hose into a transportable bundle is virtually 'an insurmountable task'" because "it is not necessary that the inventions of the references be physically combinable to render obvious the invention under review.").

Under the caselaw, the fact that the SH-CF collapsible reservoir may be insufficient to

supply the blood needed for the SABAS Device does not necessarily undermine a POSA's motive to combine them. The feasability, or lack thereof, of the proposed combination is not controlling. The issue is what a POSA would have learned at the time of the invention from each of the references and what the combination would have suggested. Here, reasonable minds could differ as to whether a POSA, under either party's proposed definition, would rely on the SABAS Device as a prior art reference in an effort to address the problem to be solved, or would have expected a likelihood of success. Reasonable minds could also differ as to whether a POSA would be motivated to combine the two devices even assuming that the combination may impede the functioning of the SABAS Device.

As to whether the combination yielded nothing more than a predictable result, Defendant argues that making a device more "portable" is not "inventive." Defendant relies on a 1952 case which held that the "elements must cooperate in such a manner as to produce a new, unobvious, and unexpected result." *Application of Lindberg*, 194 F.2d 732, 736 (C.C.P.A. 1952). The combination "must amount to an invention." *Id.* As part of its discussion, the court indicated that the portability or movability of a claimed device is not sufficient by itself to patentably distinguish it over prior art unless there are new or unexpected results. *Id.* at 735; *see also Gardner v. TEC Sys., Inc.*, 725 F.2d 1338, 1345-46 (Fed. Cir. 1984) (discussing whether an air bag with dimensions claimed in the patent performed any differently than an air bag with different dimensions disclosed in the prior art and holding that absent distinct performance, the dimensional recitation in the claim limitation did not serve to distinguish the prior art in a significant way); *In re Huang*, 100 F.3d at 138, 139 (modification of prior art reference may result in "great improvement and utility over the prior art, [but] it may still not be patentable if

the modification was within the capabilities of one skilled in the art," unless the claim produces a "new and unexpected result which is different in kind and not merely in degree from the results of the prior art") (internal quotation marks omitted).

Defendant's assertion that portability cannot be an innovative feature overstates the caselaw. Instead, a combination of prior art elements is patentable even if portability is the distinguishing feature over the prior art but only if the new combination in the claimed invention creates a new and unexpected result. Thus, the question is whether the combination of prior art yields anything more than predictable results to one of ordinary skill in the art. Guentzler opines that the combination of claim elements in Claim 18 does not produce unexpected results. Guentzler Jan. 2015 Supp'l Inv. Rep. ¶ 76, ECF 210-3 (stating that the elements, "when combined, produce exactly the results a person of ordinary skill in the art would expect: a device that pumps simulated blood to a simulated wound to simulate trauma"). In my review of the record, I do not find an argument or opinion by Plaintiff directly addressing the "predictable" or "unexpected result" issue.[13] Nonetheless, based on what is in the record, it is arguable that the "inventive contribution" present in Claim 18 is the flexibility and adaptability of the disclosed system which a POSA would not have expected from combining the SABAS and SH-CF Devices.

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[13] I have spent considerable time reviewing the record, but it is extensive, comprising nearly 300 pages of briefing in the current cross-motions, numerous expert reports, and dozens of exhibits. It is possible I overlooked Plaintiff's discussion of this issue. I note that Stevick challenges Guentzler's opinion that the combination did not produce unexpected results. But, Stevick states only that Guentzler's opinion is based on circular, and thus unconvincing, argument. Stevick June 2015 Inv. Rep. ¶ 33, ECF 98-5; Stevick Aug. 2017 Supp'l Reb. Inv. Rep. at 10 (quoting June 2015 Report), ECF 224-5. Other than this, I do not see that Stevick affirmatively opines as to why or how the combination of the SABAS and SH-CF Devices produces a new, unpredictable, or unexpected result.

There are issues of fact regarding motive to combine the SABAS and SH-CF Devices given the reasonable but contrary inferences as to whether either party's proposed POSA would rely on the SABAS Device as a prior art reference, would have expected a likelihood of success, would have been deterred by the lack of functionality of the combination, and as to whether the combination yielded a novel, unexpected result.

2. Other Proposed Combinations

All of Defendant's other proposed combinations rely on similar arguments which do not warrant extensive, separate discussion. Generally, Defendant asserts that any combination of the SABAS and/or either Niiranen Patent with the SH-CF and/or the Zelenak Patent would have been obvious for the same reasons discussed above. Plaintiff raises similar arguments, including that combining either Niiranen patented device with a collapsible reservoir would not have produced an operational system and that a POSA would not have been motivated to look to the Zelenak Patent as prior art because it is unrelated to trauma training and it lacks a wound site. Plaintiff also argues that combining the Zelenak Patent with the SH-CF Device does not create a trauma training device due to the use of a gravity switch in the Zelenak device. *See* Stevick Aug. 15, 2017 Supp'l Reb. Inv. Rep. 17-18, ECF 224-5. For the reasons discussed in the previous section, there are issues of fact regarding the motive to combine.

G. Summary re: *Graham* Factors & Motivation to Combine

Obviousness is a conclusion of law based on the underlying *Graham* factors considered with the motive to combine. In considering Plaintiff's motion for summary judgment, I construe all inferences of material fact in favor of Defendant. Thus, I assume (1) the Zelenak Patent is analogous prior art; (2) the Zelenak Patent has a valve; (3) a POSA is "a person having

familiarity with the appearance and treatment of trauma conditions, and a basic understanding of electrical and mechanical systems"; (4) combinations of various prior art devices would be functional; (5) there is no evidence of copying and other evidence of secondary considerations is present but commercial success sales figures without market share are weak; and (6) given the resolution of these factual disputes in Defendant's favor, this POSA would have been motivated to combine the SABAS Device with the SH-CF or the Zelenak Patent by a desire to satisfy the design and market need for more realistic, cost effective trauma training devices which are durable and suitable for mass casualty live training simulations.

A person having familiarity with the appearance and treatment of trauma conditions, and a basic understanding of electrical and mechanical systems (Defendant's proposed POSA), would have had knowledge of the analogous prior art devices, including the Zelenak Patent, and would have been motivated to combine the prior art devices because of the design need and pressure from the military market. In order to improve upon the prior art and create a more dynamic and realistic trauma training system that was flexible, adaptable, cost-effective, and suited to live action mass casualty simulations, this POSA would have looked for devices that included a mechanized liquid supply, moulages or wound sites with multiple lines, a collapsible reservoir, and were relatively small in size - in other words, the prior art relied on by Defendant. The combination would not have changed the respective functions of the prior art components. The combination produced a trauma training device consistent with the limiting preamble to Claim 18. The result was predictable because using a collapsible reservoir with a system that already disclosed a mechanical blood pumping system (with pump, valve, and controller) and a wound site, would predictably produce a system that was capable of simulating a more realistic and

dynamic hemorrhage simulation because it would have been more flexible, adaptable, and portable. Thus, construing the disputed inferences in Defendant's favor, Plaintiff's motion for summary judgment on obviousness must be denied.

Considering Defendant's motion, I construe the inferences in Plaintiff's favor. Thus, I assume: (1) the Zelenak Patent is not analogous prior art; (2) the combination of the SABAS and SH-CF Devices would not have been functional; (3) the combination of the either of the Niiranen patents with a collapsible reservoir from the SH-CF device would not have functioned given the compressed air/gas method disclosed in the Niiranen patents; (4) a POSA is a "person possessing at least an emergency medical technician (EMT) certificate and high school degree (or similar educational background) with a year of hands on experience in EMT training or similar work history"; (5) there is evidence of copying along with evidence of other secondary conditions of nonobviousness; and (6) given the resolution of these factual disputes in Plaintiff's favor, this POSA would have had little or no motive to combine the prior art devices because with less knowledge of mechanical and electrical systems, the relevance of the SABAS Device would have been diminished due to its size, and the functional obstacles to the combinations would have deterred consideration of them. This POSA, starting with prior art of the SABAS and SH-CF Devices and the Niiranen patents, would not have thought to combine them. This POSA would not have been motivated to choose these particular prior art references and would not have expected a likelihood of success by combining them. Additionally, given that the Zelenak Patent is the only prior art reference to teach a *portable* mechanical fluid supply system, its omission as analogous prior art would deprive this POSA of a key reference. Thus, even in the presence of market or design need, this POSA would not have been motivated to combine the prior art

references in ways suggested by Defendant.

A person possessing at least an emergency medical technician (EMT) certificate and high school degree (or similar educational background) with a year of hands on experience in EMT training or similar work history" (Plaintiff's proposed POSA), at the time of the invention would have had knowledge of the analogous prior art devices but would not have been motivated to combine the prior art devices given the differences between the claims and the prior art and given the functional impairments produced by the combinations. Considering the evidence in Plaintiff's favor, the prior art devices did not teach the particular combination of components that allowed for the flexible, portable, and adaptable system claimed in Claim 18. In this light, it could be concluded that the patent claims at issue represent a device beyond this POSA's technical knowledge and would not have been obvious at the time of the invention. Thus, when all inferences are construed in Plaintiff's favor and with the recognition of Defendant's burden being one of clear and convincing evidence, Defendant's motion on the issue of obviousness is denied.[14]

UNENFORCEABILTY- INEQUITABLE CONDUCT

Both parties move for summary judgment on Defendant's affirmative defense of inequitable conduct in which Defendant asserts Plaintiff failed to disclose three material prior art references to the PTO while prosecuting the '852 Patent. This Court has addressed the issue previously, but in the distinct context of an attorney's fee motion filed by Defendant after I granted summary judgment to Defendant in 2015. *Skedco, Inc. v. Strategic Ops., Inc.*, No. 3:13-

[14] Given my rulings, I do not separately consider Claims 19 or 20 and I do not consider Plaintiff's objections to the SABAS Device as prior art at this time.

cv-00968-HZ, 2016 WL 8678445 (D. Or. Apr. 1, 2016) (denying Defendant's motion for attorney's fees and granting in part Defendant's request for costs). Neither party has contended that my previous determination on the issue is binding here. Thus, I consider the issue anew.

I. Facts

In August 2010, the PTO issued a "Final Office Action" regarding the prosecution of Patent Application No. 11/759,891 ("the '891 Application") which was a continuation-in-part of a prior patent application, Patent Application No. 11/729,064 filed on April 23, 2007, which eventually issued as U.S. Patent No. 7, 887,330 ("the '330 Patent") on February 15, 2011. *See* Eastman Oct. 2, 2017 Decl., Ex. 14, ECF 212-4 (copy of the '891 Application); Ex. 15, ECF 212-5 (prosecution history for the '891 Application); *Id.*, Ex. 9, ECF 211-9 (copy of the '330 Patent).

This Final Office Action rejected several claims of the '891 Application, finding them anticipated under 35 U.S.C. § 102(e) by Bardsley, one of the three prior art references at issue here. *Id.*, Ex. 15 at 16-19, ECF 212-5. The "Detailed Action" section of the Final Office Action does not mention the two other prior art references at issue, which are the two Niiranen patents, but in the Conclusion section, the patent examiner noted that the two Niiranen patents as well as other prior art references all disclose mannequin forms having a pump, reservoir, conduit, controller, and sleeve simulating skin located in a common housing. *Id.*, Ex. 15 at 20, ECF 212-5. The '330 Patent, the '852 Patent, and the '891 Application (which was abandoned in December 2011), are in the same family of patent applications with King as the inventor. *See* Eastman Oct. 2, 2017 Decl., Ex. 9, ECF 211-9; Ex. 14, ECF 212-4; Ex. 15, ECF 212-5; Ex 16, 212-6 (prosecution history for the '852 Patent).

The '852 Patent began with a nonprovisional application on January 19, 2011,

Application No. 13/009,665. There appears to be no dispute that during the prosecution of the '665 Application, the three prior art references (Bardsley and the two Niiranen patents) were not disclosed to the patent examiner.

II. Legal Standards

Relevant regulations impose a duty of candor to the PTO on each named inventor, each attorney or agent that prepares or prosecutes the application, and every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor or assignee. 37 C.F.R. § 1.56. Nondisclosure of information to the PTO can support a finding of inequitable conduct which in turn can render an entire patent unenforceable. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.2d 1276, 1287, 1288 (Fed. Cir. 2011) (en banc) (explaining that the inequitable conduct doctrine evolved to include not only affirmative acts of misconduct before the PTO and the courts, but also the nondisclosure of information to the PTO; noting that the remedy for inequitable conduct as to any single claim renders the entire patent unenforceable and referring to such remedy as the "atomic bomb of patent law.").

"To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO." *Id.* at 1290. With nondisclosures of information, "clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference." *Id.* (internal quotation marks omitted). That is, the "accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." *Id.* Intent and materiality are separate requirements and each must be established by clear and convincing evidence. *Id.* The court may not use a "sliding scale" in its analysis. *Id.*

A. Intent

In cases of omission, direct evidence of a deliberate intent to deceive is rare and thus, indirect and circumstantial evidence may be considered. *Id.* Nonetheless, the evidence "must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances." *Id.* (internal quotation marks omitted). The court may not infer intent solely from materiality. *Id.* And, "[p]roving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive." *Id.*

Importantly, "to meet the clear and convincing evidence standard, the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence." *Id.* (internal quotation marks omitted). Thus, "when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." *Id.* at 1290-91.

B. Materiality

Under *Therasense*, a "but-for materiality" is required, meaning Defendant has to show by clear and convincing evidence that the PTO would not have allowed a claim had it been aware of the undisclosed information. *Id.* at 1291.[15] The relevant question is "whether the PTO would have allowed the claim if it had been aware of the undisclosed reference." *Id.* In making this

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[15] The *Therasense* court also noted that while ordinarily, "but-for materiality must be proved to satisfy the materiality prong of inequitable conduct," in cases of *affirmative* acts of egregious misconduct, "such as the filing of an unmistakably false affidavit, the misconduct is material." 649 F.3d at 1292. Defendant suggests that this standard applies here. I reject the invitation. Defendant cites no cases extending this standard to cases of omission and I find no basis for applying it to inequitable conduct arguments based solely on omissions. *See Everlight Elecs. Co., Ltd. v. Nichia Corp.*, 143 F. Supp. 3d 644, 658 (E.D. Mich. 2015) (the "per-se materiality" standard applies upon the showing of a false affidavit or declaration but the "but-for materiality" standard is used with withheld information), *aff'd*, Nos. 2016-1577, 2016-1611, 2018 WL 286119 (Fed. Cir. Jan. 4, 2018) (affirming district court's conclusion of no inequitable conduct without reaching issue of materiality).

patentability determination, the court applies the preponderance of the evidence standard and gives claims their broadest possible construction. *Id.* at 1291-92; *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1345 (Fed. Cir. 2013) ("Because the analysis of this *but-for* materiality requirement is from the perspective of the PTO, we apply the preponderance of the evidence standard in assessing whether the withheld or misrepresented information would have blocked patentability").[15]

III. Discussion

A. Intent

As I stated in the April 1, 2016 attorney fee opinion, given the timing of the August 2010 PTO action citing the three prior art references as invalidating prior art on a related patent and the application of the '852 Patent coming just five months later, "the facts allow for an inference that King or patent prosecution counsel George Metzenthin had some incentive to deliberately omit the references in the prosecution of the '852 Patent[.]" *Skedco, Inc.*, 2016 WL 8678445, at *12. (D. Or. Apr. 1, 2016). In the context of the attorney fee motion, Plaintiff relied on Metzenthin's Declaration to argue that the failure to include the three references in the '852 Patent application was oversight. With that, I concluded that Metzenthin's statements raised an inference of "negligence or even gross negligence, but not a specific intent to deceive." *Id.* As a result,

[15] The parties do not address the preponderance of evidence standard. At least one court has recently expressed confusion in applying this standard in the context of analyzing an alleged infringer's allegation of material misrepresentation. *Barry v. Medtronic, Inc.*, 245 F. Supp. 3d 793, 802-03 (E.D. Tex. 2017) (discussing CAFC cases on "but for materiality" and noting that it was "less clear" "how, and to which aspect of the issue, the different standards of proof are to be applied when a Defendant alleges that there was a material misrepresentation" and remarking that "this court must admit to some uncertainty as to exactly which aspects of the inquiry the preponderance of the evidence standard is to be applied"), *appeal filed*, No. 17-2463 (Fed. Cir. Aug. 23, 2017).

because there were multiple inferences, Defendant could not establish deceptive intent in support of an attorney's fee award based on inequitable conduct. *Id.*

Here, Plaintiff again relies on Metzenthin's Declaration in which he recalls being involved in the prosecution of the '665 Application which became the '852 Patent, and the earlier '891 Application. Metzenthin Decl. ¶ 4, ECF 128. He states that before the allegations of inequitable conduct, he was unaware of references in the '891 Application that were not cited in the '665 Application. *Id.* ¶ 6. He explains that the omission of references from the '891 Application which were cited in the '665 Application was inadvertent on his part and "certainly not intentional." *Id.* ¶ 7. Elizabeth Arwine, the Chief Patent Attorney for the United States Army Medical Research and Materiel Command, declares that she oversees patent applications owned by the Army, and oversaw those for the '891 Application and the '665 Application. Arwine Decl. ¶ 2, ECF 225. She retained outside counsel Cahn & Samuels to prepare and prosecute both applications. *Id.* ¶ 3. She makes the same assertions as Metzenthin: before these allegations, she was unaware of any failure to cross-cite the references between the two applications and any failure to disclose references in connection with the '665 Application was inadvertent and not intentional. *Id.* ¶¶ 5, 6. Finally, Corey Mack, who was an associate at Cahn & Samuels during the relevant time, was involved in the prosecution of the two applications and makes the same statements: before these allegations, he was unaware of any failure to cross-cite the references between the two applications and any such failure to disclose references to the PTO in connection with the '665 Application was inadvertent and not intentional. Mack Decl. ¶¶ 2, 3, 5, 6, ECF 226.

Defendant argues that there is no reasonable explanation to justify the withholding of the

Niiranen patents and the Bardsley Application from the PTO during the prosecution of the '852 Patent other than to specifically deceive the PTO. Defendant observes that the same family of patents is involved, King is the inventor, and Cahn & Samuels, LLP was King's representative. The attorneys knew of the prior art, knew the prior art was material, and yet failed to cite to these prior art references during the prosecution of the '852 Patent. Defendant characterizes this as "blatant withholding" resulting in a violation of the duty of candor. Def.'s Am. Mot. for Sum. J. 50, ECF 227.

Defendant contends that the only reasonable inference from the facts is that the omission of the key references was deliberate. Additionally, Defendant argues that deliberate collusion to withhold material references is demonstrated by the fact that three separate patent practitioners failed to cite to the references. Furthermore, Defendant argues that the Court cannot overlook the clear bias and motivation for patent prosecution counsels' submission of affidavits admitting negligence.

In support, Defendant cites to a 2014 CAFC case which affirmed a district court finding of inequitable conduct based on the withholding of a material prior art reference. *Am. Calcar, Inc. v. Am. Honda Motor Co., Inc.*, 768 F.3d 1185 (Fed. Cir. 2014). There, although the inventor had provided a limited disclosure of the prior art navigation system, the disclosure excluded material information and details about the system which, according to the defendant, were those that were claimed in the patents in suit. *Id.* at 1188, 1190-91.

In its decision, the district court found that the inventor was "constantly feeding" information to his patent attorney but did not give the attorney information about the operational details of the prior art navigation system, did not tell the attorney about his personal experience

with the system, did not give the attorney a copy of the navigation system manual which he possessed, and failed to provide the attorney with relevant photos of the navigation system display screens. *Am. Calcar, Inc. v. Am. Honda Motor Co., Inc.*, No. 06cv2433 DMS (KSC), 2012 WL 1328640, at *10 (S.D. Cal. Apr. 17, 2012). The court found that the only reasonable inference to be drawn from these facts was that the inventor made a deliberate decision to withhold that information from his patent attorney and the PTO. *Id.*

The district court then explained why an inference of negligence was not reasonable. *Id.* It rejected the idea that the failure to disclose the navigation system details was a mistake or accident. That the inventor "disclosed some information about the system and withheld other information demonstrates a deliberative process, not an accident or a mistake." *Id.* Finally, the court found that the inventor's interactions with his counsel refuted an inference of negligence or gross negligence because the evidence showed that the inventor "had ample time and opportunity" to provide the information to his patent counsel and "took advantage of both to send 'waves' of information, but he never sent the operational details of the [] navigation system." *Id.* Thus, it was not reasonable to infer either negligence or gross negligence. *Id.* As indicated above, the CAFC affirmed the district court's conclusion. 768 F.3d at 1190-91.

I agree with Defendant that with an omission, it must rely on circumstantial evidence. And I agree that affidavits or declarations by patent counsel are fairly characterized as self-serving. Nonetheless, the facts in *American Calcar* are distinguishable. Here, there is no evidence that the inventor withheld any information from patent counsel. There is no information that patent counsel withheld any prior art in other applications or disclosures. Importantly, the evidence relied on by the district court in *American Calcar* to support its finding

that the inventor did not act negligently or recklessly was that the inventor provided the prior art reference in support of the prosecution of the patent but *omitted* the key details which formed the basis of the claimed invention. Here, with a wholesale failure to cite to the prior art reference, deliberate conduct is not the only inference created.

Deliberate intent to deceive is one reasonable inference. But, another reasonable inference is that patent counsel acted negligently or recklessly. When the evidence is considered in a light most favorable to Plaintiff, a reasonable factfinder could conclude that negligence or recklessness is an equally reasonable explanation for counsel's failure to cite to the prior art references and thus, because deceitful intent is not the single most reasonable inference, Defendant does not meet its burden to establish inequitable conduct. Viewing the evidence in a light most favorable to Defendant, however, I deny Plaintiff's motion on this issue. A reasonable factfinder could conclude that the single most reasonable inference from the evidence is that patent counsel acted with a deliberate intent to deceive the PTO. Even though the evidence allows for an inference of a lesser *mens rea*, reasonable minds could conclude that deceit is the single most reasonable inference. As a result, there is an issue of fact regarding intent to deceive.

B. Materiality

Defendant argues that the facts conclusively establish that the PTO would not have allowed the '852 Patent to issue had it known of the undisclosed Bardsley Application and the Niiranen patents. As noted above, all three references were noted by the PTO in its Final Office Action on the '891 Application. Several claims of the '891 Application were rejected as anticipated by Bardsley. And, the patent examiner stated that the Niiranen patents disclosed mannequin forms having a pump, reservoir, conduit, controller, and sleeve simulating skin

located in a common housing. *Id.* Patent prosecution counsel knew about the references as well. Guentzler opines that the Bardsley Application discloses all of the limitations of Claim 18 of the '852 Patent. Guentzler July 13, 2015 Supp'l Inv. Rep. ¶¶ 20-37, ECF 219-5.

Plaintiff argues that but-for materiality is not shown because (1) the government subsequently disclosed all three references to the PTO in connection with two other related patent applications and both times the PTO found no grounds to reject the related application based on those references; and (2) the three references are cumulative of prior art that *was* disclosed in the '852 Patent Application and thus, the three references are not material. *See Impax Labs., Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1374 (Fed. Cir. 2006) ("Information is material to patentability when it is not cumulative to information already of record or being made of record in the application[.]"); *Mentor Graphics Corp. v. EVE-USA, Inc.*, 13 F. Supp. 3d 1116, 1123 (D. Or. 2014) (party asserting "inequitable conduct must explain why the withheld information is material and not cumulative and how an examiner would have used this information in assessing the patentability of the claims.") (internal quotation marks omitted). *Osram Sylvania, Inc. v. Am. Induction Techs., Inc.*, No. CV 09-8748-R, 2011 WL 5143630, at *11 (C.D. Cal. Oct. 28, 2011) ("Information is cumulative if it teaches no more than what a reasonable examiner would consider to be taught by the prior art already of record before the PTO") (citing *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1574–75 (Fed. Cir. 1997)).

Plaintiff's counsel Nathan Brunette explains that United States Patent Application No. 15/155,312 ("the '312 Application") was filed on May 16, 2016 and is a continuation of United States Patent Application No. 13/683,348 ("the '348 Application"), which is a continuation of the

application that led to the '852 Patent. Brunette Oct. 2, 2017 Decl. ¶ 10, ECF 224. The '348 Patent was granted as United States Patent No. 9,342,996 ("the '996 Patent"). *Id.* The '312 Application is the "grandchild" of the '852 Patent. *Id.* It has claims similar in scope to the '852 Patent. *Id.*

In prosecuting the '348 Application, the Army, owner of the '852 Patent, disclosed to the PTO all patent invalidity and unenforceability arguments asserted by Defendant in its 2015 summary judgment briefs. Oct. 6, 2015 Notice of Supp'l Auth., ECF 134; *see also id.*, Ex. 1 at 8, 9, 19-21 (PTO Office Action regarding the '348 Application, including copies of Information Disclosure Statements filed in August and September 2015). The Army also disclosed all references asserted by Defendant in this litigation as prior art, including the two Niiranen patents, a Bardsley patent, and a Bardsley patent application publication. *Id.*; *see also id.* at Exs. 1, 2. The PTO rejected various claims of the '348 Application "on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of [the '852 Patent] in view of claims 1-8 of [the '330 Patent]." *Id.*, Ex. 1 at 3-6.[16]

In prosecuting the '312 Application, the three prior art references at issue in the inequitable conduct affirmative defense were disclosed to the PTO. Brunette Oct. 2, 2017 Decl. Ex. 9 at 17-18, ECF 224-9. In a June 2017 Office Action, the PTO rejected claims 1-18 "on the

[16] "Double patenting" "precludes one person from obtaining more than one valid patent for either (1) the same invention, or (2) an obvious modification of the same invention." R. Harmon, et al., *Patents & the Fed. Circuit* 1350-51 (11th ed. 2013). The doctrine "polices the proper application of the patent term for each invention." *Id.* at 1351. Statutory double patenting is based on statutory language requiring "'a patent' for any new and useful invention." *Id.* (citing § 101 of the Patent Act). "Non-statutory, or 'obviousness-type' double patenting is a judicially created doctrine adopted to prevent claims in separate applications or patents that do not recite the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection." *Id.*

ground of nonstatutory double patenting as being unpatentable over claims 1-22 of [the '996 Patent]." *Id.* at 5.

Plaintiff argues that because it disclosed the three prior art references in the '348 Application and in the '312 Application, and because the PTO did not rely on these prior art references in subsequently invalidating these applications for a device similar to that in the '852 Patent, Defendant cannot meet its burden of establishing that the PTO would have disallowed the '852 Patent if the references had been disclosed.

Next, as to its cumulative argument, Plaintiff cited to the following prior art references in prosecuting the '852 Patent: (1) United States Patent No. 3,027,655 ("Alderson"); (2) United States Patent No. 6,790,043 ("Aboud"); and (3) an application published under the "Patent Cooperation Treaty" bearing PCT International Publication No. WO 96/42076 which is titled "Anatomical Simulator for Videoendoscopic Surgical Training." Brunette Oct. 2, 2017 Decl., Ex. 12, ECF 224-12 (Alderson); Ex. 13, ECF 224-13 (Aboud); Ex. 14, ECF 224-14 (PCT Publication); *see also* '852 Patent at 1, 2 (citing the three references). Plaintiff argues that these references are cumulative to the prior art disclosed in prosecuting the '852 Patent because the three prior references disclose (1) a bleeding simulator including the following: pump, valve, controller, wound site, and rigid hard-walled reservoir similar to the Niiranen patents and SABAS Device (Alderson); (2) a cadaveric surgical training system with flexible reservoir, valve, and compressed air fluid pressurization system similar to Bardsley (Aboud); and (3) a surgical trainer including pump, valve, wound site, and rigid tray as reservoir, similar to the Niiranen patents and SABAS Device (PCT Int'l Pub. No. WO 96/42076).

When examining the evidence in a light most favorable to Plaintiff, I cannot determine on

summary judgment that the Bardsley reference or the two Niiranen patents, considered separately or collectively, are not material under the but-for materiality standard. First, the PTO's rejection of the '891 Application due to Bardsley, and its citation to the Niiranen patents, is relevant information but it may not be dispositive of the references' materiality to the '852 Patent. *E.g.*, *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1362-69 (Fed. Cir. 2003) (prior art reference was omitted from application for patents-in-suit but was relied on by different examiner to invalidate family of applications related to application for patents-in-suit; court noted that the "mere fact" that the examiner of the family of applications relied on the prior art reference was "informative, but not dispositive" of materiality to the patents-in-suit). Second, a factfinder could determine that because the PTO did not expressly rely on these three prior art references in later rejecting related applications in which the references were disclosed, the '852 Patent would also not have been rejected because of them. And third, because the three omitted prior art references related to devices similar to those disclosed in the prosecution of the '852 Patent, a factfinder could reasonably determine that these three prior art references are cumulative and therefore not material.

On the other hand, when viewing the evidence in a light most favorable to Defendant, an inference of but-for materiality is reasonable. All three references were noted by the PTO in its Final Office Action on the '891 Application, several claims of the '891 Application were rejected as anticipated by Bardsley, and the '891 Application patent examiner noted that the Niiranen patents disclosed mannequin forms having a pump, reservoir, conduit, controller, and sleeve simulating skin located in a common housing. *Id.* Given that the '891 Patent Application is similar to the '852 Patent, a factfinder could conclude that, just like the claims in the '891

Application, the '852 Patent would not have issued if the three prior art references had been disclosed.

Additionally, although the PTO did not expressly cite to the prior art references when invalidating the subsequent applications which disclosed the references, without evidence as to whether the PTO's practice is to set forth all possible bases for rejection (e.g. to multiple, alternative bases for rejection) or to just one of several, a factfinder could determine that here, the PTO cited to only one of possibly many bases for invalidating the subsequent patents and thus, its failure to cite to these prior art references is not, in fact, probative of their lack of materiality as to the '852 Patent. Based on these inferences, a reasonable factfinder could determine that the omitted three prior art references meet the but-for materiality standard required to establish inequitable conduct.

Moreover, while Plaintiff includes copies of the prior art references of Alderson, Aboud, and the PCT International Publication in support of its cumulative argument, it offers only conclusory argument and fails to assert particularities. *E.g.*, Pl.'s Mot. for Sum. J. 41, ECF 223 ("the three references are all cumulative of prior art that was disclosed in the '852 Patent's application"; citing to exhibits and listing components); Pl.'s Reply 36, ECF 238 ("the three references at issue were cumulative to other prior art references cited in the prosecution history of the '852 Patent"); Pl.'s Opp. 42, ECF 233 ("all three references at issue all are cumulative of prior art that was disclosed in the '852 patent's application"). Similarly, in support of its argument, Defendant cites to the '891 Application, the Bardsley Application, and the abstract of the Bardsley Application which total almost 400 pages, yet Defendant provides no particular page cite to assist the Court in evaluating the evidence. *E.g.*, Def.'s Am. Mot., ECF 227 45-46 (citing

to Eastman Oct. 2, 2017 Decl., Exs. 15, 17, 18). Overall, the Court finds the materiality arguments to be conclusory in nature and not particularly helpful to resolution on summary judgment. As the *Dayco* court observed, "[w]hether Wilson [the reference omitted from the patents-in-suit application but found to invalidate claims in a related family of applications] meets the threshold level of materiality would require a detailed factual analysis of the relevance of the teachings of that reference both with respect to the claims of the patents-in-suit and with respect to the other prior art references that were before the examiner." *Id.* No such "detailed factual analysis" is included in the summary judgment briefing.

Because, on the present record, reasonable factfinders could reach contrary conclusions regarding materiality and intent, I deny both parties' motions as to inequitable conduct.

REMAINING ISSUES

I. Affirmative Defenses Other Than Obviousness & Inequitable Conduct

In its Answer to the Second Amended Complaint, Defendant asserts nineteen separate affirmative defenses. Def.'s Ans. ¶¶ 26-44, ECF 19. The Ninth Affirmative Defense asserts that one or more claims of the '852 Patent is invalid or void for failing to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and 112. *Id.* ¶ 34. The only one of those raised in the summary judgment briefing is § 103 addressing obviousness. The Sixteenth Affirmative Defense asserts that Plaintiff's claims are barred in whole or in part by fraud on the PTO or by Plaintiff's inequitable conduct. *Id.* ¶ 41. Only Plaintiff's inequitable conduct is raised in the summary judgment briefing.

Plaintiff moves for summary judgment on all other affirmative defenses (including those asserted in the Ninth and Sixteenth Affirmative Defenses, meaning those based on §§ 101, 102,

112, and fraud on the PTO, but not raised in the summary judgment motions). Defendant did not move for summary judgment on any of these affirmative defenses and made no argument supporting these defenses in its brief opposing Plaintiff's motion. During oral argument on the summary judgment motions, I referred to all of the affirmative defenses, exclusive of obviousness and inequitable conduct, as no longer being "alive." Tr. of Dec. 12, 2017 Oral Arg. 96, ECF 256. Defendant offered no contrary position to indicate that it was still relying on any affirmative defense other than obviousness and inequitable conduct.

In view of Plaintiff's legal arguments and uncontested facts related to these affirmative defenses, and Defendant's implicit concession that it is not asserting any of these affirmative defenses, I grant Plaintiff's motion for summary judgment as to the following affirmative defenses: (1) First Affirmative Defense - acquiescence; (2) Second Affirmative Defense - waiver; (3) Third Affirmative Defense - consent; (4) Fourth Affirmative Defense - laches; (5) Fifth Affirmative Defense - estoppel; (6) Sixth Affirmative Defense - unclean hands; (7) Seventh Affirmative Defense - lack of right, title, or interest; (8) Eighth Affirmative Defense - noninfringement; (9) portions of the Ninth Affirmative Defense - invalidity based on §§ 101, 102, or 112; (10) Tenth Affirmative Defense - innocent infringement; (11) Eleventh Affirmative Defense - "no causation"; (12) Twelfth Affirmative Defense - failure to state a claim; (13) Thirteenth Affirmative Defense - no irreparable harm; (14) Fourteenth Affirmative Defense - adequate legal remedy; (15) Fifteenth Affirmative Defense - patent exhaustion, patent misuse, first sale doctrine; (16) portion of the Sixteenth Affirmative Defense - fraud; (17) Seventeenth Affirmative Defense - damages limited by §§ 286, 287; (18) Eighteenth Affirmative Defense - failure to mitigate; and (19) Nineteenth Affirmative Defense - marking/notice under § 287.

II. Evidentiary Objections

I have previously addressed Plaintiff's evidentiary objections to Guentzler's testimony regarding the POSA. I also addressed Defendant's objection to Stevick's lack of post-CAFC decision infringement opinions and his testimony about long-felt need.

Plaintiff also objects to almost 100 paragraphs[17] over seven different expert reports submitted by Guentzler as well as statements he made in another report. Pl.'s Opp. 45-46, ECF 233. Plaintiff argues that Guentzler inaccurately states the law in each of these paragraphs. Plaintiff clarifies that it does not seek to strike testimony about how the accused products or prior art devices function, but only to Guentzler's erroneous legal assertions regarding claim scope and his conclusory applications of erroneous claim scope to the technical facts. *Id.* at 46 n.6.

I deny the motion to strike these objections as moot because none of Guentzler's legal assertions impacted the resolution of the summary judgment motions.

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[17] Many of the objections are to the same assertion by Guentzler, but just repeated in a different report.

CONCLUSION

Plaintiff's Motion for Partial Summary Judgment [223] is (1) granted as to literal infringement, (2) denied as moot as to infringement under the doctrine of equivalents, (3) denied as to obviousness; (4) denied as to inequitable conduct, and (5) granted as to all affirmative defenses other than obviousness and inequitable conduct. Defendant's Amended Motion for Summary Judgment [227] is denied as moot as to infringement under the doctrine of equivalents and denied in all other respects. The parties' evidentiary objections/motions to strike are denied or denied as moot.

IT IS SO ORDERED.

Dated this 12 day of FEB, 2018

Marco A. Hernandez
United States District Judge