

# United States Court of Appeals for the Federal Circuit

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**IVERA MEDICAL CORPORATION,**  
*Plaintiff-Appellant*

v.

**HOSPIRA, INC.,**  
*Defendant-Appellee*

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2014-1613, 2014-1614

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Appeals from the United States District Court for the Southern District of California in Nos. 3:11-cv-01246-H-RBB, 3:12-cv-01582-H-RBB, Judge Marilyn L. Huff.

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Decided: September 8, 2015

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DAVID J.F. GROSS, Faegre Baker Daniels LLP, Minneapolis, MN, argued for plaintiff-appellant. Also represented by THEODORE MICHAEL BUDD, CHAD DROWN, EVA BETH STENSVAD.

ADAM R. HESS, Venable LLP, Washington, DC, argued for defendant-appellee. Also represented by MEAGHAN KENT, MARTIN LYNN SAAD; PAUL F. STRAIN, Baltimore, MD.

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Before NEWMAN, REYNA, and TARANTO, *Circuit Judges*.

REYNA, *Circuit Judge*.

Ivera Medical Corp. (“Ivera”) sued Hospira, Inc. (“Hospira”) in the Southern District of California alleging infringement of U.S. Patent Nos. 7,780,794 (the ’794 patent), 7,985,302 (the ’302 patent), and 8,206,514 (the ’514 patent). The district court granted summary judgment of invalidity, finding the asserted patent claims obvious under 35 U.S.C. § 103. Ivera appeals. For the reasons that follow, we reverse and remand.

## BACKGROUND

### A. The Patents-in-Suit.

The ’514 patent is a continuation of ’302 patent, which is a continuation of the ’794 patent. All three patents share the same written description.<sup>1</sup> The patents explain that medical implements, such as catheters and luer ports, are common sites for transmissions of pathogens into patients. ’794 patent col. 1 ll. 32–35. To prevent these types of transmissions, medical staff traditionally swabbed a site before making connections to medical implements. *Id.* col. 1 ll. 41–45. The swabs came in a small pad of cotton gauze soaked in a cleaning agent (e.g., isopropyl alcohol) and packed in a foil package to prevent evaporation. *Id.* col. 1 ll. 45–47. After swabbing, the site is allowed to dry, killing any pathogens. *Id.* col. 1 ll. 48–55.

In practice, these swabbing procedures were often “overlooked” or “poorly executed.” *Id.* col. 1 ll. 56–58. To overcome this problem, the inventors provided a cleaning device that includes a cap that, when used, reliably disin-

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<sup>1</sup> For simplicity, we refer below to the written description of the ’794 patent.

fects a medical implement. For example, FIG. 6, provided below, shows a cross-sectional diagram of a cleaning device 100 that includes a cap 102. *Id.* col. 6 ll. 19–20. Cap 102 includes threads 105 adapted to receive a medical implement, and first and second cleaning materials 107 and 108. *Id.* col. 6 ll. 26–30 and 49–52. When the medical implement is twisted into cap 102, first cleaning material 107 compresses radially, cleansing the sides of the implement, and second cleaning material 108 compresses axially, cleansing the foremost surface of the implement. *See id.* col. 7 ll. 27–33.

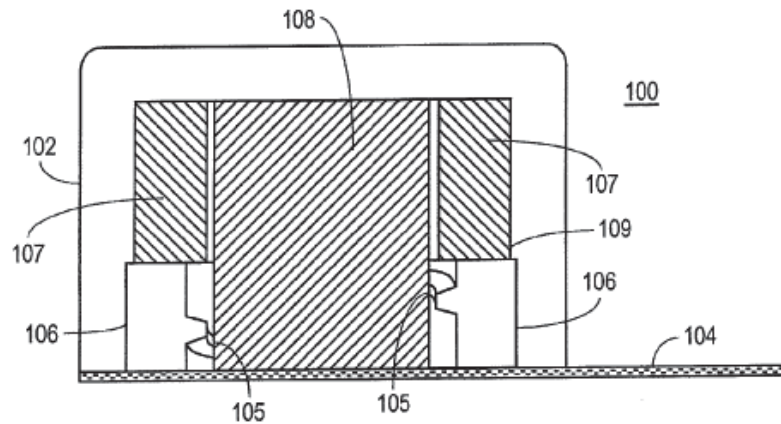


FIG. 6

Central to the parties' arguments on summary judgment are openings that permit venting of the interior of the cap. The patents describe two embodiments of these openings. First, in FIG. 6, threaded ring 106 can create "a small vent aperture or opening" relative to the inner wall of cap 102 to allow evaporation of the cleaning agent in cap 102. *Id.* col. 6 ll. 37–43. Second, in FIG. 14 (provided below), holes 164 are formed in housing 162 of the cap. Holes 164 "can promote evaporation of the cleaning

agent, particularly when the housing covers a site of a medical implement to be disinfected.” *Id.* col. 8 ll. 15–17.

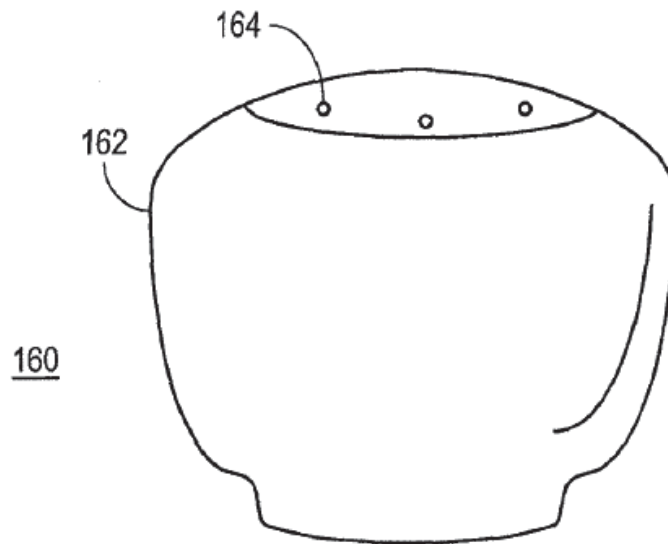


FIG. 14

The asserted claims of the patents-in-suit recite cleaning devices that include a “second opening,” “aperture,” or “means for venting” that inhibit pressure buildup and allow for evaporation.<sup>2</sup> For example, claim 13 of the ’794 patent recites:

13. A cleaning device for a medical implement, the cleaning device comprising:

a cap having a first opening to an inner cavity, an inner surface of the first opening including one or

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<sup>2</sup> We refer to these limitations collectively as “vents.”

more threads adapted to receive a site of the medical implement;

a cleaning material formed of a compressible material that is at least partially secured in the inner cavity, the cleaning material containing a cleaning agent;

*a second opening in the cap* to allow evaporation of the cleaning agent from the inner cavity and to inhibit a buildup of pressure in the cap when the cleaning material is compressed by the site of the medical implement and a removable covering that covers the first opening and the second opening to the inner cavity prior to coupling the threads of the cap with the site of the medical implement via the first opening.

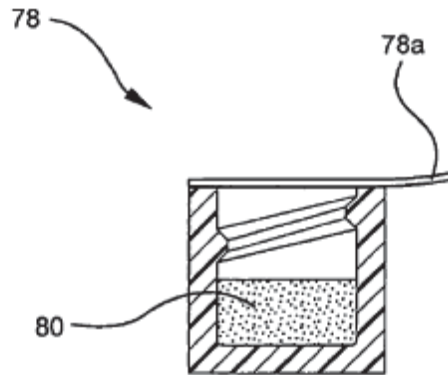
'794 patent col. 10 ll. 1–17 (emphasis added).

## B. The Prior Art.

### 1. Hoang.

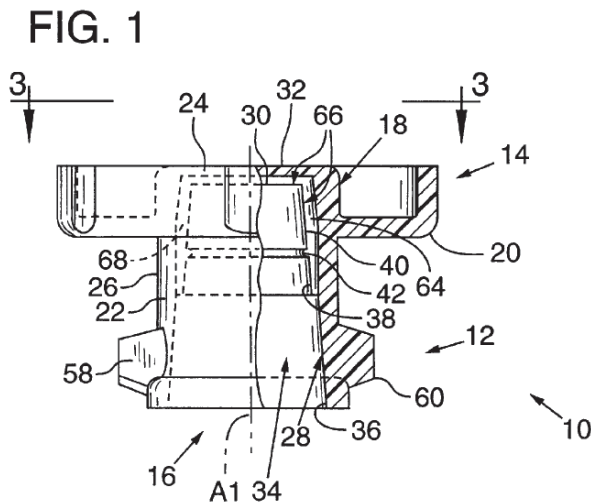
U.S. Patent Application Publication No. 2007/0112333 (“Hoang”) describes a “device for antiseptically maintaining a patient fluid line access valve.” Hoang, ¶ 5. The parties focus their attention on FIG. 10b of Hoang, which is provided below. FIG. 10b shows a cap device 78 that has a lid 78a and a pad 80. *Id.* ¶ 43. Cap device 78 can be twisted onto a patient’s valve using its threads (not numerically referenced in FIG. 10b). *Id.* ¶ 44. Pad 80 can be used as a “dry” pad or a “wet” pad. *Id.* ¶ 43. When used as a “dry” pad, pad 80 is impregnated with an antimicrobial agent that maintains antiseptic conditions on the access portion of a valve. *Id.* ¶ 23. When used as a wet pad, pad 80 is impregnated with a cleaning agent and, optionally, an antimicrobial agent. *Id.* ¶ 27. In this latter example, pad 80 can clean the valve as cap device 78 is twisted on to the valve. *Id.* ¶ 44.

FIG. 10B



## 2. Chin-Loy.

U.S. Patent No. 5,954,957 (“Chin-Loy”) describes a cap adapted to cover blood ports or other hydraulic connection ports for medical devices such as hemodialysis machines. Chin-Loy col. 3 ll. 19–23. FIG. 1 of Chin-Loy, provided below, shows a cap 10 with a first end 12 defining a female portion 16, which receives a male blood port. *Id.* col. 3 ll. 54–57. Side wall 22 and end wall 24 together define a receptacle 34 that receives the male nipple. *Id.* col. 4 ll. 5–7. Cap 10 can be twisted onto a blood port when the port is threaded or can “snap on” for unthreaded ports. *Id.* col. 4 ll. 32–35, col. 4 ll. 46–49. Cap 10 also includes a channel 66 defined by interior surface 28. *Id.* col. 5 ll. 1–2. When cap 10 is attached to a blood port, channel 66 permits “venting of the medical device through the male blood nipple while maintaining an internal condition of the medical device until time of use.” *Id.* col. 2 ll. 41-43 and col. 5 ll. 12–15.



3. White.

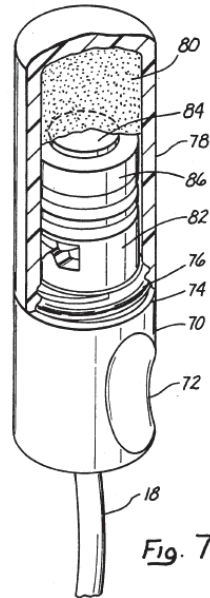
U.S. Patent No. 5,242,425 (“White”) describes a catheter assembly that includes a distal member and a proximal member.<sup>3</sup> FIG. 7 of White, provided below, shows an example catheter assembly that includes a distal member 70 having a finger grip 72. White col. 7 ll. 23–25. Distal member 70 is connected to flexible catheter tubing 18 and proximal member 82. *Id.* col. 7 ll. 29–32. Proximal member 82 has a self-sealing septum 84 through which a needle can be inserted to introduce liquids into catheter tubing 18. *Id.* col. 7 ll. 1–6.

Distal member 70 has an externally threaded shoulder 74 that is adapted to receive internal threads of outer protective cap 78. *Id.* col. 7 ll. 26–27. Outer protective cap 78 contains a sponge 80 that is saturated with an

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<sup>3</sup> In White, the “distal end” is the end closest to the patient and “proximal end” is the end exposed to the outside world. White col. 2 ll. 45–50.

antiseptic. *Id.* col. 7 ll. 27–29. When outer protective cap 78 is twisted onto externally threaded shoulder 74, the antiseptic from sponge 80 can “bathe the exterior surfaces of distal member 70, proximal member 82, and self-sealing septum 84.” *Id.* col. 7 ll. 29–35.



### C. Prosecution History.

In February 2007, Bobby Rogers and Paul DiPerna filed non-provisional application no. 11/705,805 (the “805 application”), which led to the ’794 patent. In response to a September 2009 Office Action, which rejected all of the claims as either anticipated by Hoang or obvious over Hoang and various secondary references, the applicant amended the claims to recite, *inter alia*, vents that allow for evaporation or drying of the cleaning agent. J.A. 5412–18. In response, the examiner allowed the application. J.A. 5029–33. In the Notice of Allowance, the examiner stated that “the reviewed prior art does not disclose or render obvious a medical implement cleaning device comprising a cap having holes or openings for venting the



device while in use,” J.A. 5033, and that Hoang does not disclose “vent holes, apertures, or additional openings to inhibit vacuum [sic] in the cap cleaning device.” J.A. 5034. The ’794 patent issued thereafter in August 2010.

The ’794 and ’302 patents were each subject to *ex parte* reexamination. In each of these proceedings, the examiner initially rejected the claims over various references. In at least the reexamination of the ’794 patent, the examiner considered the Hoang reference. J.A. 5097–98. The examiner determined that the challenged claims of the ’794 and ’302 patents were patentable over the cited prior art based at least partially on the vent limitations. J.A. 38; J.A. 54; J.A. 5097–98; J.A. 5161–62.

Hospira later requested *inter partes* reexamination of the patents-in-suit, which the United States Patent and Trademark Office granted. After the examiner rejected claims in an Action Closing Prosecution (“ACP”), Ivera attempted to enter seven declarations, including one from an inventor of the Hoang reference, Minh Hoang, and another from Dr. Alan Buchman, the sole inventor of a prior art reference relied on during the *inter partes* reexaminations, but not at issue here. J.A. 5473. In the Right of Appeal Notice (“RAN”), the examiner determined that these declarations would not be considered because Ivera had not explained why this evidence was not presented earlier in the proceedings. J.A. 5473.

Assessing the merits, the examiner rejected all of the challenged claims as obvious over the combination of Hoang and Chin-Loy (among other rejections). J.A. 5467–68, 5513–14, 5553–54. The examiner concluded that it would have been obvious to one of ordinary skill to include “the venting channel of Chin-Loy in the cap housing of Hoang because it would allow for venting from the cap interior while preventing the infiltration of microorganisms to maintain the sterile condition of the catheter access site.” J.A. 5468. The examiner also concluded that

because threaded luer connections are not fluid-tight, a threaded opening (such as the ones disclosed in Hoang and White) can meet the vent limitations. *See* J.A. 5521. Ivera informs us that it is appealing the rejections to the Patent Trial and Appeal Board. Appellant's Br. 18.

#### D. Procedural Posture.

Ivera sued Hospira for infringement of the '794 and '302 patents in 2011 and for infringement of the '514 patent in 2012. In October 2013, the district court issued its claim constructions for the disputed terms of all of the patents-in-suit. Relevant here, the district court construed the term "opening" or "first opening" to mean "an entrance or exit to the inner cavity of the cap," "second opening" to mean "a second, distinct channel or pathway that extends from the interior to the exterior of the cap," and "aperture" to mean "a channel, pathway, hole, gap, or split." J.A. 5433, 5435, 5437. The district court also construed "means for venting" under 35 U.S.C. § 112, ¶ 6,<sup>4</sup> to mean "the following combination of proposed terms: (a) a threaded ring that fits into a groove that is formed in the inside edge surface of the cap near the opening, where the threaded ring includes or creates with the cap wall a small vent aperture or opening; (b) holes in the housing of the cap; and (c) permitted equivalents of (a) and (b)." J.A. 5439. The parties do not challenge these constructions before us.

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<sup>4</sup> Paragraph 6 of 35 U.S.C. § 112 was replaced with newly designated § 112(f) when § 4(c) of the America Invents Act (AIA), Pub. L. No. 112-29, took effect on September 16, 2012. Because the applications resulting in the patents-in-suit were filed before that date, we refer to the pre-AIA version of § 112.

In April 2014, the district court granted Hospira's motion for summary judgment of invalidity. J.A. 9. The district court found that the scope of the prior art included Hoang, Chin-Loy, and White. J.A. 13. The court further found that the level of ordinary skill is a person with "a bachelor's degree in mechanical engineering, biomedical engineering, or a comparable field with anywhere from two to five years' work in the disposable medical device industry." J.A. 16.

Considering the differences between the prior art and the claimed inventions, the court found that the "patents-in-suit contain the same elements that perform the same functions they had been known to perform in the prior art," J.A. 16, and that the "arrangement of elements in the asserted claims do[es] not yield anything other than predictable results," J.A. 18. The court noted, however, that Hoang does not disclose the vent limitations. J.A. 19. Still, a person of ordinary skill would not "need the benefit of hindsight to realize that adding a vent would relieve possible pressure on the inside of the cap." J.A. 19. According to the court, a person of ordinary skill would recognize the benefits of adding a vent as allegedly taught in Chin-Loy, i.e., it would allow venting of the interior of the medical device through a blood port during sterilization. J.A. 19 (citing Chin-Loy col. 5 ll. 1–20). A person of ordinary skill would also recognize that adding a second opening would allow the cleaning agent to "vent onto the exterior of the medical implement, sterilizing a larger portion of it," as allegedly described in White. J.A. 19 (citing White col. 7 ll. 23–35). Thus, the district court determined that "the record demonstrates no triable issue of material fact on obviousness for the asserted claims of the patents-in-suit." J.A. 20. The district court further found that Ivera's evidence of secondary indicia of non-obviousness did not rebut this conclusion, stating that "[t]he asserted claims encompassed obvious subject mat-

ter regardless of evidence of secondary factors, and as a result fail to meet the requirement of § 103.” J.A. 21.

Ivera timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

#### DISCUSSION

Summary judgment is appropriate if “the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). We review a grant or denial of summary judgment under the law of the regional circuit, which in this case is the Ninth Circuit. *Aristocrat Techs. Austl. Pty Ltd. v. Int’l Game Tech.*, 709 F.3d 1348, 1361 (Fed. Cir. 2013). The Ninth Circuit reviews such a decision de novo. *Humane Soc’y of the U.S. v. Locke*, 626 F.3d 1040, 1047 (9th Cir. 2010). That is, we apply the same standard applied by the district court. *Lew v. Kona Hosp.*, 754 F.2d 1420, 1423 (9th Cir. 1985). In doing so, we resolve factual disputes against the movant. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 143 (1997). We must also take into account that invalidity of a patent must be shown by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2243 (2011); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

Under 35 U.S.C. § 103, a patent may not be obtained “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”<sup>5</sup> Obviousness is a legal question based on the following underlying factual inquiries: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the

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<sup>5</sup> Again, we refer to the pre-AIA version of § 103.

differences between the claimed invention and the prior art; and (4) secondary evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). “A party seeking to invalidate a patent on obviousness grounds must demonstrate by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1347 (Fed. Cir. 2014) (internal citations and quotation marks omitted). Determining whether one of ordinary skill in the art would have been motivated to combine the teachings of different references is a flexible inquiry, and the motivation is not required to be found in any particular prior art reference. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007).

Ivera argues that a person of ordinary skill in the art would not have been motivated to add a vent to Hoang’s cap. Appellant’s Br. 33. Instead, the record shows, according to Ivera, that the conventional wisdom among those skilled in the art was that disinfecting caps should be fluid tight. *Id.* Hospira responds that Chin-Loy describes benefits of venting a cap, which would have motivated a person of ordinary skill to add a similar vent to Hoang’s cap. Appellee’s Br. 29. Hospira also cites the written description of the patents-in-suit as encouraging evaporation of cleaning agents. *Id.* A person of ordinary skill in the art would also have, according to Hospira, seen the benefit of bathing the exterior of a cap, as allegedly described in White. *Id.* at 31.

We agree with Ivera that record evidence establishes a genuine dispute over whether a person of ordinary skill would have been motivated to add a vent to Hoang’s disinfecting cap. During the *inter partes* reexaminations, Ivera submitted multiple expert declarations. As noted above, the examiner decided not to consider these declara-

tions because Ivera did not establish why it had not submitted them earlier. Hospira does not, however, challenge Ivera's reference to these declarations at the summary judgment stage before the district court. The declarations indicate that a person of ordinary skill would have desired fluid-tight disinfecting caps to retain the cleaning agent included within the cap. For example, Ivera relies on a declaration from an inventor of the Hoang reference, Minh Hoang. In his declaration, Minh Hoang states that "[a]t the time of my invention, it was the understanding and belief of persons of ordinary skill in the art, such as myself, that such a cap should seal over the access portion of the access valve and retain the cleaning solution contained in the cap." J.A. 5652. Referring to the cap described in the Hoang reference, Minh Hoang explains the cap "avoided using any pathways or channels out of the housing of the cap during placement or use on the access valve, because doing so would allow an exit of the cleaning solution from the cap, which I believed would reduce the effectiveness of the cap." J.A. 5653. Although the statements of an inventor are not controlling as to the content of a patent application, Hospira does not challenge Minh Hoang's assertion that he is a person of ordinary skill. Ivera's expert, Karl Leinsing, agreed with Minh Hoang that one of ordinary skill in the art would not seek to add a vent to Hoang's cap because doing so would cause the loss of cleaning solution. J.A. 5618. Karl Leinsing added that, in his opinion, fluid-line connections are generally presumed to be "fluid-tight to avoid leakage of any such fluid into the hospital environment." J.A. 5585.

Ivera also submitted a declaration from Dr. Alan Buchman, the sole inventor of a prior art patent cited in the *inter partes* reexaminations. In his declaration, Dr. Buchman states that his goal in creating a catheter cleaning device was to "create a device that would form a fluid-tight seal over the injection port and continuously

bathe the surface of the injection port entrance in the antimicrobial solution to obtain the best possible disinfection” and that “[e]stablishing and maintaining a fluid-tight seal over the injection port was an important aspect of my design.” J.A. 5293. It was “commonly understood,” according to Dr. Buchman, that effective disinfection of the surface of the injection port “required that it be continuously bathed in the antimicrobial fluid.” J.A. 5293-94.

Hospira argues that the prior art provides reasons to add a vent to Hoang’s cap. Appellee’s Br. 29. For example, Chin-Loy describes a channel that permits venting of the medical device during sterilization. Chin-Loy col. 5 ll. 13–15. Chin-Loy, however, relates to blood ports of hemodialysis machines. *Id.* col. 3 ll. 19–23. Hospira cites no evidence explaining how this description is relevant to disinfecting caps. Hospira has not explained, for example, whether disinfecting caps like the one described in Hoang are sterilized or would benefit from venting during such a sterilization procedure. Chin-Loy thus does not foreclose a genuine dispute over whether a person of ordinary skill would have been motivated to add a vent to Hoang’s cap.

Hospira also cites the following passage of the ’794 patent’s written description as indicating that a person of ordinary skill in the art would not seek to retain the cleaning solution, but rather seek to have the cleaning solution evaporate:

The site should be allowed to dry, usually twenty to thirty seconds, immediately prior to making any connection. This ‘drying’ period is important: when alcohol dries, it breaks open the cellular walls of microorganisms, thereby killing them.

’794 patent col. 1 ll. 51–55. This passage, however, relates to manual swabbing of a site, and Hospira presents no evidence relating these teachings to the use of disinfecting caps. In fact, earlier in the same paragraph, the patents explain that caps are designed to retain the

cleaning agent, explaining that the swabs are packed individually in a foil package to “retain the alcohol within the package and to prevent evaporation.” *Id.* col. 1 ll. 45–47. In any event, the tradeoff between the desire to retain the cleaning agent and the patents’ disclosure regarding drying is a factual matter left to the factfinder.

Finally, Hospira points to White’s disclosure of bathing “the exterior surfaces of distal member 70, proximal member 82, and self-sealing septum 84.” White col. 7 ll. 29–35. The parties dispute whether this disclosure means that the antiseptic bathes only threaded shoulder 74 of distal member 70 (as Ivera asserts), or if the antiseptic drips down the outside of distal member 70 (as Hospira asserts). Appellant’s Br. 28; Appellee’s Br. 31. White is not clear on which interpretation is correct, and neither side points to any other evidence favoring one interpretation. This dispute over the content of White is a factual dispute that we must resolve in Ivera’s favor at the summary judgment stage. *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1356-57 (Fed. Cir. 2013); *Gen. Elec. Co.*, 522 U.S. at 143. The cited passage from White does not, therefore, indicate that one of ordinary skill in the art would have sought to add a vent to Hoang’s cap.

#### CONCLUSION

For the foregoing reasons, we hold that Ivera established a genuine dispute over whether one of ordinary skill in the art would have been motivated to add a vent to the disinfecting cap described in Hoang. Accordingly, we reverse the district court’s entry of summary judgment of invalidity.

#### **REVERSED AND REMANDED**

#### COSTS

No Costs.