# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH CENTRAL DIVISION

C.R. BARD, INC., et al.,

Plaintiffs,

v.

MEDICAL COMPONENTS, INC.,

Defendant.

# MEMORANDUM DECISION AND ORDER GRANTING IN PART AND DENYING IN PART BARD'S RENEWED MOTION TO STRIKE MEDCOMP'S EXPERT OPINIONS (DOC. NO. 918)

Case No. 2:17-cv-00754

District Judge Howard C. Nielson, Jr.

Magistrate Judge Daphne A. Oberg

Discovery is a cooperative endeavor. The Federal Rules of Civil Procedure and this court's local rules embody this collaboration by requiring certain mandatory disclosures and requiring parties to meet and confer whenever discovery issues arise. Theoretically, at least, the discovery process is designed to proceed with minimal court involvement. This case contravenes that expectation. The parties have filed no fewer than thirty-two short-form discovery motions,<sup>1</sup> in addition to many other, more fulsome discovery-related motions, such as the motion at issue here.

In this motion, Plaintiffs C.R. Bard, Inc., et al. (collectively "Bard") seek to strike in part the expert opinions of Drs. Cooper, Lautin, Shoenfeld, and Kiani, and the expert opinion of Lois Romans, offered by Defendant Medical Components, Inc. ("MedComp").<sup>2</sup> The substance of

<sup>&</sup>lt;sup>1</sup> (*See* Doc. Nos. 49, 116, 117, 210, 246, 263, 295, 296, 299, 309, 315, 322, 326, 329, 333, 336, 347, 350, 351, 352, 378, 379, 768, 831, 854, 864, 916, 917, 921, 924, 929 & 941.)

<sup>&</sup>lt;sup>2</sup> (See Bard's Renewed Mot. to Strike ("Mot."), Doc. No. 918.)

Bard's argument is that MedComp and its expert witnesses are attempting an end-run around the express discovery limitations applicable to patent invalidity claims. For the reasons discussed below, Bard's motion is granted in part and denied in part.

## BACKGROUND

This infringement action concerns Bard's patents on vascular access ports. Fact discovery has closed. Each party has served their respective final infringement and invalidity contentions pursuant to this District's Local Patent Rules. More specifically, on May 18, 2023, MedComp served its Final Invalidity Contentions.<sup>3</sup> Under the applicable patent rule, final invalidity contentions are limited to ten prior art references per patent.<sup>4</sup> MedComp complied with this limitation in its Final Invalidity Contentions, identifying ten prior art references for each of the five Bard patents at issue.<sup>5</sup>

Bard now argues MedComp's experts have relied on an additional sixteen "new" or undisclosed prior art references in their expert opinions, in violation of the ten-reference limitation in patent rule 3.2(b).<sup>6</sup> Bard seeks to strike these additional references and the portions of the expert opinions relying on them.<sup>7</sup> Bard also argues certain additional references and citations in these opinions—references MedComp asserts its experts used for "background" or

<sup>&</sup>lt;sup>3</sup> (*See* Ex. G (redacted) to Mot., Def.'s Third Am. LPR 3.1 Final Unenforceability and Invalidity Contentions ("Final Invalidity Contentions"), Doc. No. 918-3.)

<sup>&</sup>lt;sup>4</sup> See LPR 3.2(b). The LPRs were renumbered effective December 8, 2023, without any substantive change. The new, renumbered rules are referenced in this decision.

<sup>&</sup>lt;sup>5</sup> (*See* Final Invalidity Contentions 101–02, Doc. No. 918-3 (identifying ten prior art references for the '639 patent, the '723 patent, the '633 patent, the '052 patent, and the '186 patent).)

<sup>&</sup>lt;sup>6</sup> (See Mot. 8, Doc. No. 918; Bard's Reply in Supp. of Mot. to Strike ("Reply") 1, Doc. No. 958.)

<sup>&</sup>lt;sup>7</sup> (*See* Mot. 6, Doc. No. 918.)

"state of the art"—must be stricken because they were undisclosed previously.<sup>8</sup> Bard further posits that any use of these references will prejudice Bard because fact discovery is over, and Bard has been deprived of an opportunity to take discovery regarding these undisclosed references.<sup>9</sup>

While the local patent rules do not specify the consequences for noncompliance with disclosure provisions, the Federal Circuit has indicated a district court "may impose any 'just' sanction."<sup>10</sup> As relevant here, under some circumstances, courts consider striking or excluding an expert report as an appropriate sanction.<sup>11</sup> However, the legal authority cited by the parties reveals that courts are split on whether an expert report may include undisclosed information for background, context, or other factual foundation,<sup>12</sup> or whether such references must always be

<sup>8</sup> (*Id.* at 9–10.)

<sup>9</sup> (*Id.* at 10.)

<sup>10</sup> See O2 Micro Int'l Ltd. V. Monolithic Power Sys., Inc., 467 F.3d 1355, 1363 (Fed. Cir. 2006).

<sup>11</sup> See, e.g., *Phigenix, Inc. v. Genentech, Inc.*, 783 F. App'x 1014, 1020 (Fed. Cir. 2019) (unpublished) (noting that "exclusion" is often an appropriate sanction); *Life Techs. Corp. v. Biosearch Techs., Inc.*, No. C 12-00852, 2012 U.S. Dist. LEXIS 132478, at \*7 (N.D. Cal. Sept. 17, 2012) (unpublished) (striking the portions of an expert report offering undisclosed invalidity theories).

<sup>12</sup> See, e.g., Finjan, Inc. v. Symantec Corp., No. 14-cv-02998, 2018 U.S. Dist. LEXIS 14952, at \*12 (N.D. Cal. Jan. 30, 2018) (unpublished) (denying a motion to strike an expert's use of undisclosed research thesis noting that it was not used as prior art to establish invalidity but to "demonstrate[] background information about the technology at issue and the state of the art at the relevant time"); *Finjan, Inc. v. Sophos, Inc.*, No. 14-cv-1197, 2016 U.S. Dist. LEXIS 68128, at \*36 (N.D. Cal. May 24, 2016) (unpublished) (adopting an approach "allowing previously undisclosed references to be used as background material, so long as they are not asserted as invalidating prior art references"); *Digit. Reg. of Tex., LLC v. Adobe Sys.* ("*Digit. Reg. 1*"), No. CV 12-01971, 2014 U.S. Dist. LEXIS 58113, at \*17, \*20 (N.D. Cal. Apr. 24, 2014) (unpublished) (allowing references as background information but not to establish the elements in the patents were met by the prior art); *Digit. Reg. of Tex. v. Adobe Sys., Inc.* ("*Digit. Reg. 2*"), No. C 12-1971, 2014 U.S. Dist. LEXIS 115565, at \*29 (N.D. Cal. Aug. 19, 2014) (unpublished)

stricken from the report.<sup>13</sup> No party has cited any decision from the District of Utah or the Tenth Circuit on this issue.

#### **ANALYSIS**

Bard asks the court to strike all the purported additional references from MedComp's experts' opinions. Although Bard provides a table listing where some of these references may be found,<sup>14</sup> Bard does not identify, with the necessary specificity, exactly what portions of the five different expert opinions it believes should be excised. (At best, Bard identifies only the paragraphs in which such references appear,<sup>15</sup> without specifying what language from those

<sup>13</sup> See, e.g., INAG, Inc. v. Richar, LLC, No. 2:16-cv-00722, 2021 U.S. Dist. LEXIS 77546, at \*21–22 (D. Nev. Apr. 22, 2021) (unpublished) (striking the entirety of a report that relied on theories and prior art reference not disclosed in defendant's invalidity contentions); *Pactiv Corp. v. Multisorb Techs, Inc.*, No. 10 C 461, 2013 U.S. Dist. LEXIS 75585, at \*6 (N.D. Ill. May 29, 2013) (unpublished) (striking portions of an expert report citing references that were not disclosed in invalidity contentions even as "background information" or as "complementary" to understanding the invalidity references); *see also Life Techs. Corp*, 2012 U.S. Dist. LEXIS 132478, at \*7 (striking portions of a report citing references not disclosed in invalidity contentions).

 $^{15}$  (See id.)

<sup>(</sup>explaining how an expert may be permitted to use undisclosed references "to explain further how the chosen prior art references disclose required limitations"); *Verinata Health, Inc. v. Sequenom, Inc.*, No. C 12-865, 2014 U.S. Dist. LEXIS 116382, at \*16 (N.D. Cal. Aug. 20, 2014) (unpublished) (allowing the use of a prior art article not cited in invalidity contentions for "foundational or background material," but not "as prior art that allegedly renders the asserted claims" obvious); *Genentech, Inc. v. Trustees of the Univ. of Pa.*, No. C 10-2037, 2012 U.S. Dist. LEXIS 16959, at \*12–13 (N.D. Cal. Feb. 9, 2012) (unpublished) (concluding that expert citation to references, including clinical trials, not disclosed in a final infringement contention "does not render it unusable for laying an historical foundation to research that was disclosed"); *Ziilabs Inc. v. Samsung Elecs. Co.*, No. 2:14-cv-203, 2015 U.S. Dist. LEXIS 158549, at \*11 (E.D. Tex. Aug. 24, 2015) (unpublished) (precluding the use of undisclosed prior art as the basis for expert's invalidity opinion but allowing its use for "background material," for "state of the art," and to establish what a person of ordinary skill in the art would have known or understood).

<sup>&</sup>lt;sup>14</sup> (See Ex. A to Mot., Bard's Chart 1–7, Doc. No. 920-1 (sealed).)

paragraphs should be stricken and why.) This lack of specificity is noteworthy because some of those same paragraphs also reference prior art which has been duly identified.<sup>16</sup> Indeed, Bard itself recognizes MedComp's experts also relied on disclosed references.<sup>17</sup> The court cannot and will not do this work for Bard.<sup>18</sup> Accordingly, the most the court can do at this point is reaffirm its consistent position that MedComp's experts' opinions, to the extent they opine on invalidity, may only rely on the ten prior art references presented in MedComp's Final Invalidity Contentions.

# A. Use of Undisclosed References as "Prior Art" to Establish Invalidity is Impermissible

It is beyond challenge that the limit of ten prior art references in the local patent rules

applies to MedComp's Final Invalidity Contentions. Many times, this court has informed

MedComp of the ten-reference limitation and demanded MedComp's compliance with it.<sup>19</sup> And,

in fact, MedComp's Final Invalidity Contentions only identify ten prior art references. To the

<sup>&</sup>lt;sup>16</sup> (*See, e.g.*, Ex. C to Mot., Cooper opinion ¶¶ 66, 77, 83, 84, 85, Doc. No. 920-3 (sealed) (referring to the Quinn disclosed prior art); Ex. F to Mot., Kiani opinion ¶¶ 264, 279, 280, 281, 328–30, 349–50, Doc. No. 920-6 (sealed) (also referring to Quinn and referring to the disclosed Herts reference).)

<sup>&</sup>lt;sup>17</sup> (*See* Mot. 4, Doc. No. 918, (recognizing that the experts also rely on the disclosed Quinn reference).)

<sup>&</sup>lt;sup>18</sup> See, e.g., *Life Techs. Corp.*, 2012 U.S. Dist. LEXIS 132478, at \*13 (refusing to strike entire paragraphs from an expert report "merely because they contain a citation to an undisclosed reference," and noting that some may stand).

<sup>&</sup>lt;sup>19</sup> (*See, e.g.*, Order Granting in Part and Den. in Part Pls.' Short Form Mot. to Strike Portions of MedComp's Final Invalidity Contentions 2, Doc. No. 434 (ordering "MedComp to reduce its final disclosures to a total of ten (10) pieces of prior art per patent" from the 14 identified); Tr. of Hr'g 94:23–25 (Oct. 20, 2021), Doc. No. 797 (informing MedComp that its amended final contentions "must also include only the ten prior art references as ordered [in Doc. No. 434]").)

extent MedComp's experts purport to rely on prior art references other than the ten identified in MedComp's Final Invalidity Contentions, that use runs afoul of the local patent rules, MedComp's representations, and this court's admonitions. MedComp's experts may not rely on undisclosed references as prior art for their opinions that the patents are invalid.

For example, Dr. Cooper appears to expressly rely on the "teachings of . . . Bard's prior art PowerPICC" as a basis for his opinion that the claims in the '639 patent are "not inventive."<sup>20</sup> Because the PowerPICC is not one of MedComp's ten disclosed prior art references, such a use is impermissible in that context. Moreover, earlier in this action, MedComp sought to amend its Final Invalidity Contentions to add the PowerPICC catheter as one of its ten prior art references. This court denied that motion<sup>21</sup>—a determination further limiting the use of the PowerPICC reference.<sup>22</sup>

It is a closer question, however, whether Dr. Cooper's use of Bard's "Lift Loc" infusion set is impermissible. Although there is no express reference to Lift Loc in MedComp's final ten prior art references, MedComp asserts Lift Loc was the infusion set (and perhaps the only infusion set) described in the PORTS reference, which was one of the ten disclosed prior art

<sup>&</sup>lt;sup>20</sup> (See, e.g., Ex. C to Mot., Cooper opinion ¶ 65, Doc. No. 920-3.)

<sup>&</sup>lt;sup>21</sup> (*See* R. & R. to Den. Def.'s Mot. to Am. Final Infringement Contentions ("R.&R.") 7–8, Doc. No. 645.) The parties' objections to this report and recommendation were overruled by the district court. (*See* Min. Order, Doc. No. 704.)

<sup>&</sup>lt;sup>22</sup> But see Genentech, Inc., 2012 U.S. Dist. LEXIS 16959, at \*10–12 (allowing the use of some references, despite the court's previously denial of leave to amend, where the party disavowed any intention to rely on the references to establish invalidity, and because the court did not find they were trying an "end run" around the denial order).

references. At this juncture, MedComp's assertion is enough to salvage Dr. Cooper's citation to Lift Loc—subject to future pretrial or trial challenge following expert discovery.<sup>23</sup>

Finally, most of Dr. Cooper's opinion concerns his testing of PowerPICC and Lift Loc to determine if, before 2005, these two Bard products (and two other related Bard products) were "substantially free of plasticizer."<sup>24</sup> Whether this is a relevant or admissible opinion remains an open issue—and one that is not currently before the court. It may be useful for the parties to recall this court's previously notation that "Bard admits in its pleading that the PowerPICC patent itself states it is 'substantially free of plasticizer,' rendering additional testing and discovery redundant [on that issue]."<sup>25</sup> Nevertheless, at this stage, it is enough that these testing references in Dr. Cooper's opinion appear to be used to support a disclosed invalidity theory—that prior art was already substantially free of plasticizer<sup>26</sup>—such that completely striking these references is unwarranted.<sup>27</sup>

<sup>&</sup>lt;sup>23</sup> Although MedComp offers a similar argument in support of the PowerPICC reference—i.e., that it is a catheter described in the DIS reference which was disclosed, (*see* Final Invalidity Contentions 101, Doc. No. 918-3 (listing BARD\_MEDCOMP\_0023916-28)), the fact that this court denied use of the PowerPICC as a prior art reference forecloses that argument.

<sup>&</sup>lt;sup>24</sup> (Reply 7, Doc. No. 958; Ex. C to Mot., Cooper opinion ¶¶ 31–48, Doc. No. 920-3 (sealed).)

<sup>&</sup>lt;sup>25</sup> (See R .& R. 8 n.3, Doc. No. 645.)

<sup>&</sup>lt;sup>26</sup> (*See, e.g.*, Final Invalidity Contentions 106, 129–30, 142 Doc. No. 918-3 (relying on Quinn and Herts as prior art).)

<sup>&</sup>lt;sup>27</sup> See, e.g., *GREE*, *Inc. v. Supercell Oy*, No. 2:19-cv-310, 2021 U.S. Dist. LEXIS 28109, at \*7–8 (E.D. Tex. Feb. 16, 2021) (unpublished) (recognizing that an expert was allowed "to provide additional details and examples for a previously disclosed invalidity theory relating to a prior disclosed reference" and that such use was permissible).

### B. Some Citation and Discussion of Undisclosed References is Permissible

As an overarching issue, it does not appear MedComp's experts use any of the challenged references to introduce any new, undisclosed theories of invalidity. Even the references discussed above concerning PowerPICC and Lift Loc do not support any new invalidity theory; rather, their use appears consistent with the invalidity theories already asserted in MedComp's Final Invalidity Contentions. Even Bard has not argued otherwise.<sup>28</sup> Yet the cases Bard cites in support of striking expert reports generally involve (and rely on) an expert's introduction of a new theory of invalidity late in the litigation.<sup>29</sup> Although Bard is correct that MedComp's expert opinions may not introduce theories which were not set forth in the invalidity contentions, expert opinions are also not limited to a rote restatement of those contentions. Rather, "expert reports are expected to provide more information than is contained in infringement contentions."<sup>30</sup> For example, they may "include information obtained during discovery, including that provided by opposing parties," and they "must identify the facts or data considered by the witness in forming

<sup>&</sup>lt;sup>28</sup> The only new "theory" Bard expressly identifies in its motion (and this, only in its reply brief) is that Dr. Kiani asserted the Port ID patent is "invalid" for "improper inventorship." (*See* Reply 5, Doc. No. 958). Bard contends this is a new theory because MedComp's disclosed "improper inventorship" contentions only addressed priority and not invalidity. (*See id.*) But the portions of Dr. Kiani's opinion Bard references, while mentioning inventorship is "grounds to invalidate a patent," center on a priority challenge: "a common inventor was needed for Bard to obtain benefit of the March 4, 2005 filing date of the Bard '518 Provisional Application." (*See* Ex. F to Mot., Kiani opinion ¶ 186, Doc. No. 920-6 (sealed).)

<sup>&</sup>lt;sup>29</sup> (*See, e.g.*, Mot. 2, Doc. No. 918 (quoting *LoganTree LP v. Garmin Int'l, Inc.*, No. 17-1217, 2021 U.S. Dist. LEXIS 242099, at \*50 (D. Kan. Dec. 20, 2021) (unpublished) ("[A] party may not use an expert report to introduce new infringement theories, new infringing instrumentalities, new invalidity theories, or new prior art references not disclosed in the parties' infringement contentions or invalidity contentions." (citation omitted)).)

<sup>&</sup>lt;sup>30</sup> See Digit. Reg. 1, 2014 U.S. Dist. LEXIS 58113, at \*17, \*20.

their opinions."<sup>31</sup> In fact, Bard acknowledges background references that do not present new invalidity theories are permitted in expert reports.<sup>32</sup>

Turning then to Dr. Shoenfeld, Dr. Lautin, and Lois Romans, Bard's main claim is that these experts include in their opinions their own purported use (or their knowledge of use) of some of the claimed methods of the '639 patent before its priority date.<sup>33</sup> As an initial matter, Bard's motion does not make it clear that this personal use should be considered "prior art" under the local patent rules, such that MedComp should have disclosed it in its contentions.<sup>34</sup>

<sup>33</sup> (Mot. 4–5, Doc. No. 918.)

<sup>34</sup> Relevant here, the version of 35 U.S.C. § 102 applicable to patents effectively filed before March 16, 2013, defines "prior art" to include products or methods "known or used by others in this country, or patented or described in a printed publication in this or a foreign country." 35 U.S.C. § 102(a). Similarly, LPRs 2.4(d) and 3.2(d) require identification of prior art in a party's invalidity contentions if the item has been "offered for sale or publicly used or known." In *Carella v. Starlight Archery & Pro Line Co.*, 804 F.2d 135, 139 (Fed. Cir. 1986), the Federal Circuit recognized that the statutory language "known or used by others" in 35 U.S.C. § 102(a) has been determined to mean that it was "knowledge or use which is accessible to the public."

<sup>&</sup>lt;sup>31</sup> (*See id.* at \*19 (internal quotation marks and alterations omitted); *see also* Tr. of Hr'g 18:3–13 (June 22, 2021), Doc. No. 706 (acknowledging that "obviously, an expert report is going to have background, is going to explain technology, et cetera, et cetera. . . . [T]he local patent rules don't contemplate that an expert report is limited to whatever number of documents are cited in the infringement contentions").)

<sup>&</sup>lt;sup>32</sup> (See Reply 8, Doc. No. 958 (quoting *Illumina Inc. v. BGI Genomics Co., Ltd.*, No. 20-cv-01465, 2021 U.S. Dist. LEXIS 162838 (N.D. Cal. Aug. 27, 2021) (unpublished), for the proposition that additional background was permissible because it did not present a "new invalidity theory" but rather was "further evidentiary support for the theory previously disclosed," and *Celgene Corp. v. Hetero Labs Ltd.*, No. 17-3387, 2021 U.S. Dist. LEXIS 159262 (D.N.J. June 15, 2021) (unpublished), for the idea that LPR disclosure requirements prevent a party from using an expert report "to introduce new infringement theories, new infringing instrumentalities, new invalidity theories, or new prior art references not disclosed in the parties' infringement contentions or invalidity contentions").)

While it may be that the experts' prior use was "public,"<sup>35</sup> Bard has not established the experts' references to their own use was both "public" *and* offered as a prior art basis for their invalidity opinions. Nor has Bard cited any legal authority to support striking an expert's prior use based on the failure to make a pre-expert report disclosure concerning such use.<sup>36</sup> In the expert opinions at issue, it appears such use is either (1) cited to support the experts' discussion as to what a person of ordinary skill in the art knew or should have known at the time, or (2) used to corroborate or validate the invalidity contentions taught by the disclosed prior art references, particularly the Herts and Quinn references. It also appears the use, and the experts' knowledge or practice of such use, may be relevant to MedComp's inequitable conduct affirmative defense—which is not expressly subject to the prior art disclosure obligations of the local patent rules. For these reasons, the fact that MedComp did not expressly disclose the prior use of these individuals in its invalidity contentions does not necessarily require the references be stricken.<sup>37</sup>

During upcoming expert discovery, Bard will be able to probe these experts as to their actual prior use and explore how such use supports their expert testimony. Bard may have

<sup>&</sup>lt;sup>35</sup> See Minn. Min. & Mfg. Co. v. Rsch. Med., Inc., 679 F. Supp. 1037, 1049 (D. Utah 1987) (finding public use where practicing surgeons shared ideas concerning prior art with other surgeons and citing cases addressing visitors or other third parties being exposed to the use).

<sup>&</sup>lt;sup>36</sup> Under Rule 703 of the Federal Rules of Evidence, an expert's opinion may be based on "facts or data in the case that the expert has been made aware of *or personally observed*." Fed. R. Evid. 703 (emphasis added).

<sup>&</sup>lt;sup>37</sup> See, e.g., *Finjan, Inc.*, 2018 U.S. Dist. LEXIS 14952, at \*12 (denying a motion to strike an expert's use of an undisclosed research thesis, noting that it was not used as prior art to establish invalidity but to "demonstrate[] background information about the technology at issue and the state of the art at the relevant time"); *Ziilabs Inc.*, 2015 U.S. Dist. LEXIS 158549, at \*11 (permitting the use of undisclosed prior art references in an expert report so long as they were used as "(1) background material relevant to the technology at issue; (2) state of the art; and (3) establishing what one of skill in the art would have known at the time of the invention").

challenges to that testimony after expect discovery has been completed—but it will likely be a merits challenge, not a "nondisclosure" challenge of the sort raised here. The appropriate forum and manner for any such challenge is before the district judge, either at trial or through a pretrial motion in limine or *Daubert* challenge. At this stage (before expert discovery is complete), it is sufficient that the experts' prior use and experience relates to what a person of ordinary skill would have known or validates or corroborates the experts' opinions on invalidity and obviousness (which are based, in part, on other disclosed prior art references or rely on other experts' opinions).<sup>38</sup>

Furthermore, as noted above, Bard has not established how any of the references it challenges, such as the prior use references discussed above, add any new invalidity theories to MedComp's contentions. For example, the experts' discussion of the use of power injection (in prior Bard ports or non-Bard ports before 2005) dovetails with the assertion in MedComp's Final Invalidity Contentions that Bard and others in the field knew of this use before Bard sought and received its patent.<sup>39</sup> In addition, MedComp's contentions assert that the Herts prior art

<sup>&</sup>lt;sup>38</sup> (See, e.g., Ex. B to Mot., Shoenfeld opinion ¶¶ 27, 28, 48, 85, 94, 97, Doc. No. 920-2 (sealed) (relying on Herts and on other expert opinions and discussing the principles and properties of power infusion); Ex. D to Mot., Lautin opinion ¶¶ 23, 36, Doc. No. 920-4 (sealed) (citing Herts); Ex. E to Mot., Romans opinion ¶¶ 32–42, 75–77, Doc. No. 920-5 (sealed) (discussing uses of contrast media and mechanical injectors in ports and relying on other experts' opinions).)

<sup>&</sup>lt;sup>39</sup> (*See, e.g.*, Final Invalidity Contentions 100, Doc. No. 920-7 (sealed) (disclosing as invalidity contentions that: (1) before 2005, Bard was "aware of the public sale and use of the Vortex port, its use of power injection, and its ability to withstand power injection"; (2) the Vas-a-Cath or Port-a-Cath ports were "used in power injection procedures prior to 2005"; (3) Bard "knew that the use of power injection via prior art ports 'is common' prior to 2004"; (4) Bard knew that commercially available ports "were 'capable of withstanding power injection"; and (5) "prior to 2005 clinicians were 'power injecting through non-indicated ports at their facility").) Bard did not object to these contentions.

reference teaches that the BardPort and other commercially available ports were used for power injection before 2005.<sup>40</sup> Thus, the experts' recitation of how they used or knew of the use of power injection in ports before 2005 does not introduce a new invalidity theory.<sup>41</sup>

MedComp also asserts that its experts may cite to and discuss references contained within the disclosed prior art references.<sup>42</sup> Bard argues that allowing the experts to do so would render meaningless the ten-prior-reference limit.<sup>43</sup> Although Bard does not cite any legal authority supporting this broad proposition, it has practical appeal.<sup>44</sup> Allowing MedComp to rely on any reference cited in a permitted and disclosed prior art reference, as additional prior art, would exponentially increase the prior art limits set by the local patent rules. Rather than streamlining the invalidity dispute for trial, such a practice could make it unmanageable. The local patent rules were adopted for a purpose. The structure of local patent rules 2.4(d), 3.2(b), 7.1(a)(2), and 7.1(b)(2) reflects a narrowing process, requiring the parties to move from a broad set of prior art references to a narrower set, ultimately identifying the most relevant prior art references to be presented to the factfinder. Allowing MedComp's experts to rely on an innumerable number of

<sup>42</sup> (Def.'s Resp. to Renewed Mot. to Strike 5–6, Doc. No. 951.)

<sup>43</sup> (Reply 3, Doc. No. 958.)

<sup>&</sup>lt;sup>40</sup> (*See id.* at 118–19, 290.)

<sup>&</sup>lt;sup>41</sup> See, e.g., Celgene Corp., 2021 U.S. Dist. LEXIS 159262, at \*48–50 (noting that undisclosed references may be used to specifically articulate a prior disclosed invalidity theory or where the reference is to "expand on theories previously set out" in the contentions).

<sup>&</sup>lt;sup>44</sup> See, e.g., Celgene Corp., 2021 U.S. Dist. LEXIS 159262, at \*80 (observing that an "incorporated by reference" approach to prior art disclosures would turn the potential number of prior art references into the "hundreds" and is "hardly a means of complying with a Local Patent Rule aimed at clarity and notice to the opposing party of what prior art references will be relied upon to claim that the patent is invalid").

additional references as prior art to establish invalidity, solely because they were listed or mentioned in the actual prior art references MedComp disclosed, would frustrate that goal. Accordingly, as a general matter, use of those references as "prior art" is impermissible. But that is not to say all these citations or references must be stricken from the experts' opinions.

Several of these references, such as the Vas-a-Cath, Vortex, and Port-a-Cath, are products and documents that were both identified in some of MedComp's prior art references and disclosed in MedComp's Final Invalidity Contentions<sup>45</sup> and pleadings.<sup>46</sup> A fair reading of MedComp's Final Invalidity Contentions put Bard on notice that these references do not advance new invalidity theories, and it should be no surprise to Bard that MedComp's experts considered them. Moreover, these references were cited so early in this litigation (some as early as September 2017), that Bard was aware of them and was in a position to seek discovery concerning them. This greatly diminishes Bard's claims of prejudice.<sup>47</sup>

<sup>&</sup>lt;sup>45</sup> (*See, e.g.*, Final Invalidity Contentions 8, 100–102, 134, 153, 174, 196, 220 (identifying Vas-a-Cath); 18, 100, 128, 134, 153, 155–61, 164–67, 169–74, 290 (identifying Port-a-Cath); 8, 17–18, 100–02, 134, 153, 174, 196, 220 (identifying Vortex), Doc. No. 920-7 (sealed).) Moreover, Bard's DIS document (BARD\_MEDCOMP\_00023916–28), which was expressly disclosed as prior art, was described as "discussing the features and uses of the Vortex Port, Bard's prior art ports, and the Vas-a-cath port." (*See id.* at 101.)

<sup>&</sup>lt;sup>46</sup> (*See, e.g.*, Def.'s Am. Countercls. ¶¶ 61, 69, 78-81, 85, 87, 147, 155, 164–67, 171, 173, 227, 235–36, 244–47, 251, 253, 255–56, 260, 262, 325, 333 (identifying Vortex) (filed Sept. 17, 2017), Doc. No. 40; *id.* ¶¶ 61, 65, 84, 147, 151, 155, 171, 227, 231, 235–36, 240, 244, 250–51, 253, 259-60, 262, 329, 333, 348, 349, 351, 418, 422, 437–38, 440 (identifying Port-a-Cath).).

<sup>&</sup>lt;sup>47</sup> See, e.g., *TQ Delta, LLC v. Adtran, Inc.*, No. 14-954, 2019 U.S. Dist. LEXIS 155470, at \*8–9 (D. Del. Sep. 12, 2019) (unpublished) (denying the plaintiff's motion to strike expert reports on invalidity and finding lack of prejudice because: (1) experts are entitled to cite background references; (2) the plaintiff itself produced all but two of the references and all the references were publicly available; and (3) some of the references establish background knowledge of a person of ordinary skill in the art—and what a person of ordinary skill in the art would have known is crucial to an invalidity analysis).

Similarly, Bard takes issue with the experts' citations to the Carlson and Gebauer articles.<sup>48</sup> But not only did MedComp disclose both references early in this action, it also provided Bard with copies of them.<sup>49</sup> As MedComp points out, Bard also affirmatively produced copies of these articles in this action.<sup>50</sup> And some of the references Bard objects to are its own products. MedComp's experts' consideration of Bard's own ports and infusion kits does not introduce any new theory of invalidity (and Bard has not argued otherwise).<sup>51</sup>

For the most part, it appears MedComp's experts cite these products and references: as background material; in reference to state of the art in ports and infusion sets; to outline the history of power injection use; as support for what a person of ordinary skill in the art would have known; or to corroborate the disclosed references they rely on for their invalidity opinions, such as Herts and Quinn. Such citations and references are permissible.<sup>52</sup>

<sup>48</sup> (*See* Mot. 9, Doc. No. 918; Reply 2, Doc. No. 958.)

<sup>50</sup> (See, e.g., BARD MEDCOMP 00030520-26; BARD MEDCOMP 00824427 & 00824677.)

<sup>51</sup> Courts recognize expert reports "may include information obtained during discovery, including that provided by opposing parties," even if that information was not disclosed in the infringement contentions. *See Digit. Reg. 1*, 2014 U.S. Dist. LEXIS 58113, at \*19–20.

<sup>&</sup>lt;sup>49</sup> (*See, e.g.*, Def.'s Third Am. Ans. ¶¶ 158, 232, Doc. No. 148; Def.'s Third Am. Countercls.
¶¶ 30–32, 74, 76, 78–81, 85–86, 93, 189, 204 (citing Gebauer); ¶¶ 29, 60–61, 74, 78, 80, 85–86, 89, 93, 189, 220 (citing Carlson), Doc. No. 148; Ex. V to Am. Ans., Carlson article, Doc. 148-3; Ex. W to Am. Ans., Gebauer article, Doc. No. 148-4; *see also* Fifth Am. Ans. ¶ 158, Doc. No. 806.)

<sup>&</sup>lt;sup>52</sup> See GREE, 2021 U.S. Dist. LEXIS 28109, at \*2, 7–8; *TQ Delta*, 2019 U.S. Dist. LEXIS 155470, at \*8–9; *Finjan, Inc.*, 2018 U.S. Dist. LEXIS 14952, at \*11; *Ziilabs*, 2015 U.S. Dist. LEXIS 158549, at \*2, 11; *Genentech*, 2012 U.S. Dist. LEXIS 16959, at \*12–13; *Digit. Reg. 1*, 2014 U.S. Dist. LEXIS 58113, at \*12; *Verinata Health*, 2014 U.S. Dist. LEXIS 155470, at \*16; *see also Tech Pharmacy Servs., LLC. v. Alixa Rx LLC*, No. 4:15-cv-766, 2017 U.S. Dist. LEXIS 122230, at \*9–10 (E.D. Tex. Aug. 3, 2017) (unpublished) (refusing to strike expert reference "as long as [the expert] uses it to establish knowledge of a POSITA and not as invalidating prior art").

It bears repeating, however, that while MedComp's experts are not barred from discussing and citing these references in their expert opinions in such a manner, they may not base their invalidity opinions on any undisclosed references. If it later develops (following further expert discovery or in pretrial processes) that MedComp's experts are using these references as "prior art" or in some other improper manner, Bard may challenge such use in pretrial motions in limine or at trial.<sup>53</sup> But Bard has not established these references should be stricken now.

Deferring such a determination until trial (or until motions in limine are addressed) is supported by the local patent rules. Under patent rule 7.1(a)(2), MedComp must limit the number of prior art references it will use in support of its invalidity theories "to a manageable subset" of the ten previously identified prior art references. And under patent rule 7.1(b)(2), presumptively, this manageable subset of prior art references is three. In other words, under patent rule 7.1, presumptively, only three of the prior art references the expert relied on may be used at trial. "Background references in an expert report can provide useful context to the court in understanding the expert's opinion, but they do not thwart the goal of limiting the scope of litigated issues to a manageable level, because they do not expand the number of prior art

<sup>&</sup>lt;sup>53</sup> See, e.g., Genentech, 2012 U.S. Dist. LEXIS 16959, at \*12 n.15 (noting that if the plaintiff intends to use the undisclosed reference at trial to assert invalidity, "the undersigned leaves it to the presiding judge any further determination of whether [plaintiff's] effort is proper"); *see also Tech Pharmacy Servs*, 2017 U.S. Dist. LEXIS 122230, at \*9–11 (denying a motion to strike an undisclosed reference in expert report but advising the defendant that because the reference was allowed for a limited purpose, the expert must be careful not to use the knowledge of the person of ordinary skill in the art as a "backdoor" for introducing the reference as invalidating prior art—and further noting that "vigorous cross-examination, a presentation of contrary evidence, and a careful instruction on the burden of proof for proving invalidity serve as better remedies than excluding [the expert's] testimony").

references that must be addressed by the plaintiff's expert and, if the case ultimately goes to trial, presented to the jury."<sup>54</sup> The identification of what "final" prior art references may be used at trial, and, relatedly, how they may be used, is to be determined at a much later date.

Finally, a brief word about prejudice. Bard asserts it has been prejudiced because it has been surprised by these new references and is now unable to take discovery related to them.<sup>55</sup> As noted above,<sup>56</sup> Bard's prejudice claim is greatly weakened by the fact that many of the purported new references cited by MedComp's experts were identified in MedComp's pleadings and invalidity contentions,<sup>57</sup> were produced by Bard in discovery, or appear to be Bard's own products. Although Bard argues in its reply brief that "the vast majority of MedComp's new references are not Bard products,"<sup>58</sup> Bard does not identify which references are not its own products. A review of the expert opinion of Dr. Cooper reveals that many of the products he references (which are also referenced by Drs. Kiani and Shoenfeld) are, in fact, Bard products

<sup>56</sup> (*See supra* at 13–14 & n.37–41.)

<sup>57</sup> MedComp correctly points out that some of the additional prior art references cited by their experts were disclosed within the prior art references included among its Final Invalidity Contentions. For example, the Vas-a-cath and Vortex ports were identified and described in the DIS reference that was disclosed as a prior art reference to the '639 patent and were disclosed in MedComp's Final Invalidity Contentions, and the BardPort SlimPort, the Bard Implantable Port, the Bard Titanium Implantable Port, the Port-a-cath, and the LiftLoc (all of which are Bard products) were all referenced or discussed by MedComp in its Final Invalidity Contentions. Although these Final Infringement Contentions were served on May 18, 2023, Bard did not lodge any objection to them.

<sup>58</sup> (See Reply 10, Doc. No. 958.)

<sup>&</sup>lt;sup>54</sup> Bos. Sci. Corp. v. Cook Grp. Inc., No. 1:17-cv-03448, 2022 U.S. Dist. LEXIS 38423, at \*9 (S.D. Ind. Mar. 3, 2022) (unpublished).

<sup>&</sup>lt;sup>55</sup> (See Mot. 10, Doc. No. 918.)

(such as the PowerPICC, LiftLoc, MiniLoc, Bard Adult Titanium Port, and BardPort) and appear to have been presented by Bard to the Food and Drug Administration, presented by Bard in connection with its own patent prosecutions, or identified in Bard's own infringement contentions. Moreover, expert discovery has not closed. Bard remains free to depose MedComp's experts to discover information about their use of these references.

#### **CONCLUSION**

For the reasons discussed above, and as limited above, Bard's motion<sup>59</sup> is denied in part and granted in part. It is denied insofar as Bard seeks to strike specific portions of the expert reports, but is granted (1) insofar as Bard seeks a ruling that MedComp's experts may not base their invalidity opinions on any undisclosed prior art references and (2) to the extent Bard seeks to prevent MedComp's experts' reliance on the underlying references mentioned, contained, or cited within MedComp's disclosed prior art references—as prior art to establish invalidity because using these underlying references as prior art to establish invalidity is impermissible.

DATED this 12th day of March, 2024,

BY THE COURT:

Gapline A. Olierg

United States Magistrate Judge

<sup>&</sup>lt;sup>59</sup> (Mot., Doc. No. 918.)