

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

BOSTON SCIENTIFIC CORP. and)	
BOSTON SCIENTIFIC SCIMED, INC.,)	
)	
)	
Plaintiffs,)	
)	
v.)	No. 1:17-cv-03448-JRS-MJD
)	
COOK MEDICAL LLC,)	
)	
Defendant.)	

Order on Various Matters

In anticipation of trial, Plaintiffs, Boston Scientific Corp. and Boston Scientific SciMed, Inc., filed a Motion to Narrow Issues for Trial, (ECF No. 1081), which is now before the Court. Additionally, the Court will address several issues discussed at the May 25, 2023, telephonic pretrial conference.

A. Exclusion of Barry Slowey from Cook's Witness List

On May 1, 2023, Boston Scientific moved to strike Barry Slowey from Cook's trial witness list. (ECF No. 1020.) Although Slowey was identified in Rule 26 disclosures and appeared on various witness lists, he was not listed as a trial witness in Cook's final witness list leading up to the originally scheduled February trial. After an emergency continuance, and upon the Court's request that the parties provide updated trial documents to *narrow* issues and streamline litigation, Cook filed an updated Final Trial Witness List adding Slowey. (ECF No. 1010.) The Court withheld ruling on Boston Scientific's Motion pending discussion at the May 25 telephonic conference. (See ECF No. 1076.)

At the conference, Cook urged the Court that it "needs" Slowey as a witness because Cook would be prejudiced if Slowey, who will be present at trial and who will testify via deposition in Boston Scientific's case-in-chief, is precluded from testifying in Cook's own case-in-chief. Cook argues that the jury in that scenario would be confused and potentially draw adverse inferences against Cook since Slowey, the president of Cook's endoscopy division, would be seated at trial but would not have a "voice" of his own. Notwithstanding that the jury in fact will hear from Slowey via deposition testimony and that Boston Scientific stated it would not make an "empty chair" argument to the jury in any event, these same set of circumstances existed in February, when Slowey was not listed as a witness a mere three days before trial. This argument does not justify the addition of Slowey now.

Cook additionally argues in conclusory fashion that "circumstances have changed" since the Court's summary judgment order such that Slowey's testimony (as opposed to the testimony of Ms. Martinez-Smith on the same topics) is necessary. However, without actually examining the testimony Cook plans to elicit from Slowey, it is difficult for the Court to determine how the circumstances since February have changed. Cook urges, at least in part that the summary judgment order would be used by Boston Scientific to argue willfulness. Again, this is not a change in circumstance in that the order issued prior to the emergency continuance, in that the order made no mention of willfulness, in that Boston Scientific stated it would not be citing to the Court or the order, and in that Boston Scientific would have been arguing willfulness even absent the order. In short, no showing has been made as to why

Slowey's testimony is now necessary, almost four months after the original trial date much less as to why he would be more appropriate than the originally designated witness, Ms. Martinez-Smith, who will also be testifying at trial on other issues.

Even if the Court allows Slowey's addition, the issue of the *scope* of his testimony remains. In Cook's disclosures, Slowey was only designated as knowledgeable about "[s]ubjects for which Mr. Slowey was designated as a Rule 30(b)(6) witness in this action [i.e., document retention], as well as the subjects addressed during Mr. Slowey's [2017] deposition." (ECF No. 1019-4 at 7.) And when asked to disclose "the individuals having primary responsibility for the engineering, design, development, testing, regulatory approval, manufacturing, marketing, and sales of the [Accused Products]," (*see* ECF No. 1019-5), Cook did not list Slowey. For at least this reason, Boston Scientific did not depose Slowey again. Now, Boston Scientific is worried that if Slowey is allowed as Cook's witness, he will testify on issues for which he was not disclosed: e.g., the development of the Instinct Plus (which was not released until well after Slowey's 2017 deposition), recent market conditions, and Defendant's state of mind as to continued infringement post-2019. The Court agrees that if Slowey is permitted to testify at all, he can only do so on "[s]ubjects for which [he] was designated as a Rule 30(b)(6) witness in this action, as well as the subjects addressed during Mr. Slowey's deposition." But without examining the testimony that Cook plans to elicit, the Court cannot rule on whether the testimony is within the scope of Cook's initial disclosures.

For these reasons, the Court **defers ruling on** Boston Scientific's Motion to Strike. (ECF No. 1020.) Instead, the parties have indicated they will disclose witness batting orders the night before each day of trial. (See ECF No. 1088.) On the night before Cook plans to call Slowey to testify (or earlier if Cook is prepared to proffer his testimony sooner), Cook will proffer Slowey's testimony, which will be subject to follow-up by Boston Scientific and then a ruling by the Court as to whether Slowey can testify and the scope of any such testimony.

B. Reliance on Cook's Own Patents for Written Description Defense

The Court had previously withheld ruling on Boston Scientific's Motion in Limine No. 8 regarding whether Cook can reference its own patents when arguing its written description defense. (See ECF No. 982.) The Court heard argument on the issue at the telephonic conference. For the following reasons, Cook is precluded from relying on its own patents for its written description defense.

"To satisfy the written description requirement, a patent's specification must 'reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.'" *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). "Such possession must be 'shown in the disclosure.'" *Id.* Generally, "[w]hen determining whether a specification contains adequate written description, one must make an 'objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.'" *Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011) (citation omitted).

Despite the "four corner inquiry," Cook contends that extrinsic evidence may be admitted in the written description context. Broadly, that may be true, though the law has recently been muddled. *See Biogen Int'l GMBH v. Mylan Pharms. Inc.*, 18 F.4th 1333 (Fed. Cir. 2021) (affirming district court finding of invalid written description wherein the district court had relied, in part, on extrinsic evidence). *But see Biogen Int'l GMBH v. Mylan Pharms. Inc.*, 28 F.4th 1194, 1202 (Fed. Cir. 2022) (Lourie, J., dissenting) (urging a rehearing en banc to ensure that courts do not misinterpret *Biogen* to allow extensive reliance on extrinsic evidence in the written description context). Regardless, extrinsic evidence must still be *relevant* to the written description inquiry to be admissible. *See, e.g., id.*

Here, Cook's own patents have absolutely *no bearing* on whether Boston Scientific's Asserted Patents contained an adequate written description. Cook's argument is understood to be: (1) if Cook's Instinct and Instinct Plus infringe Boston Scientific's patents, then by definition, those patents cover Cook's products; (2) yet, Cook was able to obtain a patent (subsequent to the patents-in-suit) that also covers the Instinct and Instinct Plus; (3) thus, because the Patent Office granted Cook's patent over Boston Scientific's asserted patents, this is evidence supporting a lack of adequate written description in the Boston Scientific patents. Stated differently, had Boston Scientific's patents adequately disclosed the Instinct/Instinct Plus (which are covered by the Asserted Claims), then Cook's patent would have been denied. This is a legally flawed argument. Cook's patent (which can be narrower and claim additional features) can issue subsequent to Boston Scientific's patent and still be

valid even if a single product is covered by both patents. For example, assume Boston Scientific's patent claims features A, B, and C and Cook's patent claims A, B, C and D. If the Instinct contains features A, B, C, and D, then it is covered by *both* patents. The Boston Scientific patent can adequately disclose claimed features A, B, and C in satisfaction of the written description requirement without then acting as prior art that prevents Cook's patent from issuing. After all, the Boston Scientific patent does not disclose feature D which would be needed to impede Cook's patent. Even if it did, this might be reason to question the validity of Cook's patent rather than the validity of Boston Scientific's patent. *See PSC Comput. Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004) (holding that a disclosed but unclaimed invention is dedicated to the public). The operative question is whether the written description of Boston Scientific's patent is sufficient to support a finding that the inventor was in intellectual possession of the invention embodied in its asserted claims.

Cook's own patents have no relevance to whether Boston Scientific's patents have an adequate written description; Cook is **precluded** from relying on its patents for that defense.

C. Motion to Narrow Issues for Trial

Boston Scientific's Motion to Narrow Issues for Trial, (ECF No. 1081), seeks a ruling on four issues: (1) whether Cook and its witnesses should be barred from stating that it relied on the advice of counsel; (2) whether Cook can present a prosecution laches defense; (3) whether Cook can argue that adverse events and

product recalls relate to damages; and (4) whether trial should be bifurcated.¹ The Court addresses each in turn.

1. Reliance on Advice of Counsel

The Court previously precluded "[Cook] and its witnesses from suggesting that they *relied* on the advice of counsel *to form the basis of [Cook's] good faith belief of noninfringement, thus rebutting an allegation of willful infringement.*" (ECF No. 982 at 3 (emphasis added).) Boston Scientific now contends that Cook is violating that order through its counter designations to Boston Scientific's witness by deposition, Vihar Surti. The Court is not persuaded.

First, Cook has repeatedly indicated that it will not assert an advice of counsel defense at trial, and there is no reason for the Court to think otherwise. Second, Surti is a witness that Boston Scientific itself, not Cook, plans to introduce via deposition. Under Fed. R. Civ. P. 32(a)(6), Cook is allowed to "require the offeror to introduce other parts that in fairness should be considered with the part introduced." Of course, these counter designations must still not run afoul of the Court's orders, but the Court does not find that they do so here.

Boston Scientific cites several of Cook's counter designations from Surti's deposition as purported violations of this Court's motion in limine ruling. None are convincing. For example, Cook counter designates the following question and answer from Boston Scientific's counsel: "During the development of the Instinct Plus, do you recall any moments in which someone at Cook made any comments relating to

¹ Cook's timeliness argument as to Boston Scientific's Motion is not frivolous; however, because both parties have filed several motions leading up to trial, it is best to resolve these disputes on their merits.

ensuring that the Instinct Plus did not infringe any Boston Scientific patent?" (ECF No. 1002-7.) Surti responds, "There's a conversation between a patent attorney and an engineer." Of all of Boston Scientific's citations, this testimony is the closest to being improper, yet it does not rise to an assertion by Cook that it relied on counsel for a good faith belief that it was not infringing Boston Scientific's patents. At most, this testimony suggests that counsel "made comments" related to "ensuring that the Instinct Plus did not infringe any Boston Scientific patent." But a juror would not know the substance of these "comments," and they do not imply a reliance on counsel for a good-faith defense. For all the juror knows, Cook's counsel may have told the engineer that the Cook products *did* potentially infringe Boston Scientific's patents. In any event, Cook is still **precluded** from making an argument to the jury that Cook relied on an opinion of counsel of noninfringement, and its witnesses may not suggest that they relied on the advice of counsel to show a good faith belief of noninfringement.

Accordingly, the motion to preclude Cook's counter designations as to Vihar Surti is **denied**.

2. Prosecution Laches

Boston Scientific next seeks to preclude Cook from asserting its prosecution laches defense. This motion, which is tantamount to a motion for summary judgment, is untimely, the deadline for summary judgment motions having already expired. Cook may present the prosecution laches defense to the Court at the appropriate time. *See infra* Section C.4.

As for Boston Scientific's argument that "there is no legal basis for Cook's prosecution laches defense" because the patents were filed post-GATT (General Agreement on Tariffs and Trade), (ECF No. 1082 at 8; *see also Cancer Rsch. Tech. Ltd. v. Barr Lab'ys, Inc.*, 625 F.3d 724, 732 (Fed. Cir. 2010)), courts still allow defendants to assert it, *see, e.g., Seagan Inc. v. Daiichi Sankyo Co.*, No. 2:20-CV-00337-JRG, 2022 WL 2789901, at *4–5 (E.D. Tex. July 15, 2022).

Cook may present a prosecution laches defense during the equitable phase of the trial.

3. Adverse Events and Product Recalls

Boston Scientific argues that Cook should be precluded from arguing that product recalls and adverse events relate to damages, asking the Court to revisit its ruling on Boston Scientific's MIL No. 7. The Court found such evidence relevant to damages. (ECF No. 982 at 8.) At the final pretrial conference, Cook represented that it had evidence of a product recall but that it would not present such evidence unless Cook's expert, Dr. Ginsberg, could support the relevance of the evidence to the damages period.² (Transcript of Final Pretrial Conference at 202:17–203:6, ECF No. 951.) Dr. Ginsberg's testimony does not support the relevance of that particular product recall evidence. (ECF No. 1031-1 at 13.)

Without testimony tying that product recall to the damages period, evidence of the product recall is no longer relevant. The Court thus **reconsiders** its ruling on

² Cook did not represent that it would present no evidence implicated by MIL No. 7 unless Dr. Ginsberg supported relevancy. Instead, Cook made a representation about a particular product recall that occurred before the damages period.

Boston Scientific's MIL No. 7 to the extent that Cook and its witnesses are **precluded** from offering evidence and argument regarding the product recall for Resolution II, which the Court understands occurred before the damages period.

Boston Scientific further argues that the dismissal of all claims asserted under the '371 patent defeats the relevance of all product recalls and adverse events. Despite that dismissal, evidence of product recalls (other than the particular recall referenced above) and adverse events remains relevant to damages because Boston Scientific still seeks to recover lost profits damages based on its Resolution clip sales. And any potential prejudice may be cured with an appropriate jury instruction. *See Abbott Lab'ys v. Sandoz, Inc.*, 743 F. Supp. 2d 762, 786–87 (N.D. Ill. 2010). Accordingly, Boston Scientific's motion to otherwise reconsider the Court's ruling on MIL No. 7 as to adverse events and any product recalls during the damages period related to products other than Resolution II is **denied**.

4. Bifurcation of Trial

Cook previously moved for an order allowing Cook to present evidence to the jury regarding issues to be decided by the bench. Cook argued that the evidence on these issues significantly overlaps with its evidence on noninfringement and invalidity based on prior art, which are jury issues, so it would be most efficient to present the evidence relating to bench issues to the jury.

Boston Scientific's response was largely that the equitable issues should not be referred to an advisory jury. At the time, Boston Scientific never disagreed with Cook's assertion that the evidence on the equitable issues overlaps with the evidence

on the jury issues. Relying on Cook's assertion of significant overlap of evidence on equitable and jury issues, and after weighing the benefits of presenting such overlapping evidence to the jury against the risk of unfair prejudice to Boston, the Court granted Cook's motion. (Order on Motion Regarding Evidence Presented to Jury on Issues to be Decided by the Bench, ECF No. 971.)

Boston's Motion to Narrow Issues for Trial asks the Court to take evidence *solely* related to equitable issues outside the presence of the jury. Boston's Motion is in accord with the Court's reasoning for granting Cook's motion in the first instance: evidence related to equitable issues that overlaps with evidence related to legal issues may be presented to the jury. Boston does not oppose the presentation of evidence to the jury that relates to an equitable issue as well as a legal issue, but suggested at the May 25 pretrial conference that any overlapping evidence is minimal. Also at the conference, Cook said it had no objection to presenting "purely equitable" evidence—evidence solely related to an equitable issue—outside the jury's presence.

The Court's ruling on Cook's Motion Regarding Evidence Presented to the Jury was made immediately following the order on summary judgment and immediately prior to the then February 6, 2023, trial date. The passage of time, Cook's inability to provide concrete examples of overlapping evidence laid against Boston's ability to provide examples that the purported "overlapping" evidence is actually distinctly severable (e.g., prior art offered for invalidity is different than prior art offered for inequitable conduct), has allowed for reconsideration, which is warranted here.

"[A]llegations of inventor misconduct before the USPTO relevant to an inequitable conduct defense, while irrelevant to infringement, may influence a jury's decision on that issue by suggesting that the inventor is untrustworthy." Patent Case Management Judicial Guide, Third Edition (2016) at § 8.1.1.1.2. A limiting instruction may alleviate the prejudice to Boston, but removing the evidence from the jury's consideration eliminates all risk of any prejudice. Presenting evidence *solely* related to equitable issues outside the jury's presence also will conserve juror resources and "will avoid jury confusion and ensure that the jury's decision is based on proper and relevant evidence." *Id.*

The evidence that relates solely to equitable issues is minimal. Cook stated at the conference that it has only one live witness and three witnesses by deposition testimony that will offer such evidence. Presenting those witnesses' testimony and other evidence outside the jury's presence poses no obstacle to the presentation of evidence. Moreover, it now seems that the "overlap" in the evidence that relates both to equitable issues and to legal issues may not be as significant as the Court once thought. Witnesses who have evidence that relates to jury issues and other evidence that relates to equitable issues can be held over during a lunch or other break, or testify at the beginning of the day or the end of the day to provide the evidence related to the equitable issues outside the jury's presence. This will allow for the efficient and orderly presentation of evidence. As for evidence that relates both to legal issues and to equitable issues, even if subject to objection as to whether it is actually overlapping or dual in nature, there is no risk of having to repeat evidence; the Court

of necessity will hear all evidence—whether it is presented in or outside the jury's presence.

To the extent Cook still seeks to have the equitable issues tried with an advisory jury, that request is **denied**. Because Cook has no objection to presenting "purely equitable" evidence outside the jury's presence, an advisory jury is no longer feasible.

D. Conclusion

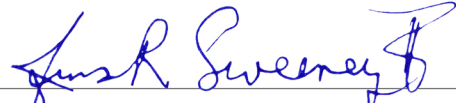
Boston Scientific's Motion to Narrow Issues for Trial, (ECF No. 1081), is **granted**. In light of that Motion as well as discussion at the pretrial telephonic conference, the Court issues the following rulings:

1. The Court **defers ruling on** Boston Scientific's Motion to Strike. (ECF No. 1020.) The Court will allow Cook to proffer the testimony it will elicit before trial, subject to Boston Scientific follow-up; whether Slowey can testify and, if so, on what issues, will then be determined.
2. Cook is **precluded** from relying on its own patents for its written description invalidity defense.
3. Cook's counter designations as to Vihar Surti are **not excluded**.
4. Cook **may** present a prosecution laches defense during the equitable phase.
5. Cook and its witnesses are **precluded** from offering evidence and argument regarding the product recall for Resolution II. Other evidence of adverse events and product recalls during the damages period are **not excluded**.
6. To the extent Cook still seeks to have the equitable issues tried with an advisory jury, the request is **denied**. Additionally, evidence related solely to

equitable issues will not be presented in front of the jury. No argument related to equitable issues will be presented to the jury.

SO ORDERED.

Date: 05/27/2023



JAMES R. SWEENEY II, JUDGE
United States District Court
Southern District of Indiana

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