

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BOSTON SCIENTIFIC CORPORATION)
and BOSTON SCIENTIFIC SCIMED,)
INC.,)

Plaintiffs/Counterclaim)
Defendants,)

v.)

Civil Action No. 15-980-LPS-CJB

COOK GROUP INCORPORATED and)
COOK MEDICAL LLC,)

Defendants/)
Counterclaimants.)

MEMORANDUM ORDER

At Wilmington this **2nd day of June, 2017**.

WHEREAS, the Court has considered the parties' letter submissions, (D.I. 219, 237, 253), relating to Defendants Cook Group Incorporated and Cook Medical LLC's (collectively, "Cook" or "Defendants") pending Motion for Leave to File an Amended Pleading ("Motion"), (D.I. 218), as well as the parties' arguments made during the May 31, 2017 teleconference with the Court;

NOW, THEREFORE, IT IS HEREBY ORDERED that:

1. Cook's Motion is DENIED without prejudice to its ability to file one further motion for leave to amend.
2. Federal Rule of Civil Procedure 15(a) provides that, other than in certain circumstances where a party may amend a pleading as a matter of course, a party may do so "only with the opposing party's written consent or the court's leave." Fed. R. Civ. P. 15(a)(2). The rule further explains that a court should "freely give leave [to amend the pleadings] when justice

so requires.” *Id.*

3. In line with the requirements of Rule 15(a), the Third Circuit has adopted a liberal approach in allowing amendments, in order to ensure that “claim[s] will be decided on the merits rather than on technicalities.” *Dole v. Arco Chem. Co.*, 921 F.2d 484, 487 (3d Cir. 1990); *see also Paoli v. Stetsler*, Civil Action No. 12-66-GMS-CJB, 2013 WL 2154393, at *3 (D. Del. May 16, 2013). The “factors [that a court should] consider in weighing a motion for leave to amend are well-settled: (1) whether the amendment has been unduly delayed; (2) whether the amendment would unfairly prejudice the non-moving party; (3) whether the amendment is brought for some improper purpose; and (4) whether the amendment is futile.” *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, Civ. No. 11-54-SLR, 2012 WL 2365905, at *2 (D. Del. June 21, 2012) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)); *see also Grayson v. Mayview State Hosp.*, 293 F.3d 103, 108 (3d Cir. 2002).

4. With regard to the first factor, the Court finds that Cook’s proposed amendment has not been unduly delayed. The Court previously extended the deadline for Defendants to plead inequitable conduct to April 28, 2017. (*See* Oral Order dated March 27, 2017). Defendants filed the instant Motion, which seeks to add an affirmative defense and counterclaim of inequitable conduct, on April 28, 2017. (D.I. 218) Because Defendants complied with the Court-imposed deadline, the Court cannot find undue delay here.

5. As to the second factor, the Court recognizes that fact discovery has closed. (D.I. 78 at 2; *see also* D.I. 237 at 5) Yet it concludes that any prejudice that Plaintiffs may suffer from the filing of Cook’s amended pleading now would be minimal. This is particularly so given the fact that the Court will accommodate reasonable requests by Plaintiffs to the extent that they

need relief from the current schedule to conduct discovery on any surviving inequitable conduct affirmative defense and counterclaim. (See Oral Order dated March 27, 2017)

6. With regard to the third factor, Plaintiffs argue that “Cook’s motion was filed for improper purposes[.]” (D.I. 237 at 5) The Court, however, does not have a sufficient record on which to make that finding. Again, Cook filed its Motion prior to the Court-imposed deadline, and, in doing so, it relied significantly on recently obtained deposition testimony in order to bolster its claims. (See *e.g.*, D.I. 218, ex. 1 at ¶¶ 147, 174, 177, 251-54, 278-82, 293-94, 296-308, 334; D.I. 219 at 2; D.I. 237, ex. 2) Though Plaintiffs fault Cook for the timing of its Motion—suggesting that Cook intentionally filed it late in the case simply to cause prejudice to Plaintiffs’ pre-trial efforts—the Court does not have enough before it to find that Cook has engaged in sharp practice here.

7. Much of the parties’ briefing focuses on the fourth factor: whether Defendants’ proposed amended pleading would be futile. “An amendment is deemed futile if it could not withstand a motion to dismiss.” *Enzo Life Scis., Inc. v. Digene Corp.*, 270 F. Supp. 2d, 484, 489 (D. Del. 2003) (citing *Satellite Fin. Planning Corp. v. First Nat’l Bank*, 646 F. Supp. 118, 120 (D. Del. 1986)); see also *Cornell Univ. v. Illumina, Inc.*, C.A. No. 10-433-LPS-MPT, 2016 WL 3046258, at *6 (D. Del. May 27, 2016). The parties here agree that the Court’s analysis as to futility “is the same as under Rule 12(b)(6)[,] [and] that all factual allegations and all reasonable inferences [drawn from the pleading] are accepted as true[.]” *Roquette Freres v. SPI Pharma, Inc.*, C.A. No. 06-540-GMS, 2009 WL 1444835, at *3 (D. Del. May 21, 2009), and so for

purposes of resolving this Motion, the Court will utilize the Rule 12(b)(6) standard as well.¹

8. In order to sufficiently plead inequitable conduct under Federal Rule of Civil Procedure 9(b), Defendants “must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the [United States Patent and Trademark Office (“PTO”).” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). The pleading “must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.” *Id.* at 1328-29. Absent “affirmative egregious misconduct[,]” not at issue here, the materiality prong of the *Exergen* test requires a “but-for” showing. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291-93 (Fed. Cir. 2011). In other words, the party making an inequitable conduct claim must show that but for an omission or misrepresentation by the patent applicant, the PTO would not have allowed a patent claim to issue. *Id.*

9. Defendants’ proposed amended pleading, as it stands, is insufficient under Rule 9(b) because it does not sufficiently articulate how the allegedly omitted information is but-for material and non-cumulative “of the information already on the record[,] by identifying the

¹ *But see Agere Sys. Guardian Corp. v. Proxim, Inc.*, 190 F. Supp. 2d 726, 736 (D. Del. 2002) (“However, while it is clear that a court *may* deny a party leave to amend a complaint, or even grant a motion to strike, based on futility, this court hesitates to undergo a rigorous 12(b)(6) analysis of the claims alleged to be futile based on less than complete briefing, especially in light of the deferential standard under which the court must consider 12(b)(6) motions. The court believes the better course is to liberally allow amendments that state a colorable claim and defer judgment as to whether they survive a motion to dismiss for failure to state a claim until such time when that motion is raised.”) (emphasis in original).

particular claim limitations that are absent from the record.” *St. Jude Med., Cardiology Div., Inc. v. Volcano Corp.*, Civil Action No. 12-441-RGA, 2014 WL 2622240, at *1 (D. Del. June 11, 2014). As the United States Court of Appeals for the Federal Circuit has stated, “[s]uch allegations are necessary to explain both ‘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.” *Exergen*, 575 F.3d at 1329-30. Instead what Cook does in its proposed pleading is describe the allegedly material prior art over the course of 188 paragraphs, (D.I. 218, ex. 1 at ¶¶ 138-325), and identify the claims that would allegedly not have issued but for the omission of the prior art, (*id.* at ¶¶ 345-49), without identifying “the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record[.]” or sufficiently and clearly “explain[ing] ‘how’ an examiner would have used [the allegedly withheld prior art] in assessing the patentability of the claims[.]” *Exergen*, 575 F.3d at 1329-30 (citations omitted). Cook leaves it to the Court to parse through all 188 paragraphs and try to make the requisite connections, if it can, with little guidance from Cook on how to do so.

10. While Defendants’ proposed amended pleading is currently insufficient, it strikes the Court that it would be possible for Defendants to better articulate how the allegedly omitted prior art would have been but-for material to the issuance of the asserted patents. Therefore, the Court will permit Defendants to file a renewed motion for leave to file an amended pleading (along with a revised proposed amended Answer and Counterclaims) by no later than **June 9, 2017**.

11. The Court also finds that the briefing limitations imposed by the Scheduling Order for motions to amend, (D.I. 17 at ¶ 9), are unfairly restrictive in this context, given that the Court

may need to engage in a Rule 12(b)(6) analysis that would ordinarily occur on resolution of a motion to dismiss. As such, IT IS HEREBY ORDERED that if Defendants choose to file a renewed motion for leave to amend, the procedures for briefing such a motion will be altered as follows: (1) Defendants' renewed motion shall be accompanied by an opening brief not to exceed seven (7) single-spaced pages; (2) by no later than **June 16, 2017**, Plaintiffs shall file an answering brief not to exceed seven (7) single-spaced pages; and (3) by no later than **June 21, 2017**, Defendants shall file a reply brief not to exceed three (3) single-spaced pages.

12. Because this Memorandum Order may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Memorandum Order. Any such redacted version shall be submitted no later than **June 9, 2017** for review by the Court, along with a motion for redaction that includes a clear, factually-detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Memorandum Order.



Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE