

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

DR. MARK A. BARRY,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 20-1787-RGA-SRF
)	
STRYKER CORPORATION, et al.,)	
)	
Defendants.)	

REPORT AND RECOMMENDATION

Presently before the court in this patent infringement action are the following motions brought by plaintiff Dr. Mark A. Barry (“Plaintiff”): (1) a motion for leave to file a first amended complaint against defendants SeaSpine Holdings Corporation, SeaSpine Orthopedics Corporation, and SeaSpine, Inc. (collectively, “SeaSpine”) under Federal Rules of Civil Procedure 16(b) and 15(a), (D.I. 123);¹ (2) a motion to strike SeaSpine’s third affirmative defense of unclean hands under Federal Rule of Civil Procedure 12(f), (D.I. 125);² and (3) a motion to strike defendant Stryker Corporation’s (“Stryker”) third affirmative defense of unclean hands, (D.I. 128).³ For the following reasons, Plaintiff’s motion to amend is DENIED. I recommend that the court DENY Plaintiff’s motion to strike SeaSpine and Stryker’s third affirmative defenses as untimely under Fed. R. Civ. P. 12(f)(2), and I recommend that the court STRIKE SeaSpine and Stryker’s third affirmative defenses *sua sponte* under Fed. R. Civ. P.

¹ The briefing associated with the pending motion to amend is found at D.I. 124, D.I. 141, and D.I. 149.

² The briefing associated with the pending motion to strike SeaSpine’s third affirmative defense of unclean hands is found at D.I. 126, D.I. 140, and D.I. 148.

³ The briefing associated with the pending motion to strike Stryker’s third affirmative defense of unclean hands is found at D.I. 129, D.I. 150, and D.I. 162.

12(f)(1) to the extent that the theories underlying those affirmative defenses sound in fraud under Fed. R. Civ. P. 9(b).⁴

I. BACKGROUND

A. Facts Regarding the Stryker Action

Plaintiff filed his case against Stryker on December 30, 2020 (the “Stryker Action”), alleging causes of action for infringement of five patents: U.S. Patent Nos. 7,670,358 (“the ’358 patent”), 8,361,121 (“the ’121 patent”), 9,339,301 (“the ’301 patent”), 9,668,787 (“the ’787 patent”); 9,668,788 (“the ’788 patent;” collectively, the “patents-in-suit”). (D.I. 1 at ¶¶ 6-30) The patents-in-suit claim a method and system for aligning vertebrae that can be used in spinal surgeries. (*Id.* at ¶¶ 6, 11, 16, 21, 26) Stryker moved to dismiss Plaintiff’s complaint, and the motion was denied on May 11, 2021. (D.I. 10; D.I. 15) Stryker filed its answer on May 25, 2021, asserting an affirmative defense of unclean hands but no counterclaim or affirmative defense alleging inequitable conduct. (D.I. 16)

In February of 2022, Stryker’s counsel confirmed that it was not presently asserting allegations of inequitable conduct and did not include any allegations of inequitable conduct in its initial invalidity contentions. (D.I. 129, Ex. 2 at 1) Plaintiff served interrogatories in August seeking the legal and factual bases for Stryker’s unclean hands defense. (*Id.*, Ex. 3 at 3) Stryker

⁴ A motion to amend the complaint is a nondispositive matter within the purview of Fed. R. Civ. P. 72(a). *See Cornell Univ. v. Illumina, Inc.*, C.A. No. 10-433-LPS-MPT, 2017 WL 89165, at *8 (D. Del. Jan. 10, 2017). Consequently, the court’s decision on Plaintiff’s motion to amend the complaint is made as a Memorandum Opinion governed by the clearly erroneous or contrary to law standard set forth in 28 U.S.C. § 636(b)(1)(A). *Id.* Plaintiff’s motions to strike affirmative defenses are dispositive, and the court’s decision on the motions to strike takes the form of a Report and Recommendation governed by the *de novo* standard of Rule 72(b) and 28 U.S.C. § 636(b)(1)(B). *See Sonos, Inc. v. D&M Holdings Inc.*, C.A. No. 14-1330-RGA-MPT, 2016 WL 4249493, at *3 n.37 (D. Del. Aug. 10, 2016).

served its responses to the interrogatories on September 14, 2022, disclosing the basis for its affirmative defense of unclean hands as follows:

Plaintiff's infringement claims should be barred for the additional reason that Dr. Barry comes to the Court with unclean hands. Dr. Barry has engaged in misconduct, namely, inequitable conduct before the Patent Office, that has an immediate and necessary relation to the equity he seeks related to Stryker's alleged patent infringement in this case. His actions are in violation of conscience that affect the equitable relations between the parties. Dr. Barry engaged in inequitable conduct by knowingly and intentionally failing to properly disclose to the Patent Office information that was material to patentability during prosecution of each of the Asserted Patents. Dr. Barry and other persons associated with prosecution of the Asserted Patents failed to disclose each of Dr. Barry's three pre-critical date, paid, public surgeries, which were individually and collectively material to the patentability to each claim of the Asserted Patents. Dr. Barry's inequitable conduct before the Patent Office relates directly to his ability to obtain the patent rights he now asserts in this case against Stryker.

(*Id.*, Ex. 1 at 8) On October 20, 2022, Stryker confirmed that it did not intend to seek leave to amend the answer to raise an inequitable conduct defense and maintained that its interrogatory response explained only the basis for its unclean hands defense. (*Id.*, Ex. 5 at 1)

On December 2, 2022, Stryker supplemented this interrogatory response to provide greater detail regarding Plaintiff's alleged misrepresentations to the U.S. Patent and Trademark Office ("PTO") and to add allegations of litigation misconduct by Plaintiff in support of its unclean hands defense. (D.I. 150, Ex. 1 at 17-23) In the supplementation, Stryker described the dates and circumstances surrounding three allegedly non-experimental surgeries performed by Plaintiff for profit before the critical date, which were not disclosed to the PTO. (*Id.*, Ex. 1 at 18, 20) Stryker's allegations of litigation misconduct stem from these same misrepresentations. Specifically, Stryker maintains that Plaintiff engaged in litigation misconduct by filing and maintaining lawsuits with knowledge that the patents-in-suit are invalid in view of the prior surgeries, alternately taking the position that the prior surgeries were or were not experimental. (*Id.*, Ex. 1 at 20-22)

B. Facts Regarding the SeaSpine Action

On June 2, 2021, Plaintiff filed a civil action against SeaSpine for infringement of the same patents-in-suit brought against Stryker (the “SeaSpine Action”). (C.A. No. 21-806-RGA, D.I. 1) After the court denied SeaSpine’s partial motion to dismiss the complaint, SeaSpine served its answer and counterclaims on February 9, 2022. (C.A. No. 21-806-RGA, D.I. 14; D.I. 17) Plaintiff moved to dismiss SeaSpine’s counterclaims but did not file a corresponding motion to strike any of SeaSpine’s affirmative defenses. (C.A. No. 21-806-RGA, D.I. 20) In response to Plaintiff’s motion to dismiss, SeaSpine amended its counterclaims as a matter of right on March 16, 2022. (C.A. No. 21-806-RGA, D.I. 25)

The SeaSpine Action was subsequently consolidated with the Stryker Action in a scheduling order entered by the court on March 21, 2022. (D.I. 43) Under the consolidated scheduling order, the deadline for amended pleadings was June 3, 2022, and the fact discovery deadline was February 17, 2023. (*Id.* at ¶¶ 3, 4(e))

1. Facts relevant to the pending motion to amend

The complaint in the SeaSpine action defines the term “SeaSpine Products” to mean “the Daytona™ Deformity System, the Daytona® Small Stature Spinal System, and any other SeaSpine instruments manufactured, sold, distributed, loaned, consigned, or otherwise used to derotate *en bloc* multiple levels of vertebrae.” (C.A. No. 21-806-RGA, D.I. 1 at ¶ 51) Consistent with this definition, Plaintiff’s first set of requests for production served in March of 2022 define the term “Defendant Product” to mean any product “intended for or capable of being used in a medical procedure to correct a spinal deformity condition including, but not limited to, the *en bloc* derotation of multiple levels of vertebrae,” including the Daytona™ Deformity System and the Daytona® Small Stature Spinal System (together, the “Daytona Systems”). (D.I.

141, Ex. 2 at 3) The discovery requests distinguish these accused instruments from the “Associated Products,” which cover “implants such as rods, pedicle screws, and set screws” and any product that is used or capable of being used with a Defendant Product. (*Id.*)

On May 25, 2022, about a week before the deadline to amend pleadings, SeaSpine served its responses to Plaintiff’s discovery requests, objecting to the production of any documents for implants or derotation systems that were not explicitly accused of infringement. (D.I. 68, Ex. A) Specifically, SeaSpine objected to requests that “seek[] materials related to products that Plaintiff has not accused of infringing any claims of the Asserted Patents, and which plainly do not infringe any claims of the Asserted Patents. Defendants will not produce information about products that are not accused of infringing any of the claims of the Asserted Patents.” (*See, e.g., id.*, Ex. A at 9)

The parties participated in a discovery dispute hearing before the District Judge on July 21, 2022. (D.I. 87) The focus of Plaintiff’s dispute was on SeaSpine’s refusal “to provide discovery on any derotation systems other than the specifically accused Daytona products.” (D.I. 68 at 1) Plaintiff stressed that information on other similar derotation systems was not publicly available, and SeaSpine should therefore be compelled to produce documents that would allow Plaintiff to assess whether additional derotation systems infringe. (*Id.* at 2) Plaintiff did not seek discovery on implant systems that could be combined with derotation systems from other product lines.

The District Judge denied Plaintiff’s motion to compel and instead ordered SeaSpine to supplement its interrogatory response to provide Plaintiff with a list of the names of SeaSpine’s product lines. (D.I. 87 at 20:7-13) From this list, the District Judge indicated that Plaintiff could perform research on additional product lines and determine whether to accuse additional

products. (*Id.*) On August 4, 2022, SeaSpine complied with the court's order by supplementing its interrogatory response to identify each of its product lines. (D.I. 79; D.I. 149, Ex. 4 at 8-10) Over the next two weeks, Plaintiff served his first and second amended identifications of accused products. (D.I. 80; D.I. 88; D.I. 109, Exs. B-C) In these identifications, Plaintiff identified the Mariner derotation system as well as the Malibu, NewPort, Atoll OCT, Sierra, and NorthStar pedicle screw systems. (D.I. 109, Ex. C)

SeaSpine refused to produce core technical documents in response to Plaintiff's second amended identification of accused products based on its position that the amended identification was inconsistent with the allegations in the complaint and Plaintiff's representations during the July 21 discovery dispute hearing. (D.I. 108, Ex. F at 1-2) SeaSpine indicated it would not produce the documents until Plaintiff amended the complaint and the infringement contentions to reflect the newly identified product lines. (*Id.*) A discovery dispute teleconference was held on October 26, 2022, and the court denied Plaintiff's motion to compel the production of core technical documents on the pedicle screw systems listed in Plaintiff's second amended identification of accused products. (D.I. 118 at 48:6-52:16) Plaintiff objected to the court's discovery ruling and moved to amend the complaint on November 9, 2022. (D.I. 123) Plaintiff's objections were subsequently overruled. (D.I. 206)

2. Facts relevant to the pending motion to strike

On March 16, 2022, SeaSpine served its answer and affirmative defenses, which included its third affirmative defense asserting equitable estoppel, waiver, unclean hands, and acquiescence. (C.A. No. 21-806-RGA, D.I. 25 at 14) SeaSpine served invalidity contentions setting forth an inequitable conduct claim on June 30, 2022. (D.I. 64) About a month later, SeaSpine notified Plaintiff that it intended to move to amend the answer to include allegations of

inequitable conduct. (D.I. 96, Ex. E) SeaSpine filed the motion to amend on August 19, 2022. (D.I. 89; D.I. 89-1 at ¶¶ 47-316) The court denied the motion on November 15, 2022, finding that SeaSpine lacked good cause to amend because it was aware of the facts underlying the proposed amendment from a document production made by Plaintiff more than two months before the expiration of the deadline to amend pleadings. (D.I. 130 at 5)

In September of 2022, Plaintiff served interrogatories seeking the legal and factual bases underlying SeaSpine's affirmative defense of unclean hands. (D.I. 126, Ex. 2 at 3) SeaSpine responded on October 20, 2022, citing its motion for leave to amend its pleading to add an affirmative defense of inequitable conduct and representing that the same legal and factual bases referenced in the motion to amend applied to SeaSpine's equitable defense of unclean hands. (*Id.*, Ex. 1 at 6)

II. LEGAL STANDARDS

A. Motion to Amend under Rules 16(b)(4) and 15(a)(2)

Rule 15(a)(2) of the Federal Rules of Civil Procedure provides that after a responsive pleading has been filed, a party may amend its pleading "only with the opposing party's written consent or the court's leave," and "[t]he court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). The decision to grant or deny leave to amend lies within the discretion of the court. *See Foman v. Davis*, 371 U.S. 178, 182 (1962); *In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). The Third Circuit has adopted a liberal approach to the amendment of pleadings. *See Dole v. Arco*, 921 F.2d 484, 487 (3d Cir. 1990). In the absence of undue delay, bad faith, or dilatory motives on the part of the moving party, the amendment should be freely granted, unless it is futile or unfairly prejudicial to the non-moving party. *See Foman*, 371 U.S. at 182; *In re Burlington*, 114 F.3d at 1434.

If a party seeks leave to amend after a deadline imposed by the scheduling order, the court must apply Rule 16 of the Federal Rules of Civil Procedure. *See WebXchange Inc. v. Dell Inc.*, C.A. No. 08-132-JJF, 2010 WL 256547, at *2 (D. Del. Jan. 20, 2010). A court-ordered schedule “may be modified only for good cause and with the judge’s consent.” Fed. R. Civ. P. 16(b)(4). “The good cause element requires the movant to demonstrate that, despite diligence, the proposed claims could not have been reasonably sought in a timely manner.” *Venetec Int’l v. Nexus Med.*, 541 F. Supp. 2d 612, 618 (D. Del. 2010). The focus of the good cause inquiry is on diligence of the moving party, rather than on prejudice, futility, bad faith, or any of the other Rule 15 factors. *See Glaxosmithkline LLC v. Glenmark Pharms. Inc.*, C.A. No. 14-877-LPS-CJB, 2016 WL 7319670, at *1 (D. Del. Dec. 15, 2016). Only after having found the requisite showing of good cause will the court consider whether the proposed amended pleading meets the Rule 15(a) standard. *See E. Minerals & Chems. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000).

B. Motions to Strike under Rule 12(f)

Rule 12(f) permits a court to “strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f). Motions brought under Rule 12(f) are generally disfavored and should not be granted “unless the insufficiency of the defense is clearly apparent.” *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 356 (D. Del. 2009) (internal quotation marks and citation omitted); *see also Fesnak & Assocs., LLP v. U.S. Bank Nat’l Ass’n*, 722 F. Supp. 2d 496, 502 (D. Del. 2010). Moreover, district courts have inherent, discretionary authority to manage their dockets and limit the number of asserted claims in the interests of economy for the court, counsel, and the litigants. *See VLSI Tech. LLC v. Intel Corp.*, C.A. No. 18-966-CFC, 2020 WL 4437401, at *1 (D. Del. Aug. 3, 2020).

III. DISCUSSION

A. Motion to Amend the Complaint

Plaintiff moves for leave to amend the complaint to expand the realm of “SeaSpine Products” beyond the Daytona Systems and comparable derotation systems identified in the operative complaint. (*See, e.g.*, D.I. 123, Ex. 2 at ¶¶ 51-52) To that end, Plaintiff’s proposed amended complaint articulates a theory of infringement based on a combination of derotation instruments from the Daytona Systems used with implants from numerous other SeaSpine product lines. (*Id.*) Because the deadline for amended pleadings passed on June 3, 2022, the issue before the court is whether Plaintiff has satisfied the good cause standard under Rule 16(b)(4). (D.I. 43 at ¶ 3) This inquiry focuses on Plaintiff’s diligence and requires consideration of whether Plaintiff could have reasonably sought the proposed amendments in a timely manner. *Venetec Int’l*, 541 F. Supp. 2d at 618.

Plaintiff’s motion to amend the complaint is denied because he has not made the requisite showing of diligence. The original complaint contained only one paragraph touching on the theory that Plaintiff seeks to broaden in the proposed amended complaint. (C.A. No. 21-806-RGA, D.I. 1 at ¶ 56) The paragraph alleges that the accused Daytona Systems “can be used with the Daytona and/or Malibu™ line of implantable products.” (*Id.*) The operative complaint includes as an exhibit the Surgical Technique Guide for the accused Daytona Systems, which identifies the use of the Malibu implantable system. (*Id.*, Ex. F at 1, 18) Nothing in the original pleading indicates compatibility between instruments from the Daytona Systems and implant systems other than Malibu.

Plaintiff’s present theory is that SeaSpine’s Daytona Systems and Mariner Adult Deformity System can be used with other implantable systems which Plaintiff now identifies as

accused products in the proposed amended complaint. (D.I. 123, Ex. 2 at ¶¶ 51-52) There is no dispute that Plaintiff's proposed amendments rest on information that was publicly available to Plaintiff at the time the operative complaint was filed in 2021. Plaintiff's counsel confirmed at oral argument that the Malibu Instructions for Use ("IFU"), which was attached as an exhibit to the proposed amended pleading, was available at the time the original complaint was filed "and we could have found it." (3/7/2023 Tr. at 20:11-21:11) This exhibit states that "[t]he Daytona System contains various instruments specifically designed to work with the Malibu implants as well as various other implants in the NewPort System. Daytona sterilization trays contain Malibu implants." (D.I. 123, Ex. 1 at Ex. G at 1) This publicly available IFU provided notice that implant systems other than Daytona and Malibu may be compatible with instruments from the Daytona Systems. Nonetheless, Plaintiff did not seek leave to amend the complaint before the deadline for amended pleadings.

Plaintiff also failed to pursue his new theory during the July 21 hearing before the District Judge on Plaintiff's motion to compel discovery from SeaSpine. (D.I. 87) At the time, Plaintiff was on notice that SeaSpine objected to producing discovery on all unaccused products, including the SeaSpine implant systems. (D.I. 68, Ex. A) Nonetheless, Plaintiff focused exclusively on discovery relating to derotation systems during the hearing, without mentioning his outstanding document requests regarding SeaSpine's implant systems.

During the hearing, the court repeatedly described the Daytona Systems as the only accused systems and focused on the potential existence of other derotation systems, stating that "I don't think we're interested in screws right now[.]" (D.I. 87 at 13:12-13; *see also id.* at 6:1-10, 7:19-23, 20:3-5) The court emphasized that discovery on unaccused products would not be permitted, and Plaintiff bore the responsibility of identifying accused products: "[I]t's the

Plaintiff's job to name accused products and get discovery on accused products. If it's not an accused product, I'm not going to be [ordering] discovery on it[.]" (*Id.* at 20:14-21:1) To that end, the court ordered SeaSpine to supplement an interrogatory response to identify and briefly describe each SeaSpine product line so Plaintiff could investigate "what is or is not capable of derotation" and determine whether to accuse other derotation systems of infringement. (*Id.* at 21:6-22:4)

At no point during this exchange did Plaintiff explain that he was also accusing or intended to accuse SeaSpine's implant systems of infringement, or that he was pursuing discovery on implant systems that had not yet been produced. Even when SeaSpine expressed concern that Plaintiff's discovery requests were not limited to spinal derotation systems and described the broad scope of the requests as "the crux of our objection," Plaintiff remained silent on the matter of implant systems, other than to generally state "I'm aware of many of [SeaSpine's] product lines. I am not aware that there's any connection between anything other than Daytona and derotation." (*Id.* at 15:22-16:8, 18:1-4) Plaintiff's counsel's failure to provide context on the role of the implant systems, even after SeaSpine voiced concerns about producing discovery beyond derotation systems, cannot be squared with the conduct of Plaintiff's counsel during the October 26 discovery dispute. (D.I. 118 at 53:18-63:7)

Plaintiff's lack of diligence continued after the July 21 hearing. Despite being on notice from both SeaSpine and the court that he would not receive discovery on unaccused products, Plaintiff did not seek leave to amend the complaint. As a result, the realm of accused "SeaSpine Products" in the operative pleading remained circumscribed to "instruments," and not implants, and allegations of compatibility with Daytona instruments extended only to the Malibu line of implantable products. (*Compare* C.A. No. 21-806-RGA, D.I. 1 at ¶¶ 51, 56, *with* D.I. 123, Ex. 2

at ¶¶ 51-52 (expanding definition of “SeaSpine Products” to include combinations of instruments and implants)). Instead of seeking leave to amend the pleading, Plaintiff used SeaSpine’s supplemental interrogatory response to amend his identification of accused products, adding seven SeaSpine implant systems. (D.I. 109, Ex. C) This failed to remedy the pleading deficiency and violated the spirit of the court’s July 21 ruling, which was expressly intended to allow Plaintiff to determine “what is or is not capable of derotation” and did not contemplate SeaSpine’s implant systems. (D.I. 87 at 21:20-22:4)

Here, it is undisputed that Plaintiff could have accused the implant systems it now seeks to add from the start of the litigation. It is also undisputed that Plaintiff could have pleaded a theory of compatibility between instrument and implant systems from different product lines in the original complaint based on publicly available information. Yet Plaintiff did not move to amend the complaint until nearly a year and a half after the operative complaint was filed, and more than five months after the deadline for amended pleadings had passed. These facts establish Plaintiff’s lack of diligence in seeking the proposed amendment. *See Carrier Corp. v. Goodman Global, Inc.*, 49 F. Supp. 3d 430, 433 (D. Del. 2014).

Plaintiff argues that diligence should be measured from the time Plaintiff became aware of the need to amend the complaint. (D.I. 124 at 7) The authority Plaintiff cites does not support his position. In *TC Technology LLC v. Sprint Corp.*, C.A. No. 16-153-RGA (D. Del. Feb. 11, 2019), the court found good cause to allow an amendment to add a willful infringement claim because the claim was based on new information obtained in a witness deposition that occurred only about a month before the proposed amendment was made. (D.I. 124, Ex. 2 at 4) In this regard, *TC Technology* supports the court’s conclusion that diligence should be measured from the time the information underlying the proposed amendments became available. Here, the

evidence cited in support of Plaintiff's proposed amendments was publicly available on SeaSpine's website since the inception of the case in 2021. (D.I. 123, Ex. 1 at Exs. G-J; 3/7/2023 Tr. at 21:1-14, 32:16-33:4)

The facts of *Enzo Life Sciences, Inc. v. Digene Corp.*, are distinguishable because the proposed amendment to add a claim of inequitable conduct was based on recent deposition testimony. 270 F. Supp. 2d 484, 489 (D. Del. 2003). Although the publicly available prosecution history also supported the inequitable conduct claim, the court concluded that the heightened Rule 9(b) standard for inequitable conduct justified the defendant's efforts to confirm the factual allegations through deposition discovery before bringing the claim. *Id.* In this case, Plaintiff's proposed amendments are not brought under the heightened Rule 9(b) standard. While the proposed amendments are based on documents recently uncovered by Plaintiff, there is no dispute that these documents have been publicly available since the operative complaint was filed. (3/7/2023 Tr. at 21:1-14; D.I. 123, Ex. 1 at Exs. G-J)

Plaintiff's reliance on the Sixth Circuit's decision in *Inge v. Rock Financial Corp.* is neither binding nor persuasive. 281 F.3d 613 (6th Cir. 2002). There, the plaintiff's motion to amend was made to cure deficiencies identified in the district court's order dismissing the case. *Id.* at 626. Here, in contrast, the proposed amendments are not made to salvage the case from dismissal. Instead, Plaintiff's proposed amendments are made to justify an expansion of discovery into multiple additional product lines of uncertain relevance that have many noninfringing uses and do not, by themselves, infringe. (3/7/2023 Tr. at 20:2-10, 23:2-11, 37:8-24)

In sum, Plaintiff has not established good cause for the proposed amendments under Rule 16(b)(4) because the record shows that the information underlying Plaintiff's proposed

amendments was available to Plaintiff prior to the expiration of the deadline for amended pleadings on June 3, 2022. (*Id.*) Because Plaintiff has not satisfied the good cause standard under Rule 16(b)(4), the court need not reach the merits of Plaintiff's arguments under Rule 15(a). *See Premier Comp Sols., LLC v. UPMC*, 970 F.3d 316, 319 (3d Cir. 2020) ("A party must meet [the Rule 16(b)(4)] standard before a district court considers whether the party also meets Rule 15(a)'s more liberal standard.").

B. Motion to Strike SeaSpine's Third Affirmative Defense of Unclean Hands

Plaintiff moves to strike SeaSpine's third affirmative defense of unclean hands. (D.I. 125) I recommend that the court deny Plaintiff's motion as untimely to the extent that it is brought under Rule 12(f)(2), which provides that "[t]he court may strike from a pleading an insufficient defense. . . (2) on motion made by a party either before responding to the pleading or, if a response is not allowed, within 21 days after being served with the pleading." Fed. R. Civ. P. 12(f)(2). It is undisputed that SeaSpine's affirmative defense of unclean hands was made on March 16, 2022, and Plaintiff's motion to strike was filed nearly eight months later, on November 10, 2022. (C.A. No. 21-806-RGA, D.I. 25; D.I. 125) Therefore, the motion to strike is untimely on its face.

Plaintiff maintains that his motion to strike is timely because it was brought within 21 days of SeaSpine's disclosure of its unclean hands theory in its interrogatory responses served on October 20, 2022. (D.I. 148 at 2) But Rule 12(f)(2) provides no such exception. The relevant event under Rule 12(f) is the filing of the answer, not a "representation through counsel" related to the defendant's defenses. *See Chervon (HK) Ltd. v. One World Techs., Inc.*, C.A. No. 19-1293-GBW, 2022 WL 14812531, at *2 (D. Del. Oct. 26, 2022) (denying a motion to strike inequitable conduct claims filed 314 days after the amended answer was filed).

Nonetheless, I recommend that the court strike SeaSpine's affirmative defense of unclean hands *sua sponte* under Rule 12(f)(1), to the extent that the affirmative defense sounds in fraud under Rule 9(b). Fed. R. Civ. P. 12(f)(1) ("The court may strike from a pleading an insufficient defense . . . (1) on its own[.]"). "The pleadings standard for unclean hands depends on the specific conduct alleged. A counterclaim or affirmative defense that alleges fraudulent conduct must be pled with particularity under Rule 9(b)." *Allergan USA, Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 19-1727-RGA, 2022 WL 11819975, at *3 (D. Del. Oct. 20, 2022) *see Targus Int'l LLC v. Victorinox Swiss Army, Inc.*, C.A. No. 20-464-RGA-CJB, 2020 WL 7264199, at *2 (D. Del. Dec. 10, 2020) (explaining that an affirmative defense of inequitable conduct must meet the heightened pleading requirements of Rule 9(b)). The factual allegations in SeaSpine's operative answer are insufficient to satisfy the heightened pleading standard for an affirmative defense of unclean hands based on allegations of inequitable conduct.

There is no meaningful dispute that SeaSpine relies on the factual allegations of inequitable conduct in its proposed amended answer to bolster its third affirmative defense. In its interrogatory responses, SeaSpine expressly alleges that the factual allegations in its proposed amended answer set forth the legal and factual bases to support the equitable defenses included in its third affirmative defense. (D.I. 126, Ex. 1 at 6) ("The proposed Amended Answer sets forth legal and factual bases that support Defendants' Equitable Defenses."). But SeaSpine's motion to amend its answer was subsequently denied as untimely. (D.I. 130) As a result, the operative answer is the one filed on March 16, 2022. (C.A. No. 21-806-RGA, D.I. 25) SeaSpine does not point to any allegations in the operative answer that are sufficient to withstand scrutiny under Rule 9(b), instead arguing that Plaintiff was on notice of the factual bases for the

affirmative defense and Plaintiff's motion to strike "elevates form over substance." (D.I. 140 at 5-7)

Because SeaSpine's operative answer does not satisfy the heightened pleading standard under Rule 9(b), and because allowing SeaSpine to proceed with its third affirmative defense would effectively allow it to circumvent the court's ruling on the motion for leave to amend the answer, I recommend that the court strike SeaSpine's unclean hands defense under Rule 12(f)(1) only to the extent that the affirmative defense sounds in fraud under Rule 9(b). The recommendation is made without prejudice to SeaSpine's ability to pursue an affirmative defense of unclean hands under the Rule 8 pleading standard.

C. Motion to Strike Stryker's Third Affirmative Defense of Unclean Hands

Plaintiff moves to strike Stryker's third affirmative defense of unclean hands. (D.I. 128) I recommend that the court deny Plaintiff's motion as untimely to the extent that it is brought under Rule 12(f)(2). It is undisputed that Stryker's answer and affirmative defenses were filed on May 25, 2021, and Plaintiff's motion to strike Stryker's third affirmative defense was filed more than a year later, on November 11, 2022. (D.I. 16; D.I. 128) Stryker's subsequent disclosure of the basis for its unclean hands defense in interrogatory responses served on September 14, 2022 does not alter the analysis for the reasons set forth at § III.B, *supra*. (D.I. 129, Ex. 1 at 8; *see also* Ex. 5 at 1) Therefore, Plaintiff's motion to strike is untimely on its face.

Nonetheless, I recommend that the court strike Stryker's third affirmative defense of unclean hands *sua sponte* under Rule 12(f)(1), to the extent that the affirmative defense sounds in fraud under Rule 9(b). Fed. R. Civ. P. 12(f)(1). Stryker's answer and affirmative defenses do not contain sufficient factual allegations to support a defense of unclean hands based on a theory of misconduct before the United States Patent and Trademark Office ("PTO"). (D.I. 16)

Instead, the factual bases underlying Stryker's affirmative defense of unclean hands are set forth in its interrogatory responses, which describe Plaintiff's alleged misconduct before the PTO. (D.I. 129, Ex. 1 at 8; Ex. 5) For the reasons explained at § III.B, *supra*, Stryker's discovery responses are insufficient to satisfy the heightened Rule 9(b) pleading standard.

Stryker's supplemental interrogatory responses, served several weeks after Plaintiff's motion to strike, set forth an additional theory that Plaintiff engaged in a pattern of litigation misconduct by initiating and maintaining lawsuits despite his knowledge of his misconduct before the PTO. (D.I. 150, Ex. 1 at 20-22) At oral argument, Stryker argued that these allegations of litigation misconduct are based on unconscionability and bad faith, as opposed to fraud, and they are therefore not subject to the heightened pleading standard.⁵ (3/7/2023 Tr. at 53:5-54:10, 55:16-25)

In this district, the law is well-established that "[t]he pleadings standard for unclean hands depends on the specific conduct alleged." *Allergan USA*, 2022 WL 11819975, at *3. In *Allergan*, for instance, the court applied the Rule 8 standard to an affirmative defense of unclean hands based on litigation misconduct where the plaintiff allegedly used the defendant's confidential information obtained in the course of litigation to draft patent claims. *See id.* But an unclean hands defense that depends on proof of fraud falls within the scope of the heightened Rule 9(b) standard. *See AbbVie Inc. v. Boehringer Ingelheim Int'l GmbH*, C.A. No. 17-1065-MSG-RL, 2018 WL 2604825, at *2 (D. Del. June 4, 2018). And there is no dispute that an

⁵ Stryker's counsel went on to argue that case law applying Rule 9(b) extends only to allegations of fraud, and not mistake. (*Id.* at 56:1-57:3) Rule 9(b) of the Federal Rules of Civil Procedure, entitled "Fraud or Mistake; Conditions of Mind," provides that, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). For clarity of the record, "mistake" is expressly included in the scope of Rule 9(b).

unclean hands defense based on allegations of inequitable conduct sounds in fraud. *See Senju Pharm. Co., Ltd. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 306 (D. Del. 2013).

Here, proof of Plaintiff's alleged "litigation misconduct" rises and falls with Stryker's allegations of misrepresentations before the PTO. Stryker's supplemental interrogatory responses allege that "Dr. Barry has engaged in a pattern of litigation misconduct before this Court and other District Courts by filing and maintaining lawsuits asserting patents with knowledge that they are invalid based on his own prior public use(s) and/or prior sale(s) that Dr. Barry *admits* were not experimental." (D.I. 150, Ex. 1 at 20) The interrogatory responses go on to explain that these prior uses were the same three surgeries performed on August 4, August 5, and October 14, 2003 that Plaintiff allegedly failed to disclose to the PTO during prosecution of the patents-in-suit. (*Id.*, Ex. 1 at 18, 20-21) Stryker cannot salvage an unclean hands defense based on inequitable conduct by renaming the allegations "litigation misconduct" in a transparent effort to invoke the Rule 8 standard a few weeks after Plaintiff moved to strike Stryker's unclean hands defense. *See Gilead Scis., Inc. v. Merck & Co., Inc.*, 888 F.3d 1231, 1239 (Fed. Cir. 2018) (cautioning against "the potential for misuse of this necessarily flexible doctrine" of unclean hands).

For these reasons, I recommend that the court strike Stryker's unclean hands defense *sua sponte* under Rule 12(f)(1). The recommendation is made without prejudice to Stryker's ability to pursue an affirmative defense of unclean hands under the Rule 8 pleading standard. I further recommend that the court deny Stryker's alternative request for leave to amend its answer to conform to the evidence. (D.I. 150 at 9) As the court previously held in the Memorandum Opinion denying SeaSpine's motion for leave to amend the answer, Stryker's unclean hands defense is based on factual allegations of inequitable conduct that were not timely raised. (D.I.

130 at 4-7) (describing inequitable conduct allegations based on Plaintiff's filings with the PTO, the *Medtronic* and *DePuy* litigations, and a March 2022 document production).

IV. CONCLUSION

For the foregoing reasons, Plaintiff's motion to amend the complaint is DENIED. (D.I. 123) I recommend that the court DENY Plaintiff's motions to strike SeaSpine and Stryker's third affirmative defenses of unclean hands. (D.I. 125; D.I. 128) Finally, I recommend that the court STRIKE SeaSpine and Stryker's third affirmative defenses of unclean hands *sua sponte*, only to the extent that those affirmative defenses sound in fraud under Fed. R. Civ. P. 9(b) as described herein.

Given that the court has relied upon material that technically remains under seal, the court is releasing this Report and Recommendation under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Report and Recommendation should be redacted, the parties shall jointly submit a proposed redacted version by no later than **March 27, 2023**, for review by the court, along with a motion supported by a declaration 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." See *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (internal quotation marks omitted)). If the parties do not file a proposed redacted version and corresponding motion, or if the court determines the motion lacks a meritorious basis, the documents will be unsealed within fourteen (14) days of the date the Report and Recommendation issued.

The portion of the court's decision on Plaintiff's motion to amend the complaint is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a), and D. Del. LR 72.1(a)(2). The

portion of the court's decision on Plaintiff's motions to strike the third affirmative defenses of Stryker and SeaSpine is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b). The objections and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the court's website, <http://www.ded.uscourts.gov>.

Dated: March 20, 2023



Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE