

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

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

Plaintiffs,)

v.)

Civil Action No. 18-1869-CFC-CJB

MICRO-TECH ENDOSCOPY USA INC.,)
MICRO-TECH (NANJING) CO., LTD.)
and HENRY SCHEIN INC.,)

Defendants.)

MEMORANDUM ORDER

At Wilmington, Delaware this **1st day of April, 2020**.

WHEREAS, Plaintiffs Boston Scientific Corp. and Boston Scientific Scimed, Inc., (“Plaintiffs”) have filed a Motion to Strike Defendants’ Affirmative Defenses of Inequitable Conduct Against the ’371 and ’725 Patents, (D.I. 95) (the “Motion”), and Defendants Micro-Tech Endoscopy USA Inc., Micro-Tech (Nanjing) Co., Ltd. and Henry Schein Inc. (“Defendants”) have opposed it, and the Court¹ having considered the parties’ briefs, (D.I. 96; D.I. 100; D.I. 102), and having determined that telephonic oral argument, (D.I. 103), is not necessary to resolve the Motion:

NOW, THEREFORE, IT IS HEREBY ORDERED as follows:

With regard to the two affirmative defenses at issue, Defendants allege that Plaintiffs committed inequitable conduct before the United States Patent and Trademark Office (“PTO”) in

¹ This case is referred to the Court for all pretrial matters (excluding claim construction) up to and including expert discovery. (D.I. 22; D.I. 82)

the prosecution of United States Patent Nos. 9,980,725 (“the '725 patent”) and 8,974,371 (“the '371 patent”).² Defendants’ theory, as set out in the pleading at issue, is as follows. Plaintiffs make products—the Resolution™ Clip and Resolution 360™ Clip (the “Resolution Clip products”)—which are alleged to embody certain aspects of Plaintiffs’ patents-in-suit. (See D.I. 1 at ¶¶ 13-15) Plaintiffs sought approval from the United States Food and Drug Administration (“FDA”) to market their Resolution Clip products. In seeking such approval, Plaintiffs identified devices manufactured by Olympus to the FDA, and Plaintiffs also told the FDA that their Resolution Clip products were ““substantially equivalent”” to the Olympus devices. (D.I. 83 at *Defendants’ Affirmative Defenses*, at ¶¶ 11-13, 318-20; D.I. 100 at 2) But then years later, when prosecuting the '371 and '725 patents, Plaintiffs (and, more specifically, inventor Russell Durgin and prosecuting attorney Oleg Kaplun) did not disclose the Olympus devices to the PTO as relevant prior art. (*Id.*) To sum up Defendants’ theory, Mr. Durgin’s and Mr. Kaplun’s awareness of the Olympus prior art through Plaintiffs’ prior FDA dealings, coupled with their failure to disclose the same prior art to the PTO, constitutes a deceptive act in an effort to procure the patents in-suit. (*Id.*)

A party raising a counterclaim of inequitable conduct must do so “with particularity[.]” Fed. R. Civ. P. 9(b); *see also Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326-27 (Fed. Cir. 2009); *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). This means identifying the

² In their Complaint, Plaintiffs assert three patents: the '725 patent, the '371 patent and United States Patent No. 7,094,245 (“the '245 patent”). (D.I. 1 at ¶ 1) In their First Amended Answer, Defendants raise the defense of inequitable conduct against all three patents in-suit. (D.I. 83 at *Defendants’ Affirmative Defenses*, at ¶¶ 11-13 ('725 patent), 23-308 ('245 patent), 318-20 ('371 patent)) With the Motion, Plaintiffs only challenge Defendants’ inequitable conduct defense as to the '371 and '725 patents—not as to the '245 patent. (D.I. 96 at 1)

“specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Exergen*, 575 F.3d at 1327; *see also St. Jude Medical*, 2014 WL 2622240, at *1. To identify the “how” and “why,” a defendant must show how the omitted prior art reference “is not cumulative of the information already on the [patent prosecution] record” by identifying the particular claim limitations in that reference that are absent from the prior art of record. *St. Jude Medical*, 2014 WL 2622240, at *1 (citing *Exergen*, 575 F.3d at 1329-30).

It is as to this “how” and “why” requirement where, at a minimum, Defendants’ pleading founders. Plaintiffs correctly point out that Defendants’ inequitable conduct allegations (which total only three paragraphs for each of the two defenses at issue) fail to disclose precisely what limitations were not in the prior art of record before the PTO (and, thus, what limitations were embodied in the Olympus device prior art that, had the PTO been aware of them, would have had a material impact on the patentability of the patents at issue). (D.I. 96 at 2; D.I. 102 at 2)

Therefore, Plaintiffs’ Motion is GRANTED. But the Court will allow Defendants one more chance to amend and re-plead these defenses. Federal Rule of Civil Procedure 15(a) and the United States Court of Appeals for the Third Circuit both take a liberal approach to amending pleadings, *e.g.*, *In re Fisker Auto. Holdings, Inc. S’holder Litig.*, Civil Action No 13-2100-CFC, 2018 WL 5113964, at *3 (D. Del. Oct. 12, 2018), and affirmative defenses are no exception, *St. Jude Medical*, 2014 WL 2622240, at *2; *Alza Corp. v. Par Pharm., Inc.*, Civil Action No. 13-1104-RGA, 2014 WL 12908353, at *2 (D. Del. May 27, 2014).³ The Court therefore ORDERS that Defendants may file a further amended Answer and Affirmative Defenses that attempts to address these issues, if they wish to do so, by no later than **April 14, 2020**.

³ Plaintiffs also challenged the affirmative defenses for lack of detail as to the relevant knowledge of Mr. Kaplun and Mr. Durgin. (D.I. 102 at 2) To the extent Defendants seek to re-plead, they would be wise to bolster their allegations in that regard as well.

Christopher J. Burke

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE