UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SHELLIE BROEDER, AMY DELGADO, MARISA SAYERS, MICHELLE MARTINEZ, and ANITA MENDIOLA **Plaintiffs,** **v.** **HOLOGIC, INC.,** **Defendant.**	**Case No. 1:23-cv-10823-ADB**

PLAINTIFFS' MEMORANDUM IN SUPPORT OF OPPOSED MOTION FOR LEAVE TO FILE FIRST AMENDED COMPLAINT

INTRODUCTION

Plaintiffs and the other related cases pending before this Court[1] bring personal injury claims related to their implantation of BioZorb® 3D bioabsorbable marker device (the "BioZorb Device"). The parties are engaged in phased discovery with Phase I specifically focused on discovery and motions based on the learned intermediary doctrine. *See* ECF Nos. 14 at 3, 15 (1:22-cv-12194); ECF Nos. 21 at 3, 22 (1:22-cv-11895).

[1] *See Evers et al. v. Hologic, Inc.*, No. 1-22-cv-11895 (D.Mass); *Block et al. v. Hologic, Inc.*, No. 1:22-cv-12194 (D.Mass); *Chambers et al. v. Hologic, Inc.*, No. 1:23-cv-10260 (D. Mass.); *Shirkey et al. v. Hologic, Inc.*, No. 1:23-cv-10579 (D. Mass.); *Stine et al. v. Hologic, Inc.*, No. 1:23-cv-10599 (D. Mass.); *Baker et al. v. Hologic, Inc.*, No. 1:23-cv-10717 (D. Mass.); *Rivera et al. v. Hologic, Inc.*, No. 1:23-cv-11012 (D. Mass.); *Slater et al. v. Hologic, Inc.*, No. 1:23-cv-10717 (D. Mass.); *English et al. v. Hologic, Inc.*, No. 1:23-cv-11512 (D. Mass.); *Webb et al. v. Hologic, Inc.*, No. 1:23-cv-11823 (D. Mass.); *Price et al. v. Hologic, Inc.*, No. 1:23-cv-12011 (D. Mass.); *Heffner et al. v. Hologic, Inc.*, No. 1:23-cv-12278 (D. Mass.); *Blanchenay et al. v. Hologic, Inc.*, No. 1:23-cv-12458 (D. Mass.); *Austin et al. v. Hologic, Inc.*, No. 1:23-cv-12651 (D. Mass.); *Swafford et al. v. Hologic, Inc.*, No. 1:23-cv-12687 (D. Mass.); *Bonvillain et al. v. Hologic, Inc.*, No. 1:23-cv-12833 (D. Mass.); *Ciers et al. v. Hologic, Inc.*, No. 1:23-cv-13215 (D. Mass.); *Broeder et al. v. Hologic, Inc.*, No. 1:24-cv-10823 (D.Mass); *Galaini et al. v. Hologic, Inc.*, 1:24-cv-11939 (D.Mass)(collectively, the "BioZorb Device Litigation').

Defendant filed motions for summary based on the learned intermediary doctrine, however, within those motions, Defendant also contends Plaintiffs have inadequately pled their design defect claims. The proposed Amended Complaint set forth in Exhibit A seeks to cure pleading deficiencies addressed by Defendant in their motions for summary judgment and add additional facts concerning the FDA Class I recall of BioZorb. The amendments are unrelated to the learned intermediary doctrine issue and would not be futile, as it seeks to cure Defendant's issues with Plaintiffs' alleged pleading deficiencies unrelated to the learned intermediary doctrine discovery and the addition of certain facts concerning the recent FDA Class I recall of BioZorb is not unfairly prejudicial to the Defendant.

ARGUMENT

Fed. R. Civ. P. 15(a) guides the Court's decision in granting leave to amend by stating "[t]he court should freely give leave when justice so requires." "A liberal, pro-amendment ethos dominates the intent and the judicial construction of Rule 15(a)." 3 James W.M. Moore et al., MOORE'S FEDERAL PRACTICE, §15.14[1] (3d ed. 1997). *See also Federal Deposit Ins. Corp. v. Consolidated Mortg. & Finance Corp.,* 805 F.2d 14, 16 (1st Cir. 1986). Courts have universally recognized the permissive nature of Rule 15(a).[2]

"In the absence of any apparent or declared reason – such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party . . . futility of the amendment, etc. –

[2] *See, e.g., Subaru v. General Ship*, 167 F.R.D. 342, 343 (D. Mass. 1996); *Nerney v. Valente & Sons*, 66 F. 3d 25, 28 (2nd Cir. 1995); *Shane v. Fauver*, 213 F. 3d 113, 115-117 (3rd Cir. 2000); *Engstrom v. First Nat'l Bank*, 47 F. 3d. 1459,1464 (5th Cir. 1995); *Jet, Inc. v. Sewage Aeration Sys.,* 165 F. 3d 419, 425 (6th Cir. 1999); *Figgie Int'l Inc. v. Miller*, 966 F. 2d 1178, 1180-1181 (7th Cir. 1992); *Frey v. City of Herculaneum*, 44 F. 3d 667, 672 (8th Cir. 1995); *Lopez v. Smith*, 203 F. 3d 1122, 1130 (9th Cir. 2000); *Forbus v. Sears Roebuck*, 30 F. 3d 1402, 1405 (11th Cir. 1994).

the leave sought should, as the rule requires, be freely given. *Foman v. Davis,* 83 S.Ct. 227, 230 (1962). The *Foman* standard has consistently been followed in this jurisdiction. "The leave sought should be granted unless the amendment would be futile or reward undue delay." *Abraham v. Woods Hole Oceanographic Inst.*, 553 F.3d 114, 117 (1st Cir. 2009), *citing Adorno v. Crowley Towing & Transp. Co*., 443 F.3d 122, 126 (1st Cir. 2006*). See, e.g. Vargas v. McNamara,* 608 F.2d 15 (1st Cir. 1979); *Savoy v. White,* 139 F.R.D. 265, 267 (D. Mass. 1991) (same).

Futility depends on the posture of the case. *Hatch v. Dep't for Child., Youth & Their Fams.*, 274 F.3d 12, 19 (1st Cir. 2001). The burden on the Plaintiffs seeking amendment is largely dependent on the phase and timing of the litigation – the earlier it is, the lesser the Plaintiffs' burden. *See Steir v. Girl Scouts of the USA,* 383 F. 3d 7, 11-12 (1st Cir. 2004). By agreement, the Parties engaged in Phase I with discovery and motions expressly focused on the learned intermediary doctrine. While discovery focused on the learned intermediary doctrine has begun no motions for summary judgment have been filed. "If leave to amend is sought before discovery is complete and neither party has moved for summary judgment, the accuracy of the 'futility' label is gauged by reference to the liberal criteria of Federal Rule of Civil Procedure 12(b)(6)." *Meuse v. Nat'l P.I. Servs., LLC*, No. 21-CV-11533-ADB, 2023 WL 6961883, at *4 (D. Mass. Oct. 20, 2023) (*citing Hatch*, 274 F.3d 19). However, even for those matters with completed intermediary doctrine related discovery and motions for summary judgment are pending, the proposed amendments to the complaint are unrelated to the discovery completed.

Plaintiffs first learned of Defendant's claims of inadequate pleading of the design defect claims in related litigation and seek to amend to avoid similar claims in the present case. Plaintiffs seek to amend their complaint to cure the issues raised related to the pleading of the

design defect claims, to add additional facts concerning the FDA Class I recall of BioZorb, and Defendant's failure to adequately warn physicians and patients about BioZorb's risks. "[A] proposed amendment is futile only if it could not withstand a 12(b)(6) motion to dismiss." *Hatch*, 274 F.3d 19 (*citing Rose v. Hartford Underwriters Ins. Co.*, 203 F.3d 417, 421 (6th Cir.2000)). Plaintiffs' proposed amendments are not futile as they address Defendant's claims of inadequate pleading of the design defect claims and seek to cure those issues. Plaintiffs also seek to amend their complaint to add recent developments concerning the FDA Class I recall of BioZorb and examples of Defendant's failure to warn.

By granting leave to file the proposed Amended Complaint at this relatively early phase of the litigation, the Court will minimize costly and unnecessary battles between the Parties.

CONCLUSION

WHEREFORE, Plaintiffs respectfully request that the Court grant this motion for leave to file an amended complaint in this matter.

Dated: August 21, 2024.

Respectfully submitted,

/s/Christina D. Crow
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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non registered participants on August 21, 2024.

/s/Christina D. Crow
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