UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: BIOZORB DEVICE PRODUCTS LIABILITY LITIGATION This Document Relates to: All Plaintiffs In Case Nos. 1:22-cv-11895-ADB; 1:22-cv-12194-ADB; 1:23-cv-10260-ADB; 1:23-cv-10579-ADB; 1:23-cv-10599-ADB	**Civil Action No. 1:22-cv-11895 (ADB)**

DEFENDANT HOLOGIC, INC.'S MEMORANDUM IN SUPPORT OF OMNIBUS MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINTS

I. INTRODUCTION

Despite multiple opportunities to amend their complaints, Plaintiffs in the Track A and Track B cases still fail to allege the facts necessary to state a claim for negligent design defect (Count II). Plaintiffs contend that the design of Defendant Hologic, Inc.'s ("Hologic") BioZorb device was defective, but the negligent design defect allegations in their amended complaints remain entirely conclusory. Plaintiffs allege that the device caused injury, but do not point to any particular aspect of the BioZorb that constitutes a defect. Nor do they connect any (unspecified) defect in the BioZorb to any claimed negligent conduct by Hologic. While Plaintiffs allege that a safer alternative design to the BioZorb exists, they also fail to identify any such alternative design – instead pointing to a different product entirely (titanium clips). What is more, the complaints are not tailored to the state laws applicable to each Plaintiff. As a result, they often fail to plead facts necessary to state a claim under the relevant state's negligent design defect laws, such as the "risk-benefit" or "consumer expectations" test.

At this stage, given the failure to cure these problems after several chances, Plaintiffs'

design defect claims should be dismissed with prejudice.

II. RELEVANT PROCEDURAL HISTORY

Plaintiffs filed their initial complaints in the Track A and B cases[1] between November 2022 and March 2023. Plaintiffs' original complaints each contained identical design defect allegations.

Between February and April 2024, Hologic filed summary judgment motions pertaining to the majority of the Track A plaintiffs. While those motions largely involved the "learned intermediary" doctrine, Hologic also argued that Plaintiffs' design defect claims were inadequately pleaded under the laws of the states at issue. In particular, Hologic pointed out the same deficiencies that are the subject of this Motion: that Plaintiffs failed to identify any aspect of the BioZorb's design that constituted a design defect, *see, e.g.*, Case No. 1:22-cv-11895-ADB, ECF No. 73, at 16–17; that Plaintiffs did not include any allegations of negligent conduct leading to a design problem, *see id.*; and that simply pointing to an entirely different product such as titanium clips does not establish the existence of a feasible alternative design. *See id.* at 17.

In opposing those motions, Plaintiffs cited documents provided by Hologic in discovery that Plaintiffs contended "demonstrate[] that there were defective aspects of BioZorb's design, and other reasonable design alternatives were feasible," including documents pertaining to a "QuickZorb" design. *E.g.*, Case No. 1:22-cv-11895-ADB, ECF No. 87, at 17–18 (Mar. 15, 2024). However, Plaintiffs did not in response to those motions seek leave to amend their complaints to incorporate any such documents or new theories based on those documents, or to otherwise cure the problems Hologic identified.

In May 2024, after the summary judgment briefing in the Track A cases was largely

[1] The five Track A and B cases include *Evers et al. v. Hologic, Inc.*, No. 22-cv-11895; *Block et al. v. Hologic, Inc.*, No. 22-cv-12194; *Chambers et al. v. Hologic, Inc.*, No. 23-cv-10260; *Shirkey et al. v. Hologic, Inc.*, No. 23-cv-10579; and *Stine et al. v. Hologic, Inc.*, No. 23- cv-10599.

complete, Plaintiffs notified Hologic that they wanted to amend their complaints in the *Evers* and *Block* Track A cases, even though the December 1, 2023 amendment deadline had already passed. *See* Case No. 1:22-cv-11895-ADB, ECF No. 21, at 3. Despite its lateness, Hologic did not oppose amendment on the condition (among other things) that the amendment would not "impact or affect any pending learned intermediary motions for summary judgment" and would "not be construed as a waiver of any right to oppose or object to any future request to amend the Complaints." Case No. 1:22-cv-12194, ECF No. 119-1; Case No. 1:22-cv-11895-ADB, ECF No. 137-1. The Court then granted Plaintiffs' unopposed motions for leave to amend, and Plaintiffs filed their amended complaints in the *Block* and *Evers* actions on May 20, 2024. *See* Case No. 1:22-cv-11895-ADB, ECF Nos. 137–139; Case No. 1:22-cv-12194-ADB, ECF Nos. 119–121. Despite the fact that Hologic had challenged Plaintiffs' design defect allegations in its summary judgment motions in *Evers* and *Block*, Plaintiffs did ***not*** seek to amend their design defect allegations at that time.

Months later, in late August 2023, Plaintiffs filed motions for leave to amend their complaints again. These motions to amend included the Track A cases in which a prior stipulated amendment had already been granted. They also included the Track B actions, in which summary judgment briefing had largely been completed by that time.

This time, Plaintiffs ***did*** ask to amend their design defect claims, ostensibly to address the issues identified in Hologic's summary judgment motions. *See, e.g.*, Case No. 1:22-cv-11895-ADB, ECF No. 161 at 2 ("The proposed Second Amended Complaint set forth in Exhibit A seeks to cure those alleged [design defect] deficiencies addressed by Defendant in their motions for summary judgment."). Yet Plaintiffs' amendments sought to add only minimal, boilerplate language. Specifically, Plaintiffs added the allegation that "[t]he design of the BioZorb Marker is defective because of design aspects, including, but not limited to, its shape, surface, texture,

material, and integration of parts." *E.g.*, Case No. 1:22-cv-11895-ADB, ECF No. 178, ¶ 71. Plaintiffs also added a paragraph that states, without factual elaboration, that "BioZorb's shape, surface, texture, material and integration of parts could all have been feasibly changed to make the device less harmful." *Id.* ¶ 72. Those two conclusory paragraphs were the only allegations added regarding an alleged design defect.

The Court granted Plaintiffs' motions for leave to amend, as to the design defect claims only, on September 6, 2024. *See* Case No. 1:22-cv-11895-ADB, ECF No. 168. As had been discussed at the status conference held on September 5, 2024, the parties then negotiated a process for Hologic to challenge the allegations in the newly filed amended complaints. *See* Case No. 1:22-cv-11895-ADB, ECF No. 176-1. Pursuant to that agreement, on October 18, 2024, Plaintiffs filed their amended complaints.[2] Hologic now timely moves to dismiss the design defect claims.

III. LEGAL STANDARD

A. Rule 12(b)(6)

To survive a motion to dismiss, a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *accord Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). "Factual allegations must be enough to raise a right to relief above the speculative level" (*Twombly*, 550 U.S. at 555), and courts "are not bound to accept as true a legal conclusion couched as a factual allegation,'" *Iqbal*, 556 U.S. at 678 (internal quotation marks and citation omitted); *see also Shay v. Walters*, 702 F.3d 76, 82–83 (1st Cir. 2012) (applying *Twombly* and concluding that complaint did not satisfy plausibility pleading standard).

[2] Plaintiffs filed amended complaints in each of the subject cases on September 17, 2024. To resolve a dispute between the parties as to whether those complaints were within the scope of the Court's partial grant of leave to amend, Plaintiffs re-filed further amended complaints by agreement of the parties on October 18, 2024. *See* Case No. 1:22-cv-11895-ADB, ECF No. 176-1.

B. Choice of Law

"The law of Massachusetts is that ordinarily the substantive law governing an action of tort for physical injury is that of the place where the injury occurred." *Cohen v. McDonnell Douglas Corp.*, 450 N.E.2d 581, 585 (Mass. 1983) (citation omitted); *see also* Restatement (Second) of Conflict of Laws § 146 (1971) (in personal injury actions, "the local law of the state where the injury occurred determines the rights and liability of the parties" unless some other state has a more significant relationship to the dispute). Following the Restatement, Massachusetts courts routinely apply the law of the place of injury in product liability cases such as this. *See, e.g.*, *Paye v. Atrium Med. Corp.*, No. CV 22-10005-FDS, 2023 WL 349894, at *7 (D. Mass. Jan. 20, 2023) (applying Massachusetts substantive law to non-resident personal injury plaintiff's design defect and other claims because "Plaintiff's surgery took place in Attleboro, Massachusetts"); *Monroe v. Medtronic, Inc.*, 511 F. Supp. 3d 26, 33 (D. Mass. 2021) (applying Nebraska substantive law to design defect and other claims where the "implantation of the mesh and the subsequent injuries and treatment appear to have occurred" in Nebraska).

The Court, in its recent summary judgment order, similarly determined "that the state where each Plaintiff's injury occurred will provide the negligence standards to be applied in determining Hologic's liability" under the learned intermediary doctrine. Case No. 1:22-cv-11895-ADB, ECF No. 170, at 19. There is no reason to depart from that holding on the issue of design defect liability. Therefore, the law of the state in which each Plaintiff suffered her claimed injury (i.e., was implanted with the BioZorb and resided at the time) governs that Plaintiff's claim.[3]

[3] Based on Plaintiffs' allegations regarding the location of their BioZorb implantation and state of citizenship, and as discussed in Hologic's summary judgment motions, the following state laws apply for each plaintiff: California (Rita Melkonian, Anne Thalman, and Denice Chambers); Colorado (Pamela Gibson); Florida (Nerissa Burke); Illinois (Pamela Mazzanti); Indiana (Tricia Willard); Michigan (Beth Deuel and Diane Lyon); New York (Christina Patras, Julie Block, and

IV. ARGUMENT

Plaintiffs fail to state a negligent design defect claim. The design defect amendments in the latest complaints are perfunctory, and their amended complaints therefore suffer from the same fundamental flaws that Hologic pointed out in its summary judgment briefs. In particular, Plaintiffs' negligent design defect claims continue to suffer from the following pleading defects.

First, Plaintiffs still do not identify any particular aspect of the BioZorb's design that constitutes a ***defect***, which mandates dismissal under the laws of all states at issue. Plaintiffs now allege that "[t]he design of the BioZorb Marker is defective because of design aspects, including, but not limited to, its shape, surface, texture, material, and integration of parts." *E.g.*, Case No. 1:22-cv-11895-ADB, ECF No. 178, ¶ 71. However, this "laundry list" allegation is entirely conclusory, as it does not specify ***which*** component or aspect of the device is allegedly defective or ***how*** any such element (or combination of them) is defective. *See, e.g.*, *Wilkins v. Genzyme Corp.*, No. CV 21-10023-DPW, 2022 WL 4237528, at *23, *26–27 (D. Mass. Sept. 14, 2022) (dismissing Indiana negligent design defect claim and noting that "'[a] bare allegation of a 'defect' is no more than a legal conclusion' that is insufficient to state a claim") (citation omitted), *aff'd in part, rev'd in part on other grounds*, 93 F.4th 33 (1st Cir. 2024); *Dilley v. C.R. Bard, Inc.*, No. 2:14-CV-01795-ODW (ASx), 2014 WL 2115233, at *4 (C.D. Cal. May 21, 2014) (dismissing California negligent design defect claim that failed to explain "how the product was defective");

Kimberly Taylor); North Carolina (Karen Ensley); Ohio (Rebecca Shirkey); Pennsylvania (Tina Stine, Joye Rishell, and Joanna Perez); South Carolina (Cynthia Kresch); Texas (Della Debbas and Katy Wharton); Washington (Diane Anderson); and Wisconsin (Plaintiff Shelley Evers). *See* Case No. 1:22-cv-11895-ADB, ECF No. 169, ¶¶ 4–7, 31, 39; Case No. 1:22-cv-12194-ADB, ECF No. 145, ¶¶ 4–5, 11–12, 17–18; Case No. 1:23-cv-10599-ADB, ECF No. 131, ¶¶ 4–5, 10–11, 15–16, 20–21, 26–27; Case No. 1:23-cv-10579-ADB, ECF No. 104, ¶¶ 4–5, 13–14, 20–21, 25–26, 32–33; Case No. 1:23-cv-10260-ADB, ECF No. 113, ¶¶ 4–5, 11–12, 16–17, 21–22, 27–28.

Branham v. Ford Motor Co., 390 S.C. 203, 225 (2010) (under South Carolina law, plaintiff must "point to a design flaw in the product"). This fundamental failure to identify what aspect of the product's design is defective warrants dismissal of the design defect claims.

Second, Plaintiffs do not allege that any defect in the BioZorb resulted from any negligent conduct by Hologic. Plaintiffs' claim is a *negligent* design defect claim, not a strict liability claim. As one would expect, most of the states at issue for the Track A and B plaintiffs therefore require a showing that the defect resulted from the defendant's negligence. *See, e.g.*, *McGrain v. C.R. Bard, Inc.*, 551 F. Supp. 3d 529, 541 (E.D. Pa. 2021) (under Pennsylvania law, "[t]o plead a viable claim for negligent design, a plaintiff must plead facts to plausibly show that the defendant failed to exercise reasonable care in the adoption of a safe design"); *Kamlade v. LEO Pharma Inc.*, No. 1:21-cv-00522-DAD-EPG, 2022 WL 358429, at *5 (E.D. Cal. Feb. 7, 2022) ("A plaintiff alleging a design defect claim under a negligence theory must allege and prove 'that the defect in the product was due to negligence of the defendant.'") (quoting *Chavez v. Glock, Inc.*, 207 Cal. App. 4th 1283, 1305 (2012)). Here, Plaintiffs' negligent design defect count does not even include a boilerplate allegation of negligence or breach of duty which resulted in a design defect, let alone well-pleaded ***factual*** allegations as to the particular conduct they claim was negligent. In the absence of any allegations (factual or otherwise) that Hologic acted negligently or failed to act with reasonable care in designing the BioZorb, Plaintiffs' design defect claims should be dismissed.

Third, Plaintiffs still do not adequately allege the existence of a feasible alternative design for the BioZorb, as required under the negligent design defect laws of some of the states at issue. In their prior complaints, Plaintiffs alleged that "titanium clips that have been on the market for years that carry less clinical risk to the patient" constitute a "technologically feasible and practical

alternative design." *E.g.*, Case No. 1:22-cv-11895-ADB, ECF No. 139, ¶ 73. Hologic explained in its summary judgment papers that titanium clips, an entirely different product than the BioZorb, cannot constitute a feasible alternative design. *See, e.g.*, *Tersigni v. Wyeth*, 817 F.3d 364, 368 (1st Cir. 2016) (requiring plaintiff "to show that the product in question could have been more safely designed, not that a different product was somehow safer"); *Bell v. Boehringer Ingelheim Pharms., Inc.*, No. 17-1153, 2018 WL 2447788, at *5 (W.D. Pa. May 31, 2018) ("[A]n alternative design must not be an altogether essentially different product."); *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 405 (S.D.N.Y. 2013) ("[A]n allegation that [defendant] could have manufactured a different product altogether, or that others have done so, does not itself make out a plausible claim of a design defect."). Plaintiffs' amended complaints fare no better, as they still point to titanium clips as an alleged feasible alternative design. *E.g.*, Case No. 1:22-cv-11895-ADB, ECF No. 178, ¶ 74. And while Plaintiffs include the conclusory allegation that "[i]n the oncological surgical market, alternative designs exist that are mechanically feasible, safer, and cost significantly less than BioZorb," that allegation also does not identify any particular alternative design. *See id.*

Fourth, Plaintiffs fail to plead the necessary facts to state a claim under the negligent design defect laws of those states that utilize a "risk-benefit" or "consumer expectations" test for negligent design defect. Plaintiffs never plead that the risks of the BioZorb outweigh its benefits, as required under the risk-benefit test. *See, e.g.*, *Bartholic v. Scripto-Tokai Corp.*, 140 F. Supp. 2d 1098, 1111 (D. Colo. 2000) (under Colorado law, "[t]he proponents of a design-defect claim bear the burden of demonstrating that, on balance, the risk of danger inherent in a challenged design outweighs the benefits of such a design"). While Plaintiffs do allege that "BioZorb's design poses a high gravity of danger" (*E.g.*, Case No. 1:22-cv-11895-ADB, ECF No. 178, ¶ 75), that is different than pleading that the risks of the device outweigh its benefits. Plaintiffs' allegations also fail

under a "consumer expectations" test. Plaintiffs never allege anything about whether consumers' expectations were met or that the BioZorb was "unsafe to an extent beyond that which would be contemplated by the ordinary consumer." *Payne v. Paugh*, 190 Wash. App. 383, 408 (2015) (applying Washington law).

* * *

Below, we provide authority demonstrating that these pleading deficiencies mandate dismissal of Plaintiffs' claims in all states at issue in the Track A and B cases:

California (Plaintiffs Rita Melkonian, Anne Thalman, and Denice Chambers): Under California law, "[a] plaintiff alleging a design defect claim under a negligence theory must allege and prove 'that the defect in the product was due to negligence of the defendant.'" *Kamlade*, 2022 WL 358429, at *5 (quoting *Chavez*, 207 Cal. App. 4th at 1305). "'As with a general negligence claim, the plaintiff must show breach of duty, causation, and damages.'" *Id.* (citation omitted). "A product is not negligently designed so long as 'the manufacturer took reasonable precautions in an attempt to design a safe product or otherwise acted as a reasonably prudent manufacturer would have under the circumstances.'" *Torres v. Taser Int'l, Inc.*, 277 F. App'x 684, 686 (9th Cir. 2008) (quoting *Barker v. Lull Eng'g, Co.*, 20 Cal. 3d 413, 434 (1978)). "Without factual allegations that identify a product defect, and allege that the defect resulted from Defendants' negligence, no plausible claim is stated." *Marroquin v. Pfizer, Inc.*, 367 F. Supp. 3d 1152, 1164 (E.D. Cal. 2019).

Plaintiffs nowhere (1) allege that Hologic failed to exercise reasonable care in designing the BioZorb; or (2) point to any particular aspect of the BioZorb's design that constitutes a defect.

Colorado (Plaintiff Pamela Gibson): Under Colorado law, to make out a negligent design claim, Plaintiff must "prove that the product was defective" because it "is in a defective condition unreasonably dangerous to the user or consumer." *Haffner v. Stryker Corp.*, No. 14-CV-00186-

RBJ, 2014 WL 4821107, at *2, *5 (D. Colo. Sept. 29, 2014) (citations omitted); *see also Watson v. Vista Outdoor, Inc.*, No. 16-CV-00514-CMA-KLM, 2016 WL 11523306, at *3 (D. Colo. June 29, 2016) (dismissing design defect claim that provided "almost no factual detail about the [product's] purported design flaw"). To determine whether a product's design is unreasonably dangerous, Colorado uses the risk-benefit test. *Walker v. Ford Motor Co.*, 406 P.3d 845, 849–50, 852 (Colo. 2017) (stating that "the risk-benefit test essentially subsumes the issue of negligence"). "The proponents of a design-defect claim bear the burden of demonstrating that, on balance, the risk of danger inherent in a challenged design outweighs the benefits of such a design." *Bartholic v. Scripto-Tokai Corp.*, 140 F. Supp. 2d 1098, 1111 (D. Colo. 2000) (citation omitted). The risk-benefit test sets forth seven non-exclusive factors for courts to consider, including the availability of a safer alternative design. *See Shaffer v. FCA US LLC*, No. 1:20-cv-03167-CNSMEH, 2022 WL 17268723, at *4 (D. Colo. Nov. 29, 2022) ("Courts examine . . . . (3) The availability of the substitute product which would meet the same need and not be as unsafe.").

Plaintiff (1) fails to point to any particular aspect of the BioZorb's design that constitutes a defect; and (2) does not plead facts needed to satisfy the risk-benefit test, including that the device's risks outweigh its benefits, that a safer alternative design exists, or facts evaluating any other factor that Colorado uses to assess negligent design defect. *See Wood v. Am. Med. Sys. Inc.*, No. 1:20-cv-00441-DDD-KLM, 2021 WL 1178547, at *10 (D. Colo. Mar. 26, 2021) ("availability of a different device is irrelevant" in evaluating the existence of an alternative design, and noting that "availability of different devices does not establish a design defect in the device at issue").

Florida (Plaintiff Nerissa Burke): "In the law of negligence, a product is defective when the manufacturer has a duty to exercise reasonable care so that its products will be reasonably safe for use in a foreseeable manner, and the manufacturer has breached that duty." *Cook v.*

MillerCoors, LLC, 829 F. Supp. 2d 1208, 1217 (M.D. Fla. 2011); *see also Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270, 1288 (M.D. Fla. 2009), *aff'd*, 634 F.3d 1296 (11th Cir. 2011). "To prove any products liability claim sounding in negligence, including negligent design . . ., a plaintiff must show '(1) that the defendant owed a duty of care toward the plaintiff, (2) that the defendant breached that duty, (3) that the breach was the proximate cause of the plaintiff's injury, and (4) that the product was defective or unreasonably dangerous.'" *Cook*, 829 F. Supp. 2d at 1217. "The complaint must contain factual allegations about what was in fact defective about the product." *Witt v. Howmedica Osteonics Corp.*, No. 13-cv-20742-JLK, 2013 WL 6858395 at *2 (S.D. Fla. Dec. 30, 2013) (holding that the plaintiff's allegation of design defect in a knee prosthesis was insufficient because the plaintiff failed to plead "specific allegations as to the components which Plaintiff alleges are defective and how those components are defective"); *see also Wolicki-Gables*, 641 F. Supp. 2d at 1287 ("[p]roof of negligent design" requires "evidence of the existence of [a] defect in the product").

Plaintiff nowhere (1) alleges that Hologic failed to exercise reasonable care in designing the BioZorb; or (2) points to any particular aspect of the BioZorb's design that constitutes a defect.

Illinois (Plaintiff Pamela Mazzanti): Under Illinois law, "[a] product liability action asserting a claim based on negligence, such as negligent design, falls within the framework of common law negligence." *Calles v. Scripto-Tokai Corp.*, 224 Ill. 2d 247, 270 (2007). "To state a negligence claim based on a defective product, 'a plaintiff must establish the existence of a duty of care owed by the defendant, a breach of that duty, an injury proximately caused by that breach, and damages.'" *Griffin v. Medtronic, Inc.*, No. 17 CV 927, 2017 WL 4417821, at *4 (N.D. Ill. Oct. 5, 2017) (citation omitted). "A negligence claim accounts for a defendant's fault as well as

the product's condition." *Id.* (citation omitted). The complaint must allege "facts to demonstrate how the device's design was defective." *Id.*

Plaintiff nowhere (1) alleges that Hologic failed to exercise reasonable care in designing the BioZorb; or (2) points to any particular aspect of the BioZorb's design that constitutes a defect.

Indiana (Plaintiff Tricia Willard): "In product liability claims alleging a product design defect, the [Indiana Products Liability Act] substitutes a negligence standard for strict liability and prescribes the applicable standard of care." *Simpson v. Gen. Dynamics Ordnance & Tactical Sys.-Simunition Operations, Inc.*, 429 F. Supp. 3d 566, 577 (N.D. Ind. 2019) (quoting *TRW Vehicle Safety Sys., Inc. v. Moore*, 936 N.E.2d 201, 214 (Ind. 2010)) (internal quotations and alterations omitted). Therefore, a plaintiff "must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product." *Id.*

Plaintiff (1) nowhere alleges that Hologic failed to exercise reasonable care in designing the BioZorb device. Nor does Plaintiff's complaint (2) point to any particular aspect of the BioZorb that was defective. *See, e.g.*, *Wilkins*, 2022 WL 4237528, at *23, *26–27 (dismissing Indiana negligent design defect claim and noting that "'[a] bare allegation of a 'defect' is no more than a legal conclusion' that is insufficient to state a claim") (citation omitted).

Michigan (Plaintiffs Beth Deuel and Diane Lyon): In Michigan, "two theories will support a finding of negligent design:" (1) the "traditional" theory that "questions whether the design chosen renders the product defective," and (2) a theory based on a failure to warn. *Gregory v. Cincinnati Inc.*, 538 N.W.2d 325, 328–29 (Mich. 1995). The Michigan Supreme Court has adopted a "pure negligence, risk-utility test" to determine whether a manufacturer should be held liable for a defectively designed product based on the "traditional" negligent design theory. *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176, 186 (Mich. 1984); *see also Gregory*, 538 N.W.2d at

329 (the risk-utility test is used to determine whether "the manufacturer exercised reasonable care in making the design choices it made"). Among other things, this test "requires Plaintiff to present a reasonable alternative design" – *i.e.*, a "'practical and feasible' alternative that would have reduced the risk of particular injury at issue without impairing the product's usefulness or desirability." *McClarty v. C.R. Bard Inc.*, No. 4:14-CV-13627-TGB-RSW, 2020 WL 6075520, at *4 (E.D. Mich. Oct. 15, 2020) (quoting M.C.L. § 600.2946(2)).

Here, Plaintiffs' negligent design claim is predicated on the traditional theory – that "[t]here are technologically feasible and practical alternative designs that would have reduced or prevented the Plaintiffs' harm." *E.g.*, Case No. 1:22-cv-11895-ADB, ECF No. 178, ¶ 73. However, Plaintiffs (1) do not allege that a reasonable alternative design exists or evaluate other factors under the risk-utility test. Plaintiffs also (2) fail to allege a specific design defect, and their design defect claim therefore fails under Michigan law. *See Barnes v. Medtronic, PLC*, No. 2:17-CV-14194, 2019 WL 1353880, at *2 (E.D. Mich. Mar. 26, 2019) ("[plaintiff] has not alleged an alternative [design] for Defendants' product—only alternative *products*, which are insufficient as a matter of law to establish a design defect claim"); *Austin v. Mitsubishi Elecs. of Am., Inc.*, 966 F. Supp. 506, 515 (E.D. Mich. 1997) (plaintiffs did not make out claim where "[n]o design defect has been identified" and no alternative designs proposed).

New York (Plaintiffs Christina Patras, Julie Block, and Kimberly Taylor): Under New York law, "a plaintiff must plead sufficient facts to show that . . . it was feasible to design the product in a safer manner." *Tears v. Bos. Sci. Corp.*, 344 F. Supp. 3d 500, 509–10 (S.D.N.Y. 2018). The plaintiff must also identify the "specific problem or defective component" of the device. *Id.* at 510.

Plaintiffs fail to satisfy either requirement. Plaintiffs do not (1) identify a feasible alternative design to the BioZorb, instead pointing to a different product (titanium clips). *See, e.g.*, *Hilaire v. DeWalt Indus. Tool Co.*, 54 F. Supp. 3d 223, 248 (E.D.N.Y. 2014) (trap saw was "an entirely different product [that] could have been used" and therefore not a feasible alternative design to a table saw). Plaintiffs (2) also fail to identify any particular aspect of the BioZorb that was defective. *See, e.g.*, *Tears*, 344 F. Supp. 3d at 510 (dismissing design defect claim because plaintiff "failed to allege with sufficient specificity *how* the design of the [device] was defective," explaining that it "is not enough to point to the risks associated" with the product).

North Carolina (Plaintiff Karen Ensley): Section 99B-6 provides a cause of action for design defect claims if plaintiff proves that "the manufacturer acted unreasonably in designing or formulating the product" and also proves that either: (1) the manufacturer "unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design . . . that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product"; or (2) the product's design was "so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design." N.C. Gen. Stat. §§ 99B-6(a)(1)-(2).

Plaintiff's complaint is devoid of facts sufficient to support a claim for design defect under either theory. Plaintiff (1) fails to allege a feasible alternative design to the BioZorb, and (2) nowhere alleges that Hologic acted unreasonably or that a reasonable person would not use the BioZorb. Plaintiff also (3) fails to identify any particular aspect of the BioZorb that was defective. A "naked allegation" that a device is defective and has the potential to cause injury simply does not identify how a device's ***design*** is inadequate. *See Asby v. Medtronic, Inc.*, 673 F. Supp. 3d 787, 793 (E.D.N.C. 2023) (dismissing complaint that "fail[ed] to identify how the design is

inadequate"); *see also Beaver v. Pfizer Inc.*, No. 1:23-cv-00281-MR, 2024 WL 234725, at *4 (W.D.N.C. Jan. 22, 2024) ("conclusory allegations" and "bare assertions" that prescription drug was "poorly designed" and "negligently developed" insufficient).

Ohio (Plaintiff Rebecca Shirkey): The Ohio Products Liability Act ("OPLA") "abrogate[d] all common law product liability claims or causes of action." *Bowles v. Novartis Pharms. Corp.*, No. 3:12-CV-145, 2013 WL 5297257, at *7 (S.D. Ohio Sept. 19, 2013) (citing Ohio Rev. Code § 2307.71(B)). Consequently, Plaintiff's common law negligent design defect claim should be dismissed. *See Bowles*, 2013 WL 5297257, at *7–8 (dismissing negligent design defect claim that was abrogated by OPLA); *Michelson v. Volkswagen Aktiengesellschaft*, 99 N.E.3d 475, 481–82 (Ohio Ct. App. 2018) (same).

Even if Plaintiff's claim had been properly pled under OPLA, it would still fail. Under Ohio law, "a product is defective in design or formulation if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation . . . exceeded the benefits associated with that design or formulation." Ohio Rev. Code § 2307.75(A); *see also* Ohio Rev. Code § 2307.75(B)-(C) (providing a list of non-exhaustive factors to consider in evaluating foreseeable risks and benefits). "[A] product will not be considered defective unless the plaintiff demonstrates that a practical and technically feasible alternative design to the product was available and would have prevented the harm for which the plaintiff seeks to recover, without substantially impairing the usefulness of the product." *Huffman v. Electrolux Home Prods.*, 129 F. Supp. 3d 529, 541 (N.D. Ohio 2015) (quoting *Zang v. Cones*, 34 N.E.3d 955, 961 (Ohio App. 2015)); *see also* R.C. § 2307.75(F) (same). "[D]esign defect claims require that the complaint contain factual allegations as to which portions of the product failed." *Grubbs v. Smith & Nephew, Inc.*, No. 1:19-CV-248, 2020 WL 5305542, at *5 (S.D. Ohio Sept. 4, 2020).

Plaintiff does not (1) allege that a practical and technically feasible alternative design to the BioZorb was available, or (2) that the foreseeable risks associated with the BioZorb's design exceeded the benefits of that design, as required under Ohio law. Nor does Plaintiff (3) identify any particular aspect of the BioZorb that was defective. *See, e.g.*, *Williams v. Bos. Sci. Corp.*, No. 3:23 CV 1409, 2023 WL 9596983, at *2 (N.D. Ohio Dec. 11, 2023) (dismissing Ohio design defect claim where "[t]he Amended Complaint contains no statements regarding a plausible defect in the mesh" and only "tenders naked assertions devoid of further factual enhancement"); *Grubbs*, 2020 WL 5305542, at *5 (dismissing design defect claim that "does not allege how the product was defectively designed").

Pennsylvania (Plaintiffs Tina Stine, Joye Rishell, and Joanna Perez): Under Pennsylvania law, "[t]o plead a viable claim for negligent design, a plaintiff must plead facts to plausibly show that the defendant failed to exercise reasonable care in the adoption of a safe design." *McGrain*, 551 F. Supp. 3d at 541. "Conclusory allegations that a product was negligently designed are not, on their own, sufficient to plead a viable claim." *Id.* While "evidence of an alternative, feasible, safer design is not an 'absolute prerequisite' to the advancement of a design-defect claim," "[i]t is an essential element of Plaintiff's liability case . . . if her claim is 'predicated on a theory of design defect based upon the availability of an alternative safer design,'" in which case Plaintiff then "must plead in her complaint what that alternative, safer design might be." *Houtz v. Encore Med. Corp.*, No. 4:14-CV-0536, 2014 WL 6982767, at *6 (M.D. Pa. Dec. 10, 2014) (citation omitted).

Plaintiffs (1) do not allege that Hologic failed to exercise reasonable care in designing the BioZorb device. Nor do Plaintiffs (2) identify any particular aspect of the BioZorb that was defective or identify any alternative safer design. *See Salvio v. Amgen Inc.*, No. 2:11-CV-00553, 2012 WL 517446, at *7 (W.D. Pa. Feb. 15, 2012) (concluding that "an alternative design must not

be an altogether essentially different product" and dismissing negligent defect claim); *McGrain*, 551 F. Supp. 3d at 541–42 (dismissing negligent design claim where the "allegations fail to address either the design of Defendants' product or the availability of safer, feasible alternatives in any level of meaningful detail"); *Foge, McKeever LLC v. Zoetis Inc.*, 565 F. Supp. 3d 647, 654 (W.D. Pa. 2021) (dismissing negligent design claim where the allegations "lack adequate specificity as to why the design was flawed, or . . . what alternative formulation would be feasible and adopted").

South Carolina (Plaintiff Cynthia Kresch): Under South Carolina law, "[l]iability for a design defect may be based on negligence, strict tort, or warranty." *Jolly v. Gen. Elec. Co.*, 435 S.C. 607, 649 (Ct. App. 2021), *aff'd sub nom. Jolly v. Fisher Controls Int'l, LLC*, 443 S.C. 511 (2024). "In an action based on strict tort or warranty, plaintiff's case is complete when he has proved the product, as designed, was in a defective condition *unreasonably dangerous* to the user when it left the control of the defendant, and the defect caused his injuries." *Id.* (citation omitted). "Liability for negligence requires, in addition to the above, proof that the manufacturer breached its duty to exercise reasonable care to adopt a safe design." *Id.* A plaintiff proceeding under any sort of design defect claim in South Carolina must "point to a design flaw in the product and show how [an] alternative design would have prevented the product from being unreasonably dangerous." *Branham v. Ford Motor Co.*, 390 S.C. 203, 225 (2010); *see also Jolly*, 435 S.C. at 649–51 (requiring evidence of a reasonable alternative design).

Plaintiff (1) nowhere alleges that Hologic failed to exercise reasonable care in designing the BioZorb, and (2) fails to allege a feasible alternative design to the BioZorb, as required under South Carolina law. Plaintiff also (3) fails to "[identify] . . . a specific design flaw" in the BioZorb: "the plaintiff must offer some evidence beyond the product's failure itself to prove that it is unreasonably dangerous." *Graves v. CAS Med. Sys. Inc.*, 735 S.E.2d 650, 658–59 (S.C. 2012).

Texas (Plaintiffs Della Debbas and Katy Wharton): "A manufacturer owes a duty to its customers under Texas law to design a product such that its use doesn't involve an unreasonable risk of harm." *Moncibaiz v. Pfizer Inc.*, 532 F. Supp. 3d 452, 461 (S.D. Tex. 2021). "With that particular duty in mind, the elements of a negligent-design claim are otherwise the same as that of a traditional negligence claim—duty, breach, causation, and damages." *Id.*

Plaintiffs must "identify a specific defect [in the BioZorb] . . . by competent evidence," *Kia Motors Corp. v. Ruiz*, 432 S.W.3d 865, 881 (Tex. 2014), that is a "producing cause of the injury for which the plaintiff seeks recovery." *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009). Plaintiffs must also identify a feasible alternative design. *See Am. Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997) ("Negligent design . . . claims are predicated on the existence of a safer alternative design for the product. Absent an alternative design, a claim for negligent design . . . fails as a matter of law.") (internal citation omitted).

Plaintiffs do not (1) allege that Hologic breached a duty of care in designing the BioZorb. Plaintiffs also (2) fail to identify any particular aspect of the BioZorb that was defective, and (3) fail to allege a safer alternative design to the BioZorb. *See Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760, 770 (Tex. App. 2009) (plaintiff cannot prove "a safer alternative design exists by pointing to a substantially different product, even when the other product has the same general purpose as the allegedly defective product") (citing *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th Cir. 1999)); *see also Baksic v. Ethicon Inc.*, 659 F. Supp. 3d 763, 773–74 (W.D. Tex. 2023) (summary judgment granted where plaintiffs' experts reports only pointed to "alternative procedures or substantially different products rather than alternative designs").

Washington (Plaintiff Diane Anderson): Under Washington law, "for a design defect claim against a medical device manufacturer of an unavoidably unsafe product under comment k,

. . . the standard is negligence and the focus is on the conduct of the manufacturer to use reasonable care to design a medical product that is reasonably safe." *Payne v. Paugh*, 190 Wash. App. 383, 410 (2015). Where comment k does not apply, Washington applies the risk utility and consumer expectations tests. *See id.* at 412. The consumer expectations test "requires the plaintiff to show the product was unsafe to an extent beyond that which would be contemplated by the ordinary consumer." *Id.* at 408 (citations omitted). Plaintiffs who rely on the risk-utility test instead of the consumer expectations test "must prove the existence of an alternative design." *Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wash. 2d 493, 503 (2000).

Here, to the extent comment k applies, Plaintiff (1) does not allege that Hologic failed to use reasonable care in designing the BioZorb. Even if comment k did not apply, Plaintiff (2) fails to state a claim under the consumer expectations or risk-utility tests because she does not allege that the BioZorb is unsafe to an extent beyond that which would be contemplated by the ordinary consumer, does not identify any particular aspect of the BioZorb that was defective, and does not allege an alternative design to the BioZorb. *See, e.g.*, *Lovold v. Fitness Quest Inc.*, No. C11-569Z, 2012 WL 529411, at *2 (W.D. Wash. Feb. 16, 2012) (holding that plaintiff failed to meet her burden under the risk-utility test because she "did not allege any defects in [the device], and failed to identify what, if any, alternative design could more safely serve the same purpose and the challenged product at a comparable cost and in a similar manner").

Wisconsin (Plaintiff Shelley Evers): To prevail on a negligent design defect claim in Wisconsin, "[t]he plaintiff must prove that the defendant failed to exercise ordinary care and that this failure caused the harm." *Insolia v. Philip Morris Inc.*, 216 F.3d 596, 604 (7th Cir. 2000). A plaintiff must also "identify a particular design feature that is alleged to be defective." *Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 768 N.W.2d 674, 684 (Wisc. 2009).

Here, Plaintiff (1) nowhere alleges that Hologic failed to exercise ordinary care in designing the BioZorb. Plaintiff also (2) does not identify any particular aspect of the BioZorb that was defective and therefore fails to state a design defect claim under Wisconsin law. *See Godoy*, 768 N.W.2d at 683 ("a determination that a product is *defective* is not identical to a determination that the product was *defectively designed*. Put another way, the fact that a defect exists does not compel the conclusion that the source of the defect is the product's design. This distinction makes a difference."). Merely pointing to an entirely different ***product*** as allegedly superior does not suffice to establish a specific design flaw in the device at issue here. *Cf. Godoy*, 768 N.W.2d at 683–84 (plaintiffs could not predicate negligent design claim based on presence of lead because "[r]emoving lead from white lead carbonate pigment would transform it into a different product").

V. CONCLUSION

For the reasons stated herein, Hologic respectfully requests that the Court dismiss Plaintiffs' design defect claims in the Track A and B actions with prejudice.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Pietro A. Conte, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), on November 11, 2024.

/s/ *Pietro A. Conte*
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