

**IN THE SUPERIOR COURT OF THE STATE OF DELAWARE**

**KULWINDER KAUR,** )

Plaintiff, )

v. )

**C.A. No.: N19C-07-117 PEL**

**BOSTON SCIENTIFIC** )

**CORPORATION (d/b/a/** )

**MANSFIELD SCIENTIFIC, INC.** )

**& MICROVASIVE INC.),** )

Defendant. )

**OPINION AND ORDER ON DEFENDANT’S  
MOTION FOR SUMMARY JUDGMENT  
GRANTED, IN PART, AND DENIED, IN PART**

Submitted: February 4, 2022

Decided: May 11, 2022

*Robert J. Leoni, Esquire, Shelsby & Leoni, Wilmington, Delaware,  
Attorney for Plaintiff.*

*Colleen D. Shields, Esquire, Eckert, Seamans, Cherin & Mellott, LLC, Wilmington,  
Delaware, Attorney for Defendant.*

Jones, J.

Kulwinder Kaur (“Kaur” or “Plaintiff”), a resident of California, has brought the instant products liability action. Plaintiff alleges that she was implanted with a pelvic mesh device, known as the Obtryx Transobturator Mid-Urethral Sling System (“Obtryx”), which was manufactured by Boston Scientific Corporation (“BSC” or “Defendant”). Kaur alleges that the Obtryx was defective and has caused her physical injuries. Plaintiff has asserted a cause of action for negligence, breach of warranty and failure to warn. BSC has moved for summary judgment. This is the Court’s decision on the summary judgment. For the reasons stated herein, BSC’s motion is GRANTED, in part, and DENIED, in part.

### **STANDARD OF REVIEW**

Under Superior Court Civil Rule 56, a party is entitled to summary judgment if there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law.<sup>1</sup> A material issue of fact exists if “a rational finder of fact could find some material fact that would favor the nonmoving party in a determining way[.]”<sup>2</sup> The factual record on a summary judgment motion must be viewed in the light most favorable to the non-moving party.<sup>3</sup>

The initial burden is on the moving party to demonstrate there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter

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<sup>1</sup> Del. Super. Ct. Civ. R. 56(c).

<sup>2</sup> *Deloitte LLP v. Flanagan*, 2009 WL 5200657, at \*3 (Del. Ch. Dec. 29, 2009).

<sup>3</sup> *Gruwell v. Allstate Ins. Co.*, 988 A.2d 945, 947 (Del. Super. Ct. 2009).

of law.<sup>4</sup> If the moving party meets the initial burden, the burden shifts to the non-moving party to show that a genuine issue of material fact exists.<sup>5</sup> “It is not enough for the opposing party merely to assert the existence of such a disputed issue of fact... [i]f the facts permit reasonable persons to draw from them but one inference, the question is ripe for summary judgment.”<sup>6</sup> Where a moving party submits an affidavit in support of a motion for summary judgment, the opposing party must submit a countervailing affidavit or other evidence, or the moving party’s affidavit will be presumed to be true.<sup>7</sup>

### **APPLICABLE LAW**

Delaware follows the “most significant relationship” choice of law approach from the *Restatement (Second) of Conflict of Law*.<sup>8</sup> This approach “provides that the law of the state that has the most significant relationship to the occurrence and the parties under the principles stated in [§] 6 is governing law.”<sup>9</sup> Section 6 provides that the following seven (7) factors are relevant to the choice of law inquiry:

- (a) The needs of the interstate and international systems;
- (b) The relevant policies of the forum;
- (c) The relevant policies of other interested states and the relative interests of those states in the determination of the particular issue;
- (d) The protection of justified expectations;
- (e) The basic policies underlying the particular field of law;
- (f) Certainty, predictability and uniformity of result; and

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<sup>4</sup> *Brzoska v. Olson*, 668 A.2d 1355, 1364 (Del. 1995).

<sup>5</sup> *Id.* (citing *Moore v. Sizemore*, 405 A.2d 679, 680 (Del. 1979)).

<sup>6</sup> *Id.* (citing *Wootten v. Kiger*, 226 A.2d 238, 239 (Del. 1967)).

<sup>7</sup> *Highline Financial Services, Inc. v. Rooney*, 1996 WL 663100, at \*1 (Del. Super. Ct., Oct. 25, 1996).

<sup>8</sup> *Sinnott v. Thompson*, 32 A.3d 351, 354 (Del. 2011).

<sup>9</sup> *Id.* (citing *Restatement (Second) of Conflict of Laws §145(1)*).

(g) Ease in the determination and application of the law to be applied.<sup>10</sup>

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[W]hen applying the section 6 factors, courts should take into account the following four contacts:

- (a) The place where the injury occurred;
- (b) The place where the conduct causing the injury occurred;
- (c) The domicile, residence, nationality, place of incorporation and place of business of the parties; and
- (d) The place where the relationship, if any, between the parties is centered.<sup>11</sup>

Plaintiff is a citizen of California and all her relevant treatment occurred in California. As such, California has the most significant interest in having its substantive law applied to Plaintiff's claims being that the injury occurred in California and the relationship between Plaintiff and Defendant is centered in that state. Thus, this Court will apply the substantive law of California in this case.

### **UNCONTESTED CLAIMS**

Plaintiff does not oppose BSC's motion for summary judgment claims based on failure to warn, breach of warranty and manufacturing defect. Therefore, BSC's motion for summary judgment as to these claims is GRANTED.

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<sup>10</sup> *Id.* (citing *Restatement* at §6(2)).

<sup>11</sup> *Id.* (citing *Restatement* at §145(2)).

## DESIGN DEFECT

In a medical device case under California law,<sup>12</sup> “the test of negligent design involves a balancing of the likelihood of harm to be expected from a [product] with a given design and the gravity of harm if it happens against the burden of the precaution which would be effective to avoid the harm.”<sup>13</sup> “Even if a manufacturer has done all it reasonably could have done to warn about a risk or hazard related to a product’s design, a reasonable person could conclude that the magnitude of the reasonably foreseeable harm as designed outweighed the utility of the product as designed.”<sup>14</sup>

Given the inherent nature of the Defendant’s pelvic mesh product, the consumer expectation test is inapplicable and the relevant analysis is under the risk-benefit test.<sup>15</sup> In evaluating the adequacy of a product’s design under the risk-benefit test, a jury may consider, among other relevant factors, the gravity of the danger posed by the challenged design, the likelihood that said danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would

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<sup>12</sup> In a non-medical device case, the consumer expectation test is used. That test proves that “a product may be found defective in design if the Plaintiff demonstrates that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.” *Barker v. Lull Eng’g Co.*, 20 Cal. 3d 413, 429 (1978); *Shabham v. Johnson & Johnson*, 2020 WL 5894590 (C.D. Cal. 2020).

<sup>13</sup> *Merrill v. Navegar, Inc.*, 26 Cal. 4th 465, 479 (Cal. 2001).

<sup>14</sup> *Tucker v. Wright Med. Tec., Inc.*, 2013 WL 1149717, at \*7 (N.D. Cal., Mar. 19, 2013) (citing *Chavez v. Glock, Inc.*, 207 Cal. App. 4th 1283, 1305 (Ct. App. 2012)).

<sup>15</sup> *Soule v. General Motors Corp.*, 882 P.2d 298 (Cal. 1994); *Morson v. Superior Court*, 90 Cal. App. 4th 775, 793-95 (Cal. 2001).

result from an alternative design.<sup>16</sup> BSC contends that the Plaintiff has not presented proof to meet this burden. Specifically, Defendant contends that Plaintiff has no evidence of a safer alternative design that would have not caused injury.

Viewing the evidence in a light most favorable to Plaintiff, the evidence supports a design defect claim. Plaintiff has offered the opinions of two board-certified urogynecologists, Dr. Thomas Margolis and Dr. Bruce Rosenzweig, whose reports describe the danger posed by the usage of non-medical grade polypropylene in permanent medical implants in the human body.<sup>17</sup> They both also outline the likelihood those dangers would occur.<sup>18</sup>

Dr. Rosenzweig has offered a safer alternative design, the usage of medical grade polypropylene resin in the creation of the mesh used in Obtryx rather than the use of Marlex polypropylene.<sup>19</sup> There is evidence that shows that this alternative design was not only “mechanically feasible” but it was a product that was available at the time of Kaur’s implantation in 2013.

Dr. Rosenzweig has offered the opinion that medical grade resin existed at the time of Ms. Kaur’s implant and using this resin as a basis for the mesh in the Obtryx would have reduced the injuries of the type suffered specifically by Ms. Kaur. Dr.

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<sup>16</sup> *Barker v. Lull Engineering Co.*, 573 P.2d 443 (Cal. 1978).

<sup>17</sup> *See*, Exhibit “P” to Plaintiff’s Response to Defendant’s Motion for Summary Judgment at 49-53; Exhibit “Q” of Plaintiff’s Response to Defendant’s Motion for Summary Judgment at 10-12.

<sup>18</sup> *Id.*

<sup>19</sup> Marlex polypropylene resin was used by BSC to manufacture the polypropylene mesh contained in the BSC mesh products.

Margolis has opined that the defects of the Obtryx, bulleted in his report, were the cause of Ms. Kaur's injuries. The defects outlined in Dr. Margolis' report, to which he attributes Ms. Kaur's injuries, were the same defects of the Obtryx Dr. Rosenzweig opined would have been corrected by usage of the medical grade resin, namely degradation. These reports in combination meet Plaintiff's burden.

Viewing the evidence in a light most favorable to Plaintiff, there exist a genuine issue of material fact as to whether Plaintiff has a viable design defect claim. Therefore, Defendant's motion for summary judgment on Plaintiff's design defect claim is DENIED.

### **PUNITIVE DAMAGES CLAIM**

Under California law, punitive damages are available in tort claims where it is proven by "clear and convincing" evidence that the defendant is 'guilty' of 'oppression, fraud, or malice[.]'"<sup>20</sup> "Malice" is defined as "conduct which is intended by the defendant to cause injury to the plaintiff or despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights or safety of others."<sup>21</sup> California courts have held that corporations cannot have the mental requisite necessary to award punitive damages.<sup>22</sup> A Plaintiff seeking punitive damages from a corporation must prove malice on behalf of the corporation's

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<sup>20</sup> *Sanchez v. Bos. Sci. Corp.*, 38 F.Supp.3d 727, 739 (S.D.W.Va. 2014) (citing Cal. Civ. Code § 3294(a)). *See also Boeken v. Philip Morris Inc.*, 127 Cal.App.4th 1640, 26 Cal.Rptr.3d 638, 67 (Ct.App.2005).

<sup>21</sup> Cal. Civ.Code § 3294(c)(1).

<sup>22</sup> *Ayat v. Society Air France*, 2007 WL 1100315 (N.D. Cal., Apr. 11, 2007).

employees.<sup>23</sup> This requires a showing that corporate leaders acted with such intent.<sup>24</sup> For punitive damages in a product liability action, Plaintiff must provide evidence that “the Defendant placed a product on the market in a conscious disregard of the safety of consumers and others.”<sup>25</sup> The amount of damages is a fact question, first committed to the discretion of the jury and next to the discretion of the trial judge on a motion for new trial.<sup>26</sup>

Viewing the evidence in a light most favorable to the Plaintiff, there exists a genuine issue of material fact as to whether BSC engaged in conduct justifying an award of punitive damages.<sup>27</sup> The evidence supporting the claim includes in part:

- Defendant knew its resin supplier was hesitant to supply polypropylene resin for implantation into the human body and in response to this hesitation moved its business to a different supplier.
- BSC presented data on the mesh in the Obtryx to physicians and the public that it had already been told was implausible.

Therefore, BSC’s motion for summary judgment on the punitive damages is DENIED.

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<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Ehrhardt v. Brunswick Inc.*, 186 Cal. App 3d 734, 741 (Cal. 1986).

<sup>26</sup> *Izell v. Union Carbide Corp.* 231 Cal. App 4th 962 (Cal. 2014).

<sup>27</sup> Defendant maintains that its compliance with FDA standards precludes an award of punitive damages. While compliance with FDA standards may be a relevant factor in a punitive damages analysis, California law is clear that it is not a total bar. *Buell-Wilson v. Ford Motor Company*, 141 Cal.App.4th 525, 565 (Cal. App. 2007). I also reject at this point BSC’s argument that there has been no evidence presented that Defendant’s corporate leadership consciously desired to harm them. There has certainly been evidence presented to date that, at certain levels, BSC acted in such a way to justify an award of punitive damages. Whether these actions were done at the appropriate corporate level to impose punitive damages is an issue requiring a more fully developed trial record.

**IT IS SO ORDERED.**

*/s/ Francis J. Jones, Jr.*  
Francis J. Jones, Jr. Judge

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