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IN THE SUPREME COURT OF THE STATE OF DELAWARE

MARY RUMBO and PAUL RUMBO, *Plaintiffs Below, Appellants* v. AMERICAN MEDICAL SYSTEMS, INC., *Defendant Below, Appellee*	No. 155, 2021 On Appeal from C.A. No. N13C-04-300 PEL in the Superior Court of the State of Delaware

APPELLANTS' OPENING BRIEF

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NATURE OF PROCEEDINGS

This is the Opening Brief of Plaintiffs Below/Appellants Mary Rumbo and Paul Rumbo in support of their appeal from the Opinion and Order ("Opinion and Order") dated April 29, 2021 (attached as Exhibit A) issued by the Honorable Andrea L. Rocanelli, in the Superior Court of the State of Delaware in Civil Action No. N13C-04-300 PEL (the "matter below."). That Opinion and Order granted Defendant-Appellee American Medical Systems' ("AMS") Motion for Summary Judgment. AMS' motion centered around the timeliness of Plaintiff's filing, and did not in any manner assess the merits of the Appellants' claims.

In sum, the Court held that Mrs. Rumbo's initial complaint (A2-A3) which was filed on April 27, 2013, was well past the date of her statute of limitations to file suit. The Superior Court's reasoning and basis for the granting of Defendant-Appellee's Motion for Summary Judgment is included in Exhibit A. Plaintiffs-Appellants timely filed their notice of appeal on May 17, 2021. (A339-A340).

The matter below was a product liability action initiated by Plaintiffs-Appellants Mary Rumbo and Paul Rumbo against Defendant-Appellee AMS. Mrs. Rumbo alleged several causes of action against AMS regarding two of its pelvic mesh products: the Monarc sling and the Perigee cystocele repair. These products were intended to help women suffering from two primary conditions: sudden urinary

incontinence ("SUI") and Pelvic Organ Prolapse ("POP"). However, these transvaginal mesh products have caused women implanted with them considerable problems, and have been the center of considerable litigation for more than a decade. Many transvaginal mesh matters were consolidated in the Southern District of West Virginia, MDL No. 2327, and saw several consolidations in a number of State Court forums, including here in the Superior Court of Delaware.[1]

Nonetheless, the Monarc and Perigee products, which have since been recalled from the market and are no longer sold, were implanted in Mrs. Rumbo in 2006. Mrs. Rumbo endured six revision surgeries of these products[2], which caused her considerable pain over the remaining course of her life. Mrs. Rumbo died on April 19, 2020.

The Superior Court erred in granting Defendant-Appellee American Medical System's motion for summary judgment. In granting that motion, the Superior Court relied on two primary facts in so ruling: (1) that Mrs. Rumbo indicated in her Plaintiff's Fact Sheet—which is the equivalent of an interrogatory response in this sense—that Mrs. Rumbo knew "immediately" upon awakening from her initial

[1] The varying Delaware Superior Court Transvaginal Mesh litigations were consolidated under Master Docket C.A. No. N11C-07-212 MMJ.

[2] Appellant Mary Rumbo underwent implantation of Monarc and Perigee Mesh on April 4, 2006. Subsequently, she had revision surgeries on: (1) June 9, 2006, (2) July 27, 2006, (3) December 20, 2011, (4) November 5, 2012, (5) September 10, 2013, and (6) November 11, 2015.

transvaginal mesh implant surgery in 2006 that she "knew" her injuries were attributable to her mesh, and (2) that Mrs. Rumbo testified that, even if she was not aware of the cause of her injuries in 2006, that after seeing a television commercial regarding the transvaginal mesh litigation in 2009, that she became aware at that point. Both conclusions were incorrect and do not correlate with Delaware jurisprudence on this issue.

It is well-settled that Delaware Courts apply the discovery rule to cases where "a plaintiff may remain blamelessly ignorant of the potential claim even after a latent injury reveals itself through physical ailments. The limitations period for a toxic tort does not begin immediately upon the onset of physical problems if the symptoms are reasonably attributable to another cause and the plaintiff is not on notice of the tortious cause." *See Brown v. E.I. duPont de Nemours & Co., Inc.,* 820 A. 2d 362, 368 (Del. 2003).

However, the Superior Court held that because Mrs. Rumbo was in severe pain when she awoke from that April 4, 2006 surgery that she "knew or should have known" that she had a potential cause of action against Defendant-Appellee AMS at that point. The Court also held that her deposition testimony corroborated this response, even though it did not. In fact, Mrs. Rumbo's testimony makes it clear that she was unsure about what the cause of her injuries were in 2006. Further, Dr. Andre Godet, who implanted the Monarc and Perigee mesh in Mrs. Rumbo, testified

that even he did not have any "objective" way to determine what the cause of Mrs. Rumbo's pain and continued incontinence were, even as he was preparing to conduct a revision surgery on Mrs. Rumbo's mesh products in or around May and June of 2006.

The Superior Court concurrently held that, even if Mrs. Rumbo did not know what the cause of her injuries was in 2006, it was in 2009 when she saw a television commercial relating to the ongoing transvaginal mesh litigation that she knew, or had reason to know, that the AMS products that were implanted in her in 2006 had caused her injuries.

But even that testimony does not support the Superior Court's decision. It is clear from a plain reading of the testimony that Mrs. Rumbo was simply guessing, and further, she actually tied her viewing of the commercial to her retaining an attorney, which occurred in August 2011. The Superior Court did not even assess that testimony in its decision.

Finally, the Superior Court erred in not reserving the question of when Mrs. Rumbo "knew or should have known" that her injuries and symptoms were attributable to the AMS mesh products for a finder of fact. The question of when a Plaintiff became aware of, or should have become aware of, a potential cause of action is province of the jury, and removing that option from the jury was an error of law.

This Court cannot allow such findings to stand and must reject the Superior Court's findings that are "based on faulty factual predicates, unsupported by the record." *See Unitrin, Inc. v. Am. Gen. Corp*., 651 A.2d 1361, 1385 (Del. 1995) (reversing and remanding). Thus, for all the reasons below, the decision of the Superior Court must be reversed, and this matter reinstated for all proceedings.

SUMMARY OF ARGUMENT

The Superior Court erred in three ways in granting summary judgment on the statute of limitations in this transvaginal mesh matter:

1. First, the Superior Court held that Plaintiff-Decedent Mary Rumbo was aware, or should have been aware, of the cause of her injuries in 2006. In so doing, the Superior Court ignored the inconclusive testimony of Mary Rumbo and Dr. Andre Godet which indicated that, in or around the Spring of 2006, neither Mrs. Rumbo nor Dr. Godet were certain of what the causes of her symptoms were, and further, that those symptoms could not objectively be, nor does any of it establish the high burden defendant must meet in order to establish entitlement to summary judgment. The Superior Court further held that, even if Mrs. Rumbo did not know in 2006 that her injuries were caused by the Monarc and Perigee products, that when she saw a television commercial on the mesh litigation, that became a potentially "triggering" date for the statute of limitations as well. This was also error, because Mrs. Rumbo's testimony clearly indicated that she was simply guessing as to when she saw the commercial that the Court held was the "trigger" date for the statute of limitations.

2. Finally, the Superior Court erred in not sending the question of when the Plaintiff-Appellant Mary Rumbo "knew or should have known" that her injuries were connected to the implantation of the Monarc sling and the Perigee cystocele

mesh products to the finder of fact. It is well-settled in Delaware jurisprudence that such a question is the provision of the jury, and the granting of Summary Judgment denied the fact finder its opportunity to determine when Mrs. Rumbo knew or should have known that her symptoms and injuries were connected to the AMS Monarc and Perigee products.

As will be shown below, there is a question of material fact as to when Mrs. Rumbo became aware of the causation of her injuries, a factual question that makes granting summary judgment impossible, as the testimony is not, in any way, conclusive. In sum, the Trial Court's factual findings are frequently unsupported or contradicted by the record.

STATEMENT OF FACTS

A. Background facts: Implantation of the AMS Devices and Mrs. Rumbo's Treatment in Alaska.

The events that initiated this transvaginal mesh product liability action date back nearly two decades. In 2002, Mary Rumbo was a 47-year-old woman who, on May 17, 2002, underwent a (1) pubovaginal sling and (2) a cystocele repair at Providence Medical Center in Alaska by Dr. Andre Godet. (*See* A124, Deposition of Mary Rumbo ("M. Rumbo Dep.") at 19:5-8). Post-operatively Mrs. Rumbo saw some improvement for some time. Ultimately, however, she began to experience mild urinary retention, and in 2006 developed a recurrent cystocele and vaginal vault prolapse. (A126, M. Rumbo Dep. at 30:4-12).

In approximately 2006, Mrs. Rumbo again began to suffer from incontinence, the presence of vaginal vault prolapse (or descending of the organs) and a recurrent cystocoele. (A126, M. Rumbo Dep. at 30:25-32:22). In an effort to treat these symptoms, Dr. Godet, in or around April 2006, recommended a "new" method of surgical repair of both the anterior compartment defect as well as incontinence via the surgical implantation of polypropylene mesh. (*See* Deposition of Dr. Andre Godet ("Godet Dep."), A137 at 86:13-89:17; *see also* A126, M. Rumbo Dep. at 33:8-19).

On April 4, 2006, Dr. Godet implanted the AMS Perigee cystocele repair mesh and the AMS Monarc sling into Plaintiff Mary Rumbo; the intent of the use of

these mesh products was to prevent further recurrences of POP and SUI. (A126, M. Rumbo Dep. at 33:8-16). Mrs. Rumbo was given a pamphlet and shown an informational video by Dr. Godet before the implantation of the mesh. (A127, M. Rumbo Dep. at 34:14-35:7). Dr. Godet did not present any other options to Mrs. Rumbo other than the mesh to treat these symptoms (A127, M. Rumbo Dep. at 35:8-10) and only advised Mrs. Rumbo of the general risks of surgery, but not of mesh specific problems, such as mesh erosion or pain. (A127, M. Rumbo Dep. at 35:11-21).

Immediately after awakening from the mesh implant surgery, Mrs. Rumbo felt pain that she described as a "10." (A127, M. Rumbo Dep. at 36:10-24). In response to this, Dr. Godet immediately conducted a CT Scan on Mrs. Rumbo to try and ascertain the cause of her pain (as well as her incontinence symptoms). (A127 at 37:7-25). Dr. Godet offered Mrs. Rumbo both pain medication (A128, M. Rumbo Dep. at 38:1-8) and estrogen cream in order to "help the lining of [Mrs. Rumbo's] vagina and keep it moist so I wouldn't be dry." (A128, M. Rumbo Dep. at 38:9-15).

However, after several additional examinations, Mrs. Rumbo was told by Dr. Godet that he could feel mesh eroding through the vaginal wall. (A128, M. Rumbo Dep. at 38: 24-39:9). She testified that the mesh was "wrapping around her urethra" and "was exposed down into my urethra" but a close reading of the testimony indicates that Mrs. Rumbo seemingly co-mingled these facts with things that

occurred later in time. (A128, M. Rumbo Dep. at 39:5-9) ("It was wrapping around my urethra. It was wrapped around. So he [Dr. Godet] had to take me back to the OR, and he said he snipped it off. ***Oh, I'm going ahead.***")

Nonetheless, Dr. Godet then conducted the first of many mesh excision surgeries on Mrs. Rumbo on June 9, 2006. (A128, M. Rumbo Dep. at 39:10-18). Dr. Godet offered no promises from this excision surgery, and only indicated that he "was hoping [Mrs. Rumbo's symptoms] would be better" once he excised the eroding mesh. (A128, M. Rumbo Dep. at 39:13-18.) However, even after the mesh was removed, Mrs. Rumbo's pain and incontinence continued. (A128, M. Rumbo Dep. at 39:19-21).

Almost immediately after the June 9, 2006 surgery, Mrs. Rumbo continued to experience severe pain in her pelvic area. During a physical examination of Mrs. Rumbo in or around early July 2006, Dr. Godet noted that more mesh was exposed, and Mrs. Rumbo was suffering from urinary incontinence once again. (A128, M. Rumbo Dep. at 40:22-41:24.) Because of this, Mrs. Rumbo underwent another mesh removal surgery on July 27 2006, conducted by Dr. Godet. (A129, M. Rumbo Dep. at 43: 8-13). This July 2006 surgery did not alleviate Mrs. Rumbo's issues, and Dr. Godet advised her in August 2006 that the mesh had embedded into her bladder. (A129, M. Rumbo Dep. at 44:16-45:2). Dr. Godet felt that he could no longer assist Mrs. Rumbo at that point and advised her to see another physician with more

experience. (A129, M. Rumbo Dep. at 45:3-7). At that point, Mrs. and Mr. Rumbo returned to the Taxarkana area of Texas, outside of Dallas.

B. Return to Texas and Varying Treatments in Texas.

Having exhausted her treatment options in Alaska, Mr. and Mrs. Rumbo returned to Texas in 2007 (A129, M. Rumbo Dep. at 45:8-18) and has been treating there with several different physicians ever since, such as Dr. Alan Carley and Dr. Ash (A123, M. Rumbo Dep. at 8:5-9:18). She has had three mesh explant surgeries in Texas, (A149, Plaintiff's Fact Sheet ("PFS")) and a variety of other surgeries in Texas, such as the insertion of a pain pump and a pudendal nerve block. *(Id.*). She was also diagnosed as septic in 2009, which was when she began to visit Dr. Alan Carley in Texas. (A130, M. Rumbo Dep. at 46:2-11).

Mrs. Rumbo underwent several additional mesh revision surgeries after returning to Texas, including a mesh removal surgery on December 11, 2011 conducted by Dr. Alan Carley, a November 5, 2012 mesh revision surgery conducted by Dr. Alan Carley, a mesh removal surgery on September 10, 2013 conducted by Dr. Phillipe Zimmern at University of Texas Southwestern, and a mesh and anchor explant surgery conducted by Dr. Sanjay Vasvada on November 11, 2015.

C. Television Advertising

Mrs. Rumbo also testified that it was attorney advertising relating to transvaginal mesh that triggered her belief that perhaps she had a lawsuit. (A132,

M. Rumbo Dep. at 121:25-122:4)("A. I do not remember. All I remember is it said something about pelvic mesh, and I'm like "Paul, that's what's wrong with me. Maybe that's what's wrong with me.' Because at the time I didn't really know [what was wrong]."") Mrs. Rumbo testified that she was unsure when she saw these commercials. (A132, M. Rumbo Dep. at 120:25-121:4)("Q. Do you remember approximately when you saw the advertisement? A. I think it was 2009 is when I first started filling out paperwork, ***I think. I'm not sure, ma'am. I'm sorry.***") (emphasis added).

D. Proceedings Below

This matter was initiated via the filing of a short form complaint on April 27, 2013. (A28-A29). Defendant-Appellee AMS filed its motion for summary judgment on the statute of limitations on August 11, 2020, alleging that Mrs. Rumbo knew, or should have known that she had a possible cause of action against AMS regarding the Monarc and Perigee products as early as 2006. (A005-A0096). Plaintiff-Appellee opposed on September 10, 2020. (A0097-A182). On September 24, 2020, AMS filed its Reply Brief. (A184-A224).

On January 26, 2021, AMS submitted supplemental precedent out of the Southern District of Indiana. (A225-A241). Oral argument took place on January 27, 2021 (A242-299). Subsequently, the Superior Court ordered supplemental briefing from both sides. Defendant-Appellee filed their supplemental brief on

March 23, 2021. (A300-318). Plaintiffs-Appellants filed their supplemental brief on March 26, 2021. (A319-338). On April 29, 2021, the Superior Court granted Defendants' Motion for Summary Judgment. (*See* Opinion and Order dated April 29, 2021 ("Opinion and Order"), Exhibit A). Plaintiffs-Appellants Notice of Appeal was filed on May 19, 2021. (A339-340).

ARGUMENT

I. THE TESTIMONY AND EVIDENCE OFFERED BY AMS DID NOT CONCLUSIVELY ESTABLISH THAT THIS MATTER IS TIME BARRED

A. Question Presented

Whether the Superior Court correctly held that Plaintiffs' Fact Sheet Responses entirely undermine the remaining testimony indicating that she was not aware of the cause of her mesh injuries until 2011. This question was presented below at A004-A224.

B. Standard of Review

Review of the Superior Court's decision on a motion for summary judgment is *de novo. See ConAgra Foods Inc. v. Lexington Ins. Co.*, 21 A.3d 62, 68 (Del. 2011)("We review the Superior Court's grant or denial of a summary judgment motion *de novo"*); *see also Richards v. Copes-Vulcan, Inc.*, 213 A.3d 1196; *In re: Asbestos Litigation (Collins)*, 673 A.2d 159, 160 (Del. 1996); *Merrill v. Crothall-American, Inc.*, 606 A.2d 96, 99 (Del. 1992).

In Delaware, summary judgment is granted only if the moving party establishes that there are no genuine issues of material fact in dispute and judgment may be granted as a matter of law. *See* Super. Ct. Civ. R. 56(c). All facts are viewed in a light most favorable to the non-moving party. *See Hammond v. Colt Indus. Operating Corp.*, 565 A.2d 558, 560 (Del. Super. 1989). Summary judgment may

not be granted if the record indicates that a material fact is in dispute, or if there is a need to clarify the application of law to the specific circumstances. *See Barba v. Carlson,* 2014 Del. Super. LEXIS 198, *4 (Del. Super. April 8, 2014)(*citing* Super. Ct. Civ. R. 56(c)). The party who makes a motion for summary judgment must supply evidentiary material sufficient to enable the Court to resolve the mover's contentions in his favor. *See Hurtt v. Goleburn,* 330 A.2d 134 (Del. Super. 1974).

C. Merits of the Appeal

Delaware applies a two-year statute of limitations for product liability matters such as the one below. Moreover, it is well-settled that Delaware Courts apply the "discovery rule" in assessing the date that the statute of limitations begins to run. *See Brown v. E.I. duPont de Nemours & Co., Inc.,* 820 A. 2d 362, 368 (Del. 2003)("A plaintiff may remain blamelessly ignorant of the potential claim even after a latent injury reveals itself through physical ailments. The limitations period for a toxic tort does not begin immediately upon the onset of physical problems if the symptoms are reasonably attributable to another cause and the plaintiff is not on notice of the tortious cause.")[3]

[3] In the briefing below, there was a question of whether Delaware, Texas or Alaska law applied. Appellee initially argued for Alaska as they felt it was most favorable to them in their pursuit of a dismissal (A10-A13), but the Superior Court held that Delaware law applied (and that the law of all three states applied the discovery rule; therefore, a choice of law of analysis was so similar as to make little to no difference.) (*See* Opinion and Order, Exhibit A at pp. 5-9). Nonetheless, it must be noted that Alaska and Texas apply virtually the same "discovery" rule to the statute of limitations. *See Reasner v. State,* 394 P.3d 610, 614 (Alaska 2017)(the statute of limitations begins to run on the date "when a reasonable person has enough information to alert

Further, this Court has previously held that a trial court must engage in a diligent factual inquiry when making its determination as to when the statute of limitations begins to run:

> To apply the discovery exception, the court must conduct a fact-intensive inquiry to determine whether a plaintiff was blamelessly ignorant of a potential claim or dilatory in pursuing the action. A plaintiff may remain blamelessly ignorant of the potential claim even after a latent injury reveals itself through physical ailments. The limitations period for a toxic tort does not begin immediately upon the onset of physical problems if the symptoms are reasonably attributable to another cause and the plaintiff is not on notice of the tortious cause.

See Brown, *supra,* 820 A.2d at 368.

The Superior Court failed to make the appropriate factual inquiry in determining if the Discovery Rule should apply here. [4] Instead, the Superior Court selected materials that supported its decision to dismiss while ignoring other material, such as testimony from Mary Rumbo and Dr. Godet, that showed Mrs.

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that person that he or she has a potential cause of action or should begin an inquiry to protect his or her rights"); *Enterprise-Laredo Associates v. Hachar's, Inc.,* 839 S.W.2d 822, 838 (Tex. App. 1992)(An exception to the general rule is known as the discovery rule and the rule is used to determine when the cause of action accrued. . . [t]he discovery rule tolls the running of the limitations period until the time the injured party discovers or through the use of reasonable care and diligence should have discovered the injury")(*citing Moreno v. Sterling Drug Inc.,* 787 S.W.2d 348, 351 (Tex. 1990).

[4] Alaska and Texas apply a nearly identical analysis of the discovery rule. *See Ranes & Shine, LLC v. MacDonald Miller Alaska, Inc.*, 355 P.3d 503, 509 (Alaska 2015)(Determining the [date of notice inquiry] requires a "fact-intensive" analysis); *Enterprise-Laredo Associates v. Hachar's, Inc.,*839 S.W.2d 822, 838 (Tex. App. 1992)("the question of whether one has exercised reasonable diligence to discover an injury is a question of fact, unless the evidence is such that reasonable minds may not differ as to its effect.")

Rumbo did not know (nor should she have known) that the mesh was the cause of her injuries. Further, despite the complete lack of clarity, the Superior Court took no further steps to try and determine the exact date Mrs. Rumbo inquired, and ultimately retained, an attorney.

1. **The Plaintiff's Fact Sheet does not Undermine the Considerable amount of Testimony that shows that it was not Conclusive in 2006 that Mrs. Rumbo "knew or should have known" that the AMS Pelvic Mesh was the Cause of her Injuries.**

One of the two primary components of the Superior Court's decision is that Mrs. Rumbo, supposedly, indicated that she was aware of the causal connection between her injuries and the Defendant-Appellee's Mesh immediately. (*See* Opinion and Order, Exhibit A at p. 10-11). Specifically, the Superior Court held that:

> [Mary] Rumbo's assertion that [she] did not and could not have discovered that her injuries were related to AMS Pelvic Mesh are undermined by Rumbo's "Fact Sheet" in which Mary Rumbo stated that she knew "Immediately" and/or "One week post operation" that her injuries were caused by the AMS Pelvic Mesh.
>
> (Opinion and Order, Exhibit A at p. 10-11).

The Superior Court is referring to a portion of Mrs. Rumbo's Plaintiff's Fact Sheet at Section II, ¶ 6(c), which indicates:

> *6.c. When did you first attribute these bodily injuries to the pelvic mesh products?*
>
> *[A]. Immediately.*
>
> (*See* A147).

Thus, the Superior Court held that Mary Rumbo knew (or should have known) as soon as she awoke on April 4, 2006 and felt substantial pain in her vagina, that her injuries were caused by a defect in the AMS Monarc or Perigee transvaginal mesh products. Although Mrs. Rumbo had two products implanted on April 4, 2006, neither the Superior Court (nor the Defendant-Appellee in the briefing below) specified which product they believe Mrs. Rumbo knew was defective in 2006.

This was error because a substantial amount of testimony from Mrs. Rumbo indicates that she was not aware of the specific cause of her injuries. The Superior Court incorrectly held that simply having the symptoms that Mrs. Rumbo would later learn were caused by a defect in the mesh is enough to establish that Mrs. Rumbo was on "notice inquiry" of a possible claim against AMS. As will be shown below, the Superior Court's holding is in contrast to several cases that have held that simply having the symptoms that a plaintiff later learns were related to a defect in mesh, or even having a revision surgery, is not enough to establish that Plaintiff had knowledge sufficient to begin to take steps to protect her rights to a lawsuit.

2. Mrs. Rumbo's Testimony on her Knowledge of the cause of her Injuries in 2006 Belies the Superior Court's Holding.

Mrs. Rumbo offered considerable testimony that supports the argument that she was not "immediately" aware that either of the AMS pelvic mesh products were the cause of her pain and injuries. Importantly here, Mrs. Rumbo testified that Dr. Godet immediately conducted a CT Scan on Mrs. Rumbo after her first mesh implant

surgery to try and ascertain the cause of her pain (as well as her incontinence symptoms)(A127 at 37:7-25). Even more critically, Dr. Godet, at that point, offered Mrs. Rumbo both pain medication (A128 at 38:1-8) and estrogen cream, in order to "help the lining of my vagina and keep it moist so I wouldn't be dry." (A128 at 38:9-15). This kind of treatment does not implicate the mesh, but is, instead, generalized and exploratory treatment.

Thus, at the time of the first surgery in April 2006, there is nothing in the record indicating that Mrs. Rumbo knew, or should have known, about the cause of her injuries being directly related to the AMS Monarc and Perigee products. Dr. Godet conducted a CT-Scan and only offered pain medication and estrogen cream, both of which are not treatments which would indicate an issue with the design of the AMS mesh products at issue in this matter.

The same is true of Mrs. Rumbo's discussions with Dr. Godet in May and June 2006, which is the time period immediately before her first revision surgery. To be clear, Dr. Godet testified that he advised Mrs. Rumbo in June 2006 that there was mesh extrusion (A0074, Godet Dep. at 134:12-14) and that the mesh possibly could have caused her "irritative" symptoms. (A0079, Godet Dep. at 151:12-15).

Dr. Godet testified that, after conducting a pelvic exam in 2006, even he was not certain what the cause of Mrs. Rumbo's pain and symptoms were, because those symptoms were inconclusive. (*See* A0077-A0078, Godet Dep. at 145:1-146:24)("Q.

Did you do a pelvic exam? A. Pelvic exam was done and the vaginal tissue appeared healthy. Whitish discharge without an odor in the midline area. She was tender. The tissue was a little, in my words, granular, but I didn't see any exposed mesh. Q. Uh-huh. A. So she just seemed irritated in that area . . . **without obvious reason, and I guess concern was something lingering or untreated**.")(emphasis added)

Indeed, when specifically asked, Dr. Godet indicated that he was *not* certain that the mesh was the cause of Mrs. Rumbo's symptoms at that time in May 2006. (A0077-A0078, Godet Dep. at 145:13-146:5)("Q. And under your recommendations you said the patient will likely require removal of all palpable and exposed mesh. Would you have communicated that to Mrs. Rumbo? A. Yes. Q. And what was your basis for that? A. So given her persistent, bothersome symptoms – and to be honest, I don't know if she had continued estrogen at that point; I don't make that clear, but the tissues looked healthy . . . except for where there was a bit of discharge. The basis for the – possibly requiring further intervention was this persistent discharge and her complaints. **Hard to really prove to me in this setting, you know, is – is the mesh an ongoing issue here or not**.") (emphasis added). Finally, Dr. Godet noted that there was no "objective" way to know what the cause of her irritative symptoms were. (A0079, Godet Dep. at 151:16-18)("Q. But there's nothing that you have objectively do – objectively do to know for sure? A. Correct. Correct.")

The Superior Court did not even *assess* this critical testimony from Dr. Godet, the implanting surgeon—that is, the doctor who both implanted the mesh surgically *and* treated Mrs. Rumbo immediately after her surgeries and conducted her revision surgeries. Yet, at the same time, the Superior Court considered the testimony that justified its ruling, such as Dr. Godet testifying that he found exposed mesh in May 2006. (*See* Opinion and Order, Exhibit A, p. 2). The Superior Court even held that "Mary Rumbo stated unequivocally in her deposition testimony, the AMS Pelvic Mesh failed to relieve her symptoms and caused her pain 'immediately' after the 2006 Pelvic Mesh Implant surgery." (*See* Opinion and Order, Exhibit A, p. 12). The Court held in this manner despite clear testimony from the implanting physician himself which showed that even he was not aware of the cause of Mrs. Rumbo's symptoms. And yet, the Superior Court determined that Mrs. Rumbo should have been aware of what the cause of her symptoms were. This was error.

Mrs. Rumbo's testimony corroborates that of Dr. Godet's in the sense that there was no objective way to know what the cause of Mrs. Rumbo's issues were in the Spring and early Summer of 2006. Mrs. Rumbo did not describe being told anything about the mesh being the cause of her injuries in or around June 9, 2006—the time of her first revision surgery. Instead, she was told on June 9, 2006 that the mesh had eroded through her vaginal wall. (A128, M. Rumbo Dep. at 39: 3-9). She testified that the mesh was "wrapping around her urethra" and "was exposed down

into my urethra" but a close reading of the testimony indicates that Mrs. Rumbo seemingly co-mingled these facts with things that occurred later in time. (*Id.* at 39:5-9)("It was wrapping around my urethra. It was wrapped around. So he [Dr. Godet] had to take me back to the OR, and he said he snipped it off. **Oh, I'm going ahead**.")(emphasis added).

Nonetheless, this testimony does not establish that Mrs. Rumbo knew (or should have known) that, on June 9, 2006, a defect in the AMS Monarc or Perigee mesh was the cause of her injuries. What it does indicate is that she was aware that her symptoms[5], such as pain and incontinence, were not resolved by the mesh, that she was suffering from additional complications as a result of her mesh implantation procedure, and that she needed some of the mesh excised in the hopes of relieving those complications. (A128, M. Rumbo Dep. at 39:13-18)("Q. And before Dr. Godet did the excision surgery, did he talk about any specific risks or benefits to the surgery or just general surgical risks? A. He was hoping that once he clipped off the exposed mesh that things would be better. That's all he said.[]")

But this is not enough to conclusively establish that Mrs. Rumbo was aware, or should have been aware, that these symptoms were tied to a defect in the product,

[5] The same is true of Mrs. Rumbo's dyspareunia. Mrs. Rumbo began experiencing dyspareunia immediately after the mesh was put in in 2006. (A131, M. Rumbo Dep. at 91:20-16; A168, Deposition of Paul Rumbo at 39:3-5). But having this symptom does not establish that Mrs. Rumbo knew, or should have known, that a defect in the AMS products were the cause.

which is what the Defendant must show here. *See Smith & Nephew Birmingham Hip Resurfacing Hip Implant Products Liability Litigation MDL No. 2775*, 2018 U.S. Dist. LEXIS 198316, at *34 (D. Md. Nov. 19, 2018)("[r]evision surgery, alone, only tells a plaintiff that she is suffering from complications as a result of [their] implant procedure, but it is silent as to the cause of that complication. Without more information, a reasonably conscientious patient could not deduce whether the cause of her injury is her doctor's malpractice, something unique to her own medical history, an unfortunate but accepted ill-effect of the . . . device, or a true product defect.")

Mrs. Rumbo also testified that until she saw pelvic mesh attorney advertisements on television, she had no idea what the possible root cause of her injuries were. (A132, M. Rumbo Dep. at 121:25-122:4)("A. I do not remember. All I remember is it said something about pelvic mesh, and I'm like "Paul, that's what's wrong with me. Maybe that's what's wrong with me.' Because at the time I didn't really know.") This testimony makes it clear that Mrs. Rumbo did not know or have reason to known in 2006 what the cause of her injuries were. At the least, it creates a *question of fact* that a factfinder should be called upon to determine.

None of the above establishes, as a matter of law, that Mrs. Rumbo was aware, or should have been aware, that her symptoms were caused by a defect in the mesh in 2006. That is why the Superior Court erred in its ruling—though it was presented

with all of this material and testimony, the Superior Court ignored it. (A350)(indicating that all of this testimony is undermined by Mrs. Rumbo's two Plaintiff Fact Sheet responses). It is well-settled that the standard for granting summary judgment is high. Summary Judgment should only be granted where the moving party establishes the absence of any genuine issue of material fact. *See Moore v. Sizemore*, Del. Supr., 405 A.2d 679, 680-81 (1979).

Here, however, the Court incorrectly held that AMS *conclusively* established the absence of any genuine issue of material fact. (Opinion and Order, Exhibit A, pp. 10-11). The testimony detailed above confirms this, no matter what was said in the Plaintiff's Fact Sheet. Mrs. Rumbo did not have information that conclusively establishes that she was aware of her injuries being caused by a defect in subject mesh as early as 2006, or on the date of her first revision surgery on June 9, 2006, as the Superior Court held.[6]

In fact, all the testimony is to the contrary, and certainly enough to require denial of this motion and reversal of the Superior Court's decision. There is no testimony or evidence that conclusively established that Mrs. Rumbo knew of, or

[6] Defendants would need to establish the same under Texas or Delaware law. *See Enterprise-Laredo Associates v. Hachar's, Inc.*,839 S.W.2d 822, 838 (Tex. App. 1992),("the question of whether one has exercised reasonable diligence to discover an injury is a question of fact, unless the evidence is such that reasonable minds may not differ as to its effect."); *see also Brown*, 820 A.2d 362 at 368 ("the court must conduct a fact-intensive inquiry to determine whether a plaintiff was blamelessly ignorant of a potential claim or dilatory in pursuing the action"). For all the reasons included herein, Defendants would also fail to meet the summary judgment threshold under Delaware or Texas law.

had reason to know of, AMS' role in her injuries in 2006. The Superior Court ignored Mrs. Rumbo's uncertainty as to when she saw these commercials, and instead argues that the next exchange of testimony conclusively establishes that Mrs. Rumbo knew, in 2009, that she potentially had a lawsuit. But a reading of the testimony indicates that Mrs. Rumbo was not certain when she saw the advertisement, or when she contacted a lawyer, and that she was simply guessing about it being in 2009; however, as noted above, the Superior Court claimed that this considerable testimony was "undermined" by Mrs. Rumbo's fact sheet. This was error, and on its own, is sufficient for this Court to reverse.

3. Mrs. Rumbo did not Conclusively Establish That She Saw an Advertisement for Vaginal Mesh cases in 2009.

On the same point, the Superior Court alternatively held that, even if Mrs. Rumbo had not known in 2006 that her injuries were caused by her AMS mesh, her testimony regarding a television advertisement that she supposedly saw in 2009 regarding transvaginal mesh lawsuits established a date that she knew, or should have known, that the mesh caused her injuries. (*See* Opinion and Order, Exhibit A, pp. 12)("Even if 2006 was not the pivotal date for notice of a potential claim, the 2009 television commercial put Rumbo on notice.")

But as with several other comments made in the varying depositions mentioned above, Mrs. Rumbo did not *conclusively* testify when she saw an advertisement for vaginal mesh lawsuits. Though she *guessed* that 2009 was a

possible date, she testified that she did not recall when, exactly, she saw these commercials. (A132, M. Rumbo Dep. at 120:25-121:4)("Q. Do you remember approximately when you saw the advertisement? A. I think it was 2009 is when I first started filling out paperwork, ***I think. I'm not sure, ma'am. I'm sorry.***") (emphasis added).

First, the obvious—from the testimony, Mrs. Rumbo is speculating about when she saw the commercials on television. This is far from the absolute statement Defendants make it out to be. Second, Mrs. Rumbo is tying her recollection of the commercial to when she first signed up with an attorney, which was in August 2011, not 2009.[7] Mrs. Rumbo's complaint was filed on April 27, 2013, which is within two years of that August 2011 date. (A002-003). This testimony, taken in total, is not enough for the Court to have leaned in favor of dismissal, which, again, requires there to be *conclusive* proof that the statute of limitations expired for the Court to rule as a matter of law.

But the Superior Court ignored Mrs. Rumbo's uncertainty as to when she saw these commercials, and instead argues that the next exchange of testimony conclusively establishes that Mrs. Rumbo knew, in 2009, that she potentially had a lawsuit. But a reading of the testimony indicates that Mrs. Rumbo was not certain

[7] Though this same argument was raised during the motion below, no assessment of the date of retainer was taken by the Superior Court.

when she saw the advertisement, or when she contacted a lawyer, and that she was simply guessing about it being in 2009. But as noted above, AMS entirely ignored the clear testimony that Mrs. Rumbo was not sure when she first saw that commercial and took no further steps to try and determine the date Mrs. Rumbo inquired, and ultimately retained, an attorney.

4. Other Courts Have Rejected the Same Arguments Presented by Defendants-Respondents Here.

Several Courts have held that in the context of a medical device, the date of the revision does *not* trigger the date of "notice inquiry" because a revision surgery does not immediately and conclusively establish that the cause of the revision surgery was due to a defect in the product.

In a transvaginal mesh matter with facts and arguments that are almost identical to the ones presented here, the District of Oregon denied a similar request for summary judgment. *See Long v. Ethicon, Inc*., 2020 U.S. Dist. LEXIS 147385, at *12-15 (D. Or. June 29, 2020). The *Long* Court rejected virtually the same arguments that Defendant-Appellee made below, holding that "[w]hether Long should have been aware of the substantial possibility that the TVT product was the cause of her ongoing injuries as opposed to other aspects of her surgical history or health conditions, and whether Long was subject to a duty to inquire about facts that may trigger the statute of limitations is itself a genuine issue of material fact." *Id.* at *13-14 (*citing Kildow v. Berg, Inc.*, 796 F. Supp. 2d 1295 (D. Or. 2011).

The facts of *Long* are nearly identical to the facts here. Mrs. Rumbo also continued to suffer the exact same symptoms she had prior to the implantation of the mesh immediately after the mesh was implanted. At no point during his course of treatment did Dr. Godet indicate that the mesh may have been defective, though he did excise the mesh in an effort to relieve Mrs. Rumbo's symptoms. After her first revision surgery on June 9, 2006, Mrs. Rumbo continued to experience these same symptoms. (A128, M. Rumbo Dep. at 39:10-18). The symptoms continued after the second revision surgery as well. (*Id.* at 39:19-21). Going into the July 27, 2006 revision surgery, Mrs. Rumbo still had these same symptoms. (*Id.* at 40:22-41:24.) And even after the July 27, 2006 surgery, Mrs. Rumbo continued to suffer from symptoms, requiring her to return to Texas. (A129, M. Rumbo Dep. at 45:8-18).

Ultimately, nothing indicates that before Mrs. Rumbo saw the television advertisement on transvaginal mesh that she, or her husband, were aware of the *specific* defect in the AMS Monarc and Perigee products. For those reasons, the Court incorrectly held that there was conclusive proof that Mrs. Rumbo knew, or should have known, in 2006 and/or 2009 that she had a cause of action against AMS.

II. DELAWARE CONSIDERS THE DISCOVERY RULE A QUESTION OF FACT FOR THE JURY AND THE FAILURE TO PASS THIS QUESTION TO THE FINDER OF FACT WAS ERROR

A. Question Presented

Whether the District Court correctly determined if the determination of the Discovery rule is resolvable as a matter of law, or if the determination of when the Plaintiff "knew or should have known" must be a question of fact for the jury. This matter was raised below at A300-A335.

B. Standard of Review

The standard of review on this issue is also *de novo.* *See supra,* Section II.B.

C. Merits of the Appeal

It is well-settled that, in Delaware, the application of the discovery rule requires a fact intensive inquiry that must be submitted to the jury. *See Estate of Sanchez Valdez v. Burlington Northern Santa Fe. Ry.*, 2020 Del. Super. 2991 (Sup. Ct. New Castle Cty. Dec. 15, 2020)("where, as here, there is a genuine dispute regarding a material fact, summary judgment is not appropriate. Furthermore, applying the discovery rule requires a fact intensive inquiry that must be submitted to the jury. Therefore, if BNSF wishes to present this factual dispute at trial, then the jury will be asked to apply the discovery rule to determine the date on which Valdez knew or should have known that his cancer was caused by exposure to toxic substances during his employment by BNSF as a machinist.")

The cases that support this standard are legion in Delaware. *See Silverstein v. Fischer,* 2016 Del. Super. LEXIS 234, at *17 (Sup. Ct. New Castle Cty. 2016)("[w]hether that renders the injury "inherently unknowable" to the Silversteins is an unresolved question of fact for the jury. Similarly, if the injury is "inherently unknowable," whether the Silversteins are "blamelessly ignorant" is also a question for the jury. Therefore, the Court cannot rule that, as a matter of law, the "discovery rule" does not toll the statute of limitations"); *Crest Condo. Ass'n v. Royal Plus, Inc.,* 2017 Del. Super. LEXIS 642, at *14(Del. Sup. Sussex Cty. 2017)(" There are factual questions in dispute, namely whether the doctrines of inherently unknowable injuries and fraudulent concealment tolled the statute of limitations. Plaintiffs have submitted adequate evidence to show that the facts of this case may support the finding that one or both of these doctrines apply. Therefore, these are questions of fact that must be left to the jury"); *Ocimum Biosolutions Ltd. v. AstraZeneca UK Ltd.*, 2019 Del. Super. LEXIS 640, at *19 (Del. Sup. Ct. 2019)("Whether a statute of limitations was tolled generally is a question of fact")

Courts in Delaware have applied the discovery rule generously to claims such as the instant matter, where a blameless Plaintiff was unaware of the cause of her injuries. *See Bendix Corp. v. Stagg,* 486 A.2d 1150, 1153 (Del. 1984)("here, the Superior Court properly denied Bendix's motion for summary judgment as it is still controverted when his asbestosis manifested itself and became ascertainable").

Albeit in an Asbestos matter, the Delaware Supreme Court has denied summary judgment and held that "mere exposure to asbestos" accompanied by 'symptomatology associated with asbestosis may not suffice . . . to render a plaintiff chargeable with knowledge that his harm is attributable to asbestos." *See Collins v. Pittsburgh Corning Corp. (In re: Asbestos Litigation)*, 673 A.2d 159, 162 (Del. 1996). As with Mrs. Rumbo, mere exposure to the mesh, accompanied by her injuries that she would later learn were connected to the mesh, is not enough to charge her with knowledge that the mesh caused her injuries in 2006 when she first had her revision surgeries.

The same is true regarding the question of whether Mrs. Rumbo only learned of her injuries when she saw transvaginal mesh advertising on television. In *Estate of Sanchez Valdez v. Burlington Northern Santa Fe,* 2020 Del. Super. LEXIS 2991, *supra*, the Plaintiff was diagnosed with laryngeal cancer in 2014, which he alleged occurred due to his exposure to toxic chemicals while employed by defendant Burlington Northern Santa Fe ("BNSF"). *Id.* at *3-4. The lawsuit in question was not filed until September 29, 2017. *Id.* at *4. Though there were some issues with the Plaintiff's method of service, the Superior Court considered the discovery rule in cases (like this transvaginal mesh litigation) where the Plaintiff may have been exposed to a toxic substances years before symptoms arise. *Id.* at *6. Ultimately, the Court denied summary judgment and held that the discovery rule was applicable,

because there was a dispute between the parties regarding the "question of when Valdez knew or should have known that his laryngeal cancer was the result of exposure to toxic substances in the BNSF workplace." *Id.* at *6. Notably here, the court further held that " . . .applying the discovery rule requires a fact intensive inquiry that must be submitted to the jury." *Id.* at *7.

As in *Estate of Sanchez Valdez,* this matter was not ripe for summary judgment, as there was nothing that conclusively established what Mrs. Rumbo knew in 2006, or anything that conclusively established when Mrs. Rumbo saw the television advertisement that she indicated connected the issue of her injuries. These issues are in dispute, and that dispute must be resolved by the jury. Notably, AMS will still be allowed to raise their statute of limitations arguments at trial, even if this appeal is successful. Plaintiff-Appellant Paul Rumbo, however, would be denied his day in Court if the Superior Court is affirmed. The motion should have been denied under Delaware law, which is what the Superior Court held was applicable. This Court should reverse and remand for all the reasons detailed above.

CONCLUSION

WHEREFORE, Plaintiff respectfully request that this Honorable Court reverse or vacate the Judgment of the Superior Court and reinstate and remand this matter for all pre-trial and trial proceedings.

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