#2015
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IN RE: ALLODERM® LITIGATION CASE CODE 295	
MICHAEL SIMINERI and KAREN SIMINERI, h/w, Plaintiffs, v. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-5972-11 CM Civil Action **ORDER**

The above matter having been opened to the Court by Lowenstein Sandler LLP, attorneys for defendant LifeCell Corporation, on application for an Order barring plaintiff from introducing any evidence or argument about LifeCell's porcine product, Strattice, at the time of trial, and the Court having considered all papers submitted by the parties and the arguments of counsel and for good cause and the reasons ~~stated on the record by the Court,~~ set forth in the attached memorandum of decision

It is on this the 20th day of November, 2015,

ORDERED that defendant's motion is hereby ~~granted; and it is further~~ denied without prejudice.

~~ORDERED that plaintiffs~~ are barred from introducing any evidence or argument ~~about Strattice at the time of trial~~; and it is further

ORDERED that a copy of this Order be ~~served~~ posted online on all counsel of record within 7 days hereof.

11/21/17

Hon. Jessica R. Mayer, J.S.C.

OPPOSED

PAPERS CONSIDERED

	Yes	No	Date
Notice of Motion	✓		
Movant's Affidavits	✓		
Movant's Brief	✓		
Answering Affidavits	✓		
Answering Brief	✓		
Cross Motion			
Movant's Reply			
Other			

SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
JESSICA R. MAYER, J.S.C.
JUDGE

MIDDLESEX COUNTY COURTHOUSE
P.O. BOX 964
NEW BRUNSWICK, NEW JERSEY 08903-964

NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

Memorandum of Decision on Defendant's Motion *In Limine* to Bar Plaintiffs from Introducing Evidence or Argument Regarding Strattice™

In Re: AlloDerm® Litigation, Case Code 295

Michael Simineri and Karen Simineri v. LifeCell Corporation

Docket No. MID-L-5972-11 CM

For Plaintiffs: Lawrence R. Cohan, Esq., Joseph J. Fantini, Esq., and Sol H. Weiss, Esq., Anapol Weiss.

For Defendant: David W. Field, Esq., Stephen R. Buckingham, Esq., Lowenstein Sandler LLP.

Dated November 20, 2015

Defendant LifeCell Corporation ("LifeCell" or "Defendant") moves to bar evidence and argument regarding LifeCell's porcine mesh product, Strattice™. Counsel for the parties presented oral argument on this motion during a case management conference held on November 17, 2015. Upon considering the arguments of the parties, legal memoranda, exhibits and relevant case law,[1] the court determines that LifeCell's motion to bar evidence and argument regarding Strattice™ is **DENIED WITHOUT PREJUDICE.**

[1] The parties signed a consent order stipulating that New Jersey law governs all issues in the AlloDerm® cases. See consent order dated January 15, 2015.

Defendant moves to bar evidence and argument regarding Strattice™, a porcine biological mesh product created by LifeCell subsequent to the development and marketing of AlloDerm®. Defendant argues that (1) Strattice™ was not commercially available at the time of Mr. Simineri's hernia repair surgery with AlloDerm®; (2) evidence and argument about Strattice™ would be unfairly prejudicial because it would imply a superior alternative product; and (3) the reasons for the development and promotion of Strattice™ and the reduced promotion of AlloDerm® following the launch of Strattice™ are irrelevant and highly prejudicial. Defendant argues that any discussion of Strattice™ was rendered moot upon this court's dismissal of Plaintiffs' defective design claim,[2] where Strattice™ was rejected as a potential safer alternative design. Defendant asserts that evidence or argument regarding LifeCell's testing and subsequent promotion of Strattice™, or Strattice™'s comparative superiority to AlloDerm®, would confuse the jury and "create an irrelevant [and] time consuming side-show about the comparative efficacy of AlloDerm® and Strattice™."[3] The heart of Defendant's argument is that Strattice™ is a unique product which was not commercially available at the time of Mr. Simineri's surgery, and thus it is irrelevant to Plaintiffs' failure-to-warn claim.

Plaintiffs oppose Defendant's motion, arguing that although Strattice™ was not commercially available at the time of Mr. Simineri's surgery, it had been in the development process prior to October 24, 2007. Plaintiffs contend that a motivation for developing Strattice™ was LifeCell's awareness of certain dangerous propensities and high failure rates associated with Alloderm® when used in ventral hernia repair. As such, Plaintiffs argue that certain evidence relating to the development of Strattice™ is relevant to what LifeCell knew or should have known

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[2] See Order and Memorandum of Decision on Defendant's Motion for Partial Summary Judgment as to Plaintiffs' Claims for Design Defect, dated August 14, 2015.

[3] Defendant's Brief in Support of Motion *In Limine* to Preclude Plaintiff Michael Simineri from Introducing Testimony or Evidence at Trial Regarding Strattice™ ("Def.'s Br.") 1.

about AlloDerm® prior to Mr. Simineri's 2007 hernia surgery. Plaintiffs also assert that LifeCell conducted some level of testing on AlloDerm® in conjunction with the development of Strattice™,[4] which test results bear on what LifeCell knew or should have known about AlloDerm®. Finally, Plaintiffs argue that LifeCell's promotion of Strattice™ and its purported acknowledgment of Strattice™ as a superior product for hernia repair are also indicative of LifeCell's knowledge of the shortcomings of AlloDerm®.

Under New Jersey law, a manufacturer has a duty to warn of the adverse effects of a prescription medical product "of which they know or should have known on the basis of reasonably obtainable or available knowledge." Feldman v. Lederle Lab., 97 N.J. 429, 434 (1984). Unless subject to specific exclusions, "all relevant evidence is admissible." N.J.R.E. 402. Under the New Jersey Rules of Evidence, "'[r]elevant evidence' means evidence having a tendency in reason to prove or disprove any fact of consequence to the determination of the action." N.J.R.E. 401. Evidence is considered relevant if there is a logical connection between the proffered evidence and what the party seeks to prove. See Furst v. Einstein Moomjy, Inc., 182 N.J. 1, 15 (2004) (citing State v. Hutchins, 241 N.J. Super. 353, 358 (App. Div. 1990)). Evidence which is relevant to the action may nonetheless be excluded "if its probative value is substantially outweighed by the risk of (a) undue prejudice, confusion of issues, or misleading the jury . . . ." N.J.R.E. 403.

LifeCell began developing Strattice™ in 2002,[5] well before Mr. Simineri's hernia repair surgery with AlloDerm®. As part of this product development plan, LifeCell also conducted testing involving AlloDerm®.[6] One of the reasons for such testing included "trying to understand better the mechanism of action of AlloDerm as a stand-alone product, trying to understand how it

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[4] Plaintiffs' Response to Defendant's Motion *In Limine* to Bar Plaintiff from Introducing any Evidence or Argument Regarding Strattice™ ("Pls.' Br.") 7; Certification of Joseph J. Fantini ("Fantini Cert.") Ex. F, 15:24-16:8.
[5] Fantini Cert., Ex. F, 16:19-20.
[6] Id. at 14:24-15:10; 16:3-12.

worked in animal models, how it repopulated, how it revascularized [sic], how it regenerated and remodeled into host tissue."[7] Thus, although Strattice™ was not commercially available at the time of Mr. Simineri's 2007 hernia surgery, LifeCell's development of Strattice™ before that date was arguably intertwined with its knowledge of AlloDerm®. Similarly, internal meeting notes, training materials and sales documents for Strattice™ may bear on what LifeCell knew or should have known about AlloDerm® during the development of Strattice™, prior to Mr. Simineri's 2007 AlloDerm® surgery.[8]

However, evidence or argument focusing solely on Strattice™'s alleged superiority as a hernia repair product, or LifeCell's resource allocation in developing Strattice™ as opposed to AlloDerm®, is overly prejudicial and confusing to the jury. Whether or not Strattice™ is a better product than AlloDerm® has no bearing on whether or not LifeCell failed to warn of the alleged dangerous propensities or characteristics of AlloDerm®.

The issue here, as with Defendant's simultaneously filed motion to bar medical literature, emails, or other documents dated after October 24, 2007, is that there is no way for the court to determine at this time which Strattice™ documents are or are not relevant to Plaintiffs' claim. Accordingly, the court declines to make a broad ruling barring all evidence and testimony relating to Strattice™; the issue is reserved for trial.

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[7] Id. at 16:3-8 (emphasis added).

[8] See, e.g., Fantini Cert. Ex. K, NJALLO_039012, which notes "customers not convinced of AlloDerm long term strength" in the context of July 2006 meeting minutes of the Strattice™ "commercialization team."

For the foregoing reasons, LifeCell's motion to bar evidence and argument regarding Strattice™ is **DENIED WITHOUT PREJUDICE.**

4/21/17

Jessica R. Mayer, J.S.C.