Sills Cummis & Gross P.C.

Client Alert Product Liability Law

D'Addario v. Johnson & Johnson – New Jersey Federal Court Addresses Express Pre-Emption In Class III Medical Device Case

In *D'Addario v. Johnson & Johnson, et al.*, No. 19-15627, 2023 WL 239395 (D.N.J. Jan. 18, 2023), the United States District Court for the District of New Jersey addressed express pre-emption principles in a product liability case involving Class III breast implants. By way of background, in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the U.S. Supreme Court held that the express pre-emption clause of the 1976 Medical Device Amendments ("MDA"), 21 U.S.C. §360k(a), pre-empted certain state law claims against Class III medical devices that were approved through the pre-market approval ("PMA") process. Specifically, the Court held that the MDA expressly pre-empted state law claims that sought to impose requirements on Class III PMA-approved products that were different from or in addition to those requirements already imposed by federal statutes and FDA regulations. The *Riegel* decision, however, did not expressly pre-empt all state law claims. Rather, the *Riegel* court held that when authorized by state law, the MDA did not prevent plaintiffs from asserting claims that the manufacturer failed to adhere to federal requirements ("parallel claims"), because such claims did not impose requirements that were in addition to or different from those imposed by federal law.

The *D'Addario* Court addressed this exact issue on defendants' motion to dismiss. In *D'Addario*, Plaintiff underwent reconstructive breast surgery after a breast cancer diagnosis and mastectomy. During the reconstructive breast surgery, Plaintiff received textured breast implants manufactured by Defendants Johnson & Johnson, Ethicon, Inc., and Mentor Worldwide, LLC. Defendants' breast implant products were Class III medical devices that were approved by the FDA through the PMA process. Plaintiff alleged that during the manufacturing process used to make the breast implants textured, silica and polyurethane particles shed and remained on the surface of the breast implants. Plaintiff further alleged that the silica and polyurethane deposits remaining on the surface of the products caused inflammation that ultimately led Plaintiff to develop a form of cancer called breast implant-associated large cell lymphoma ("BIA-LGL"). After receiving this diagnosis, Plaintiff underwent surgery to have the breast implants removed.

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Plaintiff filed suit against the Defendants asserting violations of the Connecticut Product Liability Act ("CPLA") under various theories, including manufacturing defect, breach of implied warranties, failure to warn, and negligent misrepresentation. Plaintiff amended her Complaint before the Defendants responded, and Defendants subsequently moved to dismiss the First Amended Complaint on express pre-emption grounds under the MDA and *Riegel*. Defendants also argued that Plaintiff's claims were not pled with sufficient facts to comply with *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). The court held that the claims in Plaintiff's First Amended Complaint were inadequately pled and granted Defendants' motion to dismiss without prejudice, allowing Plaintiff a final opportunity to replead her claims. *See D'Addario v. Johnson & Johnson*, 2021 WL 1214896 (D.N.J. Mar. 31, 2021).

Plaintiff filed a Second Amended Complaint asserting the same theories of liability under the CPLA. As to the manufacturing and breach of warranty claims, the Second Amended Complaint asserted that the breast implants were defective because they contained silica and polyurethane deposits on the surface and were not properly sterilized and therefore, did not conform with FDA-required specifications and Current Good Manufacturing Practice ("CGMP") regulations. The Second Amended Complaint also alleged that defendants failed to comply with FDA requirements including post-approval adverse event reporting, and failed to conduct post-approval studies mandated by the FDA. As to her failure to warn claim, Plaintiff alleged that although warnings regarding the risks of developing BIA-LCL were supposed to accompany the defendants' breast implants, the defendants did not provide Plaintiff's surgeon with a copy of the product warnings.

In response to the Second Amended Complaint, Defendants renewed their motion to dismiss on express pre-emption grounds. The court explained that although the MDA has a "broad express pre-emption provision," plaintiffs may still pursue a narrow "parallel claim" premised on a violation of FDA regulations. In determining whether a plaintiff's claim is expressly pre-empted by the MDA, the court held that it must determine: (1) if the FDA has established requirements applicable to the specific device at issue; and (2) whether plaintiff's claims are based on state requirements that are different from or in addition to the federal requirements applicable to the device. If the answer to both questions is yes, then plaintiff's claims are pre-empted. If the answer to the second question is no, then plaintiff has stated a parallel claim that is not expressly pre-empted by the MDA. *D'Addario*, 2023 WL 239395 at *3.

Applying these principles to Plaintiff's specific claims, the court held that Plaintiff had sufficiently pled parallel manufacturing defect and implied warranty claims. The court noted that the Second Amended Complaint sufficiently alleged that the breast implants were not sterilized and contained debris and therefore, did not conform to the FDA's CGMP regulations or the PMA approval for the device. The court also noted that Plaintiff's implied warranty claim was also premised on the theory that Defendants impliedly warranted that the product met all applicable FDA requirements. Because

these claims did not seek to impose requirements different from or in addition to those imposed by federal law, and "merely" paralleled applicable FDA requirements, the court permitted Plaintiff's manufacturing defect and implied warranty claims to proceed. *Id*. at *4-5.

With respect to Plaintiff's failure to warn claim, the court noted that Plaintiff conceded that the Defendants' breast implants included a warning label that warned about the risks of developing BIA-LCL. The court, however, also noted that the Second Amended Complaint alleged that the product's warning label was not provided to Plaintiff's surgeon. If the evidence established that Plaintiff's surgeon was not provided with the warning that was supposed to accompany the breast implants, as required by the PMA approval for the product, the court held that Plaintiff's failure to warn claim was not pre-empted because it simply paralleled federal requirements. Because the issue of whether Plaintiff's surgeon was actually provided with the warnings that were supposed to accompany the breast implants was an issue of fact that could not be decided on a motion to dismiss, the court also permitted Plaintiff's failure to warn claim to proceed. *Id*.at *8-9.

Finally, the court dismissed Plaintiff's negligent misrepresentation claim with prejudice because Plaintiff did not plead the claim with sufficient particularity to meet the heightened pleading requirements of Fed. R. Civ. P. 9(b). *Id*.at *7.

This case illustrates that even when a Class III medical device is at issue, it can still be challenging for a manufacturer to obtain a full dismissal of plaintiff's claims on express pre-emption grounds. *D'Addario* joins a long list of cases from the District of New Jersey that have permitted plaintiffs to pursue a "parallel" manufacturing defect claim where the complaint alleges sufficient facts to support such a claim. The *D'Addario* decision is somewhat of an outlier because it allowed Plaintiff's failure to warn claim to proceed even though Plaintiff conceded that the product contained a warning that addressed the condition Plaintiff suffered from. The court took a very liberal approach when it allowed Plaintiff's failure to warn claim to proceed based on the bare allegation that the specific product at issue lacked the FDA-required warning.

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