ORIGINAL

20-5094
No._____

In The
Supreme Court of the United States

ANITA LAUX, Petitioner

vs.

MENTOR WORLDWIDE, LLC, Respondent

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

Attorney For Petitioner
Anita Laux, Pro Se
P. O. Box 7212
Westlake Village, CA 91359
(805) 443-9909

QUESTIONS PRESENTED

(1) Whether state-law claims against a medical device manufacturer, based on duties that parallel federal requirements, preempted by the Medical Device Amendments ("MDA"), 21 U.S.C. 360 et seq., to the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. 301 et seq.?

(2) Whether the FDA's Current Good Manufacturing Practices ("CGMPs"), 21 C.F.R. 820.1 et seq., citing specific CGMPs requirements 21 C.F.R. 820.1(c), 820.72 - 820.90, can support state-law claims based on duties that parallel, rather than add to, federal requirements, will survive express preemption?

(3) Whether state-law claims against a medical device manufacturer, based on duties that parallel federal requirements, under 21 U.S.C 360k(a), and 21 C.F.R. 808.1(d), are not preempted, premised that a complaint need only allege enough facts to state a claim that is plausible on its face, to satisfy the Twomby/Iqbal pleading requirements, are sufficient to meet the specificity and plausibility standards of Federal Rule of Civil Procedure 8(a)?

LIST OF PARTIES

[✓] All parties appear in the caption of the case on the cover page.

[ ] All parties **do not** appear in the caption of the case on the cover page. A list of all parties to the proceeding in the court whose judgment is the subject of this petition is as follows:

RELATED CASES

1) Laux v. Mentor Worldwide, LLC, No.2:16-cv-01026-ODW-AGR
U.S. District Court for the Central District of California
Judgment entered November 8, 2017.

2) Laux v. Mentor Worldwide, LLC, No. 17-56832
U.S. Court of Appeals for the Ninth Circuit
Judgment entered November 26, 2019.

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OTHER

IN THE

SUPREME COURT OF THE UNITED STATES

PETITION FOR WRIT OF CERTIORARI

Petitioner respectfully prays that a writ of certiorari issue to review the judgment below.

OPINIONS BELOW

[✓] For cases from **federal courts**:

The opinion of the United States court of appeals appears at Appendix A to the petition and is

[✓] reported at Laux v. Mentor Worldwide, LLC, No. 17-56832 (9th Cir. 2019); or,

[ ] has been designated for publication but is not yet reported; or,

[ ] is unpublished.

The opinion of the United States district court appears at Appendix B to the petition and is

[✓] reported at Laux v. Mentor Worldwide, LLC, 295 F. Supp.3d 1094 (C.D. Cal. 2017); or,

[ ] has been designated for publication but is not yet reported; or,

[ ] is unpublished.

[ ] For cases from **state courts**:

The opinion of the highest state court to review the merits appears at Appendix _____ to the petition and is

[ ] reported at _____; or,

[ ] has been designated for publication but is not yet reported; or,

[ ] is unpublished.

The opinion of the _____ court appears at Appendix _____ to the petition and is

[ ] reported at _____; or,

[ ] has been designated for publication but is not yet reported; or,

[ ] is unpublished.

JURISDICTION

[✓] For cases from **federal courts:**

The date on which the United States Court of Appeals decided my case was November 26, 2019.

[ ] No petition for rehearing was timely filed in my case.

[✓] A timely petition for rehearing was denied by the United States Court of Appeals on the following date: February 14, 2020, and a copy of the order denying rehearing appears at Appendix C.

[✓] An extension of time to file the petition for a writ of certiorari was granted to and including July 13, 2020 (date) on March 19, 2020 (date) in Application No. 202 APPENDIX N. ***See Supreme Court ORDER on March 19, 2020,
***In light of COVID-19, extended deadline to file any petition for writ of certiorari is extended to 150 days.

The jurisdiction of this Court is invoked under 28 U. S. C. § 1254(1).

[ ] For cases from **state courts:**

The date on which the highest state court decided my case was _____.
A copy of that decision appears at Appendix _____.

[ ] A timely petition for rehearing was thereafter denied on the following date: _____, and a copy of the order denying rehearing appears at Appendix _____.

[ ] An extension of time to file the petition for a writ of certiorari was granted to and including _____ (date) on _____ (date) in Application No. ___A_____.

The jurisdiction of this Court is invoked under 28 U. S. C. § 1257(a).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

21 U.S.C. 360k

(a) General Rule[.] Except as provided in subsection (b), of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt Requirements. Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if --

[See lengthy provision citation in Appendix O].

21 C.F.R. 808.1(d)

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521 (a) of the act because they are not "requirements applicable to a device" within the meaning of section 521 (a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

[See lengthy provision citation in Appendix P].

21 C.F.R. 820.1

(a) Applicability. (1) Current Good Manufacturing Practice (CGMP) requirements are set forth in this quality system regulation.

[See lengthy provision citation in Appendix Q].

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED (CONTINUED)

21 C.F.R. 820.1(c)

(c) Authority. Part 820 is established and issued under authority of sections 501, 502, 510, 513, 514, 515 ,518, 519, 520, 522, 701, 704, 801, 803 of the act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 3601, 371, 374, 381, 383). The failure to comply with any applicable provision in this part renders a device adulterated under section 501 (h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.
[See lengthy provision citation in Appendix Q].

21 C.F.R. 820.72

(a) Control of inspection, measuring, and test equipment. Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic, measuring, and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented.
[See lengthy provision citation in Appendix Q].

21 C.F.R. 820.75

(a) Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures.
[See lengthy provision citation in Appendix Q].

21 C.F.R. 820.80

(a) General. Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.
[See lengthy provision citation in Appendix Q].

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED (CONTINUED)

21 C.F.R. 820.90

(a) Control of nonconforming product. Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedure shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organization responsible for the nonconformance. The evaluation and any investigation shall be documented.

(b) Nonconformity review and disposition. (1) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications.

[See lengthy citation in Appendix Q].

OTHER PROVISION INVOLVED

Restat 2d of Torts, 402A
Special Liability of Seller of Product for Physical Harm to User or Consumer

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although
(a) the seller has exercised all possible care in the preparation and sale of his product, and

OTHER PROVISION INVOLVED -Continued

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

(see lengthy citation in Appendix S)
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STATEMENT OF THE CASE

Petitioner Anita Laux's case presents significant questions:

(1) Whether state-law claims against a medical device manufacturer, based on duties that parallel federal requirements, preempted by the Medical Device Amendments ("MDA"), 21 U.S.C. 360 et seq., to the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. 301 et seq.?

(2) Whether the FDA's Current Good Manufacturing Practices ("CGMPs"), 21 C.F.R. 820.1 et seq., citing specific GMPs requirements 21 C.F.R. 820.1(c), 820.72-820.90, can support state-law claims based on duties that parallel, rather than add to, federal requirements, will survive express preemption?

(3) Whether state-law claims against a medical device manufacturer, based on duties that parallel federal requirements, under 21 U.S.C. 360k(a) and 21 C.F.R. 808.1(d) are not preempted, premised that a complaint need only allege enough facts to state a claim that is plausible on its face, to satisfy the Twombly and Iqbal pleading requirements, are sufficient to meet the specificity and plausibility standards of Federal Rule of Civil Procedure 8(a)?

A central issue in Laux's petition is whether federal law preempts product liability claims against a manufacturer of a class III medical device where a patient claims she was harmed with life-threatening and permanent injuries.

Laux alleged a state law claim for strict liability (manufacturing defect) arising out of injuries Laux suffered after being surgically implanted on December 30, 2005, with silicone inflatable saline-filled breast implants manufactured by Mentor. The implants were surgically removed on May 23, 2014. The breast implants at issue are a Class III medical device approved by the Federal Drug Administration (FDA") under the premarket approval process of the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act. The breast implant valves allegedly leaked saline fluid and entrapped Ms. Laux's scar tissue into the valves, with the scar tissue reaching deeply into the valve orifices, caused the valves to be unable to securely seal to prevent leakage.

Causes of Action: Count One- Products Liability (Manufacturing Defect);

Count Two- Negligence;

Count Three- Breach of Warranty.

Laux has pleaded a Cause of Action under state law claims based on duties that parallel federal requirements on manufacturing defects, that are neither different, nor add to federal requirements, to avoid express preemption.

Under California tort law, 21 U.S.C. 360k(a) does not prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations; the states duties in such a cases "parallel", rather than add to, federal requirements." Stengel v. Medtronic, Inc. (2013) 704 F3d 1224, 1228.

The implant shells, valves, and valves orifices and valves caps, were not manufactured in accordance to Mentor's own specifications; the shells, valves, and valve orifices and valve caps were not manufactured in accordance with the FDA's Quality Systems Regulations and Current Good Manufacturing Practices, 21 C.F.R. 820.1 et seq., "requires each manufacture to put in place processes to test products for compliance with product specifications, to check and document compliance with product specifications before products are accepted for sale and use, and to identify and control nonconforming products," thereby rendering the device "adulterated." Plaintiff Laux's complaint alleges that the Mentor saline breast implants had failed to comply with section 21 C.F.R. 820.90 regarding nonconforming products, and that the product implanted in plaintiff Laux failed to comply with product specifications as approved by the FDA through the premarket approval process. Said defects violated Mentor's duties, which shows a violation of federal law, which parallel state law claims. See Bausch v. Stryker Corp, 630 F.3d 546 (7th Cir. 2010)(citing 21 C.F.R. 820.1(c), 820.72-820.90). App.

55 and App. 212-227. The district and 9th Cir. erroneously overlooked Laux's specific pleadings of the FDA's Current Good Manufacturing Practices.

The District and 9th Cir. erroneously held that Laux's state law claims are expressly preempted under the MDA to the FDCA. However, Seventh Circuit said, "Federal Law is clear: for manufactures of a Class III medical device, the Quality System Regulations and Current Good Manufacturing Practices adopted by the FDA under its delegated regulatory authority are legally binding requirements." See Bausch v. Stryker Corp., 630 F.3d 546, 554-556 (7th Cir. 2010).

On November 26, 2019, the 9th Cir. erroneously dismissed Laux's case based on express preemption. Laux's case should not be expressly preempted based on the recent ruling of Weber v. Allergan, Inc., 940 F.3d 1106, 1111 (9th Cir. 2019). Laux case is distinguishable from the Weber v. Allergan, Inc., 940 F.3d 1106, 1111 (9th Cir. 2019). Weber had silicone breast implants, alleged silicone gel bleed. Weber did not have valves on her breast implants, as Laux did have valves on her breast implants. The Weber implants were manufactured by Allergan, and the Laux implants were manufactured by Mentor. The manufacturing process for silicone-gel implants compared to saline-filled implants with valves, have different manufacturing processes from one another. Laux's implants had alleged defective valves leaking saline with evidence of scar capsule tissue stuck inside

the implant valves. Laux has pleaded a Twombly and Iqbal pleading standard. App. 174-186. Whereas, in Weber's oral argument (9th Cir. 2019), an exception to Riegel dissent was argued. The lower courts erred in not distinguishes the major difference between Weber and Laux.

It is significantly important for the courts to know that Weber has two different appeal cases: Weber v. Allergan, Inc. 940F.3d 1106 (9th Cir. 2019) and another appeal: Weber v. Allergan, Inc. No. 13-17017, (9th Cir. 2015). In 2015, the 9th Cir. held that the allegations in Weber's complaint in 2015, are sufficient to meet the particularity and plausibility standards of Federal Rule of Civ. P. 8(a). See Ashcroft v. Iqbal, 556 U.S. 662, 678, (2009). Laux's case is similar to Weber's 9th Cir. 2015 pleadings of Twombly and Iqbal, where the 9th Cir. opinioned that Weber had successfully pleaded parallel state-law claims that were not preempted. See Weber v. Allergan, Inc., 13-17017. App. 44.

Laux alleges, Respondent/Defendant (Mentor) had duties and obligations set forth in various sections of the Restatement (Second) of Torts, including but not limited to 402A. Restatement (Second) of Torts, 402A, cited on Laux's original and only Complaint. App. 55. Strict liability can hold a manufacturer liable for the defective condition of the product that is unreasonably dangerous. App. 234. State law tort claims that parallel federal requirements are not preempted by the

MDA. To properly plead parallel claims to survive preemption, a plaintiff must allege facts (1) showing an alleged violation of FDA regulations or requirements related to the device, and (2) establishing a casual nexus between the alleged injury and the violation, Erickson V. Boston Sci. Corp. (C.D. Cal. 2011), 846 F. Supp.2d 1085, 1092. The district and 9th Cir. mistakenly asserts that Laux failed to identify any specific, federal required specification or requirements that Mentor violated in manufacturing her Silicone Inflatable Saline-Filled implants. Laux alleges violations of CGMPs requiring manufacturers to: document all Corrective Action and Preventative Actions taken by the Manufacturer to address non-conformance and other internal quality control issues, 21 C.F.R. 820.100 et seq., and establish Quality Management System procedures to assess potential causes of non-conforming products and other quality problems, 21 C.F.R. 820.70 et seq. and 21 C.F.R. 820.90 et seq. These are all FDA regulations that dictate how a manufacturer must handle the nonconformance of an approved device. While the complaint does not cite a specific FDA warning regarding these violations, Laux has alleged enough factual support to plead a violation of these regulations, particularly by showing that the injury caused by the product in Laux had to have come from a nonconforming product. Laux's expert Dr. Blais, PhD, specifically demonstrates a product that does not conform, as documented in his Failure

Analysis Report and in his testimony transcripts filed at district in which Dr. Blais' findings of mold, using a microscope, identified aspergillus family, which is a genus of over two-hundred mold species inside Laux's implants and Laux's scar capsule tissue invading the valves, and scar tissue reaching deeply into the valve orifices. The manufacture of the valves on the implants were allegedly "dented in valves" with debris stuck in the valves where the saline leaked out as expert Dr. Kolb, MD, testified. Expert Dr. Blais, PhD, testified the valves were "caved-in" with the valve cap undersized in relation to the valve orifice which was oversized with Laux's scar tissue stuck in the valves causes the valves to leak which led to mold identified as asperguillus family (a genus consisting of over two-hundred mold species), inside Laux's breast implants.

On June 27, 2018, the 9th Cir. filed an ORDER stating that Appellant Laux has demonstrated that this appeal involves non-frivolous issues. App. 45-46. The Order to show cause is therefore discharged. 9th Cir. granted Laux permission to proceed forward with appeal. The district court erred in denying Ms. Laux's motion to amend complaint. Laux's motion to amend complaint would not have caused an undue delay, nor been futile. Laux has zero previously amended complaints. Here in Laux's case, as in Bausch v. Stryker, the 7th Cir. opinioned the district court erred in denying Bausch to leave to amend the complaint was an

abuse of discretion. App. 274. "As a general matter, Rule 15, ordinarily requires that leave to amend be granted at least once when there is a potential curable problem with the complaint or other pleading. A Plaintiff is entitled to amend the complaint once as a matter of right, Fed. R. Civ. P. 15(a), and the court should "freely give leave [for a party to file an amended complaint] when justice so requires." Fed. R. Civ. P. 15(a)(2). Amendment would not be futile. See Foman v. Davis, 371 U.S. 178, 182 (1962). App. 275. " A district court abuses its discretion when it bases its decision on an erroneous view of the law or a clearly erroneous assessment of the facts." United States v. Morales, 108 F.3d 1031, 1035 (9th Cir. 1997)(en banc). District court abused its discretion in denying plaintiff Laux leave to amend complaint when Laux has identified the standards she believes the manufacture of her implants violated, thereby would adequately plead parallel state-law claims under 21 U.S.C. 360k(a) and 21 C.F. R. 808.1(d). See 21 C.F.R. 820.1 et seq.; Bausch v. Stryker Corp. 630 F.3d 546 (7th Cir. 2010). App. 182. Laux filed her Motion to Leave to Amend Complaint, as she has identified additional facts she can plead that if added to her complaint would satisfy the Twombly and Iqbal pleading standard, under Fed. R. Civ. P. 8(a). See App. 174-186. Laux's original and only complaint should have served the purposes of Rule 8, stating a claim for relief that was "plausible on its face" as required by Iqbal and

Twombly. Courts give special consideration to pro se litigants requesting leave to amend. Flowers v. First Hawaiian Bank, 295 F.3d 966, 976 (9th Cir 2002). App. 179. A pro se litigant is entitled to notice of the complaints deficiencies and an opportunity to amend prior to dismissal. Laux could have amended the issue on the original complaint that alleges not only violations of "regulatory" standards, but also violations of "industry standards" that are different from or in addition to the federal regulatory standards. Since the district court abused its discretion in denying Laux, pro se, her right to amend complaint, the cited 21 U.S.C. 360e(d)(2) on complaint would have been excluded from Laux's complaint. Laux's complaint was filed by Laux's former attorney, who represented Laux from 12/2015 to 2/2017. Laux declares that if she was given the right to amend her complaint, she could have excluded the PMA clause of 21 U.S.C. 360e(d)(2), because that claim would be preempted under section 360k. Here in Laux's case, as in Bausch v. Stryker, App. 268, that 7th Cir. opinioned that "The only significant issue we see with the original complaint is it alleges not only violations of "regulatory" standards, but also violations of "industry standards" that are different from or in addition to the federal regulatory standards, those claims would be preempted under section 360k. Yet complaints that combine legally valid and invalid claims are common. When a complaint asserts claims that are legally valid and those

that are not, the correct judicial response is not to dismiss the complaint, let alone with prejudice." App. 269. As here in Bausch's case, Laux should have been granted leave to amend complaint to try to fix any deficiencies. Laux's case is based on merits and the 9th Cir. ruled Laux's case in non-frivolous. This shows district court abused its discretion in denying Laux her entitlement to amend complaint. Laux has zero previous amended complaints.

The district and appeals court erroneously overlooked Laux's expert testimony transcripts filed at district court. Laux's expert testimony transcripts were presumed to be missing from district record. However, most profoundly, Ms. Laux located the expert witnesses testimony transcripts filed at district court that includes Dr. Kolb, MD and Dr. Blais, PhD, in which experts testimonies shows that Laux has raised a genuine dispute of material fact. The district and 9th Cir. erroneously overlooked the nonmoving party [Laux] did produce specific evidence to show that a genuine dispute exists. Fed. R. Civ. P. 56(e). In addition, Ms. Laux has raised a genuine issue of material fact as Ms. Laux has preserved her actual breast implants as evidence that shows the implant valves have entrapped Ms. Laux's scar capsule tissue inside the valves, reaching deeply into the valve orifices. Laux entered her actual evidence of implants into discovery at district. Plaintiff Laux alleged that the Mentor saline breast implants were adulterated due to

manufacturing practices of a non-conformance product under 21 C.F.R. 820.90. App. 222-223. Said defects violated Mentor's duties, which shows a violation of federal law, which parallel state law claims. Therefore, Laux's state law claims are not expressly preempted under the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act. Laux has pleaded general device specific CGMPs 21 C.F.R. 820.1(c) 820.72-820.90. App. 55. See Bausch v. Stryker Corp. App.244-276 and Bass v. Stryker Corp. App. 277-300, in which the 7th Cir. Court of Appeals and the 5th Cir. Court of Appeals opinioned that CGMPs are sufficient in pleading parallel state law claims that are not preempted, to the extent they are based on manufacturing defect claims.

At district court, Plaintiff Laux's Complaint was filed with documents [Failure Analysis Report] attached to the Complaint. App. 47-107. Documents attached to the complaint are critical and are consistent with pleadings and consistent with filed expert testimony transcripts. App. 108-171. And, are consistent with filed published peer-reviewed articles. App. 172-173. The aforementioned documents are shown to have a direct correlation between the alleged manufacturing defects on the Mentor breast implant valves, in which the valves entrapped Ms. Laux's scar capsule tissue into the valves and the scar capsule tissue reaching deeply into the valve orifices, caused the valves to leak, in addition to the

mismatched oversized valve orifices in relation to the undersized valve caps, leaked the saline fluid, which led to Ms. Laux's injuries. Expert Dr. Blais, PhD testified that Ms. Laux's implants were examined under a microscope where Dr. Blais identified "aspergillus" which is a genus of over two-hundred mold species inside Ms. Laux's implants. App. 154-155. App. 73.

The implant leaked not just one way, but in both directions, and whatever is in the implant would get out into the breast. Dr. Blais testified, Yes. Dr. Blais testified he told the FDA about implants leaking in both directions, before the PMA approval. App. 165. Dr. Blais testified he does not know if the FDA credited his theory or not. The fact is they [FDA] were informed. App. 165. Dr. Blais testified that the FDA approved the protocol to manufacture Ms. Laux's implants, but they did not approve the product that Ms. Laux got. App.165. The Mentor breast implants were not manufactured in accordance with the FDA's Quality System Regulations and Current Good Manufacturing Practices, 21 C.F.R. 820.1, et seq., 820.1(c), 820.72-820.90; which among other things "require each manufacture to put in place processes to test products for compliance with product specifications, to check and document compliance with product specifications before products are accepted for sale and use, and to indentify and control nonconforming products," thereby rendering the device "adulterated."

App. 55. See, e.g., Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010)(citing 21 C.F.R. 820.1(c), 820.72-820.90. App. 55. The Mentor Saline Breast Implants contained manufacturing defects when they left the Defendants' possession, to wit: "Errors occurred in the formulation of the shells and the way in which they were cured..."; Mechanical defects were obvious on cursory inspection"; There was an "ill-fitting valve cap on both implants, which self-expelled from the valve orifice"; "A competent quality assurance protocol would have noted the defects are rejected the implants"; "Explanted mammary implants with deviant fabrication characteristics are found in significant quantities, raising concerns about manufacturing and prevailing quality assurance practices"; Both of Ms. Laux implants embody all of the above noted problems and most probably leaked from the outset"; "The examination [performed by expert Dr. Blais, PhD [App. 64-107]), also revealed multiple fabrication errors including deformed parts, an oversize valve orifice and undersize valve cap"; "[N]either of the valves on Ms. Laux's implants had the capacity to securely retain the fluid within the shells and had no ability to protect the valve mechanism from capsular tissue invasion";..."Tissue invasion of the valve mechanism is a sequela of faulty or deformed valve components, as demonstrated for both of Ms. Laux's implants." On Dr. Blais' testimony transcripts filed at district [App. 156], Mentor asked Dr.

Blais "Are you familiar with the phenomenon where after placement of breast implants a tissue capsule forms around the implants?" Dr. Blais said, "Yes". Mentor said "Okay. Are you familiar with that there can be tissue ingrowth into the valves?" Dr. Blais testified, "Only if the valve is faulty." "In order for an object or entity to penetrate the implant, there must be a breach." App. 157.

Furthermore, Dr. Blais' Failure Analysis Report" examination findings on Ms. Laux's scar capsule tissue had invaded the valves reaching deeply in the valve orifice. App. 74. "Typically, pannus [scar capsule tissue], forms from the wall of the capsule and ultimately encompasses the valve cap strap. If the valve cap does not reliably close the valve orifice, pannus [scar capsule tissue] then invades the valve system. For a correctly manufactured implant where the valve cap is secure and where the valve cap lies snugly against the shell surface, there would be no space for pannus to grow and embedment of the valve cap in pannus would be improbable." App. 74.

Expert Dr. Blais' Failure Analysis Report was attached to Ms. Laux complaint filed at district. App. 47-107.

The 9th Cir. denied Mentor their motion to strike's Ms. Laux's experts testimonies that were quoted on Appellant Ms. Laux's Opening Brief, filed on 12/6/2018, [docket 25-1, 25-2], 435 pages filed, zero deficiencies.

Ms. Laux's expert Dr. Kolb, MD, testified that both of Ms. Laux's implants were obviously leaking and debris stuck inside the valves and that the valves are defective. App. 126.

The valve is not right. There's fluid missing. There's stuff floating in the implants. That is not normal. App. 127. Dr. Kolb testified that she certainly saw debris, which she knows to be a breeding ground for mold; is that right? "That's correct." App. 139 - 140. Dr. Kolb testified that Ms. Laux's implants had defective valves because there's tissue ingress into the valves. App. 129.

Dr. Kolb testified that through her clinical observation and clinical experience that Mentor's valves on saline implants are defective and allow ingress and egress of fluid and materials. App. 133. Dr. Kolb's clinical observation and clinical experience are consistent with Dow Corning engineering data regarding the Mentor implants valve's and shells. Dow Corning studied what the shell is made of. And it starts to disintegrate in eight to ten years. And this is exactly what we see in terms of this patient [Laux] because she didn't have a history of trauma...There was internal debris in the implants as a result of defective valves, which lead to the patient's fibromyalgia and biotoxin disease. App. 136-137. Dr. Kolb testified, "Well, but we see a correlation between how much stuff is in that valve and how leaky the implants are." App. 150. Mentor said the tissue ingrowth

into the valve is a thing that can happen through nobody's fault. However, Dr. Kolb testified, "Right. Except that if the patient--except if that defect leads to a leak, not a leak where the implant deflates, but just an ability of the mold to get in there and grow and be a little bit leaky so it can get out, then the patient can get sick. App. 150.

The above specific manufacturing defects that Expert Dr. Kolb, MD opinioned through her filed testimony transcripts are consistent with Dr. Blais', PhD testimony transcripts [App. 152-171], filed at district, stating that the Mentor valves were manufactured in a defective condition that are unreasonably dangerous, and said defects are in direct correlation with published peer-reviewed articles "Microbial Growth Inside Saline-Filled Breast Implants" and "Fungal Growth Inside Saline-Filled Implants". App. 172-173.

REASONS FOR GRANTING THE PETITION

Pursuant to Supreme Court Rule 10(a)(c): Considerations governing review on writ of certiorari:

- (a) a United States court of appeals has entered a decision in conflict with the decision of another United States court of appeals on the same important matter; has decided an important federal question in a way that conflicts with a decision by a state court of last resort; or has so far departed from the accepted and usual course of judicial proceedings, or sanctioned such a departure by a lower court, as to call for an exercise of the Court's supervisory power;
- (c) a state court or a United States court of appeals has decided an important question of federal law that has not been, but should be, settled by the Court, or has decided an important federal question in a way that conflicts with relevant decisions of this Court.

There is a Circuit Split whether the FDA's Current Good Manufacturing Practices can support a state-law claim that parallel federal requirements, that will survive express preemption. A circuit split supports granting of this petition. Supreme Court Rule 10(a)(c).

The circuit split between the appellate courts, whether the Current Good Manufacturing Practices will support a parallel state-law claim surviving express preemption.

The Fifth and Seventh Circuits have held that a common law claim premised on a generally applicable requirement or industry-wide regulation survives express preemption. See Bass v. Stryker Corp, (5th Cir. 2012,) and Bausch v. Stryker Corp, (7th Cir. 2010). App. 244-278. and App. 277-300.

In contrast, the Eighth and Eleventh Circuits, have expressly preempted claims premised on an industry-wide regulation and have instead held that the requirement be specific to the device in question. See In re Medtronic, Inc., Sprint Fidelis Leads, (8th Cir. 2010), and Wolicki-Gables v. Arrow International, (11th Cir. 2011).

Under California tort law 21 U.S.C. 360k(a) does not prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel"; rather than add to, federal requirements."

In the Supreme Court rulings in Medtronic v. Lohr, and in Riegel v. Medtronic fell on different sides of the line between the two types of FDA review for medical devices, The Court correctly noted that "(n)othing in the 360k denies [the state]

the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." Since Riegel, various circuit have addressed the issue of whether federal law preempts state law claims against medical device manufacturers that "parallel" federal requirements, without imposing any additional requirements.

The Riegel court discussed a parallel requirements exception to the general rule of preemption. This parallel requirement exception is far from clear. Which state law claims survive preemption under the parallel requirement exception? The preemption doctrine created a narrow gap. a two-step analysis:

(1) the alleged conduct must violate the FDCA, and

(2) the plaintiff must have a cause of action under state law independent of the FDCA.

Petitioner Laux's case presents a "narrow gap". The parallel requirements exception should apply to her case:

1) Laux claims a cause of action under state-law claims against a medical device manufacturer, based on duties that parallel federal requirements, that are not expressly preempted by the Medical Device Amendments ("MDA"), 21 U.S.C. 360 et seq., to the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. 301 et seq., as Laux alleges the manufacturer of her implants violated, thereby would adequately

plead parallel state-law claims under 21 U.S.C. 360k(a) and 21 C.F.R. 808.1(d), that the alleged conduct of Mentor violated the FDCA.

Laux has alleged, Pursuant to 21 U.S.C. 360k(a) and 808.1(d), Exemptions From Federal Preemption of State and Local Medical Device Requirements. App. 182-183. The above citing on 21 U.S.C. 360k(a) and 808.1(d) are filed in district courts records under Laux's Memorandum of Points and Authorities in Support of Motion for Leave to Amend Complaint, Pursuant to FED.R. Civ. P. 15(a)(2), and Fed.R. Civ. P.8(a), Twombly/Iqbal pleadings with additional facts that Laux has identified to be added to her complaint]. App. 174-186.

In addition, the Mentor valve orifices and valve caps with scar capsule tissue entrapped inside the valves, were not manufactured in accordance with general device federal requirements under specific CGMPs 820.1(c), 820.72-820.90. App. 55. Plaintiff Laux's complaint alleges that the Mentor saline breast implants had failed to comply with section 21 C.F.R. 820.90 regarding nonconforming products, and that the product implanted in plaintiff Laux failed to comply with product specifications as approved by the FDA through the premarket approval process. Said defects violated Mentor's duties, which shows a violation of federal law, which parallel state law claims. See Bausch v. Stryker Corp, 630 F.3d 546 (7th Cir. 2010)(citing 21 C.F.R. 820.1(c), 820.72-820.90). App. 55 and App. 212-227.

2) Ms. Laux's has claimed a cause of action under state law independent of the FDCA. Restatement (Second) of Torts, 402A. App. 55. Laux alleges that the defective condition of the Mentor Silicone Inflatable Saline-Filled breast implants are unreasonably dangerous.

Certiorari on conflicts between circuit courts is granted as of course only on narrow issues.

There is reasonable probability the Supreme Court will grant certiorari because one of the key hallmarks of an issue the Court is likely to consider sufficiently important is that it is recurrent and has generated directly conflicting rulings by the federal courts of appeals. Such conflicts, by undermining the desired uniformity of federal law, are often considered to merit resolution by the Supreme Court because, absent such review, they will persist, having been decided by courts whose rulings are otherwise definitive within their territorial jurisdiction absent Supreme Court review.

1) The unresolved Circuit split is a compelling reason to support granting the petition for writ of certiorari. Supreme Court Rule 10(a)(c).

2) Ms. Laux's petition should sufficiently meet the requirements of a "Narrow Gap", which should warrant granting the petition for writ of certiorari.

3) Ms. Laux's petition is of national importance, which should warrant Supreme Court review. The Implant valves leaked without a rupture or deflation. Without a rupture or deflation of breast implants, a consumer is not alerted to seek medical assistance. This puts a consumer in an unreasonably dangerous medical condition. The alleged defective condition of the implant valves become automatic cycles of filling and releasing of fluids without signs of rupture or deflation. Ingress and egress of fluids through the implant valves, allows consumer's scar tissue to become entrapped inside the implant valves, reaching deeply into the valve orifices. This is of urgent national importance for others who may have saline breast implants with valves.

CONCLUSION

The petition for a writ of certiorari should be granted for reasons in the aforementioned: (1) Circuit Split

(2) Narrow Gap

(3) National Importance

Plaintiff/Appellant/Petitioner Anita Laux, Pro Se, was denied her entitlement to amend complaint, zero previous amendments. Laux requests justice to be impartial, for the Supreme Court to have Laux's case heard at least once, before it is totally dismissed. Especially, since Petitioner Laux's 9th Cir. appeal was ruled non-frivolous.

Respectfully submitted,

Anita Laux 7/13/2020

Anita Laux, Pro Se
Attorney for Petitioner
P. O. Box 7212
Westlake Village, CA 91359
(805) 443-9909

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