10-25-2018

Jill Sikkelee v. Precision Airmotive Corp

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 17-3006

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JILL SIKKELEE, individually and as personal representative
of the estate of David Sikkelee, deceased,
Appellant

v.

PRECISION AIRMOTIVE CORPORATION;
PRECISION AIRMOTIVE LLC, individually and as
Successor-in-Interest to Precision Airmotive Corporation;
BURNS INTERNATIONAL SERVICES CORPORATION,
individually and as Successor-in-Interest to Borg-Warner
Corporation, and Marvel-Schebler,
a Division of Borg-Warner Corporation;
TEXTRON LYCOMING RECIPROCATING ENGINE
DIVISION, a Division of Avco Corporation;
AVCO CORPORATION; KELLY AEROSPACE, INC.,
individually and Joint Venturer and as Successor-in-Interest;
KELLY AEROSPACE POWER SYSTEMS, INC., individually
and as Joint Venturer and Successor-in-Interest, also known as
Electrosystems, Inc., also known as Confuel, Inc.;
ELECTROSYSTEMS, INC., individually and as Joint Venturer
and as Successor-in-Interest, also known as

Consolidated Fuel Systems, Inc., also known as Confuel, Inc.;
CONSOLIDATED FUEL SYSTEMS, INC.,
also known as Confuel, Inc.

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APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA
(D.C. No. 4-07-cv-00886)
District Judge: Hon. Matthew W. Brann

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Argued: July 11, 2018

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Before: SHWARTZ, ROTH, and RENDELL, Circuit Judges.

(Filed: October 25, 2018)

David I. Katzman
Bradley Stoll
Katzman Lampert & Stoll
100 West Big Beaver Road
Suite 130
Troy, MI 48084

Tejinder Singh [ARGUED]
Goldstein & Russell
7475 Wisconsin Avenue
Suite 850
Bethesda, MD 20814

Counsel for Appellant

Catherine B. Slavin
Gordon & Rees
1717 Arch Street
Suite 610
Philadelphia, PA 19103

Amy M. Saharia
Kannon K. Shanmugam [ARGUED]
Williams & Connolly
725 12th Street, N.W.
Washington, D.C. 20005

Counsel for Appellees Textron Lycoming Reciprocating Engine Division and AVCO Corp.

Kathleen L. Nastri
Jeffrey R. White
American Association for Justice
777 6th Street, N.W.
Suite 200
Washington, D.C. 20001

Counsel for Amicus Appellant American Association for Justice

Daryl E. Christopher
Schmidt Kramer
209 State Street
Harrisburg, PA 17101

Counsel for Amicus Appellant Pennsylvania Association for Justice

Lauren L. Haertlein
General Aviation Manufacturers Association
1400 K Street N.W.
Suite 801
Washington, D.C. 20005

Counsel for Amicus Appellee General Aviation Manufacturers Association

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OPINION OF THE COURT

SHWARTZ, Circuit Judge.

David Sikkelee died in a plane crash, and his wife, Plaintiff Jill Sikkelee, brought state-law strict liability and negligence claims against the engine's manufacturer, AVCO Corporation, and its Textron Lycoming Reciprocating Engine Division ("Lycoming"), among other defendants. Sikkelee alleges that the engine has a design defect. We previously held that Sikkelee's state-law claims are not barred based on the doctrine of field preemption, but we remanded to allow the District Court to consider whether they are barred under conflict preemption. Sikkelee v. Precision Airmotive Corp. (Sikkelee II), 822 F.3d 680 (3d Cir. 2016), cert. denied, AVCO Corp. v. Sikkelee, 137 S. Ct. 495 (2016). The District Court concluded the claims are conflict-preempted and that, even if they were not, Lycoming is entitled to summary judgment on Sikkelee's strict liability and negligence claims based on Pennsylvania law. Sikkelee v. AVCO Corp. (Sikkelee III), 268

F. Supp. 3d 660 (M.D. Pa. 2017). The Court also revisited an earlier ruling and granted summary judgment in favor of Lycoming on Sikkelee's claim that Lycoming violated 14 C.F.R. § 21.3 because it failed to notify the Federal Aviation Administration ("FAA") of the alleged defect. Sikkelee v. AVCO Corp. (Sikkelee IV), No. 4:07-CV-00886, 2017 WL 3310953 (M.D. Pa. Aug. 3, 2017).

We conclude that the District Court erred in concluding Sikkelee's claims are conflict-preempted because Lycoming has not produced clear evidence that the FAA would not have allowed it to change the engine's design as set forth in the type certificate. The Court also erred in granting Lycoming summary judgment on Sikkelee's strict liability and negligence claims because there are genuine disputes of material fact concerning, among other things, causation. However, it properly granted summary judgment on her failure-to-notify-the-FAA claim. Thus, we will reverse the Court's order granting summary judgment on conflict-preemption and state-law grounds, affirm its order granting Lycoming's motion for reconsideration on the failure-to-notify claim, and remand for further proceedings.

I

A[1]

In July 2005, David Sikkelee was piloting a Cessna 172N aircraft (the "Cessna" or "aircraft") when it crashed

[1] Because the parties do not dispute the relevant factual, statutory, or regulatory backgrounds, we draw largely from our

shortly after taking off from Transylvania County Airport in Brevard, North Carolina. He was killed in the crash. At that time, the aircraft had a Textron Lycoming O-320-D2C engine (the "engine"). Sikkelee alleges the aircraft lost power and crashed due to a defect in the design of the engine and its carburetor—which, when working properly, regulates the mixture of fuel and air entering the engine's cylinders.

In 1966, the FAA issued Lycoming a type certificate for the engine. A type certificate certifies that the design of the aircraft or its part performs properly and satisfies federal aviation regulations. Lycoming's engine's type certificate included approval of an MA-4SPA carburetor, which was manufactured by a different company, Marvel-Schebler. The MA-4SPA carburetor consists of two halves—the float bowl, on bottom, which contains fuel, and the throttle body, on top, which meters the flow of air and fuel to the cylinders—and the two halves are joined by four hex-head bolts and lock-tab washers. The FAA initially required safety wire to be used to prevent the bolts on MA-4SPA carburetors from loosening. 29 Fed. Reg. 16,317, 16,318 (Dec. 5, 1964). Lycoming asked the agency to remove that requirement and instead allow the use of hex screws and lock tabs, and the agency permitted it to do so. Lycoming implemented the change with an engineering change order, which was signed by Lycoming's Designated Engineering Representative ("DER").[2] The company

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prior opinion in this case, Sikkelee II, 822 F.3d 680, and the District Court's opinion, Sikkelee III, 268 F. Supp. 3d 660.

[2] The FAA may delegate to certain qualified persons—designated engineering representatives ("DERs")—the authority to conduct examinations, testing, and inspections necessary to issue a certificate, and to issue a certificate. 49

subsequently included the lock tab washer in its design and maintenance instructions.

Lycoming manufactured the engine at issue here in 1969 in Pennsylvania and shipped it to an aircraft company in England the same year. At that time, it was equipped with a Marvel-Schebler MA-4SPA carburetor.

Lycoming has been aware the carburetor's screws were not completely effective in holding together the float bowl and throttle body. The FAA sent Lycoming a letter in 1971, listing sixteen incidents of the screws on the Marvel-Schebler

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U.S.C. § 44702(d)(1); see 14 C.F.R. §§ 183.1, 183.13, 183.15, 183.29 (designation of DERs and termination of such designation); FAA Order 8110.37F, Designated Engineering Representative (DER) Handbook (2017); see also Steenholdt v. FAA, 314 F.3d 633, 634-35 (D.C. Cir. 2003) (discussing appointment and designation of DERs and the FAA's oversight of DERs). DERs are typically members of the private sector and employees of aircraft manufacturers, see United States v. S.A. Empresa de Viacao Aerea Rio Grandense (Varig Airlines), 467 U.S. 797, 807 (1984); FAA, Order 8110.37F, at 2-1 to 2-2, but their specific roles, authorizations, and responsibilities are established by agreement between the DER and the FAA office responsible for supervising the DER, FAA, Order 8110.37F, at 2-2, app. C at C-1. In determining whether a manufacturer meets the requirements for a type certificate, a DER must follow the same procedures an FAA engineer must follow. See 14 C.F.R. § 183.29(e); FAA, Order 8110.37F, at 2-1. DERs may approve minor design changes and, if specifically authorized, also may approve major changes. FAA, Order 8110.37F, at 2-2, 4-4; see infra at 19.

carburetor loosening. The FAA sent another letter in 1972 referring to these incidents again and met with Lycoming representatives to advise the company that reports of loosening screws were still being received. Indeed, by that time, the FAA had forwarded to Lycoming forty-five "Malfunction or Defect Reports on this subject." App. 557. The agency requested Lycoming to "review these reports and provide comments to this office as to any action you may propose that will help in alleviating this problem." Id. The same year, the FAA also issued a memorandum stating that "Marvel Schebler carburetors are a part of the engine type design and are not approved separately. The type certificate holder is responsible for the type design and also the correction of service problems." App. 579.

Lycoming responded to these reports in 1973 with Service Bulletin 366 ("SB366"). SB366 acknowledged that "[i]nstances have been reported of leakage through the gasket between the bowl assembly and throttle body of the carburetor, evidenced by fuel stains in the area of the leak. Leakage of this type is accompanied by loose screws that attach the bowl and throttle body." App. 567. Lycoming advised that during inspection, the screws should be checked for tightness, and if there appeared to be leakage and the screws were loose, the bowl should be removed, the gasket should be replaced, and the screws should be retightened.[3]

[3] Between 2003 and 2008, Lycoming discussed internally how to revise SB366. An updated bulletin ("SB366A") was issued in 2007, again recommending, during inspection, to ensure the screws are tight and, if they are loose, to replace the gasket and retighten them.

Service records show that the problem persisted. Owners and mechanics reported to Lycoming loose screws, leaking carburetors, and poor engine performance. In 2004, Precision Airmotive LLC ("Precision"), which acquired the Marvel-Schebler carburetor line, wrote Lycoming two letters regarding the carburetor's screws and leaking. As described in its first letter, in reviewing the FAA's service difficulty report database, Precision "identified a trend": "[o]ne of the items that has been reported on multiple occasions is loose bowl to body attach screws on the MA-4SPA model carburetor," and "a significant percentage of the incidents were on the Cessna 172 aircraft," App. 581, the type of aircraft Sikkelee was flying. Precision identified no such trends with other carburetor models, or with the MA-4SPA on other aircraft. In its next letter, Precision confirmed the same trend and, although reports of loose bowl screws had not increased since the 1970s, "there continue[d] to be reports of loose screws on certain carburetors, particularly those used on O-320 engines in Cessna 172 aircraft." App. 582. Precision recommended that Lycoming identify the circumstances that allowed screws to loosen and "evaluate[ ]" "the pros and cons of a different attachment system." App. 583.

The engine in Sikkelee's plane was in storage until 1998, when it was installed into the Cessna in accordance with the type certificate.[4] The engine was removed from the aircraft in 2004, after the aircraft was struck by lightning, and defendant Triad Aviation, Inc. overhauled the engine. As part of the overhaul, defendants Kelly Aerospace, Inc. and Kelly Aerospace Power Systems, Inc. (together, "Kelly") "completely rebuilt or overhauled" the carburetor and shipped

[4] Lycoming did not install the engine.

it back to Triad for installation. App. 616. Kelly held both an FAA repair station certificate, which permitted Kelly to overhaul Marvin-Schebler carburetors, and a parts manufacturer approval ("PMA") from the FAA, which permitted Kelly to manufacture certain carburetor replacement parts. The carburetor was rebuilt with a combination of parts. It appears one-half was manufactured by Marvel-Schebler in the 1960s and one-half by Marvel-Schebler in the 1970s, and Kelly used its own aftermarket parts to join the two components. Kelly performed this work in accordance with the service manual and bulletins Lycoming and Precision had issued, such as SB366, which recommended that the technician detach the two halves of the carburetor, replace the gasket, and reassemble the carburetor using new lock tabs. The carburetor as overhauled had the same design as the original carburetor.

The plane was placed back into service, and in July 2005, David Sikkelee rented it. The Cessna crashed shortly after takeoff. David Sikkelee was killed, and his brother, who was a passenger, sustained severe injuries but survived. Sikkelee asserts that the crash was the result of the carburetor's faulty design for attaching the float bowl and throttle body. She alleges that vibrations from the engine loosened the bolts holding the float bowl and throttle body together, which allowed fuel to leak out of the carburetor into the engine and caused the Cessna to crash.

B

In 2007, Sikkelee filed a wrongful-death and survival action against Lycoming, Kelly, and other defendants in the United States District Court for the Middle District of Pennsylvania. She asserted several Pennsylvania state-law

claims, including for strict liability and negligence, and in 2010, the District Court granted defendants' motion for judgment on the pleadings, holding that her claims fell within the preempted field of air safety described in Abdullah v. American Airlines, Inc., 181 F.3d 363 (3d Cir. 1999). Sikkelee v. Precision Airmotive Corp., 731 F. Supp. 2d 429 (M.D. Pa. 2010). Sikkelee then filed an amended complaint, asserting state law claims but incorporating federal standards of care by alleging violations of several FAA regulations. After motion practice and settling her claims with Kelly, Sikkelee narrowed her claims against Lycoming to strict liability, negligence, and failure to warn, relying on 14 C.F.R. § 21.3. Just before trial, the Court expressed concern that the federal standards of care did not allow the Court to formulate intelligible or practical legal standards. It ordered Sikkelee to submit further briefing on the appropriate standard of care, and subsequently invited Lycoming to file a motion for summary judgment.

The District Court granted Lycoming partial summary judgment on the ground that the FAA's issuance of a type certificate for the engine meant that the federal standard of care had been satisfied. The Court denied summary judgment on Sikkelee's failure-to-warn claims, which were based on Lycoming's alleged violation of 14 C.F.R. § 21.3 for failure to "report any failure, malfunction, or defect in any product, part, process, or article" that Lycoming made. Sikkelee v. Precision Airmotive Corp. (Sikkelee I), 45 F. Supp. 3d 431, 459-60 (M.D. Pa. 2014). The District Court certified its order for immediate appeal to address "the reach of Abdullah and the scope of preemption in the airlines industry." Sikkelee II, 822 F.3d at 687.

We granted interlocutory review and held field preemption does not apply to state-law aircraft products liability claims because (1) "the Federal Aviation Act, the General Aviation Revitalization Act of 1994, and the regulations promulgated by the [FAA] reflect that Congress did not intend to preempt aircraft products liability claims in a categorical way," id. at 683; (2) "Congress has not created a federal standard of care for persons injured by defective airplanes," id. at 696; and (3) "the type certification process cannot as a categorical matter displace the need for compliance in this context with state standards of care," id. Thus, aircraft products liability cases like Sikkelee's may proceed using a state standard of care, "subject to traditional principles of conflict preemption, including in connection with the specifications expressly set forth in a given type certificate." Id. at 683. We therefore vacated the grant of summary judgment in Lycoming's favor and remanded for further proceedings. Id. at 683, 709.

Lycoming again moved for summary judgment, asserting Sikkelee's claims are subject to conflict preemption and would, in any event, fail under Pennsylvania law. The District Court granted Lycoming's motions, concluding (1) Sikkelee's claims were conflict preempted because FAA regulations made it impossible for Lycoming to unilaterally implement the design changes Pennsylvania law allegedly would have required, Sikkelee III, 268 F. Supp. 3d at 692-709, and (2) there was no genuine dispute of material fact as to either her negligence or strict liability claims, id. at 709-15. The District Court also reconsidered its earlier summary judgment order, Sikkelee I, 45 F. Supp. 3d at 435, and granted summary judgment to Lycoming on Sikkelee's claim that

Lycoming violated 14 C.F.R. § 21.3. Sikkelee IV, 2017 WL 3310953, at *2-3.

Sikkelee appeals.

II[5]

A

We exercise plenary review of the District Court's orders granting summary judgment. Sikkelee II, 822 F.3d at 687. We apply the same standard as the District Court, viewing facts and drawing all reasonable inferences in the non-movant's favor. Hugh v. Butler Cty. Family YMCA, 418 F.3d 265, 266-67 (3d Cir. 2005). Summary judgment is appropriate where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

We also review questions of preemption de novo. Sikkelee II, 822 F.3d at 687. Preemption is an affirmative defense on which Lycoming bears the burden of production and persuasion. In re Vehicle Carrier Servs. Antitrust Litig., 846 F.3d 71, 84 (3d Cir. 2017); El v. Se. Pa. Transp. Auth., 479 F.3d 232, 237 & n.6 (3d Cir. 2007).

B

Lycoming asserts Sikkelee's claims are conflict-preempted under the doctrine of impossibility preemption

[5] The District Court had jurisdiction pursuant to 28 U.S.C. § 1332(a). We have jurisdiction pursuant to 28 U.S.C. § 1291.

because it "cannot independently do under federal law what state law requires." Appellee's Br. at 38. It also argues that Sikkelee's claims fail as a matter of Pennsylvania law and the District Court properly granted summary judgment on her § 21.3 claim. We will first address Lycoming's preemption defense.

1

The doctrine of preemption has constitutional roots in the Supremacy Clause, which provides that "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Congress thus has the power to preempt state law. Arizona v. United States, 567 U.S. 387, 399 (2012). We are nevertheless mindful that the federal and state governments "possess concurrent sovereignty" in some areas. Sikkelee II, 822 F.3d at 687. For example, we assume "that the historic police powers of the States were not to be superseded by [a] [f]ederal [a]ct unless that was the clear and manifest purpose of Congress." Id. (quoting Wyeth v. Levine, 555 U.S. 555, 565 (2009)). This presumption against preemption applies in the context of aviation products liability law. Id. at 690-92, 707-08.

There are several types of preemption: express and implied, and within implied, field and conflict. Express preemption has not been asserted and, in Sikkelee II, we held Congress has not preempted the field of state-law design- and manufacturing-defect claims concerning aircraft products, id.

at 683.[6] We did not, however, decide whether conflict preemption bars Sikkelee's claims. See id. at 683, 695, 702, 709.

There are two types of conflict preemption: (1) impossibility preemption, where compliance with both federal and state duties is impossible; and (2) obstacle preemption, where compliance with both laws is possible, but state law poses an obstacle to the full achievement of federal purposes. In re Vehicle Carrier Servs., 846 F.3d at 84. Lycoming argues Sikkelee's claims are barred under impossibility preemption.[7] "The question for 'impossibility' [preemption] is whether the private party could independently do under federal law what state law requires of it." PLIVA, Inc. v. Mensing, 564 U.S. 604, 620 (2011).

[6] We concluded the Federal Aviation Act and related regulations "do not indicate a clear and manifest congressional intent to preempt state law products liability claims; Congress has not created a federal standard of care for persons injured by defective airplanes; and the type certification process cannot as a categorical matter displace the need for compliance in this context with state standards of care." Sikkelee II, 822 F.3d at 696. We also held the General Aviation Revitalization Act of 1994 ("GARA"), Pub. L. No. 103-298, 108 Stat. 1552 (codified at 49 U.S.C. § 40101 note), does not express any such congressional intent. Sikkelee II, 822 F.3d at 696-99.

[7] Because preemption is an affirmative defense, we examine only the defense asserted before us. In re Vehicle Carrier Servs., 846 F.3d at 84.

"Pre-emption analysis requires us to compare federal and state law. We therefore begin by identifying the state tort duties and federal . . . requirements applicable to" Lycoming. Id. at 611. Under Pennsylvania law, a seller may be liable in strict liability and negligence for injuries caused by its defective products. The test for strict liability is set forth in the Restatement (Second) of Torts § 402A (1965). Tincher v. Omega Flex, Inc., 104 A.3d 328, 351, 384-433 (Pa. 2014).[8] This requires a plaintiff to prove: "(1) that the product was

[8] Section 402A provides:

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

Restatement (Second) of Torts § 402A.

defective; (2) that the defect was a proximate cause of the plaintiff's injuries; and (3) that the defect causing the injury existed at the time the product left the seller's hands." Pavlik v. Lane Ltd./Tobacco Exps. Int'l, 135 F.3d 876, 881 (3d Cir. 1998) (citing Davis v. Berwind Corp., 690 A.2d 186, 190 (Pa. 1997)). A plaintiff may prove a "defective condition" exists by showing either "(1) the danger is unknowable and unacceptable to the average or ordinary consumer" (the "consumer expectations standard"), or "(2) a reasonable person would conclude that the probability and seriousness of harm caused by the product outweigh the burden or costs of taking precautions" (the "risk-utility standard"). Tincher, 104 A.3d at 335, 387, 389.

Pennsylvania law also recognizes a negligence cause of action for products liability. See Tincher, 104 A.3d at 383-84; Phillips v. Cricket Lighters, 841 A.2d 1000, 1008 (Pa. 2003). To maintain such a claim, a plaintiff must demonstrate "[1] that the defendant had a duty to conform to a certain standard of conduct; [2] that the defendant breached that duty; [3] that such breach caused the injury in question; and [4] actual loss or damage." Phillips, 841 A.2d at 1008 (citation and internal quotation marks omitted).

Sikkelee argues that Lycoming's design for affixing the carburetor parts was defective and that, under Pennsylvania law, Lycoming would be liable for failing to use a different design. Specifically, she asserts that Lycoming should have used safety wire to secure the bolts that attach the float bowl and throttle body.

3

We next examine the federal regulations applicable to the design of aircraft products. Congress has imposed federal oversight of certain aspects of aviation. Sikkelee II, 822 F.3d at 684. The 1958 Federal Aviation Act consolidated regulatory authority in a single entity, the FAA, and adopted the earlier statutory framework for the promulgation of minimum standards for design safety and the process for the issuance of certificates that indicated compliance with those regulations. Id. Under federal law, an aviation-products manufacturer must obtain a type certificate from the FAA. 49 U.S.C. § 44704(a); 14 C.F.R. § 21.31; Sikkelee II, 822 F.3d at 684. "[A] type certificate . . . certifies that a new design for an aircraft or aircraft part performs properly and meets the safety standards defined in aviation regulations, 49 U.S.C. § 44704(a); 14 C.F.R. § 21.31." Sikkelee II, 822 F.3d at 684 (emphasis omitted).[9] If the FAA determines that a product "is properly

[9] The FAA also issues

> production certificate[s], which certif[y] that a duplicate part produced for a particular plane will conform to the design in the type certificate, 49 U.S.C. § 44704(c); 14 C.F.R. § 21.137. Before a new aircraft may legally fly, it must also receive . . . an airworthiness certificate, which certifies that the plane and its component parts conform to its type certificate and are in condition for safe operation. 49 U.S.C. §§ 44704(d), 44711(a)(1).

Sikkelee II, 822 F.3d at 684 (emphasis omitted).

designed and manufactured, performs properly, and meets the regulations and minimum standards prescribed under [49 U.S.C. §] 44701(a)," it issues a type certificate. Sikkelee II, 822 F.3d at 684 (alteration in original) (quoting 49 U.S.C. § 44704(a)(1); see also 14 C.F.R. § 21.21. A type certificate includes

> the type design, which outlines the detailed specifications, dimensions, and materials used for a given product; the product's operating limitations; a "certificate data sheet," which denotes the conditions and limitations necessary to meet airworthiness requirements; and any other conditions or limitations prescribed under FAA regulations.

Sikkelee II, 822 F.3d at 684 (citing 14 C.F.R. §§ 21.31, 21.41; FAA, Order 8110.4C, change 5, Type Certification, ch. 3-3(a) (2011)). A type certificate remains in effect "until surrendered, suspended, revoked, or a termination date is otherwise established by the FAA." Id. at 685 (quoting 14 C.F.R. § 21.51).

A manufacturer generally must make the product in accordance with that certificate. A manufacturer may make a "minor" change through "a pertinent 'method acceptable to the FAA.'" Id. (quoting 14 C.F.R. § 21.95). A minor change "is one that has no appreciable effect on the weight, balance, structural strength, reliability, operational characteristics, or other characteristics affecting the airworthiness of the product." 14 C.F.R. § 21.93(a). All other changes are "major" changes. Id.; see also Sikkelee II, 822 F.3d at 703 n.21; 14 C.F.R. pt. 43, app. A (listing major alterations and repairs).

Major changes require advance FAA approval and issuance of an amended or supplemental type certificate. 49 U.S.C. § 44704(b); Sikkelee II, 822 F.3d at 685, 703 n.21; 14 C.F.R. §§ 21.97; FAA Order 8110.4C, change 1, Type Certification, ch. 4-1(a), 4-2 (2011). A DER may approve minor changes and, with specific authorization, may approve major changes. FAA, Order 8110.37F at 2-2, 4-4; see supra note 2.

The FAA also regulates aftermarket parts. A manufacturer seeking to make replacement parts generally must obtain a PMA, which allows the manufacturer to produce replacement parts for use on certificated products. See 14 C.F.R. §§ 21.8, 21.9, 21.303(a). A PMA holder may manufacture aftermarket parts, but must do so in accordance with the type certificate for the product, and must follow the same procedures as the type certificate holder. 14 C.F.R. §§ 21.8, 21.9, 21.303(a), 21.319; FAA Order 8120.22A, Production Approval Process, ch. 4-5, at 4-7 to 4-8 (2016). The manufacturer may obtain a PMA by showing (1) its product is identical to the certificated product, through evidence of a licensing agreement; (2) its product is identical to the certificated product, without a licensing agreement; or (3) tests and computations showing that its product meets airworthiness requirements. See 14 C.F.R. § 21.303; FAA, Order 8120.22A, 4-7 to 4-8. The process for changing a PMA design is the same as that for certificated designs; changes are classified as "major" and "minor," and major changes must receive FAA approval before they can be included in the design, while minor changes can be approved using a method acceptable to the FAA. 14 C.F.R. § 21.319. At oral argument, the parties agreed that Sikkelee's proposed change to the

carburetor's design would be a minor change.[10] We need not decide whether the change would be minor or major because, either way, there is no impossibility preemption here.

4

Lycoming asks us to affirm the District Court's ruling on impossibility preemption because its FAA-approved type certificate precludes it from unilaterally changing its design, and thus it could not simultaneously comply with federal and state law, where state law would require it to adopt a different design. Lycoming relies primarily on PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011), and Mutual Pharmaceutical Co. v. Bartlett, 570 U.S. 472 (2013). In contrast, Sikkelee relies on the impossibility preemption standard articulated in Wyeth v. Levine, 555 U.S. 555 (2009). To understand the relevance of these cases, some background is required.

All three of these cases concerned tort claims relating to warning labels provided in connection with pharmaceutical drugs. PLIVA and Bartlett involved claims against generic drug manufacturers. Under federal law, a generic drug manufacturer may produce a drug that is identical to one made by a brand-name manufacturer, but when it receives permission to do so, it must use the same FDA-approved design and warning labels as the brand-name manufacturer. See Bartlett, 570 U.S. at 483-84, 486; PLIVA, 564 U.S. at 612-13, 612 n.2. This is because the generic manufacturer is given

[10] Although we disagree with our dissenting colleague's characterization of the concession concerning whether the change here would be minor, Dissent at 12, we agree that the distinction is irrelevant to the preemption issue before us.

the opportunity to market its product without performing the same comprehensive testing as the brand-name manufacturer performed on its product, with the idea being that such examination is not needed if the products and warnings are identical. See, e.g., In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 143-44 (3d Cir. 2017); In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II), 751 F.3d 150, 153 (3d Cir. 2014). Thus, both the products and the warnings must be identical.

PLIVA involved state-law failure-to-warn claims against manufacturers of a generic drug. 564 U.S. at 608-09, 611-12. Generic drug manufacturers are required, under the Food, Drug, and Cosmetic Act (the "FDCA") and FDA regulations, to use labels that match those of the brand-name manufacturers, and these generic drug manufacturers may not "independently chang[e]" their labels. Id. at 618. Assuming state law required a different label, the Supreme Court concluded federal law did not permit the generic company to do what state law required—provide a different, stronger label, id. at 617-18—and thus, it was impossible for the generic company to change the warnings, id. at 618.

The Supreme Court reached the same conclusion in Bartlett, where the manufacturer of a generic drug was sued for an alleged design defect. 570 U.S. at 475. In Bartlett, the Court held redesign was not possible because "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based." Id. at 483-84. As a result, the Court concluded "state-law design-defect claims like New Hampshire's that place a duty on manufacturers to render a drug safer by either altering its composition or altering

its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." Id. at 490. Thus, in both cases, the state-law claims were conflict-preempted because it would be impossible to comply with the federally mandated label and the modified label purportedly required by state law. Id. at 486-87, 490; PLIVA, 564 U.S. at 618, 624.

Lycoming argues that it—like the generic drug manufacturers in those cases—cannot unilaterally change the FAA-approved design in the type certificate without FAA approval, and thus, it cannot both comply with federal law and do what Sikkelee claims state law requires it to do. Similarly, Lycoming asserts Kelly could not unilaterally alter the carburetor's design because, as a PMA holder, it was obliged to follow the design as set forth in Lycoming's type certificate.

We are not persuaded. In PLIVA and Bartlett, the defendant generic manufacturers were obligated to use the design and labeling of their brand-name counterparts. Lycoming is not in that position. As discussed above, the Federal Aviation Act and FAA regulations require FAA approval of a type certificate and changes to it. Lycoming, however, is not stuck with the design initially adopted and approved in a type certificate. Indeed, Lycoming has made numerous changes to the type certificate for its O-320 engine, which the FAA approved in short order. As to the carburetor specifically, Lycoming was in communication with the FAA about its design, sought to change the requirement that safety wires be used, and obtained FAA permission to use hex screws and lock tab washers instead.

This case therefore is more like Wyeth, where the preemption defense failed. In Wyeth, the Supreme Court concluded the plaintiff's state-law failure-to-warn claim against a brand-name drug manufacturer was not preempted because a "changes being effected ['CBE']" regulation permitted it to change a label to strengthen a warning upon filing a supplemental application with the FDA, and the brand-name manufacturer did not need to wait for agency approval. 555 U.S. at 568. Thus, "absent clear evidence that the FDA would not have approved a change to [the drug's] label, [the Court could] not conclude that it was impossible for Wyeth to comply with both federal and state requirements." Id. at 571.

The principles of Wyeth apply here. The nature of FAA regulations and Lycoming's interactions with the FAA—including the changes it has made to its type certificate—demonstrate that Lycoming could have—indeed it had—adjusted its design. Thus, Lycoming is in a position more akin to that of the brand-name manufacturer in Wyeth than that of the generic manufacturers in PLIVA and Bartlett, who were unable to deviate from the brand-name manufacturers' labels.[11]

[11] Our dissenting colleague encourages us to read "the Supreme Court's impossibility decisions in concert," Dissent at 15. We have done so and have considered how the principles in Wyeth, PLIVA, and Bartlett apply to the FAA regulatory scheme. Unlike the generic manufactures in PLIVA and Bartlett, who must accept without modification, the brand-names' approved design, Lycoming had the freedom to request changes to its type certificate to change its design, just like a brand-name manufacturer. Although the FAA does not explicitly have a CBE-type process that allows the certificate holder to make a change before obtaining approval, the FAA

For Lycoming to be entitled to an impossibility-preemption defense, it must present "clear evidence that the [FAA] would not have approved a change." Wyeth, 555 U.S. at 571.[12] This it cannot do.

There is no evidence in the record showing that the FAA would not have approved a change to the carburetor's screws

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allows the certificate holder to request permission to make a minor or major change.

[12] Sikkelee "propose[s] the following rule: When a defendant can implement a change or alteration to a design, product, or article without first seeking approval from an employee of the FAA, a state-law claim requiring that change is not preempted unless the defendant proves with clear evidence that the FAA would reject the change or alteration." Appellant's Br. at 22-23, 34. She thus proposes a rule based on approval by an actual employee of the FAA. Sikkelee argues that any DER-approved changes do not involve FAA approval because DERs are not FAA employees (and can be employees of the manufacturers themselves): "[w]hile the DER represents the government, he is emphatically not the government, and that defeats impossibility." Appellant's Br. at 35; see also id. at 23, 33-36.

We decline to adopt the rule Sikkelee proposes. As we have noted, see supra n.2, DERs are agents of the FAA, and so their involvement does not mean the FAA has not approved a design. Second, to the extent she is arguing FAA approval provides no guarantee of safety because the agency delegates much of its certification work to DERs, we have rejected that argument and noted that the involvement of DERs in the certification- and change-approval process alone cannot defeat conflict preemption. Sikkelee II, 822 F.3d at 708.

or attachment system. To the contrary, viewing the record in the light most favorable to the nonmovant, it shows that the FAA likely would have approved a change, which also would have meant Kelly would not have used the same allegedly defective design when it overhauled and reinstalled the carburetor in 2004. The FAA was aware, as its correspondence with Lycoming shows, that the carburetor's screws loosened in some cases and caused fuel to leak. As a result, the FAA asked Lycoming to review the malfunction or defect service reports of loosening screws "and provide comments to this office as to any action you may propose that will help in alleviating this problem." App. 557. The FAA also reminded Lycoming that "Marvel Schebler carburetors are a part of the engine type design and are not approved separately. The type certificate holder is responsible for the type design and also the correction of service problems." App. 579. This shows that the FAA wanted Lycoming to address the situation. Moreover, the FAA had previously required the use of safety wire, the very design change Sikkelee alleges would have cured the defect. Based on this record, the FAA likely would have approved a proposed change to the attachment system. Thus, it was not "impossible" for Lycoming to change its allegedly defective design, and Lycoming's conflict-preemption defense fails.

In addition, allowing state-law claims to proceed in this context complements, rather than conflicts with, the federal scheme. See Fellner v. Tri-Union Seafoods, L.L.C., 539 F.3d 237, 249 (3d Cir. 2008) ("[S]tate tort law and other similar state remedial actions are often deemed complementary to federal regulatory regimes, and this appears to be such a case."). "[T]he regulations are framed in terms of standards to acquire FAA approvals and certificates—and not as standards governing manufacturing generally," which indicates "that the

acquisition of a type certificate is merely a baseline requirement." Sikkelee II, 822 F.3d at 694. Thus, "in the manufacturing context, the statutory language indicating that these are 'minimum standards,' means what it says." Id. (internal citation omitted) (quoting 49 U.S.C. § 44701). State-law claims, such as Sikkelee's, supplement the federal scheme and further its central purpose: safe aircrafts.[13]

[13] The FAA, in its brief submitted to our Court in connection with the last appeal, asserts the FAA's express approval of an aircraft or part design would preempt, under conflict preemption principles, a plaintiff's state tort suit arguing for an alternative design. App. 1183. We noted the FAA's position that "to the extent that the FAA has not made an affirmative determination with respect to the challenged design aspect, and the agency has left that design aspect to the manufacturer's discretion, the claim would not be preempted." Sikkelee, 822 F.3d at 702 (quoting FAA Letter Br. at 11; App. 1184). We concluded:

> A type certificate thus would not create such a conflict in the FAA's view where unilateral changes are permissible without preapproval or where an allegation of negligence arises after the issuance of a type certificate, such as claims related to . . . issuance of service bulletins to correct an issue that has come to the manufacturer's attention . . . .

Id. at 702 n.19 (citing FAA Letter Br. at 10-11, 12-13 n.2; App. 1183-86). That is precisely the situation here: Lycoming was aware the carburetor's screws could and did come loose on numerous occasions, leading to fuel leaks—in the Cessna 172

Moreover, "immuniz[ing] aircraft and aviation component part manufacturers from liability for their defective product designs" is "inconsistent with the [Federal Aviation] Act and its goal of fostering aviation safety." Amicus Am. Ass'n for Justice Br. at 4-5. A manufacturer would have little incentive to correct problems with its plane or parts if it could rely on a type certificate to avoid liability. This would undermine both the goal of the federal regulatory regime and the interests of states in ensuring the safety of their residents.[14]

For these reasons, the District Court erred in holding Sikkelee's claims were conflict-preempted and granting Lycoming summary judgment on that basis.

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in particular—and Lycoming issued service bulletins in an apparent attempt to address the issue (but did not change the design). Thus, our conclusion that Sikkelee's claims are not preempted is consistent with the FAA's position on the impact of state law on the federal regulatory scheme.

[14] Our dissenting colleague opines that preemption applies because the regulatory scheme does not allow a certificate holder to unilaterally make a change, even though they could request permission to do so. Taking this view to its logical conclusion means that certificate holders could be aware of conditions that threaten safety or airworthiness and not be required to take any action to address those conditions. This approach would insulate the certificate holder from liability and leave those injured without a remedy.

C

We next address Sikkelee's state-law strict liability and negligence claims and conclude Lycoming is not entitled to summary judgment on them.

Sikkelee asserts Lycoming's engine design is defective, Lycoming knew about the problem and failed to correct it, and the engine's defect proximately caused David Sikkelee's death. She further argues the engine's condition did not substantially change between 1969 and the crash, and any changes that did occur were reasonably foreseeable. She also argues that Lycoming is liable for defects in the overhauled carburetor because manufacturers can be liable for defects in aftermarket parts installed on their products. Lycoming disputes Sikkelee's arguments as to causation, substantial change, foreseeability, and negligence, and argues that it cannot be held liable because it was not in the replacement carburetor's chain of distribution.

The District Court should have permitted Sikkelee's strict liability and negligence claims to be decided by the jury. Pennsylvania law provides that whether a product is defective "is a question of fact ordinarily submitted for determination to the finder of fact; the question is removed from the jury's consideration only where it is clear that reasonable minds could not differ on the issue." Tincher, 104 A.3d at 335. Similarly, the issues of proximate causation, whether a change to the product was substantial, and whether that change was reasonably foreseeable, are generally for the jury. Merriweather v. E.W. Bliss Co., 636 F.2d 42, 44-45 (3d Cir. 1980); Hamil v. Bashline, 392 A.2d 1280, 1287-88 (Pa. 1978);

D'Antona v. Hampton Grinding Wheel Co., 310 A.2d 307, 310 (Pa. Super. Ct. 1973).

Here, the record indicates that reasonable minds could differ on these issues. For example, there is a genuine dispute of material fact as to causation. Sikkelee's experts posit the carburetor—due to its loosening screws and fuel leakage—caused the engine to fail and the plane to crash, while Lycoming's experts dispute Sikkelee's experts' conclusions. Moreover, contrary to Lycoming's argument, there are circumstances in which a manufacturer can be held liable for a component part that caused a plaintiff's injury, even when the part was made by a different entity, and particularly when that entity was required to follow the manufacturer's design. See D'Antona, 310 A.2d at 309-10 (holding that "appellant's averment that a defective condition in [the] machine caused the wheel to explode sufficiently states a cause of action against [defendant] despite the fact that the explosion occurred in a component part manufactured by someone else"); see also Pridgen v. Parker Hannifin Corp., 916 A.2d 619, 623 (Pa. 2007) ("[W]e agree with [plaintiffs'] observation that [defendants, including Lycoming] sit at the top of the aviation food chain with respect to all components comprising the type certificated engine. Thus, in the absence of GARA repose, [defendants] might indeed be liable for design defects in replacement parts and/or the aircraft systems within which such components function." (citation and internal quotation marks omitted)).

Therefore, the District Court erred in granting Lycoming summary judgment on Sikkelee's state-law claims.[15]

D

Finally, Sikkelee argues the District Court erred in granting Lycoming summary judgment on her failure-to-notify-the-FAA claim, based on 14 C.F.R. § 21.3. That provision provides that "[t]he holder of a type certificate (including amended or supplemental type certificates), a PMA, or a TSO [technical standard order] authorization, or the licensee of a type certificate must report any failure, malfunction, or defect in any product or article manufactured by it that it determines has resulted in any of the occurrences listed in paragraph (c) of this section." 14 C.F.R. § 21.3(a). Paragraph (c) includes situations that fit the alleged defect and carburetor malfunction here. Id. § 21.3(c)(1)-(2), (6), (10). Sikkelee argues Lycoming failed to comply with this regulation, and the FAA would have taken corrective action if Lycoming had complied.

Lycoming is entitled to summary judgment on this claim. Sikkelee has attempted to use a federal duty and standard of care as the basis for this state-law negligence claim.

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[15] We note the District Court made repeated reference to Sikkelee's $2 million settlement with Kelly. Sikkelee III, 268 F. Supp. 3d at 690, 709, 717. The settlement with Kelly is irrelevant to any of the legal issues presented here, and we hope the District Court's analysis and tone were not influenced by it. See, e.g., id. at 717 (stating that because of this settlement, "sympathy for unrealized pecuniary losses is not in order for the Plaintiff here").

See Reply Br. at 17 ("Lycoming is liable in negligence for failing to report known product defects to the FAA."). However, as we held in Sikkelee II, "Congress has not created a federal standard of care for persons injured by defective airplanes." 822 F.3d at 696; cf. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348, 353 (2001) (holding state-law fraud-on-the-FDA claims were impliedly preempted by federal law, and noting that "were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in question[ ]. On the contrary, the existence of these federal enactments is a critical element in their case"). The District Court therefore properly granted summary judgment to Lycoming on this claim.

III

For the foregoing reasons, we will reverse the District Court's order granting Lycoming summary judgment on Sikkelee's state-law claims, affirm the Court's order granting Lycoming's motion for reconsideration on Sikkelee's failure-to-warn-the-FAA claim, and remand for further proceedings.

ROTH, Dissenting in Part

The Majority holds that Sikkelee's claims against Lycoming are not conflict preempted. Applying the Supreme Court's decision in *Wyeth v. Levine*,[1] the Majority concludes that, because Lycoming has not produced clear evidence that the FAA would have prevented Lycoming from implementing certain design changes to the engine, it was not impossible for Lycoming to unilaterally implement the design changes allegedly required under Pennsylvania law.

The Majority errs in two key ways. First, the Majority takes a piecemeal approach to the Supreme Court's impossibility preemption precedents, without considering it in the aggregate. Second, the Majority misframes the applicable regulatory regime, which requires prior FAA approval for all changes, major and minor.

Without disregarding *Wyeth*, I find that, given the nature of the regulatory regime at issue, the Supreme Court's subsequent decisions in *PLIVA, Inc. v. Mensing*[2] and *Mutual Pharmaceutical Co. v. Bartlett*[3] are controlling. In short, applicable FAA regulations prohibited Lycoming from implementing the allegedly required change without some form of prior FAA approval. As a result, under the Supreme Court's conflict preemption precedents, compliance with state law would have been impossible. I therefore respectfully

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[1] 555 U.S. 555 (2009).
[2] 564 U.S. 604 (2011).
[3] 570 U.S. 472 (2013).

dissent from the portion of the Majority opinion that holds that Sikkelee's claims are not conflict preempted.[4]

I.

The Majority and all parties to this appeal agree that the Supreme Court's recent decisions in *Wyeth*, *PLIVA*, and *Bartlett* set out the governing standards for impossibility preemption. Although the Majority opinion cogently summarizes those decisions, it fails to consider their combined import. Together, those decisions present a cohesive standard: when federal regulations prevent a manufacturer from altering its product without prior agency approval, design defect claims are preempted; when federal regulations allow a manufacturer to independently alter its product without such prior approval, design defect claims ordinarily are not preempted. Revisiting *Wyeth*, *PLIVA*, and *Bartlett* shows why that is the applicable standard.

In *Wyeth*, the plaintiff suffered serious injury after receiving an intravenous administration of the brand-name drug Phenergan, through a method known as "IV push." The drug's FDA-approved label included a general warning about the risks involved in IV administration but did not specifically

[4] I agree with my colleagues that the District Court correctly granted summary judgment in favor of Lycoming on Sikkelee's failure-to-notify-the-FAA claim based on 14 C.F.R. § 21.3. I therefore join Part II.D of the Majority opinion. In addition, I reach the question of preemption in this Dissent because I agree with my colleagues that there are disputed issues of material fact that would preclude summary judgment on the merits of Sikkelee's state-law tort claims.

instruct physicians to use the safer "IV drip" method instead of the riskier "IV push" method.[5] The plaintiff brought state-law claims for negligence and strict liability against the drug maker, Wyeth, premised upon Wyeth's failure to include on the label a more specific warning about the dangers of IV push administration. Wyeth argued that the plaintiff's claims were conflict preempted because the FDA had approved Phenergan's label, and FDA regulations generally forbid drug makers from altering an approved label, rendering it impossible for Wyeth to comply with its state-law duty to enhance the label. The Supreme Court, however, rejected Wyeth's conflict preemption defense because an exception in the FDA regulations, the so-called "changes being effected" (CBE) exception,[6] allowed drug makers to unilaterally add warnings to their labels, subject to the FDA's authority to subsequently rescind or modify such changes.[7] Setting out the rule now applied by the Majority in this case, the Court held that "absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements."[8]

The Supreme Court returned to conflict preemption two years later in *PLIVA*.[9] *PLIVA* involved a set of facts generally similar to those of *Wyeth*: Plaintiffs took Defendant's drug, suffered an injury, and brought state-law tort claims against Defendant premised upon Defendant's

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[5] *Wyeth*, 555 U.S. at 559-60.
[6] 21 C.F.R. § 314.70(c)(6)(iii).
[7] *Wyeth*, 555 U.S. at 568-71.
[8] *Id*. at 571.
[9] 564 U.S. 604.

failure to include a sufficient warning on the drug's label.[10] The Court, however, noted a key distinction from *Wyeth* with regard to the applicable federal regulations. The drug at issue in *PLIVA* was a generic, and FDA regulations required that generic drugs bear the exact same warning label as their brand-name equivalent.[11] The regulations for generic drugs included no exception comparable to the CBE provision that allowed brand-name makers to unilaterally alter their warning label.[12] Notably, however, the Court did not find that generic drug makers were incapable of ever making their warning labels safer. Instead, relying on the representations of the FDA as amicus, the Court assumed that generic drug makers "could have proposed—*indeed, were required to propose*—stronger warning labels to the [FDA] if they believed such warnings were needed" and that "[i]f the FDA had agreed that a label change was necessary, it would have worked with the brand-name manufacturer to create a new label for both the brand-name and generic drug."[13]

Despite this duty, the Court concluded that, for purposes of conflict preemption, such a regulatory regime rendered it impossible for the generic manufacturer to simultaneously comply with state tort law and the federal regulatory requirement without prior agency approval. The Court explained that "[t]he question for 'impossibility' is whether the private party could *independently* do under federal law what state law requires of it."[14] There, the drug

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[10] *Id*. at 609-10.
[11] *Id*. at 613.
[12] *See id*. at 614-15.
[13] *Id*. at 616 (emphasis added).
[14] *Id*. at 620 (emphasis added).

maker could not. The Court specifically noted that the drug maker would not have satisfied its state law duties by proposing changes to the label or otherwise engaging in dialogue with the FDA. Rather, "[s]tate law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label."[15]

PLIVA concludes with a clear standard: "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes."[16] In the Supreme Court's words, "*Wyeth* is not to the contrary."[17] That is so because the CBE regulation "applicable to Wyeth allowed the company, of its own volition, to strengthen its label in compliance with its state tort duty."[18]

Finally, in *Mutual Pharmaceutical Co. v. Bartlett*,[19] the Supreme Court reaffirmed and further clarified its conflict preemption analysis. *Bartlett*, like *PLIVA*, began as a state-law tort suit against a generic drug manufacturer whose product had injured the plaintiff. The federal regulatory scheme was the same. The key factual distinction was that, in *Bartlett*, the plaintiff's state-law claims alleged a design

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[15] *Id*. at 619.
[16] *Id*. at 623-24.
[17] *Id*. at 624.
[18] *Id.*
[19] 570 U.S. 472.

defect, not merely a failure to warn.[20] The plaintiff argued—and the First Circuit had held—that such claims were not preempted because the drug manufacturer could comply with both state and federal law by simply choosing not to make the drug at all.[21] The Supreme Court rejected this line of reasoning. The Court noted that preemption doctrine "presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability."[22] The Court concluded that the drug maker could have satisfied its duty under state law only by altering the drug's composition or its label. Because federal regulation did not allow the drug maker to implement either of these measures without prior FDA approval, the state-law design defect claim was preempted.[23]

Distilled to their essence, the Supreme Court's recent conflict preemption decisions present a guiding principle: When a manufacturer operating in a federally regulated industry has a means of altering its product independently and without prior agency approval—such as a brand-name drug manufacturer who may implement labeling alterations via the CBE process—state-law claims against the manufacturer alleging a tortious failure to make those alterations ordinarily are not preempted; but, when federal regulations prohibit a manufacturer from altering its product without prior agency approval, state-law claims imposing a duty to make a different, safer product are preempted. Crucially, the question is not whether a manufacturer may ever alter its

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[20] *Id*. at 479.
[21] *Id*.
[22] *Id*. at 488.
[23] *Id*. at 491-92.

product under the applicable federal regulatory scheme. Rather, the question is whether a manufacturer may do so without prior agency approval. Thus, despite being decided after *Wyeth*, *PLIVA* and *Bartlett* are more logically understood as setting the general standard for impossibility preemption in cases involving an industry subject to thorough federal regulation prohibiting independent changes to an agency-approved product. By contrast, the clear evidence standard announced in *Wyeth* applies only if the regulatory regime includes an exception, such as the CBE process, allowing manufacturers to independently implement design changes without prior agency approval.

The Third Circuit's recent decision in *In re Fosamax*[24] reflects a faithful application of this principle. *Fosamax*, like *Wyeth*, was a state-law action against a brand-name drug maker who could have unilaterally updated its warning label by availing itself of the CBE exception. Applying *Wyeth*, the Third Circuit held that "the mere availability of a CBE label amendment" could, but "would not always[,] defeat a manufacturer's preemption defense, because the FDA retains authority to reject labeling changes."[25] The Court concluded that "where there is 'clear evidence that the FDA would not have approved a change' to the label, federal law preempts state-law claims premised on the manufacturer's failure to make that change."[26] Because the drug maker could have

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[24] *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268 (3d Cir. 2017), *cert. granted sub nom. Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290, 2018 WL 3148288 (U.S. June 28, 2018).

[25] *Id*. at 283.

[26] *Id*. (quoting *Wyeth*, 555 U.S. at 571).

unilaterally implemented labeling changes via the CBE exception and had not offered clear evidence that the FDA would have subsequently rejected the proposed label amendment, this Court held that the drug maker's impossibility preemption defense failed. Accordingly, *Fosamax* is entirely consistent with the core principle we derive from *Wyeth*, *PLIVA*, and *Bartlett*.

II.

With the Supreme Court's impossibility preemption framework squarely in focus, I turn to the applicable federal regulatory regime, which prohibited Lycoming from making changes to its engine without first obtaining FAA approval. The Federal Aviation Act of 1958 (the Act)[27] established the FAA and empowered it to promulgate and enforce safety regulations in the field of civil aeronautics. Thus, FAA regulations and the Act itself prescribe the operative safety standards for the manufacture of airplanes and their components, including aircraft engines. For an aircraft engine manufacturer who wishes to produce a particular model of engine, the first step in the regulatory process is obtaining a "type certificate" from the FAA to confirm compliance with applicable safety standards.[28] With limited exceptions not applicable here, a manufacturer cannot produce an aircraft engine unless a type certificate for that specific engine design has been obtained by the manufacturer or an entity with whom the manufacturer has a licensing agreement.[29] When applying for a type certificate, an engine

[27] Pub. L. No. 85-726, 72 Stat. 731.
[28] *See* 49 U.S.C. § 44704(a); 14 C.F.R. § 21.21.
[29] *See* 14 C.F.R. § 21.6.

manufacturer is required to submit, among other things, "a description of the engine design features, the engine operating characteristics, and the proposed engine operating limitations,"[30] as well as "the type design, test reports, and computations necessary to show that the product to be certificated [sic] meets the applicable airworthiness . . . requirements."[31] The "type design" portion of the application "outlines the detailed specifications, dimensions, and materials used for a given product."[32] This Court has previously described the type certification process as "intensive and painstaking."[33] The issuance of a type certificate by the FAA represents the FAA's "find[ing] that the . . . aircraft engine . . . is properly designed and manufactured, performs properly, and meets the regulations and minimum standards prescribed under [the Act]."[34]

As the Majority acknowledges, once the FAA has approved a particular engine design and issued a type certificate, the engine manufacturer must continue to manufacture the engine in compliance with the type certificate.[35] The manufacturer may not make changes to the engine design without FAA approval.[36] Federal regulations

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[30] 14 C.F.R. § 21.15.
[31] 14 C.F.R. § 21.21(b).
[32] *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 684 (3d Cir. 2016).
[33] *Id.*
[34] 49 U.S.C. § 44704(a)(1).
[35] Maj. Op. at 19.
[36] *See* 14 C.F.R. §§ 21.95, 21.97 (requiring FAA approval for both minor and major changes).

divide possible changes to an engine model into two categories: "major changes" and "minor changes."[37]

A minor change is "one that has no appreciable effect on the weight, balance, structural strength, reliability, operational characteristics, or other characteristics affecting the airworthiness of the product,"[38] and thus "may be approved under a method acceptable to the FAA."[39] One of these methods is to receive approval from an individual engineering expert who has been certified by the FAA as a Designated Engineering Representative (DER). DERs may be hired by a manufacturer, but their authority to approve minor changes exists solely as the result of a delegation of authority by the FAA, as allowed under the Act.[40] DERs act "within limits prescribed by and under the general supervision of the [FAA] Administrator,"[41] and their decisions may be appealed to the Administrator or reconsidered by the Administrator at his or her own initiative.[42] As the Majority correctly notes, "DERs are agents of the FAA, and so their involvement does not mean the FAA has not approved a design."[43] Accordingly, DER approval is a form of FAA approval. Although the applicable regulations, including the availability of DERs, provide manufacturers with flexibility when seeking to implement minor changes, neither federal regulations nor any other

[37] 14 C.F.R. § 21.93.
[38] *Id*.
[39] 14 C.F.R. § 21.95.
[40] *See* 49 U.S.C. § 44702(d).
[41] 14 C.F.R. § 183.29.
[42] 49 U.S.C. § 44702(d)(3).
[43] Maj. Op. at 25 n.12.

authority cited by the Majority or by Sikkelee supports the conclusion that a manufacturer may actually implement a minor change prior to receiving FAA approval.[44]

All changes that are not minor are classified as major.[45] A manufacturer seeking to implement a major change must first obtain a new or supplemental type certificate from the FAA.[46] A manufacturer applying for approval of a major change must "[p]rovide substantiating data and necessary descriptive data for inclusion in the type design" and must show that the proposed change complies with all FAA regulations.[47] As such, it is clear that major changes require prior FAA approval. Aside from major and minor changes, FAA regulations provide no other means through which an original manufacturer can implement changes to the design of a type certified product.[48] In other words, in the field of safety regulation of civil aeronautics, there is no CBE process for a manufacturer to effect changes to a type certificate prior to FAA approval of that change.

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[44] Sikkelee argues that prior DER approval provides manufacturers with such an avenue, because DER approval is not actually FAA approval. Appellant's Br. at 33. As noted above, all three members of this Panel reject that argument.

[45] 14 C.F.R. § 21.93.

[46] 14 C.F.R. § 21.113.

[47] 14 C.F.R. § 21.97.

[48] As correctly summarized in the Majority opinion, additional FAA regulations govern changes to airplane parts made by aftermarket parts manufacturers who hold an FAA-issued PMA. Maj. Op. at 20. These regulations are not directly applicable to an original manufacturer such as Lycoming.

Moreover, concerning major versus minor changes, the Majority asserts that, at oral argument, both parties agreed that Sikkelee's proposed change to the carburetor would be a minor change.[49] In fact, the parties were not in such perfect agreement. Lycoming's precise position at oral argument was that, while Lycoming viewed the proposed change as having no impact on airworthiness and thus as minor, Sikkelee's theory of tort liability inherently required the conclusion that the change was major.[50] I find Lycoming's argument persuasive and note the inherent tension in Sikkelee's position that a proposed change could have prevented the crash but, at the same time, should be considered minor, *i.e.*, having no impact on airworthiness. However, the question need not be resolved. Sikkelee's claims are preempted regardless of whether the proposed change is classified as minor or major because, as we have explained, both processes require prior FAA approval before they are implemented.

III.

As a result of this comprehensive regulatory scheme, Sikkelee's strict liability and negligence claims against Lycoming are conflict preempted. Lycoming, as the original manufacturer of and type certificate holder for the O-320-D2C engine (the Engine), had two paths through which it could lawfully implement changes to the Engine's design: the minor change process for changes having no appreciable

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[49] Maj. Op. at 20-21.

[50] See Oral Arg. Audio Recording at 32:25-48, available at http://www2.ca3.uscourts.gov/oralargument/audio/17 3006_Sikkeleev.Precision-Airmotive.mp3.

impact on the airworthiness of the Engine, or the major change process for all other changes. As outlined above, both paths would have required prior FAA approval before Lycoming could implement a proposed change. No exception akin to the CBE process in *Wyeth* applied here. Accordingly, the regulatory regime places this case squarely in the realm of *PLIVA* and *Bartlett*.

That result is readily apparent when we consider the question of impossibility in the precise language provided by the Supreme Court: Could Lycoming independently do under federal law what state law required of it,[51] *i.e.*, alter the design of the carburetor's fastening mechanism from lock-tab washers to safety wire? Under the applicable FAA regulations, the answer to that fundamental question is clearly no, regardless of whether such a change would have been minor or major. *PLIVA* and *Bartlett* instruct that that answer is sufficient to find conflict between Lycoming's state and federal duties, and thus to create impossibility preemption. We must go no further. We should not inquire into the likelihood that the FAA might have approved a proposed change.[52]

The Majority disagrees, finding that *Wyeth* provides the applicable standard and that we must thus consider

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[51] *Cf. PLIVA*, 564 U.S. at 620.

[52] *PLIVA*, 564 U.S. at 623 ("[P]re-emption analysis should not involve speculation about ways in which federal agency and third-party actions could potentially reconcile federal duties with conflicting state duties. When the 'ordinary meaning' of federal law blocks a private party from independently accomplishing what state law requires, that party has established pre-emption.").

whether Lycoming offered sufficient evidence that the FAA would have rejected the proposed change. But, in support of its application of *Wyeth*, the Majority fails to identify any provision in the federal regulations that would have allowed Lycoming to independently implement the proposed change without prior FAA approval. Quite the contrary, the Majority candidly acknowledges that the FAA does not have a CBE-type process.[53] That should be the end of our *Wyeth* inquiry. But instead, the Majority relies on "the nature of FAA regulations and Lycoming's interactions with the FAA" to support its conclusion that Lycoming "could have . . . adjusted its design" and that *Wyeth*'s standard should thus apply.[54] In particular, the Majority points out that Lycoming has amended its type certificate for the O-320 engine a number of times over the years and that Lycoming had been "in communication with the FAA" about the carburetor design and reports of loose bolts.[55]

I take no issue with those statements to the extent that they are simply factual assertions.[56] But the Majority errs in concluding that those facts establish that *Wyeth* alone supplies the applicable standard for conflict preemption analysis in this case. Reading the Supreme Court's impossibility preemption decisions in concert, the key initial question for impossibility is not whether a manufacturer has engaged in

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[53] Maj. Op. at 24 n.11.
[54] Maj. Op. at 24.
[55] Maj. Op. at 23.
[56] It bears noting that nothing in the record suggests these amendments occurred without prior FAA approval. *See* J.A. 561. *See also* J.A. 559-61 re list of applications for and revised type certificates issued by FAA for the Engine.

dialogue with a federal agency regarding possible design changes or even whether the agency might ultimately approve a proposed change at the conclusion of such dialogue. Rather, as previously stated, we must start with the question whether the manufacturer could have implemented the change independently, *i.e.*, without prior agency approval. This issue was, in fact, addressed in *PLIVA*, where the Supreme Court expressly contemplated whether a preemption defense was foreclosed by the type of manufacturer-agency dialogue that the Majority now relies upon. There, the Court assumed that a generic drug maker had a duty to warn the FDA of safety problems and could have proposed and asked the FDA to approve a new warning label for both the generic and brand-name drug.[57] But that fact did not defeat preemption or even trigger the *Wyeth* inquiry because the manufacturer still could not independently implement the proposed change without prior agency approval.[58] The case here is similar.

Likewise, the Majority may well be correct that "the FAA wanted Lycoming to address the situation"[59] of loosening bolts in the Engine's carburetor. But that alone does not negate impossibility, because nothing in the record or FAA regulations suggests that Lycoming could have implemented any design changes without prior FAA approval. On the contrary, the natural reading of the regulations is that FAA approval is required for any change, major or minor.[60] In fact, it would be logical to infer that Lycoming and the FAA engaged in dialogue about bolt

[57] *PLIVA*, 564 U.S. at 616-17.
[58] *Id*. at 619-20.
[59] Maj. Op. at 26.
[60] *See supra* section II.

loosening precisely because both parties recognized that FAA approval would be required before Lycoming could implement any remedial design change. That Lycoming "has made numerous changes to the type certificate for its O-320 engine"[61] also does not alter the impossibility analysis. As outlined above, changes to a type certificate, whether minor or major, require prior FAA approval, and the record reflects such approval for the other changes that Lycoming made.[62]

Ultimately, although this case involves a detailed regulatory regime governing a complex industry, the correct result of this appeal is dictated by a few key facts. Under FAA regulations, Lycoming, as the original manufacturer of and type certificate holder for the Engine, had two means of implementing changes to its design—the major change process and the minor change process. The plain language of the regulations and the record in this case show that, under either process, some form of FAA approval would have been required before Lycoming could have implemented the design change proposed by Sikkelee. Thus, the answer to the fundamental question of impossibility preemption—could Lycoming independently do under federal law what state law allegedly required of it—is clearly no. The Supreme Court instructs that such an answer supports a finding of impossibility preemption and requires that our inquiry go no further.

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[61] Maj. Op. at 23.

[62] J.A. 559-61 (Type Certificate Data Sheet No. E-274) (listing applications for and issuance of new or revised type certificates for O-320 engine models between 1952 and 2003).

IV.

For the reasons stated above, I conclude that the Majority has erred by relying upon *Wyeth* in isolation and by expanding its inquiry to consider whether Lycoming presented clear evidence that the FAA would not have approved the design change now proposed by Sikkelee. FAA regulations prohibited Lycoming from independently implementing changes to the design of the Engine without prior FAA approval. As such, pursuant to *PLIVA* and *Bartlett*, Lycoming has established a valid impossibility preemption defense. I therefore respectfully dissent in part from the Majority opinion and would affirm the judgment of the District Court.