IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

JILL SIKKELEE, Individually and : Case No. 4:07-cv-00886-MWB

as Personal Representative of the :

ESTATE OF DAVID SIKKELEE, : (Judge Brann)

deceased,

Plaintiff :

v. :

PRECISION AIRMOTIVE :

CORPORATION, et al.,

Defendants :

SUPPLEMENTAL BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT ON THE GROUND OF CONFLICT PREEMPTION

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Defendant AVCO Corporation, on behalf of its Lycoming Engines Division (Lycoming), submits this Supplemental Brief on the issue "[w]hether Plaintiff's state law tort claims are conflict preempted," as directed by the Court at oral argument on May 19, 2017 and as ordered on May 22, 2017 (Doc. 561):

I. INTRODUCTION

At oral argument, the Court identified undeniable logical contradictions in the arguments made by Jill Sikkelee (Sikkelee). Sikkelee has argued throughout the litigation that Lycoming controls Kelly to such an extent that it could have forced Kelly to change the design of a given Kelly part and, indeed, that the federal regulatory scheme makes Lycoming's control so great that it is a "de facto manufacturer" of Kelly's parts. But, if Sikkelee is correct, then this same regulatory scheme is in conflict with the central premise of her case.

The very federal regulations that Sikkelee argues make Lycoming liable for parts it did not manufacture or supply also mandate that any change in design (including the change she proposes here) be approved by the Federal Aviation Administration (FAA). The argument that Sikkelee must win to avoid conflict preemption—that the federal regulatory regime allows a manufacturer significant latitude—makes Lycoming's relationship to the carburetor parts too tenuous to support her state law theory of tort liability.

II. SUPPLEMENTAL ARGUMENT

Sikkelee has steadfastly maintained that Lycoming had complete control as a design service provider" or a "de facto manufacturer" responsible under Pennsylvania law for parts Kelly designed, manufactured, and installed on the used Marvel-Schebler carburetor. Sikkelee has now made a course correction, or more accurately, jumped ship, avowing that Lycoming does not stand in Kelly's shoes for purposes of FAA approvals of the Kelly replacement parts. If federal law makes Lycoming responsible for the design of someone else's parts under state law, ¹ then the potential preemptive effect of federal law on those claims necessarily follows those parts.

The operative actual facts underlying this lawsuit are simple and incontrovertible. Lycoming manufactured and sold an aircraft engine in 1969, after receiving design and production approvals from the FAA. Thirty-five years later, in 2004, the engine was overhauled by someone else (Triad), which procured a used Marvel-Schebler carburetor that was overhauled by someone else (Kelly), using a carburetor overhaul manual from someone else (Precision) and installing parts it (Kelly) designed and manufactured with the approval of the FAA. Kelly parts—including the gasket, hex head screws, and lock tab washer—were

¹ Lycoming does not concede, and in fact disputes, the existence of any defects in the Kelly parts or that it can be liable under Pennsylvania strict liability or negligence law for parts actually manufactured and sold by others.

expressly approved by the FAA, which authorized Kelly to manufacture those parts to be used as new replacement parts on used carburetors. Sikkelee does not dispute these facts.

Sikkelee instead asks this Court to accept unreasonable inferences drawn solely from the ipse dixit of her putative experts and unsupported by the summary judgment record. Namely, and as she has argued throughout the winding course of the litigation, Sikkelee contends that Lycoming singlehandedly dominated and controlled what transpired in 2004 such that it could be liable under Pennsylvania common law for defects in parts designed, manufactured, and supplied by others acting without Lycoming's participation or knowledge.

In opposition to the Conflict Preemption Motion, however, Sikkelee was forced to retreat somewhat from this fictive position, admitting facts relating to the separate design, production, and installation of the Kelly replacement parts (Doc. 546 ¶¶ 1-23) that are directly at odds with the tall tales she told a half-dozen years ago. At oral argument, Sikkelee's counsel conceded in similar fashion that Kelly's "economic motivation" is to produce parts for Lycoming engines (N.T. May 19, 2017 at 138) and to do so by attempting to "mimic" what goes on new engines,²

² Sikkelee's counsel made the following points at oral argument:

^{• &}quot;If you want to make parts to put on Lycoming engines, you mimic the design as closely as possible" (N.T. May 19, 2017 at 101) (emphasis added)

which is a matter of free will and not subject to control by Lycoming. There would be no need for Kelly to "strive to mimic" or to follow "as closely as possible" or to "come as close to the original as you can get it," of course, if Lycoming in fact approved or controlled the design of these parts.

Sikkelee never explains how Lycoming could compel Kelly to do anything, including changing the design of its FAA PMA parts. Sikkelee ignores the fact that other Kelly design aspects used at the 2004 overhaul (such as the brass carburetor float) were different from the parts Lycoming's OEM carburetor was supplying at the time (such as the polymer carburetor float). (Doc. 234-11 at 2 of 9; Doc. 549 ¶ 42; Doc. 549-3).

Even if the Court were to accept Sikkelee's alternate versions of reality, and the logic maze attendant thereto, the specific design aspects challenged (the Kelly fasteners) were approved by at least two FAA employees acting in official capacities, and not by Lycoming. Any change to the FAA approved Kelly design aspects similarly required approval by the FAA, not Lycoming. Although

^{• &}quot;[T]he way you prove ... that your parts are suitable for use on a type certified design and safe for use on that design ... is [to] create something as close to the original as you can get it" (N.T. May 19, 2017 at 102) (emphasis added)

^{• &}quot;PMA parts strive to mimic the OEM manufacturers" (N.T. May 19, 2017 at 102) (emphasis added)

[•] Kelly "followed the OEM designs as closely as possible" (N.T. May 19, 2017 at 139) (emphasis added)

Pennsylvania law can impose tort duties on Lycoming, it cannot bend the will of the federal government. Sikkelee's state law tort claims are conflict preempted.

A. The Possibility of Possibility Does Not Make The Impossible Possible

The Court inquired at oral argument about analogous regulatory regimes for purposes of conflict preemption analysis. (N.T. May 19, 2017 at 191). The FAA and the Third Circuit each looked to prescription drug cases in framing conflict preemption issues. Because of the nature and effect of the regulatory approvals at issue, Lycoming agrees that the prescription drug cases most closely parallel the conflict preemption issues before the Court. Its disagreement is with how Sikkelee has cast the issues and which line of U.S. Supreme Court prescription drug cases is on point.

Sikkelee argues that this case is akin to <u>Wyeth v. Levine</u>, 555 U.S. 555 (2009), wherein the Supreme Court held that it was not impossible for a brand name drug manufacturer to comply with state tort law and federal labeling laws because the manufacturer could make certain labeling changes without approval from the Food & Drug Administration (FDA) and without violating the FDA's changes being effected (CBE) regulations. Absent clear evidence that the FDA would not have approved those changes, the Supreme Court declined to conclude it was impossible to comply with both state and federal law. <u>Id.</u> at 571.

Lycoming submits that this case is on all fours with <u>PLIVA</u>, <u>Inc. v. Mensing</u>, 564 U.S. 604 (2011), involving labeling claims against a generic drug manufacturer, and <u>Mutual Pharm. Co. v. Bartlett</u>, 133 S. Ct. 2466 (2013), involving design defect (and warnings) claims against a generic drug manufacturer. In <u>PLIVA</u>, the Supreme Court held that failure to warn claims were barred by impossibility preemption because the duty of sameness prohibited generic manufacturers from unilaterally changing the warning used by the brand name manufacturer. 564 U.S. at 623-24. In <u>Bartlett</u>, the Supreme Court held that design defect claims were barred by impossibility preemption because the sameness requirement prohibited generic manufacturers from unilaterally changing the composition or labeling of the drug. 133 S. Ct. at 2470.

The situation before this Court is not one where a manufacturer can independently, and of its own volition, make changes required by state law. As the FAA explained, the situation before the Court is one where **any** design change requires approval by the FAA. (FAA Amicus Ltr. at 5, 15) (Doc. 534-1). The FAA's approval process "must be accorded due weight under a conflict preemption analysis." Sikkelee v. Precision Airmotive Corp., 822 F.3d 680, 708 (3d Cir.), cert. denied, 137 S. Ct. 495 (2016).

Unlike Wyeth, FAA approval holders are situated like the generic drug manufacturers in the Supreme Court impossibility cases, the significant difference

being that the FAA does not distinguish between classes of manufacturers. Regardless whether they manufacture type certified products or replacement parts to go on type certified products, FAA design and production approval holders may not deviate from the FAA approved design of their own volition. All major and minor design changes require FAA approval. Cf. Yates v. Ortho-McNeil-Janssen Pharms., Inc., 808 F.3d 281, 300 (6th Cir. 2015) (applying Bartlett preemption to design defect claims against brand name drug manufacturer); Utts v. Bristol-Meyers Squibb Co., No. 16cv5668, 2016 U.S. Dist. LEXIS 178335, *33-34 (S.D.N.Y. Dec. 23, 2016) (applying Bartlett preemption to negligent design defect claims against brand name manufacturer relating to the nature of the composition of the drug).

Sikkelee nevertheless urges the Court to apply the <u>Wyeth</u> line of cases, including <u>In Re Fosamax Prods. Liab. Litig.</u>, 852 F.2d 268 (3d Cir. 2017), to support her view that the design changes she advocates are ones that may be made independently and without FAA approval. Importantly here, the Supreme Court has limited <u>Wyeth</u> to those situations where a manufacturer can, "of its own volition, ... strengthen its label in compliance with its state tort duty." <u>PLIVA</u>, 564 U.S. at 624.

Neither Lycoming nor Kelly nor Precision nor any other aviation manufacturer can unilaterally change the design of products approved by the FAA.

Even minor design changes require FAA approval, as the FAA explicates in the amicus filing submitted at the behest of the Third Circuit. (FAA Amicus Ltr. at 5, 15) (Doc. 534-1). The FAA's interpretation of its own regulations is entitled to deference in conflict preemption analysis. <u>PLIVA</u>, 564 U.S. at 613. <u>Wyeth</u> does not control the design defect claims before this Court.

<u>Fosamax</u> likewise should be limited to the <u>Wyeth</u> line of cases. In framing the <u>Wyeth</u> labeling issue before it as a question of fact, the panel in <u>Fosamax</u> did not overrule decades worth of Third Circuit precedent holding that preemption is a question of law³ and could not do so under 3d Cir. I.O.P. 9.1.

Nor does Sikkelee's identification of ostensible factual issues provide a path forward. To Sikkelee's way of thinking, questions as to (1) the "scope of delegations" afforded to a Designated Engineering Representative (DER) and (2)

See, e.g., South Jersey Sanitation Co. v. Applied Underwriters Captive Risk Assurance Co., 840 F.3d 138, 143 (3d Cir. 2016) ("preemption determinations are questions of law"); In re Fed.-Mogul Global Inc., 684 F.3d 355, 364 n.16 (3d Cir. 2012) ("[t]he scope of preemption presents a pure question of law"); Roth v. Norfalco LLC, 651 F.3d 367, 374 (3d Cir. 2011) ("preemption ... determinations [a]re based on questions of law"); Elassaad v. Independence Air, Inc., 613 F.3d 119, 124 (3d Cir. 2010) ("preemption determination ... is a question of law"); Deweese v. Nat'l R.R. Passenger Corp., 590 F.3d 239, 244 n.8 (3d Cir. 2009) ("a preemption determination . . . is a question of law"); Travitz v. Northeast Dep't ILGWU Health & Welfare Fund, 13 F.3d 704, 708 (3d Cir. 1994) ("[t]he issue of preemption is essentially legal"); Pennsylvania Med. Soc'y v. Marconis, 942 F.2d 842, 846 (3d Cir. 1991) ("[t]he question of preemption involves an issue of law"); Pokorny v. Ford Motor Co., 902 F.2d 1116, 1119 (3d Cir. 1990) ("the question of whether [an] action is pre-empted . . . involves a pure issue of law").

as to "whether the FAA would have refused to allow Lycoming's DER to implement this change to the design" are factual matters to be resolved by a jury under <u>Wyeth</u> and <u>Fosamax</u>. (N.T. May 19, 2017 at 120, 123). These are issues of law, not fact, and neither is material to the parts on the airplane claimed to be causally related to the happening of the accident.

The first ostensible "fact" issue Sikkelee presents—the scope of delegations afforded the FAA DER at Lycoming—is not an issue of fact but an issue of law and, more importantly, is completely irrelevant. The Kelly carburetor parts on the airplane, the only parts relevant to causation, were not approved by an FAA DER but by FAA employees in FAA offices in Boston and Atlanta.

The second ostensible "fact" issue Sikkelee presents—whether the FAA would have refused to allow the Lycoming FAA DER to implement a design change—is not an issue of fact but an issue of law. The FAA DER at Lycoming could not approve Kelly PMA parts or "implement a change" to Kelly PMA parts because the modification or replacement part regulations under which those PMA parts were approved do "not apply to … [p]arts produced under a type or production certificate." 14 C.F.R. § 21.303(b)(1). That is a matter of law, not fact, and not material to the task before the Court.

Lycoming does not have the ability to wave a magic wand and change someone else's FAA approved design. Even if Lycoming somehow had the ability

to "implement changes" to FAA PMA parts, which it does not, those design changes still have to be approved by the FAA. (FAA Amicus Ltr. at 5, 15) (Doc. 234-1). As in <u>Bartlett</u>, "the mere 'possibility' that the FAA would approve a hypothetical application for an alteration does not make it possible to comply with both federal and state requirements." <u>Sikkelee</u>, 822 F.3d at 704.

The Supreme Court has made clear that conflict preemption analysis turns on duties imposed by state law. In this case, Sikkelee advances a strict liability theory of design defect based upon risk-utility analysis, including the availability of an alternative safer design under Tincher v. Omega Flex, Inc., 104 A.3d 328, 389-90 (Pa. 2014). Accord Surace v. Caterpillar, Inc., 111 F.3d 1039, 1042 (3d Cir. 1997) (applying the "Wade factors," including alternative design, as part of risk-utility analysis under Section 402A). Sikkelee's negligence design defect claims likewise require proof of alternative design. See Smith v. Yamaha Motor Corp., 5 A.3d 314, 322-23 (Pa. Super. 2010) (requiring proof of alternative design in a negligent design case); Kosmack v. Jones, 807 A.2d 927, 931 (Pa. Commw. 2002) (same). Sikkelee's state strict liability and negligence claims for design

Sikkelee's sole expert evidence of design defect, alternative design, and causation is through the opinion testimony of Donald E. Sommer. Since Lycoming moved to exclude his testimony in 2013, several courts have found him unqualified to offer opinions regarding aircraft component design or alternative design because he lacks training or experience in the field of aircraft design and manufacture. See, e.g., Rodgers v. Beechcraft Corp., No. 15-CV-129, 2017 U.S. Dist. LEXIS 15372, at *31-33 (N.D. Okla. Feb. 3, 2017) (opinions regarding alternative design of

defect are preempted because the FAA expressly approved the challenged design aspects and changes to the FAA approved design require FAA approval. Sikkelee, 822 F.3d at 704.

Although Lycoming did not seek summary judgment on the failure to warn claims on conflict preemption grounds, those claims are inextricably intertwined with the design defect claims. For one thing, the efficacy of warnings is part of the risk-utility calculus under <u>Tincher</u>. 104 A.3d at 389-90. For another, the failure to warn theory is that Lycoming failed to warn of the design defects Sikkelee alleges. The strict liability and negligence warning claims are part and parcel of the preempted design defect claims and are themselves conflict preempted. <u>Cf.</u> <u>Cellucci v. Gen. Motors Corp.</u>, 676 A.2d 253, 255 (Pa. Super. 1996) (allowing **any** common law claims would create an actual conflict between the federal and state law such that the state law was impliedly preempted).

B. Application of Conflict Preemption Is Case Specific

The Court made inquiry as to what types of state law claims would not be conflict preempted. (N.T. May 19, 2017 at 136). Conflict preemption is case specific and turns on both the governing federal law and its interplay with the

landing gear system); Rodgers v. Beechcraft Corp., No. 15-CV-129, 2016 U.S. Dist. LEXIS 183587, at *9-10 (N.D. Okla. Nov. 29, 2016) (same); Laugelle v. Bell Helicopter Textron Inc., No. 10C-12-054, 2014 Del Super. LEXIS 508, at *22-24 (Del. Super. Oct. 1, 2014) (opinions regarding alternative design of power turbine governor).

governing state law. As the FAA elucidates in its amicus letter, products liability claims based on a design aspect not expressly approved by the FAA are not impliedly preempted. (FAA Amicus Ltr. at 3) (Doc. 534-1). Products liability claims based on a design defect because the product failed to comply with its FAA approvals would not be preempted. Mitchell v. Collagen Corp., 126 F.3d 902, 913 (7th Cir. 1997). Products liability claims based on manufacturing defects in the nature of a deviation from a federal design standard might not be conflict preempted, depending on the nature of the manufacturing defect claim. Sikkelee, 822 F.3d at 702 n.19 (failure to conform manufacturing process to the specifications in a type certificate). Breach of express warranty, arising from representations made and forming the basis of a contractual bargain, might not conflict with federal law. See Utts, 2016 U.S. Dist. LEXIS 178335, at *38-39. There may or may not be others, depending on duties imposed by applicable state law.

This Court need not confront the potential preemptive effect of federal law on the tort law of this or other jurisdictions or under other factual scenarios because the tort claims before it are predicated on a theory of design defect based upon the availability of an alternative safer design and failure to warn of those design defects under Pennsylvania law. The specific design aspects Sikkelee calls into question were expressly approved by the FAA so any claim that the design

should have been different conflicts with the FAA's application of the federal standards.

C. Minimum Standards Do Not Affect Impossibility

The FAA prescribes minimum national standards for aircraft design and construction in furtherance of "Congress' interest in national uniformity in safety standards with oversight by a single federal agency." (FAA Amicus Ltr. at 12) (Doc. 534-1). Where, as here, federal regulation is designed to strike a balance between competing interests, "state regulation ... must yield to the extent that it clashes with the balance struck by Congress." Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 152 (1989).

Caraker v. Sandoz Pharms. Corp., 172 F. Supp. 2d 1018 (S.D. III. 2001), alluded to at oral argument, (N.T. May 19, 2017 at 186, 188), does not compel a contrary illation. That court's view was that certain regulations promulgated by the FDA did not have conflict preemptive effect because the FDA drug labeling standards were "minimum standards" open to supplementation by state law. Caraker, 172 F. Supp. 2d at 1033. Declining to apply a conflict preemption decision from the Seventh Circuit in the medical device context, the Caraker court looked to aviation cases instead and noted that the Supreme Court referred to the aircraft type certification process as "creating 'minimum safety standards." Id. at

1044 n.23 (citing <u>United States v. Varig Airlines</u>, 467 U.S. 797, 797 (1981); (other citations omitted)).

The dicta in <u>Caraker</u> relating to aircraft certification does not trump binding precedent in this case. After a lengthy discussion of the Federal Aviation Act and other transportation industry statutes, including those with comparable minimum standards language, <u>Sikkelee</u>, 822 F.3d at 699-701, the Third Circuit concluded that "the Supreme Court's preemption cases in the transportation context support that aircraft design and manufacture claims are not field preempted, but remain subject to principles of conflict preemption." Id. at 701.

D. Express Preemption Provisions Do Not Affect Impossibility

Sikkelee's counsel made sweeping pronouncements at oral argument regarding the effect of express preemption provisions on the availability of conflict preemption, arguing the Airline Deregulation Act and the federal statute of repose provision (GARA) as somehow being in play. (N.T. May 19, 2017 at 191-93). This argument is a smokescreen, already addressed by the Third Circuit on appeal. Sikkelee, 822 F.3d at 701 n.17 ("Because the [Supreme] Court has been willing to apply conflict rather than field preemption even in situations where an *express* preemption clause is at play, conflict preemption appears especially apt in a case like this one where there is no such clause to counsel in favor of field preemption") (emphasis in original) (citations omitted). See also Geier v. Am. Honda Motor

<u>Co.</u>, 529 U.S. 861, 869 (2000) (the inclusion of an express preemption provision does not "bar the ordinary working of conflict pre-emption principles").

E. FAA Designee Approvals Make Possibility Impossible

Asseverating the ability of aviation manufacturers to make unilateral design changes, Sikkelee declares that FAA DERs appointed pursuant to 14 C.F.R. pt. 183 act on behalf of their employers, not the FAA. While this alternate reality may be how Sikkelee would like things to be, the reality is that "designees have a unique status. While we [the FAA] refer to these persons and organizations informally as 'designees', under part 183 they are referred to as "representatives of the Administrator." 70 Fed. Reg. 59932 (Oct. 13, 2005) (emphasis added).

Even if Sikkelee's reasoning had any bearing on the particular design approvals at issue, which it does not, the Third Circuit already disapproved the position being set forth here. Sikkelee argued on appeal that the regulatory regime, in her view tantamount to self-policing, "should play no role in even conflict preemption." The Third Circuit rejected her argument, inculcating that the same argument "was raised in <u>Bartlett</u> and failed to carry the day." <u>Sikkelee</u>, 822 F.3d at 708. Where "a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." <u>Arizona v. California</u>, 460 U.S. 605, 618-19, (1983). Sikkelee may not like the regulatory

regime promulgated in 14 C.F.R. pt. 183, but the Third Circuit readily dispensed with such contretemps on appeal and she may not resurrect them now.

A final word about FAA approvals is in order. To the extent that Sikkelee asserts (wrongly) that only design approvals by actual employees of the FAA trigger conflict preemption, approval by employees of the FAA is precisely what occurred here. The drawings for the gasket and the lock tab washer are stamped "FAA Approved" (Doc. 533-2) or "FAA-PMA Design Approval ANE-140" (Doc. 533-1; Doc. 533-4). The FAA PMA approvals for the gasket, lock tab washer, and screw are signed by "Jay J. Pardee, Manager, Engine Certification Office, ANE 140." (Doc. 533-5 at 7 of 7; Doc. 533-7 at 7 of 7). Minor changes to certain parts—including the gasket material that Sikkelee's putative expert Sommer claims is defective on page 29 of his expert report—all were approved by "Paul C. Sconyers, Associate Manager, ACE-117A, Atlanta Aircraft Certification Office." (Doc. 533-6; Doc. 546-6; 546-7).

Each of these approvals is an approval by an FAA employee acting as a representative of the federal government—the very occurrence Sikkelee identifies as necessary for a Supremacy Clause conflict between federal and state law to arise—and this Court should disregard the misdirection tactics employed here.

III. CONCLUSION

Sikkelee's state tort law claims are all conflict preempted. The design aspects in question were expressly approved by the FAA. Changes to the design of the parts at issue require FAA approval so it is impossible to comply with both federal law and state law duties, either those articulated by Pennsylvania courts or those advocated by Sikkelee in her expansive, untethered view of the reach of Pennsylvania tort law. Inasmuch as Sikkelee suggests that there are fact questions as to whether the FAA would in fact approve any such design changes, the "possibility of possibility" does not defeat preemption. PLIVA, 564 U.S. at 624 n.8. Lycoming is entitled to summary judgment to the remaining state law tort claims in this case on conflict preemption grounds.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that, on June 16, 2017, a true and correct copy of the foregoing **Supplemental Reply Brief in Support of Motion for Summary Judgment on Ground of Conflict Preemption** was served by electronic means, upon all counsel of record through the Court's ECF system.

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