



# Expect Further Clearance: Conflict Preemption for Aviation Manufacturer Defendants in Holding Pattern

By Lee C. Schmeer

The argument that state law design defect claims are preempted by federal law because the state law at issue conflicts with federal law presents an attractive defense for the aviation manufacturer defendant. After all, the Federal Aviation Regulations (FARs) require the manufacturer or designer to navigate a complex web of standards, testing, and benchmarks before the Federal Aviation Administration (FAA) certifies an aircraft or component for flight. The conflict preemption argument essentially boils down to this: the manufacturer could not feasibly comply with the plaintiff's proposed alternate designs or warnings, typically made in conjunction with state law tort claims, because it is illegal to unilaterally alter a product that the FAA already has type certificated, and the state law claim therefore conflicts with, and is preempted by, the controlling federal law. Just the sort of paradox that can present a strong defense for the manufacturer.

Two U.S. Supreme Court cases—one recently decided in May 2019 and the other currently awaiting the Court's decision whether to grant certiorari—may impact the conflict preemption landscape significantly. The recently decided case, *Merck Sharp & Dohme Corp. v. Albrecht*,<sup>1</sup> focused on a pharmaceutical warning label, and the other, *Avco Corp. v. Sikkelee*,<sup>2</sup> involves a petition for certiorari that squarely addresses the conflict preemption issue in an aviation design defect context. *Merck*, although a pharmaceutical case, provides another important defense theory for the aviation entity arguing for conflict preemption. Indeed, pharmaceutical defect and warning label cases have yielded by far the most extensive body of case law addressing conflict preemption over the last decade, and the parallels between relevant Food and Drug Administration (FDA) and FAA guidelines are undeniable. Furthermore, the Supreme Court has the opportunity in *Sikkelee* to provide concrete guidance to the aviation bar on the extent to which compliance with the FARs' certification standards preempts state law defect claims. Should the Court deny certiorari in *Sikkelee*, the defense bar should keep the faith: the Third Circuit's holding from which the manufacturer defendant appealed is narrow and based on specific facts.

Finally, this article briefly discusses how the two recent 737 MAX 8 accidents, which have thrust FAA certification squarely into the crosshairs of the media and lawmakers, may impact conflict preemption in the

aviation context. Specifically, the accepted practice of having a manufacturer's designated engineering representative (DER), rather than an FAA employee, carry out some certification work will now undergo increased scrutiny.<sup>3</sup>

## Conflict Preemption Background

Preemption arguments derive from the U.S. Constitution's supremacy clause, which provides that "the Laws of the United States . . . shall be the supreme Law of the Land."<sup>4</sup> "Preemption" comes in three basic forms: express, field, and conflict preemption. The type of preemption defense applicable in a given situation largely depends on the plain language and pervasiveness of, and intent behind, the federal regulations involved.

Express preemption arises when Congress includes plain language in a federal statute providing that state laws that differ from the federal scheme are without effect. Neither the Federal Aviation Act nor other legislation typically invoked in aviation product liability cases—e.g., the General Aviation Revitalization Act—contains an express preemption provision,<sup>5</sup> so litigants typically must focus on implied preemption, which is comprised of both field and conflict preemption.

Field preemption arises when Congress manifests its intent to preempt state law<sup>6</sup> by pervasively legislating over the subject matter.<sup>7</sup> Conflict preemption in aviation products litigation often arises when a manufacturer cannot comply with federal law while simultaneously implementing the design change a plaintiff contends would have prevented the accident at issue and was required under state law standards of care because it would have prevented the accident at issue.<sup>8</sup> A court conducting a conflict preemption analysis must ascertain "whether the private party could independently do under federal law what state law requires of it."<sup>9</sup>

The federal regulatory scheme governing certification of aircraft and aircraft components is "onerous" and "requir[es] numerous submissions that precisely detail the specifications of the proposed aircraft, its engine, and related components."<sup>10</sup> Once initial certification is complete, the certificate holder may make significant design changes only after receiving FAA approval and upon the issuance of a supplemental type certificate.<sup>11</sup>

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## The Impact of FDA Regulations and *Merck*

A trio of Supreme Court cases decided over the last decade have played a significant role in shaping the current rule for conflict preemption and, accordingly, have played a central role in the development of preemption arguments in aviation litigation. In the first case, *Wyeth v. Levine*, FDA regulations permitted a brand name pharmaceutical manufacturer to change a warning label unilaterally, leading the Court to conclude that it was not impossible for the manufacturer to comply with state requirements that would have required a change to the warning label without running afoul of federal law, which did not require the change but did not prohibit it either—i.e., the manufacturer could make whatever changes to product labeling were required by the applicable state law.<sup>12</sup>

Two later cases further shaped the Supreme Court rule on conflict preemption. In *PLIVA, Inc. v. Mensing*, the Court held that conflict preemption bars state law claims where “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.”<sup>13</sup> Finally, in *Mutual Pharmaceutical Co. v. Bartlett*, the Court held that “state laws that require a private party to violate federal law are pre-empted and, thus, are ‘without effect.’”<sup>14</sup>

The typical aviation design defect case involves allegations by a plaintiff that a defendant should have designed, manufactured, or installed some design modification (almost always of the “major” variety because it would impact the aircraft’s power plant or overall airworthiness), to replace whatever allegedly faulty design was on board at the time of the accident. Thus, the usual aviation case is more analogous to *PLIVA* and *Bartlett* than *Wyeth*, because aviation manufacturers are not permitted to implement a design change unilaterally, but instead *first* must receive federal regulatory approval.

The Supreme Court’s latest pharmaceutical preemption case, *Merck Sharp & Dohme Corp. v. Albrecht*, features a slightly different fact pattern from the standard aviation situation and those addressed in the three preceding bellwether Supreme Court preemption cases. The case centered around allegations by hundreds of women that Merck failed to warn users of the drug Fosamax of an associated increased risk of femoral fractures. The Third Circuit previously held that a plaintiff’s state law tort claims are not federally preempted unless the manufacturer adduces evidence that it was “highly likely” the FDA would have rejected the label change (we will see similar language in a Third Circuit aviation preemption case shortly).

In *Merck*, the FDA already had considered and *rejected* a proposed warning label addressing the issues relied on by the plaintiffs. Merck claimed that the FDA’s informed rejection of a previous label change pre-vented it from altering the Fosamax warning label to

include the plaintiffs’ proposed warnings. Merck argued that the plaintiffs’ claims were conflict preempted because it could not have satisfied the state law duties the plaintiffs would foist upon it while simultaneously complying with federal law—particularly where the FDA was purportedly aware of the risk of the injury addressed in the warning through Merck’s proposal package relating to the rejected warning label change.

The plaintiffs argued that the FDA rejected only a specific phrasing of the proposed warning—one that included a warning for a lesser risk without explicitly including femoral fracture—and that Merck was free to propose other warnings related to the plaintiffs’ claimed injury. Drug makers, the plaintiffs claimed, “are responsible at all times for keeping their labels up to date,” even where the FDA has rejected a certain label or evidences some uncertainty about the proper way to warn about a risk.<sup>15</sup> The plaintiffs claimed this issue is one that routinely is decided by jurors.

The Court<sup>16</sup> sided with Merck, holding that the question of whether the FDA would have approved a change to a drug’s warning label is an appropriate question for a judge, not a jury, and that the Third Circuit erred by finding that inquiry a question of fact. The Court also determined that “clear evidence,” a standard that appeared to be on the rise in conflict preemption jurisprudence, is evidence that the drug manufacturer informed the FDA of the reasoning for the warnings required by state law and that the FDA made an informed decision to reject the new warnings. In his concurring opinion, Justice Alito made his feelings known on the “clear evidence” standard, writing that use of the phrase in the *Wyeth* decision was little more than a “rhetorical flourish,” and not an actual standard of proof.<sup>17</sup> *Merck* is now remanded to the Third Circuit for a determination of whether the respondents’ claims are preempted.

Although *Merck* differs from the typical aviation preemption case, in which the manufacturer typically has not submitted the plaintiff’s proposed modification or warning for review by the FAA, the case still may shed light on the extent to which the Supreme Court will entertain preemption arguments. In the typical aviation case, a manufacturer sends a certification package to the FAA requesting permission to implement an alternative design, just as Merck submitted a certification package to the FDA. Should the FAA reject a proposed alternative design—just as the FDA rejected the proposed warning in *Merck*—it is easy to imagine the plaintiffs advancing a quasi-Sisyphian argument that, if successful, would preclude the defendants from relying on FAA rejection of a proposed alternative design on the basis that they should have kept trying until the FAA finally approved the perceived “upgrade” over the already certificated design or component.

In light of the similarities between the FDA alteration process—as explained in *PLIVA* and *Bartlett*—and

the process before the FAA, one might expect the preemption analysis applicable to these two industries also to be similar. Perhaps predictably in light of its initial opinion in *Merck*, the Third Circuit has not found that to be the case.

### **Sikkelee and Conflict Preemption in Aviation Design Defect Cases**

In October 2018, the Third Circuit issued its long-awaited opinion as to whether the certification processes provided in the FARs preempt state law negligence and strict liability claims. The case, *Sikkelee v. Precision Airmotive Corp.*, arose from the 2005 crash of a Cessna 172N aircraft, which resulted in the death of the plaintiff's husband, David Sikkelee. The plaintiff alleged that the crash was caused by a defective after-market carburetor in the aircraft's engine. In an apparent blow to aviation manufacturers, the court held that unless the manufacturer could adduce "clear evidence" to show that the FAA would not have approved the proposed design change, the conflict preemption doctrine would not preempt state law claims.<sup>18</sup>

The *Sikkelee* decision is challenging for aviation defendants largely because it diverges from the analogous *PLIVA/Bartlett* line of cases even though the aviation manufacturer—like the generic pharmaceutical manufacturer—cannot simply implement a proposed design change without obtaining approval from a federal regulatory body. The trouble does not stop there. The majority's test for conflict preemption in *Sikkelee* would place judges in the shoes of experienced FAA certification officials by requiring them to predict whether those officials would certify every alternative aircraft or component design proposed by the plaintiffs.<sup>19</sup>

Notwithstanding the foregoing, *Sikkelee* is not all bad news for the defense bar and their clients. The *Sikkelee* dissent abides by the more recent Supreme Court pharmaceutical guidance embodied in *PLIVA* and *Bartlett*, and may yet provide the reasoning behind a Supreme Court reversal, or for different results under similar circumstances in other federal circuits (assuming the Supreme Court does not provide clear, binding guidance). In the *Sikkelee* dissent, Judge Roth explained that she would find a claim alleging that state law required a manufacturer to change an FAA-certificated item conflict preempted where the change could not be implemented without first obtaining FAA approval.

Moreover, the majority in *Sikkelee* placed great import on discussions the defendant previously had with the FAA regarding the safety of the component at issue, and the fact that the FAA had approved similar modifications to the component in the past. The Third Circuit, therefore, did not create a categorical rule that federal aviation law never conflict preempts state tort law under impossibility principles, but rather focused

on the history of interactions between the manufacturer and the FAA. As a result, the decision in *Sikkelee* ultimately might be of only limited influence on other decisions where the facts differ.

Finally, the *Sikkelee* majority stopped short of fully adopting the plaintiff-appellant's proposed rule, which would have made the defendant's requisite "clear evidence" showing contingent on a demonstration that an FAA employee (as opposed to a DER) would have rejected the design change. The court noted that "the involvement of DERs in the certification- and change-approval process alone cannot defeat conflict preemption."<sup>20</sup>

### **FAA Certification Process in the News**

The timing of the *Sikkelee* petition for certiorari aligns with the current situation involving the Boeing 737 MAX 8 and its high-profile focus on FAA aircraft certification issues. On March 13, 2019, the FAA grounded the MAX 8 domestic fleet, as well as any international carriers operating the MAX in the United States, after two catastrophic accidents involving that aircraft model during flights by foreign carriers within a six-month period. Questions have been raised in the media about the certification of the MAX and the roles of Boeing and the FAA. The FAA certified the airplane with a new flight control system that, in certain situations, allegedly forces the aircraft into an uncommanded nose-down attitude even when a stall is not imminent.<sup>21</sup>

The two crashes have noteworthy similarities, especially the phase of flight in which they occurred. Lion Air flight 610 crashed into the Java Sea shortly after takeoff on October 29, 2018, resulting in the deaths of 189 people. Ethiopian Airlines flight 302 crashed shortly after taking off from Addis Ababa, Ethiopia, on March 10, 2019, killing all 157 people on board. While investigations into both accidents are ongoing, preliminary reports reveal that the crashes might have been caused, at least in part, by the pilots' inability to counter flight control inputs made by the MAX's Maneuvering Characteristics Augmentation System (MCAS), an anti-stall system installed in the 737 product line for the first time in the MAX.

The FAA has come under intense scrutiny for what some have alleged was a lax certification process for the MCAS and other design features unique to the MAX, including the incorporation of bigger engines and accompanying changes to the traditional 737 design necessary to accommodate those engines.<sup>22</sup> These criticisms may bolster and encourage the argument frequently espoused by plaintiffs that FAA certification does not carry with it a talismanic seal that the certificated aircraft or component is the safest possible design (particularly where, as with the MAX, DERs performed much of the certification activity).

It remains to be seen whether the MAX problems will impact conflict preemption where the defense centers on FAA certification and product alteration



regulations. At the very least, the MAX story may operate in the subconscious of a judge or justice considering the issue, even if such concerns do not overtly make their way into an opinion. Judges are, after all, humans and airline passengers, and they do not necessarily consider legal issues divorced from real-world realities and risks. The Third Circuit's recent *Sikkelee* opinion, while an overall setback for manufacturers, at least endorsed the DER process, although the court of public opinion and resultant pressure on lawmakers have been known to prompt regulatory changes. For now, a practitioner who may benefit from or need to counter a preemption argument should stay abreast of the inquiry relating to the MAX's certification.

## Conclusion

While planes fly across the country “only by federal permission, subject to federal inspection, in the hands of federally certified personnel and under an intricate system of federal commands,”<sup>23</sup> the extent to which compliance with federal certification standards preempts state law design defect claims remains very much in question. It behooves all attorneys involved in litigating aviation product liability cases to stay tuned to the developments in *Merck* and *Sikkelee*, as well as news related to the Boeing 737 MAX. Although *Merck* is distinguishable from the typical aviation case, the decision likely signals the Court's willingness to continue strengthening its implied preemption doctrine, something that at least should be mentioned in any conflict preemption argument. If the Court denies certiorari in *Sikkelee*, defendants outside the Third Circuit should continue to raise conflict preemption as a defense to design defect claims, and those within the Third Circuit should focus on distinguishing factors that would support preemption in their case notwithstanding the narrow holding in *Sikkelee* (although they will be arguing in what seemingly has become the federal circuit court most hostile to implied preemption defenses).

## Endnotes

1. 139 S. Ct. 1668 (2019).

2. No. 18-1140 (U.S. filed Mar. 1, 2019). On June 24, 2019, the Court invited the solicitor general to file a brief expressing the views of United States as to whether the Court should grant certiorari. See *Avco Corp. v. Sikkelee*, SCOTUSBLOG, <https://www.scotusblog.com/case-files/cases/avco-corp-v-sikkelee/> (last visited Aug. 19, 2019).

3. See, e.g., Ted Mann & Siobhan Hughes, *Fast-Tracked Aircraft Certification, Pushed by Boeing, Comes under the Spotlight*, WALL ST. J. (Mar. 24, 2019), <https://www.wsj.com/articles/fast-tracked-aircraft-certification-pushed-by-boeing-comes-under-the-spotlight-11553428800>.

4. U.S. CONST. art. VI, cl. 2.

5. 49 U.S.C. § 40101 note.

6. See *Sikkelee v. Precision Airmotive Corp.*, 907 F.3d 701,

709 n.6 (3d Cir. 2018).

7. *Nat'l Fed'n of the Blind v. United Airlines, Inc.*, 813 F.3d 718, 734 (9th Cir. 2016) (affirming dismissal of the plaintiffs' claims due to the preemptive effect of the Air Carrier Access Act, which pervasively regulated the airport service at issue).

8. Obstacle preemption is another form of conflict preemption, which occurs when state law presents an “obstacle” to the purposes or requirements of federal law. *Id.* This form of preemption is not at issue in the cases discussed in this article.

9. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011).

10. *Sikkelee v. Avco Corp.*, 268 F. Supp. 3d 660, 667 (M.D. Pa. 2017), *rev'd on other grounds*, 907 F.3d 701.

11. Other less significant design changes, or “minor” changes, still require that the change be made by a “method acceptable to the FAA.” 14 C.F.R. § 21.95. Any change that impacts airworthiness of the aircraft or component is a “major” change that requires advanced FAA approval before being rolled out to operators. 14 C.F.R. pt. 43 app. A.

12. 555 U.S. 555, 573 (2009). *But see Sikkelee*, 907 F.3d at 722 (Roth, J., dissenting in part) (“[I]n the field of safety regulation of civil aeronautics, there is no . . . process [as there was in *Wyeth*] for a manufacturer to effect changes to a type certificate prior to FAA approval of that change.”).

13. 564 U.S. at 623–24.

14. 570 U.S. 472, 475 (2013).

15. Transcript of Oral Argument at 31, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019) (No. 17-290), [https://www.supremecourt.gov/oral\\_arguments/argument\\_transcripts/2018/17-290\\_0811.pdf](https://www.supremecourt.gov/oral_arguments/argument_transcripts/2018/17-290_0811.pdf).

16. Five justices signed on to the Court's opinion, with four justices concurring (Justice Thomas authored one concurrence, while Justice Alito, joined by Chief Justice Roberts and Justice Kavanaugh, authored the other).

17. *Merck*, 139 S. Ct. at 1685 (Alito, J., concurring in the judgment).

18. *Sikkelee v. Precision Airmotive Corp.*, 907 F.3d 701, 704 (3d Cir. 2018).

19. The Fourth Circuit already has discussed the issue of judicial competency in this highly technical field. See *Holbrook v. United States*, 673 F.3d 341, 346, 350 (4th Cir. 2012) (finding that “Congress' broad delegation of discretion to the FAA recognized that an agency equipped with specialized knowledge would be best able to stay abreast of accelerating change in a technical and hazardous area and to update minimum air safety standards accordingly,” and that “[judges] are ill-equipped to revisit . . . policy decisions committed by Congress to those with greater expertise than courts”).

20. *Sikkelee*, 907 F.3d at 714 n.12 (noting that “to the extent [the plaintiff] 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”).

21. Dominic Gates, *Flawed Analysis, Failed Oversight: How Boeing, FAA Certified the Suspect 737 MAX Flight Control System*, SEATTLE TIMES (Mar. 17, 2019), <https://www.seattletimes.com/business/boeing-aerospace/>

failed-certification-faa-missed-safety-issues-in-the-737-max-system-implicated-in-the-lion-air-crash.

22. See Memorandum from Elaine Chao, Sec'y of Transp., U.S. Dep't of Transp., to Calvin L. Scovel III, Inspector Gen., U.S. Dep't of Transp. (Mar. 19, 2019), <https://www.transportation.gov/sites/dot.gov/files/docs/briefing-room/334391/memorandum-secretary-audit-certification-boeing-737-max8-2012-2017.pdf> (requesting "that the Office of Inspector General proceed with an audit to compile an objective and detailed factual history of the

activities that resulted in the certification of the Boeing 737-MAX 8 aircraft").

23. *Nw. Airlines, Inc. v. Minnesota*, 322 U.S. 292, 303 (1944); see also *City of Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 639 (1973) ("The interdependence of [factors relating to airplane safety and noise mitigation] requires a uniform and exclusive system of federal regulation if the congressional objectives underlying the Federal Aviation Act are to be fulfilled.").