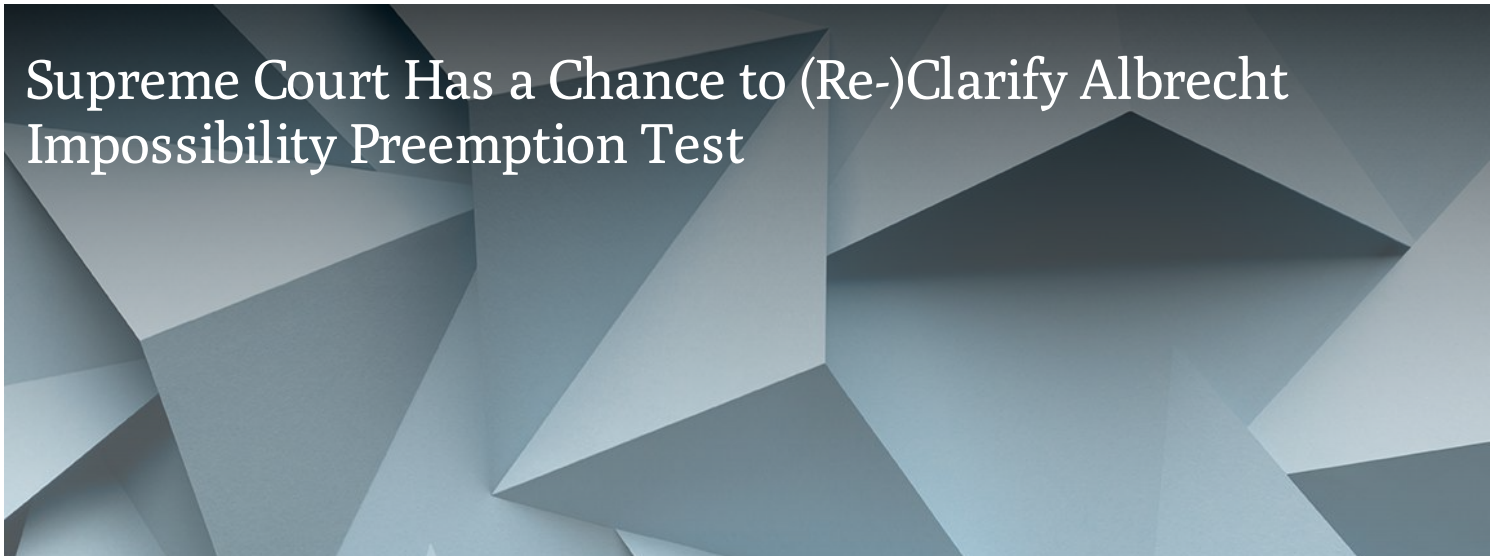
WINSTON & STRAWN LLP

BLOG

Supreme Court Has a Chance to (Re-)Clarify Albrecht Impossibility Preemption Test



APRIL 3, 2025

A cert petition filed earlier in March in the long-running *In re Fosamax (Alendronate Sodium) Products Liability Litigation* gives the Supreme Court a chance to clarify—for the second time—the Third Circuit's restrictive application of the impossibility preemption defense.

IMPOSSIBILITY PREEMPTION, *WYETH*, AND *ALBRECHT*

Readers of this blog are likely familiar with impossibility preemption. Under the doctrine, state law is preempted where it is "impossible for a private party to comply with both state and federal requirements."[1] Pharmaceutical companies can face that impossible situation in mass-tort litigation asserting state-law failure-to-warn claims when new scientific evidence identifies side effects associated with their drugs, and FDA does not or would not accept new warning language on labels.

In *Wyeth v. Levine*,[2] the Supreme Court held that FDA approval of a drug's label did not necessarily preempt state-law failure-to-warn claims because manufacturers can strengthen warnings without prior FDA approval. But it recognized that preemption is appropriate when there is "clear evidence that the FDA would not have approved a change" sought by plaintiffs.[3]

The Court "elaborate[d]" on *Wyeth*'s "clear evidence" test in *Merck Sharp & Dohme Corp. v. Albrecht*, holding that impossibility preemption is a question of law, not fact, and that "clear evidence" is not an evidentiary standard, but a description of the test the court should apply to determine "whether the relevant federal and state laws 'irreconcilably conflict[t].'"[4] Under the *Wyeth-Albrecht* test, manufacturers must show that (1) they fully informed FDA of the justifications for the warning, and (2) FDA informed manufacturers that it would not approve the warning.[5]

IN RE FOSAMAX LITIGATION

The *Albrecht* decision arose from an appeal of a 2013 ruling in the *Fosamax* litigation. The plaintiffs in *Fosamax* allege that the drug, which treats and prevents osteoporosis in postmenopausal women, can increase the risk that everyday "stress fractures" in bones progress to complete breaks, including breaks in the thigh bone called "atypical femoral fractures."[6] Merck has argued that the plaintiffs' failure-to-warn claims were preempted because FDA, in a May 2009 "Complete Response Letter," rejected its proposed warnings about "low-energy femoral shaft fractures" and stress fractures on the "precautions" section of the label.[7]

In 2013, a district court agreed that FDA's rejection was clear evidence that FDA would not have approved the label change.[8] The Third Circuit reversed, but the Supreme Court in *Albrecht* overruled the Third Circuit and remanded. On remand, a newly assigned district judge again agreed with Merck and found the claims preempted. The court recognized that the language in FDA's May 2009 letter "gives rise to competing inferences" about the basis for its rejection,[9] but considered extrinsic evidence regarding the "meaning and scope of the" letter and held that FDA was fully informed and would not have approved the warning sought by the plaintiffs.[10] This extrinsic evidence included other contemporaneous communications with FDA officials stating the agency's review of the data "did not show an increase in the risk" of atypical femoral fractures and FDA's acceptance of adverse event reports from Merck while nonetheless rejecting Merck's proposed warning.[11]

Last September, a Third Circuit panel vacated and remanded for a second time, holding that the district court erred "by giving too little weight to the required presumption against pre-emption."[12] The panel agreed that Merck had met the first prong of the *Albrecht* test by fully informing FDA about the risk of atypical femoral fractures.[13] It also agreed that Merck's proposed warning language had all the "hallmarks" of atypical femoral fractures, even without explicitly using the word "atypical."[14] But the panel nevertheless held that the company had not shown that FDA would have rejected the warning sought by the plaintiffs in the "ambiguous" Complete Response Letter.[15] The panel explained that it was not clear whether FDA's rejection was due to a lack of scientific support showing a connection between Fosamax and atypical femoral fractures or if the reference to "generic stress fractures" in the proposed warning "misidentified the risk."[16] In such a "close case," the panel held, there was a "heavy *Albrecht* presumption" that meant the court had "a duty to accept the reading that disfavors preemption."[17]

Merck sought and was denied a rehearing before the Third Circuit and filed a petition for a writ of certiorari with the Supreme Court on March 10, 2025.[18]

IMPLICATIONS OF THE THIRD CIRCUIT'S DECISION

In reading an evidentiary "presumption against preemption" into the impossibility doctrine, the Third Circuit's holding misconstrues *Albrecht* and may make the impossibility preemption defense all but impossible to assert in that circuit.

As Merck explains in its cert petition, *Albrecht* said nothing about a presumption against preemption in this area.[19] Instead, it clarified that the *Wyeth* "clear evidence" test was *not* an evidentiary standard but rather a method of determining whether federal and state laws conflict.[20] Although that test is a "demanding" one, satisfying the test is how a manufacturer "*overcomes* the presumption" that "Congress does not ordinarily intend to displace state law."[21] But "[t]o *also* wield the presumption as an evidentiary cudgel against defendants when *applying* that test double-counts it"—it layers a new evidentiary standard on top of *Albrecht*'s already-demanding two-part test.[22]

For practical purposes, manufacturers facing suits in the Third Circuit will be unable to assert impossibility preemption defenses in all but the most straightforward cases in which FDA has rejected the precise warning the plaintiff's claim seeks. By imposing "a duty to accept the reading that disfavors preemption" when faced with an ambiguous FDA action,[23] the Third Circuit's decision effectively requires that the manufacturer's reading be "the *only* reading consistent with the face of the FDA's order."[24] All a plaintiff must do, then, is "offer a colorable non-preemptive gloss on" the FDA's order and "the court is barred from even *trying* to resolve that ambiguity" under the Third Circuit's framework.[25] As Merck's petition explains, that will not be difficult to do.[26]

We are hopeful the Court will take up the petition and re-clarify the *Albrecht* test, given the importance of the defense to the pharmaceutical industry. In the meantime, manufacturers litigating similar issues in the Third Circuit should continue to build strong factual records around FDA's rejections in the hopes of overcoming the new presumption against preemption.

---

[1] *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 303 (2019) (internal citation omitted).

[2] 555 U.S. 555 (2009).

[3] *Id.* at 571.

[4] *Albrecht*, 587 U.S. at 310, 315 (quoting *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982)) (alteration in original).

[5] *Id.* at 314; *see id.* at 303.

[6] *Id.* at 305–06, 308.

[7] *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 118 F.4th 322, 333–35 (3d Cir. 2024).

[8] *Id.* at 337 (quoting *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 951 F. Supp. 2d 695 (D.N.J. 2013), *vacated*, 852 F.3d 268 (3d Cir. 2017), *vacated and remanded sub nom. Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299 (2019)).

[9] *Id.* at 342.

[10] *Id.*

[11] *Id*. at 352.

[12] *Id.* at 327.

[13] *Id.* at 349.

[14] *Id.* at 350.

[15] *Id.* at 349, 351–56.

[16] *Id.* at 352–54.

[17] *Id.* at 354, 357 (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

[18] Petition for Writ of Certiorari, *Merck Sharp & Dohme Corp. v. Albrecht*, No. 24-977, https://www.supremecourt.gov/DocketPDF/24/24-977/351597/20250310135023349_merck%20-%20cert%20petition.pdf.

[19] *Id*. at 23.

[20] *Albrecht*, 587 U.S. at 310.

[21] Petition at 25 (emphasis in original).

[22] *See id.* (emphases in original).

[23] *Albrecht*, 587 U.S. at 354 (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

[24] Petition at 23 (emphasis in original).

[25] *Id.* at 33 (emphasis in original).

[26] *Id.*

5 Min Read

Authors

Bryce Cooper

Patrick Hogan

Zoë Mulraine

Related Topics

Preemption | Pharmaceuticals | Failure to Warn

Related Capabilities

Product Liability & Mass Torts | Life Sciences

Related Professionals

Bryce Cooper

Patrick Hogan

Zoë Mulraine

This entry has been created for information and planning purposes. It is not intended to be, nor should it be substituted for, legal advice, which turns on specific facts.