Nos. 23-2226, 23-2234

# United States Court of Appeals for the Federal Circuit

MARK A. BARRY,

*Plaintiff-Appellant*,

*vs.*

DEPUY SYNTHES COMPANIES,

*Defendant,*

DEPUY SYNTHES SALES, INC., trading as DePuy Synthes Spine, MEDICAL DEVICE BUSINESS SERVICES, INC., DEPUY SYNTHES PRODUCTS, INC.,

*Defendants-Appellees.*

*Appeals from the United States District Court for the Eastern District of Pennsylvania in No. 2:17-cv-03003-PD, Judge Paul S. Diamond*

## BRIEF OF *AMICI CURIAE* THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND THE NATIONAL ASSOCIATION OF MANUFACTURERS IN SUPPORT OF PETITION FOR *EN BANC* REHEARING

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## CERTIFICATE OF INTEREST

Counsel for the Chamber of Commerce of the United States of America and the National Association of Manufacturers certifies the following:

1. The full name of the only parties represented by me are the Chamber of Commerce of the United States of America (the "Chamber") and the National Association of Manufacturers (the "NAM").
2. The names of the real parties in interest represented by me are: None.
3. All parent corporations and any publicly held companies that own 10% or more of stock in the parties represented by me are as follows: None.
4. The names of all law firms and the partners or associates that appeared for the parties now represented by me before the originating court or that are expected to appear in this court (and who have not or will not enter an appearance in this case) are as follows: None.
5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal is as follows: None.
6. Organizational Victims and Bankruptcy Cases: Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees) are not applicable because this is not a criminal or bankruptcy case. *See* Fed. Cir. R. 47.4(a)(6).

April 6, 2026 /s/ David R. Fine

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## STATEMENT OF INTEREST

The Chamber of Commerce of the United States of America (the "Chamber") is the world's largest business federation, representing 300,000 direct members and indirectly representing the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.[1]

The National Association of Manufacturers (the "NAM") is the largest manufacturing association in the United States, representing small and large manufacturers in all fifty states and in every industrial sector. Manufacturing employs nearly 13 million people, contributes $2.9 trillion to the economy annually, has the largest economic impact of any major sector, and accounts for over half of all private-sector research and development in the nation, fostering the innovation that is vital for this economic ecosystem to thrive. The NAM is the voice of the

[1] No party or counsel for a party authored this brief in whole or in part, and no entity or person, aside from *amici curiae*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

manufacturing community and leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

*Amici* are not passive observers on the subject of admissibility of expert opinions. They have direct insight into the meaning, history, and application of Rule 702 from (among other things) their active involvement in the rulemaking process that produced the December 1, 2023, amendments to the rule, which correct longstanding misconceptions of the expert-admissibility standard and promote uniform, predictable application.

Most recently, the Chamber appeared as *amicus curiae* in *EcoFactor, Inc. v. Google LLC*, 137 F.4th 1333 (Fed. Cir. 2025) (*en banc*), urging this Court to require district courts to rigorously scrutinize the reliability of expert opinions, as the 2023 amendment made unmistakably clear. In the past few months, the NAM and the Chamber have jointly asked the U.S. Supreme Court to confirm the district court's gatekeeping role with respect to expert testimony under Rule 702 in *Johnson & Johnson Consumer, Inc. v. Noohi*, No. 25-874, and *Union Carbide Corp. v. Sommerville*, No. 25-919.

*Amici* submit this brief in support of the petition for rehearing *en banc* for two critical reasons: first, the Court must reiterate in unmistakable terms that Rule 702

requires a district court to evaluate the reliability not only of an expert's methodology, but also of the application of that methodology; and second, the Court must hold that the district court's Rule 702 gatekeeping role is ongoing—allowing the court to revisit a pretrial admission decision if trial evidence compels a different conclusion.

It is particularly important for this Court to speak clearly: alone among the federal courts of appeals, the Federal Circuit has nationwide jurisdiction and persuasive influence that extends far beyond the parties before it.

## INTRODUCTION

This case presents the Court with a choice: reaffirm the rule of law it recognized in *EcoFactor* or allow a panel decision to create uncertainty about this Court's *en banc* precedent.

Last year's *en banc* decision in *EcoFactor* established beyond question that the reliability of an expert's methodology and the reliability of its application are both matters for the district court to resolve under its gatekeeping responsibility—not matters of weight for the jury. The *EcoFactor* majority faithfully interpreted Rule 702, particularly in light of the 2023 amendment that corrected some courts' persistent misreading of the rule.

The panel majority in this case defied that holding. It ruled that the district court exceeded its authority when, after hearing proffered expert testimony at trial, it concluded that the expert had not reliably applied the methodology underlying his testimony and excluded him accordingly. That ruling is indefensible under Rule 702 and *EcoFactor*, and it cannot be allowed to stand.

*Amici* ask the Court to take this appeal *en banc* to reinforce—expressly and forcefully—the holding of *EcoFactor* and the requirements of Rule 702.

The Court should also address a second point. The panel looked askance at the district court's decision to deny *in limine* exclusion motions and, after hearing testimony and cross-examination, later conclude that experts' testimony fell short of the standards of Rule 702. There is nothing improper about a district court's revisiting a pretrial Rule-702 determination—whether because it has heard fuller evidence or because trial has surfaced information unavailable at the pretrial stage. Rather, this is the very purpose of cross-examination. A district judge's duty under Rule 702 is not to make a single, inflexible ruling on a pretrial record and adhere to it stubbornly; his or her duty is to ensure that juries consider only reliable expert evidence. The panel's decision risks chilling this obligation.

The Court should grant rehearing.

## ARGUMENT

### I. As the Court recognized in *EcoFactor*, the 2023 amendment to Rule 702 emphasizes and confirms what the rule had required but some courts had not enforced: the district court has a gatekeeping role to ensure that an expert's proposed testimony rests on a reliable methodology *and* a reliable application of that methodology.

Last year, in *EcoFactor*, this Court joined other courts in recognizing the import of the 2023 amendment to Rule 702. 137 F.4th at 1339 ("In 2023, Rule 702 was amended to clarify that the proponent of expert testimony bears the burden of establishing its admissibility and to emphasize that an expert's opinion must stay within the bounds of a reliable application of the expert's basis and methodology."). In doing so, it joined other courts of appeals. *See, e.g., In re Onglyza (Saxagliptin) and Kombiglyze (Saxagliptin and Metformin) Prods. Liab. Litig.*, 93 F.4th 339, 348 n.7 (6th Cir. 2024) (2023 amendment corrected errant judicial decisions); *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 283-84 (4th Cir. 2021) (reversing admission of expert testimony and noting that then-pending amendment to Rule 702 rejected "incorrect" interpretation of rule). Subsequent to *EcoFactor*, more courts have echoed this Court's approach. *Engilis v. Monsanto Co.*, 151 F.4th 1040, 1049 (9th Cir. 2025); *Sprafka v. Medical Device Business Servs, Inc.*, 139 F.4th 656, 660-61 (8th Cir. 2025).

The Court's *EcoFactor* decision was right on the law, and it provided clear and much-needed guidance to litigants and district courts. As this Court, alone among the courts of appeals, is of nationwide jurisdiction, *EcoFactor* has been uniquely important in confirming to district courts the import of the 2023 amendment to Rule 702. *See, e.g.*, *Moore v. Barnes*, 802 F. Supp.3d 792, 817 (E.D.N.C. 2025) (applying *EcoFactor's* treatment of amendment); *Lab Corp. of Am. Holdings v. Natera, Inc.*, C.A. No. 21-669-GBW, 2025 WL 1769837 (D. Del. June 26, 2025) at *3 (same); *Silipena v. Am. Pulverizer Co.*, Civil No. 16-711, 2026 WL 608731 at *10 (D.N.J. Mar. 4, 2026) (same). The panel's departure from this *en banc* precedent threatens to sully the clarity that this Court's careful opinion brought just a year ago.

## II. The panel majority's recharacterization of the district court's holding regarding Dr. Neal misapplies Rule 702 and *EcoFactor*.

The panel majority's departure from *EcoFactor*, particularly so in its analysis of Dr. Neal's proffered testimony, necessitates rehearing *en banc*. Expert opinions, like Dr. Neal's, often rest on survey results. These surveys are required to meet Rule 702's reliability test. *See Millenium Laboratories, Inc. v. Ameritox, Ltd.*, 924 F. Supp.2d 594, 601 (D. Md. 2013).

*Amici*'s members often defend lawsuits in which plaintiffs rely on survey-based expert testimony on questionable reliability. This type of survey evidence

presents district courts with complex issues regarding proper and reliable survey design and execution. Accordingly, the Federal Judicial Center's Reference Manual on Scientific Evidence includes a lengthy section setting out guidelines specifically for survey evidence. SHARI SEIDMAN DIAMOND, REFERENCE GUIDE ON SURVEY RESEARCH, IN FED'L JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE at 681 (4th ed.).

The district court relied on the survey-specific guidance in the FJC's manual in excluding Dr. Neal's survey. It identified flaws in Dr. Neal's survey, both with respect to the representativeness of the survey sample and the survey questions themselves. That analysis is what Rule 702 and *EcoFactor* demand: the district court properly executed its gatekeeping obligation by categorizing these flaws in design as going to the inherent reliability of Dr. Neal's testimony, and not as questions of weight for the jury.

But the panel majority recharacterized the determination the district court made as one of weight for the jury. *Barry v. DePuy Synthes Cos.*, 164 F.4th 896, 910 (Fed. Cir. 2026). That is not only wrong, it is the exact type of error that the 2023 clarifying amendments to Rule 702 were designed to correct and avoid. It was the district court's duty to make threshold reliability decisions: did Dr. Barry prove that the expert developed a representative sample and that he properly drew up his

survey questions? Under Rule 702, it is for the district court to assess the reliability of an expert's application of a given methodology. A survey is a methodology, one with strict guidelines to ensure reliability. Accordingly, part of the district court's gatekeeping role is assessment of whether a survey has been conducted according to accepted protocols. The panel majority was mistaken to suggest otherwise.

The implications of the panel majority's reasoning are alarming. If the panel majority were correct, it is difficult to conceive of a situation in which the reliability of an expert's application of a methodology would ever properly be committed to the district court as a gatekeeping matter. The same logic employed here would call the issue one of weight for the jury—even though the plain language of Rule 702 and *EcoFactor* say otherwise. Consider: a patient claims lung disease caused by a factory's emissions, and the expert retained to prove causation used the wrong amount of a reagent in the test to determine whether toxic substances were present. Under the panel majority's logic, that expert's testimony would be admitted — and the defendant's only recourse would be cross-examination. That is precisely the result Rule 702 rejects.

As Judge Prost explained in her dissent in this case, the majority's approach cannot be reconciled with *EcoFactor*, and the panel majority made no real attempt to do that. 164 F.4th at 913 (Prost, J., dissenting). The panel majority referred to

*EcoFactor* and Rule 702, but it never explained how its holding was consistent with either.

## III. The panel majority incorrectly cast doubt on the propriety of the district court's questioning witnesses and revisiting its Rule-702 decisions at trial.

The panel majority suggested that it was not appropriate for the district court to question the proffered experts and then to revisit its pretrial admission decisions. The Court should take the case *en banc* to remove the shadow over the district court's approach.

Here, the district court expressly indicated in its pretrial order that its evidentiary decisions were "necessarily tentative" and that it was "prepared to revisit them during trial should any Party ask [it] to do so."[2] In that circumstance, the parties should have anticipated that the district court would revisit those decisions. *See* Fed. R. Evid. 103(b) and 2000 Advisory Committee Notes.

Even if the district court had not included that language, it still had the prerogative to revisit its pretrial orders. The district court bears the responsibility of ensuring that an expert's proposed opinions meet the reliability requirements of Rule 702. While the obligation is often referred to as a "threshold" inquiry, the purpose of the rule cuts against any suggestion that the decision, once made *in*

[2] Appx.1.

*limine*, should not be revisited if new or different evidence (or arguments) compel the conclusion that there should be a different result. During trial (or some other hearing), an expert's testimony might differ from what it was pretrial or cross-examination might highlight methodological flaws that were not apparent earlier. A district court should remain free to reappraise its admission decision when confronted with that new information just as it should be able to review any *in limine* evidentiary ruling if trial evidence calls for a different result. *See Luce v. United States*, 469 U.S. 38, 41–42 (1984).

The panel's criticism may chill district courts from reconsidering expert-admission determinations, even when newer evidence compels reconsideration, and the *en banc* court should make clear that the gatekeeping role is ongoing and subject to change.

## IV. *Amici* ask this Court to make a clear, unmistakable statement about the district court's gatekeeping role.

As the *en banc* Court recognized in *EcoFactor*, the 2023 amendment corrected some courts' erroneous application of Rule 702. The rule provides emphatically that the proponent of expert testimony bears the burden of proving *to the district court* that both the expert's methodology and application of that methodology are reliable. *EcoFactor* provided guidance to litigants and to district courts.

The panel majority in this case has made murky what Rule 702 and *EcoFactor* should have made clear. As DePuy argues in its rehearing petition, if the *en banc* Court leaves the panel decision on the books, parties and district courts will be left to wonder in any given situation whether an expert's application is to be assessed by the district court as a gatekeeping matter—per *EcoFactor* and Rule 702—or by the jury as a matter of weight—per the panel here. Given the centrality of expert testimony in so many of the cases on this Court's docket, the inconsistency and confusion are intolerable.

*Amici* ask that the Court accept *en banc* review and then make the following unambiguously clear:

1. Rule 702 imposes on the district court the gatekeeping responsibility to assess for reliability a proposed expert's methodology and application of that methodology. Neither is a determination of weight for the jury or other factfinder. *EcoFactor*, 137 F.4th at 1339-40.

2. The district court may as appropriate revisit its Rule-702 analysis—even during trial—if it learns of reasons to do so.

As the Supreme Court observed in *Daubert*, "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 595 (1993) (quotation omitted).

Rule 702 reflects a careful approach that recognizes the unique effects expert evidence may have in a case, and the courts should rigorously enforce the rule's requirements and procedures. This Court must clarify what the panel majority made unclear.

## CONCLUSION

*Amici* ask that the Court grant DePuy's petition for rehearing *en banc* and affirm the district court's judgment. That court did what Rule 702 and *EcoFactor* required of it, and the panel majority found fault. The *en banc* Court should now step in.

Respectfully submitted,

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April 6, 2026

## CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29 because it includes 2,473 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

2. This brief complies with the requirements of Federal Rule of Appellate Procedure 32(a)(5) and the typestyle requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Equity 14-point font.

**K&L GATES LLP**

/s/ David R. Fine

## CERTIFICATE OF SERVICE

I certify that I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system on April 6, 2026. I further certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

**K&L GATES LLP**

/s/ David R. Fine