No. 24-428

In the Supreme Court of the United States

EDWARDS LIFESCIENCES CORPORATION, ET AL.,
PETITIONERS

v.

MERIL LIFE SCIENCES PVT. LTD., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR THE PETITIONERS

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A. Review Is Urgently Warranted To Correct The Federal Circuit's Vast Expansion Of Section 271(e)(1)'s Safe Harbor

As previously established, this case presents an exceptionally important question under the Hatch-Waxman Act: whether an infringing act for *both* regulatory and non-regulatory uses is "*solely* for [regulatory] uses." 35 U.S.C. 271(e)(1). The Federal Circuit's position contravenes Hatch-Waxman's plain text, history, and purpose. Pet. 18-24. Its holding "distorts" the Act's "balance," "disrupt[s]" "settled expectations," is "untenable for the medical-technology industry," and threatens "profound consequences" for biotech research and investment (AdvaMed Br. 3, 13-16)—which is why it is being intensely tracked by a trillion-dollar industry, third-party experts, and top stakeholders, including "the world's largest medical-technology association."

In a transparent effort to kick up dust, Meril responds with arguments ranging from frivolous to outright false. This case checks off every box for certiorari, and Meril's meager defense confirms the need for immediate review.

1. The Act creates a limited safe harbor for infringing activity "*solely* for uses reasonably related" to the regulatory process. Notwithstanding that key qualifier ("solely for [regulatory] uses"), the split Federal Circuit held that *any* regulatory use immunizes all *non*-regulatory uses, even if an infringer engages in blatant commercial conduct. In the Federal Circuit's view, "'alternative uses'" are "'irrelevant'" to the inquiry. Pet. App. 9a. If the infringing act "is 'reasonably related to FDA approval,'" the safe harbor applies—"regardless of whether there are additional [non-regulatory] uses." *Id.* at 12a-13a, 18a.

This atextual construction reads "solely" out of the statute. Pet. 20. If an importation is for *both* regulatory and non-regulatory uses, it is not "*solely* for [regulatory]

uses." Congress explicitly cabined the safe harbor to a single category of protected activity, and refused to protect anything else—as it confirmed by narrowing the safe harbor "solely" to that enumerated use. 35 U.S.C. 271(e)(1); accord H.R. Rep. No. 857, 98th Cong., 2d Sess. Pt. 2, at 30 (1984). The Federal Circuit's contrary view renders that key qualifier meaningless, "vast[ly] expan[ding]" the safe harbor to protect a new universe of non-regulatory conduct. Pet. App. 27a (Lourie, J., dissenting). This undermines Congress's calibrated scheme, and distorts the baseline for fair competition in a trillion-dollar industry. AdvaMed Br. 13-16; Pet. 25-27.

2. a. In response, Meril insists the Federal Circuit gave "solely" its proper meaning (Opp. 11-12, 16-17), but it cannot explain what work "solely" does. Under its view, Section 271(e)(1) means the same thing with or without the term—the very definition of surplusage. If the Act is satisfied whenever "*a[ny]* use" is regulatory (even if others are not), then "solely" adds nothing. Pet. App. 11a. The Federal Circuit somehow takes the provision ("solely for uses reasonably related" to the regulatory process) and says "[i]t is not that the use must *only* be reasonably related" to the regulatory process. *Ibid.* That is upside-down. Short of redlining the statute, it is a mystery how the Federal Circuit could think a safe harbor "solely for [regulatory] uses" permits "additional [non-regulatory] uses." Pet. App. 18a.

Faced with this critical shortcoming, Meril turns to misdirection, highlighting random snippets from the decision. Opp. 11-12 (insisting "'solely'" has "significance"). But Meril misrepresents the Federal Circuit's reasoning—including the Federal Circuit's explanation of its holding. The Federal Circuit was unambiguous in permitting non-regulatory uses: once "a[ny]" regulatory use is

present (Pet. App. 11a), "'alternative uses'" are "'irrelevant'" (*id.* at 11a); the safe harbor applies "regardless of whether there are additional [non-regulatory] uses." *Id.* at 18a. This is why the dissent faulted the majority for "giv[ing] short shrift to the word "'solely'": it is impossible to "determine whether an infringing act is '*solely* for [regulatory] uses'" when "turn[ing] a blind eye" to "alternative uses." *Id.* at 20a, 25a (Lourie, J., dissenting). Meril conveniently omits these qualifiers in insisting "solely" retains meaning under the majority's decision.

Congress inserted "solely" to restrict the safe harbor; the Federal Circuit erred by striking that key limitation.

b. Unable to defend the *actual* holding, Meril tries rewriting the decision, insisting the Federal Circuit did not "ignor[e] commercial 'alternative' uses" or "'declar[e]'" those uses "'irrelevant.'" Opp. 3, 5, 14, 20, 26. Yet that is *precisely* what the Federal Circuit held. Literally. In unequivocal language: "'alternative uses'" are "'irrelevant.'" Pet. App. 9a. This is also *precisely* what the district court held. Literally. In unequivocal language: "'alternative uses are irrelevant.'" *Id.* at 52a & n.7. Only the *dissent* reached the opposite conclusion—rejecting the majority's "disregard" of "alternative uses." *Id.* at 25a, 27a, 29a ("alternative uses are crucial to determining compliance with the statute").

This issue is essential to Section 271(e)(1)'s proper construction. If "'alternative uses'" are "'irrelevant,'" a provision restricted "solely for [regulatory] uses" suddenly permits *both* regulatory and non-regulatory uses. Edwards lost below despite "numerous evidentiary bases" establishing Meril's non-regulatory use (Pet. App. 13a-14a)—all because that evidence was deemed legally irrelevant. *Id.* at 9a, 11a, 18a; contra *id.* at 29a (Lourie, J., dissenting) (faulting the majority's "disregard" of "alternative uses"). Yet "under a correct interpretation of the

law," Meril would have lost—because "the importations occurred, at least partially, for commercial reasons and thus were not entitled to safe harbor." *Id.* at 30a (Lourie, J., dissenting).[1]

The answer is binary: one reading of the statute is correct, the other is wrong, and the Act's immunity turns on the answer. Meril is free to defend the Federal Circuit's decision on the merits. But Meril cannot avoid review by pretending the holding is upside-down.[2]

c. Meril's remaining quibbles are equally baseless.

First, Meril insists Edwards' reading somehow "adds a second 'solely' to the statutory text[,] so the safe harbor would apply 'solely' to uses that are 'solely' for development of information for the FDA." Opp. 17. This is bizarre. There is no need to repeat "solely" twice—it just needs its natural meaning the one place it appears. "Solely" restricts the entirety of the remaining clause and disqualifies *non*-regulatory uses. It does its job without Meril's redundancy.

Second, Meril asserts Edwards somehow "rewrites" Section 271(e)(1)'s "'reasonably related' standard." Opp. 3, 17. Meril is confused. "Reasonably related" and "solely" are two separate pieces of the statute. They serve different purposes. "Reasonably related" defines the bounds of

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[1] Contrary to Meril's contention (Opp. 3-4), asking whether an infringing act has *some* regulatory use is not asking whether it has *solely* regulatory uses. That is the entire point of the restrictive term. Pet. App. 29a-30a (Lourie, J., dissenting).

[2] Meril is wrong that *Amgen Inc.* v. *Hospira, Inc.*, 944 F.3d 1327 (Fed. Cir. 2019), properly "analyze[d] each [use] separately." Opp. 23. That case involved *separate infringing acts*, not a single act with *multiple uses*. 944 F.3d at 1338-1339. *Amgen* aside, the majority rejected an "analyze-each-use-separately" test in favor of an "alternative-commercial-uses-are-irrelevant" standard—with the full Federal Circuit entrenching the decision. Meril's take only reinforces the urgent need for intervention.

what is a regulatory use; "solely" then restricts the safe harbor to that category.

Had Meril imported devices "solely" to recruit clinical investigators (a use "reasonably related" to the regulatory process), its conduct would be protected and this lawsuit would not exist. But Meril's conduct was *not* so limited. It also imported devices for non-regulatory uses (promotion, marketing, publicity, and potential foreign sales), which it advertised to conference attendees wholly unrelated to clinical trials. Pet. 10-12; C.A. J.A. 640 ("anybody who wants to come can do the hands-on session"). Meril thus engaged in both a regulatory use (simulator for potential clinicians) and a non-regulatory use (simulator for all other attendees). And the question is whether an importation for *both* regulatory and non-regulatory uses is "*solely* for [regulatory] uses." The fact that "solely" excludes non-regulatory uses does not "rewrite" the statute; it simply gives each term its ordinary meaning. Meril cannot dodge review by refocusing on the wrong term.

Third, Meril insists the majority's reading is "consistent with the legislative history," and "[n]othing in that legislative history supports Edwards[]." Opp. 20 n.9. Yet Meril never substantiates that assertion. It does not cite a single snippet of legislative material, let alone explain the unequivocal legislative record. Pet. 5-9, 22-24. And Congress was emphatic:

*the safe harbor did not cover "commercial activity"; competitors were "not permitted to market the patented drug during the life of the patent," and patent owners "retain[ed] the right to exclude others from the major commercial marketplace";

*"[t]he information" "developed" under the safe harbor was merely "the type" "required to obtain approval of the drug"; "all that the generic can do is test the drug for purposes of submitting data to the FDA";

*"experimental activity [would] not have any adverse economic impact on the patent owner's exclusivity during the life of a patent"; narrowly focused, Section 271(e)(1)'s "interference" with exclusive patent rights was "*de minim[i]s*";

**Roche Products, Inc.* v. *Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), "wrongly" barred activities "strictly related" to regulatory approval; Section 271(e)(1) had "the net effect of reversing [its] holding."[3]

H.R. Rep. No. 857, 98th Cong., 2d Sess. Pt. 1, at 45-46; H.R. Rep. No. 857, Pt. 2, *supra*, at 8, 27-30 & n.18.

The legislative record is a perfect fit with the statutory text. The Federal Circuit has now authorized the very conduct that Congress foreclosed in strictly narrowing the safe harbor. Meril has no answer for the legislative record.

B. Meril Cannot Wish Away The Question Presented By Rewriting The Facts

Meril next maintains the question is not factually "presented" (Opp. 27), but its posturing is transparent. There is a reason the majority and dissent decided this case on the legal question. Neither side was confused. AdvaMed is not confused. Experts tracking this case are not confused. Meril has an obvious incentive to muddy the waters, but it cannot rewrite the record.

1. According to Meril, "there is no evidence of any commercial [non-regulatory] use." Opp. 5. This is fiction. The majority itself acknowledged "numerous evidentiary bases" establishing Meril's non-regulatory use (Pet. App.

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[3] Meril says Congress went beyond reversing *Roche* (Opp. 19-20), but its logic is specious. Congress was not trying to match *Roche*'s *fact-pattern* (involving, say, drugs, not devices); Congress reversed *Roche*'s refusal to exempt activities "strictly limited" to regulatory approval. *That* was the "net effect" of Section 271(e)(1).

13a-14a), and Edwards extensively outlined those uses. Pet. 10-12 (*e.g.*, inviting thousands of registrants to "[e]xperience Meril's latest technologies," featuring a "[h]ands-on simulation" for all attendees using the imported devices).[4]

Meril won below because the majority held "*[a]ny*" regulatory use was sufficient and "'alternative'" uses were "'irrelevant.'" Pet. 14-16. There is not a single statement, anywhere, that Meril instead won due to "no evidence" of non-regulatory use (contra Opp. 5). Meril cannot rewrite the facts to avoid review.[5]

2. Meril argues there was no "commercial use" because devices left "in a bag" were *never* used (commercially or otherwise). Opp. 27. Thrice wrong.

First, it flunks the statutory text's factual inquiry: Meril imported the devices for specific uses, and the statute asks whether those uses "solely" concern regulatory approval. Here, Meril imported the devices to use in a simulator for all conference attendees (clinicians and *non-clinicians* alike). That non-regulatory commercial use is dispositive.

Second, Meril proves too much: if there were truly no uses here, then Meril also lacked a *regulatory* use—which means its importation was an act of infringement (35

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[4] Meril downplays the tradeshow's commercial value, suggesting it is a "scientific symposium" and "not a buyer-seller forum." Opp. 7. This flouts the host's own description—"unparalleled marketing opportunities" to "[b]uild your brand," "increase visibility of products and services," "generate new leads," and "connect with key clients." C.A. J.A. 730.

[5] Meril says Edwards merely "speculat[es]" how the devices would be used. Opp. 27-28. There is nothing speculative about concrete summary-judgment evidence (construed in Edwards' favor) establishing non-regulatory uses (via Meril's own admissions and promotional material). Pet. 10-12.

U.S.C. 271(a)) unprotected by the safe harbor. No court accepts that construction. Pet. App. 17a.

Finally, this was not the basis of the decision below, which rejected "'alternative'" uses as irrelevant (*not* nonexistent). Pet. App. 9a-11a, 18a. Meril cannot dodge a square legal holding with an alternative-grounds attack on competent summary-judgment evidence.

3. Meril says that because there were "no sales or offers to sell," there were no "'alternative' commercial uses." Opp. 22, 27-28 (calling this an "admission"). Wrong again. A sale is one *example* of non-regulatory activity; Meril's other "uses" constitute *other* examples of non-regulatory activity. Meril engaged in obvious promotional and marketing uses, publicizing its (infringing) product and importing devices to advance those non-regulatory uses. Those are independent *subsets* of non-regulatory activity—whether or not accompanied by a sale/offer to sell.

4. Meril insists "there was only a single 'use'—import[ing]" "the two demo devices." Opp. 12. Meril misreads the statute. The importation was the *infringing act*, not a "*use*"; the Act turns on "uses" for which the infringing act is conducted. Meril has no textual basis for conflating those separate statutory concepts.

Anyway, it is puzzling why Meril finds this helpful. Even were the infringing "act" the relevant "use," no one disputes Meril imported devices for a regulatory use; the problem is Meril did not import *solely* for regulatory uses. The majority declared "alternative" uses irrelevant; the dissent reached the opposite conclusion. That frames the statutory question perfectly.

C. The Question Presented Is Important And Warrants Review In This Case

1. The question presented has profound legal and practical importance. Pet. 25-28. It sets the line for fair competition in a trillion-dollar industry. This Court has

twice reviewed aspects of Section 271(e)(1), confirming its obvious significance. Multiple experts recognize the import of the majority's ruling—flagging this as a "pivotal moment in the [safe harbor's] interpretation" with "far-reaching implications." Pet. 4 n.1, 25. And the premier industry association (representing 500 companies worth trillions in marketshare) has cried out for immediate review. AdvaMed Br. 3; https://www.advamed.org/membership-join/membership-directory/.[6]

2. Meril responds with obvious makeweights.

a. Meril trumpets the lack of a conflict. Opp. 14. But the Federal Circuit has exclusive jurisdiction—there will never be a conflict. Absent review, that court will have the last word on this critical statute (which it misread). The need for this Court's review is just as compelling here as it was in *Merck* and *Eli Lilly*. Pet. 25-26.

Anyway, Meril misrepresents the disagreement. This issue has indeed split panels, courts, and experts, and generated significant controversy and confusion. Pet. 26 & nn.10-11. Judge Lourie's sharp dissent underscores the majority's problems, its predictable "mischief," and the urgent need to "fix" the mistake. Pet. App. 20a, 30a. AdvaMed flags the serious consequences of letting the decision stand: "sow[ing] confusion" and "undermining the 'clarity [that] is essential to promote progress' and 'investment in innovation.'" Br. 15. Even in the short time since the petition's filing, more experts have weighed in, ranking the decision one of 2024's "most influential patent decisions" with "a direct impact on innovation." Arnold, *Top Five Patent Law Decisions of 2024*, The Recorder (Dec. 3, 2024)

[6] Meril notes Edwards' ground-breaking innovations generate billions in annual revenue. Opp. 9. It is unclear why Meril thinks its own interference with a billion-dollar product is reason to *deny* review.

<https://www.law.com/therecorder/2024/12/03/top-five-patent-law-decisions-of-2024/>.

Meril quibbles with the split and commentary (Opp. 15-16 & nn.4-6), but those sources speak for themselves. Under any fair reading, there is obvious disagreement regarding the Federal Circuit's atextual construction.

b. Meril discounts AdvaMed's input and says "[t]he patent community" is "untroubled" by the decision. Opp. 16-18 & n.7. But AdvaMed is not just any random amicus. This is the premier association representing the core affected industry. It represents over 500 members, including the world's leading medical-technology companies—featuring household names and billion-dollar innovations. AdvaMed speaks on the industry's behalf; it has detailed the grave error below and the vital importance of correcting that mistake. That alone substantiates the case's importance to a trillion-dollar industry (even without other amici piling on).

Meril hints AdvaMed filed because Edwards is on its board. Opp. 18 n.7. What Meril ignores: Edwards is one of *50-plus companies* on the board—and AdvaMed represents the interests of hundreds of entities and billions in annual commerce. AdvaMed does not participate unless *AdvaMed* wishes to participate—and it saw a compelling need.

c. According to Meril, Edwards seeks "to overturn over 30 years of safe[-]harbor precedent." Opp. 14. Yet this issue was not clearly settled—until now. The panel confirmed the Federal Circuit's atextual construction and broke new ground—which is why experts call this a "pivotal" moment, others identify the Act's "wider" scope, and AdvaMed urgently emphasized the troubling implications, including destabilizing the line between innovation and competition. Pet. 25-27. This case is not being

watched because it is business as usual. Meril has incentive to downplay its importance, but the significance is self-evident.

Nor is Meril correct to highlight Congress's failure to amend the statute. Opp. 18. Congress's past revisions came earlier, and what else could Congress do? Repeat what it already said ("solely")? Add bold and underline? Include an "(and-we-really-mean-it!)" parenthetical?

Congress already restricted the safe harbor "solely for [regulatory] uses." The Federal Circuit redlined the statute to eliminate that restriction and cover non-regulatory conduct. It is unclear what Meril expects Congress to do.[7]

Finally, stare decisis is irrelevant. Opp. 17-18. This Court is not bound by the Federal Circuit, which should not get the last word on the Act—a lesson *Merck* and *Eli Lilly* already confirmed. And it is curious for Meril to claim the industry favors this decision when the industry itself (via AdvaMed) urges correcting the Federal Circuit's disruptive new rule.

3. The Federal Circuit's construction binds all future industry disputes—so the fact that *these* devices accidentally stayed in a bag is irrelevant. The question is ideally framed: Meril infringed for both regulatory and non-regulatory uses. If the latter is irrelevant (per the majority), Meril wins; if the latter is disqualifying (per the dissent), Meril loses. This vehicle is as clean as it gets.

[7] Meril is also confused: ratification principles apply when Congress confronts *this* Court's decisions, not the Federal Circuit's.

Respectfully submitted.

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DECEMBER 2024