No.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

This case presents an exceptionally important question regarding the proper scope of the Hatch-Waxman Act's regulatory safe harbor.

Under the Act, Congress declared that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention * * * *solely* for uses reasonably related" to the federal regulatory process. 35 U.S.C. 271(e)(1) (emphasis added).

In a split decision, the Federal Circuit held that Section 271(e)(1)'s safe harbor applies by identifying *any* regulatory "use," even if there are "additional" *non-regulatory* uses (including blatant commercial conduct) by the infringing party. The dissent disagreed: an infringing act with "*alternative* uses" is not "*solely* for [regulatory] uses" (35 U.S.C. 271(e)(1))—and the circuit's contrary position "ignore[s]" the "word 'solely' in the statute," invites "future mischief," and cements an "unsupported expansion of the safe harbor."

This issue is significant. It frequently arises in disputes with massive stakes. It is the repeat subject of industry and expert analysis. It has split Federal Circuit panels, divided district courts, and prompted criticism from judges and academics. This Court has twice granted review to consider the scope of the same safe-harbor provision—underscoring its obvious importance. And it sets the proper boundary between innovation and competition in a trillion-dollar industry.

The question presented is:

Whether, under Hatch-Waxman's safe harbor, an infringing act is "*solely* for uses reasonably related" to the federal regulatory process, when the infringing act is performed for both regulatory and non-regulatory uses.

PARTIES TO THE PROCEEDING BELOW AND RULE 29.6 STATEMENT

Petitioners are Edwards Lifesciences Corporation and Edwards Lifesciences LLC, the appellants below and plaintiffs in the district court. Each has no parent corporation, and no publicly held company owns 10% or more of their stock.

Respondents are Meril Life Sciences Pvt. Ltd. and Meril, Inc., the appellees below and defendants in the district court.

RELATED PROCEEDINGS

United States District Court (N.D. Cal.):

Edwards Lifesciences Corporation, et al. v. *Meril Life Sciences Pvt. Ltd., et al.*, No. 4:19-cv-6593-HSG (Oct. 16, 2020) (summary judgment)

Edwards Lifesciences Corporation, et al. v. *Meril Life Sciences Pvt. Ltd., et al.*, No. 4:19-cv-6593-HSG (May 18, 2022) (final judgment)

United States Court of Appeals (Fed. Cir.):

Edwards Lifesciences Corporation, et al. v. *Meril Life Sciences Pvt. Ltd., et al.*, No. 22-1877 (Mar. 25, 2024) (judgment)

Edwards Lifesciences Corporation, et al. v. *Meril Life Sciences Pvt. Ltd., et al.*, No. 22-1877 (Aug. 21, 2024) (order denying rehearing)

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PETITION FOR A WRIT OF CERTIORARI

Edwards Lifesciences Corporation and Edwards Lifesciences LLC respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-30a) is reported at 96 F.4th 1347. The order and opinion of the district court (App., *infra*, 31a-58a) is unreported but available at 2020 WL 6118533.

JURISDICTION

The judgment of the court of appeals was entered on March 25, 2024. A petition for rehearing was denied on August 21, 2024 (App., *infra*, 59a-60a). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISION INVOLVED

Section 271 of Title 35 of the United States Code provides in relevant part:

> **Infringement of patent**
>
> (a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.
>
> * * * * *
>
> (e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention * * * solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.
>
> * * * * *

INTRODUCTION

This case presents an important and recurring statutory question under the Hatch-Waxman Act. Under the Act, Congress created a limited safe harbor for infringing activity "*solely* for uses reasonably related" to the federal regulatory process. 35 U.S.C. 271(e)(1) (emphasis added). Notwithstanding that plain text ("solely for [regulatory] uses"), the Federal Circuit held that identifying *any* regulatory use also immunizes all other *non*-regulatory uses, even if an infringer also engages in purely commercial conduct. That holding split the panel below: in a forceful

dissent, Judge Lourie faulted the Federal Circuit for "ignor[ing]" the text, distorting Congress's design, and "vast[ly] expan[ding]" the safe harbor.

As it now stands, a safe harbor designed "solely" for regulatory approval now also shields "alternative" commercial activities—those seeking economic benefits and market advantages. The Federal Circuit's profound misreading of Section 271(e)(1) cries out for review—and the certworthiness calculus is compelling.

As a baseline matter, the Federal Circuit's position is at odds with Hatch-Waxman's plain text, history, and purpose. When a party imports a device for *any* non-regulatory use, it is not acting "*solely* for [regulatory] uses." The 2-1 decision rewrites the careful balance Congress struck in the Act, and extends statutory immunity to conduct that Congress had no reason to protect. It offers a recipe for letting infringers off the hook so long as they strategically engage in *some* protected conduct—manipulating the safe harbor, exploiting good-faith competitors, and undermining Congress's scheme.

The issue's significance is also obvious. It involves an important legal question affecting countless industry stakeholders and cutting-edge technologies. This Court has twice granted review to consider the scope of this same safe-harbor provision. See *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005); *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661 (1990). It is the repeat subject of industry and expert analysis, and judges and commentators have long criticized the Federal Circuit's position as wrong and atextual. The decision below distorts the market for patented products and undermines the patent bargain—while granting a competitive advantage to those parties most willing to exploit the safe harbor to smuggle in impermissible uses. The opportunity for "future mischief" is palpable, and "the law could usefully be

clarified" by further review, "expressly returning the word 'solely' to its Congressionally-enacted place in the statute." App., *infra*, 30a.[1]

At bottom: It is essential for a trillion-dollar industry to operate under a system of clear rules and fair competition. This issue dictates the industry baseline for that competition. Yet the decision below judicially redlines that crucial baseline and forces all stakeholders into a race to the bottom. There is a reason experts have deemed this a "pivotal moment in the interpretation of the safe harbor provision." Dr. Chen, *The Broad Impact of* Edwards, *supra*.

Finally, this is an ideal vehicle for resolving this important question. The petition raises a pure question of law: the proper construction of the statute. That issue was resolved at summary judgment, and each court below declared exhaustive evidence of Meril's commercial use "irrelevant" under the Federal Circuit's (incorrect) test.

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[1] See, *e.g.*, Dr. Fangli Chen, et al., *The Broad Impact of* Edwards v. Meril *on the Safe Harbor Provision*, Minding Your Business (Aug. 27, 2024) <https://tinyurl.com/broad-impact-edwards-meril> (the decision below "underscores the breadth of the safe harbor" and "has garnered significant attention"; the Federal Circuit's refusal to reconsider the case has "significant implications, as it solidifies the broader interpretation of the safe harbor," "potentially allowing more tangentially related activities to be shielded"); Mark Payne, *Life Sciences Cases To Watch 2024: A Midyear Report*, Law360 (July 30, 2024) <https://tinyurl.com/law360-2024-life-sciences> (flagging this question as "crucial to the life sciences industry"; "[i]f the ruling [below] stands," "'the safe harbor provision [would] cover[] allegedly infringing activities that were not previously contemplated as being covered'"); Ryan Davis, *Patent Cases To Watch In The Second Half Of 2024*, Law360 (July 11, 2024) <https://tinyurl.com/law360-2024-patent-cases> ("[a] strong dissent by Judge Alan Lourie decried * * * an overly expansive reading of the statute that wrongly protects activities done for commercial reasons"; recognizing "'very significant financial interests on both sides'").

There are no complicating factors or obstacles to resolving the statutory issue. And Judge Lourie's dissent confirms the Act's proper construction is outcome-determinative: Edwards lost under the Federal Circuit's (atextual) reading, but would have prevailed under Judge Lourie's plain-text interpretation.

The question presented raises legal and practical issues of substantial importance, and its correct disposition is essential to the Act's proper operation. Further percolation is pointless. There is no possibility of any split (in light of the Federal Circuit's exclusive jurisdiction), and the Federal Circuit's position is entrenched—as the full court's rehearing denial confirms. The entire industry will remain bound by the Federal Circuit's misinterpretation of the Act until this Court intervenes. Because this case presents an ideal vehicle for resolving this significant question, the petition should be granted.

STATEMENT

A. Statutory Background

1. Under the Hatch-Waxman Act, Congress created a "safe harbor" for "certain uses" of patented inventions in "the federal regulatory process" (*Classen Immunotherapies, Inc.* v. *Elan Pharms., Inc.*, 786 F.3d 892, 896 (Fed. Cir. 2015))—immunizing infringing activities "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs" (35 U.S.C. 271(e)(1)). See Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, Tit. II, § 202, 98 Stat. 1585, 1603.

The Act's "new" protection was important but purposely narrow: it "allow[ed] competitors" to take infringing steps "necessary to obtain [federal] regulatory ap-

proval," but it "imposed" this exemption "*only* for the purpose of obtaining premarketing approval." *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 671, 678 (1990) (emphasis added).[2] The safe harbor did not extend to "commercial activity" (which had to wait until the "patent expires"), and "[t]he information * * * developed" under the safe harbor was merely "the type * * * required to obtain approval of the drug." H.R. Rep. No. 857, 98th Cong., 2d Sess. Pt. 1, at 45-46 (1984). As Congress explained, this limited scope would advance regulatory aims without impairing patent rights: such "experimental activity [would] not have any adverse economic impact on the patent owner's exclusivity during the life of a patent." *Id.* at 46.

In short, the Act declared it "not an act of patent infringement * * * to import or to test a patented drug [1] in preparation for seeking FDA approval [2] *if marketing of the drug would occur after expiration of the patent*." H.R. Rep. No. 857, Pt. 1, *supra*, at 15 (brackets and emphasis added). Congress carefully inserted these conditions in Section 271(e)(1)'s operative clause, limiting the safe harbor "solely for [regulatory] uses." 35 U.S.C. 271(e)(1).

2. This legislation was a direct response to the Federal Circuit's earlier decision in *Roche Products, Inc.* v. *Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), which refused to excuse infringing activities "even though the[ir] only purpose" was "to seek FDA approval." H.R. Rep. No. 857, Pt. 1, *supra*, at 45-46 (describing *Roche*); *Eli Lilly*, 496 U.S. at 670 (recounting *Roche* barred infringing

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[2] In general terms, premarket approval is a process of scientific and regulatory review (by federal agencies like the FDA) to determine if a medical product or device is safe and effective. For the devices at issue here, premarket approval is necessary before the device can be marketed or sold in the United States. See, *e.g.*, App., *infra*, 3a, 33a (so explaining).

activities "even" for the "sole purpose" of seeking "regulatory approval"); see also *Roche*, 733 F.2d at 861 ("the issue in this case is narrow: does the limited use of a patented drug for testing and investigation *strictly related to FDA drug approval*" constitute "actionable" infringement; "[t]he district court held it does not"; "[t]his was an error of law") (emphasis added).

Congress found that *Roche* was "wrongly decided" and created a problem of artificially extending the patent term. H.R. Rep. No. 857, 98th Cong., 2d Sess. Pt. 2, at 28 n.18 (1984); see also H.R. Rep. No. 857, Pt. 1, *supra*, at 46 ("prevent[ing] such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date"). If regulatory "activity could not be commenced * * * until [the patent's] expiration," "the patentee's *de facto* monopoly would continue for an often substantial period until [a competitor's] regulatory approval was obtained." *Eli Lilly*, 496 U.S. at 670. This created an improper "advantage" not from "patent law" per se but "from the operation of law respecting FDA approval of drugs before they can be marketed." H.R. Rep. No. 857, Pt. 2, *supra*, at 28 n.18.[3]

Congress thus sought to "overturn" *Roche* (H.R. Rep. No. 857, Pt. 2, *supra*, at 27 n.18), and it targeted the specific problem the Federal Circuit created: Because *Roche* barred activities "strictly related" to regulatory approval (*Roche*, 733 F.2d at 861), Congress shielded activities "strictly related" to regulatory approval—those "solely

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[3] See also H.R. Rep. No. 857, Pt. 2, *supra*, at 28 n.18 ("'If one must wait until expiration of the patent to use the patented item to develop the necessary test[] results for submission to FDA for its approval, the lapse of time between testing through submission to approval to marketing is likely to be a period of years, all of which time the original patent holder enjoys the benefit of his patent past its expiration date.'").

for [regulatory] uses." 35 U.S.C. 271(e)(1); see also *Eli Lilly*, 496 U.S. at 678 (the "new" Section 271(e)(1) excused infringing "use[s] * * * only for the purpose of obtaining premarketing approval"). Under the new safe harbor, "all that the generic can do is test the drug for purposes of submitting data to the FDA." H.R. Rep. No. 857, Pt. 2, *supra*, at 30. This revived the category of activity that *Roche* prohibited, without otherwise "touch[ing]" the "value" of "the patents." *Id.* at 29 n.18.

Congress's reversal was thus coterminous with the root problem in *Roche*: Section 271(e)(1) had "the net effect of reversing [its] holding.'" H.R. Rep. No. 857, Pt. 2, *supra*, at 27; accord H.R. Rep. No. 857, Pt. 1, *supra*, at 45-46.

3. In creating this safe harbor, Congress also struck a delicate balance within the industry—one that addressed two "unintended distortions" from delays in the regulatory process. *Eli Lilly*, 496 U.S. at 661; see also *Proveris Sci. Corp.* v. *Innovasystems, Inc.*, 536 F.3d 1256, 1260 (Fed. Cir. 2008). The "first distortion" was "the reduction of effective patent life" for patentees, based on "the early years of the patent term [being] spent obtaining premarket approval." *Proveris*, 536 F.3d at 1260-1261. If an invention requires "regulatory approval, the 'clock' on [the] patent term will be running even though [the inventor] is not yet able to derive any profit from the invention." *Eli Lilly*, 496 U.S. at 669-670. The "second distortion" (as described above) was a "de facto extension * * * at the end of the patent" while "competitors spent time following patent expiration obtaining FDA premarket approval necessary for market entry." *Id.* at 1261 (detailing pre-Hatch-Waxman law under *Roche*, *supra*).

Congress thus sought to "eliminate this distortion from both ends of the patent period" (*Eli Lilly*, 496 U.S. at 670): it simultaneously extended the patent term to

compensate for regulatory delays in commercializing patents (35 U.S.C. 156(a)), while also "allow[ing] competitors to begin the regulatory approval process while [a] patent [is] still in force" (*Proveris*, 536 F.3d at 1261 (describing Section 271(e)(1))); see also *Eli Lilly*, 496 U.S. at 670-671.

Given the sole focus on permitting competitors to initiate the regulatory process, Section 271(e)(1)'s "interference" with exclusive patent rights was deemed "*de minim[i]s*"—as competitors were "not permitted to market the patented drug during the life of the patent." H.R. Rep. No. 857, Pt. 2, *supra*, at 30. Indeed, "the generic" was limited to "test[ing] the drug for purposes of submitting data to the FDA for approval," and the patent owner "retain[ed] the right to exclude others from the major commercial marketplace." *Id.* at 8, 30.[4]

B. Facts And Procedural History

1. Edwards is a leading innovator and supplier of medical devices for treating heart disease, including its renowned, patented line of "SAPIEN®" transcatheter prosthetic heart valves. App., *infra*, 32a. Meril is an India-based competitor that also makes transcatheter heart valves. *Id.* at 2a. Its Myval valve is nearly identical to Edwards' SAPIEN® valve; it received regulatory approval to sell the device in India in October 2018, and received

[4] Some stakeholders objected that permitting regulatory-based activities during the patent term would interfere with patent rights and constitute a "taking." See, *e.g.*, H.R. Rep. No. 857, Pt. 2, *supra*, at 27 & n.18, 29-30. Congress responded by noting the limited nature of the safe harbor, that it addressed only regulatory uses, that it did not permit any commercialization or market activity during the patent term, and accordingly that the effect on patent rights, again, was "de minim[i]s." *Id.* at 27-30 & n.18; H.R. Rep. No. 857, Pt. 1, *supra*, at 46. Each aspect of this response holds under a plain-text reading of Section 271(e)(1)—the safe harbor is "solely for [regulatory] uses"; it does not necessarily follow under the Federal Circuit's conflicting view of the safe harbor.

so-called CE-mark approval (authorizing European sales) in April 2019. *Id.* at 2a-3a, 33a.

A few months after receiving CE-mark approval, Meril imported two of its Myval devices into the United States for use at a major industry event in San Francisco—the 2019 Transcatheter Cardiovascular Therapeutics Conference. App., *infra*, 4a-5a. This trade conference is an annual symposium attended by thousands of industry participants. *Id.* at 4a, 35a, 37a; C.A. J.A. 730.[5] The infringing Myval devices were transported into the country by a Meril employee, along with a declaration stating the devices were for demonstration purposes only. App., *infra*, 5a.

Before arriving, Meril circulated a digital flyer advertising Meril's trade booth at the conference. App., *infra*, 35a; C.A. J.A. 884-886. The promotion invited thousands of registrants to "[e]xperience Meril's latest technologies," featuring a "[h]ands-on simulation" of the Myval device (available for all attendees, including those focused on commercial or marketing transactions); it said nothing about regulatory uses, recruiting investigators for clinical trials, or limiting the simulator's use to potential investigator candidates. C.A. J.A. 885-886; see also *id.* at 640 ("anybody who wants to come can do the hands-on session").

Meril separately sent an email blast to thousands of registrants, advertising Myval as "CE APPROVED," highlighting a "Myval CE [*i.e.*, European sales] Announcement," and inviting recipients (including hundreds

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[5] The conference host advertised the event as attracting "more than 11,000 attendees from over 100 countries," presenting "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.

in Europe where the Myval system is commercially available) to Meril's trade booth for "hands-on and VR sessions" with the imported device. C.A. J.A. 570, 670, 745-748, 889-893; see also *id.* at 746-748 ("We invite you to our Booth #943 to learn more about our innovations."). Again, the email said nothing about regulatory uses or clinical recruiting. *Id.* at 890-893. Meril also updated its Myval brochure specifically for the conference, again touting its CE-mark approval and even providing "Myval – THV Ordering Information." *Id.* at 825-826, 852.

Before the conference, Meril consulted with attorneys to draft "Instructions for TCT 2019 for Myval THV System." App., *infra*, 4a. It conveyed those instructions orally to the twenty Meril employees attending the event:

> Do not make any sales or offers for sale at the conference, or while in the United States for the US market. *You can make offer [sic] for other countries*.

Ibid. (emphasis added). The instructions permitted Meril employees to carry the imported Myval "demo units," and again did not restrict the devices' use or display to potential clinical investigators (or require any other nexus to regulatory submissions). C.A. J.A. 909.

At the conference, Meril "provided information" on the Myval system, including "visual displays," "presentations to attending physicians," "case studies" describing implantation of the Myval System, and results from a "clinical trial." App., *infra*, 36a. In addition to its marketing activities, Meril "also discussed" the Myval device with "several U.S. doctors to identify potential clinicians" for future clinical trials. *Ibid.* Meril itself later posted on LinkedIn that "2,000 people visited" its conference trade booth. App., *infra*, 37a.

Despite its advanced planning and advertising, Meril ultimately did not display the imported Myval devices at

the conference. App., *infra*, 37a, 42a. Although Meril intended to use those devices in its publicized "hands-on" simulation—Meril's undisputed reason for importing the devices—Meril's simulator malfunctioned. *Id.* at 42a. It was those "technical difficulties" alone that prompted Meril to keep the devices in a "hotel closet" and a conference "storage room." *Id.* at 2a, 37a, 42a. Meril otherwise would have used those devices in the simulator for anyone at the conference—including for potential clinical investigators (a regulatory use) and for all other attendees (a non-regulatory use). *Id.* at 42a; C.A. J.A. 640, 747, 885-886.[6]

In December 2019, months after the conference, Meril sought FDA guidance through a voluntary presubmission, proposing a clinical trial with clinical sites both inside and outside the United States. App., *infra*, 6a.[7] In response, the FDA noted that Meril's proposed trial lacked sufficient human test subjects at domestic sites. *Ibid.* Meril accordingly revised its proposal to meet FDA requirements (*ibid.*), but years later it still has not pursued a single U.S. clinical trial.

2. In October 2019, Edwards sued Meril for importing the infringing Myval devices for non-regulatory uses.

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[6] See also App., *infra*, 42a (Meril admitting that "technical difficulties with the simulation system" "result[ed]" in "the Myval Samples remain[ing] stored away during the time they were in San Francisco").

[7] The FDA's presubmission program "allows device manufacturers to request formal regulatory feedback on the device before officially engaging in the premarket approval process." App., *infra*, 34a.

App., *infra*, 6a. Meril responded that its infringing activity was protected under Section 271(e)(1)'s safe harbor. *Id.* at 6a, 38a.[8]

3. The district court granted summary judgment for Meril. App., *infra*, 31a-58a.

The court acknowledged the safe harbor was enacted for the limited purpose of "address[ing] issues created by the legal requirements for pre-market FDA approval." App., *infra*, 38a (describing Section 271(e)(1)'s history). But the court also found the Federal Circuit had assigned the provision a "br[oad]" scope. *Id.* at 40a.

According to the court (following Federal Circuit "guidance"), if an "allegedly infringing act[]" is "reasonably related to FDA approval," any "'alternative [non-regulatory] uses are irrelevant.'" App., *infra*, 52a & n.7 (quoting *AbTox, Inc.* v. *Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997)). Section 271(e)(1) applied even if infringing activities are "conducted in part for 'commercial reasons'" (*id.* at 51a), and even if the "actual purpose" is "promot[ional] rather than regulatory" (*id.* at 40a (internal quotation marks omitted)). In short, the court concluded, if an infringing act has at least *some* regulatory use, it is protected by "the section 271(e)(1) shield"—"alternative [commercial] uses are not relevant to the application of the safe harbor." *Id.* at 52a & n.7 (so concluding without any mention of the term "solely").

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[8] In its rehearing opposition, Meril suggested Edwards filed suit to "saddle Meril with legal fees to delay Meril's efforts to get FDA approval for a competing product." C.A. Reh'g Opp. 3. This is both bizarre (how would legal fees delay Meril's efforts?) and baseless. As the court below recognized, "[c]linical trials are expensive" (App., *infra*, 16a)—and the cost of developing a Class III medical device and obtaining regulatory approval easily overwhelms whatever marginal legal expense Meril has in mind.

Based on this analysis, the court found Meril's infringing activity "fall[s] squarely within the safe harbor." App., *infra*, 52a. Meril imported "the Myval Samples to the [conference]" to "'select[] qualified investigators'" for clinical trials. *Ibid.* Because *that* use was "reasonably related to FDA approval," it was "'irrelevant'" whether Meril's "*alternative* uses" were commercial. *Id.* at 52a & n.7 (emphasis added; quoting *AbTox*, 122 F.3d at 1030). As the court reasoned, once Meril established it imported the devices for at least one regulatory use, the safe harbor applied and it "need not reach" other issues. *Ibid.* The court thus brushed aside Edwards' extensive evidence that Meril imported the Myval devices for commercial uses, and declared "there is no infringement" under Section 271(e)(1). *Id.* at 52a & n.7.

4. In a split decision, the Federal Circuit affirmed. App., *infra*, 1a-30a.

a. The majority noted the Federal Circuit had "interpreted § 271(e)(1) on numerous occasions," and it found circuit precedent "clear." App., *infra*, 8a. According to the majority, "the relevant inquiry" is "whether the act of importation was for *a* use reasonably related to submitting information to the FDA." *Id.* at 11a (emphasis added). Once any such regulatory use is identified, Section 271(e)(1) was deemed satisfied—"regardless of whether there are additional [commercial] uses by [a] defendant." *Id.* at 18a (emphasis omitted). Indeed, in the majority's view, "'alternative uses'" are "'irrelevant'" to the safe-harbor inquiry. *Id.* at 9a, 11a (quoting *AbTox*, 122 F.3d at 1030).

The majority acknowledged the term "solely" in the statute, but it disagreed that "the use must *only* be reasonably related * * * to the FDA [process]." *Id.* at 11a (emphasis in original); contra 35 U.S.C. 271(e)(1) (protect-

ing activities "solely for [regulatory] uses"). On the contrary, the majority declared, the safe harbor applied unless an infringing activity was "'entirely *unrelated*'" to regulatory approval. *Id.* at 15a (emphasis altered); contra, again, 35 U.S.C. 271(e)(1) (setting out the *opposite* standard). Rather than ask whether the infringing act was "solely for [regulatory] uses," the majority instead asked whether the defendant's "'*sole* purpose'" was "'supporting * * * commercial sales,'" and whether "'the importation was wholly *unrelated* * * * to any FDA submission.'" *Id.* at 16a (second emphasis added). So long as "a[ny] use" concerned the FDA process—even if "'alternative uses'" did not—the majority held "the safe harbor is available." *Id.* at 9a, 11a.

Applying that standard, the majority found that Meril's importation "firmly resides in the § 271(e)(1) safe harbor." App., *infra*, 13a. According to the majority, Meril identified at least one qualifying regulatory use: it imported the infringing devices "to recruit[] investigators for a clinical trial to support FDA approval." *Id.* at 7a. Having identified one such qualifying use, any evidence of Meril's (non-regulatory) "'alternative uses'" became irrelevant. *Id.* at 9a, 18a (safe harbor applied "regardless of whether there are additional *uses* by defendant"). The majority thus discarded Edwards' "numerous evidentiary bases" showing Meril imported the devices "'to support commercial sales.'" *Id.* at 13a-14a. Under the majority's reasoning, the safe harbor applied unless Meril's importation was "'entirely unrelated' to any clinical recruiting." *Id.* at 15a. In fact, "[a]t bottom," Edwards lost because Meril identified at least *some* regulatory use—in the majority's view, Edwards failed to establish "'that Meril's *sole* purpose for importing Myval Devices was to support its commercial sales efforts,'" and that Meril's "'importa-

tion was wholly unrelated to recruiting clinical investigators and wholly unrelated to any FDA submission.'" *Id.* at 16a.

The majority accordingly held that "summary judgment of noninfringement [wa]s appropriate as a matter of law." App., *infra*, 12a; see also *id.* at 19a (affirming the "summary judgment of noninfringement under § 271(e)(1)'s safe harbor").

b. Judge Lourie dissented. App., *infra*, 19a-30a. As he established, the majority's holding "perpetuates the failure of [the Federal Circuit] and others to recognize the meaning of the word 'solely' in interpreting § 271(e)(1)." *Id.* at 19a. He flagged "[t]he tension between the plain language of the statute and [the Federal Circuit's] precedent," and warned the Federal Circuit's "misconstruction of § 271(e)(1) should not be left to create future mischief." *Id.* at 29a-30a. Concluding that "[Federal Circuit] case law has incorrectly given short shrift to the word 'solely' in the statute," he declared "[i]t is time to fix those errors." *Id.* at 20a.

As Judge Lourie explained, the term "solely" is a "key limitation on the meaning of the statute." App., *infra*, 27a. He recounted how "[t]he word 'solely' was included * * * to ensure that infringing activity" "performed for [non-regulatory] purposes * * * would not be exempt" (*id.* at 21a), and how the word "creates a safe harbor only for uses, sales, and importations that solely are for, as the statute says, development of information for the FDA." *Id.* at 19a-20a.

Judge Lourie then traced the history of Federal Circuit decisions to show how "solely" was judicially dropped from the text over time, producing an "unsupported expansion of the safe harbor" contrary to the "plain language of the statute itself." App., *infra*, 25a. He faulted those earlier cases for "disregard[ing]" "alternative uses

* * * once a fact-finder identifies any use reasonably related to obtaining FDA approval." *Id.* at 29a. And he explained how "alternative uses are crucial to determining compliance with the statute" (*id.* at 25a): "How is a fact-finder able to properly determine whether an infringing act is '*solely* for uses reasonably related to the development and submission of information' under federal law, when our precedent instructs him or her to turn a blind eye to the party's intent or alternative uses?" *Ibid.* (citing 35 U.S.C. 271(e)(1)).

In short, Judge Lourie concluded, "the law could usefully be clarified by an en banc holding of this court, expressly returning the word 'solely' to its Congressionally-enacted place in the statute." App., *infra*, 30a.

Judge Lourie finally analyzed how the district court mirrored the Federal Circuit's errors in examining Section 271(e)(1). As Judge Lourie explained, "the district court here wholly ignored the presence of the word 'solely' in the statute"—"[n]owhere in [its] holding and analysis does the word 'solely' appear." App., *infra*, 23a. This left "[a] key part of the statute * * * ignored." *Ibid.* And Judge Lourie found "the absence of 'solely' in the district court's stated holding was not merely a harmless omission" (*ibid.*): "the court ignored 'solely' in both its stated holding and its substantive analysis, effectively disregarding any evidence concerning Meril's commercial uses corresponding to the importation at issue" (*id.* at 24a).

Under Judge Lourie's view, this error was outcome-determinative: "under a correct interpretation of the law, particularly including adequate consideration of the word 'solely,' summary judgment for Meril should be reversed"—"the importations occurred, at least partially, for commercial reasons and thus were not entitled to the safe harbor." App., *infra*, 30a.

5. Edwards filed a petition for rehearing en banc, directly challenging the Federal Circuit's misreading of Section 271(e)'s safe harbor. The court called for a response to the petition, but it ultimately denied rehearing, refusing to reconsider its interpretation of the statute. App., *infra*, 60a.

REASONS FOR GRANTING THE PETITION

A. The Decision Below Vastly Expands Section 271(e)(1)'s Safe Harbor, Contravening Its Plain Text, History, And Purpose

Under the Hatch-Waxman Act, Congress created a limited safe harbor for otherwise-infringing acts "*solely* for uses reasonably related" to obtaining regulatory approval. 35 U.S.C. 271(e)(1) (emphasis added). This language is not difficult to understand. When a party imports a device for *any* non-regulatory use, it is not acting "*solely* for [regulatory] uses." 35 U.S.C. 271(e)(1) (emphasis added). Congress identified a single category of protected uses (those concerning regulatory approval), refused to expand that category to include anything else, and textually cabined its boundaries with an unambiguous term—"solely."

Yet according to the 2-1 split panel below, any protected use automatically insulates all non-protected uses. If "*a* use" is covered, the safe harbor applies, sweeping in "'alternative uses'" irrelevant to regulatory approval (App., *infra*, 9a, 11a (emphasis added))—including obvious attempts to commercialize competing products. In fact, under the panel's view, the only way to stop infringing activity is to prove the challenged uses were *solely commercial* in nature (*id.* at 16a)—the *inverse* of Section 271(e)(1)'s actual terms.

The Federal Circuit's position is at odds with the statutory text, history, and purpose. It judicially rewrites the

careful balance Congress struck in Section 271(e)(1), and extends statutory immunity to conduct that Congress did not protect and had no reason to protect. It offers a recipe for letting infringers off the hook so long as they strategically engage in *some* protected conduct, exploiting the safe harbor and undermining Congress's design.

There is a reason this issue has split Federal Circuit panels, divided district courts, prompted criticism from experts and stakeholders, and generated undue controversy and confusion—all of which could be avoided by simply reading Section 271(e)(1) to mean what it plainly says. Yet rather than course-correct, the panel below decided to double-down. For the first time, the Federal Circuit has confirmed that *any* regulatory use now sweeps in *all* other uses—even blatant commercial conduct. Rather than asking whether *any* uses are commercial, the court now asks whether *all* uses are commercial. The Federal Circuit has flipped the plain text on its head, and Congress's key limitation ("solely for [regulatory] uses") is now entirely gratuitous.

The panel below did not merely "perpetuate[] the [Federal Circuit's] misconstruction of the law." App., *infra*, 20a (Lourie, J., dissenting). Its novel misreading broadly expands Section 271(e)(1) to protect a new universe of infringing conduct, which is why experts view this as a "pivotal" moment for the safe harbor. Dr. Fangli Chen, et al., *The Broad Impact of* Edwards v. Meril *on the Safe Harbor Provision*, Minding Your Business (Aug. 27, 2024) <https://tinyurl.com/broad-impact-edwards-meril>.

The Federal Circuit has left Section 271(e)(1) at its breaking point. This is a critical provision affecting the proper administration of a trillion-dollar industry with

mission-critical stakes. "It is time to fix [the court's] errors" (App., *infra*, 20a (Lourie, J., dissenting)), and this Court's review is urgently warranted.

1. a. First and foremost, the decision below flouts the plain text and reads "solely" straight out of the statute. Section 271(e)(1) has the same meaning under Federal Circuit law with or without the term—it is entirely superfluous. Contra *TRW Inc.* v. *Andrews*, 534 U.S. 19, 31 (2001) (barring such readings). If Congress wanted the safe harbor to apply whenever *any* qualifying use was present, it would have said exactly that—protecting acts where *any* "use[]" is "reasonably related" to regulatory approval. Yet the "solely" qualifier has a crucial role: it excludes protection when *both* protected and unprotected uses are present. That forces parties to focus strictly on regulatory compliance, without exploiting "alternative uses" to insulate commercial conduct.

In short, there is no textual way to square the Federal Circuit's decision with the statute. "Solely" must do some work, and the work it does is obvious: the safe harbor applies if the infringing conduct is "solely" for a qualifying reason. That means any "alternative" use is disqualifying. App., *infra*, 25a (Lourie, J., dissenting). Yet the Federal Circuit wrongly instructs courts to ignore "'alternative uses'" (App., *infra*, 9a, 18a)—which it can only do by "giv[ing] short shrift to the word 'solely' in the statute." *Id.* at 20a (Lourie, J., dissenting). "The tension between the plain language" and controlling Federal Circuit "precedent" is palpable. *Id.* at 29a.

b. Rather than focus on the key term in the actual text ("solely"), the Federal Circuit instead expanded Section 271(e)(1) to sweep in concepts that indisputably are *not* there: the notion that Congress must also have intended (silently) to authorize commercial "uses"—"fund raising and other business purposes"—to ensure a party could

immediately compete on day one once the patent term expires. App., *infra*, 9a (citing earlier circuit decisions).

Yet that is not what Section 271(e)(1) is designed to do. The specific harm identified by Congress was addressed by the specific language Congress chose for the provision. Congress recognized that the regulatory-approval process could take years—and the inability to pursue that process in advance would effectively extend a patent's term. *Eli Lilly*, 496 U.S. at 669-670 (discussing "premarket regulatory approval"). That has nothing to do with any *separate* concerns about commercializing competing technology, setting up supply chains, conducting marketing and publicity efforts, etc. There is no hint, anywhere, that those separate tasks justify infringement—particularly in a provision limited "solely for [regulatory] uses." 35 U.S.C. 271(e)(1).

If the Federal Circuit is indeed correct that Congress was surely aware of those separate tasks, then there is especially no reason to presume Congress *omitted* them by accident. On the contrary, there is every reason to presume their omission was intentional—and Congress enumerated a single basis for the safe harbor because it intended to exclude all others. See, *e.g.*, *Jennings* v. *Rodriguez*, 583 U.S. 281, 300 (2018) (expressio unius). And, in fact, that principle has special force in this setting: not only did Congress list one item and refuse to include others—it further *restricted* the safe harbor, textually, by underscoring that "solely" the specified "uses" would escape the usual rule that parties cannot exploit a patent during its term. H.R. Rep. No. 857, Pt. 2, *supra*, at 30 (declaring any "interference" with patent rights "de minim[i]s").

While the Federal Circuit insists that Congress would have understood the need to take advanced steps toward marketing and commercializing a product, those separate "uses" are found nowhere in the operative text. Contrary

to the Federal Circuit's view, courts have no license to judicially "redline" the statute to improve upon the provision. *Badgerow* v. *Walters*, 596 U.S. 1, 11 (2022).

2. Section 271(e)(1)'s history and purpose confirm what the text already makes clear: the safe harbor applies "solely" for protected uses. 35 U.S.C. 271(e)(1).

Initially, Section 271(e)(1) was designed to override the Federal Circuit's earlier decision in *Roche*, which rejected any protection for activities "strictly related" to seeking regulatory approval (733 F.2d at 861). On its face, the limited safe harbor corresponds to the same question *Roche* addressed and Congress overturned. H.R. Rep. No. 857, Pt. 2, *supra*, at 27 & n.18. There is no hint Congress intended to expand the safe harbor to protect non-regulatory uses (which were not at issue), and Section 271(e)(1) accordingly should be limited to the same footprint. *Eli Lilly*, 496 U.S. at 670.

Put simply: "the legislative history expressly states that the provisions of § 271(e) 'have the net effect of reversing [*Roche*'s] holding.'" App., *infra*, 21a (Lourie, J., dissenting); see also H.R. Rep. No. 857, Pt. 2, *supra*, at 27; accord H.R. Rep. No. 857, Pt. 1, *supra*, at 45-46. Congress retained that "net effect" by enforcing a reciprocal correction; the Federal Circuit's contrary rule eliminates that calibration by sweeping in activity broader than the "narrow" category addressed by *Roche*.

The remainder of the legislative record is likewise unambiguous: the safe harbor was limited strictly to seeking regulatory approval, not other non-regulatory uses. *Eli Lilly*, 496 U.S. at 671; App., *infra*, 21a-22a (Lourie, J., dissenting). That was the essential compromise. Nowhere did Congress hint that parties could engage in commercial activity so long as they could also hook their infringing acts to *some* regulatory "use." See, *e.g.*, H.R. Rep. No.

857, Pt. 2, *supra*, at 30 ("all that the generic can do is test the drug for purposes of submitting data to the FDA").

As this Court itself recounted, Congress expanded patent rights on the front end (solely to account for regulatory delay), so it restricted patent enforcement on the back end (again, solely to account for regulatory delay). *Eli Lilly*, 496 U.S. at 669-670. The entire provision targets the regulatory process. It recognizes the delay from that process, and it sought to avoid "*de facto*" patent extensions while parties sought regulatory approval. *Ibid.* But there is no hint that Congress also sought to give competitors a head-start on commercial activities. Those activities have the potential to distort the market and unduly interfere with exclusive patent rights *before* the patent term expires. If Congress wished to permit those kinds of acts, it would have said so directly—rather than unambiguously specifying the "sole[]" uses (read: not commercial) that fall within the statutory safe harbor. See, *e.g.*, H.R. Rep. No. 857, Pt. 2, *supra*, at 8, 30 (competitors were "not permitted to market the patented drug during the life of the patent"; the patent owner "retain[ed] the right to exclude others from the major commercial marketplace").

Neither the Federal Circuit nor Meril could identify a single snippet of legislative material endorsing the Federal Circuit's sweeping position—ignoring an infringer's "alternative uses" and permitting commercial activity so long as *some* regulatory use is also present. It is rare to find such a perfect fit between the plain text and every primary component of the legislative record; it is rarer

still to find a court willing to discard that uniform legislative directive in favor of its own atextual judge-made rule.[9]

* * *

As this Court has readily confirmed, like all other statutes, the patent laws should be construed according to "the text of the statute" (*Life Techs. Corp.* v. *Promega Corp.*, 580 U.S. 140, 146 (2017)), yet the Federal Circuit has once again adopted a rule "untethered to the statutory text" (*Limelight Networks, Inc.* v. *Akamai Techs., Inc.*, 572 U.S. 915, 926 (2014)). The Federal Circuit has struck the critical term in the key clause of a crucial provision, and in doing so expanded a safe harbor designed "solely" for one "use" into immunity for *any* associated infringing activity—even for *separate* "uses" extending far beyond the regulatory process. App., *infra*, 9a, 11a, 18a.

It is exceptionally important to reestablish that Section 271(e)(1)'s text means what it says: it excuses infringing acts "solely" for "uses" concerning regulatory approval, not any corresponding marketing, advertising, commercialization, etc., so long as a party identifies *some* qualifying use along the way. The Federal Circuit has refused to reconsider its position, and this Court alone can now fix its mistake. Immediate review is warranted.

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[9] Contrary to Meril's position below (C.A. Reh'g Opp. 11-12), the plain-text analysis has nothing to do with motivation or subjective intent. It is not a question of what one hopes or aspires to accomplish with a given use. The question is both factual and objective: Meril imported the device for a specific use(s), and the statute asks whether that particular use(s) "solely" concerns regulatory approval. In this case, it is undisputed that Meril imported the devices to use in a simulator at the conference (*e.g.*, C.A. Reh'g Opp. 6 (so conceding))—displayed for both potential clinical investigators (a regulatory use) and other attendees (a non-regulatory use). That has nothing to do with mens rea—and courts can readily examine the operative question based on an ordinary factual record.

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

1. The question presented is of obvious legal and practical importance. The need for further review is self-evident. The real-world stakes are consequential: this provision defines the proper boundary between innovation and competition, and sets the marketplace rules for billion-dollar technologies in a trillion-dollar industry. Congress legislated specifically to address this problem, calibrating a solution that accounts for regulatory delay while respecting the rights of patent holders. Yet the Federal Circuit has distorted Congress's framework in a significant way—permitting extensive commercial activity that is anything but "de minim[i]s." H.R. Rep. No. 857, Pt. 2, *supra*, at 30.

It is thus no surprise that experts recognized the import of the court's ruling—flagging this as a "pivotal moment in the [safe harbor's] interpretation" with "far-reaching implications" (Dr. Chen, *The Broad Impact of* Edwards, *supra*); highlighting a sudden allowance of commercial acts that previously were barred (Payne, *Life Sciences Cases To Watch*, *supra*); and underscoring Section 271(e)(1)'s novel expansion (Courtenay C. Brinckerhoff, et al., *Federal Circuit Applies Safe Harbor to Imported Medical Device Samples*, The National Law Review (Mar. 27, 2024) <https://natlawreview.com/article/federal-circuit-applies-safe-harbor-imported-medical-device-samples> (the decision below "suggests the [safe] harbor could be wider than many believed")).

Aside from its sheer magnitude, the issue also arises with great frequency. The Federal Circuit has had "numerous" encounters with the subject. App., *infra*, 8a. This Court has twice granted review on related questions, underscoring the safe harbor's "importan[ce]." *Eli Lilly*, 496

U.S. at 661; see *Merck*, 545 U.S. at 193; see also, *e.g.*, *Abtox, Inc.* v. *Exitron Corp.*, 888 F. Supp. 6, 7 (D. Mass. 1995) (acknowledging the issue's "significance"). The question has split Federal Circuit panels,[10] divided district courts,[11] and garnered close attention from experts and industry stakeholders—who are carefully tracking this very case. See, *e.g.*, Brinckerhoff, *Federal Circuit Applies Safe Harbor*, *supra*; see also p. 4 n.1, *supra*. And yet all stakeholders are now bound by the Federal Circuit's mistaken ruling until this Court intervenes.

In the meantime, under the decision below, patent holders have no reliable way to enforce their rights. Good-faith market entrants face disadvantages when aggressive counterparts are willing to push the limit—exploiting the Federal Circuit's "misconstruction" to pursue commercial uses while others properly await a patent's expiration before engaging in non-regulatory conduct. The opportunities for "mischief" are tangible (App., *infra*, 30a (Lourie, J., dissenting)): parties are free to import patented devices to set up commercial relationships, promote and market those devices, *and* (incidentally) obtain FDA approval. App., *infra*, 9a, 11a, 18a. Under Federal Circuit law, *any* commercial activity is arguably fair game

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[10] See, *e.g.*, App., *infra*, 19a (Lourie, J., dissenting); *Momenta Pharm., Inc.* v. *Amphastar Pharm., Inc.*, 686 F.3d 1348, 1361, 1373-1374 (Fed. Cir. 2012) (Rader, J., dissenting).

[11] See, *e.g.*, *Amgen, Inc.* v. *Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 107-108 (D. Mass. 1998) (flagging earlier district-court conflicts); *Elan Transdermal Ltd.* v. *Cygnus Therapeutic Sys.*, No. 91-1314, 1992 WL 368678, at *7 (N.D. Cal. June 23, 1992) (same). While the lower-court conflicts were generally supplanted by the Federal Circuit, the fact that objective jurists initially read the safe harbor to mean what it says is a telling indication of the Federal Circuit's interpretive errors. See *Amgen*, 3. F. Supp. 2d at 107 (recounting judicial "h[olding] that the defendant must use the invention for meeting FDA requirements, and for no other purposes").

so long as the party also establishes some nexus to the regulatory process (*id.* at 18a)—despite Congress restricting the safe harbor to the regulatory process alone (35 U.S.C. 271(e)(1)). As others have long recognized, "eliminating the word 'solely'" from the safe harbor ignores the text and upsets the "narrow compromise between pioneer and generic drug companies" that Congress crafted in Hatch-Waxman. Amy Stark, *The Exemption from Patent Infringement and Declaratory Judgments: Misinterpretation of Legislative Intent?*, 31 San Diego L. Rev. 1057, 1074-1075 (1994).

The Federal Circuit's atextual position will continue to create confusion, foster litigation, and generate uncertainty—all in a regulatory environment where clear rules and fair competition are essential for industry stakeholders to plan and execute million- and billion-dollar research investments. Yet the "current trend towards expansiveness" has left "many practitioners wonder[ing] if there are any uses or commercial activities that *will* be outside the scope of the safe harbor provision." Darby T.R. Findley, *There's A Storm A Brewin': Can the Hatch-Waxman "Safe Harbor" Provision Shield Commercial Stockpiling from A Potential Downpour of Patent Infringement Allegations?*, 26 Fed. Circuit B.J. 307, 309 (2017).[12]

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[12] The Federal Circuit's decision assumes even greater significance in light of this Court's decision in *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005)—which assigned the safe harbor a broad scope for *actual* regulatory uses. 545 U.S. at 202, 207; see *Momenta*, 686 F.3d at 1356 (describing the Court's "expansive view"). Because the safe harbor covers a wide swath of qualifying uses, it becomes easier to identify (or fabricate) *any* use that might qualify—and thus, under Federal Circuit precedent, easier to excuse infringing acts with both protected and non-protected aims. A proper reading of "solely" is now essential to ensure that non-qualifying uses are not excused, and parties can safely pursue FDA approval without others abusing the system.

In the words of one expert: "Judge Lourie may be right that the 'law could usefully be clarified," "expressly returning the word 'solely' to its Congressionally-enacted place in the statute.'" Dennis Crouch, *Federal Circuit Debates Scope of 271(e)(1) Safe Harbor and the Meaning of "Solely,"* PatentlyO (Mar. 27, 2024) <https://patentlyo.com/patent/2024/03/federal-circuit-debates.html>. This Court's immediate review is warranted.

2. This case is an ideal opportunity to resolve this significant question. The dispute turns on a pure question of law: the proper construction of the statute. It arises in a clean vehicle: it was resolved at summary judgment, and each court below declared Meril's "alternative" uses "irrelevant" under (incorrect) circuit precedent. There are no complicating factors or obstacles to reaching the statutory issue. And Judge Lourie's dissent confirms the Act's proper construction is outcome-determinative: Edwards lost because the majority applied its (atextual) reading, but would have prevailed under Judge Lourie's plain-text construction. As Judge Lourie confirmed, the legal errors were dispositive.[13]

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[13] The majority (playfully) minimized Meril's infringing activity, suggesting the imported devices simply "sat in a bag." App., *infra*, 2a. This is twice inapposite. First, as established above, the only reason the devices were not displayed was Meril's simulator *malfunctioned*. See, *e.g.*, App., *infra*, 37a. Had Meril not experienced technical difficulties, the devices would have been prominently used at the conference. Second, the relevant focus is on Meril's *importation*—and there is no dispute that Meril imported the devices to use in a simulator at the conference (for both regulatory and non-regulatory uses). That tees up the statutory question perfectly: Meril's infringing act was for both "regulatory" uses and "alternative" uses. The split panel held the Act's safe harbor applied if Meril identified *any* regulatory use—even if Meril also engaged in "alternative" *non*-regulatory uses. *Id.* at 9a, 18a. If the panel's reading is correct, Meril wins; if the dissent's

Nor is there any reason to postpone review. There is no possibility of a circuit conflict (given the Federal Circuit's exclusive jurisdiction), and the full circuit denied rehearing. The Federal Circuit's position is now entrenched. It will remain the last word on this critical issue until this Court intervenes.

At bottom, the statutory question is binary: one view of "solely" is correct and the other is wrong, and "alternative" commercial uses are either permitted or not. The answer has serious economic and practical stakes. The Federal Circuit has advanced an atextual construction that undermines Congress's design and interferes with Section 271(e)(1)'s scope. This Court alone can now correct the Federal Circuit's mistake—and finally align the governing standard with the safe harbor's plain text. There is an urgent and compelling need to restore the proper statutory meaning.

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reading is correct (and "solely" means what it says), Meril loses. The vehicle is as clean as it gets.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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