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.,

Respondents.

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

BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Section 271(e)(1) of the Patent Act declares 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 development and submission of information" to the FDA.

Here, although Edwards' petition asserts that the Federal Circuit ignored "alternative" commercial uses, there was only one "use"—Meril's importation of two demonstration samples of a Myval artificial heart valve to a medical conference. The Federal Circuit analyzed that one "use" and found it was "reasonably related" to recruiting investigators for clinical trials and therefore within the safe harbor. It also recognized there was no evidence of any commercial use of the devices, including because "it is undisputed that Meril did not offer for sale or sell the Myval System" at the conference.

The dissent below—and now Edwards—advocates rewriting Section 271(e)(1) to "create[] a safe harbor only for uses, sales, and importations that ***solely*** are for . . . development of information for the FDA." This removes "reasonably related" and replaces it with "solely." The question presented is:

(1) Whether the Federal Circuit correctly determined that Meril's importation of two demonstration

samples of its medical device to a medical conference to recruit clinical trial investigators for its FDA clinical trials was protected by the safe harbor, where Edwards admitted that Meril did not sell or offer to sell the devices in the United States and where there is no evidence of any other commercial uses.

CORPORATE DISCLOSURE STATEMENT

In accordance with United States Supreme Court Rule 29.6, Respondents make the following disclosures:

Meril Life Sciences Private Limited is a subsidiary of Micro Life Sciences Private Limited, which is a subsidiary of Bilakhia Holdings Private Limited.

Meril, Inc. is a wholly owned subsidiary of Meril Life Sciences Private Limited.

No publicly held corporation owns 10% or more of Meril Life Sciences Private Limited or Meril, Inc.

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INTRODUCTION

This case is about two demonstration samples of an artificial heart valve that Meril imported to a medical conference in San Francisco to recruit clinical trial investigators for its FDA clinical trials. Those two devices were to be used with a simulator, which is a complicated instrument that allows clinicians to mimic implanting the device into a patient's aortic valve. However, because the simulator malfunctioned, the two demonstration samples were kept in a bag in a storage room at the medical conference for a few days, were never displayed or shown to anyone, and then were transported out of the United States. C.A. App. 296, 372-374.[1]

This case does not merit review by the Court. It does not present any "exceptionally important" issue with "massive stakes" (Pet. (I))—indeed, it does not involve even *de minimis* harm to any party. It is undisputed that no one from the U.S. ever saw the devices during their short stay in the storage room. *Id.* at 12; Pet. App. 2a, 37a. And these unique facts—two devices left in a storage room for a few days—are unlikely ever to be repeated.

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[1] References to "Pet. App." are to the Appendix included with Edwards' petition. References to C.A. App. are to the Appx pages of the Appendix filed in the Federal Circuit. Case No. 2022-1877, Dkt. 35.

This case also does not ask this Court to resolve any split of authority or to address a decision contrary to this Court's precedent. The petition advocates the position of a single dissenting judge, who acknowledged that "the district court in this case reasonably followed the decisions of this court in finding no genuine dispute of fact as to whether Meril's importation of two allegedly infringing Myval devices fell within the safe harbor of § 271(e)(1)." Pet. App. 20a. The petition nevertheless asks this Court to overturn over 30 years of safe harbor precedent and disrupt settled industry expectations because that precedent allegedly reads "solely" out of the statute and immunizes commercial "alternative" uses. Pet. 2-4. Neither is correct.

First, the Federal Circuit did not read "solely" out of the statute. The safe harbor of 35 U.S.C. § 271(e)(1) applies "solely for uses reasonably related to the development and submission of information" to the FDA. Relying on the statutory language as well as well-settled case law, the Federal Circuit explained that "solely" modifies "for uses," meaning that "for each act of infringement the safe harbor is available only [*i.e.*, solely] for acts or uses that bear a reasonable relation to the development and submission of information to the FDA." Pet. App. 11a. This analysis does not ignore the word "solely," let alone read it out of the statute.

Edwards' petition and the dissent assert that Section 271(e)(1) should be reinterpreted to "create[] a safe harbor only for uses, sales, and importations that ***solely*** are for . . . development of information for the FDA." *Id.* at 19a-20a (emphasis added); Pet. (I), 2, 3, 6, 9 n.4, 15, 18, 19, 21 ("solely for [regulatory] uses"). But that is rewriting the statute to remove "reasonably related" and replace it with "solely." 35 U.S.C. § 271(e)(1) ("uses ***reasonably related***" to the development of information for the FDA) (emphasis added). Congress explicitly chose to draft Section 271(e)(1) with the "***reasonably related***" standard; it cannot be rewritten to instead use a "solely" standard. This reinterpretation would also add a second "solely," such that the safe harbor would apply "solely" to uses that "solely" are for development of information for the FDA. That is not what the statute says.

Second, neither the Federal Circuit decision below nor the safe harbor precedent it applied immunizes or ignores "alternative" commercial uses. In fact, the Federal Circuit's decision is clear that "each act" or use must be analyzed separately to determine if it is reasonably related to regulatory approval. Pet. App. 10a-11a. Here, there was only one "use"—the "importation of two . . . samples of [Meril's] heart valves to a [TCTC] medical conference." *Id.* at 7a. The Federal Circuit then analyzed that one use and found it was "reasonably related"

to recruiting investigators for clinical trials required for FDA approval and therefore "firmly" within the safe harbor. *Id*. at 11a-12a, 18a.

There was no other use, let alone a commercial use. Both the district court and the Federal Circuit specifically questioned Edwards' counsel about this during oral argument, and Edwards' counsel admitted that there is no evidence that Meril sold or offered to sell the devices while in the U.S. C.A. App. 1429-1430; Oral Argument (Dec. 5, 2023) at 5:53-6:42[2]; Pet. App. 6a ("it is undisputed that Meril did not offer for sale or sell the Myval System to anyone at TCTC"). And there is no evidence of any other commercial use of the device, including because it is undisputed that the two devices remained in a bag in a storage room and were never shown to anyone. Edwards' alleged "exhaustive evidence of Meril's commercial use" is Edwards' speculation that, if the simulator had not malfunctioned, Meril might have shown the devices to conference attendees who were not potential clinical trial investigators. Pet. 4, 12. But it is undisputed that this never happened.

Thus, the Federal Circuit has not "let[] infringers off the hook" (*id.* at 3, 19), "distort[ed] the mar-

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[2] Available at https://oralarguments.cafc.uscourts.gov/default.aspx?fl=22-1877_12052023.mp3.

ket for patented products" (*id.* at 3), or "undermine[d] the patent bargain" (*id.*). These accusations all rely on the petition's assertion that the Federal Circuit ignored commercial "alternative" uses, which as explained above, it did not.

In sum, this case presents a poor vehicle for consideration of any aspect of the safe harbor, let alone the question presented. Indeed, the question presented assumes that Meril engaged in commercial, "non-regulatory uses." But, as explained above, there is no evidence of any commercial use. This case is record-bound by Edwards' admissions that Meril did not sell or offer to sell the device at the medical conference, as well as the undisputed fact that the devices remained in a bag. The petition asks the Court both to discard Edward's factual admissions and to overturn over 30 years of well-settled safe harbor precedent in favor of a reinterpretation that is contrary to the statutory text. The petition should be denied.

STATEMENT OF THE CASE

Meril started the FDA approval process for Myval well before attending TCTC.

Meril is an India-based medical device company that developed the Myval-branded transcatheter

heart valve to treat severe symptomatic native aortic valve stenosis.[3] Pet. App. 2a. Myval is a "Class III" medical device subject to strict regulatory standards in the United States. *Id.* at 3a. This means that Meril may not market or sell Myval in the U.S. without first receiving premarket approval from the FDA. *Id.*; 21 U.S.C. § 360c. To receive such approval, Meril must obtain an investigational device exemption from the FDA, identify clinical investigators to implant the device in humans, collect safety and efficacy data, and submit the data to the FDA. Pet. App. 3a.

It is undisputed that Meril's efforts to seek FDA approval spanned years leading up to the accused importation of two demonstration samples in September 2019. *Id.* at 4a. Meril first conducted preclinical investigations on cadavers and animals to determine whether Myval could be implanted safely in live human subjects. C.A. App. 295, 858, 1170, 1323-1326. In July 2019, Meril prepared a formal synopsis for a global clinical trial (called the Landmark Trial) to support FDA approval. *Id.* at 9, 1203-1216, 1139-1140, 1164.

It is undisputed that Meril began drafting a presubmission to the FDA for the Landmark Trial in

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[3] Aortic stenosis occurs when the aortic valve narrows and restricts normal blood flow. C.A. App. 295.

August 2019 (Pet. App. 3a-4a, 35a) and corresponded with the FDA about regulatory approval in August and September 2019 (*id.* at 4a, 43a). Meril also engaged an FDA consultant on September 3, 2019 to help with the FDA presubmission. *Id.* at 4a. At the same time, Meril was actively enlisting clinical trial investigators to support FDA approval, including both foreign and U.S. clinicians. C.A. App. 782, 719-727, 547. In August 2019, Meril made plans to hold an investigator meeting at the TCTC medical conference to recruit clinical trial investigators for the Landmark Trial. *Id.* at 719.

Meril recruits clinical trial investigators at TCTC.

TCTC is an annual scientific symposium featuring the latest in interventional cardiovascular medicine and attended by leading clinicians. Pet. App. 4a, 35a. TCTC is not a buyer-seller forum. Instead, it is undisputed that TCTC is an excellent scientific forum for medical device manufacturers like Meril to seek out clinicians as potential investigators. *Id.* Meril attended TCTC 2019 in San Francisco to do just that. *Id.* at 4a-6a, 35a-36a; C.A. App. 519.

Before TCTC, Meril contacted clinicians, inviting them to an investigator meeting during the conference to discuss the Landmark Trial. C.A. App. 571, 774-783, 961. Meril created a flyer and emailed conference attendees to let them know

Meril would offer "hands-on and VR sessions on Meril's TAVR [Transcatheter Aortic Valve Replacement] system." *Id.* at 372, 890-893, 1112. These virtual reality (VR) sessions use a simulator that allows clinicians to mimic implanting a Myval valve in a patient using a TAVR procedure. *Id.* at 1167-1168, 1176. The simulator is not a marketing prop; it is a complicated instrument requiring a Myval device and an echocardiogram and is used to train cardiologists in TAVR procedures. *Id.* at 1110, 1167-1169, 1176.

On September 24, 2019, Nilay Lad, a Meril employee, traveled to San Francisco to attend TCTC and hand-carried two non-commercial, demo Myval heart valves on his flight. Pet. App. 4a-5a. These Myval samples were in a bag and accompanied by a written declaration stating that the devices would be used only for demonstration with the simulator and "not used for any sales purpose." *Id.*

It is undisputed that during the conference, Meril discussed the details of the Myval system with potential clinical trial investigators from the U.S. and other countries. *Id.* at 5a-6a; C.A. App. 373. It is also undisputed that Meril held its planned investigator meeting to enlist clinical trial investigators. C.A. App. 1141, 1154. Although Meril had planned to use the two imported demo devices with the simulator to educate potential

clinical trial investigators, Meril had technical difficulties with the simulator. *Id.* at 373-374, 1110. Thus, Meril did not show either of the two Myval samples during TCTC. *Id.* at 374; Pet. 12; Pet. App. 2a, 37a. Instead, those samples remained in a bag in a storage room until they were carried to Europe by another Meril employee. C.A. App. 374, 296. It is undisputed that Meril did not sell or offer for sale any Myval devices at the conference. *Id.* at 1429-1430, 373, 1177-1178, 1107-1108; Oral Argument (Dec. 5, 2023) at 5:53-6:42.

After TCTC, Meril followed up with the clinical investigators it had met with and continued to seek their input on the Landmark Trial. C.A. App. 1218, 1220-1223. Meril also worked to finalize its FDA presubmission, which Meril submitted on December 4, 2019. *Id.* at 1194-1195, 1198-1200, 445-495 (*see, e.g.*, *id.* at 459). The FDA responded to Meril's presubmission in February 2020. *Id.* at 500-502. Meril provided a supplemental presubmission in May 2020. *Id.* at 1225-1241.

Edwards' Lawsuit and the District Court Order

Edwards sells a heart valve called Sapien. The large majority of Edwards' $6 billion in annual revenue is from sales in the U.S., where Edwards charges a premium price. Edwards hired a team of attorneys to attend TCTC 2019 to collect evidence that Edwards could use to file suit against Meril.

C.A. App. 640. Edwards filed suit just two weeks after the conference, on October 14, 2019. *Id.* at 27, 226-227, 242-248.

After allowing Edwards to take extensive discovery (*id.* at 34, 36, 1093-1094), the district court granted Meril's motion for summary judgment. Pet. App. 31a-58a. Applying precedent from this Court and the Federal Circuit, the district court found no genuine dispute of material fact that the sole "use"—importation of two demonstration Myval samples to TCTC—was reasonably related to recruiting clinical trial investigators for FDA approval and fell within the safe harbor. The district court explained that it was undisputed that "Meril had taken significant steps towards obtaining FDA approval for the Myval System" at the time of the TCTC conference, including "(1) preparing a formal clinical trial synopsis for its Landmark Trial, [C.A. App. 1203-1216]; (2) preparing a draft presubmission to seek FDA input on its clinical trial, [*id.* at 1145]; (3) communicating with the FDA regarding Meril's proposed clinical study and its presubmission, [*id.* at 376-380, 382-386]; and (4) hiring an FDA consultant to help with the FDA presubmission. [*Id.* at 371]; [*id.* at 1146-1147]." Pet. App. 43a. The district court also found it undisputed that TCTC "was attended by a large number of potential clinical trial investigators" (*id.* at 44a) and that Meril "sought out," and met with, "potential clinical researchers at the . . . []TCT Conference[]"

(*id.* at 35a). The district court found, including based on Edwards' own admissions, that it was undisputed that "Meril did not sell or offer to sell its medical device at the medical conference." *Id.* at 44a; C.A. App. 1429-1430.

The Federal Circuit decision and Edwards' petition for rehearing

The majority of the Federal Circuit panel, Judges Stoll and Cunningham, affirmed. Pet. App. 1a-19a. The majority recognized it was undisputed that (1) Meril had taken significant steps toward obtaining FDA approval for Myval before TCTC (*id.* at 3a-4a, 11a), (2) TCTC is attended by a large number of potential clinical trial investigators (*id.* at 11a-12a), (3) Meril met with potential clinical trial investigators at TCTC (*id.* at 4a-5a), (4) Meril provided a premarket approval submission to the FDA in December 2019 after its meetings at the conference and continued to communicate with the FDA (*id.* at 6a, 11a), and (5) "no sales or offers for sale [of Myval] were made at TCTC" (i*d.* at 12a).

The majority correctly applied the law to these undisputed facts. The majority explained that "[t]he safe harbor exception in § 271(e)(1) applies '*solely* for uses reasonably related to the development and submission of information' to the FDA." *Id.* at 11a. The majority also specifically explained the significance of the word "solely" in the statute:

> Read in context, "solely" modifies "for uses." Meaning, for each act of infringement the safe harbor is available only for acts or uses that bear a reasonable relation to the development and submission of information to the FDA. *Merck KGaA* [*v. Integra Lifesciences I, Ltd.*], 545 U.S. [193,] 205-07 [(2005)].

Id. Thus, the safe harbor inquiry requires identifying the relevant "acts or uses" and whether those acts or uses are "reasonably related" to FDA approval. *Id.*

That is exactly the analysis the majority did here. It explained that the undisputed facts show there was only a single "use"—importation of the two demo devices to TCTC. *Id.* at 11a-12a. The majority followed a long line of safe harbor cases—both from this Court and the Federal Circuit—in concluding that this one "use" was "reasonably related" to FDA approval because device sponsors are required to "select[] qualified investigators and provid[e] them with the necessary information to conduct clinical testing." *Id.* (citing *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1523 (Fed. Cir. 1992) (citing 21 C.F.R. § 812.40)); *see also Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1263 (Fed. Cir. 2008) ("demonstrat-

ing an implantable defibrillator at medical conference was 'reasonably related' to FDA approval because it facilitated the selection of clinical trial investigators"); *Intermedics, Inc. v. Ventritex Co.*, No. 1992-1076, 1993 WL 87405, at *3 (Fed. Cir. Feb. 22, 1993) (same); *Chartex Int'l PLC v. M.D. Pers. Prods. Corp.*, No. 1992-1556, 1993 WL 306169, at *4 (Fed. Cir. Aug. 12, 1993) (same). And the majority followed safe harbor precedent in rejecting Edwards' argument that the district court erred in not considering Meril's alleged "commercial purposes," explaining that "underlying purposes" and "intent" are not relevant "as long as the use is reasonably related to FDA approval." Pet. App. 8a-11a (citing *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997)); *Momenta Pharms., Inc. v. Teva Pharms. USA Inc.*, 809 F.3d 610, 621 (Fed. Cir. 2015); *Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1339 (Fed. Cir. 2019).

Judge Lourie dissented. The dissent acknowledged that the district court "reasonably followed" well-established safe harbor precedent. Pet. App. 20a. But it advocated reinterpreting the statutory language such that the safe harbor would apply "only for uses, sales, and importations that solely are for . . . development of information for the FDA." *Id.* at 19a-20a.

Edwards petitioned for panel rehearing and rehearing *en banc*. The Federal Circuit denied both requests. Edwards' petition to this Court followed.

REASONS FOR DENYING THE PETITION

Edwards asks this Court to overturn over 30 years of safe harbor precedent because the Federal Circuit majority purportedly excused commercial "alternative uses" and ignored the word "solely" in the statute. Edwards is wrong on all counts and its petition should be denied.

I. THE FEDERAL CIRCUIT'S DECISION BELOW APPLIES WELL-SETTLED SAFE HARBOR PRECEDENT

Edwards' petition does not ask this Court to resolve a split in authority. Indeed, the Federal Circuit's decision below applies well-settled safe harbor precedent and does not conflict with any decision of this Court, the Federal Circuit, or any lower court. As explained above, Judge Lourie's dissent readily acknowledges that "the district court in this case reasonably followed the decisions of this court in finding no genuine dispute of fact as to whether Meril's importation of two allegedly infringing Myval devices fell within the safe harbor of § 271(e)(1)." Pet. App. 20a. In fact, every court to have addressed the facts here—non-sale demonstrations of medical devices at conferences where the device sponsor is preparing to apply for FDA

approval—has ruled this activity is protected by the safe harbor. *Telectronics*, 982 F.2d 1520; *Intermedics*, 1993 WL 87405; *Chartex*, 1993 WL 306169.

Edwards' petition asserts that this issue has "split Federal Circuit panels" and "divided district courts."[4] Pet. (I). But the two district court cases that Edwards points to (*id.* at 26 n.11), both from decades ago, did the same analysis that the Federal Circuit did here. Both cases explain that "'solely' in Section 271(e)(1) is correctly read as modifying 'uses'" and held that the safe harbor applied because each "use" was "reasonably related" to FDA approval. *Elan Transdermal Ltd. v. Cygnus Therapeutic Sys.*, No. 91-CV-1314, 1992 WL 368678, at

[4] The petition also points to a handful of web articles (Payne, Davis, Crouch, Brinckerhoff), a law firm blog post (Chen), and two journal articles (Findley, Stark) as showing "close attention" and "criticism from experts." Pet. 4, 19, 25-28. But the web articles just report on and summarize the Federal Circuit's decision below—a decision Edwards admits applies settled law. Likewise, the Chen blog post acknowledges that the decision "*maintains*" the scope of activities that fall within the safe harbor. The quote from Findley (2017) is directed to this Court's decisions in *Merck* (safe harbor applies to preclinical activities) and *Eli Lilly* (safe harbor applies to medical devices) and Federal Circuit decisions addressing post-FDA approval activities—not the issues here. And the Stark journal comment is from 1994, and cannot possibly address *Abtox*, *Momenta*, *Amgen*, or the numerous other cases directed to the issues here that came after.

*7-9 (N.D. Cal. June 23, 1992); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 107-11 (D. Mass. 1998).[5] And the only split panel on this issue is Judge Lourie's dissent.[6] This Court has declined to grant review in the circumstances here—where the lower courts are all in harmony and a single litigant and one interested amicus seek to change the result.

Deprived of the narrative that the Federal Circuit below defied safe harbor precedent, Edwards adopts the position of the one dissenting judge. But that view misinterprets the statute. Section 271(e)(1) applies "*solely* for uses reasonably related to the development and submission of information" to the FDA. Citing decades of precedent, the Federal Circuit below correctly explained that "solely" modifies "for uses," which means that, "for each act of infringement the safe harbor is available only [*i.e.*, solely] for acts or uses that bear a reasonable relation to the development and submission of in-

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[5] Both cases also explain that two prior cases had incorrectly focused on "purposes" rather than "uses," which was an "unwarranted rewriting of the statute." *Elan Transdermal*, 1992 WL 368678, at *9; *Amgen*, 3 F. Supp. 2d at 107.

[6] Edwards also points to Judge Rader's dissent in *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012). Pet. 26 n.10. But that dissent addresses application of the safe harbor to post-FDA approval activity, which has nothing to do with the issue here.

formation to the FDA." Pet. App. 11a. This analysis does not read the word "solely" out of the statute, as Edwards contends.

Judge Lourie's dissent advocates for reinterpreting the statute such that it "creates a safe harbor *only* for uses, sales, and importations that *solely* are for . . . development of information for the FDA." *Id.* at 19a-20a (emphases added). Edwards' petition adopts this position. Pet. 3 ("'*solely*' for regulatory approval"), 7 ("'strictly related' to regulatory approval"). But this is rewriting the statute to replace the language that Congress chose—"reasonably related"—with "solely." 35 U.S.C. § 271(e)(1) ("uses reasonably related" to the development of information for the FDA). This reinterpretation also 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. Congress explicitly chose the "reasonably related" standard and Edwards cannot rewrite it to substitute in a completely different "solely" standard. *Life Techs. Corp. v. Promega Corp.*, 580 U.S. 140, 146 (2017) ("We look first to the text of the statute.").

In addition, *stare decisis*, which is paramount in statutory cases, dictates against Edwards' plea to overturn over 30 years of settled safe harbor precedent on which the public and the biotechnology

and pharmaceutical industries rely.[7] *Kimble v. Marvel Ent., LLC*, 576 U.S. 446, 456 (2015) ("we apply statutory *stare decisis* even when a decision has announced a 'judicially created doctrine' designed to implement a federal statute"). This is particularly true here, where Edwards asks this Court to reinterpret the statute in a manner that is inconsistent with the statutory text. Edwards' insistence that the Federal Circuit has interpreted the safe harbor contrary to Congress' intent ignores that Congress has never seen fit to amend the safe harbor statute despite wholesale revisions to the Patent Act, including under the America Invents Act. *Id.* ("Congress's continual reworking of the patent laws—but never of [the statute at issue]—further supports leaving the decision in place").

The Federal Circuit's opinion below is also consistent with this Court's two safe harbor decisions.[8] This Court has made clear that the safe harbor applies to medical devices, such as those at issue here.

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[7] The patent community is also untroubled by the safe harbor case law, as underscored by the lack of *amici curiae* supporting the petition other than one organization with Edwards' Corporate Vice President on its board. *See* https://www.advamed.org/about/advamed-board-of-directors/ (last visited December 20, 2024).

[8] This Court has rejected other petitions asking that it modify or reconsider the scope of the safe harbor. *See, e.g.*, *Classen Immunotherapies, Inc. v. Elan Pharms., Inc.*, No. 17-1409 (June 11, 2018).

Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990). And contrary to Edwards' argument that the safe harbor is narrow and applies only to "obtaining premarketing approval" (Pet. 8), this Court has explained that the safe harbor provides a "wide berth" that "extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA." *Merck*, 545 U.S. at 202. This Court has also instructed that the safe harbor applies to activities preceding an FDA submission, which would include recruiting clinical trial investigators, as it is undisputed Meril did here. *Id.* ("there is simply no room . . . for excluding certain information from the [safe harbor] exemption on the basis of the phase of research in which it is developed").

Edwards argues that Congress enacted the safe harbor only to address *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), a case holding that pharmaceutical testing to support FDA approval was *not* insulated from patent infringement liability. Pet. 6-8 (asserting that the safe harbor is "coterminous" with reversing *Roche's* holding). But this Court's precedent confirms that Edwards is incorrect. Indeed, if the safe harbor were limited to reversing *Roche*, it would not apply to medical devices (as this Court held in *Eli Lilly*) or to "any phase of research" (as this Court held in *Merck*). As this Court has explained, the safe harbor cannot be interpreted "so

narrowly as to render [its] stated protection of activities leading to FDA approval . . . illusory." *Merck*, 545 U.S. at 207.[9]

In sum, the Federal Circuit's decision is consistent with 30 years of well-settled safe harbor precedent, including from this Court, and it does not read "solely" out of the statute, as Edwards contends. The Court should not overturn this settled precedent in favor of Edwards' reinterpretation, which is contrary to the statutory text.

II. THE FEDERAL CIRCUIT'S DECISION BELOW DOES NOT IGNORE COMMERCIAL "ALTERNATIVE" USES

Both the petition and the amicus brief repeatedly mischaracterize the Federal Circuit as ignoring commercial "alternative" uses and "declar[ing] exhaustive evidence of Meril's commercial use 'irrelevant.'" Pet. (I), 3-4, 13-15, 18, 20, 23; *see also* Amicus Br. 2, 9, 12-13. But both the district court and the Federal Circuit found only one "use"—the "importation of two . . . samples of [Meril's] heart valves to a [TCTC] medical conference." Pet. App. 7a. The Federal Circuit then correctly analyzed

[9] The Federal Circuit's safe harbor case law is also consistent with the legislative history. Nothing in that legislative history supports Edwards' and the dissent's reinterpretation of the safe harbor statute.

that one use and found that it was "reasonably related" to recruiting clinical trial investigators for FDA approval and therefore within the safe harbor. *Id.* at 11a-12a, 18a. That conclusion was based on undisputed facts, including: (1) Meril had taken significant steps toward obtaining FDA approval for Myval before TCTC (*id.* at 3a-4a, 11a), (2) TCTC is attended by a large number of potential clinical trial investigators (*id.* at 11a-12a), (3) Meril met with potential clinical trial investigators at TCTC (*id.* at 4a-5a), and (4) Meril continued to consult with those clinical trial investigators and provided a premarket approval submission to the FDA in December 2019 and continued to communicate with the FDA (*id.* at 6a, 11a).

There was no other use and certainly no other commercial use. "[I]t is undisputed that Meril *did not offer for sale or sell* the Myval System to anyone at TCTC." *Id.* at 6a (emphasis added). Edwards' counsel admitted this multiple times during oral argument:

> THE COURT: Let me just make sure I'm clear. There's no dispute that there were no offers for sale or sales made at the conference; is that correct?
>
> MR. HANLE: Correct . . .

> THE COURT: Just—I—I fully understand your argument, but sounded like the answer to my question is yes. Right?
>
> MR. HANLE: Yes, We have no evidence that – that actual offers for sale was [sic] made.

C.A. App. 1429-1430; *see also* Oral Argument (Dec. 5, 2023) at 5:53-6:42. These unequivocal statements are judicial admissions that foreclose Edwards' suggestion of "alternative" commercial uses. *See Wells Fargo Bank, N.A. v. Mesh Suture, Inc.*, 31 F.4th 1300, 1313 (10th Cir. 2022) (judicial admissions "have the effect of withdrawing a fact from contention").

Edwards' alleged "exhaustive evidence of Meril's commercial use" is that—if the simulator had not malfunctioned—"Meril otherwise would have used those devices in the simulator for" demonstrations to both clinical trial investigators (which Edwards admits is within the safe harbor) and potentially other attendees of the medical conference (which Edwards asserts is a "non-regulatory" commercial use). Pet. 4, 12. But it is undisputed that the devices were not shown to these attendees. *Id.* at 12; Pet. App. 2a, 37a. So, Edwards' "exhaustive evidence" of Meril's commercial use is Edwards' speculation of what Meril might have done in some alternate universe if the simulator

would have worked. There was never any commercial use at all.

Edwards also repeatedly mischaracterizes the Federal Circuit's opinion. It asserts that the Federal Circuit erred (i) by finding the "safe harbor applied unless an infringing activity was 'entirely unrelated' to regulatory approval" (Pet. 15) or (ii) by requiring that Edwards prove the "challenged uses were *solely* commercial" (*id.* at 16, 18). But these cited portions of the Federal Circuit decision are clearly referring to *Edwards' arguments* and explaining why they are wrong. Pet. App. 15a, 16a (both quoting from Edwards' own brief). Edwards also uses selective quotations to argue that the Federal Circuit held that "any protected use automatically insulates all non-protected uses." Pet. 18; *see also id.* at 15 (arguing that safe harbor applies "regardless of whether there are additional *uses* by defendant"); Amicus Br. 2, 12-14. But the cited passage merely explains that subjective intent is irrelevant even if a defendant engages in multiple uses. Pet. App. 18a. As noted above, there was only one "use" here. And in cases involving more than one "use," Federal Circuit precedent carefully analyzes each one separately. For example, in *Amgen*, the Federal Circuit assessed "each act of manufacture" and determined that 7 of the 21 manufactured batches were "reasonably related" to regulatory approval and fell within the safe harbor, while the remaining 14 were not. 944

F.3d at 1339-40 (Fed. Cir. 2019). Edwards' representation that the Federal Circuit just looks for one qualifying use and then excuses all additional commercial uses is not correct.

Rather than an alternative "***use***," Edwards is really arguing that Meril had an alternative commercial ***subjective intent*** or ***purpose*** for importing the devices, in addition to recruiting clinical trial investigators. But this argument is pure speculation because it is undisputed that there were no commercial activities at all—no display of the device to anyone, no sales, and no offers to sell. More importantly, the language of the statute is clear that the safe harbor inquiry focuses on ***uses***, not on purposes or intent. 35 U.S.C. § 271(e)(1) ("***uses*** reasonably related") (emphasis added).

AdvaMed's amicus brief and the dissent argue that courts should be required to determine a party's subjective intent or purpose before applying the safe harbor. Pet. App. 25a (intent is "crucial to determining compliance with the statute"); Amicus Br. 7 ("The safe harbor's text requires courts to assess the object or purpose of the otherwise-infringing act at issue."). But as Edwards admits, "the plain-text [safe harbor] analysis has nothing to do with motivation or subjective intent" because the text of the statute focuses on "uses," not intent or purpose. Pet. 24 n.9. Indeed, other sub-sections of Section 271 refer to subjective intent, purpose, or

knowledge, but not the safe harbor, confirming that Congress purposefully chose not to include it. *E.g.*, 35 U.S.C. § 271(c) ("knowing the same to be especially made or especially adapted for use in an infringement"); *id.* at 271(e)(2) ("if the purpose of such submission is to obtain" regulatory approval).

AdvaMed is also not correct that the word "for" in the statute requires that courts attempt to divine a party's "intended goal"—*i.e.*, its subjective intent. AdvaMed in fact admits—albeit in a footnote—that "[t]he correct test does not require an inquiry into the infringer's subjective intent." Amicus Br. 9 n.3. The sole case AdvaMed cites, *Oklahoma v. United States Department of Health & Human Services*, 107 F.4th 1209 (10th Cir. 2024), does not hold otherwise. That case says nothing about subjective intent, and instead merely confirms that the statutory language—"refer . . . for abortions"—requires a referral to be "for" an abortion rather than neutral medical counseling. *Id.* at 1222.

AdvaMed also relies on one reference to "intent" in *Merck* in which the Court explained that "[b]asic scientific research . . . performed without the intent to develop a particular drug . . . is surely not 'reasonably related to'" regulatory approval. Amicus Br. 8 (citing *Merck*, 545 U.S. at 205-06). But this dicta in *Merck* is simply discussing whether the research is even aimed at developing something that would require FDA approval. *Merck*

does not instruct that the safe harbor assess subjective intent. In fact, *Merck* explains that whether a use is "reasonably related" is an objective test that focuses on whether there is a "reasonable basis" for believing that the activities will lead to information that would be appropriate for submission to the FDA. *Merck*, 545 U.S. at 207.[10]

Finally, the petition and amicus assert that, by ignoring commercial "alternative" uses, the Federal Circuit "let[s] infringers off the hook" (Pet. 3, 19), "distorts the market for patented products" (*id.* at 3), and "undermines the patent bargain" (*id.*). But as explained above, the Federal Circuit does not ignore commercial "alternative" uses and certainly did not do so here, where Edwards' admissions and the undisputed facts confirm there was no commercial use.

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[10] This Court has interpreted "reasonably" or "reasonable" language as implying an objective test. *See, e.g.*, *Cnty. of L.A., Cal. v. Mendez*, 581 U.S. 420, 427 (2017) ("reasonableness" of use of force under the Fourth Amendment "is evaluated under an 'objective' inquiry"); *Bus. Guides, Inc. v. Chromatic Commc'ns Enters., Inc.*, 498 U.S. 533, 554 (1991) (alleged violations of Rule 11—which requires "an inquiry reasonable under the circumstances"—are subject to an "objective standard").

III. THIS CASE IS A POOR VEHICLE FOR ADDRESSING THE SAFE HARBOR

The petition identifies the question presented as whether "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 [commercial] uses***." Pet. (I) (emphasis added). But this case does not present this question because, as explained above, there were no non-regulatory commercial uses. Edwards admitted at least three times that Meril did not sell or offer to sell the devices in the U.S. Pet. App. 6a; C.A. App. 1429-1430; Oral Argument (Dec. 5, 2023) at 5:53-6:42. As explained above, Edwards' alleged "exhaustive evidence" of Meril's commercial use is Edwards' speculation that Meril might have shown the devices to medical conference attendees who were not potential clinical trial investigators if the simulator had not malfunctioned. But this did not actually happen and there were no other commercial uses because it is undisputed that the devices remained in a bag in a storage room. Pet. 12; Pet. App. 2a, 37a. The undisputed facts of this case simply do not present the question presented, which presupposes that there were "non-regulatory [commercial] uses."

And even if this Court finds that the question presented is correctly before the Court with this factual record, this case would be an exceptionally

poor vehicle for addressing the scope of the safe harbor statute. The facts here—two demonstration samples left in a bag in a storage room and never shown to anyone—are unique and unlikely to ever be repeated. As noted above, Edwards' alleged evidence of "commercial use" is pure speculation. In addition, Edwards lost based on the district court applying well-settled law to admissions that Edwards made following discovery, including that there were no commercial activities. This case is record-bound and will have the same result—no patent infringement liability—regardless of whether this Court undertakes review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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