***No. 22-1877***

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**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE FEDERAL CIRCUIT**

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EDWARDS LIFESCIENCES CORPORATION,
EDWARDS LIFESCIENCES LLC,
*Plaintiffs - Appellants,*

v.

MERIL LIFE SCIENCES PVT. LTD., MERIL, INC.,
*Defendants - Appellees.*

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Appeal from the United States District Court for the Northern District of California
Case No. 4:19-cv-06593-HSG, Judge Haywood S. Gilliam, Jr.

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# DEFENDANTS-APPELLEES' RESPONSE TO PETITION FOR REHEARING EN BANC

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August 5, 2024

# CERTIFICATE OF INTEREST

Counsel for Defendant-Appellees Meril Life Sciences Pvt. Ltd., and Meril, Inc. certify the following pursuant to Federal Circuit Rule 47.4:

1. The full name of every party or amicus represented by me is:

   Meril Life Sciences Pvt. Ltd., and Meril, Inc

2. The name the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   As indicated in item 1.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

   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

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

| Law Firm | Partners and Associates |
|---|---|
| Fenwick & West LLP | Jeffrey A. Ware<br>Michelle E. Irwin<br>Chieh Tung (no longer with Fenwick & West LLP)<br>Sapna S. Mehta (no longer with Fenwick & West LLP) |

5. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case.

None.

6. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees).

None/Not applicable.

Dated: August 5, 2024

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## INTRODUCTION

This case does not merit *en banc* review. Edwards acknowledges that the majority correctly applied longstanding Federal Circuit precedent to the undisputed facts. Displeased with the outcome, Edwards nonetheless urges this Court to unravel over 30 years of safe harbor precedent because that precedent allegedly excuses commercial "alternative uses" and ignores the word "solely" in Section 271(e)(1). Neither is correct.

The safe harbor applies "solely for uses reasonably related to the development and submission of information" to the FDA. Relying on the statutory language as well as Supreme Court and Federal Circuit precedent, the majority explained that "solely" modifies "for uses," meaning that "for each act of infringement the safe harbor is available only ["solely"] for acts or uses that bear a reasonable relation to the development and submission of information to the FDA." Op.10. This analysis does not ignore the word "solely."

Edwards 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." Dissent.1; Pet.12 ("solely for [regulatory] uses"). But that is putting "solely" in the wrong place. Section 271(e)(1) protects uses "***reasonably related*** to the development and submission of

information" to the FDA, not "solely" for "development and submission of information" to the FDA.

Edwards is also not correct that this Court's precedent "immuniz[es] infringing acts" by finding that "so long as *some* 'use' qualifies for protection, *everything* is protected—including non-qualifying, commercial, 'alternative uses.'" Pet.2. To the contrary, this Court's precedent carefully analyzes ***each*** "use" to determine if it is "reasonably related" to FDA approval. *See, e.g.*, *Amgen, Inc. v. Hospira, Inc*., 944 F.3d 1327 (Fed. Cir. 2019) (analyzing 21 "uses" and finding only 7 fell within the safe harbor). That is exactly what the majority did here.

Edwards argues the majority erred in rejecting its allegation that Meril had an alternative commercial ***purpose*** or ***intent*** when it imported the heart valves. Pet.7-10. But as the majority recognized, this allegation lacks factual support—it is undisputed that "no sales or offers for sale were made at TCTC." Op.11. More importantly, this Court has explained that the safe harbor inquiry focuses on "***uses***" as recited in the statute, not subjective "purposes" or "intent." 35 U.S.C. §271(e)(1) ("solely for ***uses***"). The majority correctly explained that Edwards' argument was contrary to the statutory language and a long line of cases from this Court. Op.8-10.

Finally, contrary to Edwards' representation, there are no "staggering economic…stakes" at issue here. Pet.22. This case is about two demo samples of

artificial heart valves that Meril kept in a bag in a storage room at a medical conference for a few days, that were never shown to anyone, and that were then transported out of the U.S. There is absolutely ***no harm*** to Edwards. Edwards filed suit to saddle Meril with legal fees to delay Meril's efforts to get FDA approval for a competing product—the exact opposite of what the safe harbor was intended to do. Edwards' petition has the same goal and lacks merit. It should be denied.

## BACKGROUND

### I. 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. Appx370. Myval is a "Class III" medical device subject to strict regulatory standards in the United States. Appx296; Appx370. Meril may not lawfully market or sell Myval in the U.S. without first receiving premarket approval from the FDA. 21 U.S.C. § 360c; Appx296; Appx370-371. To receive premarket 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. Appx296; Appx370.

It is undisputed that Meril's efforts to seek FDA approval spanned years leading up to the accused importation of two demonstration samples to TCTC in

September 2019. Appx1138; Appx1163. Meril first conducted preclinical investigations on cadavers and animals to determine whether Myval could be safely implanted in live human subjects. Appx295; Appx858; Appx1170; Appx1323-1326. In July 2019, Meril prepared a formal synopsis for a global clinical trial (Landmark Trial) to support FDA approval. Appx9; Appx1203-1216; Appx1139-1140; Appx1164.

It is undisputed that Meril began drafting a presubmission to the FDA for the Landmark Trial in August 2019 (Appx1145; Appx1011; Appx370-371; Appx510-511) and corresponded with FDA about regulatory approval in August and September 2019 (Appx371; Appx376-380; Appx382-386). Meril also engaged an FDA consultant on September 3, 2019 to help with the FDA presubmission. Appx388; Appx371; Appx390-395; Appx1029-1030; Appx1146-1149. At the same time, Meril was actively enlisting clinical trial investigators to support FDA approval, including foreign and U.S. clinicians. Appx782; Appx719-727; Appx547. It is undisputed that in August 2019, Meril made plans to hold an investigator meeting at TCTC to recruit clinical trial investigators for the Landmark Trial. Appx719.

## II. 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.

Appx371-373; Appx296; Appx1154. TCTC is not a buyer-seller platform. Instead, it is undisputed that TCTC is an ideal scientific forum for medical device manufacturers like Meril to seek out clinicians as potential investigators. *Id.*; Appx517. Meril attended TCTC 2019 in San Francisco to do just that. Appx296; Appx371-372; Appx519.

Before TCTC, Meril contacted clinicians, inviting them to an investigator meeting during the conference to discuss the Landmark Trial. Appx571; Appx774-783; Appx961. Meril created a flyer and sent an email to conference attendees to let them know Meril would offer "hands-on and VR sessions on Meril's TAVR [Transcatheter Aortic Valve Replacement] system." Appx372; Appx890-893; Appx1112. These virtual reality (VR) sessions use a simulator that allows clinicians to mimic implanting a Myval valve in a patient using a TAVR procedure. Appx1167-1168, Appx1176. 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. Appx1110; Appx1167-1169, Appx1176.

Nilay Lad, a Meril employee, traveled to San Francisco on September 24, 2019 to attend TCTC and hand-carried two non-commercial, demo Myval heart valves on his flight. Appx372. The Myval samples were in a bag and accompanied by a written declaration making clear the devices would only be used

for demonstration with the simulator and "not used for any sales purpose." Appx402; Appx372.

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, including Dr. Ramesh Daggubati, the associate chief of Cardiology at NYU Winthrop Hospital. Appx373; Appx1218; Appx1220-1223. It is also undisputed that Meril held its planned investigator meeting to enlist clinical trial investigators. Appx1141; Appx1154. 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. Appx373-374; Appx1110. Thus, Meril did not show either of its two physical Myval samples during TCTC. Appx374. The two samples remained in a bag in a storage room until they were carried to Europe by another Meril employee. *Id.*; Appx296. It is undisputed that Meril did not sell or offer for sale any Myval devices at the conference. Appx1429-1430; Appx373; Appx1177-1178; Appx1107-1108; Oral Argument (Dec. 5, 2023) at 5:53-6:42.[1]

After TCTC, Meril followed up with the clinical investigators it had met with and continued to seek their input on the Landmark Trial. Appx1218; Appx1220-1223. Meril also worked to finalize its FDA presubmission, which

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

Meril submitted on December 4, 2019. Appx1194-1195, Appx1198-1200; Appx445-495 (*see, e.g.*, Appx459). The FDA responded to Meril's presubmission in February 2020. Appx500-502. Meril provided a supplemental presubmission in May 2020. Appx1225-1241. These facts are undisputed.

## III. 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. Appx640. Edwards filed suit just two weeks after the conference, on October 14, 2019. Appx27; Appx226-227, Appx242-248.

After allowing Edwards to take extensive discovery (Appx34, Appx36; Appx1093-1097), the district court granted Meril's motion for summary judgment. Appx1-20. Applying precedent from the Supreme Court and this Court, the district court found no genuine dispute of material fact that the sole alleged "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 TCT conference, including "(1) preparing a formal clinical trial

synopsis for its Landmark Trial, [Appx1203-1216]; (2) preparing a draft presubmission to seek FDA input on its clinical trial, [Appx1145]; (3) communicating with the FDA regarding Meril's proposed clinical study and its presubmission, [Appx376-380; Appx382-386]; and (4) hiring an FDA consultant to help with the FDA presubmission. [Appx371]; [Appx1146-1147]." Appx9. The district court also found it undisputed that TCT "was attended by a large number of potential clinical trial investigators" (Appx10) and that Meril "sought out," and met with, "potential clinical researchers at the…[]TCT Conference[]" (Appx4). And the district court found that—despite extensive discovery—it was undisputed that "Meril did not sell or offer to sell its medical device at the medical conference." Appx10; Appx1429-1430.

## IV. THE PANEL DECISION

The majority of the panel, Judges Stoll and Cunningham, affirmed. Op.1-17. The majority recognized it was undisputed that (1) Meril had taken significant steps toward obtaining FDA approval for Myval before TCTC (*id.*3-4, 11), (2) TCTC is attended by a large number of potential clinical trial investigators (*id*.11-12), (3) Meril met with potential clinical trial investigators at TCTC (*id.*4-5), (4) Meril provided a premarket approval submission to the FDA in December 2019 after its meetings at the conference and continued to communicate with FDA (*id.*6, 11), and (5) "no sales or offers for sale [of Myval] were made at TCTC" (i*d*.11).

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.*10. 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)]. It is not that the use must only be reasonably related to the development and submission of information to the FDA. *See, e.g.*, *Amgen*, 944 F.3d at 1339.

*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.*11-12. The majority followed a long line of cases from this Court 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) ("demonstrating 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 Federal Circuit precedent in rejecting Edwards' argument that the district court erred in not considering Meril's alleged "commercial purposes," explaining that "underlying purposes" and "intent or alternative uses" are not relevant "as long as the use is reasonably related to FDA approval." Op.8-11 (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*, 944 F.3d at 1339.

Judge Lourie dissented. The dissent acknowledged that the district court "reasonably followed" this Court's precedent. Dissent.2. But it advocated for revisiting that precedent and 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*.1.

## ARGUMENT

Both Edwards and the dissent acknowledge that the majority correctly applied this Court's safe harbor case law to the undisputed facts of this case. Yet

Edwards asks this Court to overturn ***over 30 years*** of safe harbor case law because the majority purportedly excused commercial "alternative uses" and ignored the word "solely" in the statute. As explained below, Edwards is wrong on all accounts and its petition should be denied.

## I. THIS CASE INVOLVES ONLY ONE "USE" UNDER THE SAFE HARBOR STATUTE.

Edwards' argument that the majority erred by excusing commercial "alternative uses" is not correct. Pet.2, 9-10, 12-14. Consistent with the undisputed facts, the majority found only one "use"—the "importation of two…samples of [Meril's] transcatheter heart valves to a [TCTC] medical conference." Op.7. The majority then correctly analyzed whether that one use was "reasonably related" to regulatory approval, and concluded that it was, again based on the undisputed facts. *Id.*11-12. There was no other use, let alone a commercial use. "[I]t is undisputed that Meril *did not offer for sale or sell* the Myval System to anyone at TCTC." *Id.*5 (emphasis added). Indeed, Edwards' counsel admitted this during oral argument three times. Appx1429-1430; Oral Argument (Dec. 5, 2023) at 5:53-6:42.

Rather than an alternative "***use***," Edwards is really arguing that Meril had an alternative commercial ***intent*** or ***purpose*** for importing the devices, in addition to recruiting clinical trial investigators. Pet.9-10. Edwards' 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). Indeed, Congress could have drafted the statute to recite "purposes" or "intent," but it did not. And for good reason. It is impossible to know a party's subjective intent or purpose.

As the majority correctly pointed out, numerous panels of this Court have addressed Edwards' argument and have rejected it. In *Abtox*, the patentee made the exact same argument that Edwards makes here—that defendant's "actual purpose" in conducting tests on its device was commercial, not to secure FDA approval. 122 F.3d at 1027. The *Abtox* panel explained that the language of Section 271(e)(1) makes clear that the inquiry focuses on "***uses***" and requires that "the otherwise infringing act be performed 'solely for *uses* reasonably related to' FDA approval." *Id*. at 1030 (emphasis in original). The statute "does not look to the underlying purposes or attendant consequences of the activity" and the defendant's "intent or alternative uses are irrelevant to its qualification to invoke the section 271(e)(1) shield." *Id*.

In *Momenta*, a different panel re-emphasized that Section 271(e)(1) "does not look to the underlying purposes or attendant consequences of the activity." 809 F.3d at 621. And in *Amgen*, yet another panel explained that a defendant's

"additional underlying purposes do not matter as long as…the manufacture of any given batch of drug substance [the "***use***"] was reasonably related to developing information for FDA submission." 944 F.3d at 1339; *see also Intermedics*, 1993 WL 87405, at *5 ("Reliance on section 271(e)(1) is not precluded by manifestation of an intent to commercialize…."). Contrary to Edwards' representation, this issue has not "split multiple panels." In fact, multiple different panels have addressed Edwards' exact argument here and all have unanimously rejected it.[2]

## II. THE PANEL AND THIS COURT'S PRECEDENT CORRECTLY INTERPRET "SOLELY."

Edwards' argument that the majority and this Court's precedent ignore the word "solely" is also wrong. Section 271(e)(1) applies "*solely* for uses reasonably related to the development and submission of information" to the FDA. The majority 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 information to the FDA." Op.10. The majority's interpretation is consistent with the language of the statute and canons of statutory construction. *See* Antonin Scalia & Bryan A.

[2] Judge Wallach wrote a dissent in *Momenta* that addressed the majority's opinion regarding Section 271(g), but he concurred with the majority opinion on Section 271(e)(1).

Garner, *Reading Law: The Interpretation of Legal Texts* 152 (2012) (reciting canon that a modifier "normally applies only to the nearest reasonable referent").[3]

The majority's interpretation is consistent with the legislative history. The legislative history simply confirms that Congress enacted Section 271(e)(1) in response to *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), a pre-safe harbor case holding that pharmaceutical testing to support FDA approval was not insulated from patent infringement liability. H.R. Rep. No. 98-857, pt. 2, at 27-30 (1984). Nothing in the legislative history supports or even mentions Edwards' or the dissent's new interpretation of the statute.[4] The majority's interpretation is also consistent with this Court's precedent and Supreme Court case law. *See, e.g., Amgen*, 944 F.3d at 1339 ("The relevant inquiry [is]…whether each act of manufacture was for uses reasonably related to submitting information to the FDA."); *Merck KGaA*, 545 U.S. at 202 (describing safe harbor as providing a "wide berth" that "extends to all uses of patented inventions that are reasonably related to the…submission of *any* information under the FDCA").

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[3] *See, e.g.*, *Koninklijke Philips N.V. v. Quectel Wireless Sols. Co.*, No. 2023-1221, 2024 WL 3042238, at *3 (Fed. Cir. June 18, 2024) (reciting canon and collecting cases).

[4] The dissent also argues that "[t]he legislative history makes clear that the exemption 'does not permit the commercial sale of a patented drug by a party using the drug to develop information'" for FDA approval. Dissent.4. This is irrelevant here, as it is undisputed that there was no sale or offer for sale.

Edwards argues that Section 271(e)(1) should be reinterpreted such that it applies "*solely* for regulatory uses." Pet.12. But Edwards puts "solely" in the wrong place. Section 271(e)(1) does not say a use must "solely" be for development and submission of information to the FDA. It says the safe harbor extends "solely" to "uses" that are "*reasonably related to* the development and submission of information" to the FDA. The dissent likewise suggests that the statute "creates a safe harbor *only* for uses, sales, and importations that *solely* are for…development of information for the FDA." Dissent.1 (emphases added); Pet.10. But this misstates the statute and in effect 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. *Id.* Edwards and the dissent violate multiple canons of statutory construction, including the nearest-referent rule discussed above. Their interpretation also would render the words "reasonably related" meaningless. *Hibbs v. Winn*, 542 U.S. 88, 101 (2004) (a "statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant").

Edwards' argument that the majority required Edwards to "prove the challenged uses were *solely commercial* in nature" is wrong. Pet.12. The majority only refers to ***Edwards' argument*** that the Myval devices "were imported exclusively for use as commercial sales tools" and explains that "the inferences

that Edwards asks this court to draw are not reasonably drawn from the evidence." Op.12-13.

## III. EDWARDS' ARGUMENTS DO NOT JUSTIFY *EN BANC* REVIEW.

None of Edwards' arguments justifies *en banc* review. The panel decision creates no new law and admittedly correctly applies decades of this Court's safe harbor precedent to the undisputed facts. As explained above, neither the majority nor this Court's precedent ignores the word "solely" or immunizes commercial "alternative uses." Edwards' argument that the safe harbor inquiry should focus on subjective purposes or intent is contrary to the statutory language ("solely for ***uses***"). The dissent and Edwards' suggestion to undo 30 years of settled law to rewrite Section 271(e)(1) to apply to acts that "***solely*** are for…development of information for the FDA" (Pet.12; Dissent.1) is also contrary to the statutory language ("***reasonably related*** to the development and submission of information" for the FDA).

Edwards' representation that this issue has "split multiple panels of this Circuit" and "divided district courts" is wrong. Edwards tellingly does not identify any "divided district courts." The Supreme Court and **all** panels of this Court have interpreted Section 271(e)(1) exactly the same way—to give effect to the word "solely." *See* Op.7-8 (citing *Merck KGaA*, 545 U.S. 193). **All** panels of this Court that have addressed Edwards' argument that the safe harbor inquiry should focus

on subjective purposes and intent have unanimously rejected it. *See Abtox*, 122 F.3d 1019; *Momenta*, 809 F.3d 610; *Amgen*, 944 F.3d 1327; *Intermedics*, 1993 WL 87405. And **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 found this activity protected by the safe harbor. *Telectronics*, 982 F.2d 1520; *Intermedics*, 1993 WL 87405; *Chartex*, 1993 WL 306169.

Edwards is also not correct that this case or the issues Edwards raises here have "garnered close attention from experts." Pet.18-21, 3, 13. The quote from Findley is directed to the Supreme Court's decisions in *Merck KGaA* (safe harbor applies to pre-clinical activities) and *Eli Lilly* (safe harbor applies to medical devices) and decisions from this Court addressing post-FDA approval activities—not the issues here. *Id.*20. Similarly, the quote from Server includes a footnote making clear that it is specifically referring to this Court's decisions addressing post-FDA approval activities. *Id.* The Stark law review comment appears to be written by a law student and is from 1994. It cannot possibly address *Abtox*, *Momenta*, *Amgen*, or the numerous other cases directed to the issues here that came after. The Crouch article merely summarizes the opinion, agrees that the majority followed precedent, and notes the dissent's position. And while the National Law

Review article states that the safe harbor may be "wider than many believed," even Edwards acknowledges that the majority decision applies established law.

The facts of this case—two devices left in a bag—are unique and unlikely to ever be repeated. The undisputed facts show that there were no commercial "alternative uses." And there was ***no harm*** to Edwards.

## CONCLUSION

Edwards' petition for *en banc* review should be denied.

Dated: August 5, 2024

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

1. This brief complies with the type volume limitation of Federal Circuit Rule 35(e)(2). This brief contains 3,875 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b).

2. The brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Civil Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Office Word Version 2010 in 14-point Times New Roman.

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Respectfully submitted,

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