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 OF ADVANCED MEDICAL TECHNOLOGY ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

The Advanced Medical Technology Association (AdvaMed) is the world's largest medical technology association representing device, diagnostics, and digital technology manufacturers that are transforming healthcare through earlier disease detection, less invasive medical procedures, and more effective treatments. Its 400-plus member companies span every field of medical science, and range from cutting-edge startups to multinational manufacturers. AdvaMed's members are dedicated to advancing clinician and patient access to safe, effective medical technologies. They also require a well-functioning patent system to continue to innovate in ways that save lives. AdvaMed thus has a keen interest in ensuring that the Hatch-Waxman Act's safe harbor is given it proper scope.

INTRODUCTION AND SUMMARY OF ARGUMENT

In the Hatch-Waxman Act, Congress established a limited safe harbor that shields otherwise-infringing

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[1] No counsel for a party authored this brief, in whole or in part, and no counsel for a party or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity other than *amicus curiae* or its counsel made a monetary contribution to this brief's preparation or submission. *Amicus* provided the parties timely notice of its intent to file this brief pursuant to Rule 37.2.

conduct undertaken "solely" for the purpose of obtaining regulatory approval. 35 U.S.C. § 271(e)(1). The Federal Circuit has turned that narrow exception on its head, holding that the safe harbor protects all infringing acts—including those taken for "alternative uses" wholly unrelated to regulatory approval—so long as the infringer can show that the infringing act was *also* related, however tangentially, to the regulatory approval process. Pet. App. 9a. Thus, the court held that Meril's infringing importation of patented transcatheter heart valve systems for demonstration at an industry trade show fell within the safe harbor, even though Meril imported the devices for a variety of commercial, non-regulatory purposes. The court of appeals thus read "solely" out of the statute—and replaced it with "partially."

With that core textual error at the foundation of the Federal Circuit's decision, the court continued to make a hash of the safe harbor in related ways. First, the court misframed the basic inquiry as whether Meril's "importation" of the patented transcatheter devices was "reasonably related" to the regulatory approval process, even though the statute requires the subsequent "uses" of those devices to be "reasonably related" to regulatory approval, not the infringing act of importation (which must be "solely" for such uses). The court then compounded that error when it assessed the "reasonably related" standard exclusively against back-office regulatory actions at Meril—without considering Meril's *commercial* "use" of the patented devices at the trade show. Finally, the Federal Circuit declared that an infringer's purpose

for the infringing act—even if wholly commercial—is simply irrelevant to the applicability of the safe harbor, contrary to both the text of the statute and this Court's precedent.

The question presented is exceptionally important. The Hatch-Waxman Act struck a delicate balance between the interests of innovator and generic companies, and the safe harbor is an integral part of that compromise. The decision below distorts that balance, converting Congress's narrow exception into an easily exploited loophole for bad-faith actors. And it will have profound consequences for the medical technology industry, which relies on clear rules and a fair patent system to incentivize the development of life-changing technologies. Judge Lourie is thus exactly right that the scope of the safe harbor urgently needs to be "clarified." Pet. App. 30a (Lourie, J., dissenting). This Court should grant review to do just that.

ARGUMENT

I. The Federal Circuit Has Rewritten The Safe Harbor's Text

Section 271(e)(1) provides 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 under a Federal law[.]" As petitioners correctly explain (and we will not rehash here), the court of appeals' interpretation of that provision has erased the word "solely" from the safe harbor altogether. Pet. 18-24. That core mistake is the key error undermining the statute and frustrating

the balance that Congress struck in the Act. The Federal Circuit's misreading threatens great "mischief" in the industry, and it warrants this Court's intervention. Pet. App. 30a (Lourie, J., dissenting).

And that critical, baseline misreading also led the Court to make several related errors—all of which likewise sow confusion, promote abuse, and undermine Congress's carefully crafted regulatory scheme. This Court can rectify all of the Federal Circuit's related errors by granting review and answering "no" to the question presented.

1. The Federal Circuit's opinion went off track almost immediately. It framed the question presented under the safe harbor as whether Meril's "*importation*" of the patented transcatheter devices "was reasonably related" to the regulatory process. See Pet. App. 7a (emphasis added); see also *id.* at 52a n.7 (district court asking whether the "*infringing acts* were reasonably related to FDA approval") (emphasis added). That is the wrong question.

The safe harbor applies to infringing acts undertaken "solely for uses reasonably related" to the regulatory process. 35 U.S.C. § 271(e)(1). Under the statute's text, then, it is the "uses" of the patented invention that are afforded the latitude of being "reasonably related" to regulatory approval—not the infringing act (in this case, importation). See *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (the safe harbor "extends to all *uses* of patented inventions that are reasonably related" to the regulatory process) (emphasis added).

As the text confirms, however, the infringing acts themselves are afforded no such leeway under the safe harbor. Those acts—the making, selling, importing of the patented invention—must be "solely" for uses related to the regulatory process. 35 U.S.C. § 271(e)(1). Yet the court of appeals did not ask whether Meril's infringing conduct was "solely" for such uses, as the statute commands. Instead, it asked whether Meril's "importation" was "reasonably related" to the regulatory process—thus jumping over "solely" altogether. Pet. App. 7a (internal quotation marks omitted).

Unsurprisingly, by asking an inapposite question, the court of appeals gave an inapposite answer. It went on to hold that Meril's "*importation* and transportation of the" infringing devices was "'reasonably related' to FDA approval." Pet. App. 12a-13a (emphasis added) (quoting *Telectronic Pacing Sys., Inc.* v. *Ventritex, Inc.*, 982 F.2d 1520, 1523 (Fed. Cir. 1992)). That is because, the court explained, the importation was "another step in the right direction 'on the road to regulatory approval.'" *Id.* at 12a (quoting *Merck*, 545 U.S. at 207). Perhaps a "step in the right direction" is enough, in some cases, to make an infringer's subsequent "uses" of a patented invention "reasonably related" to the regulatory approval process. But it's not enough to make the infringing act (here, importation) "solely" for such uses—particularly where, as here, non-regulatory uses are also in the mix.

The court of appeals thus improperly widened the scope of the safe harbor at the outset, replacing "solely" with "reasonably related" as the standard

against which to judge the infringing act. As a result, lower courts will now ask only whether the infringing conduct, *writ large*, is "reasonably related" to the regulatory process—rather than whether that conduct was "solely" for uses reasonably related to regulatory approval, as the statute requires.

2. In addition to asking the wrong question, the court of appeals looked at the wrong facts. It held that Meril's infringing conduct was protected by the safe harbor in light of "undisputed * * * material facts" showing that "Meril had taken steps toward obtaining FDA approval for its transcatheter heart valves"—namely, "preparing a formal clinical trial synopsis"; "preparing a draft presubmission to seek FDA input"; "hiring an FDA consultant to help with the FDA presubmission"; and "communicating with the FDA." Pet. App. 12a (internal quotation marks omitted).

Those back-office activities may show that Meril was in fact planning to seek premarket approval to sell devices in the United States. But they say nothing about the relevant question: whether Meril imported the devices at issue solely for such regulatory uses. The court of appeals simply identified *some* activities at Meril's corporate offices, and then stopped there—holding that it was enough that those activities related to regulatory approval, even if Meril's other activities did not. But the court could not determine if Meril's uses were "solely" for regulatory approval without examining whether all of its uses were relevant uses, as Section 271(e)(1) requires.

That error unmoors the safe harbor from its statutory text and rips an entire-company-sized hole

through it. Under the Federal Circuit's rule, there no longer needs to be an exclusive nexus between the use of a patented invention and the regulatory process; *all* regulatory activity at the company now goes in to the mix—and immunizes non-regulatory, commercial uses. If that is indeed the test under the safe harbor, it's hard to imagine what won't pass.

3. The Federal Circuit made things still worse when, reaffirming its precedents, it declared that its "interpretation of § 271(e)(1) applies the safe harbor regardless of the defendant's intent or purpose behind the otherwise infringing act." Pet. App. 18a; see *AbTox, Inc.* v. *Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997) (holding that the statue "does not look to the underling purposes" of the infringer's activity). The court of appeals thus affirmed the district court's conclusion that, because an infringer's "underlying purposes are not relevant to the safe harbor inquiry," Meril's alleged "commercial intent" for importing the transcatheter devices was beside the point. Pet. App. 52a & n.7; see *id.* at 18a. The Federal Circuit's position is grammatically flawed and contravenes this Court's decision in *Merck*.

The safe harbor's text requires courts to assess the object or purpose of the otherwise-infringing act at issue. That is because it shields only those infringing acts that are "for" uses reasonably related to the regulatory approval process. 35 U.S.C. § 271(e)(1). The preposition "for" is "used as a function word to indicate purpose," "an intended goal," or "the object" of an activity. Merriam-Webster Dictionary, https://tinyurl.com/5ddt4e6u; see also *Oklahoma* v. *United States Dep't of Health & Hum. Servs.*, 107

F.4th 1209, 1222 (10th Cir. 2024) ("The preposition *for* means *because of* or *on account of*") (citing 6 Oxford English Dictionary 25 (2d ed. 1989)). Accordingly, courts "generally consider the preposition *for* to link conduct to a particular purpose." *Oklahoma*, 107 F.4th at 1222 (citing cases). The safe harbor's use of "for" thus requires that the infringing act be undertaken for the sole purpose of engaging in uses related to the regulatory approval process—and not for the purpose of drumming up commercial sales.

This Court has recognized as much. In *Merck*, the Court explained that "[b]asic scientific research on a particular compound, performed *without the intent* to develop a particular drug or a *reasonable belief* that the compound will cause the sort of physiological effect the researcher intends to induce, is surely not 'reasonably related to the development and submission of information' to the FDA." *Merck*, 545 U.S. at 205-206 (emphasis added); see *Momenta Pharms., Inc.* v. *Amphastar Pharms., Inc.*, 686 F.3d 1348, 1374 (Fed. Cir. 2012) (Rader, C.J., dissenting) ("*Merck* said that as long as an activity was *intended* for submission to obtain approval, then § 271(e)(1) applies even if the information is not actually submitted."). Thus, as Judge Lourie explained below, "[t]he purpose of the infringing act is meaningful and important to determining the safe harbor." Pet. App. 20a (Lourie, J., dissenting).[2]

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[2] The legislative history further demonstrates that the safe harbor looks to the purpose of the infringing conduct: "The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the *purpose* is to prepare for commercial activity which will

The court of appeals' contrary view caused it to discount evidence showing that Meril's purpose for importing the infringing devices was commercial, and thus not solely to generate data for regulatory review: In advance of the trade conference Meril invited registrants to try out the devices first-hand; touted that the devices were approved for European sales; and informed registrants where they could purchase the devices abroad. See Pet. 10-12. The Federal Circuit's error is bound to confuse litigants and courts. "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 Federal Circuit precedent "instructs him or her to turn a blind eye to a party's intent or alternative uses?" Pet. App. 25a. The court of appeals has no answer.[3]

II. The Decision Below Distorts The Safe Harbor And Fosters Uncertainty And Gamesmanship That Will Stifle Innovation

1. The Hatch-Waxman Act reshaped the landscape for innovator and generic manufacturers in the

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begin after a valid patent expires, is not a patent infringement." H.R. Rep. No. 98-857, pt. 1, at 45, 1984 U.S.C.C.A.N. 2647, 2678 (1984) (emphasis added).

[3] The correct test does not require an inquiry into the infringer's subjective intent. Rather, it asks whether the infringing conduct was (solely) "for" a regulatory purpose (that is, for uses related to regulatory approval), or "for" a non-regulatory purpose (*e.g.*, for commercial uses). Here, Meril's infringement was undertaken at least in part "for" the non-regulatory purpose of attracting commercial interest in the transcatheter devices by conference attendees.

pharmaceutical and medical device industries. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, Tit. II, § 202, 98 Stat. 1585, 1603. The Act was "designed to respond to two unintended distortions of the [] patent term produced by the requirement that certain products," including pharmaceuticals and medical devices, "must receive premarket regulatory approval." *Eli Lilly & Co.* v. *Medronic, Inc.*, 496 U.S. 661, 669 (1990).[4] First, the holder of a patent relating to such products would "not be able to reap any financial rewards during the early years of the term," as that period was consumed by product testing and application procedures necessary to obtain regulatory approval—all while the "clock" on the patent term was running. *Ibid.* Second, would-be generic competitors experienced delay in market entry, since they could not conduct the (infringing) tests necessary for regulatory approval until the expiration of the patent's term. *Id.* at 670.

"The Hatch-Waxman Act remedied both distortions, striking a careful balance that is embodied in the statute." *Classen Immunotherapies, Inc.* v. *Biogen IDEC*, 659 F.3d 1057, 1071 (Fed. Cir. 2011). For innovator companies, the Act provided a patent extension for products that were subject to lengthy regulatory delays. 35 U.S.C. § 156(f). And for generic companies, the Act created the safe harbor to allow the copier, "prior to the expiration of a patent, to engage in otherwise infringing activities necessary

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[4] In *Eli Lilly* the Court held that the safe harbor also applies to certain medical devices, and not just pharmaceuticals. 496 U.S. at 672.

to obtain regulatory approval." *Eli Lilly*, 496 U.S. at 671.

"The Hatch-Waxman Act was accordingly a compromise between two competing sets of interests: those of innovative drug manufacturers, who had seen their effective patent terms shortened by the testing and regulatory processes; and those of generic drug manufacturers, whose entry into the market upon expiration of the innovator's patents had been delayed by similar regulatory requirements." *Warner-Lambert Co.* v. *Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003); see *AbTox*, 122 F.3d at 1029 (the "Act supplied tradeoff benefits to competing segments of the pharmaceutical industry).[5] Section 271's safe harbor is an essential part of that compromise. See *Momenta*, 686 F.3d at 1354.

2. The decision below upends the compromise established by Congress and makes the patent system ripe for abuse.

Section 271(e)(1) permits otherwise-infringing activity "solely for" regulatory uses. That narrow exception—when applied as written—advances Congress's goal of allowing generic drug and device manufacturers to engage in the experimentation

[5] "The legislative history of the Hatch-Waxman Act demonstrates that the Act's readjustment of the scope of the patent right for pharmaceutical products represented the culmination of a 'long . . . effort to combine and balance these two objectives' of innovation and cost." *Biotechnology Indus. Org.* v. *District of Columbia*, 505 F.3d 1343, 1347 (Fed. Cir. 2007) (per curiam) (Gajarsa, J., concurring in the denial of the petition for rehearing en banc) (quoting 130 Congr. Rec. 23058).

necessary for regulatory approval before the inventor's patent expires, so they can hit the ground running with commercial activities "*after* [the] valid patent expires." *Classen*, 659 F.3d at 1071 (internal quotation marks omitted and emphasis added). But the decision below expands the safe harbor to protect infringing conduct undertaken for "alternative" uses that are not related to regulatory approval. That flouts the Safe Harbor's text while serving none of Hatch-Waxman's legitimate ends. See H.R. Rep. No. 98-857, pt. 2, at 30, 1984 U.S.C.C.A.N. 2686, 2714 (under the safe harbor, "*all* that the generic can do is test the drug for purposes of submitting data to the FDA") (emphasis added).

"As with other problems of interpreting the intent of Congress in fashioning various details of this legislative compromise, the wisest course is to adhere closely to what Congress has written." *Rodriguez* v. *Compass Shipping Co.*, 451 U.S. 596, 617 (1981). The Federal Circuit has strayed beyond what Congress has written, in multiple ways: by writing "solely" out of the statute; by wrongly reading "reasonably related" to modify the infringing act, rather than "uses"; by eschewing the required "sole" nexus between the infringer's conduct and the regulatory approval process; and by disregarding any evidence of the infringer's commercial purpose. The decision below thus "disturb[s] this careful balance of interests" embodied in the Hatch-Waxman Act. *United States* v. *Students Challenging Regul. Agency Procs. (SCRAP)*, 412 U.S. 669, 697 (1973).

That is bad enough. But it gets worse. The decision below gives non-innovator drug and medical

technology competitors *carte blanche* to intentionally infringe a patent, so long as they make some *de minimis* effort to pursue regulatory approval. That's because, according to the Federal Circuit, "alternative" commercial "uses" do not matter; an infringer's commercial purpose does not matter; and back-office regulatory activity (somehow) satisfies the "reasonably related" standard.

Consider the low bar here. Meril was able to ensconce itself in the safe harbor by pointing to some regulatory doings at its office—while the Federal Circuit expressly discounted Meril's alleged commercial purpose for importing the patented devices, and its "alternative uses," as irrelevant. Pet. App. 24a (Lourie, J., dissenting) (quoting Pet. App. 52a n.7). That toothless standard will only "create future mischief," encouraging bad-faith actors to seek pretextual "regulatory'" uses of an infringing drug or device so that they can simultaneously employ any other non-regulatory uses that they wish. See Pet. App. 18a (holding that an infringer's intent is irrelevant under the safe harbor, "regardless of whether there are additional *uses* by defendant").

3. Such an uncertain and easily abused system is untenable for the medical technology industry, which needs clear, well-functioning rules to incentivize the development of life-changing technologies.

Patents "exist to promote creation." *Ass'n for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013). The medical device industry has created—and created a lot. Advanced medical devices and diagnostics have contributed to a five-year increase in average life expectancy in the United

States between 1980 and 2019.[6] In 2019, the medical technology industry was responsible for $148.7 billion in sales and revenues in the United States[7]—an amount projected to cross the $300 billion mark by 2030.[8] And that's just the United States, which makes up 40% of the global market and is a net exporter of medical technology abroad.[9] Notably, prices for medical devices are growing more slowly than the Consumer Price Index, thus keeping healthcare costs down while providing real value to patients.[10]

If the growth of the medical technology industry continues, it will be fueled by remarkable, patent-based breakthroughs in burgeoning areas like wearable devices, nanotechnology, artificial intelligence, and robotics. But to reach its full potential—and deliver life-saving technologies to medical professionals and patients—the industry needs clear and fair rules for all participants. "[T]he encouragement of investment-based risk is the fundamental purpose of the patent" system, which incentivizes innovative medical device companies and

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[6] AdvaMed, Medical Device Industry Facts, https://tinyurl.com/4tcd5prk.

[7] AdvaMed, The Economic Impact of the Medical Technology Industry, at 1 (2021), https://tinyurl.com/49khbken.

[8] KPMG International, Medical Devices 2030, at 16 (2018), https://tinyurl.com/2hd69pk5.

[9] AdvaMed, Medical Device Industry Facts, *supra*.

[10] AdvaMed, Estimates of Medical Device Spending in the United States, at 3 (June 2021), https://tinyurl.com/mt9y8v55.

other inventors to "continue costly development efforts." *Sanofi-Synthelabo, Inc.* v. *Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (internal quotation marks omitted). And the medical technology field in particular is a research-and-development driven industry that invests billions in pursuit of medical breakthroughs.[11] Often, those innovator companies are start-ups tied to a single technological innovation, the success of which depends entirely on intellectual property. Such companies should not have their property rights and considerable investment usurped by judicial revision of the patent system.

To the contrary, this Court has instructed that "courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 724 (2002). But that is just what the Federal Circuit has done here for medical technology companies, which have made considerable investments in research and technology based on the promise that that the safe harbor—like all the patent laws—will be enforced as written by Congress. See *id.* at 731 (inventors "rely on the promise of the law to bring the invention forth").

At a minimum, the decision below sows confusion over the proper scope of the safe harbor—undermining the "clarity [that] is essential to promote progress" and "investment in innovation." *Festo*, 535 U.S. at 730 (2002). That uncertainty harms not only innovator companies, but also good-faith generic

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[11] Ernst & Young, Pulse of the MedTech Industry Report, at 9 (2024), https://tinyurl.com/3kfvwj83.

competitors. Those companies, too, need to know what is allowed under the safe harbor and what isn't, and the uncertainty created by the decision below will needlessly foster expensive patent litigation that clogs dockets and threatens innovation. Generic manufacturers are also are entitled to rely on the (correctly interpreted) safe harbor to conduct experimental research for legitimate regulatory purposes—without competition from bad-faith actors seeking to exploit the loophole created by the Federal Circuit. This Court's guidance is urgently needed to "clarify the proper scope" of Section 271(e)(1). *Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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