No. 19-1061

In the
Supreme Court of the United States

DR. REDDY'S LABORATORIES, LTD.
AND DR. REDDY'S LABORATORIES, INC.,
Petitioners,

v.

ELI LILLY & COMPANY,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF

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Only this Court can resolve what it meant by the "tangential" exception to prosecution history estoppel announced in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002). It is unclear where that exception in *Festo* came from. Pet. 8-10; AAM-Amicus 11-12. And for eighteen years, in case after case, beginning with the remand in *Festo* itself, the judges of the Federal Circuit have struggled to make sense of it and divided over its meaning. Pet. 17-24. Sometimes the Federal Circuit applies the "tangential" exception by asking why the patentee narrowed its claims *in the way it did*. Other times it only asks why the patentee narrowed its claims *at all*.

This case starkly presents that methodological divide and the difference it makes. Lilly narrowed its claims from "antifolate" to "pemetrexed disodium." Why did Lilly choose pemetrexed *disodium*, rather than a broader term like "pemetrexed" that would have literally encompassed Petitioners' product? The prosecution record has no explanation that could have put the public on notice, and Lilly has no explanation even now. Lilly's opposition argues that no explanation is necessary, and that patent owners should be able to argue in litigation that some of the claim scope they surrendered in prosecution was simply unnecessary. Lilly drives that point home in simple terms when it embraces Hospira's fruit hypothetical. In Lilly's view, Lilly need not explain the choice of "disodium," and the hypothetical patentee need not explain "Red Delicious." BIO 18-19 & n.4. According to Lilly, all that matters is what (purportedly) motivated the patentee to narrow the

claims at all, not *why they were narrowed in the way they were*. The parties' disagreement on this point is not "factbound"; it is methodological and clearly presented here.

The Federal Circuit's approach is wrong and allows patentees to manipulate the scope of their patents when convenient: narrowing claims in prosecution to get a patent, then broadening those claims in litigation to cover a competitor's product. That bait-and-switch approach is a long-recognized abuse of the patent system. *White v. Dunbar*, 119 U.S. 47, 51 (1886) (patent is not "like a nose of wax, which may be turned and twisted in any direction"); *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014) (patentees have "incentives to inject ambiguity into their claims"). For more than 100 years, prosecution history estoppel has been a vital check on such abuse. Pet.6-7. As the amicus briefs underscore, the Federal Circuit's approach threatens the vitality of prosecution history estoppel, at great cost to the public.

This case is an ideal vehicle to resolve the meaning of *Festo*'s "tangential" exception. The exception's applicability resolves this entire case. The salient facts are undisputed and uncomplicated. And the conflict between the rationale below and the principles *Festo* announced is unusually stark. *Festo* explained that all three exceptions to prosecution history estoppel avoid unfairness from the inherent limits of language. 535 U.S. at 734-35. Prosecution history estoppel, in turn, forecloses the doctrine of equivalents unless the patentee can "show that at the time of the amendment one skilled in the art could not

reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Id.* at 741. Lilly does not even try to reconcile the decision below with those principles. Lilly does not contend the limits of language stood in the way of literally claiming pemetrexed salts, nor does it offer any explanation why it could not reasonably have been expected to have done so.

Instead, Lilly mainly accuses petitioners of disagreeing with each other about why this Court's review is warranted. Nonsense. Petitioners agree completely. As both petitions and amicus AAM explain in similar terms, the Federal Circuit's methodological error was to ask why Lilly amended its claims *at all* rather than why Lilly amended *in the way it did*. Pet. 18-24; Petition, *Hospira, Inc. v. Eli Lilly & Co.*, No. 19-1058 (U.S. Feb. 24, 2020), 19-21 ("19-1058 Pet."); AAM-Amicus 12. That approach is inconsistent with *Festo* and with Federal Circuit decisions rejecting arguments like Lilly's. Fundamentally, it allows patentees to manipulate the scope of their claims in litigation by arguing—as Lilly does here—that in hindsight they surrendered more patent scope than they needed to during the application process. Pet. 18-24; 19-1058 Pet. 19-21; AAM-Amicus 12. The claim becomes the proverbial "nose of wax."

This Court struck a "careful balance" in *Festo* between the interests of inventors and the public, and emphasized that even with a doctrine of equivalents, "A patent holder should know what he owns, and the public should know what he does not." 535 U.S. at 731. Review is needed to restore that balance.

I. Respondent Has No Coherent View Of *Festo*'s "Tangential" Exception, And Neither Does The Federal Circuit.

1. Lilly denies that the Federal Circuit treats the tangential exception as a free pass for buyer's remorse. BIO 4, 9-10, 15-16, 24. But by asking only what motivated the patentee to narrow its claims *at all*, rather than why the patentee narrowed its claims *in the way it did*, Lilly and the Federal Circuit necessarily embrace a buyer's-remorse principle. Lilly's opposition bears that out.

When the Examiner rejected Lilly's claims, Lilly had choices over both *whether* and *how* to amend its claims in response. Lilly focuses exclusively on "whether" but ignores "how." BIO 6, 27. Lilly argues the "reason for [its] amendment was to avoid" a particular piece of prior art, not to "distinguish pemetrexed disodium from different salt forms of pemetrexed." BIO 6; *see* BIO 15, 27. That framing ignores *how* Lilly amended its claims: Lilly limited them to "pemetrexed *disodium*." The word "*disodium*" *necessarily* distinguishes other salt forms, much as "Red Delicious" distinguishes other types of applies. Lilly has no explanation for why its deliberate choice of the word *disodium* should have no consequences.

Many years later, Petitioners had made substantial investments in reliance on Lilly's surrender of antifolates other than pemetrexed disodium. They designed around Lilly's product by making pemetrexed *ditromethamine*. Lilly's litigation-driven argument for invoking the tangential exception can only be called buyer's remorse. In the Federal Circuit's view, Lilly is excused from

prosecution history estoppel merely because Lilly "did not need or intend to cede" Petitioners' ditromethamine product when it narrowed its claims. App-20. But that post-hoc rationale gives no explanation for *why Lilly made the choice it did*, much less point to anything in the prosecution history to put the world on notice that it was surrendering less than all antifolates (other than pemetrexed disodium).

Lilly confirms its buyer's-remorse rationale when it embraces Hospira's fruit hypothetical. BIO 18-19 & n.4. As Lilly tells it, it does not matter *how* a patent applicant responds to a prior art rejection. When limiting words like "disodium" or "Red Delicious" become inconvenient years later in litigation, the patentee can invoke the tangential exception by arguing it just was "focused" on avoiding particular prior art, without giving any reason for its *specific choice*, let alone demonstrate the reason for *that choice* is tangential to the accused equivalent. *Id.*

By allowing patentees to avoid prosecution history estoppel in this way, the Federal Circuit invites patentees to manipulate the scope of their claims. Yesterday the patent holder needed to narrow its claims to overcome a rejection. Today the goal is to broaden the claims to cover a competitor's product. That casts aside *Festo*'s theory of the doctrine of equivalents as premised on the limits of language, defeats any sensible notion of public notice, and turns the patent claim's text into the proverbial "nose of wax."

2. Lilly notes that *Festo* refers to the doctrine of equivalents and prosecution history estoppel as "flexible." Lilly's opposition repeats its "flexible"

mantra throughout, while accusing Petitioners of endorsing "rigid" rules. BIO 4, 11-15, 19, 22. This argument was predictable, *see* AAM-Amicus 17-18, but wrong. Lilly's misreads *Festo*'s references to "flexibility."

Festo explains that "the rule of prosecution history estoppel" is "flexible" in the sense that it has exceptions that account for the inherent limits of language. 535 U.S. at 739-41. That is because the doctrine of equivalents is "premised on language's inability to capture the essence of innovation." *Id.* at 734. Narrowing amendments "undercut[] that premise" because they indicate that the inventor "turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter." *Id.* at 734-35.

The exceptions to prosecution history estoppel, however, refer to circumstances when a narrowing amendment does not "undercut" the "premise" of the doctrine of equivalents. In other words, prosecution history will not bar resort to the doctrine of equivalents *if* the patentee can "show that at the time of the amendment one skilled in the art *could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent*." *Id.* at 741 (emphasis added). That is the "flexibility" *Festo* refers to. *Festo* rejected a "complete-bar rule" for prosecution history estoppel that had no exceptions, in favor of a "flexible-bar rule" with exceptions. *Id.* at 730, 737.

Lilly does not other try to reconcile its position with *Festo*'s principles. Lilly has no argument that

inherent limits of language stood in the way of claiming "pemetrexed" or "pemetrexed salts," as opposed to "pemetrexed disodium." Nor does it contend that it "could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Id.* at 741. Indeed, Lilly's implicit rejection of *Festo* is particularly clear when it insists that "there is no reason to expect that the prosecution history will address the reasons why the patentee did not use alternative, broader language encompassing the equivalent." BIO 27. Again, *Festo* says the opposite: all three exceptions to prosecution history estoppel require the patentee to "show that at the time of the amendment one skilled in the art could not reasonably be expected *to have drafted a claim that would have literally encompassed the alleged equivalent.*" 535 U.S. at 741.

Festo reaffirms that even with a doctrine of equivalents, "[a] patent holder should know what he owns, and the public should know what he does not." *Id.* at 731. Consistent with the "delicate balance" the law strikes between the interests of inventors and the public, *id.,* the public must accept some "uncertainty as the price of ensuring the appropriate incentives for innovation," *id.* at 732, but prosecution history estoppel remains a vital check on the doctrine of equivalents. The decision below upsets that careful balance and allows patentees like Lilly to evade prosecution history estoppel without making the requisite showing that their narrowing amendment does not undercut the premise of the doctrine of equivalents.

3. Lilly mainly fights this Court's review by accusing petitioners of disagreeing with each other and denying any inconsistency in the Federal Circuit's decisions. Both arguments are unsound.

The petitions (and amicus AAM) all identify the same methodological error: asking what motivated the patent applicant to amend its claims *at all*, rather than why it amended *in the way it did*.* Pet. 18-24; 19-1058 Pet. 19-21; AAM-Amicus 12. That is the core of the problem. That approach is contrary to this Court's precedents, undermines prosecution history estoppel, and allows patent owners to manipulate the scope of their patents. Lest there be any doubt, Dr. Reddy's agrees with all of Hospira's arguments. The Court should grant both petitions and consolidate them.

Lilly's assertions of consistency within the Federal Circuit likewise blink reality. Lilly contends that "there is no separate line of cases … asking why the patentee chose the precise language that it did …." BIO 22. Yet, the *Felix*, *Amgen*, *Biagro*, *International Rectifier*, *Schwarz*, and *Festo* (Fed. Cir.) decisions, *see* Pet. 18-20, all ask precisely that question. And all of them pointedly reject arguments, like Lilly's, that the patentee was focused on avoiding prior art and simply surrendered more than it needed to. *Id.* If Lilly is

* Lilly also suggests disagreement with the petition in *CJ CheilJedang Corp. v. ITC*, No. 19-1062. *See* BIO 20, 24-25. To be clear, Dr. Reddy's does not disagree with Petitioners' arguments in No. 19-1062. Regardless, the Solicitor General's brief in that case notes that the petition presents a "somewhat different" question, and the Solicitor General's arguments against review are specific to that case. Fed. Respondent's Br. in Opp'n, No. 19-1062 (U.S. May 21, 2020), at 24-25.

correct, then those cases all asked the wrong question, and the Court should grant certiorari and overrule them. Petitioners of course disagree, but the methodological divide over the meaning of *Festo*'s tangential exception deserves an answer.

Lilly contends that the tangential exception has not provoked dissenting opinions. BIO 3, 22. Not so. *See* Pet. 17-18. The clearest examples are perhaps Chief Judge Prost's dissent in *Regents of University of California v. Dakocytomation California, Inc.*, 517 F.3d 1364 (Fed. Cir. 2008) and Judge Dyk's dissent in *Ajinomoto v. ITC*, 932 F.3d 1342 (Fed. Cir. 2019). Both dissents criticized the majority on methodological grounds—for accepting the patentee's argument that, in hindsight, it surrendered more than it needed to avoid prior art. *Regents*, 517 F.3d at 1380-81 (Prost, J., dissenting); *Ajinomoto*, 932 F.3d at 1361-64 (Dyk, J., dissenting). Particularly in *Regents*, the disagreement focused on the legal approach of invoking the tangential exception based on surrendered-more-than-necessary buyer's-remorse arguments. This basic methodological divide began with the competing opinions on remand in *Festo* itself, has persisted for eighteen years, and is squarely presented here.

II. The Question Of What The Public Can And Cannot Rely On In A Patent's Public Record Is Important, And This Case Is The Ideal Vehicle To Resolve It.

1. Lilly disputes whether the tangential exception needs clarification, but does not dispute that this case is an exceptionally suitable vehicle. The issue is

starkly presented here, and the salient facts are undisputed and relatively simple.

Lilly has no explanation for why it chose to narrow its claims to "pemetrexed *disodium*." It began with "antifolate" claims and undisputedly could have chosen "pemetrexed," "pemetrexed salts" or other subsets of "antifolate" that included Petitioners' product. In Lilly's and the Federal Circuit's view, no explanation is needed because that is simply not a relevant question. In Petitioners' view, and under the reasoning of other Federal Circuit panels, Lilly's failure of explanation is fatal, and its argument that it did not "need" to say "disodium" is legally irrelevant. That fundamental question about the tangential exception's meaning is case-dispositive and undisputedly preserved. The Court should answer it and resolve the confusion that has persisted in the Federal Circuit for eighteen years.

Lilly only strengthens the case for review when it insists that, eighteen years after *Festo*, the Federal Circuit does not fully acknowledge the conflict within its own precedent. BIO 21-22. That only means that there is no reason to hope that percolation will improve matters. Without this Court's review, the Federal Circuit will continue to guess at what this Court meant in *Festo*, perhaps lurching back and forth between different interpretations, while patentees like Lilly continue to manipulate their patents. This Court announced the tangential exception; only this Court can say what it means.

Finally, Lilly's suggestion that the question presented is unimportant grossly misreads this Court's cases. Lilly accuses Petitioners of "recycl[ing]

concerns raised by dissenting Justices and rejected by the Court" in *Warner-Jenkinson*, *Graver Tank*, and *Winans*. BIO 26. In all three cases, the Court rejected arguments for eliminating the doctrine of equivalents outright. *Festo*, 535 U.S. at 732-33. The Court did not "reject" any role for public notice—quite the opposite. For more than 100 years, the Court has reaffirmed the vitality of prosecution history estoppel *precisely because* of the need to preserve the public notice function of claims and prosecution history. Pet. 6-7. *Warner-Jenkinson* emphasized that "the doctrine of equivalents, when applied broadly, conflicts with the definitional and public-notice functions of the statutory claiming requirement," and refined the doctrine to account for that concern. *Warner-Jenkinson Co. v. Hilton-Davis Chem. Co.*, 520 U.S. 17, 29 (1997). *Festo* reaffirmed the importance of prosecution history estoppel and public notice. 535 U.S. at 734-35. The Federal Circuit's endorsement of a post-hoc buyer's-remorse principle turns public notice on its head and upsets the "delicate balance" the doctrine of equivalents strikes between the interests of the public and inventors. *Id.* at 731.

2. Lilly's reference to the Hatch-Waxman Act is an effort at misdirection. The doctrine of equivalents and prosecution history estoppel apply equally to all patents. Lilly says Petitioners "did not design their products from scratch." BIO 28. So what? Petitioners followed the regime Congress created. And, regardless, *Warner-Jenkinson* holds that independent experimentation is of dubious relevance—and a defendant's *intent* is irrelevant—in the equivalence analysis. 520 U.S. at 35-36. Indeed, *Warner-Jenkinson* reaffirms that the Patent Act encourages

"the incremental inventor [who] design[s] around the claims, yet seek[s] to capture as much as is permissible of the patented advance." *Id.* at 36. The Hatch-Waxman Act, to the extent relevant, gives even further encouragement to generic companies to design around brand companies' patent claims, for the public's ultimate benefit. AAM-Amicus 3. The Federal Circuit should not thwart Congress' will by broadening the tangential exception to stunt activity Congress specifically encouraged.

Lilly also argues that Petitioners "effectively conceded equivalence" by submitting an FDA application. BIO 28. FDA "bioequivalence" is not infringement. *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1298 (Fed. Cir. 2009). More importantly, equivalence is no longer disputed here, which only enhances the suitability of this case as a vehicle. The case turns entirely on the tangential exception to prosecution history estoppel—no more and no less.

3. Lilly conspicuously has no response to the diverse amicus briefs explaining the importance of the question presented to patent law and to the Nation's economy. The question is vitally important, only this Court can answer it, and this case provides the ideal opportunity to do so.

CONCLUSION

For the foregoing reasons, and those in the Petition, the Court should grant certiorari.

Respectfully submitted,

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