No. _____

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

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Under patent law's "doctrine of equivalents," a patent holder can allege infringement even when the defendant does not literally practice every element of a patent claim. But if the patent applicant previously narrowed the claim during prosecution to obtain the patent, the general rule for more than 100 years has been that the patent holder cannot use the doctrine of equivalents in litigation to recapture territory between the broader pre-amendment claim and the narrower post-amendment claim. That rule is known as "prosecution history estoppel."

In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), this Court held that prosecution history estoppel does not apply 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. A patentee can make that showing in different ways, including by demonstrating that the "the rationale underlying the amendment … bear[s] no more than a tangential relation to the equivalent in question." *Id.* at 740.

The question presented is whether, under *Festo*'s "tangential" exception to prosecution history estoppel, patent owners may recapture subject matter they could have claimed in prosecution but did not, by arguing that they surrendered more than they needed to during prosecution to address a rejection by the Patent Office.

PARTIES TO THE PROCEEDING

All parties are listed in the caption.

The court of appeals issued an opinion addressing two companion appeals together (Fed. Cir. Nos. 18-2128 and 18-2126), though it issued separate judgments in each appeal. This petition arises from Appeal No. 18-2128. In Appeal No. 18-2126 (the other companion appeal), the parties were Eli Lilly & Company, and Hospira, Inc.

CORPORATE DISCLOSURE STATEMENT

Dr. Reddy's Laboratories, S.A. is the parent company of Petitioner Dr. Reddy's Laboratories, Inc. Petitioner Dr. Reddy's Laboratories, Ltd. is the parent company of Dr. Reddy's Laboratories, S.A.

STATEMENT OF RELATED PROCEEDINGS

This case arises from the following proceedings in the U.S. District Court for the Southern District of Indiana, and the U.S. Court of Appeals for the Federal Circuit:

Eli Lilly & Co. v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc., S.D. Ind. No. 1:16-CV-00308-TWP-MPB (judgment entered July 27, 2018)

Eli Lilly & Co. v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc., Fed. Cir. No. 18-2128 (judgment entered Aug. 9, 2019)

Although the court of appeals issued an opinion addressing two companion appeals together (Fed. Cir. Nos. 18-2128 and 18-2126, *see* App-3 & n.1), the appeals were not consolidated, and separate judgments were issued in each appeal. This petition arises from Appeal No. 18-2128. In Appeal No. 18-2126 (the other companion appeal), the parties were Eli Lilly & Company, and Hospira, Inc., and the underlying district court proceeding was *Eli Lilly & Co. v. Hospira, Inc.*, No. 1:16-CV-3460-TWP-MPB (judgment entered Dec. 9, 2019).

There are no other proceedings in state or federal trial or appellate courts, or in this Court, directly related to this case within the meaning of this Court's Rule 14.1(b)(iii).

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PETITION FOR WRIT OF CERTIORARI

During the application process for a patent, the Patent Office often rejects claims in applications, frequently because the claims are too broad in a way that renders them invalid under 35 U.S.C. §§102, 103 or 112. Faced with a rejection from the Patent Office, the applicant has a choice: **(1)** abandon the application, **(2)** dispute the rejection, or **(3)** amend the claims to address the rejection. When the applicant chooses the third option, and narrows the claims to obtain a patent, the general rule for more than 100 years—known as prosecution history estoppel—has been that the patent owner cannot later use the doctrine of equivalents in litigation to recapture territory between the broader pre-amendment claims and the narrower post-amendment claims. Were it otherwise, patent owners could accomplish a bait-and-switch by narrowing their claims to get a patent, and then effectively broadening those claims in litigation through the doctrine of equivalents.

In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740-41 (2002), this Court held that the rule of prosecution history estoppel is not absolute. A patentee will not be estopped if it 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). One way a patentee can make that showing is to demonstrate "the rationale underlying the amendment … bear[s] no more than a tangential relation to the equivalent in question." *Id.* at 740.

For the past eighteen years, over dozens of decisions, the Federal Circuit has puzzled over what this Court meant by that "tangential relation" language, and has given two irreconcilable answers. This case is the ideal vehicle to clarify *Festo* because the Federal Circuit's choice between its two answers dictated the outcome.

In this case, the Patent Office rejected Respondent Eli Lilly's claims as overbroad, and Eli Lilly responded by drafting narrower claims. It is undisputed that Respondent could easily have drafted a claim that literally encompassed Petitioners' product. Respondent had done just that in other patents and applications by claiming groups of chemical compounds. Instead, for the patent in this case, Respondent chose to narrow its claims to recite only one specific chemical compound—"pemetrexed disodium." Pemetrexed disodium is the active ingredient in Respondent's product, but not Petitioners' product. After obtaining its patent with claims only to "pemetrexed disodium," Respondent sued Petitioners, alleging infringement under the doctrine of equivalents. In Respondent's view, Petitioners' pemetrexed ditromethamine product is equivalent to Respondents' "pemetrexed disodium" claims, and Petitioners were thus liable for infringement.

On a straightforward application of *Festo*, this should have been an easy case. Indisputably, Respondent *could* "reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent," 535 U.S. at 741, when it was amending its claims to respond to the Patent Office's

rejection. Respondent had drafted precisely such claims that in other patents. And under one line of Federal Circuit precedent interpreting *Festo*, this case should have been easier still: several cases addressing this recurring fact pattern hold that a patent owner cannot invoke the tangential exception by arguing that, in hindsight, it surrendered more than it needed to address the Patent Office's invalidity rejection.

The panel in this case, however, followed a different line of Federal Circuit precedent, under which patent owner *can* invoke the tangential exception by arguing that, in hindsight, it surrendered more than it needed to address the Patent Office's invalidity rejection. In effect, the "tangential" exception is a prosecution remorse exception. Applying that approach here, the panel held that Respondent was entitled to invoke the tangential exception to prosecution history estoppel because it surrendered more than it needed to address the Patent Office's rejection. Although Respondent unambiguously surrendered Petitioners' product in prosecution (i.e., its pre-amendment claims covered Petitioners' product; its post-amendment claims did not), at a time when it knew how to capture that product, the Federal Circuit panel found that Respondent's claim amendment was "inartful" and that Respondent "did not need or intend to cede" Petitioners' product. In other words, the court considered only Respondent's "reason" for amending its claims at all rather than Respondent's "reason" for making the specific amendment it made. As a result, Petitioners were penalized for relying on the prosecution history of Respondent's patent, and were

held liable for infringement based on a compound Respondent had unquestionably surrendered.

The Federal Circuit's confusion over the meaning of *Festo*'s "tangential" exception warrants this Court's review. It is a recurring question whose answer this Court should not leave in its current panel-dependent state. Both of the Federal Circuit's approaches cannot be right, and the approach taken here and in other cases is wrong. In its cases that treat the "tangential" exception as a prosecution-remorse exception, the Federal Circuit undermines an important legal limit on the doctrine of equivalents and threatens the public-notice function of patent claims. If it is to remain true that "a patent holder should know what he owns, and the public should know what he does not," *Festo*, 535 U.S. at 731, the Court should grant certiorari and reverse.

OPINIONS BELOW

The Federal Circuit's opinion is reported at 933 F.3d 1320 and reproduced at App-1-30. The order denying rehearing en banc is reproduced at App-31-32.

Although the court of appeals' opinion addressed two companion appeals together (Fed. Cir. Nos. 18-2128 and 18-2126), the appeals were not consolidated, and separate judgments were issued in each one. This petition arises from Appeal No. 18-2128. Relevant underlying district court opinions are the opinion following the bench trial—reported at 323 F. Supp. 3d 1042 and reproduced at App-33-49—and the unreported order denying summary judgment of noninfringement, available at 2017 WL 6387316 and reproduced at App-50-74.

JURISDICTION

The Federal Circuit issued its opinion on August 9, 2019. Petitioners filed a timely petition for rehearing en banc, which the court denied on November 8, 2019.

On January 24, 2020, the Chief Justice extended the time for filing a petition for certiorari to and including February 24, 2020. This Court has jurisdiction under 28 U.S.C. §1254(1).

STATEMENT OF THE CASE

A. Legal Background

Every patent application must include "claims," where the applicant "particularly point[s] out and distinctly claim[s] the subject matter which the inventor … regards as the invention." 35 U.S.C. §112(b). A patent grants its owner the right to exclude others from making, using, or selling the claimed invention. 35 U.S.C. §154(a)(1). Claims define the scope of those rights and provide notice to the public. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 835 (2015); *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 909-10 (2014).

The judicially-created "doctrine of equivalents" expands a patent owner's ability to sue others "beyond the literal terms in a patent." *Festo*, 535 U.S. at 727. For example, a patent owner may assert that claims to "cone" shaped railcars are infringed by octagonal-pyramid shaped railcars. *Winans v. Denmead*, 56 U.S. (15 How.) 330, 342-44 (1854). Or "alkaline earth metal silicate" claims may be infringed by magnesium silicate (magnesium is not an alkaline earth metal). *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339

U.S. 605, 610-12 (1950). The underlying "premise" of the doctrine is "language's inability to capture the essence of innovation." *Festo*, 535 U.S. at 734. If patent owners were strictly limited to the literal scope of their claims, competitors could easily circumvent patents by making insubstantial modifications that the patentee could not reasonably have anticipated during the drafting and application process. *Id.* at 733-34.

Because the doctrine of equivalents permits infringement theories that reach beyond the text of the claims, it necessarily "renders the scope of patents less certain." *Festo*, 535 U.S. at 732. This Court has said that the public must tolerate some uncertainty as "the price of ensuring the appropriate incentives for innovation." *Id.* at 732. But that price is not unlimited. "There can be no denying that the doctrine of equivalents, when applied broadly, conflicts with the definitional and public-notice functions of the statutory claiming requirement." *Warner-Jenkinson v. Hilton Davis Chem. Co.,* 520 U.S. 17, 29 (1997). Even with the doctrine of equivalents, "[a] patent holder should know what he owns, and the public should know what he does not." *Festo*, 535 U.S. at 731.

An important limit on the doctrine of equivalents is prosecution history estoppel. *Id.* at 727. If the Patent Office rejects claims in an application as invalid, and the patent applicant responds by narrowing the claims, "this prosecution history estops him from later arguing that the subject matter covered by the original, broader claim was nothing more than an equivalent." *Id.* "Competitors may rely on the estoppel to ensure that their own devices will not be

found to infringe by equivalence." *Id.* That has been the general rule for more than 100 years. *See, e.g.*, *Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 220-21 (1940).; *Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136-37 (1942); *Smith v. Magic City Kennel Club*, 282 U.S. 784, 790 (1931); *Weber Elec. Co. v. E.H. Freeman Elec. Co.*, 256 U.S. 668, 677-78 (1921); *Morgan Envelope Co. v. Albany Perforated Wrapping Paper Co.*, 152 U.S. 425, 429 (1894); *Shepard v. Carrigan*, 116 U.S. 593, 598 (1886). A narrowing amendment for patentability reasons "undercuts [the] premise" of the doctrine of equivalents, which is that the applicant somehow "lacked the words" to include the defendant's product in its claims. *Festo*, 535 U.S. at 734. Instead, it suggests that the applicant focused on a particular claim element and made a deliberate choice to narrow it. *Id*. Without prosecution history estoppel, "the inventor might avoid the [Patent Office's] gatekeeping role and seek to recapture in an infringement action the very subject matter surrendered as a condition of receiving the patent." *Id.*

In *Festo*, this Court refined the rule of prosecution history estoppel. The general rule is still that when a patentee narrows claims in prosecution to comply with any provision of the Patent Act, the amendment "may be presumed to be a general disclaimer of the territory between the original claim and the amended claim." 535 U.S. at 740 (citing *Exhibit Supply*, 315 U.S. at 136-37); *id.* at 737 ("We must regard the patentee as having conceded an inability to claim the broader subject matter or at least as having abandoned his right to appeal a rejection.").

The patentee can rebut the presumption of estoppel by showing that when the amendment was made, "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. *Festo* stated three ways the patentee might make that showing:

> **[1]** The equivalent may have been unforeseeable at the time of the application; **[2]** the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or **[3]** there may be some *other* reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.

Id. at 740-41 (emphasis and numbers added).

The first and third parts of that passage—"unforeseeable" and "some other reason … the patentee could not reasonably be expected to have described" the equivalent—appear to have been proposed in the Solicitor General's amicus brief. *See* Br. for U.S. as *Amicus Curiae* *25-26, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 2001 WL 1025650 (U.S. Aug. 31, 2001). The "unforeseeable" part is readily understandable: patent applicants cannot reasonably be expected to account for equivalents that do not yet exist and are not foreseeable. *Festo*, 535 U.S. at 738; *see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 619 (Fed. Cir. 2000) (Rader, J., concurring and dissenting) ("A primary justification for the doctrine of equivalents is to accommodate after-

arising technology. … A claim using the terms 'anode' and 'cathode' from tube technology would lack the 'collectors' and 'emitters' of transistor technology that emerged in 1948. Thus, without a doctrine of equivalents, infringers in 1949 would have unfettered license to appropriate all patented technology using the out-dated terms 'cathode' and 'anode'.") (cited in Br. for U.S., 2001 WL 1025650, at *25-26).

The "some other reason" language, *see* Br. for U.S., 2001 WL 1025650 at *26, simply reiterates the broader principle: prosecution history estoppel should not apply if, at the time the amendment was made, the patent applicant could not reasonably have been expected to literally claim the alleged equivalent—whether due to the limits of language or some other obstacle akin to unforeseeability. Indeed, *Festo* reiterated several times that the unifying principle is that prosecution history estoppel should not apply if, at the time of amendment, the applicant "could not reasonably be expected" to have drafted a claim literally covering the alleged equivalent or "lacked the words" to claim the alleged equivalent. 535 U.S. at 734, 740, 741.

The "tangential" passage, however, was not suggested in any brief in *Festo*. The Court's opinion did not explain the "tangential" passage at length or derive it from precedent. The Court simply said that there is no "call to foreclose claims of equivalence for aspects of the invention that have only a peripheral relation to the reason the amendment was submitted," 535 U.S. at 738, announced the test for rebutting the presumption of prosecution history estoppel, and left

the Federal Circuit and the district courts to apply it going forward.

The Federal Circuit has treated *Festo* as announcing three exceptions to prosecution history estoppel—including the "tangential" exception—and has developed distinct precedent for each exception. *See, e.g.*, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003) (en banc) ("three rebuttal criteria," "[t]he second criterion" being the tangential exception); *Lucent Techs., Inc. v. Gateway, Inc.*, 525 F.3d 1200, 1217-18 (Fed. Cir. 2008) (rejecting patentee's argument for applying "the tangential exception").

B. Factual Background

Respondent Lilly markets and sells an anti-cancer drug under the brand name ALIMTA.[1] ALIMTA's active ingredient is the chemical compound *pemetrexed disodium*. Pemetrexed disodium is in a class of chemicals called antifolates. It is also a "salt"—a compound formed by bonding positive ions with negative ions (one negative pemetrexed ion with two positive sodium ions).

Lilly owns or licenses several patents that cover ALIMTA's active ingredient, some of which expired before this litigation began. Two of Lilly's licensed patents claimed groups of chemicals (pyrrolo-pyrimidine derivatives) using chemical formulas with variables. *See*, *e.g.*, Dr. Reddy's Opening Br. at 15, No. 18-2128 (Fed. Cir. Feb. 7, 2019), ECF#62. Another Lilly patent claimed "pemetrexed," and stated that

[1] "CA-Appx" refers to the joint appendix filed with the court of appeals, Fed. Cir. No. 18-2128, ECF#53 (filed Jan. 30, 2019).

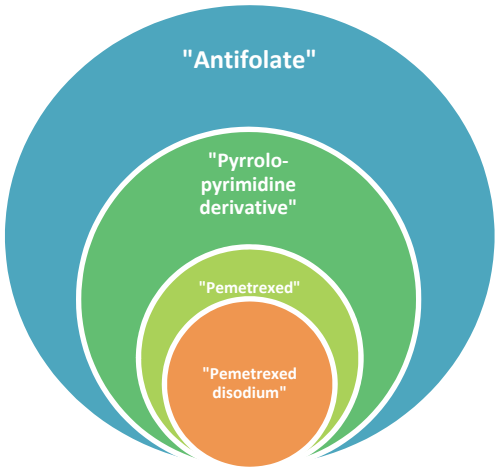
"[a]s used herein, the term '*pemetrexed*' refers to the stable salts, acids, and free bases thereof." CA-Appx7977(3:10-20); CA-Appx7978(5:19-6:39). The patent in this case, however, claims only the specific compound *pemetrexed disodium*—not all stable salts of pemetrexed. *See, e.g.*, CA-Appx53 (11:25-12:4 (claim 12)).

When Lilly was applying for its patent, its claims initially covered the entire class of antifolates, including all pemetrexed salts. An exemplary claim in the application recited "administration of an antifolate" to a patient. CA-Appx7860 (claim 2). The examiner rejected Lilly's claims as invalid in light of prior art. Among other things, a 1978 publication (Arsenyan) disclosed similar treatments using *methotrexate*, which is an antifolate. CA-Appx7868. In response, Lilly specifically narrowed its claims from all "*antifolate*[*s*]" to the "pemetrexed disodium" ingredient in its ALIMTA product. Lilly deleted every instance of "antifolate" in every claim, and substituted "*pemetrexed disodium*" each time. *See, e.g.*, CA-Appx7877 (claim 2).

Lilly then argued to the Patent Office that its amended claims were valid because Lilly had narrowed them from "an antifolate" to only "pemetrexed disodium." Lilly's submission with its amended claims repeated sixteen times that it claimed only "pemetrexed disodium," and its submission never suggested that its amended claims included anything else. *See, e.g.*, CA-Appx7880 ("There is no disclosure in Arsenyan … of the invention as presently claimed. In particular, Arsenyan … does not disclose pemetrexed disodium …"); *id.* (prior art does not

disclose "pemetrexed disodium, or for that matter any other antifolate."). Lilly successfully obtained a patent, with claims limited to "pemetrexed disodium."

Undisputedly, Lilly's amendment from "antifolate" to "pemetrexed disodium" narrowed the claims in the application further than Lilly necessarily needed to go to address the Patent Office's rejection. As illustrated below, Lilly might have claimed a subset of "antifolates" that did not include methotrexate ("pyrrolo-pyrimidine derivatives," for example), as Lilly had done in other patents. Or Lilly might have claimed "pemetrexed" as it had done in other patents.



Instead, Lilly chose to claim only the "pemetrexed disodium" compound.

Relying on this Court's precedent, Lilly's competitors—including Petitioners and others—designed around Lilly's claims by creating products that did not use pemetrexed disodium. Petitioners' product uses a different compound, *pemetrexed ditromethamine*. Pemetrexed ditromethamine is an

antifolate and a pemetrexed salt, and was covered by Lilly's original claims to "an antifolate." But it is undisputedly not pemetrexed disodium and thus not within the literal scope of Lilly's claims to "pemetrexed disodium."

Lilly nonetheless sued Petitioners and others, asserting infringement under the doctrine of equivalents.

C. Proceedings Below

In this case, Lilly prevailed in district court, and the Federal Circuit affirmed. The district court and court of appeals decisions both turned on whether Lilly's narrowing amendment (from "antifolate" to "pemetrexed disodium") fit within *Festo*'s "tangential exception."

All agreed that **(1)** Lilly made the amendment to secure its patent, **(2)** Petitioners' pemetrexed ditromethamine fell within the surrendered territory, and **(3)** Lilly bore the burden to rebut the presumption of prosecution history estoppel. Lilly contended that *Festo*'s "tangential exception" applied, *i.e.*, that the reason for Lilly's narrowing amendment bore only a tangential relation to Petitioners' product.

Lilly's argument was based on remorse at having surrendered more than it needed to in prosecution. It argued that the "tangential exception" applied because it did not need to surrender Petitioners' product to answer the Patent Office's rejection and because Petitioners' product fell within the unnecessarily-surrendered territory. In other words, Lilly characterized the "reason" for its amendment as distinguishing a particular piece of prior art, and contended that unnecessarily-surrendered scope was

therefore "tangential" to that reason. *See, e.g.*, Lilly Br. Opposing Summ. J. at 26, No. 16-CV-308, (S.D. Ind. Sept. 21, 2007), ECF #171 ("[T]he claims were narrowed to avoid a certain prior art species (the antifolate methotrexate), and the narrowing excluded other species (pemetrexed salts) that were unrelated to the prior art *and did not need to be excluded in order to avoid it*."); Lilly Response Br. at 8, 46, No. 18-2128, (Fed. Cir. Dec. 3, 2018), ECF#43 ("[T]he purpose of the amendment was to avoid the Arsenyan reference …. If a patentee was making an amendment for one reason, and in so doing excludes an equivalent that is unrelated to the reason for the amendment, the tangentiality exception excuses the patentee's failure to claim that equivalent.").

Lilly never contended that it lacked the words to draft a claim covering Petitioners' product. In response to Petitioners' arguments that Lilly could easily have claimed Petitioners' product (*e.g.*, by claiming "pemetrexed" or pyrrolo-pyrimidine derivatives *as it had done in other patents*, or any number of options readily available to a sophisticated pharmaceutical company), Lilly contended that such arguments "collapsed the tangentiality exception" with the "separate" unforeseeability exception. Lilly Response Br. at 45-47, No. 18-2128, (Fed. Cir. Dec. 3, 2018), ECF#43. Lilly contended that it was irrelevant whether it could have made "other hypothetical amendments" to its claims. *Id.* at 43-44; Lilly Opp'n to Rehearing at 9, No. 18-2128, (Fed. Cir. Oct. 23, 2019), ECF#97.

The district court and the court of appeals both accepted Lilly's arguments. On appeal, Petitioners

argued that Lilly's remorse at having surrendered more than it needed to in prosecution cannot fit *Festo*'s "tangential" exception as a matter of law. Actavis—another generic who had relied on Lilly's prosecution history to design around Lilly's claims, but had been found to infringe under the doctrine of equivalents—filed a supportive amicus brief.

A panel of the Federal Circuit affirmed, reasoning that the tangential exception applied because Petitioners' product was part of the claim scope Lilly surrendered in prosecution but "did not need or intend" to surrender to avoid the Patent Office's rejection:

> [T]he particular type of salt to which pemetrexed is complexed relates only tenuously to *the reason for the narrowing amendment, which was to avoid Arsenyan*.... [T]he reason for the amendment was not to cede other, functionally identical pemetrexed salts.
>
> * * *
>
> The prosecution record implies that Lilly's amendment, *inartful* though it might have been, was prudential in nature and *did not need or intend to cede* other pemetrexed salts.

App-20 (emphasis added). Much as Lilly had done in its briefs, the panel cast Lilly's "reason" for its amendment as surrendering only the scope it needed to surrender to answer the Patent Office's rejection. In other words, the panel inquired into the reason why Lilly amended its claims at all, not the reason why Lilly amended its claims in the way it did. The panel then reasoned that the unnecessarily-surrendered

scope that included Petitioners' product was "tangential" to Lilly's reason for amending its claims. App-24-25 ("implausible that the reason for Lilly's amendment was to surrender other pemetrexed salts"; "the prosecution history strongly indicates a less sweeping and more sensible reason for Lilly's amendment: to surrender antifolates other than pemetrexed. Thus, we conclude … that Lilly's amendment was merely tangential to pemetrexed ditromethamine.").

The same week as the decision in this case, a divided panel of the Federal Circuit decided *Ajinomoto Co. v. ITC*, 932 F.3d 1342 (Fed. Cir. 2019), where the majority and dissent disagreed over whether the "tangential exception" to prosecution history estoppel applied. Like the panel in this case, the *Ajinomoto* panel majority based its analysis on a *post hoc* assessment of whether the patentee needed to surrender as much as it did to address an examiner's rejection. *Id.* at 1355. The dissent responded that the majority's analysis was inconsistent with precedent and that "[t]he problem with the majority's analysis is that it ignores how the patentee deliberately elected to narrow the claims." *Id.* at 1363 (Dyk, J., dissenting).

In this case, Petitioners sought rehearing, supported by an amicus curiae. After requesting a response from Lilly, the court of appeals denied rehearing. App-31-32.

REASONS FOR GRANTING THE PETITION

I. The Federal Circuit Is Internally Divided On The Meaning Of The "Tangential Exception" To Prosecution History Estoppel.

This Court first announced the "tangential exception" to prosecution history estoppel in *Festo* in 2002, stating that prosecution history estoppel will not apply if "the rationale underlying the amendment … bear[s] no more than a tangential relation to the equivalent in question." 535 U.S. at 740. That passage does not appear to have antecedents in this Court's prior precedent, nor was it suggested in any brief in that case. For the past eighteen years, in dozens upon dozens of appeals raising the issue, the Federal Circuit has struggled to figure out what that language means, and has developed a body of precedent around the "tangential exception" to prosecution history estoppel.

Beginning with the remand in *Festo* itself, the meaning of the "tangential exception" has divided panels, provoked separate opinions disagreeing with earlier decisions, and generally led to confusion. *See, e.g.*, *Festo*, 344 F.3d at 1369 (consulting dictionaries for meaning of "tangential"); *id.* at 1384 (Newman, J., dissenting), (disagreeing with majority's treatment of "tangential" exception); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335, 1346-48 (Fed. Cir. 2007) (Rader, J., concurring) ("[F]rankly, this court might well have justifiably reached a different result in both" earlier decisions applying the tangential exception); *Regents of Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1380-82 (Fed. Cir. 2008) (Prost, C.J., dissenting); *Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 523 F.3d

1304, 1321-22 (Fed. Cir. 2008) (Newman, J., dissenting); *Ajinomoto*, 932 F.3d at 1361-64 (Dyk, J., dissenting).

Federal Circuit precedent has crystallized around two irreconcilable approaches.

1. Under one approach, the court asks why the patentee made *the specific narrowing amendment it chose to make*. *See, e.g*, *Felix v. Am. Honda Motor Co.*, 562 F.3d 1167, 1184 (Fed. Cir. 2009) ("If Felix had intended *only* to add a channel and not add a gasket, he could easily have simply amended original claim 1 to add limitation (e) and not limitation (f)."); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1315 (Fed. Cir. 2006) ("if the patentee had wished only to limit the claims to human EPO, the patentee could have done so by continuing to use the adjective 'human' … in the third preliminary amendment; instead the patentee chose to further narrow the claims …").

Under that approach, the "tangential exception" applies when an amendment adds multiple limitations to a claim at the same time, and not all relate to an examiner's rejection. The limitations unrelated to the examiner's rejection may fit the tangential exception. Judge Dyk's dissenting opinion in *Ajinomoto* applies that approach. 932 F.3d at 1361-64. By the same token, the "tangential exception" generally does not apply where the alleged equivalent and the reason for the amendment both concern the same claim element. Where, as here, the patentee focused on a particular claim element, and responded to an examiner's rejection by narrowing in a way that excludes a defendant's allegedly equivalent product,

the rationale for the narrowing amendment cannot be "tangential" to the alleged equivalent. *Honeywell*, 523 F.3d at 1316 ("Because the alleged equivalent focuses on the IGV limitation, the amendment bore a direct, not merely tangential, relation to the equivalent."); *Biagro W. Sales, Inc. v. Grow More Inc.*, 423 F.3d 1296, 1306 (Fed. Cir. 2005) ("Because both the reason for the amendment and the asserted equivalent relate to the concentration of the fertilizer," the tangential exception does not apply.).

Decisions in that line further hold that patent owners *cannot* invoke the "tangential exception" by arguing that, in retrospect, they narrowed their claims more than they needed to in response to an examiner's rejection. *See, e.g.*, *Ajinomoto*, 932 F.3d at 1362-63 (collecting cases); *Int'l Rectifier Corp. v. IXYS Corp.*, 515 F.3d 1353, 1359 (Fed. Cir. 2008) ("IR's decision to claim that structure using the limiting term 'adjoining,' *whether or not required to overcome the rejection*, cannot be described as only tangentially related …") (emphasis added); *Lucent*, 525 F.3d at 1218; *Schwarz Pharma, Inc. v. Paddock Labs., Inc.*, 504 F.3d 1371, 1377 (Fed. Cir. 2007) ("[T]hat the inventors may have thought after the fact that they could have relied on other distinctions in order to defend their claims is irrelevant and speculative ...."); *Festo*, 344 F.3d at 1371. To accept such an argument would turn the "tangential" exception into a buyer's remorse exception, by ignoring *how* the patent applicant chose to amend its claims in response to a rejection and focusing instead on what the applicant wished it had done.

Judge Bryson's opinion in *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356 (Fed. Cir. 2005)—often cited by decisions in this line of cases—explains that patentees frequently make such surrendered-more-than-I-needed-to arguments, but that "there is no principle of patent law that the scope of a surrender of subject matter during prosecution is limited to what is absolutely necessary to avoid a prior art reference that was the basis for an examiner's rejection." *Id.* at 1361 (rejecting buyer's-remorse argument in the context of claim construction); *id.* at 1363 (applying prosecution history estoppel for similar reasons).

2. The Federal Circuit's other approach is diametrically opposite to the first. Some panels accept precisely the type of buyer's-remorse arguments that other panels reject and base the tangential-exception inquiry on a *post hoc* assessment of what the patent applicant needed to surrender to avoid an examiner's rejection. Those panels begin by phrasing the "reason" for the disputed narrowing amendment as surrendering only what was necessary to avoid a specific rejection—often to distinguish a particular piece of invalidating prior art. *See, e.g*, *Insituform Techs., Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360, 1370 (Fed. Cir. 2004) ("the narrowing amendment in this case was for the purpose of distinguishing the invention over Everson."); *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841, 849 (Fed. Cir. 2006) ("The patentee added the 'differentially spaced' limitation to distinguish the diaphragm mouth call from a prior art device that consisted of a shelf-like structure positioned on top of the membrane without any spacing.").

It generally follows, in those panels' view, that unnecessarily surrendered claim scope is "tangential" to that reason—without regard to the applicant's choice of how far to go in avoiding the examiner's rejection. *See, e.g.*, App-19-20; *Ajinomoto*, 932 F.3d at 1355; *Regents*, 517 F.3d at 1378; *Primos*, 451 F.3d at 849 (Unlike the prior art, "[t]he accused device, … includes a dome that is spaced above the membrane. Because the accused device's dome includes the spacing, the amendment was merely tangential…").

The panel in this case took that approach. It considered why Lilly amended its claims at all, not why Lilly chose to amend its claims by narrowing from "an antifolate" to "pemetrexed disodium." Thus, the panel concluded that "the reason for the narrowing amendment … was to avoid Arsenyan," and "not to cede other, functionally identical, pemetrexed salts." App-20. From there, the panel reasoned that "Lilly's amendment, *inartful* though it might have been, was prudential in nature and *did not need or intend to cede* other pemetrexed salts." *Id.* (emphasis added). In the panel's view, it was irrelevant that Lilly chose to give Arsenyan a wide berth and literally *did* "cede other pemetrexed salts" by narrowing its claims from "antifolate" to the specific "pemetrexed disodium" compound in its product, even though Lilly knew how to claim more broadly.

The *Ajinomoto* majority's analysis likewise asked why the patentee amended its claims at all, and relied on a *post hoc* assessment of what scope the patent owner *needed* to surrender to avoid the examiner's rejection—while largely ignoring what the patent owner actually *did* surrender, 932 F.3d at 1355

(reason was to amend the claims to "no longer include[] the prior-art *E. coli* YfiK protein"), and finding that the tangential exception did not apply where the alleged equivalent was not part of the scope the patent owner needed to surrender (without regard for the fact that the patent owner did surrender that scope). *Id.* *Ajinomoto* and this case both cited earlier Federal Circuit decisions as supporting their approach, including the *Regents* case, where the dissent contended that the majority had erroneously accepted a surrendered-more-than-I-needed-to argument from the patent owner. 517 F.3d at 1380-81. (Prost, C.J., dissenting). App-23-24.

3. The two approaches are fundamentally irreconcilable. Under the first approach, the patent owner's reasons for making *the particular amendment it made* drive the analysis. And the result is usually that the patent owner cannot escape prosecution history estoppel by arguing that it surrendered more than it needed to. Under the second approach, the patent owner's reasons for *amending the claim at all* drive the analysis. And there, the same argument produces the opposite result: the patent owner *can* escape prosecution history estoppel by arguing that it surrendered more than it needed to. This difference in approaches has split Federal Circuit panels. *Ajinomoto*, 932 F.3d at 1363 (Dyk, J., dissenting) ("The majority adopts a slightly different version of Ajinomoto's untenable [surrendered-more-than-necessary] argument" and "ignores *how* the patentee deliberately elected to narrow the claims." (emphasis added)); *Regents*, 517 F.3d at 1380-82 (Prost, C.J., dissenting). To be sure, if the patentee *did* need to surrender what it did— if the patentee amended its

claims to distinguish prior art that contains the defendant's alleged equivalent—then the patentee will lose under both approaches. *Festo*, 344 F.3d at 1369 ("Although we cannot anticipate the instances of mere tangentialness that may arise, we can say that an amendment made to avoid prior art that contains the equivalent in question is not tangential; it is central to allowance of the claim."). But where, as here and in many other cases, the defendant's product was not within the prior art the Patent Office cited, but within the scope the patentee surrendered to avoid that prior art, the applicability of the "tangential" exception will depend on which panel the parties draw on appeal.

So it was here: the choice of approach dictated the outcome in this case. Had the first approach been taken, prosecution history estoppel would have applied. The court would have asked why Lilly chose the amendment it did, not just why Lilly amended the claims at all. Here, Lilly chose to narrow an element of its claims from "antifolate" to "pemetrexed disodium." Petitioners' product (pemetrexed ditromethamine) is equivalent to that *same* narrowed element.[2] Lilly's reason for the particular amendment it made—*i.e.*, its choice of how far to go in narrowing the "antifolate" term to avoid prior art—"bore a direct, not merely tangential, relation to the equivalent." *Honeywell*, 523 F.3d at 1316.

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[2] It is undisputed that "pemetrexed disodium" is one element, not two. *See* Lilly Br. on Appeal at 61, No. 18-2126, (Fed. Cir. Nov. 13, 2018), ECF#28; Dr. Reddy's Reply Br. at 19, No. 18-2128, at 19 (Fed. Cir. Jan. 16, 2019), ECF#46 (citing *id.*).

But because the panel took the second approach, it focused on Lilly's reasons for amending the claims at all and on what Lilly wished it had done in hindsight. Thus, the panel held that prosecution history estoppel would not apply based on the view that Lilly's amendment, "*inartful* though it might have been, was prudential in nature and *did not need or intend to cede* other pemetrexed salts." App-20 (emphasis added). Absent this Court's review, the applicability of the "tangential exception" will continue to depend—as it did here—on which panel the parties draw on appeal.

II. The Decision Below Cannot Be Reconciled With This Court's Precedents.

Both approaches cannot be right, and the approach applied here is plainly wrong.

Festo reiterated several times that the "exceptions" to prosecution history estoppel—including the "tangential" exception—are all instances where *the patentee could not reasonably be expected to have described the insubstantial substitute in question*. *See* 535 U.S. at 741 (the third exception is "some *other* reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.") (emphasis added); *id.* (To avoid prosecution history estoppel, "[t]he patentee must 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."). That is because the doctrine of equivalents is "premised on" the inherent limits of language, 535 U.S. at 734, and recognition that inventors cannot be expected to

anticipate every insubstantial change a competitor might make. *Id.* at 731-32. A narrowing amendment to a particular element, however, "undercuts that premise" as to that element, and shows "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." 535 U.S. at 734-35.

Here, it is beyond dispute that Lilly *could* "reasonably be expected to have" claimed Petitioners' product when it made its narrowing amendment. 535 U.S. at 741. Lilly did precisely that in other patents, claiming "pemetrexed" or pyrrolo-pyrimidine derivatives. Lilly did not "lack[] the words," *id.* at 735—it had used them before. The *premise* of the doctrine of equivalents, and the unifying principle behind the exceptions to prosecution history estoppel, is thus conspicuously absent here. Lilly's choice to claim "pemetrexed disodium" rather than some broader set of compounds is just that—a choice. To relieve Lilly of the consequences of that choice because it was "inartful" or "not need[ed] or intend[ed]" is thus directly contrary to *Festo*.

More fundamentally, the approach the panel took undermines prosecution history estoppel as a limit on the doctrine of equivalents and threatens the public-notice function of patent claims. Even with the doctrine of equivalents, "[a] patent holder should know what he owns, and the public should know what he does not." *Festo*, 535 U.S. at 731. For more than 100 years, prosecution history estoppel has allowed a patent owner's competitors to "rely on … the public record of the patent proceedings" to know *ex ante*

whether "their own devices will … be found to infringe by equivalence." *Id.* at 726; *see also Statement of the Case §A, supra*.

Under the approach the panel applied here, the public cannot objectively rely on narrowing amendments in prosecution to learn what a patent holder does not own. Patent owners will be able to argue—as Lilly did here—that the "reason" for any narrowing amendment was to avoid a particular rejection, and that any surrender of scope that was not necessary to that reason is "tangential." This invites precisely the sort of circumvention of the examination process that prosecution history estoppel is designed to prevent, where "the inventor might avoid the [Patent Office's] gatekeeping role and seek to recapture in an infringement action the very subject matter surrendered as a condition of receiving the patent." *Festo*, 535 U.S. at 734. The approach taken to the tangential exception in cases like *Honeywell*, *Biagro*, and Judge Dyk's *Ajinomoto* dissent is faithful to this Court's precedent. The approach taken here and in similar cases is not.

III. The Question Presented Is Important, And This Case Is The Ideal Vehicle To Resolve It.

Only this Court can explain what it meant when it announced the "tangential" exception in *Festo*. The Federal Circuit has debated that question for eighteen years, over dozens of decisions, and given two irreconcilable answers. There is no reasonable prospect that further percolation would improve the situation. Nor, given the Federal Circuit's exclusive jurisdiction and the doctrine of equivalents' character as judge-made law, is there any role for another court

or Congress to clarify the meaning of the tangential exception. "There is perhaps no question more important to the health of patents than the scope and application of the judicially-created doctrine of equivalents." *Litton Sys., Inc. v. Honeywell, Inc.*, 145 F.3d 1472, 1472 (Fed. Cir. 1998) (Plager, J., dissenting from denial of rehearing en banc). The Federal Circuit's confused treatment of the "tangential" exception throws the scope and application of the doctrine of equivalents into disarray.

As the amicus briefing below confirms, the meaning of the "tangential exception" is important because it affects the ability of productive companies to determine their potential liability *ex ante*, before making substantial investments in competing products. Developing and securing FDA approval of a generic drug product, for example, typically costs millions of dollars. *See, e.g.*, FTC, EMERGING HEALTH CARE ISSUES 14 (June 2009), https://tinyurl.com/voe5myd. Analogous costs for follow-on biologic manufacturers are hundreds of millions of dollars or more. *Id.* A new semiconductor plant costs *billions* of dollars. MICHAELA D. PLATZER & JOHN F. SARGENT, JR., CONG. RESEARCH SERVICE: U.S. SEMICONDUCTOR MANUFACTURING 9 (June 2016), https://tinyurl.com/tyhlptk. Too much uncertainty in the scope of patents chills beneficial investments in legitimate products. This Court's precedent recognizes the same point: "If competitors cannot be certain about a patent's extent, they may be deterred from engaging in legitimate manufactures outside its limits, or they may invest by mistake in competing products that the patent secures." *Festo*, 535 U.S. at 732; *see also, e.g.*, *Merrill v. Yeomans*, 94 U.S. 568,

573-74 (1876) ("The public should not be deprived of rights supposed to belong to it, without being clearly told what it is that limits these rights."). Although the doctrine of equivalents requires the public to tolerate some uncertainty, "[t]here can be no denying that the doctrine of equivalents, when applied broadly, conflicts with the definitional and public-notice functions of the statutory claiming requirement." *Warner-Jenkinson*, 520 U.S. at 29. Even with the doctrine of equivalents, "[a] patent holder should [still] know what he owns, and the public should know what he does not." *Festo*, 535 U.S. at 731.

This case is an ideal vehicle to resolve the meaning of the tangential exception. For one thing, the applicability of the tangential exception decides the entire case. It is undisputed that the predicates for prosecution history estoppel apply—*i.e.*, that Lilly made a narrowing amendment that triggers prosecution history estoppel unless an exception applies. Lilly has not argued that either of *Festo*'s other two exceptions apply; it has relied entirely on the tangential exception. If Lilly can invoke the tangential exception, its infringement claims succeed; if not, its infringement claims fail.

For another, this case cleanly exemplifies a recurring fact pattern in patent litigation: a patent applicant surrenders more than necessary to avoid a rejection in prosecution, then tries to recapture some of that claim scope in litigation. *See Norian*, 432 F.3d at 1361 ("[I]t frequently happens that patentees surrender more through amendment than may have been absolutely necessary to avoid particular prior art."). And it is uniquely clear here that when Lilly

amended its claims, it did not lack the words to cover Petitioners' product: it could have claimed "pemetrexed," as it did in other patents, but instead chose to claim "pemetrexed *disodium*." To resolve this case would require little more than reaffirming the principle articulated in *Festo* that all three exceptions—including the "tangential" exception—apply only where "the patentee could not reasonably be expected to have described the insubstantial substitute in question." *See* 535 U.S. at 741.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for certiorari.

Respectfully submitted,

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