Nos. 19-1058, 19-1061

In the Supreme Court of the United States

HOSPIRA, INC.,

Petitioner,

v.

ELI LILLY AND COMPANY,

Respondent.

DR. REDDY'S LABORATORIES, LTD., ET AL.,

Petitioners,

v.

ELI LILLY AND COMPANY,

Respondent.

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

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the court of appeals correctly applied the tangentiality exception recognized in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), to the facts of these cases when it held that prosecution history estoppel does not bar respondent from pursuing an infringement claim against petitioners under the doctrine of equivalents.

CORPORATE DISCLOSURE STATEMENT

Eli Lilly and Company has no parent corporation, and no publicly held company holds 10% or more of its stock.

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BRIEF IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-31a) is reported at 933 F.3d 1320.[1] The order of the court of appeals denying rehearing en banc (Pet. App. 48a-49a) is unreported. The opinion and order of the district court granting summary judgment to respondent with

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[1] The court of appeals issued a combined opinion resolving separate appeals filed by Hospira, Inc. (petitioner in No. 19-1058) and Dr. Reddy's Laboratories, Ltd., et al., (petitioners in No. 19-1061). Respondent is filing a joint brief in opposition to both petitions. Unless otherwise noted, citations to "Pet. App." are to the appendix to the petition filed by Hospira, Inc. in No. 19-1058.

respect to petitioner Hospira, Inc. (Hospira) (Pet. App. 32a-47a) is unreported and available at 2018 WL 3008570. The findings of fact and conclusions of law issued by the district court with respect to respondent's claim against petitioners Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL) are reported at 323 F. Supp. 3d 1042 (DRL Pet. App. 33-49).

JURISDICTION

The judgments of the court of appeals were entered on August 9, 2019. A petition for rehearing was denied on November 8, 2019. The petitions for a writ of certiorari were filed on February 24, 2020. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATEMENT

Respondent Eli Lilly and Company (Lilly) manufactures and sells ALIMTA®, a drug that treats mesothelioma and certain types of lung cancer. The active chemotherapeutic agent in ALIMTA is pemetrexed. In ALIMTA, the pemetrexed is present as a salt form, pemetrexed disodium. Lilly is the assignee of U.S. Patent No. 7,772,209 (the '209 patent), which claims a method of administering pemetrexed disodium involving pretreating patients with folic acid and vitamin B_{12}. The purpose of the claimed method is to reduce the incidence of pemetrexed's potentially severe toxicities without compromising its efficacy in treating cancer.

Under the Hatch-Waxman Act, petitioners Hospira, Inc. (Hospira) and Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL) sought FDA approval to sell a different salt form of pemetrexed, pemetrexed ditromethamine. Neither Hospira nor DRL performed any human clinical trials of their pemetrexed ditromethamine products. Rather, their applications to FDA relied on Lilly's data proving the efficacy and safety of Lilly's pemetrexed disodium product ALIMTA when used in combination with folic acid and vitamin B_{12}.

Lilly sued petitioners, asserting claims for patent infringement under the doctrine of equivalents. In response, Hospira and DRL each contended that prosecution history estoppel barred Lilly from asserting infringement claims under that doctrine. Their estoppel arguments were based on a narrowing amendment Lilly made to its patent claims during prosecution of the '209 patent. To rebut the presumption of estoppel, Lilly invoked the tangentiality exception to prosecution history estoppel recognized by this Court in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002). The district court and a unanimous panel of the Federal Circuit agreed with Lilly. Based on the prosecution record, the courts found that Lilly had amended its claims to overcome prior art related to a different antifolate other than pemetrexed and that the rationale for the amendment was tangential to petitioners' equivalents, which use the same antifolate as Lilly's patented invention. The Federal Circuit denied en banc review without dissent.

Petitioners argue that the decision below conflicts with this Court's decision in *Festo*. Petitioners also argue that there is an intra-circuit conflict about how to apply *Festo*. But the asserted conflicts are of petitioners' own making. None of the usual objective indicia of such conflicts—such as commentary identifying a conflict, or calls by dissenting judges for en banc review or review by this Court—exist. And petitioners tellingly cannot even agree between themselves about what the purported conflicts are.

Nor has the Federal Circuit turned *Festo*'s tangentiality exception into a categorical "buyer's remorse" exception, as petitioners claim. This Court adopted a flexible approach to prosecution history estoppel in *Festo*. The court of appeals has faithfully applied the tangentiality exception by asking whether the reason for claim amendment, as indicated by the objective prosecution record, is tangential or peripheral to the claimed equivalent. Unsurprisingly, it has reached different outcomes in cases involving different facts and records. That is no reason to grant certiorari. Nor is it reason to engraft petitioners' rigid rules onto the flexible approach announced in *Festo*.

At bottom, petitioners complain only about how the Federal Circuit applied the tangentiality exception to the facts of this case. Even if that court erred—and it did not—its fact-bound decision would not merit the Court's attention. This Court has already rejected petitioners' public notice arguments in repeatedly reaffirming the existence of the doctrine of equivalents and in adopting the tangentiality exception in the first place. The doctrine of equivalents protects patent rights, and prevents infringers from evading responsibility, in precisely the circumstances presented here. The petitions should be denied.

1. Pemetrexed, the active chemotherapeutic agent in ALIMTA, is an "antifolate." Antifolates are a class of chemotherapy drugs that fight cancer by inhibiting certain enzymes that use compounds called "folates" in the course of making DNA. Cancerous tumors need DNA in order to grow, and antifolates interfere with DNA synthesis.

The same mechanism that makes antifolates effective in treating cancer can also cause toxicity to healthy cells, particularly those that divide rapidly. When antifolates interfere with DNA production in healthy cells, it can lead to severe and even fatal consequences for patients receiving antifolate chemotherapy. These toxicities historically complicated the development of antifolates. Pet. App. 6a.

During pemetrexed's development, patients in a clinical trial suffered severe toxicities from the drug, and several patients died. This threatened to stop pemetrexed's development. But a Lilly scientist named Clet Niyikiza—the named inventor of the '209 patent—discovered a novel way to mitigate these toxicities and thereby make pemetrexed safe enough to use as a cancer treatment. Specifically, Dr. Niyikiza discovered that pemetrexed's toxicities can be significantly reduced by pretreating patients with folic acid—which is a folate—and vitamin B_{12}. This method of treatment reduces the incidence of severe toxicities that can be associated with pemetrexed treatment, but surprisingly does not compromise the drug's anticancer efficacy. The ALIMTA label instructs that a patient must receive this regimen of folic acid and vitamin B_{12} pretreatment prior to receiving ALIMTA. DRL C.A. App. 7811.

Lilly distributes ALIMTA as a solid powder formulation of pemetrexed disodium. In this form, the pemetrexed is bonded to two sodium ions. ALIMTA is not administered to patients as a solid, however. Pet. App. 35a. It is dissolved in saline solution so it can be injected into the patient intravenously. Pet. App. 35a. When pemetrexed disodium dissolves, the pemetrexed and sodium separate, or "dissociate," from each other, meaning that what is administered to a patient is a solution containing pemetrexed ions and sodium ions. Pet. App. 10a, 15a The dissociated sodium ions do not play any role in treating a patient's cancer or in the claimed invention's reduction in toxicity; the pemetrexed ions are the active ingredients that fight cancer.

2. Lilly is the assignee of the '209 patent, which claims Lilly's improved method of administering pemetrexed chemotherapy by pretreating patients with folic acid and vitamin B_{12} and then treating the patient with pemetrexed disodium.

Petitioners' prosecution history estoppel claim centers around an amendment made during the prosecution of U.S. Patent Application No. 10/297,821 (the '821 application), one of the applications leading to the '209 patent. As relevant here, Lilly's application claimed administration of "an antifolate" following pretreatment with a methylmalonic acid lowering agent (a class that includes vitamin B_{12}). The examiner rejected this claim over a prior art reference, Arsenyan, that discloses pretreatment with a vitamin B_{12} derivative before administration of methotrexate, a *different* antifolate. Arsenyan makes no reference to different salt forms of methotrexate or any other antifolate. Nor does it refer at all to pemetrexed, let alone different salt forms of pemetrexed. DRL C.A. App. 7880, 8504-8507.

In response to the Arsenyan rejection, Lilly amended its claims to replace administration of "an antifolate" with administration of "pemetrexed disodium." The reason for Lilly's amendment was to avoid Arsenyan and its disclosure of methotrexate by specifying a particular active antifolate—pemetrexed—that was not methotrexate. Pet. App. 21a. Lilly's amendment was not made to distinguish pemetrexed disodium from different salt forms of pemetrexed (which are all the same active antifolate, pemetrexed). *Id.*

The examiner withdrew the Arsenyan rejection in view of Lilly's amendment. When Lilly filed U.S. Application No. 11/776,329, which ultimately issued as the '209 patent, Lilly carried through the amendment from administering "an antifolate" to administering "pemetrexed disodium." DRL C.A. App. 46, 52-53, 5466-5470.

The '209 patent issued on August 10, 2010. The Federal Circuit and the Patent Trial and Appeal Board have affirmed its validity against repeated challenges by other of Lilly's generic competitors. *See Neptune Generics, LLC v. Eli Lilly & Co.*, 921 F.3d 1372 (Fed. Cir. 2019); *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357 (Fed. Cir. 2017).

3. Petitioners each filed a "paper" new drug application (NDA) under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(2), seeking approval to sell their own pemetrexed products before expiration of the '209 patent.[2] As "paper" NDAs, petitioners' NDAs, like abbreviated new drug applications, rely on Lilly's ALIMTA clinical data to establish the safety and efficacy of their pemetrexed products. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

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[2] The Section 505(b)(2) "paper" NDA approval pathway was added to the Food and Drug Act as part of the Hatch-Waxman Act. Like an Abbreviated New Drug Application (ANDA), a "paper" NDA allows the applicant to rely on data developed by an existing approved branded drug. However, unlike an ANDA, a "paper" NDA allows for limited modifications to the proposed product compared to the branded product, including in the dosage form, route of administration, or (as here) the salt form. *See* FDA, *Determining Whether to Submit an ANDA or a 505(b)(2) Application: Guidance for Industry* (May 2019), https://tinyurl.com/505b2guidance.

In an attempt to avoid the ’209 patent, petitioners propose to sell pemetrexed *ditromethamine*—that is, a product containing the same active antifolate (pemetrexed) in an alternate salt formulation (ditromethamine). Like ALIMTA, petitioners’ products would be dissolved in solution before administration, separating the pemetrexed ions from the salt ions and resulting in administration of pemetrexed ions to the patient. Also like ALIMTA, petitioners’ products would be administered only after pretreatment with folic acid and vitamin B_{12}, avoiding the toxicities associated with pemetrexed in the same manner as in the ’209 patent. And like the sodium in pemetrexed disodium, the tromethamine in petitioners’ pemetrexed ditromethamine is irrelevant to the treatment of cancer and to the use of the patented method to reduce pemetrexed toxicity.

4. In 2016, Lilly filed separate patent-infringement suits against petitioners in the United States District Court for the Southern District of Indiana. Lilly alleged that petitioners’ pemetrexed ditromethamine products would infringe the ’209 patent under the doctrine of equivalents. Petitioners argued that prosecution history estoppel barred Lilly from pursuing infringement under that doctrine. In response, Lilly asserted that the tangentiality exception to prosecution history estoppel rebutted the presumption of estoppel.

The district court agreed with Lilly and entered judgment in its favor against each petitioner. In each case, the court first found that a person of ordinary skill would conclude from the prosecution history that the reason for Lilly’s amendment was to avoid Arsenyan and its disclosure of the antifolate methotrexate. The court further concluded that this reason was only tangentially related to petitioners’ alleged equivalent using a different salt form of the same antifolate (pemetrexed) from the one in the patent claims. Pet. App. 40a-43a; DRL Pet. App. 37-38.

5. In a consolidated opinion, the Federal Circuit unanimously affirmed the district court's decisions regarding prosecution history estoppel. Pet. App. 1a-31a. As the court of appeals recognized, "[t]he reason for Lilly's amendment . . . was to narrow original claim 2 to avoid Arsenyan, which only discloses treatments using methotrexate, a different antifolate." Pet. App. 21a. Petitioners had urged the court to find that by making the amendment, Lilly had surrendered all antifolates except pemetrexed disodium, including petitioners' proposed pemetrexed ditromethamine equivalent. The court found "a less sweeping and more sensible reason for Lilly's amendment: to surrender antifolates other than pemetrexed." Pet. App. 26a. And the court concluded that this rationale "was merely tangential" to the equivalent at issue—a different salt form of pemetrexed. Pet. App. 26a.

In reaching this conclusion, the court of appeals considered, and rejected, various arguments from petitioners as to why the tangentiality exception should not apply. Pet. App. 19a-26a. As relevant here, DRL had argued that "an applicant's remorse at ceding more claim scope than necessary is not a reason for the tangential exception to apply." Pet. App. 22a. The court of appeals agreed with that general proposition, but rejected DRL's categorical position that the tangentiality exception can never apply when a claimant narrows a claim beyond the minimum necessary to overcome prior art. Pet. App. 22a. According to the court, "the tangential exception only exists because applicants over-narrow their claims during prosecution." Pet. App. 22a. At the same time, the court emphasized that it was not holding that the tangentiality exception automatically applies when an applicant surrenders more claim scope than necessary. Pet. App. 22a. Instead, the court explained that it was necessary to examine "the reason for an amendment" by reference to "the context in which it was made, including the prior art that might have given rise to the amendment in the first place." Pet. App. 22a. This inquiry, the court further explained, is "case-specific" and requires "direct consideration of the specific record of this case and what it shows about the reason for amendment and the relation of that reason to the asserted equivalent." Pet. App. 24a n.5.

Because the reason for Lilly's amendment was tangential to the claimed equivalent in these cases, the court held that prosecution history estoppel did not bar application of the doctrine of equivalents. Pet. App. 26a.

6. The court of appeals denied rehearing en banc without dissent. Pet. App. 48a-49a.

REASONS FOR DENYING THE PETITIONS

The petitions are about the tangentiality exception to the prosecution history estoppel exception to the doctrine of equivalents in patent law. The district court and the unanimous Federal Circuit found that the tangentiality exception applies on the facts of this case. Petitioners disagree. They argue that the Federal Circuit's decision conflicts with this Court's decision in *Festo* and with other Federal Circuit decisions, and they invite this Court to erect new, rigid rules governing the tangentiality exception. But petitioners ask this Court to grant review of a decision that the Federal Circuit did not make: the court of appeals expressly rejected the very rule petitioners claim it adopted. And petitioners ask this Court to review conflicts that do not exist. This Court has already rejected the sort of bright-line rules that petitioners purport to divine from *Festo*. None of the traditional indicia of the asserted intra-circuit conflicts exists. And the fact that petitioners do not agree on the precise conflict, or on the purportedly correct bright-line rule, further confirms that this is a "conflict" of their own making. The petitions should be denied.

I. The Federal Circuit's Decision Is Consistent with *Festo*

In *Festo*, this Court explained the circumstances in which patentees who have narrowed a claim during prosecution should nevertheless be permitted to avail themselves of the doctrine of equivalents. Among other things, the Court found no reason "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. The Federal Circuit correctly applied *Festo* to hold that prosecution history estoppel did not bar Lilly from asserting infringement-by-equivalents claims on the facts presented here, where Lilly's narrowing of the claims to one active antifolate had nothing to do with the selection of a particular pemetrexed salt. Petitioners' arguments to the contrary misconstrue the decision below and rest on the type of rigid rules that this Court rejected in *Festo*.

A. The Federal Circuit Correctly Applied *Festo*'s Flexible Test

1. The doctrine of equivalents protects patentees when infringers make "unimportant and insubstantial changes . . . which, though adding nothing, would be enough to take the copied matter outside the claim." *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950). To protect against copying by means of immaterial alterations, "[t]he scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 732 (2002). The doctrine has a long history and "remain[s] a

firmly entrenched part of the settled rights protected by the patent." *Id.* at 733.

A patentee's ability to assert infringement under the doctrine of equivalents is not unlimited. As this Court explained in *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997), "prosecution history estoppel" applies as part of the infringement analysis to prevent a patentee from using the doctrine of equivalents to recapture certain claim scope given up during prosecution. *Id.* at 30-31. In that case, the Court put the burden on the patentee to "establish the reason for an amendment required during patent prosecution," allowing a court then to decide whether that explanation was sufficient to overcome estoppel. *Id.* at 33-34. That is inherently a "flexible" inquiry, as the Court explained; that a "rule might provide a brighter line for determining whether a patentee is estopped under certain circumstances is not a sufficient reason for adopting such a rule." *Id.* at 32 n.6.

Following *Warner-Jenkinson*, the en banc Federal Circuit (in a badly fractured decision) nevertheless adopted a new, bright-line rule, under which a finding that prosecution history estoppel applied due to a narrowing amendment during prosecution *completely barred* all claims of equivalence to the narrowed element. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000) (en banc). This Court granted certiorari, vacated the Federal Circuit's decision, and once again rejected a rigid approach. This Court held that while prosecution history estoppel limits the doctrine of equivalents, it does *not* impose an absolute bar on the doctrine's application. *Festo*, 535 U.S. at 737-38.

The Federal Circuit's *per se* rule, the Court stated, was "inconsistent with the purpose of applying the estoppel in the first place—to hold the inventor to the representations made during the application process and to the inferences that may reasonably be drawn from the amendment." *Id.* at 737-38. It was also inconsistent with the Court's "consistent[] appli[cation] of [prosecution history estoppel] in a flexible way, not a rigid one." *Id.* at 738. As the Court explained, an amendment made during prosecution concedes "that the patent does not extend as far as the original claim," but "[i]t does not follow . . . that the amended claim becomes so perfect in its description that no one could devise an equivalent." *Id.*

The *Festo* Court identified various scenarios in which "the narrowing amendment . . . may still fail to capture precisely what the claim is." *Id.* For one, "[t]here is no reason why a narrowing amendment should be deemed to relinquish equivalents unforeseeable at the time of the amendment and beyond a fair interpretation of what was surrendered." *Id.* For another, there is no reason "to foreclose claims of equivalence for aspects of the invention that have only a peripheral relation to the reason the amendment was submitted." *Id.* According to the Court, a "flexible" inquiry taking into account these considerations was preferable to the "rigid" rule adopted by the Federal Circuit. *Id.*

The Court summarized its approach as follows:

> There are some cases . . . where the amendment cannot reasonably be viewed as surrendering a particular equivalent. [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. In those cases the patentee can overcome the presumption that prosecution history estoppel bars a finding of equivalence.

Id. at 740-41. As evidenced by the Court's use of the word "or," those scenarios are independent exceptions to the presumption of estoppel.

With respect to the tangentiality exception—the exception applied here—the question is "whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003) (en banc). This reason must be "objectively apparent" and "discernible from the prosecution history record[.]" *Id.* So long as the basis for application of the exception is discernible from the prosecution record, the public is on notice, eliminating any concerns about the public notice function of the claims. *See id.*

2. The Federal Circuit correctly applied these principles to the facts of this case. In the prosecution amendment at issue, Lilly narrowed its claims from administering an antifolate, in general, to administering pemetrexed disodium, in particular, in light of a prior publication (Arsenyan), "which only discloses treatments using methotrexate, a different antifolate." Pet. App. 21a. The court of appeals correctly observed that the prosecution record reveals that Lilly narrowed its original claim "to more accurately define what it actually invented, an improved method of administering pemetrexed." Pet. App. 21a. Lilly argued, and the court of appeals agreed, that a person of ordinary skill would understand that the "reason for [Lilly's] amendment was to distinguish pemetrexed from antifolates generally." Pet. App. 20a.

The Federal Circuit further correctly concluded that the rationale for the amendment was tangential to the use of petitioners' alternative pemetrexed salts in lieu of pemetrexed disodium. Pet. App. 21a-22a. As the court explained, "the particular type of salt to which pemetrexed is complexed relates only tenuously to the reason for the narrowing amendment." Pet. App. 21a. Indeed, prior art publications considered by the patent examiner showed that the form of pemetrexed could not have been relevant to the amendment, as that art disclosed methods of administering pemetrexed disodium, albeit without Lilly's inventive approach to reducing pemetrexed toxicity. Pet. App. 21a-22a. "[N]arrowing 'antifolate' to 'pemetrexed disodium' could not possibly distinguish" these publications. Pet App. 22a. The prosecution history thus makes clear that Lilly's amendment had nothing to do with the particular salt form of pemetrexed. The Federal Circuit correctly held that the tangentiality exception applies.

B. Petitioners' Arguments to the Contrary Lack Merit

Petitioners offer a series of reasons, sometimes conflicting, for why the decision below is inconsistent with *Festo*. Each of those arguments fails. If anything, it is petitioners' arguments—which attempt to divine a rigid set of rules from *Festo*'s flexible approach—that conflict with *Festo*.

1. Petitioners caricature the decision below as creating a "buyer's remorse" defense—*i.e.*, that whenever a patentee narrows more than necessary to avoid prior art based on "post-hoc" reasoning, the amendment is automatically tangential. Hospira Pet. 16, 30; DRL Pet. 20-21. The Federal Circuit did no such thing. Although neither petition acknowledges this, the court of appeals explicitly *rejected* that very rule: "[a]mendments are not

construed to cede only that which is necessary to overcome the prior art . . . nor will the court 'speculat[e]' whether an amendment was necessary." Pet. App. 22a. The court did not apply a "buyer's remorse" defense, in name or substance.

Instead, consistent with this Court's instructions in *Festo*, the Federal Circuit examined "the reason for [Lilly's] amendment" with "reference to the context in which it was made, including the prior art that might have given rise to the amendment in the first place." Pet. App. 22a. And having considered "the subject matter surrendered by the narrowing amendment," the court of appeals determined that the equivalent here bore "only a peripheral relation to the reason the amendment was submitted." *Festo*, 535 U.S. at 737-38. In other words, the court correctly analyzed prosecution history estoppel and the question of tangentiality by considering the particular facts of this case, without resort to any "rigid rule." *See Warner-Jenkinson*, 520 U.S. at 32; *see also Festo*, 535 U.S. at 738.

2. Petitioners further contend that the Federal Circuit's decision is inconsistent with a panoply of bright-line rules they purport to glean from *Festo*, but petitioners cannot even agree on what those rules are. For good reason: *Festo* announced no *per se* rules; it rejected them.

a. Hospira seizes on a single sentence from the end of the Court's opinion in *Festo* as undoing the multifaced, practical approach adopted in that case: "The 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." 520 U.S. at 741. According to Hospira, unless the patentee can show that "it could not reasonably have amended the claim so as to encompass the claimed equivalent," it cannot invoke the tangentiality exception to overcome prosecution history estoppel. Hospira Pet. 17.

The end of the opinion is not the first time that the Court used this exact language; it also did so in the very paragraph in which it articulated three separate ways that the presumption of surrender could be overcome. By divorcing this sentence from its context and focusing on whether Lilly *could* have drafted an amendment including Hospira's equivalent, Hospira improperly deprives the tangentiality exception of independent meaning. Hospira asserts that Lilly might justify its failure to draft a broader claim if it "could not have foreseen that a competitor used a different pemetrexed compound." Hospira Pet. 15. But this Court articulated unforeseeability and tangentiality as separate exceptions in *Festo*. *See* 535 U.S. at 738, 740-41. Each exception represents a different way of showing why "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. The former exception focuses on whether the equivalent was foreseeable; the latter focuses on the reason for amendment and its relation to the equivalent. Hospira's approach would merge the two exceptions into one.

Hospira's argument reads the words "be expected to" out of the sentence it invokes. *Festo* does not ask whether it was *impossible* for the patentee to draft its claims to cover the equivalents. There are varying reasons why an amended claim may fail to capture an equivalent; as this Court recognized in *Festo*, a "narrowing amendment may demonstrate what the claim is not; but it may still fail to capture precisely what the claim is." *Id.* at 738. That may occur where, as here, the patentee at the time of amendment is focused on distinguishing prior art unrelated to the equivalent in question. Tangentiality is thus a *way* in which a patentee can show that it "could not reasonably be expected" to have drafted a claim encompassing the equivalent, because there was no reason for the patentee to have considered the equivalent when making the amendment.[3]

Hospira's fruit hypothetical (at 18) illustrates the point. Consider a patentee that amends its claim describing "fruit" to one describing "Red Delicious apples." One reason why the patentee might not have drafted its claim to include "Honeycrisp apples" is because they had not yet been discovered and were thus unforeseeable as an equivalent. But another, equally valid reason might be that the issue presented by the prior art had nothing to do with different types of apples and therefore the patentee was focused on a different issue entirely. Thus, if the prior art related to bananas, there is no reason that the patentee would be reasonably expected to focus on potential equivalents within the apple family. The same amendment to avoid prior-art bananas, on the other hand, might well bar a doctrine-of-equivalents claim against grapes, as the categories of fruit covered by the claim was the issue presented by the prosecution history.[4] Hospira's approach would bar consideration of these

[3] Hospira also accuses the Federal Circuit of attempting to divine Lilly's "subjective" or "true" purpose in narrowing its claims during prosecution. Hospira Pet. 7, 24. That is plainly wrong. The court of appeals considered what the publicly available prosecution record would inform a person in the field about the objective purpose for the amendment. That is the same analysis this Court announced in *Festo*: "Prosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process." 535 U.S. at 733.

[4] Similarly, if the reason for amendment in the hypothetical was to overcome prior art related to Pink Lady apples, the amendment

issues and prohibit "claims of equivalence for aspects of the invention that have only a peripheral relation to the reason the amendment was submitted," in contravention of *Festo*. 535 U.S. at 738.

b. For its part, DRL asserts that *Festo* announced a second, *different* rule for assessing tangentiality. According to DRL, an equivalent is tangential to the rationale for a narrowing amendment—and not surrendered by the amendment—only "when an amendment adds multiple limitations to a claim at the same time, and not all relate to an examiner's rejection." DRL Pet. 18. "The limitations unrelated to the examiner's rejection may fit the tangential exception." DRL Pet. 18. But, according to DRL, the exception "generally does not apply where the alleged equivalent and the reason for the amendment both concern the same element." DRL Pet. 18.

DRL's preferred rule appears nowhere in *Festo*. This Court did not spend pages touting the benefits of a "flexible" approach to prosecution history estoppel only silently to adopt a *per se* rule governing tangentiality in particular, or prosecution history estoppel generally. That is why, although the Federal Circuit recognized that "DRL's intuition—that an amendment that narrows an existing claim element evinces an intention to relinquish that claim scope—is often correct," it correctly "decline[d DRL's] invitation" to apply a "bright-line rule" in view of *Festo* and the "equitable nature of prosecution history estoppel." Pet. App. 25a. Instead, it recognized that even where an amendment involves only a single claim element, there may be circumstances where the prosecution record reveals that "the rationale underlying the amendment . . . bear[s] no more than a tangen-

could not be said to be peripheral to the claimed equivalent of a different apple variety.

tial relation to the equivalent in question." *Festo*, 535 U.S. at 740; Pet. App. 26a.

At bottom, as with Hospira, DRL's real disagreement is with the tangentiality exception itself: DRL asserts that *Festo*'s contemplation of the tangentiality exception has no "antecedents in this Court's prior precedent, nor was it suggested in any brief in that case." DRL Pet. 17. But even if true that does not justify rewriting *Festo* or imposing artificial limitations on the exception, nor does it somehow render the decision below inconsistent with it.

c. Petitioners each also point to the Federal Circuit's decision in *Ajinomoto Co. v. ITC*, 932 F.3d 1342, 1355 (Fed. Cir. 2019), as a further example of the Federal Circuit's inconsistency with *Festo*. Hospira Pet. 23; DRL Pet. 16. Notably, the pending petition for certiorari in *Ajinomoto* relies on *yet another* supposed rule from *Festo*: that unless the prosecution record contains an "explicit and contemporaneous explanation[]" of the rationale for a narrowing amendment, a patentee cannot overcome prosecution history estoppel, regardless of what can be reasonably inferred from an objective reading of the record. *See* Pet. at i, 25, *CJ CheilJedang Corp. et al. v. ITC et al.*, No. 19-1062 (filed Feb. 24, 2020). Just like petitioners' respective theories, that rule finds no support in *Festo* or any of this Court's other cases.

d. Finally, DRL's amicus Association for Accessible Medicines (AAM) suggests yet a fourth conflict—that the decision below conflicts with this Court's decision in *Warner-Jenkinson*. AAM Amicus Br. 14-15. According to AAM, prosecution history estoppel cannot apply when the patentee does not "'establish the reason for [the] amendment during patent prosecution.'" *Id.* at 14 (quoting 520 U.S. at 34). But in *Warner-Jenkinson* there was no indication in the record of a reason for the amendment at issue. Here, the reason for Lilly's amendment—to overcome the Arsenyan reference—is undisputed and apparent in the record. *Warner-Jenkinson* does not create an explicit statement rule of the sort advocated by AAM.

* * *

There is a simple reason why the pending petitions cannot agree on how the Federal Circuit has misinterpreted *Festo*—there is no misinterpretation.

II. There Is No Intra-Circuit Conflict

Petitioners also argue that the Federal Circuit's tangentiality decisions are internally inconsistent. But here too petitioners cannot agree on the contours of the intra-circuit conflict—*i.e.*, whether the decision in this case perpetuated a preexisting split that has existed for more than a decade (DRL's position) or whether the decision in this case *created* a split with every other decision that came before (Hospira's position). Not a single Federal Circuit judge has ever acknowledged either conflict. Petitioners point to no commentators identifying a conflict. And no judge voted for rehearing en banc in this case. For good reason: the court of appeals simply applied a well-established standard to the specific prosecution record in this case.

1. DRL posits that the Federal Circuit is divided into two camps on the tangentiality exception. In some cases, DRL claims, the court considers the patentee's rationale for narrowing the claim at all, and in others the court considers the patentee's rationale for choosing the particular amendment. DRL Pet. 18-22. DRL insists that only the latter approach is consistent with *Festo*.

As far as Lilly is aware, DRL is the first (and only) party to identify this purported intra-circuit conflict. If the Federal Circuit were as profoundly divided on the legal standard governing the tangentiality exception as DRL claims, one would have expected at least one judge of that court to have commented on that division. DRL cites several dissenting and concurring opinions by Federal Circuit judges in cases involving the tangentiality exception. DRL Pet. 17. But none of those opinions suggests that the court is internally divided or has misconstrued the exception as articulated in *Festo*. And even if one could plausibly posit that every Federal Circuit judge was simply unaware of the existence of such widespread intra-circuit turmoil, surely some academic or industry commentary would have taken note. DRL cites none.

That is because the Federal Circuit has consistently assessed tangentiality by focusing on the reason, as reflected in the prosecution history, that the patentee amended its claims. *See, e.g.*, *Integrated Tech. Corp. v. Rudolph Techs., Inc.*, 734 F.3d 1352, 1358-59 (Fed. Cir. 2013); *Lucent Techs., Inc. v. Gateway, Inc.*, 525 F.3d 1200, 1218 (Fed. Cir. 2008); *Regents of Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1371 (Fed. Cir. 2008); *Insituform Techs., Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360, 1370 (Fed. Cir. 2004). There is no separate line of cases, as DRL would have it, asking why the patentee chose the precise amendment language that it did as opposed to choosing some other hypothetical wording that would also be consistent with the rationale for the amendment. Rather, when the Federal Circuit has reached different conclusions about whether the tangentiality exception applies, it has applied a consistent legal standard but reached a different answer in a different case with a different prosecution record. That is a natural consequence of the flexible approach adopted in *Festo*.

Indeed, the cases on either side of DRL's line not only acknowledge one another but explicitly distinguish each other on the facts. Take *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293 (Fed. Cir. 2006), which DRL counts as falling on the "correct" side of the asserted conflict. DRL Pet. 18. That case acknowledges and distinguishes *Insituform Techs., Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360 (Fed. Cir. 2004), which DRL characterizes as "irreconcilable" with *Amgen*'s approach. *See Amgen*, 457 F.3d at 1314 ("[U]nlike *Insituform*, where it was clear that the amendment in question was not made to limit the number of cups and overcome the prior art, the requirement that EPO have exactly 166 amino acids may have been central to the allowance of claims 2–4 over a double patenting rejection."). The opinion below likewise considered and distinguished *Felix v. American Honda Motor Co.*, 562 F.3d 1157 (Fed. Cir. 2009)—another case DRL offers as applying the "correct" test—in light of differences in the prosecution record between the cases. Pet. App. 23a-24a ("[*Felix*'s] holding was determined by that patent's prosecution history."). None of the cases suggests that other cases applied an incorrect legal standard.

DRL also frames the debate between the majority and dissent of *Ajinomoto* as illustrating its claimed intra-circuit split. DRL Pet. 18, 21. But Judge Dyk's dissent does not quibble with the legal standard applied by the majority. Instead, Judge Dyk simply disagreed with the majority's fact-based conclusion about tangentiality. *See, e.g.*, 932 F.3d at 1363 (Dyk, J., dissenting) ("[T]the rationale for the narrowing amendment (avoiding a prior art protein based on its encoding nucleotide sequence that does not meet the newly claimed hybridization requirement) directly relates to the accused equivalent (a protein made by an encoding nucleotide sequence that does not meet the newly claimed hybridization requirement)."). The divergence between the *Ajinomoto* majority and dissent raises no profound dispute of governing law.

2. Hospira, for its part, does not suggest any longstanding divide within the Federal Circuit on the tangentiality exception. To the contrary, Hospira asserts that prior to this decision, the court had *consistently* rejected the rule that a patentee surrenders only what was necessary in a narrowing amendment. In Hospira's view, it was *this case* that created the intra-circuit conflict by adopting a "buyer's remorse" defense. Hospira Pet. 27-30. That argument simply rehashes Hospira's flawed characterization of the decision below. *See* pp. 15-16, *supra*.

The decision below did not vary from the line of cases Hospira cites. The panel expressly agreed with the general proposition that "[a]mendments are not construed to cede only that which is necessary to overcome the prior art." Pet. App. 22a. As Hospira admits, the court of appeals not only considered the line of cases Hospira cites in its petition, but also explicitly distinguished them on the facts. Hospira Pet. 30. At the same time, the court recognized that "the tangential exception only exists because applicants over-narrow their claims during prosecution." Pet. App. 22a. It thus looked in this case, as it has in all cases, to the "reason for [the] amendment" to determine whether to apply the exception. Pet. App. 22a.

3. The *Ajinomoto* petitioners also argue that the decision below departs from a line of precedent, but on different grounds. According to those petitioners, this case and *Ajinomoto* depart from a requirement of an "explicit and contemporaneous explanation[]" of the reason for the amendment in the prosecution record. Pet. at 24-25 *CJ CheilJedang Corp. et al. v. ITC et al.*, No. 19-1062

(filed Feb. 24, 2020). No decision announces such a rule or even applies one in substance. Rather, the cases those petitioners cite for the proposition that "silence" cannot rebut the presumption of estoppel simply state the rule, applied by the Federal Circuit in this case, that the reason for the amendment must be "discernible from the prosecution history record." *E.g.*, *Honeywell Int'l, Inc. v. Hamilton Sunstrand Corp.*, 523 F.3d 1304, 1315 (Fed. Cir. 2008) (internal quotation marks omitted); *see also Felix*, 562 F.3d at 1184.

* * *

In *Warner-Jenkinson* and *Festo*, this Court granted certiorari to review split decisions of the en banc Federal Circuit where the circuit judges were deeply and admittedly fractured. Here, by contrast, no judge dissented from the denial of rehearing en banc. The issue of prosecution history estoppel has generated no disagreement at any level of review in these cases—whether in the district court, before the court of appeals panel, or before the en banc court considering whether to grant rehearing. There is no intra-circuit conflict that justifies this Court's intervention.

III. The Petitions Do Not Present an Important Question Warranting the Court's Review

1. The petitions also do not present an important question meriting this Court's review. Petitioners and their amici fail to identify any important policy consequences flowing from the Federal Circuit's fact-bound decision. They primarily suggest that the court's decision undermines the public notice function of patents and prosecution records in informing competitors of their potential infringement liability. *E.g.*, Hospira Pet. 17-18, 20. That argument fails, for several reasons.

As an initial matter, this Court in *Festo* already considered the "delicate balance" between protecting novel inventions and protecting the public's freedom to "pursue innovations, creations, and new ideas beyond the inventor's exclusive rights." 535 U.S. at 731. With these weighty concerns in mind, and having recognized that the "boundaries [of the patent right] should be clear," the Court announced the tangentiality exception in the very terms that the court of appeals applied. *Id.* at 730, 740. Petitioners do not ask this Court to overrule *Festo*, and there is no reason for the Court to reweigh the policy concerns that it already considered.

Festo was not the first time this Court addressed the public notice concerns raised by petitioners. It has done so in doctrine-of-equivalents cases going back to the 19th century. "Each time the Court has considered the doctrine, it has acknowledged [the uncertainty that results from the rule] as the price of ensuring the appropriate incentives for innovation, and it has affirmed the doctrine over dissents that urged a more certain rule." *Id.* at 732; *see also Warner-Jenkinson*, 520 U.S. at 29 (considering "definitional and public-notice functions of the statutory claiming requirement" but declining to eliminate doctrine of equivalents); *Graver Tank*, 339 U.S. at 609 ("Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum."). Petitioners' arguments recycle concerns raised by dissenting Justices and rejected by the Court. *See, e.g.*, *Graver Tank*, 339 U.S. at 617-18 (Black, J., dissenting) (advocating for elimination of doctrine because patent claims "gave the public to understand that whatever was not claimed did not come within his patent and rightfully be made by anyone" (internal quotation marks omitted)); *Winans v. Denmead*, 56 U.S. 330, 347 (1853) (Campbell, J., dissenting) (objecting to doctrine because "[f]ulness, clearness, exactness, preciseness, and particularity, in the description of the invention . . . and of the matter claimed to be invented, will alone fulfil the demands of Congress"). Petitioners' policy arguments are if anything "best addressed to Congress, not this Court." *Warner-Jenkinson*, 520 U.S. at 29.

In any event, the tangentiality exception promotes the public notice function of patents because courts assess the exception's applicability based on the objective prosecution record. The Federal Circuit analyzed tangentiality based on that objective record, and its decision is fully cognizant of the policy interests underlying that exception. The exception applies only when the prosecution record reveals the reason for the amendment. Here, that reason was to avoid the examiner's rejection over Arsenyan and its teachings about the distinct antifolate, methotrexate. And nothing in the prosecution record indicates that the rationale underlying the amendment had to do with distinguishing between different salt forms of pemetrexed.

If anything, it is *petitioners'* argument that courts must consider hypothetical alternative amendments that would break new ground and undermine the public notice function of the prosecution record. The tangentiality exception necessarily focuses on the rationale for the patentee's amendment—not the rationale for choosing that particular language as opposed to another hypothetical amendment that a challenger in litigation can conjure up with the benefit of hindsight. 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 when the amendment was focused entirely on something else. *E.g.*, *Insituform Techs.*, 385 F.3d at 1370. That is why courts focus on objective indicia in the record of the motivation for the actual amendment. Here, the objective indicia show that Lilly's reason for its amendment was peripheral to different salt forms of pemetrexed.

The Court should decline petitioners' request to convert this case from a fact-specific dispute over the meaning of the prosecution history for the '209 patent into a radical rethinking of the tangentiality exception.

2. The Hatch-Waxman context of this case further undermines petitioners' concerns about public notice.

Petitioners' proposed products contain the same antifolate chemotherapeutic agent as ALIMTA (pemetrexed). The only difference between petitioners' products and ALIMTA is that in solid form petitioners' pemetrexed is attached to a different counter-ion (tromethamine). When the products are dissolved in solution and administered to patients, they are effectively the same (which petitioners told FDA): the same active compound, pemetrexed, treats cancer in the exact same way, and the same patented vitamin pretreatment regimen lowers the incidence of severe toxicities that pemetrexed otherwise might cause. Indeed, petitioners did not design their products from scratch and did not prove their products' safety and efficacy independently to FDA. Rather, under the Hatch-Waxman Act, petitioners relied on Lilly's clinical data for ALIMTA to prove the efficacy and safety of their products, and the Hatch-Waxman application process required them to evaluate whether they infringed the '209 patent (and thus to consider its public prosecution record). Petitioners also were on notice from the outset that their products were equivalent to ALIMTA; their "paper" NDAs effectively conceded equivalence.

The Federal Circuit's decision in this case thus simply reinforced the long-established proposition that a patent owner may pursue infringement claims against parties who make immaterial changes to patented products in an effort to get around the patent. Petitioners' products are precisely the sort of end-run around patent protection the doctrine of equivalents is intended to prevent. The artificial rules proposed by petitioners would unfairly allow petitioners to reap for themselves the benefits of Lilly's innovation.

CONCLUSION

The petitions for a writ of certiorari should be denied.

Respectfully Submitted,

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