

No. 19-1058

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IN THE  
*Supreme Court of the United States*

HOSPIRA, INC.,

*Petitioner,*

v.

ELI LILLY AND COMPANY,

*Respondent.*

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

REPLY BRIEF IN SUPPORT OF  
PETITION FOR A WRIT OF CERTIORARI

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In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722 (2002), this Court held that when a patentee narrows a claim during prosecution to overcome a patentability rejection, a “court should presume that the patentee surrendered all subject matter between the broader and the narrower language” for purposes of the doctrine of equivalents. *Id.* at 740. It further held, however, that the patentee can overcome that presumption when “the rationale underlying the amendment ... bear[s] no more than a tangential relation to the equivalent in question.” *Id.*

That statement in *Festo* has spawned an unending stream of litigation over whether the relationship between an amendment and an equivalent is “tangential,” leading to widespread confusion. Eighteen years after *Festo*, it is now clear that the Federal Circuit cannot sort out the scope of the “tangential relation” exception on its own. This Court’s guidance is sorely needed to clarify the “tangential relation” exception and ensure it does not swallow the presumption of prosecution history estoppel.

This case is the ideal vehicle to consider that issue. The facts are undisputed and stark. Lilly could easily have narrowed its claim to pemetrexed and its salts. Instead, it chose to narrow its claim to one particular pemetrexed salt: pemetrexed disodium. Now, it seeks to avoid the consequence of that choice by expanding its claim via the doctrine of equivalents to cover competing products that are not pemetrexed disodium. The doctrine of prosecution history estoppel is designed for exactly this type of buyer’s remorse argument. The

Federal Circuit’s willingness to apply the “tangential relation” exception is irreconcilable with *Festo*’s reasoning and expands the “tangential relation” doctrine beyond what the *Festo* Court could have contemplated. And the Federal Circuit’s decision will open the door to widespread manipulation of the patent prosecution process, as patentees narrow their claims to avoid patentability rejections and then expand them during patent litigation under the doctrine of equivalents.

Lilly offers no sound reason for denying review. It does not dispute the outsized importance of prosecution history estoppel in modern-day patent litigation. Nor does it identify any factual disputes or any other vehicle problem. Lilly characterizes the decision below as a factbound application of *Festo*, but ignores large swaths of *Festo*’s reasoning that are irreconcilable with the Federal Circuit’s decision.

Lilly also claims that Hospira’s arguments conflict with the arguments in the separate petition filed by Dr. Reddy’s Laboratories, Ltd. (“DRL”). That is not so—Hospira’s arguments are entirely consistent with DRL’s arguments. The Court should grant certiorari in both cases and consolidate them for oral argument.

## ARGUMENT

### **I. The Federal Circuit’s Decision Is Inconsistent With *Festo*.**

Under *Festo*, this case should have been easy. To rebut the presumption of 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.” 535 U.S. at 741. It is plain that Lilly could reasonably have drafted a claim that would have literally encompassed the alleged equivalent. It could have simply said “pemetrexed salts.” Because Lilly rejected this obvious option and instead chose to narrow its claim to one particular pemetrexed salt—pemetrexed disodium—it should be estopped from rewriting its claim to encompass all pemetrexed salts via the doctrine of equivalents.

The Federal Circuit reached a contrary conclusion based on its view that there was a “tangential relation” between the amendment and the equivalent. But *Festo* framed the “tangential relation” exception as an *example* of a case where “one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent”—not a freestanding exception that applies even when the patentee *can* reasonably draft a claim that would have encompassed the claimed equivalent. 535 U.S. at 741; *see* Pet. 16-17.

*Festo*’s explanation of the purpose of prosecution history estoppel proves the point. *Festo* explained:

Prosecution history estoppel ensures that the doctrine of equivalents remains tied to its underlying purpose. Where the original application once embraced the purported equivalent but the patentee narrowed his claims to obtain the patent or to protect its validity, the patentee cannot assert that he lacked the words to describe the subject matter in question. The

doctrine of equivalents is premised on language's inability to capture the essence of innovation, but a prior application describing the precise element at issue undercuts that premise. In that instance the prosecution history has established 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. Thus, *Festo* holds that an exception to prosecution history estoppel is warranted in cases involving "language's inability to capture the essence of innovation." *Id.* This is plainly not such a case. Here, the Federal Circuit concluded that what Lilly "actually invented" was "an improved method of administering pemetrexed." Pet. App. 21a. If that is what Lilly "actually invented," it could have written the claim to encompass all pemetrexed salts. Indeed, as the petition pointed out, *Lilly's own prior patent* defined "pemetrexed" as "the stable salts, acids and free base forms thereof." Pet. 15 (quotation marks omitted). Lilly's decision to narrow the claim to pemetrexed disodium in the patent at issue here reflected its own strategic decision—not any imperfection in language that warrants relaxing prosecution history estoppel.

Lilly has precious little to say in response. Lilly entirely ignores the portion of *Festo* regarding "language's inability to capture the essence of innovation." Pet. 21 (quotation marks omitted). Instead, Lilly offers the conclusory assertion that when the patentee is "focused on distinguishing prior art unrelated to the equivalent in question," that

*necessarily* means the patentee “could not reasonably be expected” to have drafted a claim encompassing the equivalent—*even if the equivalent was foreseeable*. BIO 17-18. That cannot be right. If Lilly wanted its claim to encompass all pemetrexed salts, it reasonably could, and should, have narrowed its claim to the class of pemetrexed salts, rather than gratuitously limiting its claim to one specific pemetrexed salt.

Hospira’s petition offered an illustrative example. A claim in a patent application recited “fruit,” and then, in response to a rejection, the claim was amended to “Red Delicious apples.” Anyone would infer that the amendment excludes other types of apples. Otherwise, the patentee would have just said “apples.” Yet, under the Federal Circuit’s decision, a patentee could accuse Honeycrisp apples of infringement, on the theory that the patentee *could* have narrowed its claim to “apples” to overcome the rejection—a seemingly absurd result, given the patentee’s specific decision to narrow its claim to “Red Delicious apples.” Pet. 18.

Rather than distinguishing this case from that hypothetical, Lilly embraces the hypothetical—it contends that the patentee *could*, indeed, assert that all types of apples infringe, so long as the prior art did not relate to other types of apples. BIO 18-19. If the Court is troubled by the prospect that the doctrine of equivalents would apply in that scenario, it should grant certiorari and reverse.

Hospira’s petition also gave a second reason that the Federal Circuit’s decision conflicts with *Festo*. Hospira explained that the Federal Circuit’s legal standard wrongly focuses on the reason for *amending*



*the claim at all*, rather than the reason for the *particular amendment that the patentee made*—which should have been the inquiry dictated by *Festo*. Pet. 19-20. Thus, the Federal Circuit should have asked: why did Lilly use the words “*pemetrexed disodium*” in its amendment? *Id.* Lilly’s explanation for its amendment did not answer that question, because Lilly did not explain why it added the word “disodium.” Pet. 20. And if the Federal Circuit had posed the right question, it would have reached the right answer: prosecution history estoppel applies. *Id.*

Tellingly, Lilly’s response brief completely ignores this argument. Hospira will reiterate: there is no justification for the Federal Circuit’s willingness to apply the “tangential relation” exception absent any explanation in the prosecution history record for the particular words Lilly used.

Rather than address Hospira’s arguments on their merits, Lilly contends that Hospira’s arguments conflict with DRL’s arguments in DRL’s separate petition in No. 10-1061. BIO 19. There is no conflict. DRL argues that the “tangential relation” exception applies “when an amendment adds multiple limitations to a claim at the same time, and not all relate to an examiner’s rejection.” *Id.* (quoting DRL Pet. 18). Nothing in Hospira’s petition is inconsistent with that position—Hospira has not argued that the “tangential relation” exception should *never* apply to foreseeable equivalents, as Lilly claims. BIO 17.

Hospira’s argument simply addresses when the “tangential relation” exception should *not* apply. It should not apply where, as here, the patentee could

reasonably have narrowed its claim to what it now claims it *meant* to patent. And it should not apply where, as here, the patentee cannot give an explanation for the actual language of its amendment. Lilly is unable to provide any coherent response, grounded in *Festo*, to these arguments.<sup>1</sup>

## II. This Court Should Grant Certiorari.

This case warrants Supreme Court review in view of the practical importance of the “tangential relation” exception to prosecution history estoppel, and in view of the Federal Circuit’s confusion over the scope of that exception.

### A. The Federal Circuit’s decision undermines the public notice function of patents and prosecution records.

As the petition catalogued, the “tangential relation” exception to prosecution history estoppel is a constant source of litigation. Pet. 22-23. This litigation is so common for an unfortunate reason: it is a common tactic for patentees to artificially narrow a patent claim in order to induce the Patent Office into allowing the

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<sup>1</sup> There is also no inconsistency between Hospira’s argument and the argument in the petition in *CJ CheilJedang Corp. v. ITC*, No. 19-1062. That petition argues that if the prosecution history record does not contain an “explicit and contemporaneous explanation[.]” (BIO 20), the presumption of prosecution history estoppel cannot be rebutted. Here, likewise, as Hospira’s petition explained, the absence of a contemporaneous explanation for the phrase “pemetrexed disodium” should be fatal to Lilly’s argument.

claim, and then re-expand the claim after the fact via the doctrine of equivalents.

The Federal Circuit's decision will make this gamesmanship worse. The Federal Circuit permitted patentees to avoid prosecution history estoppel under the "tangential relation" exception even when it is *absolutely* clear that the patentee could have narrowed its claim so as to encompass the claimed equivalent, and even without an explanation in the prosecution history for the particular language of the amendment. As a result, if the Federal Circuit's decision stands, avoiding prosecution history estoppel will be trivially easy. The patent applicant need only write carefully-worded, self-serving statements regarding the reasons for its amendments so it may argue after the fact that those reasons are "tangential" to an equivalent. Pet. 25. The Court should not countenance such bait-and-switch tactics.

The Federal Circuit's decision profoundly undermines the public notice function of patents and prosecution history records. In a properly functioning patent system, the Patent Office, and members of the public, should be able to infer that when a claim is rejected in view of prior art, and the patentee addresses that rejection by narrowing a claim from a class of compounds to a single salt compound, it follows that the claim does not, in fact, stretch beyond that salt compound. But under the Federal Circuit's decision, they cannot. Instead, to assess the claim scope that may be regained through future litigation, they must start with the actual claim language, and then deduce all of the myriad broader claims that the patentee *could*

have asserted based on the patentee's arguments made to the Patent Office. For instance, here, Hospira was apparently required to start with the claim language—"pemetrexed disodium"—and then deduce that Lilly *could* have prosecuted a broader claim covering other pemetrexed salts without risking a patentability rejection. That holding will increase uncertainty regarding the scope of patent claims and hamper competitors' ability to design around patents.

In response to these public notice concerns, Lilly claims that Hospira seeks to overrule *Festo*, or perhaps even the doctrine of equivalents as a whole. BIO 25-27. Not so. Hospira merely asks that the Court follow *Festo*'s own reasoning, which is irreconcilable with the Federal Circuit's expansion of the "tangential relation" exception.

Lilly also claims that Hospira's position would undermine the public notice function of the prosecution record by requiring courts to "consider hypothetical alternative amendments," that can be "conjure[d] up," as opposed to the "objective record." BIO 27. That is also incorrect. As *Festo* explained, prosecution history estoppel should apply when a patentee could *reasonably* have been expected to draft claim language encompassing the claimed equivalent—not merely when such language can be "conjure[d] up." *Id.* At a minimum, prosecution history estoppel should apply where the "objective record" contains no explanation for the particular words the patentee used. Here, the "objective record" does not explain why Lilly added the word "disodium"—and as such, Lilly has not met its

burden of rebutting the presumption of prosecution history estoppel.

Finally, Lilly argues that the Hatch-Waxman context of this case undermines Hospira's concern about public notice. BIO 28. This is a red herring. First, the doctrine of prosecution history estoppel applies across patent law; it is not specific to Hatch-Waxman cases. And the Federal Circuit's application of the "tangential" exception in this case did not turn on Hatch-Waxman.

Second, to the extent Hatch-Waxman is relevant, the public notice concerns raised by Hospira are especially salient in the Hatch-Waxman context. The Hatch-Waxman Amendments are intended to *encourage* generic drug competition. Under Hatch-Waxman, generic drugs can gain FDA approval if they are bioequivalent to a reference drug that has already been approved by the FDA. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011). This scheme promotes the inexpensive manufacturing of generic drugs. *See id.* at 612-13. But "[b]ecause the FDA cannot authorize a generic drug that would infringe a patent," "a company filing an [Abbreviated New Drug Application] must assure the FDA that its proposed generic drug will not infringe the brand's patents." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405-06 (2012). Resultant patent litigation can grind the approval process to a halt. *See id.* at 408-09. It is precisely in that context in which clarity in the meaning of patent claims is most needed—and in which the Federal Circuit's expansion of the "tangential relation" exception is most harmful.

Moreover, Lilly's position implies that any drug that is *bioequivalent* to a reference drug for Hatch-Waxman purposes infringes a patent on that drug under the *doctrine of equivalents*. That position would render Hatch-Waxman ineffective in facilitating approval of generic drugs—because the mere filing of an application asserting bioequivalence to a reference drug would be a confession of infringement of a patent on the reference drug. It is no surprise that no court has ever adopted this position.

**B. The Federal Circuit's inconsistent outcomes have resulted in mass confusion.**

This Court's intervention is necessary because the Federal Circuit has shown that it will not clarify the scope of the “tangential relation” exception on its own.

The Federal Circuit concluded that prosecution history estoppel did not apply because the *purpose* of Lilly's amendment was to distinguish pemetrexed salts from other antifolates. Thus, because Lilly *could* have overcome the prior art by narrowing its claim to “pemetrexed salts,” Lilly would not be estopped from expanding its claim to other pemetrexed salts via the doctrine of equivalents. Yet, as the petition explained, the Federal Circuit has repeatedly rejected that exact argument. In other cases, the court has “held the patentees to the scope of what they ultimately claim, and we have not allowed them to assert that claims should be interpreted as if they had surrendered only what they had to.” Pet. 28-29 (quoting *Norian v. Stryker Corp.*, 432 F.3d 1356 (Fed. Cir. 2005)).

Lilly asserts that in “all cases,” the Federal Circuit looks to the “reason for the amendment,” with different factual records yielding different outcomes. BIO 24. But in every case in this line, the ultimate legal question was the same. In every case, the court’s analysis of the “reason for the amendment” established that the patentee did not need to surrender the equivalent in question to overcome the prior art. In this case, for example, the Federal Circuit’s analysis established that Lilly did not need to surrender pemetrexed ditromethamine to overcome Arsenyan. In every case, the Federal Circuit was faced with the same question: if the “reason for the amendment” establishes that the patentee did not need to surrender the equivalent to overcome the prior art, is that enough to defeat the presumption of prosecution history estoppel? In some decisions, including the decision below, the Federal Circuit answered “yes”; in others, the Federal Circuit answered “no.” The Federal Circuit’s inability to provide a consistent answer to this important question of patent law is further grounds for granting review. Pet. 29-30.<sup>2</sup>

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<sup>2</sup> Lilly claims that Hospira’s petition is inconsistent with DRL’s petition because Hospira’s petition focused on prior inconsistent cases, while DRL’s petition cited both prior consistent and prior inconsistent cases. BIO 21. Lest there was any confusion, Hospira agrees with DRL that the Federal Circuit has made the same mistake in several cases, not just this one. *See* Pet. 30 (noting that decisions on the “tangential relation” exception “turn on the random draw of Federal Circuit panel”).

The Federal Circuit's decision is wrong, has negative practical consequences, and deepens confusion over the scope of the "tangential relation" exception. The Court should grant certiorari to restore order in this important area of patent law.

### CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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