Appeal Nos. 18-2126, -2127, and -2128

In the United States Court of Appeals for the Federal Circuit

NOS. 18-2126, -2127

ELI LILLY AND COMPANY,
Plaintiff-Appellee,

v.

HOSPIRA, INC.,
Defendant-Appellant,

Appeals from the United States District Court for the Southern District of Indiana in No. 1:16-cv-3460-TWP-MPB (The Honorable Tanya Walton Pratt, J.)

No. 18-2128

ELI LILLY AND COMPANY,
Plaintiff-Appellee,

v.

DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC.,
Defendants-Appellants,

Appeal from the United States District Court for the Southern District of Indiana in No. 1:16-cv-308-TWP-MPB (The Honorable Tanya Walton Pratt, J.)

RESPONSE OF PLAINTIFF-APPELLEE ELI LILLY AND COMPANY TO JOINT PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, undersigned counsel for Plaintiff-Appellee certifies the following:

1. The full name of the party represented by me is Eli Lilly and Company.

2. Eli Lilly and Company has no parent corporation and no publicly held company owns 10 percent or more of its stock.

3. There are no additional parent corporations or publicly held companies that own 10 percent or more of the stock of the party represented by me.

4. The names of all attorneys that appeared for the party now represented by me in the district court or are expected to appear in this court (and who have not or will not enter an appearance in this case) are: Bruce R. Genderson of Williams & Connolly LLP; Galina I. Fomenkova, formerly of Williams & Connolly LLP; Alec T. Swafford, formerly of Williams & Connolly LLP; and Anne N. DePrez and Jan M. Carroll of Barnes & Thornburg LLP.

5. The title and number of any case known to me to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal are:

- *Eli Lilly and Company v. Dr. Reddy's Laboratories, Ltd.*, No. 1:19-cv-1246 (S.D. Ind.)
- *Eli Lilly and Company v. Actavis LLC*, No. 1:17-cv-982-TWP-MPB (S.D. Ind.)
- *Eli Lilly and Company v. Apotex, Inc.*, No. 1:17-cv-2865-TWP-MPB (S.D. Ind.)
- *Eli Lilly and Company v. Eagle Pharmaceuticals, Inc.*, No. 17-cv-1293 (MSG) (D. Del.)

- *Eagle Pharmaceuticals, Inc. v. Eli Lilly and Company*, No. 18-cv-1121 (MSG) (D. Del.)

/s/ *Adam L. Perlman*
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OCTOBER 23, 2019

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INTRODUCTION

The panel decision in this case applied the well-established test for the tangentiality exception to the prosecution history estoppel doctrine set forth by the Supreme Court and this Court. Petitioners assert a conflict between the panel's decision here and other decisions of this Court, but there is no such conflict. Rather, petitioners fundamentally misconstrue both the basis for the panel's decision and the tangentiality inquiry. The panel did not suggest, and Lilly did not argue, that the amendment here was tangential "because pemetrexed ditromethamine was within the unnecessarily-surrendered" claim scope, as petitioners allege, Pet. 9-10; the panel squarely considered and *rejected* the argument that a victory for Lilly would mean that an "applicant's remorse at ceding more claim scope than necessary" is "a reason for the tangential exception to apply." Slip Op. 19.

While the panel's decision is consistent with existing precedent, petitioners fail to pose any workable alternative standard for assessing tangentiality, much less establish that precedent compels it. Their principal complaint is that the tangentiality standard should be "narrow." *E.g.*, Pet. 10, 18. But as the panel recognized, under controlling Supreme Court authority, narrow does not mean nonexistent. Whenever tangentiality is at issue, the

patentee surrendered more than necessary to overcome a rejection. If patentees had to establish why they chose a particular amendment over some alternative that a challenger suggests, the logic of the tangentiality exception and its focus on the objective prosecution record would fall apart.

In the absence of a clear conflict in this Court's precedent, petitioners have at best an argument about how the established standard for tangentiality was applied to the facts of this case. But even if the panel erred—and it did not—that fact-bound disagreement would not merit the *en banc* Court's attention.

For all these reasons, rehearing *en banc* is not warranted.

BACKGROUND

I. Lilly's Amendment of Claims During Prosecution.

Plaintiff-Appellee Eli Lilly and Company (Lilly) manufactures and sells ALIMTA®, a drug that treats certain types of lung cancer and mesothelioma. The active moiety in ALIMTA® is the antifolate pemetrexed. Lilly is the assignee of U.S. Patent No. 7,772,209 (the '209 patent), which claims a method of administering pemetrexed chemotherapy that requires pretreating patients with folic acid and vitamin B_{12} to reduce the incidence of pemetrexed's potentially severe toxicities without compromising its efficacy. The claims all recite one salt form of pemetrexed, pemetrexed disodium.

Petitioners' estoppel claim centers around an amendment that was 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. Slip Op. 15. As relevant here, Lilly initially sought an independent claim directed to the administration of "an antifolate" following pretreatment with a methylmalonic acid lowering agent (a class that includes vitamin B_{12}). *Id.* at 7. The examiner rejected this claim over a prior art reference (Arsenyan) that discloses pretreatment with a vitamin B_{12} derivative prior to the administration of methotrexate, a different antifolate from pemetrexed. *Id.* Arsenyan makes no reference to different salt forms of methotrexate, pemetrexed, or any other antifolate. Appx7880, Appx8504-8507.[1]

In response to the Arsenyan rejection, Lilly amended its claims to replace administration of "an antifolate" with administration of "pemetrexed disodium." Slip Op. 7. As the panel recognized, 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. *Id.* at 17-18. Lilly's amendment was not made to distinguish

[1] All "Appx" citations refer to the *DRL* Appendix. *See Eli Lilly and Company v. Dr. Reddy's Labs., Ltd.*, No. 18-2128, ECF 53 (Fed. Cir. Jan. 30, 2019).

pemetrexed disodium from other forms of pemetrexed (which are all the same active antifolate). *Id.*

The examiner withdrew the Arsenyan rejection in view of Lilly's amendment. *Id.* at 8. 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" in a preliminary amendment. Appx46, Appx52-53, Appx5466-5470. The reason for this preliminary amendment was the same as the original amendment—to overcome the Arsenyan rejection. *See* Appx8506.

II. The District Court Litigation.

Lilly asserted claims for patent infringement under the doctrine of equivalents in separate actions against petitioners Hospira, Inc. (Hospira) and Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL), each of which seeks approval to sell pemetrexed ditromethamine, a different salt form of pemetrexed. Slip Op. 8-9. Hospira and DRL each argued that Lilly was barred from pursuing infringement under the doctrine of equivalents with respect to their pemetrexed ditromethamine products because of prosecution history estoppel. *Id.* at 9-10. Lilly did not contest that a presumption of prosecution history estoppel

applied with respect to its amendment from "an antifolate" to "pemetrexed disodium." Lilly, however, asserted that the tangentiality exception to prosecution history estoppel rebutted this presumption. *Id.* The district court agreed with Lilly, finding that the reason for Lilly's amendment—to avoid Arsenyan and its disclosure of methotrexate—was only tangentially related to an alleged equivalent with a different salt form of the same antifolate (pemetrexed). *Id.*

III. The Panel's Decision.

In a consolidated opinion, a panel of this Court unanimously affirmed the determinations regarding prosecution history estoppel in the Hospira and DRL cases. Slip Op. 15-22. As the panel 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." *Id.* at 17. The panel concluded that this reason for Lilly's amendment was only tangentially related to petitioners' proposed pemetrexed ditromethamine equivalent, which is a different salt form of the same antifolate. *Id.* at 17-18.

The panel considered various arguments from Hospira and DRL as to why the tangentiality exception should not apply. *Id.* at 18-22. As relevant to the instant petition, the panel rejected petitoners' contention the tangentiality

exception cannot apply when an amendment during prosecution narrows a claim beyond what is necessary to overcome a particular rejection. *Id.* at 19. According to the panel, "the tangential exception only exists because applicants over-narrow their claims during prosecution." *Id.* at 19. Importantly, however, Lilly never argued, and the panel did not hold, that the tangentiality exception applied *because* Lilly surrendered more claim scope than necessary. Rather, the panel applied the well-established test required by Supreme Court and circuit precedent, and compared the reason for the narrowing amendment to the particular equivalent at issue. *Id.* at 17-22.

As the panel correctly recognized, "prosecution history estoppel is resistant to the rigid legal formulae that Appellants seek to extract from [precedent]." *Id.* at 21 (citing *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1291 (Fed. Cir. 2010)). This was not a new proposition of law, but rather an application of this Court's precedential decision in *Intervet* that "there is no hard-and-fast test for what is and what is not a tangential relation." 617 F.3d at 1291. The panel thus applied the general standard to the specific facts at issue, and held that prosecution history estoppel did not bar application of the doctrine of equivalents. Slip Op. 22.

ARGUMENT

I. The Panel Decision Is Consistent With This Court's Precedent.

This Court explained in *Festo* that the tangentiality exception "asks 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., Ltd.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003). That is the standard the panel properly applied here when it held that Lilly's amendment was made in response to a rejection over a reference (Arsenyan) that disclosed a different active antifolate (methotrexate). Slip Op. 19. The panel thus concluded that the amendment had nothing to do with the equivalent in question, *i.e.*, the use of a different salt form of pemetrexed.

Petitioners dispute this conclusion, but in doing so they articulate an interpretation of the tangentiality standard so restrictive it would effectively eliminate the exception. In their view, this Court's precedents impose a burden on Lilly to show why it elected to narrow the claims to "pemetrexed disodium" specifically rather than broader, alternative formulations that petitioners can envision. Petitioners' argument misinterprets this Court's precedent and consequently gets the tangentiality analysis wrong.

1. The doctrine of equivalents protects patentees from the machinations of infringers who 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); *see also Valmont Indus., Inc. v. Reinke Mfg. Co., Inc.*, 983 F.2d 1039, 1043 (Fed. Cir. 1993). The doctrine has a long history and "remain[s] a firmly entrenched part of the settled rights protected by the patent." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 733 (2002); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 24-37 (1997).

While prosecution history estoppel imposes a limit on the doctrine of equivalents, it does *not* impose an absolute bar on that doctrine. *Festo*, 535 U.S. at 737-38; *Warner-Jenkinson*, 520 U.S. at 30. 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." *Festo*, 535 U.S. at 737-38. Accordingly, in *Festo*, the Supreme Court articulated three "exceptions" by which a patentee can rebut the presumption that a narrowing amendment gives rise to prosecution history estoppel; the tangentiality exception was one of them. 535 U.S. at 740-41.

The focus of the tangentiality analysis is on the *rationale* for the

amendment the patentee *actually made*. Nowhere do *Festo* or its progeny demand an explanation for why a patentee chose to use the particular amendment it did as opposed to other hypothetical amendments that it might have considered or that an accused infringer can in hindsight concoct. The question the cases ask is far simpler: whether "the rationale underlying the amendment . . . bear[s] no more than a tangential relation to the equivalent in question." *Id.* at 741.

The panel correctly answered that question here. Petitioners notably do not challenge the central facts on which the panel's decision as to the tangentiality exception is based. All agree that the amendment giving rise to the presumption of prosecution history estoppel narrowed administration of "an antifolate" to administration of "pemetrexed disodium." Pet. 5. The parties agree as well that this amendment was made in response to a rejection over Arsenyan, which teaches the administration of methotrexate in combination with a vitamin B_{12} derivative. *Id.* From these undisputed facts and the rest of the prosecution record, the panel correctly concluded, as did the district court, that the person of ordinary skill in the art would understand that the reason for the amendment was to narrow the claims from the universe of all antifolates—including Arsenyan's methotrexate—to just one active

antifolate, pemetrexed. Slip Op. 17-18. And it further correctly concluded that this rationale was tangential to the use of petitioners' alternative pemetrexed salts in lieu of pemetrexed disodium. *Id.*

2. In arguing for *en banc* review, petitioners contend that the panel's decision and others[2] conflict with what they contend is a line of authority holding that a patentee cannot invoke the tangentiality exception by arguing that it surrendered more claim scope than necessary. At the outset, petitioners miss the mark because that is not what Lilly argued here. And in any event, there is no conflict. The cases petitioners cite do not apply a different standard for assessing tangentiality. Rather, in each decision, the Court, like the panel here, simply applied the governing standard—set forth in *Festo* itself—to the particular facts before it.

a. *Integrated Technology* involved a "digital viewing system" where a "viewing window" inspected certain probes used in the production of semiconductor wafers. *Integrated Tech. Corp. v. Rudolph Techs., Inc.*, 734 F.3d 1352, 1355 (Fed. Cir. 2013). The equivalent involved a system that

[2] *E.g.*, *Ajinomoto Co. v. ITC*, 932 F.3d 1342 (Fed. Cir. 2019); *Regents of Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364 (Fed. Cir. 2008); *Insituform Techs. v. CAT Contracting, Inc.*, 385 F.3d 1360 (Fed. Cir. 2004).

inspected probes without the probes making contact with the viewing window. *Id.* Integrated Technologies could not establish tangentiality because it had explicitly relied on contact between the probe and the window as a reason for its amendment to distinguish the prior art. *Id.* at 1355, 1358-59. Just as in the panel decision here, the focus was on the test set forth in *Festo*: the reason for the amendment and whether that reason was tangential to the equivalent at issue. *Id.* at 1359.

b. In *Lucent*, the Court first determined that the presumption of prosecution history applied because proposed equivalent fell within the "territory between the original claims and the amended claims," but contrary to petitioner's suggestion, that did not end the analysis; the *Lucent* Court then separately considered whether the tangentiality exception applied. *Lucent Techs., Inc. v. Gateway, Inc.*, 525 F.3d 1200, 1218 (Fed. Cir. 2008). Although the *Lucent* Court ultimately rejected the applicability of the tangentiality exception, it did so by performing an analysis that, once again, was consistent with the panel's analysis here. Having determined that the accused equivalent was within the territory surrendered by the narrowing, the Court compared the reason for the amendment to the accused equivalent, and concluded on the facts of the case that there was "clearly more than a tangential relationship"

between them. *Id.*

c. *International Rectifier* likewise did not involve some sweeping pronouncement on the scope of the tangentiality exception. *International Rectifier Corp. v. IXYS Corp.*, 515 F.3d 1353, 1355 (Fed. Cir. 2008). The Court there determined only that the reason for the amendment—to limit the claims to "adjoining" structures—was not merely tangentially related to an equivalent that did not involve "adjoining" structures. *Id.* at 1359. This fact-bound determination does not in any way conflict with the panel's conclusion as to the reason of Lilly's amendment.

d. In *Schwarz*, the patentee narrowed a claim to the use of one particular stabilizer, thereby excluding an equivalent "MgO" stabilizer. *Schwarz Pharma, Inc. v. Paddock Labs., Inc.*, 504 F.3d 1371, 1374-75 (Fed. Cir. 2007). Unlike Lilly, Schwarz *did not argue* that the alleged equivalent was unrelated to the reason for its amendment to overcome the prior art rejection. *Id.* at 1377-78. Instead, Schwarz sought to invoke the tangentiality exception by arguing that in hindsight, it could have overcome a rejection without narrowing its claim—in other words, it made the erroneous argument petitioners wrongly accuses Lilly of making and the panel of accepting. *Id.* Here, Lilly has never argued, and the panel did not determine, that the

tangentiality exception applies because Lilly could have overcome Arsenyan without amending its claims to exclude pemetrexed ditromethamine, if only it had made different decisions during prosecution. Rather, the panel's holding in this case is based on the objectively apparent reason for the actual amendment Lilly made as compared to the accused equivalent.

e. Finally, *Norian*, which did not consider tangentiality or any other exception, is completely inapposite. *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356 (Fed. Cir. 2005). There, the patentee argued that the prosecution history did not trigger *Festo* at all. The Court rejected that argument because it determined that the proposed equivalent fell within the territory presumptively surrendered by the narrowing amendment. *Id.* at 1363. The Court stopped its analysis there because the patentee "d[id] not suggest that th[e] case falls within one of the exceptions to the rule of prosecution history estoppel set forth by the Supreme Court in *Festo*." *Id.* Here, of course, Lilly *does* argue, and the panel correctly held, that the case falls within the tangentiality exception.

* * *

In sum, the panel correctly applied this Court's precedent regarding the tangentiality exception to the facts of this case. Petitioners have pointed

to no case that came to a contrary result on analogous facts. Put simply, there is no conflict between the panel opinion and any precedent. The petition should be denied.

II. This Case Presents No Issue of Exceptional Importance.

En banc rehearing is not a tool for changing disputed outcomes in individual cases unless the case is one of exceptional importance with respect to questions that are likely to recur in the future. Independently of whether the panel erred (and it did not), this is not such a case. As the panel explained, the result here turned on a "case-specific focus" based on "a 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." Slip Op. 20 n.5.

Petitioners fail to identify any important consequences or overarching legal questions that the panel decision puts at issue. The closest they come is to suggest that the panel's decision undermines the public notice function of patents and prosecution records in informing competitors of their potential infringement liability. Pet. at 17-18, 20. As an initial matter, the Supreme 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." *Festo*, 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 Supreme Court announced the tangentiality exception in terms of the very test that the panel applied. *Id.* at 730, 740. There is no call for the *en banc* Court to re-weigh the policy concerns that the Supreme Court has already considered.

And in any event, it is precisely to further public notice that the tangentiality exception is evaluated on the basis of the objective prosecution record. The panel analyzed tangentiality on that basis here, and its decision is fully consistent with and cognizant of the policy interests underlying the tangentiality exception. When the exception applies, the prosecution record reveals, and the public can therefore determine, the reason for the amendment. Here, that reason was to avoid the examiner's rejection over Arsenyan and its teachings about the distinct active antifolate, methotrexate. The panel recognized expressly that the '209 patent and prosecution record "show that it is implausible that the reason for Lilly's amendment was to surrender other pemetrexed salts." Slip Op. 22. And it also recognized that rendering Lilly unable to enforce its patent against 21 U.S.C. § 355(b)(2) NDA filers such as Hospira and DRL—who did *not* develop a new antifolate of their

own, but merely relied on Lilly's clinical data to seek approval to sell pemetrexed in a different form—would "render the '209 patent worthless." *Id.*

In fact, it is *petitioners*' proposal of a new requirement for courts to consider hypothetical alternative amendments, not the panel decision, that would break new ground and undermine the public notice function of the prosecution record. The logic of the tangentiality exception and its focus on the prosecution record falls apart if the patentee must establish why it chose a particular amendment as compared to others that a challenger in litigation can come up with. Establishing tangentiality requires that the prosecution history reveal the rationale for the amendment that was made. But the prosecution history frequently will *not* reveal why the patentee chose to insert Option A instead of Option B when both are consistent with the rationale for the amendment. 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. Nor is there any logic or precedent supporting the notion that the tangentiality exception should only apply if for some bizarre reason the prosecution history happens to discuss such a reason. The fact that the prosecution record here

says nothing about different salt forms of pemetrexed is evidence *in favor of* tangentiality, not against it. 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—a dispute that was resolved in a unanimous and well-supported panel opinion—into a radical rethinking of the tangentiality exception.

CONCLUSION

The petition for rehearing *en banc* should be denied.

Respectfully submitted,

/s/ Adam L. Perlman

OCTOBER 23, 2019

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CERTIFICATE OF SERVICE

I, Adam L. Perlman, hereby certify that on October 23, 2019, I caused the foregoing document to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification to the registered attorneys of record that the document has been filed and is available for viewing and downloading.

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OCTOBER 23, 2019

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 35 and Federal Circuit Rule 35. The brief contains 3,405 words, excluding the parts of the brief exempted by Federal Circuit Rule 36(c)(2) and Federal Rule of Appellate Procedure 32(f).

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/s/ Adam L. Perlman

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