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.

On Appeal from the United States District Court for the
Southern District of Indiana, Case No. 1:16-cv-03460 (Pratt, J.)

No. 18-2128

ELI LILLY AND COMPANY,
Plaintiff-Appellee,
v.
DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC.,
Defendants-Appellants.

On Appeal from the United States District Court for the
Southern District of Indiana, Case No. 1:16-cv-00308 (Pratt, J.)

BRIEF FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS AMICUS CURIAE SUPPORTING EN BANC REVIEW

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CERTIFICATE OF INTEREST

Counsel for amicus curiae Association for Accessible Medicines certifies the following:

1. The full name of every party or amicus represented by me is:

   Association for Accessible Medicines

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   See answer to number 1.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

   Not applicable.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in the court (and who have not or will not enter an appearance in this case) are:

   Not applicable.

5. The title and number of any case known to counsel 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 is:

   Eli Lilly and Co. v. DRL, Ltd. and DRL, Inc., No. 19-CV-1246 (S.D. Ind.)
   Eli Lilly and Co. v. DRL, Ltd. and DRL, Inc., No. 16-CV-00308 (S.D. Ind.)
   Eli Lilly and Co. v. DRL, Ltd., No. 18-2128 (Fed. Cir.)
   Eli Lilly and Co. v. Actavis LLC, No. 1:17-cv-00982 (S.D. Ind.)
   Eli Lilly and Co. v. Apotex, Inc., No. 1:17-cv-02865 (S.D. Ind.)
   Eli Lilly and Co. v. Eagle Pharms., Inc., No. 1:17-cv-01293 (D. Del.)
   Eli Lilly and Co. v. Hospira, Inc., No. 18-2126 (Fed. Cir.)
   Eli Lilly and Co. v. Hospira, Inc., No. 1:16-cv-03460 (S.D. Ind.)

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INTEREST OF AMICUS CURIAE[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines. Generic drugs constitute 90% of all prescriptions dispensed in the United States, yet generics account for only 22% of total drug spending. AAM regularly participates in litigation as *amicus curiae*.

AAM and its members have a significant interest in the question presented by the petition for rehearing *en banc* in this case. Manufacturers of generic and biosimilar medicines make substantial investments to bring low-cost treatments to market. They do so based on their understanding of the scope of patent claims, as established by the public documents associated with the patent, including its prosecution-history record. When, as here, a brand manufacturer gives up particular equivalents during patent prosecution in order to secure its patent,

[1] No counsel for any party authored this brief in whole or in part, and no party, counsel, or person other than AAM, its members, and its counsel contributed money to fund the preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

generic and biosimilar manufacturers reasonably rely on the public record and the doctrine of prosecution history estoppel in seeking to design-around patent claims in order to bring low-cost generic or biosimilar medicines to market. This ability to design-around patent claims is essential to competition in the pharmaceutical industry, particularly as brand manufacturers increasingly abuse the patent system by accumulating dozens of patents near the end of a product's life-cycle in order to extend their patent monopolies.[2] Design-arounds offer the generic industry a critical tool for cutting through this patent thicket.

Until recently, generic and biosimilar manufacturers could pursue design-around strategies with confidence because, under established law, exceptions to prosecution history estoppel are "very narrow," and they can only be determined based on "objective[e]" evidence from the prosecution record. *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335, 1342 (Fed. Cir. 2007). But the panel decision in this case, and the decision issued by a divided panel earlier the same week in *Ajinomoto Co. v. ITC*, 932 F.3d 1342 (Fed. Cir. 2019), radically change that proposition. Those decisions dramatically expand the degree to which claim scope surrendered during prosecution can be recaptured under the

[2] *See* Biosimilars Council, *Failure To Launch: Patent Abuse Blocks Access to Biosimilars for America's Patients*, 5-7 (June 2019), www.biosimilarscouncil.org/resource/failure-to-launch-white-paper ("Failure To Launch").

"tangential" exception to prosecution history estoppel. In each case, the panel held that a claim amendment was tangential to an accused equivalent *even though* both the equivalent and the amendment related to the same claim element, with the Court electing to excuse surrenders of claim based merely on the patentee's *post-hoc* rationalizations of its decision to narrow its claims more than may have been strictly necessary to overcome an examiner's objection.

By turning the tangential exception into a doctrine of prosecutor's remorse, these two recent panel decisions not only directly contradict at least five of this Court's precedential decisions, but they also effectively render prosecution history estoppel a dead letter. After all, a patentee's lawyers and experts can almost always conjure up reasons why a claim amendment was narrower than needed to avoid an examiner's rejection. If these new decisions are allowed to stand, it would undermine prosecution history estoppel and badly dilute the public-notice function of patent claims. Moreover, the uncertainty created by these two decisions and their expansive approach to the tangential exception risks undermining competition-promoting investments in the generic drug and biosimilars industries, which must navigate time-consuming and expensive product-development and regulatory processes in order to bring low-cost medicines to market.

AAM accordingly urges this Court to grant the petition for rehearing *en banc*, and to then adopt a clear standard for applying the tangential exception—a standard that ensures that the exception remains "very narrow" and cannot be used to rewrite the public record.

ARGUMENT

I. The Panel Decision Will Erode The Public-Notice Function Of Patent Claims By Dramatically Expanding The Scope Of A "Very Narrow" Exception To Prosecution-History Estoppel.

A. Protecting The Public-Notice Function Of Patent Claims Requires Careful Limits On Exceptions To Prosecution History Estoppel.

Prosecution history estoppel is a critical and "well-established limit" on the doctrine of equivalents. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 30 (1997). At the most basic level, estoppel "prevents a patentee from recapturing under the doctrine of equivalents subject matter surrendered during prosecution to obtain a patent." *Cross Med. Prods.*, 480 F.3d at 1341. The doctrine thus most obviously bars a patentee from claiming equivalents that it needed to give up to overcome an examiner's rejection—for example, an equivalent that appeared in the prior art. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 735-36 (2002). But prosecution history estoppel extends well beyond just enforcing the patentee's necessary concessions. It applies with equal force when "the inventor turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and

affirmatively chose the latter." *Id.* at 735. The reasoning for that is straightforward: the "public notice function of a patent and its prosecution history requires that a patentee be held" to its affirmative choices in defining the scope of its claims. *Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003).

Given this important public notice function, the universe of exceptions to prosecution history estoppel is very limited. *Festo*, 535 U.S. at 741. For each exception, the patentee bears the burden to show a special reason why the general rule should not apply. *See, e.g., Spectrum Pharm., Inc. v. Sandoz Inc*., 802 F.3d 1326, 1337 (Fed. Cir. 2015); *EMD Millipore Corp. v. AllPure Techs., Inc.*, 768 F.3d 1196, 1204 (Fed. Cir. 2014). The inquiry is objective and the burden is strictly applied to ensure that "the public notice function of a patent and its prosecution history" retains "significance." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369-70 (Fed. Cir. 2003) (en banc).

With respect to the "tangential" exception at issue here, this Court has repeatedly cautioned that it is "very narrow." *Integrated Tech. Corp. v. Rudolph Techs., Inc.*, 734 F.3d 1352, 1358 (Fed. Cir. 2013) (citation omitted); *accord Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 523 F.3d 1304, 1315 (Fed. Cir. 2008); *Cross Med. Prods.*, 480 F.3d at 1342. The exception will only apply if "the reason for the narrowing amendment was peripheral, or not directly relevant,

to the alleged equivalent." *Festo Corp.*, 344 F.3d at 1369. Typically, those conditions will only be satisfied if the reason for the amendment and the alleged equivalent involved different aspects of the invention. *See Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1306 (Fed. Cir. 2005).

Critically, this Court has explained an alleged equivalent is *not* peripheral merely because the patentee could have rewritten its claims to include the equivalent and still obtained the patent. In other words, a patentee cannot use the tangential exception to recapture claim scope that it regrets giving up, simply by arguing that it surrendered more than was truly necessary to overcome a patentability objection. It does not matter whether a patentee *needed* to surrender a particular equivalent—only that it "chose to do so." *Integrated Tech*, 734 F.3d at 1358; *see generally* Pet. 14 (collecting decisions). Moreover, a patentee cannot rely on ambiguity about the reason for its amendment to overcome estoppel under the tangential exception. If the record is silent as to why the patentee adopted a particular amendment—or why the patentee drafted the amendment to surrender as much claim scope as it did—then prosecution history estoppel *applies*, because it means that the patentee "cannot meet [its] burden." *Felix v. Am. Honda Motor Co.*, 562 F.3d 1167, 1184 (Fed. Cir. 2009).

B. The Panel Decisions In This Case And In *Ajinomoto* Dramatically Expand The Tangential Exception By Turning It Into A Doctrine Of Prosecutor's Remorse.

The panel decisions in this case and *Ajinomoto* eviscerate prosecution history estoppel and undermine that doctrine's important public notice function.

Indeed, the panel decision here allowed the patent holder, Eli Lilly, to prevail on a "prosecutor's remorse" argument—despite conceding that such an argument "is not a reason for the tangential exception to apply." Slip op. at 19. Lilly's conduct during prosecution makes clear that the rationale for its amendment was decidedly *not* tangential to the equivalent at issue. First, in response to a prior art rejection, Lilly narrowed its claims covering a method of administration using an "antifolate" to cover only a method of administration using "pemetrexed disodium." *Id.* at 7-8. Then, Lilly referred to "pemetrexed disodium" *sixteen times* in the prosecution history. Pet. 7. That amendment and those express statements made clear to the public that Lilly was claiming only methods of administration that use pemetrexed disodium—the same chemical compound used in Lilly's chemotherapy product, ALIMTA. The alleged equivalent here—a chemically distinct pemetrexed salt—cannot plausibly be characterized as "tangential" to the rationale for Lilly's narrowing amendment.

Despite those definitive prosecution history statements, the panel concluded that Lilly had merely been "inartful" in appearing to cede the alternative salt forms

of pemetrexed, since doing so had been "prudential in nature" and unnecessary to avoid the prior art. Slip op. at 17-19. But that argument should have been irrelevant under this Court's precedent: although Lilly may not have needed to surrender alternative salt forms of pemetrexed to distinguish the prior art, "[t]he dispositive fact is that [Lilly] chose to do so." *Integrated Tech*, 734 F.3d at 1358. And there can be no doubt that it was an affirmative choice, if perhaps a poorly considered one: as Petitioners explain (Pet. 6-7), Lilly held other patents that covered pemetrexed and all of its salt forms, yet in narrowing its patent, Lilly did not use language broad enough to cover all of those options. This confirms that Lilly knew how to draft broader claims but declined to do so. And it should have eliminated any doubt that prosecution history estoppel applies here, because the doctrine is intended to prevent patent holders from recapturing claim scope after "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." *Festo*, 535 U.S. at 735.

The panel in *Ajinomoto* applied the same erroneous reasoning. *See* Pet. 15 (noting that both members of the *Ajinomoto* majority were also on the panel in this case). Just as in this case, the patentee there narrowed the claim—which originally covered the accused equivalents—to overcome an anticipation objection. 932 F.3d at 1353. As Judge Dyk described in dissent, that rationale for the amendment was

"directly related to the accused equivalent." *Id.* at 1363. The majority's contrary conclusion "ignore[d] how the patentee deliberately elected to narrow the claims" to avoid the prior art. *Id.* In both cases, it did not matter what the patentee *expressly* surrendered, because it could have *hypothetically* surrendered less.

If allowed to stand, the expansive approach to the tangential exception adopted by these two panel decisions will significantly diminish the extent to which "[t]he public [may] rely on th[e] representations" an applicant makes to secure its patent. *Ajinomoto*, 932 F.3d at 1363 (Dyk, J., dissenting) (citation omitted). The *en banc* Court should accept review in this case to ensure that what is supposed to be a "very narrow" exception to prosecution history estoppel, *Integrated Tech.*, 734 F.3d at 1358, does not become the rule, mutating into a doctrine that allows patentees to easily evade prosecution history estoppel, and thus undercuts the public-notice function of patents.

II. Guidance From The Full Court Is Needed To Clarify The Scope Of The "Tangential" Exception.

Even apart from the unsoundness of the panel decision, the uncertainty fostered by its approach to the tangential exception calls for *en banc* review, particularly given how frequently the issue recurs. *See* Pet. 12 (noting that this Court has issued "approximately two dozen precedential decisions" adjudicating the tangential exception since it was adopted in *Festo*). As Petitioners explain (Pet.

13), panels within this Circuit have been "sharply divided about what the tangential exception actually means."

The decision here makes the situation measurably worse. Not only does it join an "aberrant . . . line of cases" that "accept[] patentees' prosecution-remorse arguments," it affirmatively disavows any obligation to provide guidance about how the Court will apply the exception going forward. Pet. 17-19. Indeed, the panel criticized Petitioners' request for some "bright-line[s]" to inform the scope of the tangential exception, slip op. at 17, 19, 21, and the panel saw no need to reconcile its decision with the results from past cases that applied the tangential exception far more narrowly, *id.* at 20 n.5.

But what the panel celebrated as "case-specific focus," *id.*, leaves American businesses without any meaningful guidance as to the metes and bounds of patent claims. "[R]easonable competitors form[] their business strategies" based on the "public record of the patentee's representations concerning the scope and the meaning of [its] claims." *Springs*, 323 F.3d at 995 (citation omitted). Without clear direction from this Court as to how to interpret a patentee's surrender of claim scope, competitors will not be able to rely on prosecution history "when ascertaining the degree of lawful conduct" that is consistent with existing patent protections. *Id.*

That uncertainty will have serious for the pharmaceutical industry, where product development is both expensive and time-consuming, and where brand manufacturers now routinely create extensive patent thickets to prevent competition. *See* p. 2 & n.2, *supra*. Patent thickets have already cost the U.S. health care system *billions* of dollars, as brand manufacturers have used lifecycle-extension patents to block generic and biosimilar medicines, even after they receive regulatory approval.[3] The decisions at issue here, and the uncertainty they foster, will only make that problem worse.

Even with the abbreviated approval pathways established by Congress to speed the introduction of lower-cost generic drugs and biosimilars, it typically takes several years and millions of dollars in investment to bring generic and biosimilar products to market. In the case of biosimilars, for example, product development typically takes seven years and costs at least $100 million.[4] Generic drug and biosimilar companies must be able to forecast whether attempts to design around a brand manufacturer's patents—like those undertaken by Petitioners—are likely to incur infringement liability. The "know-it-when-we-see-it" approach to

[3] *See* Failure to Launch, *supra*, at 6-7 (describing study finding the health care system has lost $7.6 billion in biosimilar savings since 2012 as the result of patent thickets that delayed the launch of already approved biosimilar medicines).

[4] Erwin A. Blackstone & Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 AM. HEALTH & DRUG BENEFITS 469-478 (2013).

the tangential exception adopted by the panel here will frustrate good-faith efforts to compete, to the detriment of consumers.

CONCLUSION

The Court should grant the petition for rehearing *en banc*.

Respectfully submitted,

September 23, 2019

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CERTIFICATE OF COMPLIANCE

This document complies with the type-volume limitation of Fed. Cir. R. 29(b)(4), because it contains 2,550 words, excluding the portions of the brief exempted by Fed. R. App. P. 32(f).

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September 23, 2019 /s/ Brian T. Burgess

CERTIFICATE OF SERVICE

I hereby certify that on September 23, 2019, I electronically filed the foregoing brief with the Clerk of Court of the United States Court of Appeals for the Federal Circuit through the appellate CM/ECF filing system.

September 23, 2019 /s/ Brian T. Burgess