No. 19-1061

IN THE
Supreme Court of the United States

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

v.

ELI LILLY AND COMPANY,
Respondent.

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

BRIEF FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* SUPPORTING PETITIONERS

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March 27, 2020

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INTEREST OF THE *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 certiorari. 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, which includes the claims themselves as well as the prosecution history. When, as here, a brand manufacturer gives up particular equivalents during patent prosecution in order to secure a patent, generic and biosimilar manufacturers reasonably rely

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[1] AAM provided timely notice of intent to file this brief, and all parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no person other than *amicus curiae*, its members, or its counsel made a monetary contribution to the brief's preparation or submission.

on the public record and the doctrine of prosecution history estoppel in seeking to design around patent claims that were deliberately and unambiguously narrowed. This ability to design around patent claims is essential to competition in the pharmaceutical industry.

Recent decisions by the Federal Circuit, including the decision below, disregard this Court's precedent and threaten such competition. As exemplified by this case, the Federal Circuit has fundamentally misread this Court's decision in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740 (2002), in applying a broad "tangential exception" to prosecution history estoppel that is both sweeping and indeterminate. Under the Federal Circuit's approach, an amendment may be characterized as "tangential" to an equivalent anytime a court decides—typically, many years after-the-fact—that the patentee did not really "need or intend" to narrow its claims quite so far as it did. Pet. App. 20a. This doctrine of prosecutor's remorse leaves AAM's members unable to rely on the representations made by brand-name drug manufacturers to the Patent Office, since those manufacturers may now effectively rewrite their amendments years later in litigation. Absent review by this Court, these new Federal Circuit precedents will impose a significant impediment to generic and biosimilar competition, to the detriment of AAM members and the public at large.

INTRODUCTION

Clear rules for determining the scope of patent rights are "essential to promote progress," because clarity "enables efficient investment in innovation." *Festo*, 535 U.S. at 730-731. As this Court has recognized, the public "should know" the limits of a patent, so that people and companies remain free "to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights." *Id.*; *see also Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 909 (2014) ("[A] patent must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them." (quotation marks and brackets omitted)).

Under this Court's precedent, that is exactly what AAM members have been able to do. AAM members make substantial investments to bring generic and biosimilar medicines to market as early as possible, in part by seeking to design around the patent claims of brand manufacturers. And those investments have paid enormous dividends for public health. Over the last decade, generic drugs have saved the U.S. healthcare system nearly two *trillion* dollars.[2]

Two recent decisions by the Federal Circuit jeopardize the ability of AAM members to invest in new generic and biosimilar medications by making the scope of brand manufacturers' patent rights impossible to discern in advance of infringement

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[2] *See* Association for Accessible Medicines, *The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report* 10 (2019), *available at* https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf.

litigation. *See* Pet. App. 1a-30a; *Ajinomoto Co. v. ITC*, 932 F.3d 1342 (Fed. Cir. 2019), *petition for cert. pending*, No. 19-1062 (filed Feb. 24, 2020). These decisions significantly expand the "doctrine of equivalents," which, under limited circumstances, allows a patent's monopoly to extend beyond the literal claims. The Federal Circuit's misguided approach to this important issue of patent law requires this Court's review.

Under established law, if a patentee amends its patent claims to overcome a Patent Office rejection, it presumptively surrenders any equivalents that were covered by the initial claim but not by the amendment. Although the patentee may overcome that presumption of surrender in subsequent infringement litigation, it has the burden to "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." *Festo*, 535 U.S. at 741. To satisfy this burden, the patentee must put forward objective evidence from the prosecution record; it may not rely on *post-hoc* rationalizations for its amendment in order to recapture an equivalent through litigation. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33-34 (1997).

Significantly, these rules apply to *all* the grounds a patentee may invoke to overcome the presumption of estoppel, including the so-called "tangential" exception relied on by respondent Eli Lilly ("Lilly") and the Federal Circuit here. *See* Pet. 24-25; pp. 11-12, 15, *infra*. By imposing these limits on the doctrine of equivalents, the Court's precedent "gives proper deference to the role of claims in defining an invention

and providing public notice." *Warner-Jenkinson*, 520 U.S. at 33.

The decisions by the Federal Circuit in this case and in *Ajinomoto* are irreconcilable with this Court's precedent. Disregarding *Festo*'s central rationale, the Federal Circuit now allows patentees to avoid estoppel even where the prosecution history shows that the patentee "knew the words for both the broader and narrower claim, and affirmatively chose the latter." 535 U.S. at 735. All a patentee needs to do is argue that its decision to choose the narrower language was "inartful," since it did not "need or intend" to give up so much claim scope to obtain its patent. Pet. App. 20a. And if a judge credits that post-hoc explanation, based on unspecified "case-specific" factors, Pet. App. 22a n.5, the patentee can effectively rewrite its claims in litigation to block competition by companies that reasonably relied on the plain language of the amended claims and the prosecution history.

The facts of this case are stark, making it a perfect vehicle to review the Federal Circuit's misguided approach to prosecution history estoppel. Here, the Federal Circuit allowed Lilly to block generic alternatives to its cancer drug Alimta, even though generic competitors scrupulously avoided infringing claims in Lilly's patent, which covered only the compound found in Alimta: pemetrexed disodium. *See* Pet. 10-16. The prosecution record confirmed that Lilly's claims did not cover alternative compounds, including other pemetrexed salts. Specifically, in response to an examiner's rejection, Lilly amended its claims to recite *only* pemetrexed disodium—even though Lilly had previously claimed "pemetrexed," *including* the various pemetrexed salts, in other

patent applications for Alimta. Pet. App. 18a. The Federal Circuit, however, refused to hold Lilly to its prosecution choice, determining that Lilly's decision to claim only pemetrexed disodium could be disregarded under the "tangential" exception as mere "inartful" drafting. Pet. App. 20a. The court reached that conclusion even though there is *nothing* in the prosecution record that explains why Lilly chose to claim only the specific form of pemetrexed used in Lilly's commercial product.

Although the legal error in this case is especially glaring, it is not case-specific. A divided panel of the Federal Circuit made the same fundamental mistake in *Ajinomoto*, crediting the patentee's *post hoc* reconstruction of the rationale for its claim amendment, 932 F.3d at 1355, while "ignor[ing]" the specific way that "the patentee deliberately elected to narrow the claims," *id.* at 1363 (Dyk, J., dissenting).

In short, the Federal Circuit has gone badly astray in how it applies prosecution history estoppel, and its misunderstanding of this Court's precedents will have serious negative consequence. In particular, the Federal Circuit's sweeping but vague exception to prosecution history estoppel will deter "efficient investment in innovation." *Festo*, 535 U.S. at 731. As this Court has long recognized, "[a] zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field." *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942).

The impact of the Federal Circuit's decisions on competition in the pharmaceutical industry will be

especially acute. Generic and biosimilar manufacturers typically must navigate a dizzying array of patent claims given that brand manufacturers frequently adopt a strategy of accumulating numerous patents near the end of a product's life-cycle in order to extend their patent monopolies.[3] A critical tool for cutting through these patent estates is for generic and biosimilar manufacturers to design around questionable patent claims. But this path to competition is only viable if patent scope is predictable. Developing new generic and biosimilar medicines is both expensive and time-consuming, costing millions of dollars (or more) and taking several years to complete product testing and secure regulatory approval. Manufacturers will not be willing to make these investments if they lack confidence that the unequivocal representations made to the Patent Office will hold up years later during infringement litigation.

The Court should grant the petition for certiorari and reverse the Federal Circuit's decision.

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[3] *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").

ARGUMENT

I. The Federal Circuit's Unbounded "Tangential Exception" To Prosecution History Estoppel Conflicts With This Court's Precedents.

A. This Court Has Placed Important Limits On the Doctrine Of Equivalents.

1. The scope of a patentee's rights are "define[d]" by the patent's claims, *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 835 (2015) (quotation marks omitted), which must "point[] out and distinctly claim[] the subject matter which the inventor . . . regards as the invention," 35 U.S.C. § 112(b). This statutory claiming requirement "seeks to guard against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their rights." *General Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938).

Notwithstanding the Patent Act's command, the Court has held that a patentee sometimes may enforce its property right against a competitor that does not "literally infringe upon the express terms of a patent claim" if there is an "equivalence between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson*, 520 U.S. at 21 (quotation marks omitted). But the Court has also disapproved of applications of this doctrine of equivalents that are "unbounded by the patent claims," recognizing that the doctrine, if interpreted too loosely, will "conflict[] with the

definitional and public-notice functions of the statutory claiming requirement." *Id.* at 28-29.

Thus, as the Court has explained, the doctrine of equivalents must be applied in a manner that strikes a balance between two competing concerns. On the one hand, requiring clarity about the scope of a claimed invention promotes competition and innovation: a patent is "a property right; and like any property right, its boundaries should be clear." *Festo*, 535 U.S. at 730-731. On the other hand, a strict literalist application of a patent's claims would allow competitors to "exploit[]" imprecisions in the "nature of language" by making "trivial changes" to the invention. *Id.* at 733. The doctrine of equivalents accounts for the fact that "[t]he language in the patent claims may not capture every nuance of the invention," *id.* at 731, while still ensuring that the "definitional and public-notice functions of the statutory claiming requirement" are protected by treating "[e]ach element contained in a patent claim" as material and enforcing "well-established limit[s]" on the doctrine's scope, *Warner-Jenkinson*, 520 U.S. at 29-30.

2. One "well-established limit" on the doctrine of equivalents is prosecution history estoppel. *Id.* at 30. Prosecution history estoppel prevents a patentee from recapturing under the doctrine of equivalents subject matter surrendered during prosecution in order to obtain the patent. *See Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136-137 (1942). The doctrine most obviously bars a patentee from reclaiming equivalents that it gave up to overcome an examiner's patentability rejection—for example, an equivalent that appeared in the prior art. *See Festo*,

535 U.S. at 735-736; *Keystone Driller Co. v. Northwest Eng'g Corp.*, 294 U.S. 42, 48 (1935).

But prosecution history estoppel extends beyond merely enforcing the patentee's necessary concessions, because the prosecution history provides an important public record of the invention's scope. As the Court explained in *Festo*—the Court's most recent decision on the topic—because "[t]he doctrine of equivalents is premised on language's inability to capture the essence of innovation," prosecution history "may rebut the inference that a thing described was indescribable." 535 U.S. at 735-736. Following an amendment, restrictions on claim scope cannot be explained away as linguistic imprecisions; to the contrary, "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.* The public notice function of a patent and its prosecution history requires that a patentee be held to that choice. *See I.T.S. Rubber Co. v. Essex Rubber Co.*, 272 U.S. 429, 443-444 (1926) ("[L]imitations imposed by the inventor, especially such as were introduced into an application after it had been persistently rejected, must be strictly construed against the inventor and looked upon as disclaimers.").

Of course, the fact that an inventor "turned [its] attention" to the scope of a particular claim does not make the inventor clairvoyant. *Festo*, 535 U.S. at 735. "The patentee, as the author of the claim language, may be expected to draft claims encompassing readily known equivalents," but there are cases in which a skilled artisan could not have anticipated an amendment's implications for a particular equivalent. *Id.* at 740. Thus, under *Festo*, courts must "presume

that the patentee surrendered all subject matter between the broader and the narrower language," but the patentee can overcome that presumption by showing that "at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Id.* at 741.

In *Festo*, the Court identified three situations in which an 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.

Id. at 740-741. This case turns on the so-called "tangential" exception to estoppel. Pet. App. 18a. As petitioners note (at 8-9), both the origins and contours of that exception are somewhat opaque: the Court in *Festo* modeled its burden-shifting approach on the position "advocated by the United States," *Festo*, 535 U.S. at 740, but the Solicitor General's brief did not outline a potential "tangential" exception to estoppel. The full context of the Court's opinion, however, makes clear that the exception is narrow because—like the other two situations discussed by the Court—it is only applicable in cases where the patentee "could not reasonably [have been] expected to have drafted a

claim that would have literally encompassed the alleged equivalent." *Id.* at 741.

Moreover, by placing the burden on the patentee to overcome the estoppel presumption, this Court's precedent requires the patentee to put forward objective evidence from the prosecution history—not post-hoc rationalizations. "When the patentee is unable to explain the reason for the amendment, estoppel not only applies but also bars the application of the doctrine of equivalents as to that element." *Id.* at 740. Thus, when the record reveals only "the *absence* of a reason for an amendment," prosecution history estoppel *applies*, and the patentee may not invoke the doctrine of equivalents. *Warner-Jenkinson*, 520 U.S. at 33.

B. The Federal Circuit's Decision Cannot Be Squared With *Festo* and *Warner-Jenkinson*.

The approach to prosecution history estoppel adopted by the Federal Circuit here and in *Ajinomoto* conflicts with this Court's precedent, eviscerating a critical limit on the doctrine of equivalents.

As set out by petitioners, the Federal Circuit's error was fundamental, deriving from how the court framed the basic issue. Pet. 18-24; *see also* Pet. of Hospira, Inc. in No. 19-1058, at 19-21. Rather than requiring Lilly to explain the rationale for the *specific* claim language it adopted—here, narrowing the patent's claims to cover pemetrexed disodium, the formulation used in Lilly's own commercial product—the Federal Circuit looked instead to Lilly's general reason for amending its claims *at all*. Pet. App. 19a-22a. Reasoning that

Lilly had no need to distinguish between different forms of pemetrexed in order to avoid the Patent Office's prior-art rejection, the Federal Circuit concluded that Lilly had not surrendered other pemetrexed salts because its amendment had been "prudential in nature," albeit "inartful." Pet. App. 20a; *see also* Pet. App. 25a. The Federal Circuit in *Ajinomoto* applied the same form of reasoning, with the panel relying on its own assessment of the scope that the patentee needed to surrender to overcome a rejection, 932 F.3d at 1355, while "ignor[ing] how the patentee deliberately elected to narrow the claims," *id.* at 1363 (Dyk, J., dissenting). This approach to estoppel not only conflicts with the approach taken by other panels of the Federal Circuit (Pet. 18-20, 22), but it is irreconcilable with this Court's precedent for several reasons.

1. By disregarding the *specific language* that a patentee chose when amending its claims—and instead looking only to why the patentee was motivated to amend its claims in the first place—the Federal Circuit has turned the tangential exception into a doctrine of prosecutor's remorse. Any time that a patentee surrenders more than was strictly necessary to overcome a rejection, it will follow almost by definition that equivalents surrendered improvidently are merely "tangential" to the amendment's rationale. After all, the "reason for the amendment" will typically be found in "the prior art that might have given rise to the amendment in the first place." Pet. App. 21a. Under the Federal Circuit's reasoning, gratuitously surrendered equivalents are invariably "tangential" to the rationale for an amendment to avoid the prior art.

This Court's decisions, by contrast, have focused on the *particular* language used in a narrowing amendment. *Warner-Jenkinson* is illustrative. There, the patent-in-suit described a process for purifying dyes by filtering the dye through a porous membrane at certain pressures and pH levels. 520 U.S. at 21-22. The asserted claims included the requirement that the purification occur at a "pH from approximately 6.0 to 9.0"—a requirement that was added during prosecution to distinguish a prior-art reference ("Booth") that disclosed a process at a pH above 9.0. *Id.* at 22. The accused process, in turn, occurred at a pH of 5.0. *Id.* As the Court recognized, the patentee's need to overcome Booth only explained why it had adopted the *upper* endpoint of the pH range; the record did "not . . . reveal the reason for including the lower pH limit of 6.0." *Id.* at 32-33. Rather than allow the patentee to benefit from such ambiguity, the Court concluded that because "claims . . . serve both a definitional and notice function," the patentee had "to establish the reason for [this] amendment during patent prosecution." *Id.* at 33. If it failed to do so on remand, then the tie would go to the public and prosecution history estoppel would apply. *Id.*[4]

The Federal Circuit's approach to prosecution history estoppel would yield the wrong result on the facts of *Warner-Jenkinson*. Under the reasoning applied by the panel, the absence of evidence in the

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[4] *Warner-Jenkinson* preceded the Court's decision in *Festo*, which is the source of the Federal Circuit's "tangential" exception to estoppel. But *Festo* endorsed *Warner-Jenkinson*'s reasoning on this issue, building on that decision in establishing a burden-shifting rule. *See Festo*, 535 U.S. at 739-740.

prosecution record to explain the choice to include a lower pH limitation would redound to *the patentee*'s benefit. The court would identify "the prior art that . . . gave rise to the amendment in the first place" (Booth), and conclude that the patentee could claim processes with a pH under 6.0 because the patentee did not "need or intend to cede" processes below the 6.0 to 9.0 pH range in order to distinguish Booth. Pet. App. 20a. That outcome is wrong for the reason that this Court already identified: it disregards the important "notice function" that patent claims are supposed to serve. *Warner-Jenkinson*, 520 U.S. at 33.

2. The Federal Circuit's broad approach to the "tangential" exception to prosecution history estoppel also unmoors that exception from this Court's reasoning in *Festo*. As discussed, pp. 10-12, *supra*, in *Festo*, the Court explained that "[t]he doctrine of equivalents is premised on language's inability to capture the essence of invention." 535 U.S. at 734. The Court recognized narrow exceptions to estoppel based on the same understanding, reasoning that an inventor does not "suddenly [acquire] more foresight" when drafting an amendment than she had when first drafting her claims, which means she still cannot be expected to anticipate all possible equivalents. *Id.* at 738. The Court thus held that in order to rebut the presumption of prosecution history estoppel (under *any* rationale), 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." *Id.* at 741.

There is no serious argument here that Lilly "lacked the words to describe the subject matter in

question" by drafting an amendment that "would have literally encompassed the alleged equivalent." *Id.* at 734, 741. Indeed, Lilly had "claimed pemetrexed salts generally" in related patents, yet it chose to claim only "pemetrexed disodium" when narrowing the claims of the patent-in-suit. Pet. App. 18a; *see also* Pet. 10-11, 25.

Significantly, the Federal Circuit did not suggest otherwise. Instead, and remarkably, the Federal Circuit stated that Lilly's unquestioned ability to draft an amended claim that encompassed the alleged equivalent was *irrelevant*, on the theory that courts "do not demand perfection from patent prosecutors." Pet. App. 22a. That reasoning fundamentally and directly contradicts the holding of *Festo* in a manner that cannot be dismissed as a case-specific error. Stripping a single sentence from its context in *Festo*, the court has created a broad "tangential" exception to prosecution history estoppel that is completely divorced from *Festo*'s animating rationale. *See* Pet. of Hospira, Inc. in No. 19-1058, at 15-19. This Court's intervention is needed to reconnect the doctrine to *Festo*'s reasoning.

3. The Federal Circuit's approach to estoppel also conflicts with this Court's precedent because it lets patentees recover claim scope surrendered during prosecution based on post-hoc rationalizations of their amendments. Even though there is *no* evidence in the prosecution record about why Lilly chose to narrow its patent claims to cover only pemetrexed disodium rather than pemetrexed, the Federal Circuit accepted Lilly's assertion that the amendment was "prudential," meaning it was intended merely to avoid a prior art reference that did not implicate any distinction

between pemetrexed salts. Pet. App. 20a. As a result, the Federal Circuit declared that it was "unlikely that a competitor would have been justified in assuming" that alternative forms of pemetrexed would not infringe—notwithstanding that Lilly's amended claims unequivocally exclude those alternative forms. Pet. App. 20a, 21a (quotation marks omitted).

By accepting Lilly's after-the-fact explanation of its amendment without requiring Lilly to put forward objective evidence demonstrating the rationale for its *specific* choice, the Federal Circuit relieved Lilly of its "burden to show[] that the amendment does not surrender the particular equivalent in question." *Festo*, 535 U.S. at 740. This approach to estoppel makes the inquiry hopelessly indeterminate. Competitors seeking to make investments in developing products or methods that avoid infringing patent claims will be unable to rely on either the plain language of the claims or the objective record of prosecution, since a panel of the Federal Circuit might later conclude that it was "unlikely" those competitors were justified in taking an "inartful" amendment at face value. Pet. App. 20a, 21a. *Accord* Pet. of CJ CheilJedang Corp. et al. in No. 19-1062, at 18-22.

Lilly will no doubt argue in opposition to certiorari that the Federal Circuit's decision was fact-bound and case specific, since the court disavowed any effort to articulate "bright-line rule[s]" that could guide future courts or the public. Pet. App. 24a; *see also* Pet. App. 22a n.5, 23a. But the "know it when we see it" quality of Federal Circuit's application of a tangential exception to estoppel is one of the central defects with its approach, and it demands this Court's correction. After all, as this Court has recognized, "[a] zone of

uncertainty" about the scope of patent claims has the potential to "discourage invention" to almost the same extent as "unequivocal foreclosure of the field." *United Carbon*, 317 U.S. at 236; *accord Nautilus*, 572 U.S. at 909. That is why the Court has been careful to enforce "well-established limit[s]" on the doctrine of equivalents, to prevent that doctrine from undermining "the definitional and public-notice functions of the statutory claiming requirement." *Warner-Jenkinson*, 520 U.S. at 29. But the Federal Circuit's approach to prosecution history estoppel—under which the doctrine's application will turn on a judge's "case-specific" sense of whether a narrowing amendment was deliberate or merely "inartful," Pet. App. 20a, 22a n.5—leaves the public to guess about what a patent may legitimately exclude.

II. The Federal Circuit's Tangential Exception to Prosecution History Estoppel Will Undermine Competition-Promoting Investments in the Generic Drug and Biosimilar Industries.

The uncertainty created by the Federal Circuit's approach to prosecution history estoppel in this case and in *Ajinomoto* leaves American businesses without meaningful guidance as to the metes and bounds of patent claims. Reasonable competitors form their business strategies based on the public record of a patentee's representations concerning the scope and meaning of its claims. Without clear direction 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.

That uncertainty will have especially serious implications for the pharmaceutical industry, in which product development is both expensive and time-consuming, and where navigating patent claims is a routine part of doing business. As noted, p. 7, *supra*, in recent years, brand manufacturers have increasingly turned to a strategy of trying to delay generic and biosimilar competition by accumulating dozens of patents near the end of a product lifecycle based on purported innovations regarding an existing product's method of manufacture or use. *See* Failure to Launch, *supra*, at 7 n.3.[5] These patent estates chill competition by increasing the costs of market entry. Even if all of the brand manufacturer's patents are meritless, a manufacturer of generic or biosimilar medicines will typically have to incur enormous litigation expenses to prove that each patent is invalid. *See id.* at 8 (citing report estimating litigation costs of "roughly $3 million per patent"). The result is that competition is often delayed until long after a generic or biosimilar manufacturer secures regulatory approval, depriving the public of access to these lower cost medicines. Indeed, in a recent study, AAM calculated that patent-induced delays in product launches for biosimilar medicines with regulatory approval have deprived the United States healthcare system of $7.6 billion in biosimilar savings since 2012. *See id.* at 7.

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[5] This case is illustrative. Lilly obtained a compound patent that claimed pemetrexed itself *more than 25 years ago*. *See Eli Lilly & Co. v. Teva Parental Medicines, Inc.*, 689 F.3d 1368, 1373 (Fed. Cir. 2012). But Lilly has been able to prevent generic competition to its Alimta product by securing the follow-on method-of-treatment patent at issue here.

One path to avoid these patent estates is for generic and biosimilar manufacturers to design around a brand manufacturer's patent claims, as petitioners tried to do here. *See, e.g.*, *Schwarz Pharma, Inc. v. Paddock Labs., Inc.*, 504 F.3d 1371, 1374-1378 (Fed. Cir. 2007) (affirming judgment of noninfringement in favor of generic manufacturer based on prosecution history estoppel). Such efforts could lead to earlier generic and biosimilar competition and significant public savings. But this strategy is only feasible if generic and biosimilar manufacturers can reliably discern the "boundaries" of the brand manufacturer's "patent monopoly," *Festo*, 535 U.S. at 731, based on the language of its claims (as informed by the patent specification) and the prosecution history.

Even with the abbreviated approval pathways established by Congress to speed the introduction of lower-cost generic drugs and biosimilars, it takes several years and millions of dollars 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.[6] Generic drug and biosimilar companies must be able to reliably forecast whether attempts to design around a brand manufacturer's patents are likely to incur infringement liability. They cannot do so under the Federal Circuit's approach to prosecution history estoppel, which authorizes courts to "ignore how [a] patentee deliberately elected to narrow the claims," *Ajinomoto*, 932 F.3d at 1363 (Dyk, J., dissenting), and

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

thus allows brand manufacturers to recapture equivalents surrendered during prosecution by arguing that they gave up more than they intended.

* * * * *

The question presented frequently recurs in patent litigation in the lower courts. *See* Pet. of Hospira, Inc. in No. 19-1058, at 23 (collecting decisions). Given its importance to the patent system and to competition in major industries, including the pharmaceutical industry, the Court should grant review.

CONCLUSION

The Court should grant the petition for a writ of certiorari.

Respectfully submitted.

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March 27, 2020