

No. 19-1062

IN THE
Supreme Court of the United States

CJ CHEILJEDANG CORP., CJ AMERICA, INC.,
PT. CHEILJEDANG INDONESIA,
Petitioners,

v.

INTERNATIONAL TRADE COMMISSION, AJINOMOTO CO.,
INC., AJINOMOTO ANIMAL NUTRITION
NORTH AMERICA, INC.,
Respondents.

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

**BRIEF IN OPPOSITION BY RESPONDENT
AJINOMOTO**

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QUESTION PRESENTED

In patent law, the doctrine of equivalents and the doctrine of prosecution history estoppel work hand in hand to strike an appropriate balance between fairness to the inventor and notice to the public: The doctrine of equivalents prevents a would-be infringer from avoiding liability by making insubstantial changes to a patented invention, while the doctrine of prosecution history estoppel gives appropriate effect to a patentee's representations regarding the scope of its invention.

Regarding the doctrine of prosecution history estoppel, this Court's precedent holds that an applicant's narrowing claim amendment gives rise to a presumption of estoppel that bars a claim of equivalence, but that presumption may be rebutted by showing that "the rationale underlying the amendment . . . bear[s] no more than a tangential relation to the equivalent in question." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740-41 (2002). Whether an applicant has rebutted the presumption is determined on a case-by-case basis "in light of the proceedings in the PTO during the application process" and "the reason the amendment was submitted." *Id.* at 733, 738.

The question presented is: Whether the court of appeals correctly applied these principles in concluding that the particular prosecution history amendment in this case was merely tangential to the accused equivalent and thus did not estop the patentee from asserting infringement under the doctrine of equivalents.

CORPORATE DISCLOSURE STATEMENT

Ajinomoto Co., Inc. has no parent corporation and no publicly held company owns 10% or more of its stock.

The following entities own, directly or indirectly, more than 10% of the stock of Ajinomoto Animal Nutrition North America, Inc.: Ajinomoto Animal Nutrition Group, Inc. and Ajinomoto Co., Inc.

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INTRODUCTION

Consistent with the law of this Court as most recently expressed in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), the Federal Circuit reviewed the prosecution history of the patent in suit, determined the patentee’s objectively apparent reason for its narrowing amendment, and concluded that reason bore only a tangential relation to the equivalent in question so did not estop Ajinomoto’s assertion of infringement. As the court explained, the patentee’s amendment narrowed the range of proteins claimed by the patent, but did not surrender the substantively identical protein used by CJ, which escaped literal infringement simply by “codon randomizing” its DNA sequence.

CJ’s challenge to the court’s fact-specific determination on the particular prosecution history record in this case does not warrant this Court’s review. CJ decries what it calls the court’s improper “*post-hoc* rationale, in light of the accused product.” Pet. 4. But the doctrine of prosecution history estoppel has *always* required looking backward over the prosecution history of a patent, examining “the reason the amendment was submitted,” and comparing that reason to the “particular equivalent” in litigation to determine whether estoppel applies. *Festo*, 535 U.S. at 738, 740-41. CJ further protests that the decision “frustrate[s] the public notice function of the prosecution history” and creates a “zone of uncertainty” for potential competitors. Pet. 13. But these concerns “are not new.” *Festo*, 535 U.S. at 732. As this Court has repeatedly explained, “language remains an imperfect fit for invention” and some “uncertainty [in determining the scope of equivalence is] the price of ensuring the appropriate incentives for innovation.” *Id.* at 732, 738;

see also Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 33 (1997); *Festo*, 535 U.S. at 739 (“[T]he doctrine of equivalents and the rule of prosecution history estoppel are settled law. The responsibility for changing them rests with Congress.”).

Unable to identify any departure from precedent, what CJ really asks of this Court is creation of a *new* rule—to “clarify” the estoppel doctrine such that it applies only when the patentee explicitly “stated the ‘rationale’ in question on the record at the time of the amendment.” Pet. 3. But this Court’s precedents already require the patentee’s rationale to be discernible from the prosecution record. Whatever additional “clarity” CJ requests is the type of rigid, bright-line rule of estoppel this Court has repeatedly rejected. *Festo*, 535 U.S. at 738 (“[W]e have consistently applied the doctrine in a flexible way, not a rigid one.”). In any event, this case is not the proper vehicle to explore the contours of the tangential exception to prosecution history estoppel. As the Federal Circuit stated at the outset, the circumstances of this case are “unusual,” Pet. App. 19a-20a—there remains a threshold challenge to the application of prosecution history estoppel to the claim limitation at issue that the Federal Circuit declined to address, making this case ill-suited for this Court’s review.

Fundamentally, neither this case, nor the co-pending challenges in *Dr. Reddy’s Laboratories, Ltd. v. Eli Lilly & Co.* (No. 19-1061) and *Hospira, Inc. v. Eli Lilly & Co.* (No. 19-1058), represents any departure from precedent or split within the Federal Circuit. To the contrary, the decisions evidence the court’s orderly resolution of the disputes brought before it, dependent on the particular prosecution histories and the particular equivalents at issue in each individual case.

The decisions are fact-bound and unremarkable among the library of decisions that apply this Court's precedent.

The petition should be denied.

STATEMENT OF THE CASE

A. Legal Background: The Doctrine of Equivalents and the Doctrine of Prosecution History Estoppel

“Originating almost a century ago in the case of *Winans v. Denmead*, 15 How[.] 330 [(1853)],” the doctrine of equivalents operates to prevent “the unscrupulous copyist [from] mak[ing] unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law.” *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607-08 (1950). “The theory [behind the doctrine] . . . is that ‘if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form, or shape.’” *Id.* at 608 (quoting *Union Paper-Bag Mach. Co. v. Murphy*, 97 U.S. 120, 125 (1877)). Thus, although “a product or process . . . [may] not literally infringe upon the express terms of a patent claim[, it] may nonetheless be found to infringe if there is ‘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 (citing *Graver Tank*, 339 U.S. at 609).

This Court has repeatedly endorsed the protections afforded to a patentee by the doctrine of equivalents. *See, e.g., Union Water-Meter Co. v. Desper*, 101 U.S. 332, 335 (1879) (“It is . . . well known that if any one of

the parts is only formally omitted, and is supplied by a mechanical equivalent, performing the same office and producing the same result, the patent is infringed.”); *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42 (1929) (“[M]ere colorable departures from the patented device do not avoid infringement.”); *Warner-Jenkinson*, 520 U.S. at 40 (“Today we adhere to the doctrine of equivalents.”). As set out in the seminal case of *Graver Tank*:

[T]o permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing. Such a limitation would leave room for—indeed encourage—the unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law. One who seeks to pirate an invention, like one who seeks to pirate a copyrighted book or play, may be expected to introduce minor variations to conceal and shelter the piracy. Outright and forthright duplication is a dull and very rare type of infringement. To prohibit no other would place the inventor at the mercy of verbalism and would be subordinating substance to form. It would deprive him of the benefit of his invention and would foster concealment rather than disclosure of inventions, which is one of the primary purposes of the patent system.

Graver Tank, 339 U.S. at 607.

At the same time, this Court has also recognized that the doctrine of equivalents, if applied too broadly, would “conflict[] with the definitional and public-notice functions of the statutory claiming requirement,” *Warner-Jenkinson*, 520 U.S. at 29, and create “uncertainty about where the patent monopoly ends,” *Festo*, 535 U.S. at 727. Thus, there is an equally “well-established limit on non-literal infringement, known variously as ‘prosecution history estoppel’ and ‘file wrapper estoppel,’” *Warner-Jenkinson*, 520 U.S. at 30 (citation omitted), which ensures that the public “may rely on the prosecution history, the public record of the patent proceedings,” in understanding the reach of a patent’s claims, *Festo*, 535 U.S. at 727; *see also Warner-Jenkinson*, 520 U.S. at 34 (“[P]rosecution history estoppel places reasonable limits on the doctrine of equivalents . . .”).

The contours of the doctrine of prosecution history estoppel were most recently addressed by this Court in *Festo*. 535 U.S. at 726 (“This case requires us to address once again the relation between two patent law concepts, the doctrine of equivalents and the rule of prosecution history estoppel.”). There, this Court confirmed the general rule: A patentee’s narrowing amendment during prosecution is “presumed to be a general disclaimer of the territory between the original claim and the amended claim,” *id.* at 740 (citing *Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136-37 (1942)), but a patentee may rebut the presumption of estoppel by a number of showings, including that “the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question,” *id.* at 740-41. As this Court explained, “[t]here are some cases . . . where the amendment cannot reasonably be viewed as surrendering a particular equivalent.” *Id.* at 740. And

“[t]here is no reason why a narrowing amendment should be deemed to relinquish equivalents unforeseeable at the time of the amendment and beyond a fair interpretation of what was surrendered. Nor is there any call to foreclose claims of equivalence for aspects of the invention that have only a peripheral relation to the reason the amendment was submitted.” *Id.* at 738.

In confirming the “tangential” exception to prosecution history estoppel, this Court expressly rejected a “complete bar” of estoppel: “[W]e have consistently applied the doctrine in a flexible way, not a rigid one. We have considered *what* equivalents were surrendered during the prosecution of the patent, rather than imposing a complete bar that resorts to the very literalism the equivalents rule is designed to overcome.” *Id.* (emphasis added). Thus, when an applicant narrows its claims during prosecution, “the question is not whether estoppel applies but *what territory* the amendments surrendered.” *Id.* at 741 (emphasis added); *accord id.* at 737 (requiring “an examination of the subject matter surrendered by the narrowing amendment”). By permitting the patentee to demonstrate through an objective reading of the prosecution record that the equivalent in question bears “only a peripheral relation to the reason the amendment was submitted,” *id.* at 738, the doctrines of equivalents and prosecution history estoppel strike the appropriate balance. *See, e.g., Warner-Jenkinson*, 520 U.S. at 33-34 (“The presumption we have described, one subject to rebuttal if an appropriate reason for a required amendment is established, gives proper deference to the role of claims in defining an invention and providing public notice . . .”); *Hubbell v. United States*, 179 U.S. 77, 80 (1900) (“While not allowed to revive a rejected claim by a broad construction of the

claim allowed, yet the patentee is entitled to a fair construction of the terms of his claim as actually granted.”).

B. The Proceedings Below

The litigation below involved myriad disputes of infringement and validity relating to two separate patents and several different lines of accused products. In this certiorari petition, CJ challenges only a sliver of the determinations below—namely, whether Ajinomoto should have been estopped from asserting that one aspect of one product infringes one claim element of one of the asserted patents. The below recitation of facts is thus limited to only those facts that are relevant to CJ’s present challenge.

1. Ajinomoto’s Patent Provides an Innovative Method of Producing L-Tryptophan in Bacteria by Enhancing YddG Protein Activity

Ajinomoto is a world leader in innovative amino acid products and owns U.S. Patent No. 7,666,655 (“the ’655 patent”), directed to genetically engineered *E. coli* bacteria and methods of using them to produce aromatic L-amino acids, such as L-tryptophan. Pet. App. 2a-3a. These amino acids are useful in a variety of commercial applications, including for animal feed and human pharmaceutical products. The ’655 patent is founded on the inventors’ discovery that a particular gene in the *E. coli* genome, the *yddG* gene, encodes a membrane protein, the YddG protein, which transports aromatic L-amino acids out of the bacterial cell and into the surrounding culture medium where they can be collected. Pet. App. 3a. The inventors discovered that by enhancing YddG activity, they could obtain increased export, and thus yield, of aromatic L-amino acids. *Id.* The ’655 patent therefore

describes and claims *E. coli* bacteria that have been genetically engineered to have enhanced YddG activity, and methods of using those bacteria to produce aromatic L-amino acids. Pet. App. 3a-4a.

The issued claims of the '655 patent recite several limitations defining the bacteria and methods of using them. Of relevance to CJ's instant challenge, the '655 patent claims refer to the YddG protein in one of three alternative ways: limitation (A) recites the exact amino acid sequence for the *E. coli* YddG protein, "SEQ ID NO: 2"; limitation (B) recites an amino acid sequence that bears "one to five amino acid[]" differences from SEQ ID NO: 2; and limitation (C) recites an encoding DNA sequence that is capable of hybridizing to (i.e., pairing with) the complement of the DNA sequence of the *E. coli yddG* gene under specified conditions. C.A. App. 200 (21:38-49).

2. CJ Attempts to Avoid Liability by Making Insubstantial Changes to Its Infringing Bacteria Using Codon Randomization

In 2016, Ajinomoto filed suit in the International Trade Commission seeking an exclusion order to stop CJ's importation of animal-feed tryptophan products made using bacteria and methods believed to infringe Ajinomoto's patents. Pet. App. 6a. During the course of the litigation, CJ disclosed that it had designed two new bacterial strains in an attempt to avoid infringing the '655 patent. Pet. App. 6a-7a.

CJ's first design-around attempt, "Strain A," enhanced YddG activity by introducing into its *E. coli* bacteria a copy of the *yddG* gene from a closely related, but non-*E. coli*, bacteria. *Id.* (discussing the "first 'later strain'" of November 2016). Because the non-*E. coli* YddG protein produced by the incorporated gene

has a slightly different amino acid sequence than the *E. coli* YddG protein, Strain A did not literally infringe protein limitation (A) that defines the protein as SEQ ID NO: 2. But because the incorporated gene encoding the non-*E. coli* YddG protein is nonetheless substantially similar to that of the *E. coli yddG* gene, it hybridized to the complement of the *E. coli yddG* gene as specified by protein limitation (C). Pet. App. 27a n.9; C.A. App. 129-132. Thus, CJ's Strain A literally infringed the '655 patent under protein limitation (C) and failed to avoid liability. Pet. App. 27a n.9; C.A. App. 129-132.

CJ's next design-around attempt, "Strain B," is the one at issue here. To create Strain B, CJ utilized a genetic engineering technique called "codon randomization," which takes advantage of certain redundancies in the genetic code, whereby the DNA sequence of a gene can be manipulated to contain certain alterations, yet still result in production of the exact same amino acid sequence and, thus, the exact same protein with the exact same function. Pet. App. 7a (discussing the "second 'later strain'" of December 2016); *accord id.* n.5 (explaining codon randomization). Using codon randomization, CJ was able to tweak the DNA sequence encoding the literally infringing non-*E. coli* YddG protein just enough to bring Strain B outside the literal scope of the '655 patent—despite that Strain B produces the exact same, functionally equivalent non-*E. coli* YddG protein as literally infringing Strain A. Pet. App. 23a-24a; C.A. App. 843 (Q/A121); C.A. App. 551 (Q/A686). CJ's witnesses admitted that the reason for using codon randomization to create Strain B was privileged; there was no "technical" reason for doing so. C.A. App. 10694 (151:12-24, 152:15-21); C.A. App. 10641 (156:22-157:7).

Because CJ's genetic manipulation to Strain B was an insubstantial change that nonetheless resulted in the exact same YddG protein, Ajinomoto asserted that Strain B infringed the '655 patent under the doctrine of equivalents. In particular, Ajinomoto argued that CJ's use of the artifice of codon randomization was the precise type of "unimportant and insubstantial changes . . . which, though adding nothing, [was] enough to take the copied matter outside the claim" as contemplated by the equivalents doctrine set forth in *Graver Tank*, 339 U.S. at 607. C.A. App. 6378-6383. Ajinomoto asserted that CJ's codon-randomized, non-*E. coli* YddG protein of Strain B was equivalent to the *E. coli* YddG protein, limitation (A), that is recited in the '655 patent's claim 20 via dependency on claim 9. Pet. App. 17a.

3. CJ Argues It Should Escape Liability Due to Prosecution History Estoppel

a. CJ's Products

CJ's first response to Ajinomoto's charge of infringement by Strain B was to argue that Ajinomoto had failed to prove that the two YddG proteins were, in fact, equivalent. Pet. App. 24a-27a. That argument failed, as the codon-randomized, non-*E. coli* YddG protein of CJ's Strain B was functionally identical to the *E. coli* YddG disclosed in the '655 patent: the two proteins were 85-95% identical in structure, they performed the same L-amino acid membrane-transport function, and their enhanced expression increased the export and yield of L-tryptophan. *Id.*

CJ's second response was that a narrowing amendment during prosecution estopped Ajinomoto from asserting a scope of equivalence that would include CJ's codon-randomized, non-*E. coli* YddG protein. Pet.

App. 17a. CJ made this argument despite that the amendment (1) did not concern protein limitation (A), which was never amended or narrowed during prosecution and thus could not be subject to a presumption of prosecution history estoppel, and further (2) had nothing whatsoever to do with codon-randomized YddG proteins, but instead related to an entirely different prior-art protein, “YfiK.” The relevant details of the prosecution history amendment follow.¹

b. The Prosecution History

As originally filed, claim 1 recited two alternative definitions for the claimed YddG protein. Limitation (A) recited the exact amino acid sequence for the *E. coli* YddG protein, SEQ ID NO: 2, and limitation (B) recited an amino acid sequence that differed by “one or several amino acids” from SEQ ID NO: 2. Pet. App. 18a-19a; C.A. App. 5047. The examiner rejected Ajinomoto’s claim on grounds related solely to limitation (B)—namely, that the “one or several” amino acid differences limitation was so broad that it encompassed any number of unrelated non-YddG proteins, including one disclosed in Livshits et al. called “YfiK.” Pet. App. 18a-19a; C.A. App. 5378. The YfiK protein is not an aromatic L-amino acid transport protein like YddG, and Livshits neither discloses, references, or relates to the YddG protein. C.A. App. 5378; C.A. App. 803-808 (Q/A302-331). Based on Livshits, the examiner rejected that claim as lacking novelty of invention required by 35 U.S.C. § 102. Pet. App. 19a; C.A. App. 5378.

¹ All parties agree that the relevant prosecution history analysis focuses on the language in claim 1, which is incorporated into asserted claims 9 and 20.

In response to the examiner's rejection based on the unrelated YfiK protein, Ajinomoto left limitation (A) unchanged and replaced limitation (B) with language defining the protein by the hybridization characteristics of its encoding DNA sequence. Pet. App. 19a; C.A. App. 5609. Subsequently during prosecution, Ajinomoto converted limitation (B) to limitation (C) and also added a new limitation (B) that defined the protein by "one to five amino acid[]" differences from SEQ ID NO: 2. C.A. App. 5691. As a result, the issued '655 patent claims recite the three alternative ways of defining the claimed YddG protein that are described above. *See supra* 8-9.

Given that the amendment to avoid the YfiK protein was entirely inapposite to the equivalence issue in the litigation, Ajinomoto explained that prosecution history estoppel did not apply for two reasons. C.A. App. 9711-9719. First, protein limitation (A), under which infringement was asserted, was never the subject of amendment or narrowing during prosecution, so there was no presumption of estoppel to begin with. *See Festo*, 535 U.S. at 740. Second, even if there were a presumption of estoppel, the tangential exception applied because a plain reading of the prosecution record demonstrated that the amendment had nothing to do with substantively identical YddG proteins created through the artifice of codon randomization like CJ's, and everything to do with avoiding entirely different, non-YddG prior-art proteins such as YfiK.

4. The Commission and Federal Circuit Reject CJ's Prosecution History Estoppel Defense

Following a four-day hearing and an initial determination by the administrative law judge, the Commission concluded that CJ's Strain B infringed

the '655 patent under the doctrine of equivalents and that Ajinomoto was not estopped from asserting equivalence under the doctrine of prosecution history estoppel. The Federal Circuit affirmed.

1. The Commission first rejected Ajinomoto's threshold argument that there was no presumption of estoppel in the first place—despite that protein limitation (A) had never been the subject of amendment or narrowing during prosecution. Pet. App. 91a-94a. Nonetheless, the Commission agreed with Ajinomoto that the presumption of estoppel was rebutted under the tangential exception, as the prosecution history demonstrated that Ajinomoto's amendment related to entirely different, non-YddG proteins such that the scope of surrender did not extend to codon-randomized YddG proteins like those used in CJ's Strain B. Pet. App. 94a-97a.

2. The Federal Circuit affirmed, agreeing with the Commission that the tangential exception applied because the objectively evident rationale for the amendment had nothing to do with CJ's codon-randomized YddG protein. Pet. App. 17a-24a. The Federal Circuit declined, however, to address Ajinomoto's threshold argument that there was no presumption in the first place, choosing not to reach that foundational question. Pet. App. 19a-20a. While one panelist dissented from the finding of no estoppel, that outcome was based on a differing interpretation of the prosecution record at issue, not on a disagreement of legal framework. Pet. App. 39a, 43a (Dyk, J., dissenting). CJ's petition for en banc review on the issue was denied without dissent.

REASONS FOR DENYING THE WRIT

This Court should deny review because (I) CJ identifies no conflict with this Court's precedent, (II) CJ identifies no split of authority in the circuit below, and (III) the "unusual circumstance" of this case makes it a poor vehicle for this Court's review.

I. There Is No Conflict with This Court's Precedent

A. The Federal Circuit Followed *Festo* and Correctly Analyzed This Particular Prosecution History

The Federal Circuit's decision followed this Court's well-established precedent for determining the tangentiality exception to prosecution history estoppel. *See* Pet. App. 18a (citing *Festo*, 535 U.S. at 740). As directed by *Festo* and its predecessors, the Federal Circuit presumed surrender arising from Ajinomoto's amendment, examined the prosecution history to determine the scope of that surrender, and concluded that the reason for Ajinomoto's amendment was unrelated to the equivalent in question.

The prosecution record in this case is scientifically complex but doctrinally straightforward. The original claim was rejected because original limitation (B) was unbounded in its recitation of "one or several" amino acid differences such that it potentially encompassed a universe of unrelated proteins, including the entirely different prior-art YfiK protein identified by the examiner. Pet. App. 23a. Ajinomoto overcame the rejection by narrowing its claims to exclude such unrelated proteins and more specifically recite the *E. coli* YddG protein and those substantively similar to it. *Id.* By amending limitation (B) to define the claimed protein by the hybridization parameters of its

encoding DNA sequence, Ajinomoto “limit[ed] the set of proteins within the claim’s scope so that it no longer included the prior-art *E. coli* YfiK protein and, more generally, no longer allowed as wide a range of *amino acid* alterations.” *Id.* Ajinomoto’s scope of surrender thus did not include CJ’s accused equivalent, which employs a YddG protein exactly as contemplated by the ’655 patent claims, but which escapes literal infringement through codon randomization of its DNA sequence without changing the resulting protein. Pet. App. 24a (“[T]he non-*E. coli* YddG protein is identical whether produced from the codon-randomized or the [literally infringing] non-codon-randomized version of the non-*E. coli yddG* gene.”). Following an objective review of the prosecution record, the Federal Circuit discerned that “[t]he reason for the amendment had nothing to do with choosing among several DNA sequences in the redundant genetic code that correspond to the same protein.” Pet. App. 23a.

The Federal Circuit’s analysis of the particular prosecution record before it neither conflicts with precedent nor presents an exceptional legal question warranting this Court’s review. The record here amply supports the court’s conclusion that CJ’s use of codon randomization was merely tangential to the amendment during prosecution, and thus infringed the claim under the doctrine of equivalents. *See Warner-Jenkinson*, 520 U.S. at 40 (“With these limiting principles as a backdrop, we see no purpose in going further and micro-managing the Federal Circuit’s particular word-choice for analyzing equivalence. We expect that the Federal Circuit will refine the formulation of the test for equivalence in the orderly course of case-by-case determinations, and we leave such refinement to that court’s sound judgment in this area of its special expertise.”). CJ’s contention that the

law requires an overhaul simply because Ajinomoto, the Commission, and the majority below did not use the *exact* same words to describe the *exact* same rationale for the amendment during prosecution is misplaced. Pet. 11, 21. While the words used by those below to describe the amendment in question were not identical, each independently recognized from an objective reading of the prosecution history that the clear rationale for the amendment had nothing to do with the equivalent in question, and everything to do with an unrelated prior-art protein. This Court's precedent requires no more. *Festo*, 535 U.S. at 738, 740-41.

B. This Court Has Already Rejected Petitioner's Proposed Bright-Line Rule

While the Petitioner argues that the Federal Circuit departed from this Court's precedent, it is instead the *petition* that so departs by urging creation of a new bright-line rule where this Court has declined to institute such a rule in the past. In particular, CJ's question presented asks this Court to lay down a new rule: to "clarify" the doctrine of prosecution history estoppel such that it applies only when the patentee explicitly "stated the 'rationale' in question on the record at the time of the amendment." Pet. 3, 20; *accord* Pet. 18 ("[S]uch a rule . . . is the logical implication of this Court's precedent."). Apparently, CJ would require patentees, when amending claims in response to a specific examiner rejection, to simultaneously hypothesize and account for all future potential design-around strategies, and make sure to include a black-and-white statement that expressly does so. No other petition or amicus goes so far or asks so much.

The problem for CJ is that this type of bright-line approach has been consistently rejected by this Court

when addressing prosecution history estoppel, *see, e.g., Festo*, 535 U.S. at 738 (“We have considered what equivalents were surrendered during the prosecution of the patent, rather than imposing a complete bar that resorts to the very literalism the equivalents rule is designed to overcome.”), as well as in patent law generally, *see, e.g., Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 554 (2014) (“The Federal Circuit’s formulation is overly rigid.”); *Bilski v. Kappos*, 561 U.S. 593, 604 (2010) (“The Court of Appeals incorrectly concluded that this Court has endorsed the machine-or-transformation test as the exclusive test.”); *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007) (“We begin by rejecting the rigid approach of the Court of Appeals.”). Adopting CJ’s proposed bright-line rule now would upset decades of patentees’ reliance on the flexibility expounded by this Court. *E.g., Festo*, 535 U.S. at 739 (“There is no justification for applying a new and more robust estoppel to those who relied on [the] prior doctrine.”); *Warner-Jenkinson*, 520 U.S. at 32 n.6 (“[W]here, as here, the PTO may have relied upon a flexible rule of estoppel when deciding whether to ask for a change in the first place[, t]o change so substantially the rules of the game now could very well subvert the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by our decision.”); *id.* at 41 (Ginsburg, J., concurring) (“The new presumption, if applied woodenly, might in some instances unfairly discount the expectations of a patentee who had no notice at the time of patent prosecution that such a presumption would apply.”).

As this Court has made clear, patentees are not expected to foresee and account for all possible equivalents: the impossibility of doing so is the very

reason the doctrine of equivalents exists. *Graver Tank*, 339 U.S. at 607-08. Indeed, “the nature of language makes it impossible to capture the essence of the thing in a patent application,” and “[a] narrowing amendment may demonstrate what the claim is not; but it may still fail to capture precisely what the claim is.” *Festo*, 535 U.S. at 731, 738. Thus, just as patentees are not expected to initially draft claims that literally encompass all possible equivalents, they are not expected to include with their amendments explanations of which hypothetical equivalents could be covered and which could not. *Id.* at 738 (“The amendment does not show that the inventor suddenly had more foresight in the drafting of claims than an inventor whose application was granted without amendments having been submitted.”). Consistent with *Festo*, the law in the Federal Circuit has been that the court looks for the “objectively apparent reason” for the amendment which “should be discernible from the prosecution history record.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003) (en banc). Neither this Court nor the Federal Circuit has required that the objectively discernible rationale be laid out *in haec verba*.

While the patentee bears the burden of demonstrating from the prosecution history that the narrowing amendment did not surrender the particular equivalent at issue, a court’s analysis of that question must be “flexible” and inquire into not only the black-and-white words of the prosecution history, but also “the reason the amendment was submitted” and “the inferences that may reasonably be drawn from the amendment.” *Id.* at 737-38. Petitioners in this case and in *Eli Lilly* urge this Court to consider only the black-and-white words of the record and disregard the reason for the amendment apparent from the record

as a whole. Such arguments have been expressly rejected by this Court time and again. *Warner-Jenkinson*, 520 U.S. at 30-31 (commenting on over one hundred years of precedent: “It is telling that in each case this Court probed *the reasoning behind* the Patent Office’s insistence upon a change in the claims.” (emphasis added)). Both here and in *Eli Lilly*, as in prior challenges before this Court, “petitioner reaches too far in arguing that the reason for an amendment during patent prosecution is irrelevant to any subsequent estoppel.” *Id.* at 30.

It is thus well settled that the tangential exception to prosecution history estoppel allows for a patentee to rebut the presumption of estoppel by demonstrating that the rationale underlying the amendment is merely “peripheral” to the accused equivalent. In analyzing that question, a court’s job is to “explore . . . the reason (right or wrong) for the objection and the manner in which the amendment addressed and avoided the objection.” *Id.* at 33 n.7. And it is only “[w]hen the patentee is unable to explain the reason for [the] amendment,” *Festo*, 535 U.S. at 740, “[w]here no explanation is established,” *Warner-Jenkinson*, 520 U.S. at 33, that the patentee is estopped from asserting infringement over a particular equivalent. This rule is flexible and based on a fact-based determination of the particular context of the claim amendment as discerned from the prosecution record. It requires no more and no less.

The Federal Circuit correctly undertook that analysis here. Ajinomoto established the objectively evident reason for the amendment from the prosecution record: to exclude unrelated, non-YddG proteins like YfiK. Both the Commission and the Federal Circuit correctly concluded that rationale was unrelated to the

equivalent in question—a YddG protein identical to a literally infringing protein, brought outside the literal claim scope only via the artifice of codon randomization. The Federal Circuit’s reasoning was not an improper “*post-hoc*” rationale, as CJ repeatedly contends. *E.g.*, Pet. 4, 17-22. Rather, it is the way the doctrine has always worked—determining the scope of estoppel *always* requires looking backwards over the prosecution history to determine the “reasoning behind” the amendment. *Warner-Jenkinson*, 520 U.S. at 31. The Federal Circuit correctly applied this Court’s precedent. This Court should reject CJ’s invitation to create a contrary bright-line rule.

C. The Concerns of Petitioners and Amici Regarding Uncertainty and Public Notice Are Unfounded

The dire predictions of the petitioners and amici in this case and *Eli Lilly* about the “devastating” effects of the Federal Circuit’s decision on the public-notice function of the prosecution history, the “uncertainty” engendered thereby, and the deleterious effects on innovation are unfounded. Pet. 4. As an initial matter, Petitioner here is not the innovator—Petitioner is the unscrupulous copyist described in *Graver Tank* who seeks to “make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim” for which the doctrine of equivalents was created. 339 U.S. at 607-08. A bright-line rule only further serves Petitioner’s purpose.

More importantly, these policy arguments have already been addressed and answered by this Court. It is already established—and accepted—that there is some uncertainty in the counterbalance struck by the doctrine of equivalents and the doctrine of prosecution

history estoppel. As this Court explained in *Festo*: “It may be difficult to determine what is, or is not, an equivalent to a particular element of an invention.” 535 U.S. at 732. These are concerns that “are not new.” *Id.* Yet, in considering and addressing these challenges, this Court has already concluded that the inability to answer all eventualities at the time of claim drafting or amendment is not reason to create a rigid rule of estoppel. The inherent uncertainty in predicting the scope of equivalents is “the price of ensuring the appropriate incentives for innovation,” *id.*, and this Court has set forth a rebuttable presumption that strikes the appropriate balance between defining an invention and providing public notice. *Warner-Jenkinson*, 520 U.S. at 33-34 (“The presumption we have described, one subject to rebuttal if an appropriate reason for a required amendment is established, gives proper deference to the role of claims in defining an invention and providing public notice . . .”).

CJ’s arguments further ignore that the public-notice function of the prosecution history is, and always has been, subject to the limitations of language. As in any exercise that evaluates the meaning and scope of patent claims, “absolute precision is unattainable.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). The proper interpretation of the written instrument must strive to comport with the document as a whole, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-89 (1996), and “reasonable certainty” is often the pinnacle of what can be attained, *Nautilus*, 572 U.S. at 910. CJ’s suggestion that the doctrine of prosecution history estoppel should somehow demand some higher level of clarity is unrealistic, unworkable, and should be rejected.

Put simply, the Federal Circuit’s decision below does no more violence to the “public-notice” and “certainty” goals of patent law than does any court decision on claim construction, equivalence, or estoppel in the ordinary course. Despite CJ’s contentions to the contrary, the court did not manufacture, from whole cloth, an “after-the-fact” rationale for the amendment. Pet. 17. Rather, it construed the express words of the written instrument—the examiner’s rejection over “YfiK” and the patentee’s amendment to distinguish thereover—and reasonably concluded that “[t]he reason for the amendment had nothing to do with choosing among several DNA sequences in the redundant genetic code that correspond to the same [YddG] protein.” Pet. App. 23a.

II. There Is No Intra-Circuit Split

CJ additionally fails to identify any split of opinion at the Federal Circuit that warrants this Court’s review. To start, of the two decisions being challenged in this Court, the three petitioners cannot even agree on the method or manner in which the Federal Circuit is purportedly departing from established law. On the one hand, Dr. Reddy’s Laboratories urges there has been a long-festering divide at the Federal Circuit, with two divergent and irreconcilable lines of case law. *See* Pet. at 18-22, *Dr. Reddy’s Labs., Ltd. v. Eli Lilly & Co.*, No. 19-1061 (filed Feb. 24, 2020). On the other hand, CJ and Hospira argue the court’s two recent decisions have dramatically changed course from what has otherwise been 20 years of faithful application of precedent—but for different reasons. CJ urges the decisions depart from a purported requirement of “explicit and contemporaneous explanation[],” Pet. at 24-25, while Hospira paints the court as having created a new “buyer’s remorse” defense, Pet. at 27-30,

Hospira, Inc. v. Eli Lilly & Co., No. 19-1058 (filed Feb. 24, 2020).

None of these views is correct, and no petition identifies any split of opinion warranting this Court's review. To the contrary, the Federal Circuit decisions cited throughout each of the three petitions demonstrate nothing more than that court's orderly, case-by-case determination of the disputes brought before it. In each case, the Federal Circuit reviews the particular prosecution history at issue, determines the rationale underlying the patentee's amendment, and compares that rationale to the accused equivalent to determine whether the equivalent falls within the scope of the patentee's estoppel, or is only tangential thereto. As *Festo* contemplates, there will be instances in which the tangential exception is satisfied, and those where it is not.

CJ's principal argument to support a purported split is based on the court in this case allegedly violating an existing Federal Circuit "rule" that "a patentee's silence at the time of amendment precludes invoking the doctrine of equivalents." Pet. 22. First, even if there were such a rule, that argument misses the mark here, as Ajinomoto was *not* silent when amending its claims. Rather, Ajinomoto accompanied its amendment with an express explanation of the reason it was made; namely, to overcome the examiner's "cit[ation of] Livshits et al as disclosing a bacterium within the scope of [the] Claim"—that is, to overcome the examiner's citation of a prior-art reference that disclosed the entirely different, unrelated YfiK protein. C.A. App. 5617.

In any event, there is no such "rule" in the Federal Circuit. CJ relies principally on a single sentence from *Honeywell International, Inc. v. Hamilton Sundstrand*

Corp., 523 F.3d 1304, 1316 (Fed. Cir. 2008), that “[s]ilence does not overcome the presumption.” Pet. 3, 7, 25. But when read in context of the entire paragraph in which it appears, the cited paragraph of *Honeywell* (consistent with the rest of the Federal Circuit’s decisions) explains that, to satisfy the tangential exception, “the reason for the narrowing amendment” need simply “be discernible from the prosecution history record,” and it is only when “the prosecution history reveals *no* reason for the narrowing amendment[that] the presumption is not rebutted.” *Honeywell*, 523 F.3d at 1315-16 (emphasis added) (quoting *Festo*, 344 F.3d at 1369; citing *id.* at 1371-72). *Honeywell* far from supports the “silence” rule CJ propounds.

Likewise, none of the decisions by this Court support CJ’s proffered “silence” rule. CJ points to several of this Court’s decisions setting forth the basic principle that a patentee’s narrowing amendment gives rise to surrender of claim scope. Pet. 18-20. On that point, there is no dispute. But CJ’s conclusion that a patentee who intends to surrender less than the full scope between the original claim and the amended claim is “required to say so at the time,” Pet. 20, is absent from this Court’s precedents. As already explained, this Court’s directive in resolving the tangential exception includes “prob[ing] the reasoning *behind* the Patent Office’s insistence upon a change in the claims.” *Warner-Jenkinson*, 520 U.S. at 30-31 (emphasis added). When the patentee is able “to explain the reason for [the] amendment” as demonstrated by the prosecution record, and that reason is merely peripheral to the accused equivalent, the presumption is rebutted. *Festo*, 535 U.S. at 740; *see also Warner-Jenkinson*, 520 U.S. at 41-42 (Ginsburg, J., concurring) (the presumption of estoppel should not be

“applied woodenly,” and on remand, the court should determine “whether suitable reasons for including the lower pH limit were earlier offered or, if not, *whether they can now be established*” (emphasis added).

The remainder of the Federal Circuit cases cited by CJ likewise fail to demonstrate the purported circuit split. In *Felix v. American Honda Motor Co.*, the patentee’s attempts to satisfy the tangential exception failed because the prosecution history revealed an argument at odds with the patentee’s position later urged in litigation, and the patentee pointed to “no explanation in the prosecution history for the addition of the” limitation at issue. 562 F.3d 1167, 1184 (Fed. Cir. 2009). Conversely, in each of *Insituform Technologies, Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360, 1370 (Fed. Cir. 2004); *Regents of University of California v. Dakocytomation California, Inc.*, 517 F.3d 1364, 1378 (Fed. Cir. 2008); and *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1291 (Fed. Cir. 2010), the patentee succeeded in rebutting the presumption of estoppel by demonstrating that the accused equivalent was unrelated to the objectively apparent rationale for the prosecution history amendment. *See* Pet. 7-8, 25-26 (discussing decisions). In short, the differing outcomes in those cases arose from the particular prosecution histories and the particular accused equivalents at issue. Likewise here, the differing outcomes between majority and dissent do not reveal a fracture of framework, but merely a difference in application thereof. Indeed, both majority and dissent agreed that the guiding inquiry was to examine “the patentee’s objectively apparent reason for the narrowing amendment.” Pet. App. 20a; Pet. App. 39a (Dyk, J., dissenting). They simply arrived at differing interpretations of the prosecution record in this case and its relation to the accused product. *See, e.g.*, Pet. App. 43a

(Dyk, J., dissenting) (“In my view[,] . . . [t]he equivalent is directly related to the reason for the amendment . . .”). So unremarkable were these differing interpretations that the denial of en banc review had no dissent.

III. This Case Is a Poor Vehicle to Address the Tangential Exception

Even if there were some unanswered question as to the contours of the tangential exception or how to apply it (and there is not), this case is not an appropriate vehicle to address them. CJ urges this case as ideal because it would purportedly not require “weigh[ing] the evidence or the parties’ arguments.” Pet. 27. Not so. CJ’s challenge depends on this Court reviewing and interpreting a complex factual and scientific record to determine the import that a particular prosecution history amendment has on a particular accused equivalent.

Moreover, it would be of little benefit to the law for the Court to wade into the particularly odd facts of this case. The Federal Circuit explained at the outset that, “[a]s an initial matter, CJ’s argument for prosecution history estoppel in this case involves an unusual circumstance.” Pet. App. 19a-20a. That unusual circumstance is the unique situation presented where (1) the claimed protein limitation was defined in three ways, (2) only a subset of those three limitations was amended, and (3) the infringement determination does not rest on finding an equivalent of the amended claim language. Indeed, the claim limitation under which Ajinomoto asserted infringement via the doctrine of equivalents—protein limitation (A)—was *not* the subject of amendment during prosecution. Protein limitation (A) remained unchanged throughout prosecution and issued in its original form, while the

amendment CJ point to relates to the other, *nonasserted* protein limitations (B) and (C). *Id.* For that reason, Ajinomoto’s principal argument against prosecution history estoppel in this case has always been that there should be no presumption of estoppel in the first place, consistent with established law. *See, e.g., Warner-Jenkinson*, 520 U.S. at 33 (“[P]rosecution history estoppel would bar the application of the doctrine [of] equivalents *as to that element.*” (emphasis added)); *Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1375 (Fed. Cir. 2003) (prosecution history estoppel does not apply to a limitation that “was never amended and therefore cannot be subject to the *Festo* presumption”); *Honeywell Int’l Inc. v. Hamilton Sunstrand Corp.*, 370 F.3d 1131, 1144 (Fed. Cir. 2004) (en banc) (prosecution history estoppel “is determined on a limitation-by-limitation basis”); *Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1103 (Fed. Cir. 2002) (prosecution history estoppel applies only if the “limitations at issue were amended during prosecution”). The Commission resolved this threshold question against Ajinomoto, and the Federal Circuit declined to address it. Pet. App. 19a-20a. This unresolved “unusual circumstance” will cloud the import of any attempted resolution of the question here presented, making this case is a poor vehicle in which to attempt to further refine the law of prosecution history estoppel.

CONCLUSION

The petition should be denied.

Respectfully submitted,

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